MedImpact

Proposal for Pharmacy Clinical Management Services for the

State of Georgia with NASPO ValuePoint

eRFP Number: 41900-DCH0000136

APRIL 24, 2024

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Attachment U

Pharmacy Clinical Management Services

Mandatory Scored Response Worksheet

Suppliers must provide responses to all questions in the **Supplier Response section** in this document and submit them as a **single** PDF attachment **bookmarked** in sequential order with the title(s) provided in the question.

Each narrative response must adhere to any assigned page limits and be in Arial, size twelve (12) font. The narrative page count will begin after the page containing the question, i.e., the page with the question and response on the remainder of that page will count as page #0.

The narrative response, along with any required supporting material, will be evaluated and awarded points in accordance with Attachment A – Lead State eRFP, Section 6 Proposal Evaluation and Award. Documents not requested will not be evaluated.

Failure to provide responses and any required supporting documentation for all questions may result in disqualification of the proposal.

DO NOT INCLUDE ANY COST INFORMATION IN YOUR RESPONSE TO THIS WORKSHEET.

1.	**Bookmark Title: MSQ1 - Executive Summary** The Executive Summary is limited to five (5) pages. Provide an Executive Summary that illustrates the Supplier's understanding of and capability to provide the requested services as described in Attachment G - Pharmacy Clinical Management Services Scope of Work and Attachment C - Common Scope Requirements and Security Standards. The Executive Summary must include a brief corporate background of the Supplier, including the date the Supplier was formed, established, or created, total number of employees, Equal Employment Opportunity policy and current percentages in key positions, and location of the Supplier's primary and any satellite offices.

Supplier Response

MedImpact Healthcare Systems, LLC (MedImpact) is pleased to submit our proposal for Pharmacy Clinical Management Services to the State of Georgia (Lead State), Department of Administrative Services (DOAS), State Purchasing Division (SPD), and the Department of Community Health (DCH) in furtherance of the NASPO ValuePoint Cooperative Purchasing Program.

For over 30 years, MedImpact has supported Medicaid programs with innovative pharmacy clinical services grounded in proven technology and steeped in extensive knowledge and experience. Our proven platforms, processes, and solutions qualify MedImpact as the right choice for Georgia (and any Participating Entity) to provide pharmacy clinical management services that enhance the well-being of all their members.

MedImpact stands ready to support DCH's vision by delivering comprehensive clinical services for the State of Georgia. Our approach to providing credible solutions, expertise, flexibility, and innovation will enhance DCH's clinical services program. We further differentiate ourselves through extensive collaboration with our customers. Our teams are accountable, proactive, and responsive.

Background and History

MedImpact was established in 1989 by a pharmacist with the goal of providing flexible and credible solutions to payers. From our beginnings as a third-party administrator, we have spent the last 30 years investing in technology and creating innovative solutions for our customers. Today, we are still a privately held company with approximately 2,100 employees nationwide. We are the largest independent PBM in the United States utilizing proprietary technology to provide pharmacy and drug rebate services to FFS (fee-for-service) Medicaid, state agencies, health plans, and employers serving approximately 20 million lives.

We are headquartered in San Diego, California with satellite offices in Tempe and Tucson, Arizona. We are a health services technology company that has met every regulatory and technical challenge along our journey including implementing Medicaid managed care programs in the 90s, Medicare in 2006, Marketplace programs (Exchange) in 2014, and FFS Medicaid in 2021 (adding 3 more FFS contracts since that time). We are a customer focused company and proud to say that our first Medicaid customer is still a customer today. As our customers' businesses have evolved, MedImpact has been there to provide new solutions for these regulated markets.

Since the beginning, MedImpact has not waivered on our core differentiating principles of:

- Independence (we are privately held)
- Free from conflict (not owned by a health plan or own pharmacies)
- Transparency

Our mission is to deliver pharmaceutical and technology-related solutions that improve the value of healthcare. We provide superior outcomes to every customer through innovative solutions, systems, and services that provide transparency and promote choice in decision making.

The FFS PBM market has changed extensively in the last few years with the acquisition of niche vendors by large vertically integrated PBMs and the emergence of other vendors, such as MedImpact. We are an independently held company unencumbered with Wall Street expectations or competing lines of business. No drug manufacturer, distributor, or pharmacy organization serves in an ownership, day-to-day management, or board of director position within MedImpact.

Today, we continue to invest millions of dollars in clinical programs, technology, operations, and analytics to ensure we provide robust solutions for the ever-changing PBA landscape. MedImpact continue to make investments in our proprietary technology to enhance automation, visibility, accountability, and transparency. **Table 1** highlights the key adaptations and milestones of our organization since its inception.

Year	
1989	Founded MedImpact by pharmacist Fred Howe as an LLC
1992	Implemented first Medicaid health plan (California)
1993	Incorporated as MedImpact Healthcare Systems, Inc
1999	Earned NCQA accreditation and quality improvement standards compliance
2000	Established MedImpact retail pharmacy network with more than 55,000 pharmacies
2004	Became a Medicare Drug Discount Card endorsed PBM
2006	Implemented Medicare Part D program with PDP and MA-PD plans; CMS contract support provided through relationship with Transamerica
2008	Increased retail pharmacy network to more than 60,000 pharmacies Accredited by URAC for pharmacy benefit management Opened Southwest Regional Operations Center in Tempe, Arizona
2010	Launched MedImpact International, LLC
2012	Acquired SUNRx®, 340B program administration
2013	Acquired ScriptSave and Apex Affinity
2014	Implemented state-based exchange programs based on Affordable Care Act Introduced mail order pharmacy and specialty pharmacy programs to the market
2015	Implemented SAS enterprise analytic platform Received PBMI (Pharmacy Benefit Management Institute) Excellence Award
2017	Received 2-year NCQA UM certification
2019	Received a 3-year NCQA UM accreditation Launched point-of-sale rebates program Expanded MedImpact's San Diego headquarters with a second LEED-certified building Developed proprietary FFS (fee for service) Medicaid drug rebate platform, MedInvoice™ Implemented FFS Medicaid provider payment support
2020	Implemented enhanced coordination of benefits claims processing for FFS claims Awarded first Medicaid FFS contract
2021	Implemented Medi-Span as an alternative drug attribute source

	Implemented first Medicaid FFS customer
2022	Launched OTC (over the counter) Covid home test solutions Received 3-year NCQA UM reaccreditation
2023	URAC PBM accreditation renewed for 3 years Received HITRUST certification Awarded Commonwealth of Kentucky and State of Mississippi FFS Medicaid business Received an intent to award from the state of Colorado for FFS Medicaid business Acquisition of AspenRx
2024	Acquisition of Elixir Solutions

Table 1: MedImpact's Corporate History

Equal Employment Opportunity

MedImpact seeks diversity in our recruiting, hiring, and career advancing practices by posting to job boards and publications with diverse audiences. We track and analyze demographic data on our internal workforce for over/under representation including those in management and senior leadership positions. Our current percentage demographic breakdown for MedImpact's executive team is 60% female and 40% minority.

Our comprehensive nondiscrimination policy states that MedImpact does not discriminate against an applicant or employee on the basis of race, color, religion, national origin, ancestry, sex, age, physical or mental disability, military or veteran status, genetic information, sexual orientation, gender identity, gender expression, marital status, or any other characteristic protected by applicable federal, state, or local law. We verify compliance at all MedImpact facilities with the Americans with Disabilities Act. MedImpact's chief human resources officer is the equality employment opportunity officer serving as the point person to identify additional opportunities that can implement to enhance and expand the company's commitment to diversity. **Figure 1** provides a copy of MedImpact's Affirmative Action and Equal Employment Opportunity Policy.

AFFIRMATIVE ACTION AND EQUAL EMPLOYMENT OPPORTUNITY POLICY

MedImpact Healthcare Systems, Inc. (hereinafter "Company") has an enduring commitment to the concept and practice of equal employment opportunity and affirmative action as well as to affirming the value of diversity and promoting a workplace free from discrimination.

It is the policy of the Company to provide equal employment opportunities without regard to race, color, religion, sex, sexual orientation, gender identity or expression, national origin, genetic information, age, disability, marital status, veteran status, or a person's relationship or association with a protected veteran, including spouses and other family members or any other protected characteristic under applicable law. This policy relates to all aspects of employment, including recruitment, selection, job assignment, training, compensation, benefits, discipline, promotion, transfer, the use of facilities, participation in all company-sponsored employee activities, layoff, and termination processes. Provisions in applicable laws providing for bona fide occupational qualifications, business necessity or age limitations will be adhered to by the company where appropriate. Regular review helps ensure compliance with this policy.

The Company has developed and maintained a written Affirmative Action Program (AAP). The Company maintains an audit and reporting system to determine overall compliance with its equal employment opportunity mandates. I have delegated overall responsibility of the AAP to the Affirmative Action Officer, Thomas Hutton, Chief Human Resources Officer. Thomas Hutton oversees the affirmative action plan development, modification, implementation, effectiveness, reporting requirements and conducts management updates. The Company invites any applicant and/or employee to review the Company's written Affirmative Action Plan. This plan is available for inspection during normal business hours. Please request an appointment by contacting Thomas Hutton at 858-790-5675.

The Company will ensure that employees and applicants shall not be subjected to harassment due to their status described above, or any harassment, intimidation, threats, coercion or discrimination because they have engaged in or may engage in any of the following activities; (1) filing a complaint with the Company or with federal, state, or local agencies regarding status covered under this AAP, (2) assisting or participating in any investigation, compliance review, hearing, or any other activity related to the administration of any federal, state, or local equal employment opportunity or affirmative action statute pertaining to the status covered under this AAP; (3) opposing any act or practice made unlawful by section 503 and/or VEVRAA, and (4) exercising any other right protected by section 503 and/or VEVRAA or its implementing regulations in this part. Concerns and complaints related to equal opportunity based on aspects of diversity protected under federal, state, and local law, including sexual harassment complaints should be directed to the attention of Thomas Hutton at 858-790-5675.

As Chief Executive Officer of MedImpact Healthcare Systems, Inc., I fully support our affirmative action program and am committed to the implementation of the company's equal opportunity and affirmative action policies. I urge each employee to commit to carrying out the intent of these policies. Specifically, it is the responsibility of the each supervisor to ensure implementation of these policies to avoid any discrimination in employment. Violation of these policies is a disciplinary offense.

01/01/2023

Frederick Howe
Chief Executive Officer

Figure 1: MedImpact Affirmative Action and Equal Employment Opportunity Policy

Pharmacy Clinical Management Services

MedImpact has reviewed *Pharmacy Clinical Management Services Scope of Work and Attachment C - Common Scope Requirements and Security Standards* and understands the requirements of the DCH's Pharmacy Clinical Management Services FFS (Fee-for-Service) Medicaid pharmacy program

. We will work closely with DCH and all participating parties to successfully implement and carry out the coordination of all clinical programs including but not limited to:

- State PDL (Preferred Drug List) and PADL (Provider Administered Drug List)
- RetroDUR (Retrospective Drug Utilization Review) and ProDUR (Prospective Drug Utilization Review)
- UM (Utilization Management) Support
- State Advisory Board Support

We are an experienced clinical programs and Medicaid FFS partner offering DCH clinical expertise, flexible programs, and innovative tools to support DCH's clinical pharmacy program.

Expertise

MedImpact's clinical program offering is led by Dr. Kevin Chang, PharmD, BCPS, Principal FFS Medicaid Accounts and Services. Dr. Chang brings extensive clinical, operational, and strategic experience to his leadership position including formulary/PDL/PADL management, MTM (medication therapy management) programs, ProDUR, RetroDUR, and clinical reporting development. He maintains solid business relationships with customers and collaborates with leaders across operations, IT, and health services. Dr. Chang is a licensed pharmacist and a board-certified pharmacotherapy specialist. He leads a group of highly qualified and experienced CPM (clinical program managers) across several different Medicaid FFS customers and states. MedImpact's clinical staff is highly knowledgeable and experienced in the unique requirements of the Medicaid FFS population. DCH's assigned clinical pharmacy program Key Staff will report up to Dr. Chang and he will be involved in an advisory position throughout the life of the contract.

Flexibility

MedImpact's independent business model and inherent flexibility aligns with DCH without conflicting incentives to provide low net cost for DCH and your members. This value of flexibility to benefit our customers flows into how we operate all of our programs including clinical programs such as ProDUR (prospective DUR) and RetroDUR. These clinical programs and associated reporting are highly customizable and can be tailored to meet state requirements. MedImpact's ProDUR edits are modular in design, providing flexibility that makes changes to edits easy. Our modular structure supports fast-cycle customization to meet quick deadlines and maintain quality through rigorous end-to-end testing in a production environment. We fit our RetroDUR solution to DCH's needs based upon population risk and state-specific drug utilization trends. These are just a few examples of how MedImpact's flexibility at multiple levels makes managing clinical programs easy and efficient for DCH.

Innovation

MedImpact values innovation and has developed an end-to-end RetroDUR application accessible to both MedImpact and our customers. Our solution focuses on 4 core elements integral to the success of any RetroDUR program including: Identification, Intervention, Response, and Outcome. Our application utilizes technologies such as OCR (optical character recognition) to increase automation and efficiencies throughout the process. MedImpact's algorithms provide robust pre-analysis at the beginning of the process and robust outcomes reporting capabilities at the end of the process. We are also exploring direct integration with EMR (electronic medical records) systems to further enhance our offering and provide easier access for prescribers to respond to intervention letters and surveys. MedImpact continues to invest in creative and innovative programs and tools that will benefit DCH and your members.

MedImpact is confident we have the staff expertise, flexible clinical programs, and innovative RetroDUR application to enhance DCH's Pharmacy Clinical Management Services program. We will streamline your clinical programs through automation and efficiencies putting more money back into DCH's hands to invest in meaningful programs for you and your members.

2.	**Bookmark Title: MSQ2 – State Advisory Board** Bookmark Title for Supporting Material: MSQ2.1 – Sample HIV Clinical Drug Monographs Narrative description is limited to five (5) pages, not including the required supporting material. Describe your experience, ability, and method (both administrative and clinical) for providing support to the State Advisory Board as described in Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.2 State Advisory Board.

Supplier Response

MedImpact offers DCH decades of experience supporting P&T Committee's, DUR Boards, and State Advisory Boards. We provide superior drug information services including PDL and PADL recommendations, TRCs (therapeutic drug class reviews), monographs, pipeline research, and analysis. MedImpact partners with UMASS (University of Massachusetts, Clinical Program Services) to meet the unique needs of our state Medicaid agency customers. UMASS provides unbiased raw clinical data for MedImpact to customize to meet DCH-specific needs. Your assigned CPM will customize the documents for and present all clinical information to the DCH's State Advisory Board.

State Advisory Board Meeting Management

MedImpact understands the importance of organized State Advisory Board meetings and proposes the CPM as the Key Staff member to manage these meetings. We have provided more detailed information about our Key Staff in general, and this role specifically, in our response to requirement *MSQ8*.

MedImpact will recruit State Advisory Board members as directed by DCH. We understand that the Georgia DURB (Drug Utilization Review Board) was established under the authority of Section 1903(3) A of the Omnibus Budget Reconciliation Act of 1990 (OBRA) to promote patient safety through an increased review and awareness of outpatient prescribed drugs. We will work to recruit and make recommendations for DCH's review of strong candidates to fill the board positions comprised of:

- Physicians
- Pharmacists
- Members of the academic community
- Consumer advocate

MedImpact will utilize our industry connections and work with medical, pharmacy, and academic groups to identify candidates to recommend for DCH's review and possible appointment.

Recommendations

MedImpact will make recommendations to the State and the State Advisory Board regarding new or enhanced UM (Utilization Management) criteria including but not limited to clinical, fiscal, and step therapies for covered Products and all new Products. Clinical evaluation and comparative effectiveness is the first consideration in MedImpact's recommendations. If we consider drugs similarly effective based upon available data, we evaluate drugs by cost and value of the outcomes they bring to Medicaid members.

This evaluation includes a cost model review of the entire PDL and PADL by therapeutic class which uses DCH-specific utilization to estimate the fiscal impact of preferred and nonpreferred status based upon previous DCH-specific experience and the current market for the drugs within the PDL and PADL classes.

This analysis focuses on net cost to DCH factoring the FMAP (federal medical assistance percentage), federally mandated rebate, and supplemental rebates. If MedImpact is chosen for the clinical and rebate modules, DCH can access this at any time through our SRP (supplemental rebate platform) that allows for live, on-demand changes to the models to evaluate as many scenarios as necessary to make an informed decision. If another contractor is chosen for the rebate module, MedImpact will coordinate with those contractors to gather the information we need to make a full analysis. We will provide all monographs, TCRs, and cost models well in advance of the DCH's quarterly State Advisory Committee meetings.

PDL Expertise Results in Client Savings

MedImpact identified high utilization of a high net-cost, non-preferred GLP-1 Receptor Agonist class drug, recommended a PDL modification, and saved $1.6 million quarterly for our client.

Drug Monograph Development

We use drug monographs to supplement TCRs for new to market drugs in between full reviews. In addition to the TCRs provided prior to the DCH's State Advisory Board meetings, we provide clinical monographs weekly as part of new drug review information. We provide these comprehensive documents comparing the drugs within a therapeutic class on a clinical basis in advance of PDL and PADL recommendations meetings to provide sufficient time for thorough clinical review.

TCRs focus on direct comparative clinical effectiveness and safety trials, published outcomes evidence, and national consensus guidelines highlighting distinguishing characteristics among medications in a given therapeutic class. Our clinical pharmacists utilize a variety of clinical databases and resources to prepare TCRs including:

- PubMed®
- Ovid®
- UpToDate®
- MD Consult®
- MICROMEDEX®
- Vast online and print library
- 2 medical school clinical resources

These diverse resources give us access to an array of peer-reviewed medical literature. In addition, the team reviews product information from pharmaceutical manufacturers in compliance with the Academy of Managed Care Pharmacy-endorsed formulary dossier submission requirements.

Material Creation

MedImpact routinely creates and presents materials for State Advisory Board meetings tailored to specific customer needs and in alignment with federal and state rules and regulations. We create materials including but not limited to:

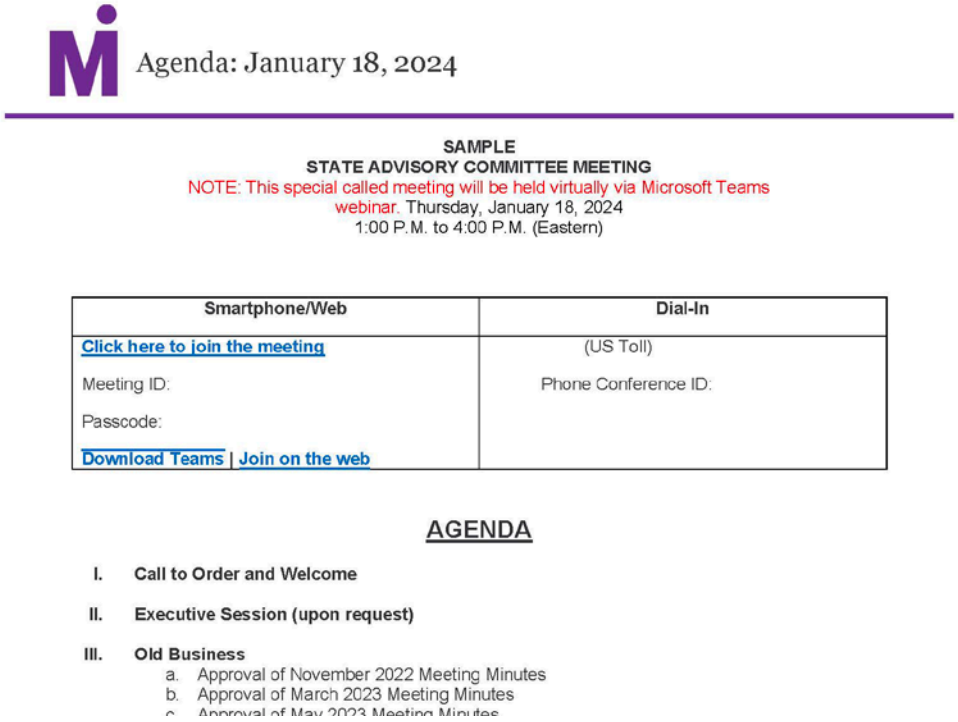
- Agendas
- Past meeting minutes
- Decision documents
- New drug analysis and recommendations
- Upcoming meeting information

We will work with DCH to solidify the standard quarterly State Advisory Board deliverables during DDI.

Material Distribution

MedImpact will provide all State Advisory Board materials to interested stakeholders including but not limited to manufacturers, providers, and advocacy organizations through a secured file. We provide SFT (secure file transfer) of all DCH information through a TLS (Transport Layer Security) encrypted website using Axway Secure Transport. Axway Secure Transport is configured via a front-end web server connecting to a back-end file repository. No files are stored on the front-end server. MedImpact also supports file level encryption through the use of PGP for added protection.

MedImpact routinely prepares and distributes meeting agendas to P&T Committees, DUR Boards, State Advisory Boards, and their members. Our agendas are clear, concise, and customized for each customer and meeting. **Figure 2** provides an excerpt snippet of a sample meeting agenda.



Agenda: January 18, 2024

SAMPLE
STATE ADVISORY COMMITTEE MEETING
NOTE: This special called meeting will be held virtually via Microsoft Teams webinar. Thursday, January 18, 2024
1:00 P.M. to 4:00 P.M. (Eastern)

Smartphone/Web	Dial-In
Click here to join the meeting	(US Toll)
Meeting ID:	Phone Conference ID:
Passcode:	
Download Teams | Join on the web	

AGENDA

I. Call to Order and Welcome

II. Executive Session (upon request)

III. Old Business
a. Approval of November 2022 Meeting Minutes
b. Approval of March 2023 Meeting Minutes
c. Approval of May 2023 Meeting Minutes

Figure 2: Sample State Advisory Board Meeting Agenda Excerpt

We will work with DCH during DDI to solidify the agenda template and confirm Board members who should receive the agendas. The CPM will also post meeting agendas on the State website as required under the Contract.

Post-Meeting Material Distribution

MedImpact routinely records meeting minutes for customers and can do so for DCH. We commit to recording the minutes and forwarding them to DCH within 3 business days after each meeting. MedImpact's meeting minutes are clear, concise, and capture all pertinent information discussed at each meeting. In addition to sending meeting minutes to DCH, we will also post them to the State's website in a timely fashion. **Figure 3** provides a snapshot of a similar website where we post information for a customer's State P&T Committee meetings.

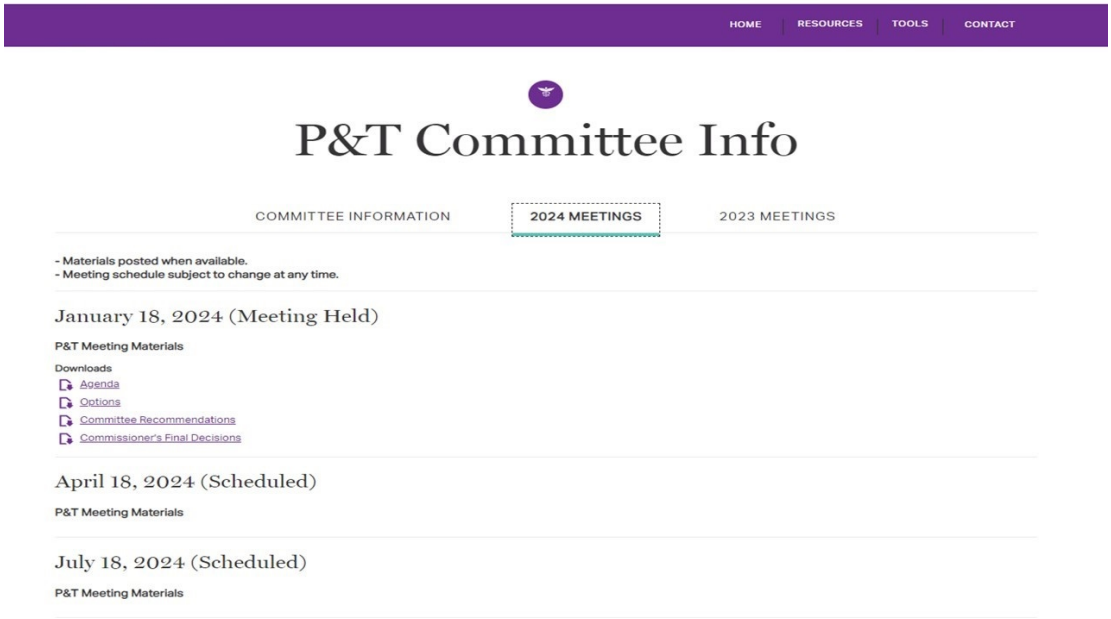


Figure 3: Sample Meeting Information Website

We are confident we can manage the quarterly State Advisory Board meetings. MedImpact is experienced in leading and supporting a variety of advisory boards and will provide DCH with everything you need from analysis to presentation to meeting information management and disbursement. We look forward to discussing DCH's needs more in depth during the DDI process.

MSQ2.1 – Sample HIV Clinical Drug Monographs

New Drug Review for Cabenuva® (cabotegravir/ rilpivirine ER suspension) and Vocabria® (cabotegravir)

Generic Name: cabotegravir and rilpivirine
Trade Name: Cabenuva®
Formulation: 400 mg/600 mg and 600 mg/900 mg extended-release injectable suspension kit
Manufacturer: ViiV Healthcare
FDA Approval Date: January 21, 2021
Product Launch Date: February 3, 2021

Generic Name: cabotegravir
Trade Name: Vocabria®
Formulation: 30 mg tablet
Manufacturer: ViiV Healthcare
FDA Approval Date: January 21, 2021
Product Launch Date: February 10, 2021

Food and Drug Administration (FDA)-approved Indication

- Cabenuva® (cabotegravir/rilpivirine ER suspension), a 2-drug co-packaged product of cabotegravir, a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI), and rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI), is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.[1]
- This agent received Fast Track and Priority Review designations from the FDA.

Food and Drug Administration (FDA)-approved Indication

- Vocabria® (cabotegravir), is a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with Edurant® (rilpivirine) for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine, for use as:
  - oral lead-in to assess the tolerability of cabotegravir prior to administration of Cabenuva® (cabotegravir/rilpivirine ER suspension).
  - oral therapy for patients who will miss planned injection dosing with Cabenuva® (cabotegravir/rilpivirine ER suspension).
- This agent received Fast Track and Priority Review designations from the FDA.

Overview/Summary

Cabenuva® (cabotegravir/rilpivirine ER suspension) is the first and only FDA-approved long-acting regimen, dosed once monthly, for the treatment of HIV-1 infection in adults. Prior to initiating treatment, oral Vocabria® (cabotegravir) and Edurant® (rilpivirine) should be administered for approximately one month to assess the tolerability of each therapy.[1-3]

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The primary goals of antiretroviral therapy are to maximally and durably suppress HIV viral load, preserve and/or restore immunologic function, reduce morbidity and mortality, and improve quality of life. There are more than 30 antiretroviral drugs in seven classes available to manage HIV infection through various mechanisms including nucleoside reverse transcriptase inhibitors (NRTIs), NNRTIs, protease inhibitors (PIs), INSTIs, fusion inhibitors, CC chemokine receptor 5 (CCR5) antagonists, post-attachment inhibitors, and attachment inhibitors. Highly active antiretroviral therapy (HAART) that includes a minimum of three drugs from two or more classes is generally recommended for the management of HIV in most patients. However, there is growing evidence that certain two-drug regimens can maintain virologic suppression.[4,5]

Clinical Guidelines

According to the United States Department of Health and Human Services (DHHS) guidelines, the INSTI-based regimens continue to be recommended as initial therapy for most people with HIV, while NNRTI and PI-based regimens are recommended only in certain clinical situations. The DHHS guideline were updated on February 24, 2021 with recommendations on using Cabenuva® (cabotegravir/rilpivirine ER suspension) and Vocabria® (cabotegravir) in patients with documented viral suppression for at least three months.[4]

Table 1. Clinical Guidelines

Clinical Guideline	Recommendations
Department of Health and Human Services: **Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV (2019)**[4]	Initial antiretroviral therapy (ART) in antiretroviral-naïve patients • Initial therapy generally consists of two nucleoside reverse transcriptase inhibitors (NRTIs) combined with an integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI), or a pharmacokinetically-enhanced protease inhibitor (PI) **Recommended initial regimens for most people with human immunodeficiency virus (HIV) (in alphabetical order):** • Recommended regimens are those with demonstrated durable virologic efficacy, favorable tolerability and toxicity profiles, and ease of use. INSTI plus 2 NRTIs: • Bictegravir/tenofovir/emtricitabine • Dolutegravir/abacavir/lamivudine* – only for patients who are HLA-B*5701-netagive • Dolutegravir plus tenofovir/emtricitabine* • Raltegravir plus tenofovir/emtricitabine* INSTI plus 1 NRTI: • Dolutegravir/lamivudine, except for in individuals with HIV RNA >500,000 copies/mL, HBV coinfection, or in whom antiretroviral treatment is to be started before the results of HIV genotype; resistance testing for reverse transcriptase or HBV testing are available *Lamivudine may be substituted for emtricitabine or vice versa **Recommended initial regimens in certain clinical situations** INSTI plus two NRTIs • Elvitegravir/cobicistat/tenofovir/emtricitabine Boosted PI plus two NRTIs (in general, boosted darunavir is preferred over boosted atazanavir): • Darunavir/cobicistat or darunavir/ritonavir plus tenofovir/emtricitabine* • Atazanavir/cobicistat or atazanavir/ritonavir plus tenofovir/emtricitabine*

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Clinical Guideline	Recommendations
	• Darunavir/cobicistat or darunavir/ritonavir plus abacavir/lamivudine* – if HLA-B*5701-netagive NNRTI plus two NRTIs: • Doravirine/tenofovir/emtricitabine* • Efavirenz plus tenofovir/emtricitabine* • Rilpivirine/tenofovir/emtricitabine* – if HIV RNA <100,000 copies/mL and CD4>200 cells/mm^3 INSTI plus two NRTIs: • Raltegravir plus abacavir/lamivudine* – if HLA-B*5701-netagive and HIV RNA <100,000 copies/mL Regimens to consider when abacavir, tenofovir alafenamide and tenofovir disoproxil fumarate cannot be used or are not optimal: • Dolutegravir/lamivudine, except for individuals with HIV RNA >500,000 copies/mL, HBV coinfection, or in whom antiretroviral treatment is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or HBV testing are available • Darunavir/ritonavir plus raltegravir (twice daily) – if HIV RNA <100,000 copies/mL and CD4>200 cells/mm^3 • Darunavir/ritonavir once daily plus lamivudine *Lamivudine may be substituted for emtricitabine or vice versa • These regimens are effective and tolerable, but have some disadvantages when compared with the regimens listed above, or have less supporting data from randomized clinical trials. • However, one of these regimens may be preferred in certain clinical situations, depending on pre-antiretroviral characteristics, ART specific characteristics, presence of other medical conditions or presence of coinfections. **Recommendations for cabotegravir/rilpivirine*** • Can be used as an optimization strategy for **people with HIV currently on oral antiretroviral therapy with documented viral suppression for at least three months** (although optimal duration is not defined) who— ○ have no baseline resistance to either medication, ○ have no prior virologic failures, ○ do not have active hepatitis B virus (HBV) infection (unless also receiving an oral HBV active regimen), ○ are not pregnant and are not planning on becoming pregnant, and ○ are not receiving medications with significant drug interactions with cabotegravir and rilpivirine. Before initiation of the intramuscular injection, patients should receive oral cabotegravir and oral rilpivirine for 28 days as an oral lead-in period to assess tolerance to these drugs. *To date, antiretroviral-experienced **participants enrolled in completed clinical trials were selected based on their history of good adherence and engagement in care**, as documented by sustained viral suppression

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Clinical Guideline	Recommendations
	at baseline. **These therapies are currently recommended for participants who are similarly engaged in care.**

HIV=human immunodeficiency virus

Pharmacokinetics

Table 2. Pharmacokinetics[1,3]

Generic Name	T_{max}	Protein binding (%)	Renal Excretion (%)	Metabolic pathways	Serum Half-Life
Cabotegravir	7 days (injection) 3 hours (tablet)	>99.8	27	UGT1A1 UGT1A9 (minor)	5.6 to 11.5 weeks (injection) 41 hours (tablet)
Rilpivirine	3 to 4 days	99.7	6	CYP3A	13 to 28 weeks

Clinical Trials

The FDA approvals of cabotegravir/rilpivirine ER suspension and oral cabotegravir were based on two Phase 3 randomized, multicenter, active-controlled, parallel-arm, open-label, non-inferiority trials, the FLAIR and ATLAS trials. In both studies, subjects randomized to receive cabotegravir/rilpivirine initiated treatment with daily oral lead-in dosing with cabotegravir 30 mg plus rilpivirine 25 mg tablets for at least four weeks followed by monthly injections with cabotegravir/rilpivirine for an additional 44 weeks. The primary endpoint in both studies was the proportion of patients with plasma HIV-1 RNA ≥50 copies/mL at week 48. A key secondary endpoint was the percentage of patients who had a plasma HIV-1 RNA <50 copies/mL at week 48.[5,6]

In the FLAIR trial (N=566), patients with HIV-1 infection who had not previously received antiretroviral therapy who received a dolutegravir INSTI-containing regimen for 20 weeks. Patients who were virologically suppressed (HIV-1 RNA <50 copies/mL) were randomized to receive either a cabotegravir/rilpivirine ER regimen or to remain on the current antiretroviral regimen. At week 48, the primary endpoint was achieved in six patients (2.1%) in the long-acting therapy group and in seven patients (2.5%) in the oral therapy group (adjusted difference, -0.4 percentage points; 95% CI [confidence interval], -2.8 to 2.1).[5]

In the ATLAS trial (N=616), virologically suppressed antiretroviral-experienced patients with HIV-1 infection were randomized to cabotegravir/rilpivirine or to remain on their current antiretroviral regimen.[6] At week 48, the primary endpoint was achieved in five patients (1.6%) in the long-acting-therapy group and three patients (1.0%) in the oral therapy group (adjusted difference, 0.6 percentage points; 95% CI, -1.2 to 2.5).

Results of both studies met the prespecified noninferiority criterion for the primary end point. Long-acting therapy was noninferior to oral therapy with respect to HIV-1 RNA level <50 copies/mL at week 48 in both trials.[5,6]

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Table 3. Clinical Trials

Study and Drug Regimen	Study Design and Demographics	Sample Size and Study Duration	End Points	Results	Study Grade*
Orkin et al[6] FLAIR Long-acting cabotegravir/long-acting rilpivirine 600 mg/900 mg IM injection, followed by 400 mg/600 mg IM injection once monthly (oral lead in therapy with cabotegravir 30 mg and rilpivirine 25 mg QD for four weeks prior to long-acting therapy) vs continue current oral therapy QD Subjects received oral induction therapy with a fixed-dose combination of 50 mg of dolutegravir, 600 mg of abacavir, and 300 mg of lamivudine once daily for 20 weeks; subjects who had plasma HIV-1 RNA levels <50 copies/mL after 16 weeks of oral induction therapy were randomized to one of the regimens above.	MC, NI, OL, PG, RCT Patients 18 years of age or older who had not previously received antiretroviral therapy, and had a plasma HIV-1 RNA level of 1000 copies/mL or higher at screening	N=566 48 weeks	Primary: Percentage of subjects who had an HIV-1 RNA level of 50 copies/mL or higher at week 48 Secondary: Percentage of subjects who had a plasma HIV-1 RNA level of less than 50 copies/mL at week 48, confirmed virologic failure, genotypic and phenotypic resistance coincident with virologic failure and adverse events	Primary: At week 48, an HIV-1 RNA level of 50 copies/mL or higher was found in six subjects (2.1%) in the long-acting therapy group and in seven subjects (2.5%) in the oral therapy group (adjusted difference, -0.4 percentage points; 95% CI, -2.8 to 2.1). Secondary: Long-acting therapy was noninferior to oral therapy with regard to the percentage of subjects with an HIV-1 RNA level of less than 50 copies/mL at week 48 (93.6% and 93.3%, respectively; adjusted difference, 0.4 percentage points; 95% CI, -3.7 to 4.5). In the long-acting therapy group, four subjects had confirmed virologic failure. No resistance testing was detected in one subject and the other three subjects had NNRTI and INSTI resistance mutations that developed during long-acting therapy. In the oral-therapy group, three subjects had confirmed virologic failure without the development of resistance mutations or phenotypic changes during treatment. The most common adverse events in the long-acting therapy group, excluding injection-site reactions, were nasopharyngitis, headache, upper respiratory tract infection, and diarrhea. Serious adverse events occurred in 18 subjects (6%) who received long-acting therapy and in 12 subjects (4%) who received oral therapy; each type of event occurred in one subject (except hepatitis A, which occurred in three subjects who received long-acting therapy), with no deaths. Adverse events that led to withdrawal from the trial occurred in nine subjects (3%) who received long-acting therapy and in four subjects (1%) who received oral therapy. In the long-	Good

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Study and Drug Regimen	Study Design and Demographics	Sample Size and Study Duration	End Points	Results	Study Grade*
				acting therapy group, the only events that led to withdrawal in more than one subject were viral hepatitis and injection-site pain (in five and two subjects, respectively).	
Swindells et al[7] ATLAS Long-acting cabotegravir/long-acting rilpivirine 600 mg/900 mg IM injection, followed by 400 mg/600 mg IM injection every four weeks (oral lead in therapy with cabotegravir 30 mg and rilpivirine 25 mg QD for four weeks prior to long-acting therapy) vs continue oral ART therapy	MC, NI, OL, PG, RCT Patients 18 years of age or older with HIV-1 who had been receiving antiretroviral drugs in an uninterrupted regimen without virologic failure and without a change in medication for at least six months before screening	N=616 52 weeks	Primary: Percentage of subjects with an HIV-1 RNA level of 50 copies/mL or higher at week 48 Secondary: Percentage of subjects with plasma HIV-1 RNA levels of less than 50 copies/mL at week 48, confirmed virologic failure, genotypic and phenotypic resistance coincident with virologic failure and adverse events	Primary: In the intention-to-treat population, HIV-1 RNA levels of 50 copies/mL or higher at week 48 were found in five subjects (1.6%) in the long-acting therapy group and three (1.0%) in the oral-therapy group (adjusted difference, 0.6 percentage points; 95% CI, -1.2 to 2.5). Secondary: The long-acting therapy was noninferior to oral therapy with respect to HIV-1 RNA level of less than 50 copies/mL at week 48 (92.5% and 95.5%, respectively; adjusted difference, -3.0 percentage points; 95% CI, -6.7 to 0.7). Three subjects in the long-acting therapy group had confirmed virologic failure, including two with HIV-1 subtype A/A1 (failure occurred at week 8 in one subject and at week 20 in the other) and one with subtype AG (in whom failure occurred at week 12). Rilpivirine resistance-associated reverse-transcriptase mutations were detected in HIV-1 RNA samples from all three subjects at the time of virologic failure, including E138A in one subject and E138K plus V108I in another (in both these subjects, the same E138 mutations were present in HIV-1 DNA at baseline) and E138E/K plus the integrase mutation N155H in the third. Two subjects also had an L74I integrase polymorphism at baseline and at virologic failure, although this accessory mutation by itself does not decrease susceptibility to INSTIs. Four subjects in the oral-therapy group had confirmed virologic failure, and reverse-transcriptase mutations were detected in three of these subjects: one had the M184I mutation, one had M184V plus G190S, and one had M230M/I.	Good

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Study and Drug Regimen	Study Design and Demographics	Sample Size and Study Duration	End Points	Results	Study Grade*
				Adverse events were more common in the long-acting therapy group and included injection-site pain, which occurred in 231 recipients (75%) of long-acting therapy and was mild or moderate in most cases; 1% withdrew because of this event. Serious adverse events were reported in no more than 5% of subjects in each group.	

*Study grading according to *U.S. Preventive Services Task Force (USPSTF)*, (See Appendix II for definition of ratings). Studies falling outside of the grading criteria defined by *USPSTF* will be noted as "Not Applicable". This indicates that the grading criteria did not appropriately fit the design of the included study, but that it was included due to the potential value of the presented data.

† Trial is registered on ClinicalTrials.gov.

Drug regimen abbreviations: IM=intramuscularly, QD=once daily,

Study abbreviations: CI=confidence interval, MC=multicenter, NI=non-inferiority, OL=open-label, PG=parallel-group, RCT=randomized controlled trial, RETRO=retrospective

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Special Populations

Table 4. Special Populations[1,2]

Population	Precaution
≥65 Years of Age	Safety and efficacy in patients ≥65 years of age have not been established.
Renal Dysfunction	Cabotegravir/rilpivirine ER suspension: No dosage adjustment is necessary for patients with mild or moderate renal impairment (CrCl ≥30 to <90 mL/min). In patients with severe renal impairment or ESRD (CrCl <30 mL/min), increased monitoring for adverse effects is recommended. Cabotegravir tablet: No dosage adjustment is necessary for patients with mild, moderate, or severe renal impairment (CrCl <90 mL/min). The effect of ESRD (CrCl <15 mL/min) on the pharmacokinetics of cabotegravir is unknown.
Hepatic Dysfunction	No dosage adjustment required in patients with mild or moderate hepatic impairment (Child-Pugh A or B). The effect of severe hepatic impairment (Child-Pugh C) on the pharmacokinetics of cabotegravir or rilpivirine is unknown.
Pregnancy / Nursing	There are insufficient human data during pregnancy to adequately assess a drug-associated risk of birth defects and miscarriage. Cabotegravir use in pregnant women has not been evaluated. Available data from the Antiretroviral Pregnancy Registry show no difference in the overall risk of birth defects for rilpivirine compared with the background rate for major birth defects of 2.7% in a U.S. reference population of the Metropolitan Atlanta Congenital Defects Program. It is not known if the components of cabotegravir or rilpivirine are present in human breast milk, affect human milk production, or have effects on the breastfed infant. Because of the potential for HIV-1 transmission (in HIV-negative infants), developing viral resistance (in HIV-positive infants), adverse reactions in a breastfed infant similar to those seen in adults, and detectable cabotegravir and rilpivirine concentrations in systemic circulation for up to 12 months or longer after discontinuing injections of cabotegravir/rilpivirine, breastfeeding while on cabotegravir/rilpivirine is not recommended.
Children	Safety and efficacy in children have not been established.
Age Restrictions	FDA approved for use in adults only.
Medicare Part B Coverage	Not applicable.

CrCl=creatinine clearance, ESRD=end-stage renal disease

Adverse Drug Events

The safety assessment of cabotegravir/rilpivirine ER suspension and oral cabotegravir is based on the analysis of pooled 48-week data from 1,182 virologically suppressed patients with HIV-1 infection in two international, multicenter, open-label pivotal trials, FLAIR and ATLAS.[1,2] The most common adverse reactions during the oral lead-in period following exposure to cabotegravir and rilpivirine tablets were headache, nausea, abnormal dreams, anxiety, and insomnia all of which occurred in at least three patients, with an incidence of ≤1%.[3] Overall, 4% of patients in cabotegravir/rilpivirine ER suspension group and 2% of patients in the control group discontinued treatment due to adverse events. Non-injection-site-related adverse events leading to discontinuation and occurring in more than one patients were headache, diarrhea, hepatitis A, and acute hepatitis

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B. The most common adverse reactions (≥2%) in adult patients in the pooled analyses from FLAIR and ATLAS are presented in the table below.[1]

Table 5. Adverse Events[1,3]

Adverse Event	Reported Frequency			
	Cabotegravir plus Rilpivirine %, N=591		Current Antiretroviral Regimen %, N=591	
	All Grades	Grade ≥2	All Grades	Grade ≥2
Injection site reactions	83	37	0	0
Pyrexia	8	3	0	0
Fatigue	5	1	<1	<1
Headache	4	<1	<1	<1
Musculoskeletal pain	3	1	<1	0
Nausea	3	<1	1	<1
Sleep disorders	2	<1	<1	0
Dizziness	2	<1	<1	0
Rash	2	<1	0	0

Contraindications and Warnings/Precautions

Table 6. Contraindication[1,2]

Contraindication	Description
Hypersensitivity	Cabotegravir/rilpivirine should not be used in patients with previous hypersensitivity reaction to cabotegravir or rilpivirine. Cabotegravir should not be used in patients with previous hypersensitivity reaction to cabotegravir.
Co-administration with certain drugs	Cabotegravir/rilpivirine is contraindicated in patients receiving the following coadministered drugs for which significant decreases in cabotegravir and/or rilpivirine plasma concentrations may occur due to UGT1A1 and/or CYP3A enzyme induction, which may result in loss of virologic response: anticonvulsants (carbamazepine, oxcarbazepine, phenobarbital, phenytoin), antimycobacterials (rifabutin, rifampin, rifapentine), systemic glucocorticoid (dexamethasone, more than a single-dose treatment), and herbal product (St. John's wort). Cabotegravir is contraindicated in patients receiving the following coadministered drugs for which significant decreases in cabotegravir plasma concentrations may occur due to UGT1A1 enzyme induction, which may result in loss of virologic response: anticonvulsants (carbamazepine, oxcarbazepine, phenobarbital, phenytoin), and antimycobacterials (rifampin, rifapentine).

Table 7. Warnings/Precautions[1,2]

Warnings/ Precautions	Description
Hypersensitivity reactions	Hypersensitivity reactions have been reported during postmarketing experience with rilpivirine containing regimens. Reactions include cases of Drug Reaction with Eosinophilia and Systemic Symptoms. Cabotegravir/rilpivirine should be discontinued immediately if signs or symptoms of hypersensitivity reactions develop.

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	Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with cabotegravir. Treatment with cabotegravir should be discontinued immediately if signs or symptoms of hypersensitivity reactions develop.
Post-injection reactions	In clinical trials, serious post-injection reactions were reported within minutes after the injection of rilpivirine, including dyspnea, agitation, abdominal cramping, flushing, sweating, oral numbness, and changes in blood pressure. The instructions for use should be followed carefully when preparing and administering cabotegravir/rilpivirine to avoid accidental intravenous administration. Patients should be observed briefly (approximately 10 minutes) after the injection. Patients experiencing a post-injection reaction should be monitored and treated as clinically indicated.
Hepatotoxicity	Hepatotoxicity has been reported in patients receiving cabotegravir or rilpivirine with or without known pre-existing hepatic disease or identifiable risk factors. Patients with underlying liver disease or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations. Monitoring of liver chemistries is recommended and treatment with cabotegravir or cabotegravir/rilpivirine should be discontinued if hepatotoxicity is suspected.
Depressive disorders	Depressive disorders (including depressed mood, depression, major depression, mood altered, mood swings, dysphoria, negative thoughts, suicidal ideation or attempt) have been reported with cabotegravir/rilpivirine or the individual drug products. Promptly evaluate patients with depressive symptoms to assess whether the symptoms are related to cabotegravir or cabotegravir/rilpivirine and to determine whether the risks of continued therapy outweigh the benefits.
Risk of adverse reactions or loss of virologic response due to drug interactions	The concomitant use of cabotegravir or cabotegravir/rilpivirine and other drugs may result in known or potentially significant drug interactions, some of which may lead to adverse events, loss of virologic response of cabotegravir or cabotegravir/rilpivirine, and possible development of viral resistance. Consider the potential for drug interactions prior to and during therapy with, and after discontinuation of cabotegravir or cabotegravir/rilpivirine; review concomitant medications during therapy with cabotegravir or cabotegravir/rilpivirine.
Long-acting properties and potential associated risks	Residual concentrations of both cabotegravir and rilpivirine may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer). It is important to carefully select patients who agree to the required monthly injection dosing schedule because non-adherence to monthly injections or missed doses could lead to loss of virologic response and development of resistance. To minimize the potential risk of developing viral resistance, it is essential to initiate an alternative, fully suppressive antiretroviral regimen no later than one month after the final injection doses of cabotegravir/rilpivirine.

Drug Interactions

Because **cabotegravir in combination with rilpivirine and cabotegravir/rilpivirine ER suspension are** complete regimens, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.[1,2]

Residual concentrations of cabotegravir and rilpivirine from **cabotegravir/rilpivirine ER suspension administration** may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer). These residual concentrations are not expected to affect the exposures of antiretroviral drugs that are initiated after discontinuation of cabotegravir/rilpivirine.[1]

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Cabotegravir is primarily metabolized by UGT1A1 with some contribution from UGT1A9. Drugs that are strong inducers of UGT1A1 or 1A9 are expected to decrease cabotegravir plasma concentrations and may result in loss of virologic response; therefore, coadministration of cabotegravir/rilpivirine with these drugs is contraindicated.[1]

Rilpivirine is primarily metabolized by CYP3A. Coadministration of cabotegravir/rilpivirine and drugs that induce CYP3A may result in decreased plasma concentrations of rilpivirine and loss of virologic response and possible resistance to rilpivirine or to the class of NNRTIs. Coadministration of cabotegravir/rilpivirine and drugs that inhibit CYP3A may result in increased plasma concentrations of rilpivirine.[3]

Coadministration of oral cabotegravir with polyvalent cation-containing products may lead to decreased absorption of cabotegravir.[1]

The table below provides information about potential drug interactions with cabotegravir and rilpivirine. The table includes potentially significant interactions but is not all inclusive.

Table 8. Drug Interactions[1,2,7]

Interacting Medication or Disease	Interaction Severity Rating*	Potential Result
Antacids containing polyvalent cations (aluminum or magnesium hydroxide, calcium carbonate)	D: Consider therapy modification	My decrease the serum concentration of oral cabotegravir. Antacid products should be administered at least two hours before or four hours after taking oral cabotegravir.
Anticonvulsants (carbamazepine, oxcarbazepine, phenobarbital, phenytoin)	X: Avoid combination	May decrease the serum concentration of rilpivirine and/or cabotegravir; coadministration is contraindicated due to potential for loss of virologic response and development of resistance.
Antimycobacterials (rifampin, rifapentine)	X: Avoid combination	May decrease the serum concentration of rilpivirine and cabotegravir; coadministration is contraindicated due to potential for loss of virologic response and development of resistance.
Antimycobacterial (rifabutin)	X: Avoid combination	May decrease the serum concentration of cabotegravir. Additionally, rifabutin may decrease rilpivirine concentrations, a drug always coadministered with IV cabotegravir. Coadministration is contraindicated due to potential for loss of virologic response and development of resistance.
Glucocorticoid, systemic (dexamethasone, more than a single-dose treatment)	X: Avoid combination	May decrease the serum concentration of rilpivirine; coadministration is contraindicated due to potential for loss of virologic response and development of resistance.
Herbal product (St John's wort)	X: Avoid combination	May decrease the serum concentration of rilpivirine; coadministration is contraindicated due to potential for loss of virologic response and development of resistance.
Macrolide or ketolide antibiotic (azithromycin, clarithromycin, erythromycin)	D: Consider therapy modification	Macrolides are expected to increase concentrations of rilpivirine and are associated with a risk of Torsade de

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Interacting Medication or Disease	Interaction Severity Rating*	Potential Result
		Pointes. Where possible, consider alternatives, such as azithromycin, which increases rilpivirine concentrations less than other macrolides.
Narcotic analgesic (methadone)	C: Monitor therapy	Rilpivirine may increase the metabolism of methadone. No dose adjustment of methadone is required when starting coadministration of methadone with cabotegravir/rilpivirine. However, clinical monitoring is recommended as methadone maintenance therapy may need to be adjusted in some patients.

*Severity rating per Lexicomp® Drug Interactions

Dosage and Administration

Prior to initiating treatment with cabotegravir/rilpivirine, oral lead-in dosing should be used for approximately one month to assess the tolerability of cabotegravir and rilpivirine.[1]

Cabotegravir/rilpivirine ER suspension must be administered by a healthcare professional who should carefully select patients who agree to the required monthly injection dosing schedule and counsel patients about the importance of adherence to scheduled dosing visits.[1]

Cabotegravir and rilpivirine should be administered as separate gluteal injection sites (on opposite sides or 2 cm apart) during the same visit.[1]

If scheduled injection is missed by ≥7 days, daily oral therapy should be taken to replace up to two consecutive monthly injection visits. If monthly injections are missed by ≥7 days and oral therapy has not been taken in the interim, patients should be reassessed for treatment reinitiation with 600 mg/900 mg IM dose.[1]

Table 9. Dosing and Administration[1,2]

Adult Dose	Pediatric Dose	Availability
HIV-1: Tablet: 30 mg PO QD for approximately one month in combination with rilpivirine 25 mg PO QD	Safety and efficacy in children have not been established.	Tablet: 30 mg
HIV-1: Injection: 600 mg/900 mg IM on the last day of oral lead-in followed by 400 mg/600 mg IM every month thereafter	Safety and efficacy in children have not been established.	Injectable suspension: **400 mg/600 mg kit** Containing single-dose vials • 400 mg/2 mL cabotegravir • 600 mg/2 mL rilpivirine **600 mg/900 mg kit** Containing single-dose vials • 600 mg/3 mL cabotegravir • 900 mg/3 mL rilpivirine Store in refrigerator at 2 to 8°C in the original carton until ready to use.*

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HIV=human immunodeficiency, IM=intramuscular, PO=by mouth, QD=once daily
*Vials should be brought to room temperature before administration and may remain in the carton for up to six hours after which they should be discarded if not used. Once drawn into syringes, the injections should be administered as soon as possible, but may remain in the syringe for up to two hours after which they should be discarded if not used.

Clinical Alternatives

Table 10. Current Alternatives

Medication	Dosing Frequency
Cabotegravir and rilpivirine	
Vocabria® (cabotegravir)	30 mg QD
Cabenuva® (cabotegravir/rilpivirine)	600 mg/900 mg IM on the last day of oral lead-in followed by 400 mg/600 mg IM monthly
Recommended Initial Regimens for Most People with HIV‡	
INSTI + 2 NRTIs	
Bictegravir/emtricitabine/tenofovir alafenamide	
Biktarvy® (bictegravir/emtricitabine/ tenofovir alafenamide)	1 tablet QD
Dolutegravir + abacavir/lamivudine	
Triumeq® (abacavir/dolutegravir/lamivudine)	1 tablet QD
Tivicay® (dolutegravir)	50 mg QD to BID
Epzicom® (abacavir/lamivudine)	1 tablet QD
Dolutegravir + emtricitabine/tenofovir	
Tivicay® (dolutegravir)	50 mg QD to BID
Truvada® (emtricitabine/tenofovir disoproxil fumarate)	200 mg/300 mg QD
Tivicay® (dolutegravir)	50 mg QD to BID
Descovy® (emtricitabine/tenofovir alafenamide)	1 tablet QD
Raltegravir + emtricitabine + tenofovir	
Isentress® (raltegravir)	400 mg BID or 1,200 mg (HD) QD
Truvada® (emtricitabine/tenofovir disoproxil fumarate)	200 mg/300 mg QD
Isentress® (raltegravir)	400 mg BID or 1,200 mg (HD) QD
Descovy® (emtricitabine/tenofovir alafenamide)	1 tablet QD
INSTI plus 1 NRTI	
Dolutegravir + lamivudine	
Tivicay® (dolutegravir)	50 mg QD to BID
Epivir® # (lamivudine)	150 mg BID

‡Recommended and alternative regimens by the United States Department of Health and Human Services guideline

Potential Advantages

- The first once-monthly injectable complete antiretroviral regimen for adults with HIV-1 infection.[1]
- An injectable route of administration offers an advantage for patients who may not be able to tolerate or absorb oral medications or have difficulty with medication adherence.
- Recommended by DHHS guidelines for patients with HIV currently on oral antiretroviral therapy with documented viral suppression for at least three months (optimal duration is not defined).

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Potential Disadvantages/Unanswered Questions

- Not indicated in antiretroviral-naïve patients or those with a history of treatment failure.[1]
- Given as separate gluteal injection sites by a healthcare professional.
- Associated with higher cost of therapy compared to DHHS recommended regimens.
- There is not pricing information available for Vocabria® (cabotegravir); however, newsblasts indicate that manufacturer intends to cover oral lead-in treatment through patient assistance program.[8]
- Per DHHS guidelines, participants in clinical trials were selected based on their history of good adherence and engagement in care. DHHS guidelines recommend Cabenuva® (cabotegravir/rilpivirine ER suspension) for patients who are similarly engaged in care.

Other Key Facts

- Available through specialty pharmacies (e.g., Accredo, CVS Caremark, etc) or buy and bill
- Being studied in phase III trials as a once every eight-week injection for treatment-experienced adults who are virologically suppressed.
- Being studied in phase III trials as a once-monthly injection for pre-exposure prophylaxis (66% lower incidence of HIV vs emtricitabine/tenofovir disoproxil fumarate). Regulatory filings expected in H1 2020.

Conclusions

Cabenuva® (cabotegravir/rilpivirine ER suspension) is the first and only FDA-approved long-acting regimen, dosed once monthly, for the treatment of HIV-1 infection in adults. Prior to initiating treatment of Cabenuva® (cabotegravir/rilpivirine ER suspension), oral lead-in treatment with Vocabria® (cabotegravir) and Edurant® (rilpivirine) should be administered for approximately one month to assess the tolerability of each therapy.[1,2]

Two Phase 3 randomized, multicenter, active-controlled, parallel-arm, open-label, non-inferiority trials, FLAIR and ATLAS, met the prespecified noninferiority criterion for the primary endpoint concluding that Cabenuva® (cabotegravir/rilpivirine ER suspension) was noninferior to current antiretroviral regimen with respect to HIV-1 RNA ≤50 copies/mL at week 48.[1,2,5,6]

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Appendix I: United States Department of Health and Human Services Food and Drug Administration Definitions for Expedited Drug Review Programs

Source:
Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics. OMB Control No. 0910-0765, May 2014. United States Department of Health and Human Services Food and Drug Administration, Rockville, MD. https://www.fda.gov/downloads/Drugs/Guidances/UCM358301.pdf.

Expedited Programs for Regenerative Medicine Therapies for Serious Conditions. Draft Guidance for Industry. Nov 2017. United States Department of Health and Human Services Food and Drug Administration, Rockville, MD.
https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/cellularandgenetherapy/ucm585414.pdf.

Program	Description
Fast Track Designation	Qualifying drugs: • A drug that is intended to treat a serious condition, AND nonclinical or clinical data demonstrate the potential to address unmet medical need • A drug that has been designated as a qualified infectious disease product Features: • Actions to expedite development and review* • Rolling review
Priority Review	Qualifying drugs: • An application (original or efficacy supplement) for a drug that treats a serious condition AND, if approved, would provide a significant improvement in safety or effectiveness • Any supplement that proposes a labeling change pursuant to a report on a pediatric study under 505A • An application for a drug that has been designated as a qualified infectious disease product • Any application or supplement for a drug submitted with a priority review voucher Features: • Shorter clock for review of marketing application (6 months compared with the 10-month standard review)

*These include meetings with FDA, including pre-IND meetings, end-of-phase 1 meetings, and end-of-phase 2 meetings to discuss study design, extent of safety data required to support approval, dose-response concerns, and use of biomarkers. Other meetings may be scheduled as appropriate.

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New Drug Review for Cabenuva® (cabotegravir/rilpivirine ER suspension) and Vocabria® (cabotegravir)

Appendix II: *U.S. Preventive Services Task Force (USPSTF)* Grading Definitions for Randomized Controlled Trials

Source: *U.S. Preventive Services Task Force Procedure Manual*. December 2015 U.S. Preventive Services Task Force, Rockville, MD. https://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual

Randomized Controlled Trials		
Definition of Ratings from Above Criteria	**Good**	Meets all criteria: Comparable groups are assembled initially and maintained throughout the study (follow-up at least 80 percent); reliable and valid measurement instruments are used and applied equally to all groups; interventions are spelled out clearly; all important outcomes are considered; and appropriate attention to confounders in analysis. Intention to treat analysis is used.
	Fair	Studies will be graded "fair" if any or all of the following problems occur, without the fatal flaws noted in the "poor" category below: Generally comparable groups are assembled initially but some question remains whether some (although not major) differences occurred with follow-up; measurement instruments are acceptable (although not the best) and generally applied equally; some but not all important outcomes are considered; and some but not all potential confounders are accounted for. Intention to treat analysis is done.
	Poor	Studies will be graded "poor" if any of the following fatal flaws exists: Groups assembled initially are not close to being comparable or maintained throughout the study; unreliable or invalid measurement instruments are used or not applied at all equally among groups (including not masking outcome assessment); and key confounders are given little or no attention. Intention to treat analysis is lacking.

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New Drug Review for Sunlenca® (lenacapavir)

Generic Name: lenacapavir
Trade Name: Sunlenca®
Formulation: 300 mg tablet and 463.5 mg/1.5 mL single-dose vials
Manufacturer: Gilead Sciences, Inc.
FDA Approval Date: December 22, 2022
Product Launch Date: December 27, 2022

Food and Drug Administration (FDA)-approved Indication

- Sunlenca® (lenacapavir), a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.[1]
- The agent received Priority Review, Fast Track and Breakthrough Therapy designations for this indication from the FDA.[2,3]

Overview/Summary

Sunlenca® (lenacapavir) is the first of a new class of antiretroviral drugs called capsid inhibitor. Lenacapavir is a multistage, selective inhibitor of HIV-1 capsid function that directly binds to the interface between capsid protein (p24) subunits in hexamers.[1,2] Lenacapavir inhibits HIV-1 replication by interfering with multiple essential steps of the viral lifecycle, including capsid-mediated nuclear uptake of HIV-1 proviral DNA (by blocking nuclear import proteins binding to capsid), virus assembly and release (by interfering with Gag/Gag-Pol functioning, reducing production of capsid protein subunits) and capsid core formation (by disrupting the rate of capsid subunit association, leading to malformed capsids).[1]

The starting dose of lenacapavir is given as oral tablets and subcutaneous injections, followed by maintenance injections every six months. Lenacapavir is given in combination with other antiretroviral(s).[1,2]

For most patients with HIV-1 infection, an effective antiretroviral regimen can be devised. Use of currently available antiretroviral drugs has resulted in a dramatic decline in the number of patients who have few treatment options because of multiclass drug-resistance. Despite this progress, some patients have experienced toxicities with and/or developed resistance to most currently available antiretroviral drugs. Maximal virologic suppression should remain the goal; however, if it cannot be achieved, the goals of antiretroviral therapy should be to preserve immunologic function, prevent clinical progression and minimize the development of further resistance that may compromise future regimens.[4]

Other antiretrovirals recently approved with a novel mechanism of action for the treatment of heavily treatment-experienced adults with multidrug resistant HIV-1 include Trogarzo® (ibalizumab-uiyk), a monoclonal antibody post-attachment inhibitor FDA-approved in 2018, and Rukobia® (fostemsavir), a gp120-directed attachment inhibitor FDA-approved in 2020. Both Trogarzo® (ibalizumab-uiyk) and Rukobia® (fostemsavir) currently require PA through MassHealth.

Clinical Guidelines

The United States Department of Health and Human Services (DHHS) guideline on the use of antiretroviral agents in adults and adolescents with HIV recommends that designing a new regimen for patients who are experiencing treatment failure should always be guided by antiretroviral history and results from current and past resistance testing. For patients with second regimen failure and beyond with multiple or extensive drug resistance with few treatment options, the guideline recommends that the new regimen include at least two, and preferably three, fully active agents, including those with novel mechanisms of action (e.g., ibalizumab or fostemsavir). If there are less than three fully active drugs, the guideline recommends including as many fully active drugs as

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New Drug Review for Sunlenca® (lenacapavir)

possible, along with potentially partially active drugs. The DHHS guideline does not currently address the place in therapy of lenacapavir.[4]

Table 1. Clinical Guidelines

Clinical Guideline	Recommendations
Department of Health and Human Services: **Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV (2020)**[4]	Initial antiretroviral therapy (ART) in antiretroviral-naïve patients • An initial antiretroviral regimen for a person with HIV generally consists of two nucleoside reverse transcriptase inhibitors (NRTIs) administered in combination with third active antiretroviral drug from one of three classes: an integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI), or a pharmacokinetically-enhanced protease inhibitor (PI) **Recommended initial regimens for most people with human immunodeficiency virus (HIV):** • Recommended regimens are those with demonstrated durable virologic efficacy, favorable tolerability and toxicity profiles, and ease of use. For people who do not have a history of long-acting injectable cabotegravir use as pre-exposure prophylaxis, the following regimens are recommended: INSTI plus 2 NRTIs: • Bictegravir/tenofovir alafenamide/emtricitabine • Dolutegravir/abacavir/lamivudine* – only for patients who are HLA-B*5701-netagive • Dolutegravir plus (tenofovir alafenamide or disoproxil) plus emtricitabine or lamivudine INSTI plus 1 NRTI: • Dolutegravir/lamivudine, except for individuals with HIV RNA >500,000 copies/mL, HBV coinfection, or in whom antiretroviral therapy is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or HBV testing are available For people with HIV and a history of long-acting injectable cabotegravir use as pre-exposure prophylaxis, INSTI genotypic resistance testing should be performed before the start of antiretroviral therapy. If treatment is begun prior to results of genotypic testing, the following regimen is recommended • Darunavir/cobicistat or darunavir/ritonavir with tenofovir alafenamide or tenofovir disoproxil plus emtricitabine or lamivudine – pending the results of the genotype test **Recommended initial regimens in certain clinical situations** • These regimens are effective and tolerable, but have some disadvantages when compared with the regimens listed above, or have fewer supporting data from randomized clinical trials. • However, in certain clinical situations, one of these regimens may be preferred.

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New Drug Review for Sunlenca® (lenacapavir)

Clinical Guideline	Recommendations

	<u>INSTI plus two NRTIs:</u>
	• Elvitegravir/cobicistat/tenofovir alafenamide or tenofovir disoproxil/emtricitabine
	• Raltegravir plus tenofovir alafenamide or tenofovir disoproxil plus emtricitabine or lamivudine
	
	<u>Boosted PI plus two NRTIs</u> (in general, boosted darunavir is preferred over boosted atazanavir)
	• Darunavir/cobicistat or darunavir/ritonavir plus tenofovir alafenamide or tenofovir disoproxil plus emtricitabine or lamivudine
	• Atazanavir/cobicistat or atazanavir/ritonavir plus tenofovir alafenamide or tenofovir disoproxil plus emtricitabine or lamivudine
	• Darunavir/cobicistat or darunavir/ritonavir plus abacavir/lamivudine – if HLA-B*5701-netagive
	
	<u>NNRTI plus two NRTIs:</u>
	• Doravirine/tenofovir disoproxil/lamivudine or doravirine plus tenofovir alafenamide/emtricitabine
	• Efavirenz plus tenofovir alafenamide or tenofovir disoproxil plus emtricitabine or lamivudine
	• Rilpivirine/ tenofovir alafenamide or tenofovir disoproxil /emtricitabine – if HIV RNA <100,000 copies/mL and CD4>200 cells/mm^3
	
	<u>Regimens to consider when abacavir, tenofovir alafenamide and tenofovir disoproxil fumarate cannot be used or are not optimal:</u>
	• Dolutegravir/lamivudine, except for individuals with HIV RNA >500,000 copies/mL, HBV coinfection, or in whom antiretroviral therapy is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or HBV testing are available
	• Darunavir/ritonavir plus raltegravir (twice daily) – if HIV RNA <100,000 copies/mL and CD4>200 cells/mm^3
	• Darunavir/ritonavir once daily plus lamivudine
	
	<u>Management of virologic failure</u>
	• Designing a new regimen for patients who are experiencing treatment failure should always be guided by ARV history and results from current and past resistance testing.
	• For second regimen failure and beyond with multiple or extensive drug resistance with few treatment options (e.g., fully active boosted PI or second generation INSTI unavailable):
	  ○ Use past and current genotypic- and phenotypic resistance testing to guide therapy.
	  ○ Confirm with a viral tropism assay when use of MVC is considered.
	  ○ Consult an expert in drug resistance if needed.
	  ○ New regimen should include at least two, and preferably three, fully active agents, including those with novel mechanisms of action (e.g., ibalizumab or fostemsavir). If <3 fully active drugs, include as many fully active drugs as possible, along with potentially partially active drugs.

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Clinical Guideline	Recommendations
	○ Consider enrollment into clinical trials or expanded access programs for investigational agents if available. ○ Discontinuation of all antiretroviral drugs is not recommended. ○ Goal of therapy is resuppression if possible; otherwise, keep viral load as low as possible and CD4 count as high as possible.

Pharmacokinetics

Table 2. Pharmacokinetics[1]

Generic Name	Bioavailability (%)	V_d (L)	Plasma protein bound (%)	Excretion (%)	Serum Half-Life
Oral lenacapavir	6 to 10	19,240	>98.5	<1 (urine) 76 (feces)	10 to 12 days
Subcutaneous lenacapavir	100	9,500 to 11,700			8 to 12 weeks

V_d=volume of distribution

Clinical Trials

The efficacy and safety of lenacapavir was evaluated in a 52-week, placebo-controlled, double-blind, multicenter, phase 3, randomized CAPELLA trial including 72 heavily treatment-experienced subjects with multidrug resistant HIV-1. Subjects were required to have a viral load ≥400 copies/mL, documented resistance to at least two antiretroviral medications from each of at least three of the four classes of antiretroviral medications (nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, protease inhibitor and integrase strand transfer inhibitor), and ≤two fully active antiretroviral medications from the four classes of antiretroviral medications remaining at baseline due to resistance, intolerability, drug access, contraindication or other safety concerns. Patients were enrolled in two cohorts, according to the change in the plasma HIV-1 RNA level between the screening and cohort-selection visits. In cohort 1, patients were first randomly assigned in a 2:1 ratio to receive oral lenacapavir or placebo in addition to their failing therapy for 14 days. During the maintenance period, starting on day 15, patients in the lenacapavir group received subcutaneous lenacapavir once every six months, and those in the placebo group received oral lenacapavir, followed by subcutaneous lenacapavir. Both groups also received optimized background therapy. In cohort 2, all the patients received open-label oral lenacapavir with optimized background therapy on days 1 through 14. Subcutaneous lenacapavir was then administered once every six months starting on day 15. A total of 72 patients were enrolled, with 36 in each cohort.[1,5]

The primary end point was the percentage of patients in cohort 1 who had a decrease of at least 0.5 $\log_{10}$ copies/mL in the viral load by day 15. A key secondary end point was a viral load of less than 50 copies/mL at week 26.[1,5]

In cohort 1, a decrease of at least 0.5 $\log_{10}$ copies/mL in the viral load by day 15 was observed in 21 of 24 patients (87.5%) in the lenacapavir group and in two of 12 patients (16.7%) in the placebo group (absolute difference, 70.8%; 95% confidence interval [CI], 34.9 to 90.0; P<0.001). The least-squares mean (±SE) change in the viral load was -2.10±0.15 $\log_{10}$ copies/mL in the lenacapavir group and 0.07±0.22 $\log_{10}$ copies/mL in the placebo group (least-squares mean difference, -2.17; 95% CI, -2.74 to -1.59). During the maintenance period in cohort 1, in evaluations performed at 26 weeks, a viral load of <50 copies/mL was reported in 29 of 36 patients (81%; 95% CI, 64 to 92) and a viral load <200 copies/mL in 32 of 36 patients (89%; 95% CI, 74 to 97). The mean change in viral load was -2.58±1.04 $\log_{10}$ copies/mL.[1,5]

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In cohort 2, a viral load of <50 copies/mL was reported in 30 of 36 patients (83%) and a viral load <200 copies/mL in 31 of 36 patients (86%). The mean change from baseline was -2.49±1.34 $\log_{10}$ copies/mL. While the patients were receiving lenacapavir, CD4+ counts increased at week 26 by a least-squares mean of 75 (95% CI, 40 to 110) in cohort 1 and 104 (95% CI, 69 to 139) in cohort 2.[1,5]

In both cohorts, lenacapavir-related capsid substitutions that were associated with decreased susceptibility developed in eight patients during the maintenance period (six with M66I substitutions).[5] (Study Grade: Good)

Special Populations

Table 3. Special Populations[1]

Population	Precaution
≥65 Years of Age	Safety and efficacy in patients ≥65 years of age have not been established.
Renal Dysfunction	No dosage adjustment is recommended in patients with mild, moderate or severe renal impairment. Lenacapavir has not been studied in patients with end-stage renal disease.
Hepatic Dysfunction	No dosage adjustment is recommended in patients with mild or moderate hepatic impairment. Lenacapavir has not been studied in patients with severe hepatic impairment.
Pregnancy / Nursing/ Males and females of reproductive potential	There are insufficient human data on the use of lenacapavir during pregnancy to inform a drug-associated risk of birth defects and miscarriage. In animal reproduction studies, no adverse developmental effects were observed when lenacapavir was administered to rats and rabbits at exposures ≥16 times the exposure in humans at the recommended human dose of lenacapavir. There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to lenacapavir during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry. The Centers for Disease Control and Prevention recommend that HIV-1-infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection. It is not known whether lenacapavir is present in human breast milk, affects human milk production, or has effects on the breastfed infant. After administration to pregnant rats, lenacapavir was detected in the plasma of nursing rat pups, without effects on these nursing pups. Because of the potential for HIV transmission (in HIV-negative infants), developing viral resistance (in HIV-positive infants) and adverse reactions in a breastfed infant similar to those seen in adults, instruct mothers not to breastfeed if they are receiving lenacapavir.
Children	Safety and efficacy in children have not been established.
Age Restrictions	FDA approved for use in adults only (age restriction not specified).

HIV-1=human immunodeficiency virus 1

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Adverse Drug Events

The primary safety assessment of lenacapavir was based on data from heavily treatment-experienced adult subjects with HIV who received lenacapavir in a Phase 2/3 trial (CAPELLA; N=72) through Week 52, as well as supportive data in treatment-naïve adult subjects with HIV who received lenacapavir in a Phase 2 trial (CALIBRATE; N=157). The most common adverse reactions reported in at least 3% of subjects in CAPELLA were nausea (4%) and injection site reactions (65%).

The most frequent adverse reactions were injection site reactions. Of the 72 subjects in CAPELLA, 65% had experienced an injection site reaction attributed to study drug through at least the Week 52 visit. Most subjects had mild (Grade 1, 44%) or moderate (Grade 2, 17%) injection site reactions. Four percent of subjects experienced a severe (Grade 3) ISR (erythema, pain, swelling) that resolved within 15 days. The injection site reactions reported in more than 1% of subjects were swelling (36%), pain (31%), erythema (31%), nodule (25%), induration (15%), pruritus (6%), extravasation (3%) and mass (3%). Injection site reactions reported in 1% of subjects included discomfort, hematoma, edema, and ulcer.

The frequency of laboratory abnormalities (Grades 3 to 4) occurring in at least 2% of subjects in CAPELLA included creatinine (>1.8 x upper limit of normal [ULN] or ≥1.5 x baseline) (13%), glycosuria (6%), hyperglycemia (5%), proteinuria (4%), alanine aminotransferase (≥5 x ULN) (3%), aspartate aminotransferase (≥5 x ULN) (3%), and direct bilirubin (>ULN) (3%).[1]

Contraindications and Warnings/Precautions

Table 4. Contraindication[1]

Contraindication	Description
Concomitant administration	Concomitant administration of lenacapavir with strong CYP3A inducers is contraindicated due to decreased lenacapavir plasma concentrations, which may result in the loss of therapeutic effect and development of resistance to lenacapavir.

Table 5. Warnings/Precautions[1]

Warnings/ Precautions	Description
Immune reconstitution syndrome	Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy. During the initial phase of combination antiretroviral treatment, patients whose immune system responds may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment.
Long-acting properties and potential associated risks with lenacapavir	Residual concentrations of lenacapavir may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer after the last subcutaneous dose). It is important to counsel patients that maintenance dosing by injection is required every six months, because missed doses or non-adherence to injections could lead to loss of virologic response and development of resistance. Lenacapavir, a moderate CYP3A inhibitor, may increase the exposure to, and therefore potential risk of adverse reactions from, drugs primarily metabolized by CYP3A initiated within nine months after the last subcutaneous dose of lenacapavir. If lenacapavir is discontinued, to minimize the potential risk of developing viral resistance, it is essential to initiate an alternative, fully suppressive antiretroviral regimen where possible no later than 28 weeks after the final injection of lenacapavir. If virologic failure occurs during treatment, switch the patient to an alternative regimen if possible.

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Injection site reactions	Administration of lenacapavir may result in local injection site reactions. If clinically significant injection site reactions occur, evaluate and institute appropriate therapy and followup. Manifestations of injection site reactions may include swelling, pain, erythema, nodule, induration, pruritus, extravasation or mass. Nodules and indurations at the injection site may take longer to resolve than other injection site reactions.

Drug Interactions

Table 6. Drug Interactions[1]

Interacting Medication or Disease	Potential Result
Strong or moderate CYP3A inducers	Lenacapavir is a substrate of P-gp, UGT1A1 and CYP3A. Drugs that are strong or moderate inducers of CYP3A may significantly decrease plasma concentrations of lenacapavir, which may result in loss of therapeutic effect of lenacapavir and development of resistance. Concomitant administration of lenacapavir with strong CYP3A inducers during lenacapavir treatment is contraindicated. Concomitant administration of lenacapavir with moderate CYP3A inducers during lenacapavir treatment is not recommended.
Combined P-gp, UGT1A1, and Strong CYP3A Inhibitors	Lenacapavir is a substrate of P-gp, UGT1A1, and CYP3A. Combined P-gp, UGT1A1, and strong CYP3A inhibitors may significantly increase plasma concentrations of lenacapavir. Concomitant administration of lenacapavir with these inhibitors is not recommended.
Drugs primarily metabolized by CYP3A	Lenacapavir is a moderate inhibitor of CYP3A. Due to the long half-life of lenacapavir following subcutaneous administration, lenacapavir may increase the exposure of drugs primarily metabolized by CYP3A initiated within nine months after the last subcutaneous dose of lenacapavir, which may increase the potential risk of adverse reactions. See the prescribing information of the sensitive CYP3A substrates for dosing recommendations with moderate inhibitors of CYP3A.
Antiarrhythmics (e.g., digoxin)	Concomitant use of lenacapavir and digoxin may increase concentration of digoxin. Use with caution and monitor digoxin therapeutic concentration.
Anticoagulants (e.g., direct oral anticoagulants [rivaroxaban, dabigatran, edoxaban])	Concomitant use of lenacapavir and direct oral anticoagulants may increase concentration of the direct oral anticoagulants. Refer to the direct oral anticoagulant prescribing information for concomitant administration with combined moderate CYP3A and P-gp inhibitors.
Anticonvulsants (e.g., carbamazepine, oxcarbazepine, phenobarbital, phenytoin)	Concomitant use of lenacapavir and carbamazepine, oxcarbazepine, phenobarbital or phenytoin may decrease concentration of lenacapavir. Concomitant administration of carbamazepine, oxcarbazepine, phenobarbital or phenytoin may result in loss of therapeutic effect and development of resistance. Concomitant administration of lenacapavir with carbamazepine or phenytoin is contraindicated. Concomitant administration of lenacapavir with oxcarbazepine or phenobarbital is not recommended. Consider use of alternative anticonvulsants.
Antiretroviral agents (e.g., atazanavir/cobicistat, atazanavir/ritonavir,	Concomitant use of lenacapavir and atazanavir/cobicistat or atazanavir/ritonavir may increase concentration of lenacapavir. Concomitant use of lenacapavir and efavirenz, nevirapine or tipranavir/ritonavir may decrease concentration of lenacapavir. Concomitant administration of efavirenz, nevirapine, or tipranavir/ritonavir may result in loss of therapeutic

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Interacting Medication or Disease	Potential Result
efavirenz, nevirapine, tipranavir/ritonavir)	effect and development of resistance. Concomitant administration with atazanavir/cobicistat, atazanavir/ritonavir, efavirenz, nevirapine, or tipranavir/ritonavir is not recommended.
Antimycobacterials (e.g., rifabutin, rifampin, rifapentine)	Concomitant use of lenacapavir and rifabutin, rifampin or rifapentine may decrease concentration of lenacapavir and may result in loss of therapeutic effect and development of resistance. Concomitant administration of lenacapavir with rifampin is contraindicated. Concomitant administration of lenacapavir with rifabutin or rifapentine is not recommended.
Corticosteroids (e.g., dexamethasone, hydrocortisone/cortisone)	Concomitant use of lenacapavir and systemic steroids may increase concentration of corticosteroids whose exposures are significantly increased by CYP3A inhibitors and can increase the risk for Cushing's syndrome and adrenal suppression. Initiate with the lowest starting dose and titrate carefully while monitoring for safety.
Ergot derivatives (e.g., dihydroergotamine, ergotamine, methylergonovine)	Concomitant use of lenacapavir and dihydroergotamine, ergotamine or methylergonovine may increase the concentration of dihydroergotamine, ergotamine or methylergonovine and is not recommended.
Herbal Products (e.g., St. John's wort)	Concomitant use of lenacapavir and St. John's wort may decrease the concentration of lenacapavir and may result in loss of therapeutic effect and development of resistance. Concomitant use is contraindicated.
HMG-CoA reductase inhibitors (e.g., lovastatin, simvastatin)	Concomitant use of lenacapavir and lovastatin or simvastatin may increase concentration of lovastatin or simvastatin. Initiate lovastatin and simvastatin with the lowest starting dose and titrate carefully while monitoring for safety.
Narcotic analgesics metabolized by CYP3A (e.g., fentanyl, oxycodone)	Concomitant use of lenacapavir and fentanyl or oxycodone may increase concentration of fentanyl or oxycodone. Careful monitoring of therapeutic effects and adverse reactions associated with CYP3A-metabolized narcotics analgesics is recommended with co-administration.
Tramadol	Concomitant use of lenacapavir and tramadol may increase concentration of tramadol. A decrease in dose may be needed for tramadol with concomitant use.
Narcotic analgesic for treatment of opioid dependence (e.g., buprenorphine, methadone)	The effects of concomitant use of lenacapavir and buprenorphine or methadone is unknown. For initiation of buprenorphine or methadone in patients taking lenacapavir, carefully titrate the dose of buprenorphine or methadone to the desired effect using the lowest feasible initial or maintenance dose. For initiation of lenacapavir in patients taking buprenorphine or methadone, a dose adjustment for buprenorphine or methadone may be needed. Monitor clinical signs and symptoms.
Opioid antagonist (e.g., naloxegol)	Concomitant use of lenacapavir and naloxegol may increase concentration of naloxegol. Avoid use of naloxegol with lenacapavir; if unavoidable, decrease the dosage of naloxegol and monitor for adverse reactions.
Phosphodiesterase-5 inhibitors (e.g., sildenafil, tadalafil, vardenafil)	Concomitant use of lenacapavir and sildenafil, tadalafil or vardenafil may increase concentration of sildenafil, tadalafil or vardenafil. Concomitant administration of lenacapavir with tadalafil for the treatment of pulmonary arterial hypertension is not recommended. Refer to the prescribing information of sildenafil, tadalafil and vardenafil for dose recommendation for use for erectile dysfunction.

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Interacting Medication or Disease	Potential Result
Sedatives/hypnotics (e.g., midazolam [oral], triazolam)	Concomitant use of lenacapavir and oral midazolam or triazolam may increase concentration of oral midazolam or triazolam. Use with caution when midazolam or triazolam is concomitantly administered with lenacapavir.

Dosage and Administration

Table 7. Dosing and Administration[1]

Adult Dose	Pediatric Dose	Availability
Multidrug-resistant HIV-1 Initiate with one of two options followed by once every six months maintenance dosing Initiation Option 1 Day 1: 927 mg SC (2 x 1.5 mL injections) 600 mg PO (2 x 300 mg tablets) Day 2: 600 mg PO Initiation Option 2 Day 1: 600 mg PO Day 2: 600 mg PO Day 8: 300 mg PO Day 15: 927 mg SC Maintenance 927 mg SC every six months (26 weeks) from the date of last injection ±2 weeks If more than 28 weeks since last injection and clinically appropriate to continue lenacapavir, restart initiation from Day 1, using either Option 1 or Option 2.	Safety and efficacy in children have not been established.	Tablet: 300 mg Single-dose vial for injection: 463.5 mg/1.5 mL

PO=by mouth, SC=subcutaneously

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Clinical Alternatives

Table 8. Clinical Alternatives

Medication	Dosing Frequency
Sunlenca® 300 mg tablet, 463.5 mg/1.5 mL vial (lenacapavir)	**Initiation Option 1** **Day 1: 927 mg SC, 600 mg PO** **Day 2: 600 mg PO** **Initiation Option 2** **Day 1: 600 mg PO** **Day 2: 600 mg PO** **Day 8: 300 mg PO** **Day 15: 927 mg SC** **Maintenance** **927 mg SC every six months (26 weeks) from the date of last injection ±2 weeks**
Rukobia® 600 mg tablet (fostemsavir)	600 mg BID
Trogarzo® 200 mg/1.33 mL vial (ibalizumab-uiyk)	2,000 mg once, then 800 mg every two weeks

Potential Advantages

- Lenacapavir is FDA-approved for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen, a population with very limited treatment options.
- Lenacapavir offers a novel mechanism of action as a capsid inhibitor.
- The cost of treatment with lenacapavir is less than the cost of fostemsavir and ibalizumab.
- In cohort 1 of the CAPELLA clinical trial a decrease of at least 0.5 $\log_{10}$ copies/mL in the viral load by day 15 was observed in 21 of 24 patients (88%) in the lenacapavir group and in two of 12 patients (17%) in the placebo group.

Potential Disadvantages/Unanswered Questions

- The place in therapy of lenacapavir has not yet been addressed in the DHHS guidelines.
- Lenacapavir is associated with high cost of therapy of $19,500 to $23,563 every six months.
- Lenacapavir is administered orally and via subcutaneous injection, compared to fostemsavir which is administered orally.

Other Key Facts

- Lenacapavir is being developed as a foundation for Gilead's future HIV therapies with the goal of offering several long-acting options that help address individual needs and preferences that may help optimize outcomes and reduce burden of care.[3]
- Gilead is studying the safety and efficacy of lenacapavir for HIV prevention in multiple ongoing clinical studies.[3]

Conclusions

Sunlenca® (lenacapavir), a HIV-1 capsid inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.[1]

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New Drug Review for Sunlenca® (lenacapavir)

Appendix I: United States Department of Health and Human Services Food and Drug Administration Definitions for Expedited Drug Review Programs

Source:
Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics. OMB Control No. 0910-0765, May 2014. United States Department of Health and Human Services Food and Drug Administration, Rockville, MD. https://www.fda.gov/downloads/Drugs/Guidances/UCM358301.pdf.

Office of Orphan Products Development. Nov 2019. United States Department of Health and Human Services Food and Drug Administration, Rockville, MD.
https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/officeofscienceandhealthcoordination/ucm2018190.htm.

Expedited Programs for Regenerative Medicine Therapies for Serious Conditions. Draft Guidance for Industry. Nov 2017. United States Department of Health and Human Services Food and Drug Administration, Rockville, MD.
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-regenerative-medicine-therapies-serious-conditions

Oncology Center of Excellence. Real-Time Oncology Review Pilot Program. Oct 2018. United States Department of Health and Human Services Food and Drug Administration, Rockville, MD.
https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OCE/ucm612927.htm.

Program	Description
Fast Track Designation	Qualifying drugs: • A drug that is intended to treat a serious condition, AND nonclinical or clinical data demonstrate the potential to address unmet medical need • A drug that has been designated as a qualified infectious disease product Features: • Actions to expedite development and review* • Rolling review
Breakthrough Therapy Designation	Qualifying drugs: • A drug that is intended to treat a serious condition, AND preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies Features: • All fast track designation features • Intensive guidance on efficient drug development (as early a phase I)† • Organizational commitment involving senior management‡
Accelerated Approval	Qualifying drugs: • A drug that treats a serious condition, AND generally provides a meaningful advantage over available therapies, AND demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit (i.e., an intermediate clinical endpoint) Features:

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New Drug Review for Sunlenca® (lenacapavir)

Program	Description
	• Approval based on an effect on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict a drug's clinical benefit
Priority Review	Qualifying drugs: • An application (original or efficacy supplement) for a drug that treats a serious condition AND, if approved, would provide a significant improvement in safety or effectiveness • Any supplement that proposes a labeling change pursuant to a report on a pediatric study under 505A • An application for a drug that has been designated as a qualified infectious disease product • Any application or supplement for a drug submitted with a priority review voucher Features: • Shorter clock for review of marketing application (6 months compared with the 10-month standard review)
Orphan Drug Designation	Qualifying Drugs: • Drugs that are intended for the safe and effective treatment, diagnosis or prevention of rare disease/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Features: • Tax credits on clinical research • Seven-year market exclusivity from the date of FDA approval • Recommendations from the FDA regarding studies required for approval • Fast track procedure • Compassionate use may be allowed in some cases
Qualified Infectious Disease Product (QIDP)	Qualifying drugs: • An antibacterial or antifungal drug intended to treat (or diagnose or prevent) serious or life-threatening infections including those caused by a resistant pathogen or qualifying pathogens listed by the Secretary under section 505E(f) of the Food, Drug, and Cosmetic Act. Features: • Fast Track designation if requested by the sponsor • Priority review (first application only; subsequent applications must qualify) • Five-year extension to any exclusivity for which the application qualifies
Regenerative Medicine Advanced Therapy Designation	Qualifying Drugs: • The drug is a regenerative medicine therapy (e.g., cell therapy, therapeutic tissue engineering product, human cell and tissue product), AND the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, AND preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. Features: • All breakthrough therapy designation features, including early interactions to discuss any potential surrogate or intermediate endpoints

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New Drug Review for Sunlenca® (lenacapavir)

Program	Description
	• Statute addresses potential ways to support accelerated approval and satisfy post-approval requirements
Real-Time Oncology Review Pilot Program	Qualifying Drugs: • Cancer drugs likely to demonstrate substantial improvements over available therapy, which may include drugs previously granted Breakthrough Therapy, Fast Track, or Priority Review Designations. • Straight forward study designs, with endpoints that can be easily interpreted (e.g., overall survival in a randomized trial). • The pilot applies only to supplemental applications for already-approved cancer drugs. Features: • Allows for earlier FDA review and feedback on top-line results from pivotal clinical trial, before formal submission to the FDA. • Allows for a more efficient, timely, and thorough review by the FDA following formal submission.

*These include meetings with FDA, including pre-IND meetings, end-of-phase 1 meetings, and end-of-phase 2 meetings to discuss study design, extent of safety data required to support approval, dose-response concerns, and use of biomarkers. Other meetings may be scheduled as appropriate.
†The Agency may suggest, or a sponsor may propose, alternative clinical trial designs or use of an interim analysis by a data monitoring committee. These trial designs may result in smaller trials or more efficient trials that require less time to complete and may help minimize the number of patients exposed to a potentially less efficacious treatment (i.e., the control group treated with available therapy).
‡FDA intends to expedite the development and review of a breakthrough therapy by intensively involving senior managers and experienced review and regulatory health project management staff in a proactive, collaborative, cross-disciplinary review. Where appropriate, FDA also intends to assign a cross-disciplinary project lead for the review team to facilitate an efficient review of the drug development program.

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New Drug Review for Sunlenca® (lenacapavir)

Appendix II: *U.S. Preventive Services Task Force (USPSTF)* Grading Definitions for Randomized Controlled Trials

Randomized Controlled Trials		
Definition of Ratings from Above Criteria	**Good**	Meets all criteria: Comparable groups are assembled initially and maintained throughout the study (follow-up at least 80 percent); reliable and valid measurement instruments are used and applied equally to all groups; interventions are spelled out clearly; all important outcomes are considered; and appropriate attention to confounders in analysis. Intention to treat analysis is used.
	Fair	Studies will be graded "fair" if any or all of the following problems occur, without the fatal flaws noted in the "poor" category below: Generally comparable groups are assembled initially but some question remains whether some (although not major) differences occurred with follow-up; measurement instruments are acceptable (although not the best) and generally applied equally; some but not all important outcomes are considered; and some but not all potential confounders are accounted for. Intention to treat analysis is done.
	Poor	Studies will be graded "poor" if any of the following fatal flaws exists: Groups assembled initially are not close to being comparable or maintained throughout the study; unreliable or invalid measurement instruments are used or not applied at all equally among groups (including not masking outcome assessment); and key confounders are given little or no attention. Intention to treat analysis is lacking.

References

1. Sunlenca® [package insert]. Foster City (CA): Gilead Sciences, Inc.; 2020 Jul.
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3. Sunlenca® (lenacapavir) Receives FDA Approval as a First-in-Class, Twice-Yearly Treatment Option for People Living With Multi-Drug Resistant HIV [press release on the Internet]. Gilead Sciences, Inc.; 2022 Dec 222 [cited 2023 Jan 7]. Available from: https://www.gilead.com/news-and-press/press-room/press-releases/2022/12/sunlenca-lenacapavir-receives-fda-approval-as-a-firstinclass-twiceyearly-treatment-option-for-people-living-with-multidrug-resistant-hiv
4. US Department of Health and Human Services (HHS). Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV [guideline on the internet]. United States: Department of Health and Human Services; 2022 [cited 2023 Jan 7]. Available from: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf.
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3.	**Bookmark Title: MSQ3 – Utilization Management Program Approach** Bookmark Title for Supporting Material: MSQ3.1 – QLL Utilization Management Criteria Narrative description is limited to four (4) pages, not including the required supporting material. Describe in detail your approach to developing Utilization Management clinical review criteria and quantity level limit (QLL) programs. Include in your response the method(s) you will utilize to ensure the criteria development process is both clinically and fiscally sound for your clients under this RFP. Refer to Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.4 Utilization Management Program.

Supplier Response

MedImpact has reviewed and understands the requirements for DCH's UM (utilization management) program as outlined in *Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.4 Utilization Management Program*. MedImpact has been providing clinical guidance for over 3 decades to our PBM customers. The Medicaid FFS clinical staff members are well versed in working with the intricacies of this line of business and the CPM will play an integral role in the support and maintenance of DCH's UM program.

MedImpact brings decades of UM experience over all lines of business including Medicaid FFS. We will support DCH's UM program by providing but not limited to the following components:

- Medical exception reviews and overrides
- Quantity limits
- Non-preferred Product determinations
- Step therapy rules
- Benefit exclusions as specified by DCH

MedImpact will work together with DCH during DDI to capture the details of UM program, identify deliverables, and finalize a collaboration plan.

Utilization Management Approach

MedImpact's UM approach aims to ensure clinically appropriate use of medications and encourage the use of the most cost-effective therapy. While this may mean more UMs, not all of these UMs are negative or disruptive to members' care. PAs (prior authorizations) ensure the medications are safe and appropriate for members. QLLs (quantity limits) prevent overdose, abuse, and waste. STs (step therapies) prompt members starting therapy to try preferred medications first before using more costly or high-risk medications.

MedImpact offers guidance on UM and clinical programs proven to deliver cost savings while maintaining quality care for pharmacy benefit participants. These programs include but are not limited to:

- Point of sale administrative edits: our claims system processes edits at the point of sale that ensure the system administers the benefit program in the manner designed.

- PA: our claims system processes edits and applies an exception and appeals review process to drugs with a high propensity of inappropriate use requiring clinical justification for coverage under the benefit program.
- ST: our claims system processes edits that evaluate prior drug therapy to ensure that the member has tried and failed the first line medications before the benefit program allows approval of second- or third-line therapy.
- QLL: Our claims system processes edits that limit the number of units or duration of therapy to an appropriate duration consistent with the medical literature or package insert for that particular drug to ensure appropriate cost-effective use.

MedImpact's FFS Medicaid QLL program is designed based on current clinical practice guidelines as well as current regulations. Examples include Controlled Substance quantity limits as well as duration edits are incorporated following CDC (Centers for Disease Control) and Prevention guidance and are compliant with SUPPORT (Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment) for Patients and Communities Act.

Our drug recommendations for UM include a combination of clinical review and therapeutic advantage as well as a consideration of total healthcare costs. We examine this by applying pharmacoeconomic principles and published outcomes research evaluations where available. MedImpact makes drug recommendations based on efficacy, safety, and cost. We coordinate PDL and PADL UM techniques such as promoting the use of generic products while balancing rebate opportunities to optimize overall savings for customers.

Promoting Appropriate Utilization

MedImpact understands that the goal of DCH's UM program is to promote the most appropriate utilization of select Products. It is in alignment with our focus on safety, efficacy, and savings for our customers and members. We are prepared to support DCH by presenting additional Products that could require UM to the State Advisory Board during quarterly meetings. MedImpact supports our current customers in this way and looks forward to applying our clinical analysis and expertise to DCH. We acknowledge that DCH, along with the State Advisory Board, makes final decisions on UM in accordance with all state and federal laws and regulations.

Clinical evaluation and comparative effectiveness is the first consideration in MedImpact's recommendations. If we consider drugs similarly effective based upon available data, we evaluate drugs by cost and value of the outcomes they bring to Medicaid members. This evaluation includes a cost model review of the entire PDL and PADL by therapeutic class which uses DCH-specific utilization to estimate the fiscal impact of preferred and nonpreferred status based upon previous DCH-specific experience and the current market for the drugs within the PDL or PADL class. This analysis will focus on net cost to DCH taking into consideration the FMAP (federal medical assistance percentage), federally mandated rebate, and supplemental rebate. If DCH chooses MedImpact for both the clinical and rebate modules, DCH can access this at

PDL Expertise Results in Client Savings

MedImpact identified shortages in the Endocrine and Metabolic Agents/Growth Hormone class, recommended an additional preferred agent for the PDL, and saved $116,007 within the drug class for our client.

any time through our SRP (supplemental rebate platform) that allows for live, on-demand changes to the models to evaluate as many scenarios as necessary to make an informed decision. If DCH chooses another vendor for the rebate modules, MedImpact will coordinate with them to gather the information we need to run the appropriate analysis. We will provide all monographs, TCRs, and cost models well in advance of the DCH's quarterly Advisory Board Committee meetings.

Developing and Maintaining UM Criteria

MedImpact will develop and maintain criteria for all DCH's covered Products. We acknowledge and understand that Products requiring UM, including metabolic and nutritional formulas, must meet DCH-approved guidelines prior to being considered covered Products. We continually develop and maintain criteria for both our internal formularies as well as customers' formularies, PDLs, and PADLs. We will work with DCH and any relevant third parties to ensure UM criteria is professionally managed, safe, and compliant. A sample cover page, table of contents, and a few pages of our UM criteria is provided in **MSQ3.1 – QLL Utilization Management Criteria**.

Develop and Maintain UM Protocols

MedImpact will develop and maintain protocols for all Products identified as requiring UM, ST (step therapy), and QLL (quantity level limits) by DCH and develop the associated web-based versions of the criteria at no additional charge. Criteria will be customizable based on DCH's requirements and MedImpact understands that all UM criteria and web-based criteria require DCH approval. We further understand that DCH-approved customized UM criteria shall be the property of DCH and not considered proprietary to MedImpact. Our CPM will be the main point of contact for DCH regarding UM development, maintenance, approval, and customization.

Our protocols for developing and maintaining criteria start with the identification of a new product or line extension of a product. The MedImpact clinical department proactively monitors new specialty drugs in the FDA pipeline nearing approval and market launch. Our clinical staff evaluate compendia, FDA indications, utilization data, and pricing to create a UM proposal for the product to submit to DCH for review and approval. We apply the same clinical process for specialty and non-specialty drugs including recommendations for UM coverage and criteria as well as PDL or PADL inclusion and tiering.

MedImpact determines cost-effectiveness by reviewing drug cost, net cost after discounts, and actual outcome of treatment under real life conditions including considerations of total healthcare costs through utilization of pharmacoeconomic principals. We base recommendations and therapeutic designations on the objective evaluation of the products' relative therapeutic efficacy, safety, member outcome, and cost-effectiveness.

Institute for Clinical and Economic Review

ICER (Institute for Clinical and Economic Review) uses a values assessment framework along with extensive stakeholder input to evaluate the clinical and economic value of prescription drugs. ICER reports provide a wealth of information on clinical value of medications including value-based price benchmarks, which reflect ICER's assessments of how medications should be priced in order for them to be considered economically justified based on the outcomes expected.

MedImpact routinely incorporates ICER reports into our presentations and monographs and considers ICER a well-respected, independent perspective on the value of medications. We summarize ICER reports customers and report MedImpact's proposed UM strategy aligns with ICER recommendations. As ICER releases new reports, MedImpact analyzes them to determine if ICER made any significant changes that impact our UM strategies.

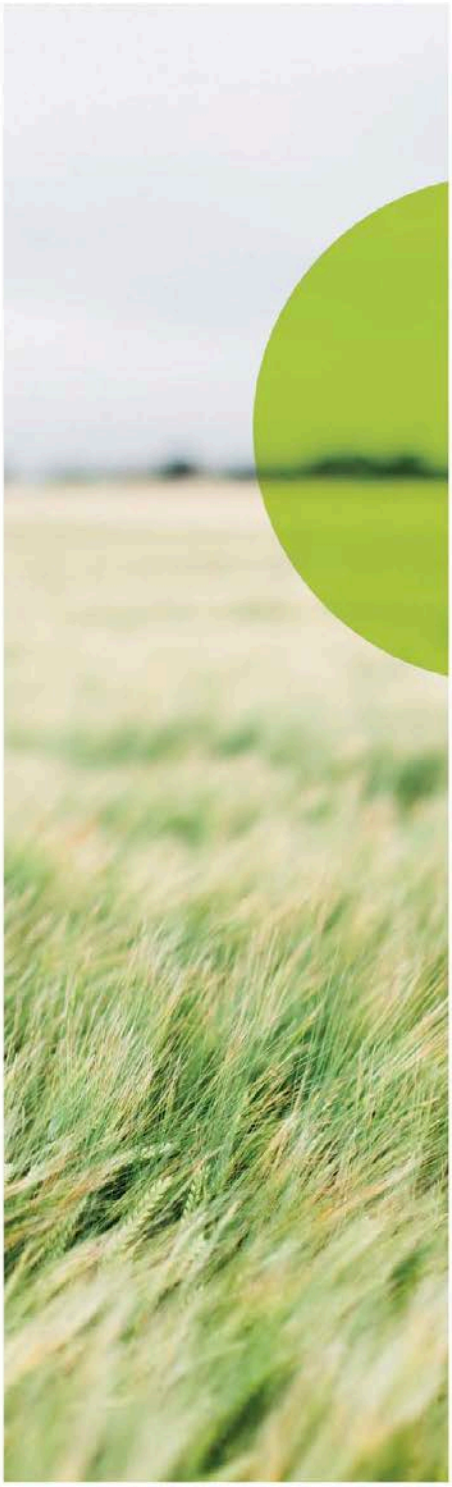
MedImpact is an experienced UM partner and will develop and maintain DCH's criteria and protocols in alignment with the overall UM approach. We look forward to working with DCH to finalize deliverables and timelines during the DDI phase of the contract.

MSQ3.1 – QLL Utilization Management Criteria

MedImpact Clinical Document

Sample Medicaid
Maximum Quantity List

VERSION: FEBRUARY 9, 2024



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Maximum Quantity List

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MAXIMUM QUANTITY LIST

Maintenance Drugs: Allow up to a **92-day supply** and **100 units.** Refer to the current PDL at the <<insert state>> Medicaid pharmacy website: <<insert website link>>

Please note that brand and generic names are provided for convenience and are NOT a guarantee of the availability of a particular product.

Abbreviations		
ADH = Adhesive	INTRAMUSC = Intramuscular	SUBL = Sublingual
AER = Aerosol	IR = Immediate Release	SUPP = Suppository
ASA = Aspirin	LA = Long Acting	SUSER = Suspension Extended Release
BLST = Blister	MP = Multiphase	SUSP = Suspension
BP = Bi-phase	Neb = Nebulizer	SYR = Syringe
CAP = Capsule	ODT = Orally Disintegrating Tablet	TAB = Tablet
CP = Capsule	OINT = Ointment	TABSENSSTR = Tablet Sensor Starter Kit
DR = Delayed Release	PEL = Pellet	TABSENSTPD = Tablet Sensor Therapy Pack
DS PK = Dose Pack	PKT = Packet	TB = Tablet
EFF = Effervescent	POWD = Powder	TD = Transdermal
ER = Extended Release	RAP = Rapid	TDWK = Transdermal Weekly
HD = High Dose	RECON = Reconstitute	W/DEV = With Device
IJ = Injection	RECT = Rectal	
INJCTR, INJCT = Injector	SP = Sprinkle	

ANALGESICS

Drug Class	Label Name	Generic Name	Quantity Limit
NARCOTIC AGONIST/ANTAGONISTS	PENTAZOCINE-NALOXONE HCL ORAL TABLET 50MG-0.5MG	PENTAZOCINE HCL/NALOXONE HCL	4 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTANYL CITRATE BUCCAL LOZENGE HD 200 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTANYL CITRATE BUCCAL LOZENGE HD 400 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTANYL CITRATE BUCCAL LOZENGE HD 600 MCG	FENTANYL CITRATE	1 PER DAY

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Maximum Quantity List

Drug Class	Label Name	Generic Name	Quantity Limit
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTANYL CITRATE BUCCAL LOZENGE HD 800 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTANYL CITRATE BUCCAL LOZENGE HD 1200 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTANYL CITRATE BUCCAL LOZENGE HD 1600 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTANYL CITRATE BUCCAL TABLET EFF 100 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTANYL CITRATE BUCCAL TABLET EFF 200 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTANYL CITRATE BUCCAL TABLET EFF 400 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTANYL CITRATE BUCCAL TABLET EFF 600 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTANYL CITRATE BUCCAL TABLET EFF 800 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	ACTIQ BUCCAL LOZENGE HD 200 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	ACTIQ BUCCAL LOZENGE HD 400 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	ACTIQ BUCCAL LOZENGE HD 600 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	ACTIQ BUCCAL LOZENGE HD 800 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	ACTIQ BUCCAL LOZENGE HD 1200 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	ACTIQ BUCCAL LOZENGE HD 1600 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTORA BUCCAL TABLET EFF 100 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTORA BUCCAL TABLET EFF 200 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTORA BUCCAL TABLET EFF 400 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTORA BUCCAL TABLET EFF 600 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, FENTANYL BUCCAL PRODUCTS	FENTORA BUCCAL TABLET EFF 800 MCG	FENTANYL CITRATE	1 PER DAY
NARCOTICS, LONG-ACTING	BUPRENORPHINE TRANSDERM. PATCH TDWK 7.5 MCG/HR	BUPRENORPHINE	4 PER 28 DAYS

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Maximum Quantity List

Drug Class	Label Name	Generic Name	Quantity Limit
NARCOTICS, LONG-ACTING	BUPRENORPHINE TRANSDERM. PATCH TDWK 5 MCG/HR	BUPRENORPHINE	4 PER 28 DAYS
NARCOTICS, LONG-ACTING	BUPRENORPHINE TRANSDERM. PATCH TDWK 10 MCG/HR	BUPRENORPHINE	4 PER 28 DAYS
NARCOTICS, LONG-ACTING	BUPRENORPHINE TRANSDERM. PATCH TDWK 15 MCG/HR	BUPRENORPHINE	4 PER 28 DAYS
NARCOTICS, LONG-ACTING	BUPRENORPHINE TRANSDERM. PATCH TDWK 20 MCG/HR	BUPRENORPHINE	4 PER 28 DAYS
NARCOTICS, LONG-ACTING	BUTRANS TRANSDERM. PATCH TDWK 5 MCG/HR	BUPRENORPHINE	4 PER 28 DAYS
NARCOTICS, LONG-ACTING	BUTRANS TRANSDERM. PATCH TDWK 10 MCG/HR	BUPRENORPHINE	4 PER 28 DAYS
NARCOTICS, LONG-ACTING	BUTRANS TRANSDERM. PATCH TDWK 20 MCG/HR	BUPRENORPHINE	4 PER 28 DAYS
NARCOTICS, LONG-ACTING	BUTRANS TRANSDERM. PATCH TDWK 7.5 MCG/HR	BUPRENORPHINE	4 PER 28 DAYS
NARCOTICS, LONG-ACTING	BUTRANS TRANSDERM. PATCH TDWK 15 MCG/HR	BUPRENORPHINE	4 PER 28 DAYS
NARCOTICS, LONG-ACTING	BELBUCA BUCCAL FILM 75 MCG	BUPRENORPHINE HCL	2 PER DAY
NARCOTICS, LONG-ACTING	BELBUCA BUCCAL FILM 150 MCG	BUPRENORPHINE HCL	2 PER DAY
NARCOTICS, LONG-ACTING	BELBUCA BUCCAL FILM 300 MCG	BUPRENORPHINE HCL	2 PER DAY
NARCOTICS, LONG-ACTING	BELBUCA BUCCAL FILM 450 MCG	BUPRENORPHINE HCL	2 PER DAY
NARCOTICS, LONG-ACTING	BELBUCA BUCCAL FILM 600 MCG	BUPRENORPHINE HCL	2 PER DAY
NARCOTICS, LONG-ACTING	BELBUCA BUCCAL FILM 750 MCG	BUPRENORPHINE HCL	2 PER DAY
NARCOTICS, LONG-ACTING	BELBUCA BUCCAL FILM 900 MCG	BUPRENORPHINE HCL	2 PER DAY
NARCOTICS, LONG-ACTING	FENTANYL TRANSDERM. PATCH TD72 12 MCG/HR	FENTANYL	10 PATCHES PER 30 DAYS
NARCOTICS, LONG-ACTING	FENTANYL TRANSDERM. PATCH TD72 25 MCG/HR	FENTANYL	10 PATCHES PER 30 DAYS
NARCOTICS, LONG-ACTING	FENTANYL TRANSDERM. PATCH TD72 50MCG/HR	FENTANYL	10 PATCHES PER 30 DAYS

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4.	**Bookmark Title: MSQ4 – Utilization Management Criteria Structure** Bookmark Title for Supporting Material: ➢ MSQ4.1 – Utilization Management Process Visual ➢ MSQ4.2 – Utilization Management Algorithm Examples ➢ MSQ4.3 – QLL Override Criteria Narrative description is limited to two (2) pages, not including the required supporting material. Describe in detail how Utilization Management criteria will be structured as outlined, but not limited to, the requirements stated in Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.4 Utilization Management Program. Provide the following supporting material: a. Visual of Utilization Management Process that supports the State's requirements as described in the SOW. b. Examples of Utilization Management criteria developed for HIV atypical anti-psychotics and GLP-1 antagonists. c. Examples of quantity level limit (QLL) override criteria for four (4) classes of drugs of therapeutic categories that should require a QLL.

Supplier Response

MedImpact has reviewed and understands the requirements for DCH's UM program as provided in *Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.4 Utilization Management Program*. We take an active role in the selection of cost-effective, therapeutically efficacious medications at the point of prescribing through drug recommendations. MedImpact utilizes the following criteria in creating, reviewing, and revising drug recommendations including UM program status and criteria:

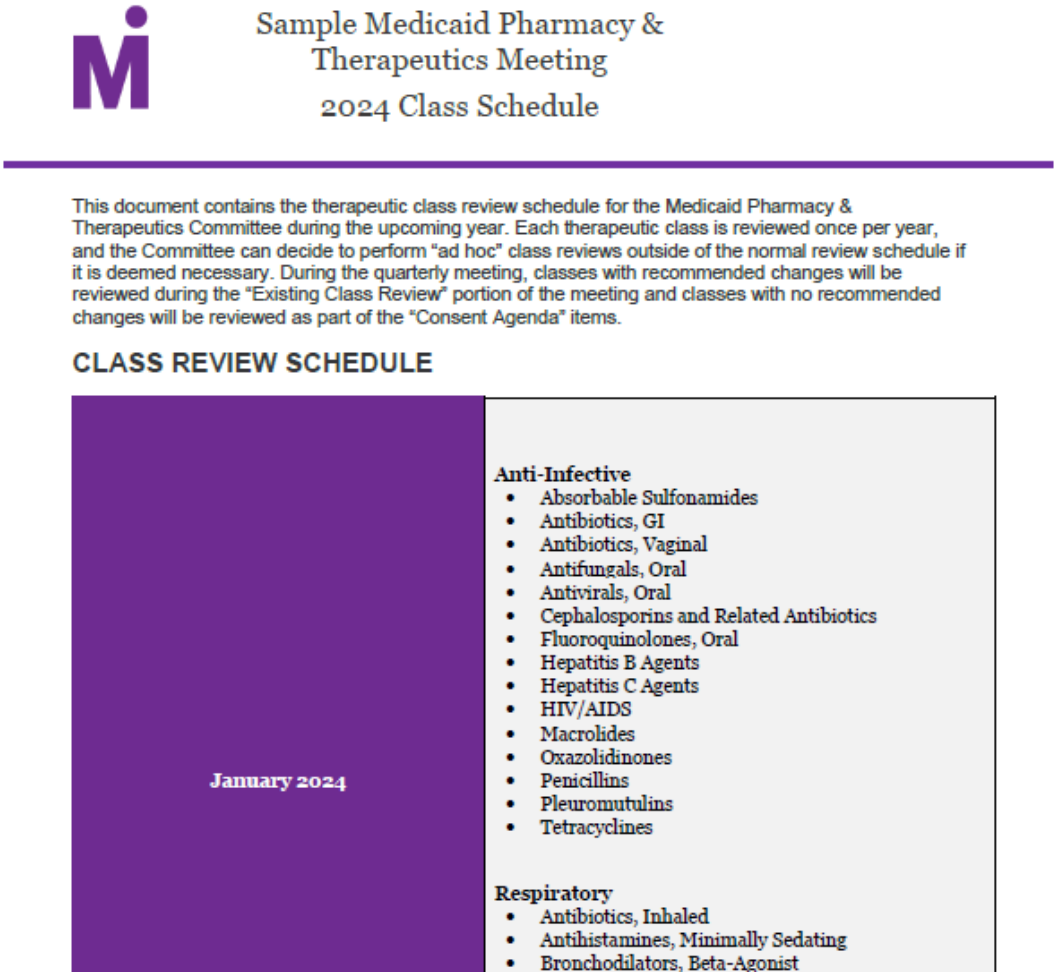
- Relative Therapeutic Efficacy including the following:
  - Safety, adverse effects, and drug Interactions
  - Efficacy
  - Strength of scientific evidence and standards of practice
  - Therapeutic need
- Cost-effectiveness, where cost is a secondary consideration to the factors associated with relative therapeutic efficacy

We consider UM techniques, such as promoting the use of generic products, while balancing rebate opportunities to optimize overall savings for customers when making recommendations.

Review and Update UM Algorithm Criteria

MedImpact's UM program consists of 2 components: NTM (new-to-market) drugs and TCR (therapeutic class reviews). We provide UM recommendations with draft criteria documents and forms for NTM drugs during quarterly Advisory meetings. MedImpact also performs reviews on several therapeutic classes at each scheduled meeting. The TCRs include reviews of updated FDA labeling,

current clinical practice guideline recommendations, cost comparison, and available alternative treatment options. MedImpact provides the recommended updates on UM with draft criteria document and forms for changed criteria based on the TCRs. The goal for TCRs is to ensure each therapeutic class is reviewed at least once every year. **Figure 4** provides an excerpt from the first page of a sample TCR schedule based on a quarterly cadence of P&T Committee Advisory meetings.



Sample Medicaid Pharmacy & Therapeutics Meeting
2024 Class Schedule

This document contains the therapeutic class review schedule for the Medicaid Pharmacy & Therapeutics Committee during the upcoming year. Each therapeutic class is reviewed once per year, and the Committee can decide to perform "ad hoc" class reviews outside of the normal review schedule if it is deemed necessary. During the quarterly meeting, classes with recommended changes will be reviewed during the "Existing Class Review" portion of the meeting and classes with no recommended changes will be reviewed as part of the "Consent Agenda" items.

CLASS REVIEW SCHEDULE

January 2024

Anti-Infective
- Absorbable Sulfonamides
- Antibiotics, GI
- Antibiotics, Vaginal
- Antifungals, Oral
- Antivirals, Oral
- Cephalosporins and Related Antibiotics
- Fluoroquinolones, Oral
- Hepatitis B Agents
- Hepatitis C Agents
- HIV/AIDS
- Macrolides
- Oxazolidinones
- Penicillins
- Pleuromutulins
- Tetracyclines

Respiratory
- Antibiotics, Inhaled
- Antihistamines, Minimally Sedating
- Bronchodilators, Beta-Agonist

Figure 4: Sample TCR Schedule Excerpt

MedImpact will review and update UM algorithm criteria for each therapeutic class and the associated UM forms annually for DCH. We will provide DCH with the finalized UM algorithm criteria after each annual review with web-based criteria and UM forms for posting on DCH's website. The CPM will be responsible for reviewing, updating, and communicating with DCH for these and all UM topics. Samples of our UM algorithms and QLL override criteria are provided in sections **MSQ4.2 – Utilization Management Algorithm Examples** and **MSQ4.3 – QLL Override Criteria**. Section **MSQ4.1 – Utilization Management Process Visual** contains a visual of our overall UM process.

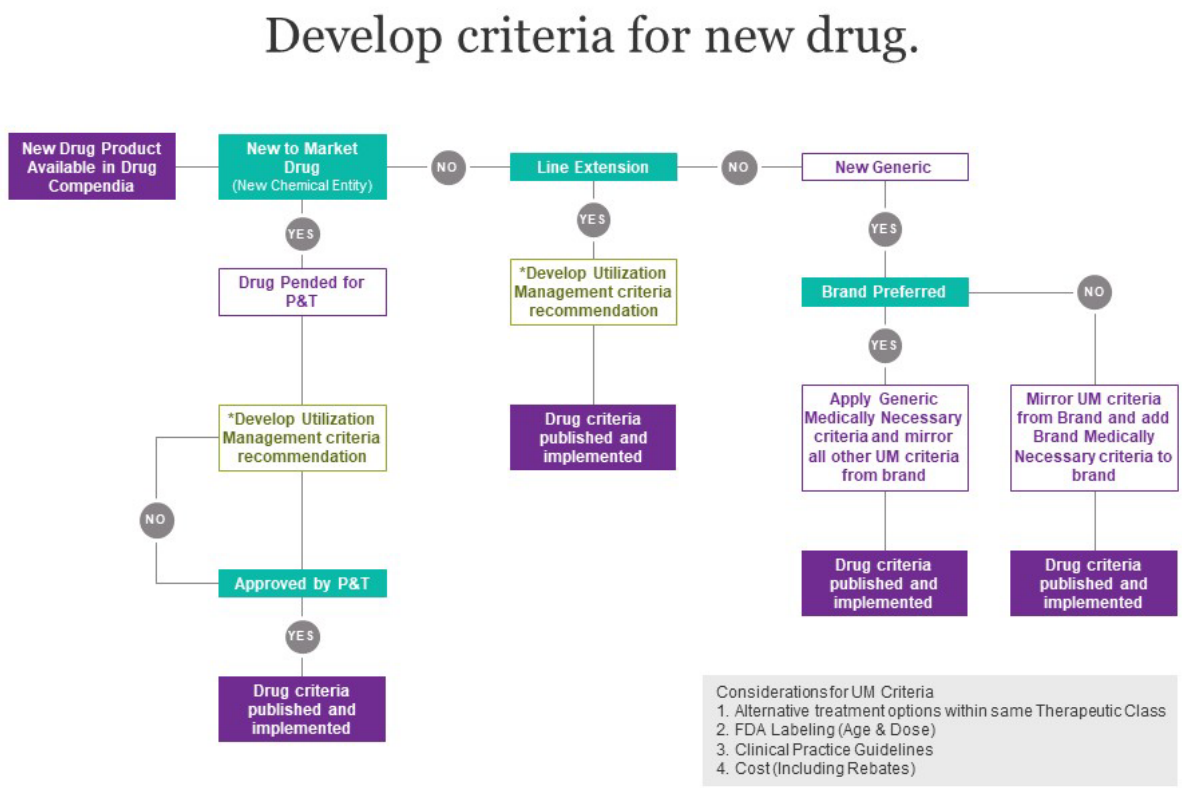
Utilization Management Criteria Structure

MedImpact manages UM criteria structure in a cyclical review cycle. We review, revisit, adjust, and repeat the process. We start the process by reviewing PDL or PADL drug lists, drug status assignments, and overall PDL or PADL structure. Next, we establish clinical criteria that are preferred

but that require special clinical consideration. We then, establish PA criteria for non-preferred products to facilitate preferred drug use adding or establishing QL age, and DUR edits based on safety, efficacy, and regulations. Lastly, we evaluate the ROI on the utilization criteria to ensure the programs achieve cost effectiveness without imposing unnecessary burdens on prescribers or members.

MedImpact is an experienced clinical partner. Our CPMs are familiar with the intricacies of the Medicaid FFS space and regularly create and manage UM algorithm criteria. Our algorithms are logical, compliant, and easy to follow. We will work with DCH during DDI to finalize UM criteria and structure.

MSQ4.1 – Utilization Management Process Visual



MSQ4.2 – Utilization Management Algorithm Examples

UM Algorithm Example

ATYPICALS ANTIPSYCHOTICS

GUIDELINES FOR USE

1. **Does the patient have an FDA approved diagnosis for the medication request?**

   If yes, continue to #2

   If no, do not approve. See denial text below.

2. **Has the patient had at least a 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to one preferred agent?**

   If yes, continue to #3

   If no, do not approve. See denial text below.

3. **Does the patient require therapy with ≥ 3 atypical antipsychotics?**

   If yes, continue to #4

   If no, approve

4. **Is the request for continuation of current therapy and the patient is stable on 3 or more agents?**

   If yes, approve

   If no, continue to #5

5. **Is the request to allow patients to taper to dual therapy and one of the previous atypical antipsychotics will be discontinued?**

   If yes, approve

   If no, continue to #6

6. **Is the request to add additional agents to existing dual therapy and has there been a two-week trial at the maximum tolerated dose of each existing therapy?**

   If yes, approve

   If no, do not approve

UM Algorithm Example

DENIAL TEXT

Our guideline named ATYPICAL ANTIPSYCHOTICS requires the following rules(s) be met for approval:

A. The patient must have an FDA approved diagnosis

B. The member had at least a 2-week trial and failure [drug did not work], allergy, contraindication [harmful for] (including potential drug-drug interactions with other medications) or intolerance [side effect] to one preferred agent in any sub-class.

C. If a member is using 3 or more atypical antipsychotics [drugs to treat mental illness]:

1. It must be a continuation of therapy and the member is stable on 3 or more drugs
2. The member needs a maximum of two months to taper to dual therapy (if one of the three agents will be discontinued)
3. The member has had a two-week trial at the maximum tolerated dose of two drugs and needs an additional drug

UM Algorithm Example

GLP-1 RECEPTOR AGONISTS

GUIDELINES FOR USE

1. **Does the patient have a diagnosis of Type 2 Diabetes (ICD-10 group E11) without chronic kidney disease?**

   If yes, continue to #2.

   If no, continue to #3.

2. **Has the patient had a trial and failure, intolerance, or contraindication to metformin (see the table at the end of the document)?**

   If yes, continue to #8.

   If no, do not approve. See the denial text at the end of the guideline.

3. **Does the patient have a diagnosis of Type 2 Diabetes (ICD-10 group E11) with chronic kidney disease (ICD-10 group N18)?**

   If yes, continue to #4.

   If no, continue to #5.

4. **Has the patient had a trial and failure, intolerance, or contraindication to concurrent metformin and SGLT2 inhibitor, or a metformin+SGLT2 inhibitor combination product (see the table at the end of the document)?**

   If yes, continue to #8.

   If no, do not approve. See the denial text at the end of the guideline.

5. **Does the patient have a diagnosis of Type 2 Diabetes (ICD-10 group E11) and atherosclerotic cardiovascular disease (ASCVD, ICD-10 group I25)?**

   If yes, continue to #8.

   If no, continue to #6.

UM Algorithm Example

6. **Does the patient have a diagnosis of Type 2 Diabetes (ICD-10 group E11) and heart failure with reduced ejection fraction (ICD-10 group I50.3)?**
   If yes, continue to #7.
   If no, do not approve. See the denial text at the end of the guideline.
7. **Has the patient had a trial and failure, intolerance, or contraindication to an SGLT2 inhibitor (see the table at the end of the document)?**
   If yes, continue to #8.
   If no, do not approve. See the denial text at the end of the guideline.
8. **Has the patient had a ≥3-month trial and failure, intolerance, or contraindication to one preferred agent?**
   If yes, approve
   If no, do not approve. See the denial text at the end of the guideline.

DENIAL TEXT

Our guideline named GLP-1 RECEPTOR AGONISTS requires the following rule(s) be met for approval:

A. One of the following:
   1. The member has a diagnosis of type 2 diabetes [a disorder with high blood sugar] without chronic [long term] kidney disease and had tried and failed [drug did not work] metformin.
   2. The member has a diagnosis of type 2 diabetes [a disorder with high blood sugar] with chronic [long term] kidney disease and had a trial and therapeutic failure [drug did not work], allergy, contraindication [harmful for] (including potential drug-drug interactions with other medications) or intolerance [side effect] to concurrent metformin and SGLT2 inhibitor.
   3. The member has a diagnosis of type 2 diabetes [a disorder with high blood sugar] and atherosclerotic cardiovascular disease [a type of heart condition].
   4. The member has a diagnosis of type 2 diabetes [a disorder with high blood sugar] and heart failure with reduced ejection fraction [a type of heart condition] and had a trial and therapeutic failure [drug did not work], allergy, contraindication [harmful for] (including potential drug-drug interactions with other medications) or intolerance [side effect] to an SGLT2 inhibitor.

B. The member has had at least a 3-month trial and therapeutic failure [drug did not work], allergy, contraindication [harmful for] (including potential drug-drug interactions with other medications) or intolerance [side effect] to a preferred GLP-1 agonist [drug in the same group]

UM Algorithm Example

ANTIVIRALS (HIV/AIDS) APRETUDE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. **Is the medication prescribed for pre-exposure prophylaxis (PrEP) of HIV?**

   If yes, continue to #2.

   If no, do not approve. See initial denial text below.

2. **Is the prior authorization request from the prescriber?**

   If yes, continue to #3.

   If no, do not approve. See initial denial text below.

3. **Is the patient negative for human immunodeficiency virus type 1 (HIV1) infection?**

   If yes, continue to #4.

   If no, do not approve. See initial denial text below.

4. **Is the patient at substantial ongoing risk of HIV exposure and acquisition, and intramuscular (IM) cabotegravir is being used for HIV-1 pre-exposure prophylaxis (PrEP)?**

   If yes, continue to #5.

   If no, do not approve. See initial denial text below.

5. **Does the patient have a history of treatment failure or known or suspected resistance to cabotegravir?**

   If yes, do not approve. See initial denial text below.

   If no, continue to #6.

6. **Will the patient be receiving concomitant therapy with ANY of the following medications that can result in significant decreases of cabotegravir?**

   - **Carbamazepine**
   - **Oxcarbazepine**
   - **Phenobarbital**
   - **Phenytoin**

1

UM Algorithm Example

- **Rifabutin**
- **Rifampin**
- **Rifapentine**
- **Dexamethasone (more than a single-dose treatment)**
- **St. John's wort**

If yes, do not approve. See initial denial text below.

If no, continue to #7.

7. **Has the patient been counseled on the importance of adherence to the regimen to maximize protection in preventing HIV-1 infection?**

   If yes, continue to #8.

   If no, do not approve. See initial denial text below.

8. **Will the patient be tested for HIV-1 infection prior to each injection?**

   If yes, continue to #9.

   If no, do not approve. See initial denial text below.

9. **Is the patient 12 years of age or older?**

   If yes, approve

   If no, do not approve. See initial denial text below.

INITIAL DENIAL TEXT

Our guideline named ANTIVIRALS (HIV/AIDS) APRETUDE requires the following rule(s) be met for approval:

A. The requested drug is being used for Pre-exposure prophylaxis [preventive] (PrEP) of HIV

B. The prior authorization request is from the prescriber

C. The patient is negative for human immunodeficiency virus type 1 (HIV1) infection

D. The patient is at substantial ongoing risk of HIV exposure and acquisition, and intramuscular (IM) cabotegravir is being used for HIV-1 pre-exposure prophylaxis [preventive] (PrEP)

E. The patient has no history of treatment failure [drug did not work] or known or suspected resistance [not responding to treatment] to cabotegravir

F. The patient will NOT receive concomitant therapy with ANY of the following medications that can result in significant decreases of cabotegravir:

UM Algorithm Example

a. Carbamazepine
b. Oxcarbazepine
c. Phenobarbital
d. Phenytoin
e. Rifabutin
f. Rifampin
g. Rifapentine
h. Dexamethasone (more than a single-dose treatment)
i. St. John's wort

G. The patient has been counseled on the importance of adherence [keeping up with] to the regimen to maximize protection in preventing HIV-1 infection

H. The patient will be tested for HIV-1 infection prior to each injection

I. Patient is 12 years of age or older

RENEWAL CRITERIA

1. **Is the medication prescribed for pre-exposure prophylaxis (PrEP) of HIV?**

   If yes, continue to #2.

   If no, do not approve. See renewal denial text below.

2. **Is the prior authorization request from the prescriber?**

   If yes, continue to #3.

   If no, do not approve. See renewal denial text below.

3. **Is the patient negative for human immunodeficiency virus type 1 (HIV1) infection?**

   If yes, continue to #4.

   If no, do not approve. See renewal denial text below.

4. **Is the patient at substantial ongoing risk of HIV exposure and acquisition, and intramuscular (IM) cabotegravir is being used for HIV-1 pre-exposure prophylaxis (PrEP)?**

   If yes, continue to #5.

   If no, do not approve. See renewal denial text below.

5. **Does the patient have a history of treatment failure or known or suspected resistance to cabotegravir?**

   If yes, do not approve. See renewal denial text below.

   If no, continue to #6.

3

UM Algorithm Example

6. **Will the patient be receiving concomitant therapy with ANY of the following medications that can result in significant decreases of cabotegravir?**

   - **Carbamazepine**
   - **Oxcarbazepine**
   - **Phenobarbital**
   - **Phenytoin**
   - **Rifabutin**
   - **Rifampin**
   - **Rifapentine**
   - **Dexamethasone (more than a single-dose treatment)**
   - **St. John's wort**

   If yes, do not approve. See renewal denial text below.

   If no, continue to #7.

7. **Has the patient been counseled on the importance of adherence to the regimen to maximize protection in preventing HIV-1 infection?**

   If yes, continue to #8.

   If no, do not approve. See renewal denial text below.

8. **Has the patient been tested for HIV-1 infection prior to each injection?**

   If yes, continue to #9.

   If no, do not approve. See renewal denial text below.

9. **Is the patient 12 years of age or older?**

   If yes, continue to #10.

   If no, do not approve. See renewal denial text below.

10. **Has the patient been adherent to their antiretroviral prophylaxis with cabotegravir?**

    If yes, continue to #11.

    If no, do not approve. See renewal denial text below.

UM Algorithm Example

11. Is the patient absent of unacceptable toxicity from the drug?

If yes, approve

If no, do not approve.

RENEWAL DENIAL TEXT

Our guideline named ANTIVIRALS (HIV/AIDS) APRETUDE requires the following rule(s) be met for approval:

A. The requested drug is being used for Pre-exposure prophylaxis [preventive] (PrEP) of HIV

B. The prior authorization request is from the prescriber

C. The patient is negative for human immunodeficiency virus type 1 (HIV1) infection

D. The patient is at substantial ongoing risk of HIV exposure and acquisition, and intramuscular (IM) cabotegravir is being used for HIV-1 pre-exposure prophylaxis [preventive] (PrEP)

E. The patient has no history of treatment failure [drug did not work] or known or suspected resistance [not responding to treatment] to cabotegravir

F. The patient will NOT receive concomitant therapy with ANY of the following medications that can result in significant decreases of cabotegravir:

   a. Carbamazepine
   b. Oxcarbazepine
   c. Phenobarbital
   d. Phenytoin
   e. Rifabutin
   f. Rifampin
   g. Rifapentine
   h. Dexamethasone (more than a single-dose treatment)
   i. St. John's wort

G. The patient has been counseled on the importance of adherence [keeping up with] to the regimen [treatment plan] to maximize protection in preventing HIV-1 infection

H. The patient is 12 years of age or older

I. The patient has been tested for HIV-1 infection prior to each injection

J. The patient has been adherent [keeping up with] to cabotegravir

K. The patient is absent of unacceptable toxicity [bad side effects] from the drug

5

UM Algorithm Example

ANTIVIRALS (HIV/AIDS) NON-PREFERRED DRUGS

GUIDELINES FOR USE

1. **Has the patient had a previous trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to ONE preferred agent?**

   If yes, approve

   If no, do not approve

DENIAL TEXT

Our guideline named ANTIVIRALS (HIV/AIDS) requires the following rule(s) be met for approval:

A. The member had a trial and failure [drug did not work], allergy, contraindication [harmful for] (including potential drug-drug interactions with other medications) or intolerance [side effect] to 1 preferred agent

1

MSQ4.3 – QLL Override Criteria

Quantity Level Limit Overide Criteria

CENTRAL NERVOUS SYSTEM: ANTI-MIGRAINE AGENTS, TRIPTANS

Triptan agents are limited to 1 package per 30 days.

1. QUANTITY LIMIT CRITERIA

One-time approval when all of the following circumstances are true:

a. NOT using triptans in combination with an MAOI (e.g., Parnate®, Marplan®, or Nardil®); **AND**

b. Patient must **NOT** have a history of ischemic heart disease; **AND**

c. Prescriber has counseled the member about the negatives (e.g., causes additional migraines) of daily use and/or overuse of triptans and will attempt to taper the quantity of triptan medication used monthly; **AND**

d. Current use of any oral or injectable prophylactic agent, such as (though not limited to):

- Antiepileptic drugs (AEDs): divalproex sodium, sodium valproate, topiramate
- Beta Blockers: metoprolol, propranolol, timolol, atenolol, nadolol
- Antidepressants: amitriptyline, venlafaxine
- NSAIDs: fenoprofen, ibuprofen, ketoprofen, naproxen
- CGRP inhibitor: Ajovy™, Emgality™ 120 mg/mL
- Botulinum toxin: Botox ®

Quantity Level Limit Overide Criteria

CENTRAL NERVOUS SYSTEM: ANXIOLYTICS

Preferred antianxiety benzodiazepines are available without a prior authorization for up to 60 days supply (cumulative) per rolling year.

1. MAXIMUM DURATION (MD) CRITERIA

If therapy is needed beyond the initial 60 days-supply allowance, the prescriber must submit a prior authorization for review.

a. Approve for **1 month** for the following diagnosis:

- Acute alcohol withdrawal

b. Approve for **6 months** for the following diagnoses / situations:

- Agoraphobia
- Anxiety
- Anxiety disorder
- Chemotherapy-induced nausea & vomiting
- Depression
- Panic attacks or panic disorder
- Social phobia
- Status epilepticus

c. Approve for **1 year** for the following diagnosis:

- Seizures/Epilepsy

Agent(s) Subject to Criteria	
alprazolam IR tablets MD	diazepam oral concentrate MD
alprazolam ER/XR MD	diazepam oral solution, tablets MD
alprazolam Intensol MD	lorazepam MD
alprazolam ODT MD	lorazepam intensol MD
Ativan® MD	oxazepam MD
chlordiazepoxide MD	Tranxene-T® MD
clorazepate MD	Xanax® MD
diazepam Intensol MD	Xanax XR MD

Quantity Level Limit Overide Criteria

CENTRAL NERVOUS SYSTEM: ANTICONVULSANTS

Diastat®/Diazepam Rectal Gel is limited to 3 kits (6 doses) per 30 days.

1. **QUANTITY LIMIT CRITERIA DIASTAT/DIAZEPAM RECTAL GEL**
   a. The patient is currently on maintenance anticonvulsant therapy; **AND**
   b. The patient has required more than 6 doses of diazepam rectal per month; **AND**
   c. The prescriber is or had consulted a neurologist regarding appropriate seizure control for the patient.

Quantity Level Limit Overide Criteria

GASTROINTESTINAL: PROTON PUMP INHIBITORS

Proton Pump Inhibitors are limited to 1 dose per day.

1. QUANTITY LIMIT CRITERIA ANTICONVULSANTS (GENERAL)

a. Initial Criteria

- The patient has a confirmed diagnosis of H.pylori infection: **OR**
- The patient had a ≥ 2-week trial and failure of once daily dosing.

b. Renewal Criteria

- The patient has a reconfirmation diagnosis of H. pylori infection or a trial of once daily dosing after the initial course of therapy; **OR**
- The patient had undergone diagnostic testing to confirm one of the following diagnoses:
  - Barrett's Esophagus
  - Schatzki's Ring
  - Hypersecretory condition (including but not limited to Zollinger-Ellison Syndrome, Multiple Endocrine Adenoma, Systemic Mastocytosis)
  - Hyperacidity in cystic fibrosis recipients, achalasia, CREST syndrome, scleroderma, or sarcoid; **OR**
- The patient has attempted 'step-down' therapy at any time from multiple to single daily dosing for at least 2 weeks.

Quantity Level Limit Overide Criteria

GENERAL QUANTITY LIMIT EXCEPTION CRITERIA

1. QUANTITY LIMIT CRITERIA

a. The request is for a protected class or behavioral health drug (e.g., antidepressants, antipsychotic, stimulant) and there is evidence that the patient is stable on the requested dose; **OR**

b. The request is for renewal and the patient has previously approved claims in the past 120 days for the requested drug at the requested dosage; **OR**

c. The patient is titrating the dosage up and the requested total daily dose is within the FDA recommended maximum daily dose for the specified indication; **OR**

d. The patient has tried and failed the requested medication within the plan's quantity limit or that prescriber provides clinical rationale as to why the patient is not able to try the medication within the plan's quantity limit; **OR**

e. The total daily dose requested is within the FDA recommended maximum daily dose for the specified indication; **OR**

f. The requested total daily dosage cannot be reached by using commercially available higher strength(s) of the medication within the plan's quantity limit **AND** the prescriber provides clinical rationale as to why the patient cannot dose consolidate.

Note: if the requested dose is not within the FDA recommended maximum daily dose for the specified indication, the prescriber must provide two articles from major peer reviewed medical journals that support the safety and efficacy of the requested drug and the intended dosage for the specified indication.

5.	**Bookmark Title: MSQ5 – RetroDUR** Narrative description is limited to six (6) pages. Describe in detail (1) the RetroDUR programs that will be made available to the State, (2) the potential customization available to the State, (3) the methods that will be utilized to identify feasible RetroDUR opportunities and targeted providers, and (4) the plan to execute intervention and assess outcomes. Refer to Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.5 Retrospective DUR (RETRO-DUR) Services.

Supplier Response

MedImpact has assisted states in administering their programs since the release of federal mandates (Title 42, Part 456, Subpart K) for Medicaid RetroDUR programs on January 2, 1993. These regulations, titled DUR Program and Electronic Claims Management System for Outpatient Drug Claims, Section 456.709 Retrospective Drug Use Review, provide a foundation for our teams to monitor prescription drug claims including predetermined monitoring standards and standard requirements for DCH's DUR board members. Within the final rule, modifications for the inclusion of over-the-counter medications enables MedImpact to enhance the review to include these products and their therapeutic effects on members. Additionally, our process complies with federal regulations Title 42, Part 438.3, Subpart S(4).

Prospective Drug Utilization Review

MedImpact employs a comprehensive prospective DUR (drug utilization review) solution that leverages technology to identify and manage drug issues and deliver measurable improvements. Our business processes apply POS (point of sale) prospective DUR reviews that are NCPDP (National Council for Prescription Drug Programs) and HIPAA (Health Insurance Portability and Accountability Act) compliant and meet Medicaid federal requirements (42 CFR 456, subpart K).

Edits

MedImpact's solution provides prospective DUR (drug utilization review) services that apply only DCH-approved edits to all claims including identified prospective DUR alerts between single line-item pharmacy claims and multi-ingredient compounds. These prospective DUR edits identify potential problems with prescriptions and validate the appropriateness of the prescribed drug against established clinical criteria. We capture and store all NCPDP (National Council for Prescription Drug Programs)-standard conflict, intervention, and outcome messages for reporting to DCH.

MedImpact's prospective DUR solution incorporates concurrent DUR logic that produces automated prospective DUR edits to identify and rectify potential safety issues during the dispensing process. We base our alerts on algorithms obtained from First Databank, which our system administers as DUR edits. While we have a library of edits, MedImpact will make recommendations to DCH for your potential utilization. Common prospective DUR edits we recommend include:

- Drug-Allergy Conflict
- Drug-Disease Contraindication
- Drug-Drug Interaction
- Therapeutic Duplication

- High Dose
- Low Dose
- Late refill or Underuse
- Ingredient Duplication
- Drug Age
- Pregnancy
- Gender
- Refill too Soon (Early Refill)

MedImpact constantly reviews and updates our ProDUR edits, logic, and recommendations based on clinical practices and regulations. We will coordinate with the PBA vendor to implement the edits and also to gather the appropriate data for overall DUR reporting purposes.

Retrospective Drug Utilization Review

Our approach to RetroDUR interventions will incorporate DCH's policy goals with population focused analysis and review. Our program utilizes relevant clinical guidelines, FDA alerts, clinical research findings, federal and DCH regulations, legislation, and policies to establish new DUR interventions and identify opportunities for innovation and educational opportunities. MedImpact's robust RetroDUR program includes all of the requirements outlined in *2.5 of Attachment G Pharmacy Clinical Management Services Scope of Work*. We will implement active and on-going educational outreach programs that, using State Advisory Board data and other data, educate physicians and pharmacists on common drug therapy problems to improve prescribing and dispensing practices. The CPM (clinical program manager) will be the lead contact regarding the RetroDUR program for DCH, the State Advisory Board, and any other relevant parties. The CPM will also report any findings of FWA (fraud, waste, or abuse) to the Program Integrity vendor.

Figure 5 outlines the RetroDUR business flow detailing the collaboration between MedImpact and DCH.

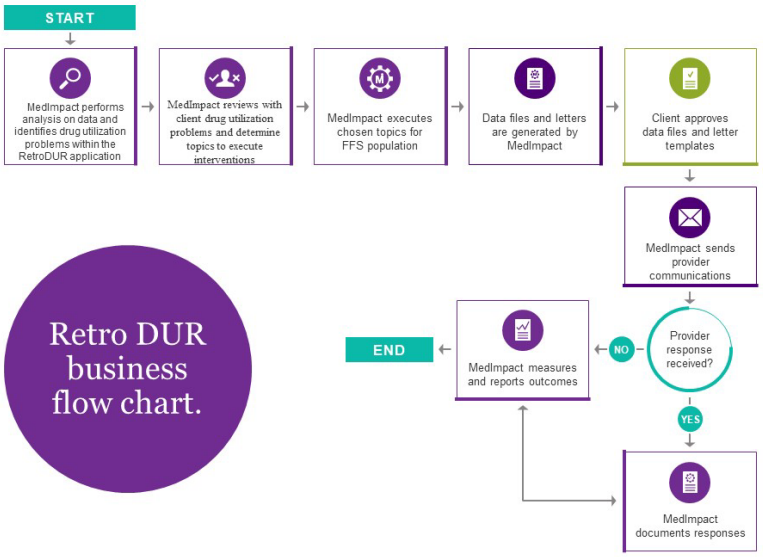


Figure 5: RetroDUR Business Flow Chart

MedImpact will comply with and maintain the RetroDUR files and criteria tables as recommended by the State Advisory Board within the 10-day business requirement of DCH's approval. Since we will also be heavily involved in preparing for and running the State Advisory Board meetings, it will be easy to integrate the recommendations and meet this deadline.

RetroDUR Application

MedImpact's RetroDUR application is designed to offer a streamlined, end-to-end solution to accommodate the custom needs of our Medicaid FFS customers. It is comprised of 4 core elements: Identification, Intervention, Response, and Outcome. These core elements work in conjunction to integrate and analyze data, provide targeted interventions, and produce successful outcomes in our single, streamlined solution. **Figure 6** provides an illustration of the 4 core elements work together in our application.

RetroDUR application core elements graphic.

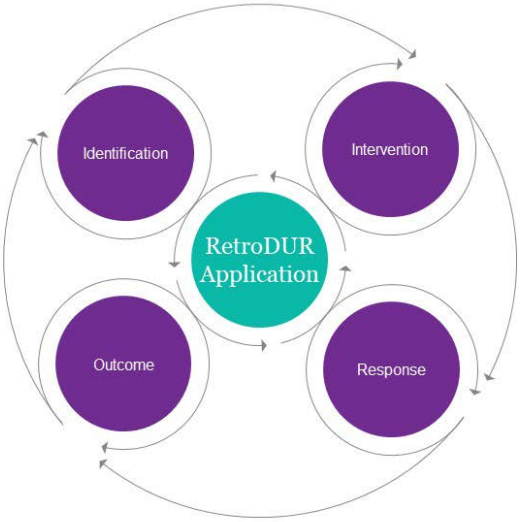


Figure 6: RetroDUR 4 Elements

Our RetroDUR application offers customizable options such as utilizing DCH's logos, applying DCH's signatures, and the ability to utilize MedImpact's Alexis-Lexus Provider directory or DCH's Provider directory with options to send communications using either or both. Within each of the 4 core elements, there are choices and parameters that can be customized to fit DCH's requirements and preferences to facilitate outcomes including custom:

- Algorithms to identify specific population
- Intervention letter contents, logos, and layouts
- Survey questions
- Communication and response collection methods

The following sections provide more detail about each of the 4 core elements including how they work together to provide a comprehensive RetroDUR solution from pre-analysis through outcomes.

Identification

The first core element is Identification, which is the pre-analysis element of the RetroDUR program. MedImpact and/or DCH will be able to log in to the application and run various analyses on drug utilization trends and identify drug utilization problems and opportunities. The system is able to incorporate and perform analyses on pharmacy claims data, member eligibility information, pharmacy provider information, prescriber information, as well as medical claims data (including but not limited to ICD-10 codes, and HCPCS codes). We will coordinate with the PBA and MMIS vendors to ensure we have all the data needed at a frequency determined by DCH post-award. The application allows flexibility and freedom to create new or adjust existing clinical algorithms for RetroDUR interventions.

The DCH assigned CPM recommends identified interventions to DCH for approval. Following this approval, we develop associated objectives, protocols, guidelines, and operational procedures. MedImpact's clinical pharmacists work with our program data analysts and corporate clinicians to develop proper algorithms for member identification and stratification via our sophisticated proprietary data analytics engine within the RetroDUR application.

MedImpact has various modules such as respiratory, cardiovascular, controlled substance, pediatric, or miscellaneous modules which include various programs and algorithms that mine the data. The customer can customize these descriptions and algorithms to align with regulations and population demographics. **Table 2** provides an example of the algorithms we utilize in our controlled substance module.

Controlled Substance Module	
Title	**Description**
Controlled Substances	Identify members receiving 10 or more prescriptions for DEA schedule II, III, IV or V controlled substances (excluding steroid hormones and drugs used to treat attention deficit hyperactivity disorder) during the previous 3 months.
Opioid Overutilization-Benzodiazepine/ Potentiators Retrospective Intervention	This enhanced retrospective drug utilization review uses proprietary advanced analytics to identify members receiving opioids with an average daily MME greater than or equal to 90 mg/day for any duration (monthly rolling 6-month look-back) from 3 or more prescribers and 3 or more participating pharmacies OR 5 or more prescribers regardless of the number of pharmacies. Of those targeted members that meet the above criteria, members with concurrent use of opioids and benzodiazepines, gabapentin (>2400mg/day), and/or pregabalin will also be identified.
Naloxone for High-Risk Opioid Use Retrospective Intervention	This enhanced retrospective drug utilization review uses proprietary advanced analytics to identify patients 18 years of age or older who received an opioid(s) over the previous 3-month time period without a history of a naloxone claim in the prior 12 months. In addition, at least one of the following criteria must be met: history of opioid addiction, obtained an average daily opioid dosage of ≥ 50 mg MME, or have been taking an opioid in combination with a benzodiazepine for at least 30 days.
Opioid Concurrent Uses	Identify members receiving opioid therapy with buprenorphine, benzodiazepines, antipsychotics, sedatives, and/or stimulants concurrently during the previous 3 months. This intervention excludes members with cancer or sickle cell disease.

Opioid Duplicative Therapy	Identify members receiving duplicative long-acting and/or short-acting opioid therapies during the previous 3 months. This intervention excludes members with cancer or sickle cell disease.
MAT Product Prescribing Outliers	Identify prescribers whose brand vs generic buprenorphine-naloxone products quantity prescribing ratio in the past 3 months was considered an outlier (defined as above 1.5 Inter-Quartile Range (IQR) from the 3rd quartile).

Table 2: Controlled Substance Module

The CPM will work with DCH to determine what modules will best fit your population and work together on any customizations to the algorithms to source the most targeted results.

Once the algorithms are finalized, they are run through the application for pre-analysis. **Figure 7** provides a specific example of the interface flow for a clinical algorithm used in our "Antipsychotics in Children" RetroDUR topic.

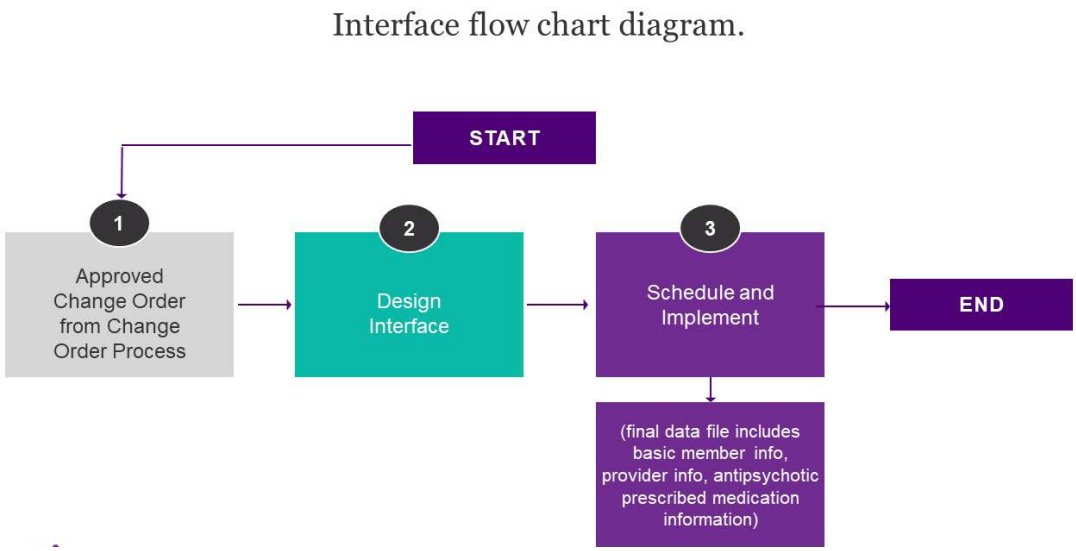


Figure 7: Antipsychotics in Pediatric Population Algorithm Flow

Once the pre-analysis is complete, the final data file with member, provider, and relevant clinical information needed for intervention communication can be reviewed within RetroDUR application or be exported and provided to DCH for approval. Once approved, the data will then be used with DCH's customized letter templates to generate the letters or interventions that will be sent to prescribers.

Intervention

MedImpact understands that an integral piece of RetroDUR program is communication with prescribers and this is the focus of the Intervention core element. Once DCH has approved the results from the Identification element and chosen the topics to focus on, the intervention letters are created during the Intervention phase. MedImpact's application has letter templates within the system that are fully customizable. DCH can choose a specific template and change any of the contents, replace or move the logos, move around the contents, or change the layout all within the application. These custom templates can be single-use or saved for future use depending on customer preferences.

In addition to customizing the letter templates, customers also select methods of communication for the intervention letters. Currently, customers can choose fax, print, or mail options and can further define the order of communication, if desired. For example, a customer could choose fax as the initial method of communication and then follow-up with a mailing as a secondary option if no response is received from the fax. MedImpact is also working on EMR system integration delivery options for a future application release. This will allow letters to be delivered directly into a prescribers' EMR for review and response.

Response

The Response core element focuses on the collection of feedback from prescribers, which provides a channel for prescriber engagement, facilitates program participation, and creates additional data for outcome reporting. In addition to the intervention letter, customers can choose to ask survey questions. These questions can be asked at either the letter level (prescribers answer the question once per letter received), or at the member level (prescribers answer the same question for each member included in the letter). Examples of the types of questions included in surveys are:

- Do you think this intervention is useful?
- Do you think the data provided is accurate?
- What action have you taken to address the drug utilization problem identified for this member?

These questions can be customized by DCH to capture feedback. In addition to the questions, if a member is already on additional therapy, there is a space for it to be noted for documentation purposes.

MedImpact can collect these responses in several different ways including mail, fax, or via an online survey portal. Customers choose their preferred method of collection. Responses received by mail or fax are scanned and the responses are captured via OCR (optical character recognition) technology. The recorded data is stored in the database and made available in the application for viewing or reporting purposes. If customers opt to utilize the online survey portal, responses are captured electronically and fed back into the application. The survey portal URL is included in the letter along with the QR code, so prescribers and/or their delegates can easily access the portal via computers or smart devices. The survey portal is secure and requires user authentication, which can be integrated with DCH's SSO (single-sign on) solution.

Outcome

The Outcome element of the RetroDUR application focuses on analyzing and reporting outcomes. The data is available within the application, so the end analysis and reporting is available right in the tool. Outcomes can be assessed after 1 or 2 quarters depending on the nature of the RetroDUR topic/s interventions being performed. MedImpact assesses outcomes in 2 ways: pre-and-post intervention comparison and prescriber survey response reporting.

Pre-and-Post Intervention Comparison

Pre-and-post intervention comparison is performed by re-executing the algorithm and reidentify the members who met the initial intervention criteria. The outcome measures success rate defined by (number of members in pre-intervention analysis minus number of members who were included in

both pre- and post-intervention analysis) divided by number of members in pre-intervention analysis times 100%.

Survey Response

If DCH opts to include prescriber surveys, those results are also captured in the application and can be reported on. Prescribers would have had the opportunity to report any actions taken (such as changing therapy, no action, and more) for each identified member. The outcome is measured by aggregation of prescriber responses.

Reporting

In addition to the RetroDUR application reporting, MedImpact provides quarterly and annual reports including the CMS annual DUR survey that includes a retrospective analysis of previous RetroDUR interventions. Within the quarterly and annual reports, we summarize our analysis of provider and member drug use patterns and complement the reports with suggestions for the development of educational strategies to improve prescribing and dispensing practices. All reports are accessible through the RetroDUR application or provided via SFTP.

MedImpact is confident our user-friendly RetroDUR application will make collaborating on and managing this program efficient and successful. We will work together during DDI and beyond to customize our end-to-end RetroDUR application to best fit DCH's changing needs.

6.	**Bookmark Title: MSQ6 – Approach to Appeals** Narrative description is limited to four (4) pages. Describe in detail your company's approach to Appeals with regards to how your company will respond to inquiries and complaints about the Utilization Management criteria and review process. Include in your response, the process for sharing this information with the State. Refer to Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.4 Utilization Management Program.

Supplier **Response**

MedImpact has reviewed and understands the requirements outlined in *Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 2.4 Utilization Management Program*. We are an experienced partner and have processes in place to handle UM criteria appeals.

UM Criteria Appeals Approach

MedImpact collaborates with the medical community including drug manufacturers when evaluating and making utilization criteria recommendations. We are open to UM criteria improvements on an ongoing basis. UM criteria appeals usually arise from prescriber concerns or from a PA and appeals team member. We utilize a peer-to-peer discussion approach to address any concerns or suggestions about criteria or other items. If we receive this type of feedback, we will gather it and review and discuss it with the state agency to determine if further evaluations are needed. If changes are warranted, we will make recommendations and present them to DCH for consideration.

If there are manufacturer complaints regarding our UM criteria, we will review rebate contracts, make sure our criteria adheres with medical, and ensure state PDL/PADL is not at risk based on our UM criteria prior to presenting any change recommendations.

UM Appeals Approach

MedImpact has developed an ERISA (Employee Retirement Income Security Act) and PPACA (Patient Protection and Affordable Care Act) compliant standard appeals program for customers that delegate this function to us. We will work with DCH during the DDI phase to determine the level of MedImpact involvement in the member appeals process. The MedImpact appeals coordinator manages all appeal requests and a clinical pharmacist reviews them. A physician review is available at the internal (first level) clinical appeals when required. **Figure 8** depicts MedImpact's appeals process.

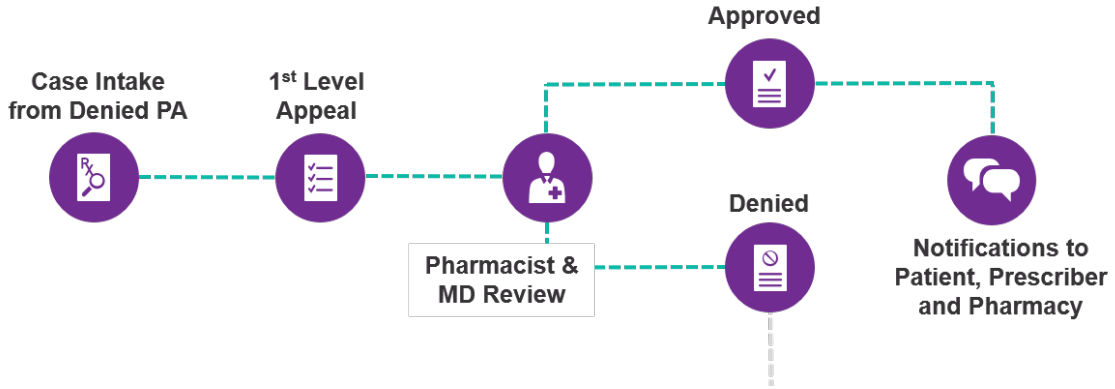


Figure 8: MedImpact's Appeal Process

We resolve the first level clinical appeal according to the timeline required by the state. If approved, we send the prescriber a notification letter by fax and we notify the member by mail. If we deny the internal clinical appeal request, next steps will be taken in alignment with DCH requirements, which we will solidify during DDI.

Tracking Written Requests

Upon receiving a written request via mail, the mail room clerk date and time stamps all pages and mail envelope when received and creates a PDF version. The mail room clerk then scans a PDF version and routes all mail addressed to the grievance and appeals department via secure email. For urgent requests, the appeal or grievance coordinator opens the email and documents the email receipt date and time. For standard requests, the mail room clerk date and time stamps the document and envelope. The appeal or grievance coordinator verifies that the request is a grievance, coverage determination, appeal (or redetermination), or inquiry.

- If the request is not an appeal or grievance, the appeal or grievance coordinator forwards the request via secure email to the correct department for managing.
- If the request is an appeal or grievance, the appeal or grievance coordinator forwards the request to the appropriate team for appeal or grievance processing.

The appeal or grievance coordinator confirms the membership of the requestor and creates a new appeal in MedResponse Appeals or a grievance case in Salesforce. The appeal or grievance coordinator attaches the PDF copy of the request to the relevant MedResponse Appeals item or Salesforce case.

Upon receiving a written request via fax, the appeals or grievance coordinator receives the request in MedResponse Appeals that automatically time-stamps with the date of when we receive the fax. The appeals or grievance coordinator verifies that the request is an appeal or grievance and performs the following:

- If the request is not an appeal or grievance, the appeal or grievance coordinator forwards the request via secure email to the correct department for managing.
- If the request is an appeal or grievance, the appeal or grievance coordinator confirms the membership of the requestor and creates a new appeal or grievance case.

MedImpact will work with DCH during the DDI process to identify all requirements and solidify a coordinated approach to managing both criteria appeals and UM appeals and grievances. We will establish a regular communication cycle to keep DCH informed of the appeals and process.

MedImpact will provide and maintain a written policy governing the management of UM denials and subsequent Appeals to DCH for review and approval. We will comply with DCH requirements governing denials and second level Appeals including communications and processing time. We currently provide such documents for our existing customers.

Automated Workflow Tool for PA Criteria Management

MedImpact will provide DCH with an automated workflow tool, MedResponse, that DCH can utilize for review and approval of PAs. We are working on a tool that will incorporate insight and access to criteria changes, modifications, deletion, or alternations as part of the UM program.

MedImpact's Criteria Management System is a comprehensive tool designed to streamline the management of PA guidelines within a PBA and Pharmacy Clinical Management Service framework. The system's key features facilitate various aspects of criteria management, from the initial request to the final approval and reporting. The following provides a brief overview of the system's functionalities:

- Request Management and Task Tracking: This feature enables users to manage the workflow of requests and tasks associated with PA guidelines. Users can enter and update details, view and assign requests, track statuses and due dates, attach documents, and capture notes. This helps ensure that all requests are handled efficiently and that nothing falls through the cracks.
- Guideline Management Configuration: This component enables users to handle the guidelines that form the basis of drug utilization management. It includes capabilities to search for, view, create, update, and tag guidelines. Users can also associate guidelines with specific customers, drugs, and business rules ensuring that guidelines are applied correctly across the system.
- Guideline Publishing: Once guidelines are finalized, they can be exported and shared in various formats including PDF and NCQA (National Committee for Quality Assurance) format. There is also a feature for the approval of finalized guidelines, which is crucial for maintaining compliance and quality standards.
- Rule Criteria: This feature is focused on the creation and management of the business rules that are applied within the system. Users can author rules, test them to ensure they work as intended, and then deploy them into the live environment.
- Criteria Management Reporting Console: Reporting is essential for oversight and management. This console enables report generation on guidelines and rules which provides insights into their usage and effectiveness.
- Criteria Management Dashboard: A dashboard provides a quick overview of the system's current state. It enables users to view all requests and tasks as well as filter to see only those items that are relevant to them personally. This helps users stay on top of their work and prioritize their actions effectively.

Overall, MedImpact's Criteria Management System provides a robust set of tools for managing the complex requirements of drug utilization management in a PBA and Pharmacy Clinical Management Service context. It is designed to enhance efficiency, ensure compliance with clinical guidelines, and streamline the management of pharmacy benefits.

MedImpact is well versed in the appeals process and will work with DCH in whatever capacity you require to support the Appeals program. We take a comprehensive approach to appeals and have worked with customers in a variety of ways to manage or support the appeals process. We will work with DCH to gather information and solidify processes during the DDI phase of the contract.

7.	**Bookmark Title: MSQ7 – Document Repository** Narrative description must be uploaded as an attachment and is limited to five (5) pages, inclusive of any diagrams. Describe in detail the design and maintenance of the document repository that will meet the requirements as outlined in Attachment C: Common Scope Requirements and Security Standards, Section 2.14.1 Document Repository and Attachment G: Pharmacy Clinical Management Services Scope of Work, Section 3.2 Document Management.
	Supplier Response MedImpact has reviewed and understands the requirements provided in *Attachment C Common Scope Requirements and Security Standards, Section 2.14.1 Document Repository and Attachment G pharmacy Clinical Management Services Scope of Work, Section 3.2 Document Management*. We are confident in our ability to provide a robust solution to meet DCH's document management requirements. We routinely create these repositories for customers and will do so for DCH. **Document Management Repository** MedImpact currently utilizes both SharePoint and Box tools as document repositories for sharing information with customers. Box can support larger files like medical images, so may be the better choice for DCH's Pharmacy Clinical Management services. However, SharePoint offers the ability to link images and files to different systems. During DDI, we will collaborate with DCH to identify your needs and choose the tool that will work best for the document repository. Once a tool is chosen, MedImpact will design, develop, and maintain an electronic document repository for DCH. These tools enables us to collaborate with customers to find, organize, edit, share, sign, store, and classify content in a secure system.

Figure 9 outlines the important functions a successful document repository performs.

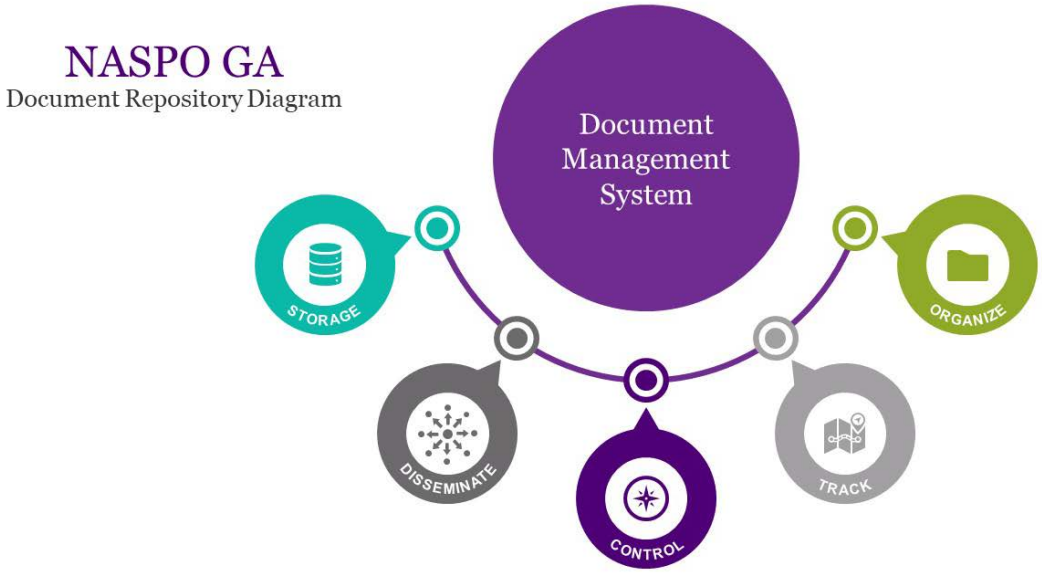


Figure 9: Document Repository Functions

MedImpact has identified the CPM (clinical program manager) to oversee the document repository. This member of the account team will be the first point of contact for DCH for any questions or concerns about the document repository. This position reports directly to the account manager and will be enabled to escalate any issues in a timely fashion.

Document Repository Options

SharePoint is a secure, user-friendly way to collaborate in an environment available on both desktop and mobile devices. It enables users to build intranet sites, create pages, document libraries, and lists. Version history and edit tracking are available for all parties accessing information on any given site. In addition to the basic features of SharePoint, web parts can be added to customize content including displaying important visuals, sharing news, and communicating updates to MedImpact and DCH team members.

Box offers a variety of products and solutions that integrate with its content cloud solution available on both desktop and mobile devices. Box offers easy-to-use collaboration in a secure and compliant environment. They also tailor product offerings to state government programs, so know the importance of security, compliance, and efficiency in the government program space and take that into account when designing their solutions. In addition to the basic collaboration features, Box also offers:

- Workflow
- Whiteboarding
- E-signature
- Integrations
- Developer Tools & APIs
- IT Administration
- Artificial Intelligence

MedImpact uses document repositories for development, team review, publication, and version control of project documentation. We partner with DCH to ensure your SharePoint or Box system enables revision history tracking which provides transparency into the work we do together. With this function enabled, the tool stamps each set of changes made during an individual editing session with the date, internal version number, and user identifier of the person who made the change. We maintain all versions under development or revision (not published as official) in a document library accessible only to authorized DCH's staff, MedImpact, authorized software developers, and reviewers.

We update customer SharePoint or Box sites at least weekly and will work with DCH during DDI to determine the best update cadence during DDI and ongoing for your Document Repository. If any deviation from this requirement is needed, MedImpact will secure approval from DCH or its designee prior to making any changes to the timeline.

Authorized User Access

MedImpact and DCH's Authorized Solution Users will have access to SharePoint or Box document repositories 24 hours per day, 7 days per week, 365 days per year. Both solutions allow for uploading or attaching new or revised versions of electronic documents and images in a variety of formats and have built in version control accessible in real-time via mobile device. SharePoint offers the added ability to link uploaded documents or images to other system documents, images, or cases.

Operations Manual

MedImpact will provide an Operations Manual for DCH which includes instructions on proper use of the Document Repository. We realize the importance of access to quality trainings and training materials and will provide DCH's users with what they need to successfully navigate and use the Document Repository. Operations Manuals will be published to the repository in the Adobe PDF so that end users cannot edit them. Each official version of the document will be assigned a publication version number. MedImpact will track the official published version numbers of each document. Trainings will include but not be limited to:

- Role-based access
- Navigation
- Download
- Documentation
- Security protocols

During DDI, we will work with DCH to identity Authorized Users in need of trainings and schedule them at a cadence that meets DCH's needs.

MedImpact will submit all records, documentation, reports, data, and other deliverables required to be produced under the terms of the Contract to DCH or its designee no later than the timeframe specific in the DCH-approved Turnover Plan. We understand the importance of having timely access to all relevant materials to provide continuity of pharmacy clinical management services to members and strive to meet all deliverable deadlines.

Project Tracking

Document Repositories enable MedImpact, DCH, and any other stakeholders to facilitate, track, and control project artifacts with ease. The Document Repository provides a centralized access point to all project activities, processes, and procedures. MedImpact will utilize SharePoint or Box to share documents, archive documents, conduct project communications, and provide DCH transparency into the work we do. This will allow the MedImpact and DCH to view updates, archive various reports, and conduct project communications quickly and easily.

SharePoint and Box both facilitate teamwork with dynamic and productive team sites for every project team, department, and division. For purposes of project management, MedImpact will use SharePoint or Box to securely share and archive DCH-specific project files, including workplans; WBS; RAIDs; RADs; RACIs; and more. MedImpact will work with the DCH and DCH's third-parties to determine and agree upon the mechanism of transferring information to SharePoint or Box on regular basis.

MedImpact will create and maintain the documentation outlined in the *Pharmacy Clinical Management Services Statement of Work*. We acknowledge and understand that DCH will review, modify, and approve all document deliverables and own all documentation developed for the purposes of this project. As outlined in our response, we do offer both SharePoint and Box as Document Repository options. Based on the requirements outlined in the RFP, we recommend SharePoint as a better fitting solution for DCH. However, we will work with DCH during DDI to explore both options and make a final determination.

8.	**Bookmark Title: MSQ8 – Staffing** Narrative description is limited to five (5) pages, exclusive of organizational chart(s) and Subcontractor contract(s) or letter(s) of agreement, if applicable. Provide a narrative description of the proposed staffing plan that details policies, plans and staffing strategies. The proposed plan must include the following: Organizational charts that provide a complete and detailed description of the proposed organizational structure the Supplier will use, including Subcontractors and how they fit into the Supplier's overall organizational structure. Roles and responsibilities of staff. Job titles and the requisite qualifications, skills, and credentials, including clinical licensures relevant to this Contract. If Subcontractors will be used, provide the following: Subcontractor's name and address. Roles and responsibilities to be delegated to the Subcontractor for purposes of this Contract. Subcontractor's qualifications to perform these roles and responsibilities. Copy of the Subcontractor contract; the State will accept a letter of agreement with a prospective Subcontractor pending formalization of a final contract with details relevant to "c" in this section. Refer to Attachment G - Pharmacy Clinical Management Services Scope of Work and Attachment C - Common Scope Requirements and Security Standards, Sections 2.15 Staff Management and 3 Staffing.

Supplier Response

MedImpact has created a staffing plan based on the staffing requirements and responsibilities presented in the *Pharmacy Clinical Management Services Scope of Work* and the overall project staffing requirements for DCH. We will utilize this staffing plan during DDI in conjunction with DCH to create the final staffing plan for approval. MedImpact realizes the integral role staffing plays during the course of a customer Contract. It is the key to building a successful relationship and, in turn, a successful pharmacy clinical program.

Purpose

The Staffing Plan provides an overview of MedImpact's resource management approach and procedures. The intended audiences of this document are team members from MedImpact, MedImpact subcontractors, DCH, and any other DCH-designated stakeholders who have a role in resource management for DCH's project. The plan encompasses:

- Staffing Management Approach
- Training
- Retention and Change Management
- Resource Requirements and Estimation

- Project Organizational Structure
  - Organization Chart with reporting relationships
- Staff Roles and Responsibilities
- Subcontractors

Scope

The Staffing Plan is applicable to the entire life cycle of the State of Georgia DCH's project. Any changes including staffing or subcontractors are subject to formal project change control procedures and approval by DCH. Increased staffing levels, if requirements or standards are not being met based on the discretion of DCH, will be provided at no additional cost to DCH. Any MedImpact or Subcontractor staff assigned to DCH will perform work under the Contract that has been approved by DCH. MedImpact will comply with all DCH staffing requirements, including but not limited to those pertaining to security, health, and safety issues.

Staffing Management Approach

MedImpact will provide DCH access to our interdisciplinary account management team who will manage all aspects of DCH's program. The account manager will serve as the daily point of contact for DCH to effectively manage DCH's needs. Our account management team promptly responds to phone or email inquiries within 1 business day, with the goal of 1-touch resolution. We will leverage a routine meetings with DCH to review the project log and address any outstanding inquiries on an agreed-upon schedule.

The account team is made up of several individuals with varying roles. MedImpact's approach to staffing and resource management is realistic, yet flexible. We provide the appropriate number of resources with the right skillsets and experience. Our strategy for the proposed staffing and organization is to meet DCH requirements by providing:

- Sufficient staffing levels to complete project activities in accordance with DCH-specified requirements.
- Adaptability to adjust staffing levels to meet changing demand (such as increases/decreases in workload).
- MedImpact team members with the appropriate skillsets, experience, and availability to perform their assigned duties.
- Strategies, processes, and tools to support effective and timely forecasting, recruitment, retention, and replacement (if necessary) of staffing to meet required staffing levels.
- Forecasting, planning, and scheduling of the project workload using resource management tools and processes, MedImpact best practices, and DCH collaboration.

MedImpact brings expertise, flexibility, and innovation to the PBM space including Pharmacy Clinical Management Services and this applies to our staffing approach as well. We design our staffing plan with flexibility to adjust with the natural ebb and flow of organizational needs. Our flexibility extends to collaborating with DCH to recruit and retain the best candidates for your Key Staff.

Training

Effective training and education are paramount to the success of any PBM program including Pharmacy Clinical Management Services. Comprehensive training involves not only initial and ongoing application training needs of teams and individuals but also updated materials, documentation, and access to support services and Key Staff members.

Account Management Team Training

Account management team training begins upon award of contract and continues through DDI, operations, and for the life of the contract. MedImpact provides extensive training on DCH's benefit design, operational overview, and any specific nuances including:

- Overview of DCH to ensure an understanding of the business
- DCH's contract terms
- DCH's active programs and services
- DCH's contacts and communication preferences
- Any other DCH expectations and strategic goals

MedImpact requires new account managers and account executives to undergo extensive training that includes classroom training, e-learning, on-the-job training, and peer coaching. In addition to completing MedImpact's corporate compliance courses which cover topics such as general corporate training, code of conduct, HIPAA, and CMS rules and regulations, MedImpact requires new key staff to attend instructor-led training to develop industry, product, and skills knowledge. We also pair new account management staff with a mentor who facilitates on-the-job experiential learning. Based on the skill and knowledge levels of the new hire, training time ranges from 6 to 12 weeks.

Cross-Training

As part of the customer onboarding process, MedImpact identifies a team of Key Staff and designated backups to provide customer support during vacations, absences, and high-volume periods. These individuals will also participate in DCH-specific cross-training to promote service excellence.

Recruitment, Retention, and Remediation

MedImpact understands that Key Staff changes can be disruptive for customers and prioritizes retention efforts to minimize any unnecessary turnover. Employee retention starts during the hiring period. Our team of human resource professionals deploys a comprehensive people strategy and a well-structured talent acquisition strategy that focuses on long-term human resources planning to seek out the most qualified individuals, assess their skills, determine where they would best fit in our organization, and ultimately convince them to join the enterprise.

We offer employees competitive salary and benefits programs while encouraging healthy work/life balance. We also foster internal promotions and employee development by identifying and tracking talented and motivated employees and then working closely with managers to determine development opportunities and help them advance their careers. This includes a tuition reimbursement program and internal leadership training tracks. MedImpact's focus on creating a robust and healthy work environment contributes to low account team turnover and an average tenure of 6 years or more for account team members.

Providing consistent and superior service to our customers is MedImpact's top priority. We consistently solicit feedback from our customers informally through regular meeting cadences and

formally through annual customer satisfaction surveys. MedImpact meets weekly with the pharmacy director to discuss the effectiveness of the program and individual team members. If needed, we can coach and council members to improve or place them on a correction plan. In event DCH chooses to remove a team member, we will work to ensure their responsibilities are addressed while we seek a replacement. If DCH requests a replacement and upon mutual agreement, the account manager will provide an update via email to DCH including the new team member's biography and transition timeline.

MedImpact will not transfer or remove key personnel without prior approval from DCH. MedImpact will provide advance notice of at least 30 calendar days before transitioning any Key Staff to another MedImpact position, project, or assignment. We will ensure appropriate staffing levels are maintained throughout the project, so objectives are met on time, including applicable privacy and security requirements.

Should a position unexpectedly become vacant or should a need arise for additional staffing, MedImpact maintains sufficient flexibility necessary to shift resources between projects. This can occur during the DDI phase and throughout ongoing operations and maintenance. MedImpact will first recruit existing staff as we have several employees with skills and experience that are like our proposed personnel. If we are unable to fill the position internally, we will execute our external recruiting plan.

Resource Requirements and Estimation

MedImpact utilized our understanding of DCH’s program and our experience with similar programs to define the resource requirements and develop staffing estimates. We have analyzed project requirements to determine the types and numbers of required staff for DCH's Clinical Management Services program. Based on the requirements outlined in the RFP, we have developed a staffing model to support all phases of project activities in accordance with DCH requirements. This approach optimizes staffing projections to meet all contract obligations and planned volume fluctuations. We also consider current staffing needs against the potential for future changes and have created a staffing approach that allows MedImpact to rapidly adjust to changes that influence work volume.

During DDI, we work in collaboration with DCH to verify anticipated transactional volumes and validate our staffing projections accordingly. These steps are critical to mitigate the risk of surprises at go-live (start of operations) that may impact response times.

Project Organizational Structure

MedImpact has developed our proposed organizational structure based on the requirements in the *Pharmacy Clinical Management Services Scope of Work* and will fill staffing positions according to our forecasts. Any additional recruiting efforts deemed necessary for the project will be initiated as quickly as possible following the contract award. The account management team will receive support from the appropriate essential resources (such as technical and business processes and staff) to ensure optimal effectiveness for DCH and its stakeholders. MedImpact’s executive leadership team will provide supplementary oversight of the project in an executive sponsor capacity.

Organizational Chart

Figure 10 shows an organizational chart illustrating MedImpact's proposed key staff, leadership support, and other support for DCH's project.

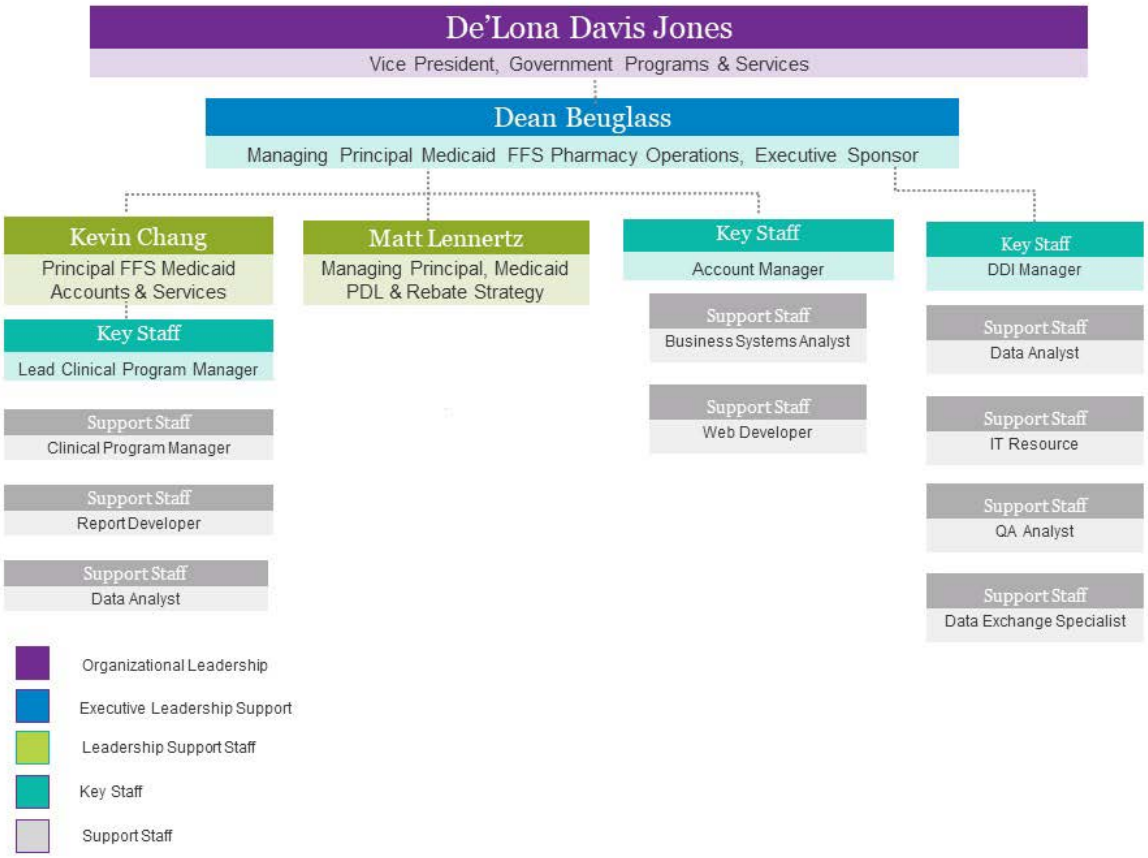


Figure 10: DCH Clinical Pharmacy Services Organizational Chart

We understand that MedImpact is responsible for maintaining the organizational chart throughout the contract by updating it within 5 business days of in event of any subsequent changes or vacancies throughout the contract.

Staff Roles and Responsibilities

MedImpact confirms that all Key Staff will be dedicated to DCH's project 100% of the time or as determined and agreed upon. Each Key Staff serves 1 role unless we seek approval from DCH in writing. All MedImpact proposed Key Staff will have experience in health care and Medicaid program operation and be available after normal work hours if DCH requires.

MedImpact confirms that all Key Staff will be dedicated to DCH's project 100% of the time or as determined and agreed upon. Each Key Staff serves 1 role unless we seek approval from DCH in writing. All MedImpact proposed Key Staff will have experience in health care and Medicaid program operation and be available after normal work hours if DCH requires.

MedImpact's proposed Key Staff will be employed or have a written, legally binding commitment to join our organization by the beginning of the DCH Contract start date. We are committed to providing experienced knowledgeable staff with the skill set to manage the unique needs of DCH's Medicaid

FFS Clinical Management program. The Key Staff member roles identified in the proposal will work on the relevant project phases from the Contract signing date and we commit to not reassigning Key Staff members except in cases of resignation or termination without advance approval from DCH.

If Key Staff must be replaced, MedImpact will provide resumes of replacement candidates to DCH and an opportunity for DCH to interview and accept potential replacements. We further acknowledge that acceptance of a potential replacement by DCH will not be withheld arbitrarily. MedImpact will obtain prior written consent from DCH before Key Staff and other proposed project staff are reassigned or replaced unless it is an emergency situation.

We will notify DCH of a Key Staff resignation or departure within 2 business days of the date a Key Staff member provided MedImpact with notice of resignation. We acknowledge that DCH reserves the right to request reassignment or replacement of Key Staff throughout the life of the Contract. MedImpact will name a temporary replacement acceptable to DCH when a Key Staff position is vacated within 5 business days of the date a Key Staff position becomes vacant and ensure permanent replacement is working on the project within 60 calendar days of the vacancy date. We also commit to naming acceptable temporary replacement staff prior to any periods of planned leave for Key Staff positions.

MedImpact is pleased to highlight the roles, responsibilities, and qualifications of the Key Staff identified for DCH's project.

Account Manager

The Account Manager will derive a complete understanding of DCH’s objectives, expectations, and desired outcomes and will serve as the single point of contact for day-to-day issues. They interact with internal departments to coordinate actions and gather information to help ensure we resolve questions, issues, and projects completely and in a timely manner. The Account Manager strictly adheres to procedural and quality standards including thorough and accurate documentation, testing protocols, and claims analysis.

Responsibilities

- Builds customer relationships through active participation in the customer team process, including adherence to agreed-upon rules of engagement and roles & responsibilities.
- Adheres to strict procedural and quality standards, including thorough and accurate documentation, testing protocols, and claims analysis.
- Uses experience, judgment, business & systems knowledge, and technical skill to plan and accomplish goals.
- Ensures appropriate levels of service and operational support to assigned customers by understanding and championing customers’ operating requirements throughout the organization, including customer business model, targeted markets, benefit design objectives, pharmacy network composition, overall claims adjudication expectations, reimbursement methodologies, metrics, and reporting tools.
- Proactively maintain and improve upon service performance levels and works across the organization to expeditiously resolve issues, escalate service recovery efforts, provide timely feedback to internal and external customers, raise customer satisfaction levels, and ensure that service gaps & lessons learned are incorporated into the customer performance and planning strategy processes.

- Leads operational initiatives in support of customer business objectives, including engagement of project management support, providing regular updates to customers, providing appropriate levels of communication between the customer & company staff, interpreting, and providing context for customer requests, and ensuring that appropriate pre- and post- production review and sign-off by the customer is executed.
- Leverages customer relationship management tools and spreadsheets for documenting all customer contacts and deliverables requiring follow-up.
- Measures service levels by including appropriate & accurate documentation of customer information, issues, projects, and work requests.
- Oversees assigned cases and ensures adherence to due dates.
- Is an active participant in customer life cycle management and strategic customer planning.
- Utilizes planning, prioritizing, and organizational skills to ensure timely deliverables, high levels of quality, and efficient use of resources to assist in claims adjudication accuracy.
- Ensures appropriate back up coverage for customers during holidays, weekends, and other times.
- Maintains commitment to operational goals in the face of obstacles.
- Actively supports other members of the core customer team, and members of the extended team, in successfully supporting customer needs and delivering flawless fundamentals.
- Promptly responds to service failures, resolves issues, and escalates concerns as appropriate.
- Actively participates in continued professional development to stay up-to-date on the latest quality management best practices and products, services, & technical enhancements.
- Completes special projects as assigned (such as leading workgroups, overseeing projects, assisting in customer implementations, executing up-sell plans in conjunction with the customer team, mentoring/training staff, and more.

Minimum Qualifications

- Bachelor's Degree or equivalent and four (4) years customer support or related account management experience in a healthcare or PBM environment; or equivalent combination of education and experience.
- Experience as a user of multiple business software applications is required Pharmacy Technician license or national certification desired.
- Intermediate to advanced skill set in MS Office; Word, Excel, PowerPoint, Project, and Outlook. Intermediate to advanced knowledge in Visio.
- Pharmacy Technician license or national certification desired.
- Outstanding numeric, verbal, written, logic, and analytical skills. Project Management 101 certification or equivalent training. Superb public presentation skills.

DDI Manager

The DDI Manager collaborates with key staff and DCH to lead the implementation process. The position is responsible for building an early relationship with customers for a successful transition. The DDI Manager ensures all stakeholders are kept well informed of the requirements, any changes, progress status, and any potential issues. They are also responsible for supporting other projects to contribute towards team goals. This position will be located remotely.

Responsibilities

- Prepare for and facilitate new customer meetings for the purposes of requirements gathering and discovery.
- Assist DCH with facilitating any impact analysis to best determine the appropriate requirements to ensure a smooth and successful implementation.
- Ensure all requirements are documented and obtain approval from DCH.
- Create and maintain a high-level project plan.
- Continuously monitor progress in terms of the status of the project and report back to internal management and subject matter team members and DCH using weekly status report formats.
- Assist with escalated customer issues, member issues, project issues as identified or requested by the customer through direct support or through the support of MedImpact subject matter experts assigned to the project.
- Provide go-live support either through remote access or internal on-site access.
- Facilitate Post Implementation Review meetings with DCH.

Minimum Qualifications

- Bachelor's degree in business, marketing, or related area preferred
- Knowledge of PBM or health care industry required
- Prefer at least 3 years project management experience, working with external customers preferably in Medicaid space
- Microsoft Office, Email, and Internet

Lead Clinical Program Manager

The Lead CPM (Clinical Program Manager) oversees staff working on the clinical analysis aspects of the project. They will work directly with DCH to support the clinical pharmacy programs including UM recommendations, RetroDUR, and Advisory Board support. The Lead CPM optimizes the clinical quality and cost-effectiveness of drug therapy for customers and their members. They focus on rational management of drug utilization by employing analytical tools and an evidence-based approach to achieve lower net cost, better health outcomes, and higher levels of satisfaction for plan sponsors and their members.

Responsibilities

- Provides recommendations to DCH that aligns with DCH's goals of lower net costs and high clinical quality.
- Provides clinical consultative services in accordance with contracted clinical services.
- Coordinates clinical utilization analyses and presentations to customers.
- Ensures timely and accurate review of plan data, according to policy, with appropriate intervention recommendations.
- Coordinates clinical support of PDL and PADL including UM recommendations, drug monographs, and other clinical support material to DCH and the Advisory Board.
- Participates in quarterly MedImpact P&T Committee meetings and in customer P&T meetings as per customer contract.
- Manages the document repository that is used for MedImpact and DCH collaboration.
- Manages the Advisory Board meeting agendas, meetings, and deliverables as well as disseminates that information before and after each meeting.

Minimum Qualifications

- PharmD (or equivalent) along with 3 – 5+ years' related experience required, preferrable in Medicaid.
- Knowledge of Microsoft Office Suite and a working knowledge of relational databases.
- Registered Pharmacist in the State of California or equivalent state.
- Analytical skills with Health Informatics experience preferred. Experience in promoting disease management or drug cost management programs preferred.

Other Staff

MedImpact will assign Other Staff to assist Key Staff in satisfactorily completing the requirements outlined in the *Pharmacy Clinical Management Services Scope of Work* throughout the applicable project phases and stages. We will provide resumes for Other Staff if requested by DCH.

Interactions Between MedImpact, DCH, and Other Entities

MedImpact staff, DCH staff, and all other entities that are involved in the implementation and operations of the *Pharmacy Clinical Management Services* will collaborate throughout the duration of the Contract. During DDI, all parties will be identified and communication and information transfer procedures will be created. MedImpact will be collaborative and proactive throughout the Contract and the communication plan developed during DDI will guide the cadence and escalation plans for communicating with all stakeholders. DCH's main point of contract throughout the length of the contract from DDI through operations will be the Key Staff.

Secure Communications

TLS (Transport Layer Security) encrypted website using Axway Secure Transport. Axway Secure Transport is configured via a front-end web server connecting to a back-end file repository. No files are stored on the front-end server. MedImpact supports file level encryption through the use of PGP for added protection. We also utilize secure email and document repositories for information sharing.

Subcontractors

MedImpact is not proposing a subcontractor for the Pharmacy Clinical Management Services module, but will abide by DCH's requirements for working with and maintaining the relationships if that changes in the future including but not limited to:

- Being responsible for all work performed by Subcontractors
- Soliciting DCH-approval of all Subcontractors
- Providing required Subcontractor information to DCH
- Complying with all federal and state requirements concerning fair employment, employment of people with disabilities, and the treatment of all employees without regard to race, color, religion, national origin, or physical disability.
- Adhering to all federal and state laws regarding Social Security registration and legal work status of employed or contracted staff.
- Performing criminal background checks and sharing results utilizing DCH-accepted criteria for all employed or contracted staff prior to project participation and periodically throughout the term of the Contract as required by DCH

In addition, all MedImpact and/or Subcontractor staff assigned to DCH's program will be located within the United States for the duration of the Contract.

MedImpact looks forward to expanding on this abridged staffing management plan during DDI in coordination with DCH to identify, capture, and finalize staffing needs for the *Pharmacy Clinical Management Services* program.

9.	**Bookmark Title: MSQ9 – Project Stages and Phases** Bookmark Title for Supporting Material: ➢ MSQ9.1 – Best Practices ➢ MSQ9.2 – Lessons Learned Narrative description is limited to five (5) pages, exclusive of required supporting material. Demonstrate your understanding of the Project Stages, Project Phases, timeline, expectations, and responsibilities as outlined in the Attachment C: Common Scope Requirements and Security Standards, Section 2.2 Project Stages and Project Phases. If your plans for the proposed services differ from the suggested outline, please explain the differences and how the proposed plan is a better fit for the State's needs. Include best practices and lessons learned that may be applied in the execution of these services and identify any additional proposed Milestones for the project.

Supplier Response

MedImpact practices a multiphase implementation approach dividing the implementation project into separate stages for both MedImpact's and DCH's complete understanding of crucial deliverable deadlines for a successful launch on the go-live date. This includes gathering requirements, developing a design plan, coding requirements, testing the benefit design, and moving the benefit into production.

MedImpact will work closely with DCH to coordinate resources to ensure a smooth transition to the operations and maintenance phase.

Stage 1 Design, Development, and Implementation

For all PBMS implementations, including Georgia's, we are committed to quality project management grounded in the PMI's PMBOK principles, which represent the leading standard for defining project management processes, tools, techniques, and plans. These principles align directly with the SEI (Software Engineering Institute's) CMMI (Capability Maturity Model Integration), ISO 9000x standards, and Lean Six Sigma continuous improvement methods.

Phase I Project Planning and Startup

MedImpact employs industry best practices, project management tools, and methodologies to help ensure seamless project management and leadership. We are committed to delivering quality project oversight and management grounded in the PMI's PMBOK principles, which represent the leading standard for defining project management processes, tools, techniques, strategies, and plans.

Project Management plans and Schedule Approved

MedImpact will establish the project schedule following key project management practices. We employ industry best practices, project management tools, and methodologies to help ensure seamless project management and leadership. We are committed to delivering quality project oversight and management grounded in the PMI's PMBOK principles, which represent the leading standard for defining project management processes, tools, techniques, strategies, schedules, and plans.

Our approach to implementation begins with project initiation including creation of a project charter, defining project management tools, and working with DCH to establish project templates. Next, is requirements-gathering and documentation which are critical to building the foundation for other SDLC activities including planning, DDI configuration, testing, and final implementation.

Requirements Validated and Approved

Our implementation strategy begins with the requirements-gathering process by creating a baseline of requirements from sources such as the RFP, proposal response, and contract negotiations. From these requirements, we formulate an IQ (Implementation Questionnaire) specifically customized to DCH. The IQ is our proprietary tool for comprehensive requirement gathering. MedImpact's business and technical analysts collaborate with DCH personnel in JAD (Joint Application Design) sessions to complete the IQ.

Information gleaned from the IQ exercise is used to update the RTM. MedImpact business and technical analysts will schedule and participate in targeted detailed requirements JAD sessions with their counterparts at DCH to validate and refine the requirements to create the interim RTM.

Upon receipt of DCH's approval of the IQ requirements documentation, our DDI Manager documents any additional steps, tasks, or program requirements into the WBS. The WBS provides a complete breakdown of the tasks required to meet all deliverables defined by DCH as well as any additional requirements defined through the IQ process. As part of this process, some tasks occur prior to the kick-off through the certification (which we consider a phase of implementation) finalization.

Phase II Design, Development, and Testing

Our approach to implementation begins with project initiation including creation of a project charter, defining project management tools, and working with DCH to establish project templates. Next, is requirements-gathering and documentation which are critical to building the foundation for a successful DDI.

Design Approval in the DDI Process Prior to Entrance to Testing

MedImpact will develop and submit to DCH a draft RSD (requirements specification document) for the proposed PBM Module components, modules, and functional areas based on the information gathered within the IQ. The draft RSD which will include, the PBA Architectural Components document, an Inventory of changes to existing requirements extracted from the RTM, clarifying information associated with requirements, inventory of new requirements extracted from the RTM, identification of the entity (person, subsystem, module) responsible for meeting each requirement, narrative describing the hardware and software configuration that will be used to meet requirements, the Logical Data Model, and the Conceptual Data Model.

User Acceptance Testing (UAT) Completed and Approved

MedImpact maintains fully integrated test environments, including a UAT environment that uses production data with de-identified customer, claims and provider data. We will provide DCH with a dedicated test environment for its exclusive use, thus enabling DCH staff to develop and submit test scenarios, input test data, and receive system outputs. Our testing team maintains a deep understanding of system solutions and business needs and is responsible for developing,

implementing, and evaluating test plans. Quality assurance metrics are developed for each implementation testing phase.

Throughout the UAT testing process, MedImpact will provide testing statistics to document the progression of UAT testing. Once it is determined by joint agreement between DCH and MedImpact that UAT testing is complete, the code base and configuration will be scheduled to move to the production environment.

Phase III Operational Readiness and Production Cutover

Throughout the course of the DDI, MedImpact will conduct periodic operational readiness walkthroughs with DCH and identified stakeholders to ensure continuous understanding of DCH's training and readiness expectations and requirements. MedImpact recognizes the importance of readiness review, in accordance with federal requirements for a monitoring system, and will develop and submit a Transition Plan for DCH's approval.

Parallel Testing Results Approved

As part of MedImpact's proposed master testing strategy, we will perform a series of parallel test cycles to ensure that claims processed through the legacy system perform the same way in MedImpact's claims adjudication system. In the event a test transaction does not perform as expected, we will provide DCH with a thorough accounting of all parallel test results including any variance and a reconfiguration and retesting plan.

Parallel Testing is done primarily, but not exclusively, to compare claim status (paid/denied), total ingredient cost, dispensing fee, copay, and total amount paid on the same claims processed by the incumbent's PBM and MedImpact's PBMS. MedImpact's parallel testing plan will include, at a minimum:

- A methodology for performance of parallel testing.
- Known differences between the parallel testing environment and the proposed production environment.
- Acceptable variance parameters based upon consensus between DCH and MedImpact.
- Parallel Testing entrance and exit criteria.

MedImpact will develop and submit to DCH a Parallel Test Results document that will include, but not be limited to, the following:

- Parallel test plan
- An update of the known differences between the parallel testing environment and the proposed production environment
- An updated list of acceptable variance parameters
- Parallel testing entrance and exit criteria
- Number of cycles performed
- Types of differences discovered in each cycle
- Resolution of differences discovered in each cycle

Operational Readiness Approved by the Centers for Medicare and Medicaid Services (CMS)

As part of the final transition stage during the DDI, MedImpact's DDI Manager will collaborate with DCH's PMO to conduct operational readiness walkthroughs with DCH using the results from the ORT (Operational Readiness Testing) checklist. During the walkthroughs we will provide demonstrations that validate the operational readiness of the system and organizational.

Operational Readiness Assessment and Attestation

Operational readiness will be assessed, and results reviewed continually during the project. The DDI Manager and team are responsible to ensure readiness throughout the project. As the project moves toward implementation, these reviews will produce a clearer picture of how that end state will impact users. For this reason, DDI Managers conduct on-the-ground assessments as close to implementation as possible.

The Operational Readiness Assessment will include a series of templates and reports:

- **Pre-Assessment Success Factors**: provides a readiness overview and helps determine to what extent key factors are in place.
- **Implementation Checklist**: precisely defines the steps required to successfully implement the end state in this specific environment.
- **Risk Assessment Report and Escalation Process**: illustrates clearly and unambiguously, the assumptions, risks, and related issues that can derail the project and the mitigation steps necessary to address those issues.

The Operational Readiness walkthroughs will provide attestation to DCH of readiness to go-live and allow for MedImpact to obtain formal approval from DCH.

Stage 2 Operations and Maintenance

During the more than 30 years we have maintained and operated our PBMS solution and infrastructure, we have developed and refined numerous operations policies, processes, and procedures that provide reliable system operations and regular maintenance that virtually eliminates downtime. At a high level, ongoing operational activities consist of, but are not limited to system changes, maintenance, and modifications, including testing and documentation, software enhancements and updates, system availability and monitoring, network Infrastructure monitoring, help desk and user support, security management, document maintenance and version control, performance monitoring and tuning, system defects resolution (record, track, resolve, and report), cooperation and compliance with state audit requests, including HIPAA, SS-A, and FTI, and escalation procedures.

Phase IV Initial Operations

Prior to go-live, all supporting implementation and post-implementation deliverables will be reviewed with DCH. Once DCH has completed their review and is satisfied with the deliverables provided by MedImpact, we obtain and document formal approval from DCH to proceed with go-live.

Go-Live Solution and/or Services

MedImpact will provide DCH a comprehensive Go-Live Support Plan that outlines compliance with all DCH readiness review requirements including NCPDP compliant payer sheets, go-live support tasks,

and a directory of designated implementation support staff available for go-live assistance.

Warranty Period

In support of our relationship with DCH, MedImpact commits to a Warranty Period, which shall last through the first 365 Calendar Days effective upon the ongoing operations and enhancement contract stage begin date. It is the goal of any program deployment to ensure complete compliance and functionality is delivered at the time of go-live, but in the event any items are identified for remediation or secondary deployment, all activity required to support these items will be provided in addition to ongoing operations and maintenance support and functionality. The Warranty Period covers the mutually agreed upon functionality requirements and MedImpact is responsible for correcting all Defects that prevent the PBMS from operating according to DCH specifications. All Defects identified by DCH or MedImpact during the Warranty Period will be corrected by MedImpact, as agreed upon through the Change Management Process, at our expense with no additional cost to DCH. MedImpact will maintain routine PBMS performance and PBMS operations while correcting any identified defects.

Phase V Operations

The Solution and/or Services are Operated and Maintained

During the more than 30 years we have maintained and operated our PBMS solution and infrastructure, we have developed and refined numerous operations policies, processes, and procedures that provide reliable system operations and regular maintenance that virtually eliminates downtime. At a high level, ongoing operational activities consist of, but are not limited to, system changes, maintenance, and modifications, including testing and documentation, software enhancements and updates, system availability and monitoring, network Infrastructure monitoring, help desk and user support, security management, document maintenance and version control, performance monitoring and tuning, system defects resolution (record, track, resolve, and report), cooperation and compliance with state audit requests, including HIPAA, SS-A, and FTI, and escalation procedures

Phase VI Turnover and Contract Closeout

The Solution and/or Services Are Turned Over

To support all transitions and turnovers, MedImpact uses a proven project management methodology to preserve continuity of services for DCH members and to help ensure a smooth handoff to new vendors. All turnover activities are validated for accuracy, schedule, and communicated to affected stakeholders. The DDI Manager uses various captured data for transition and turnover of services to a new vendor including:

- Information technology details such as data file transfer formats
- Historical data to be transferred and the timeframe for transfers
- PA transfers for continuity of care
- Clinical services and program information

Using the information collected and documented, which covers all aspects required for successful transition to a new vendor, the DDI Manager develops a detailed project workplan to plan, log, track, manage, and report on each area of the project. This plan includes detailed tasks with corresponding responsible parties, start dates, due dates, completion dates, task dependencies, resource requirements, and work hour estimates.

Project Ended

With DCH approval, MedImpact provides secure file transfer of all DCH customer information, utilization management, and historical claims data to the incoming vendor through a TLS (Transport Layer Security) encrypted website using Axway Secure Transport. Axway Secure Transport is configured using a front-end web server connecting to a back-end file repository; no files are stored on the front-end server.

As part of our design and development approach, we conduct requirements analysis using our file format, file validation approach, transfer protocol method, encryption level, media choice, and testing methods. MedImpact uses the documents developed during requirements analysis, along with changes made throughout the contract term, to identify data needs for turnover activities. This effort is led by our IT department under the direction of the turnover DDI Manager.

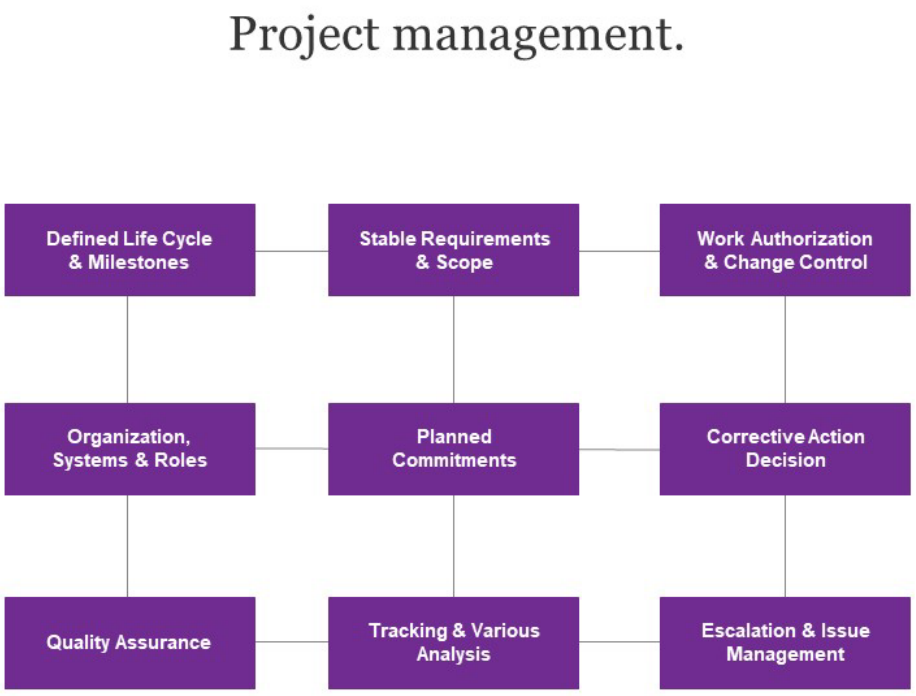
MedImpact is a NIST-certified medium impact and high impact-level compliant organization with comprehensive security, data management, and retention programs that exceed the requirements of CIA (Confidentiality-Integrity-Availability) and will process all data, regardless of media, in a secure, encrypted methodology according to the CIA concepts:

- **Confidentiality**: Data should not be accessed or read without authorization. It ensures that only authorized parties have access.
- **Integrity**: Data should not be modified or compromised in anyway. It assumes that data remains in its intended state and can only be edited by authorized parties.
- **Availability**: Data should be accessible upon legitimate request. It ensures that authorized parties have unimpeded access to data when required.

MedImpact is an experienced DDI partner and will utilize processes, procedures, and requirements to collaborate with DCH and their stakeholders to a smooth DDI and implementation.

MSQ9.1 – Best Practices

MedImpact employs industry best practices, project management tools, and methodologies to help ensure seamless project management and leadership. We are committed to delivering quality project oversight and management grounded in the PMI's PMBOK principles and the 9 Elements of Success, which represent the leading standard for defining project management processes, tools, techniques, strategies, and plans.

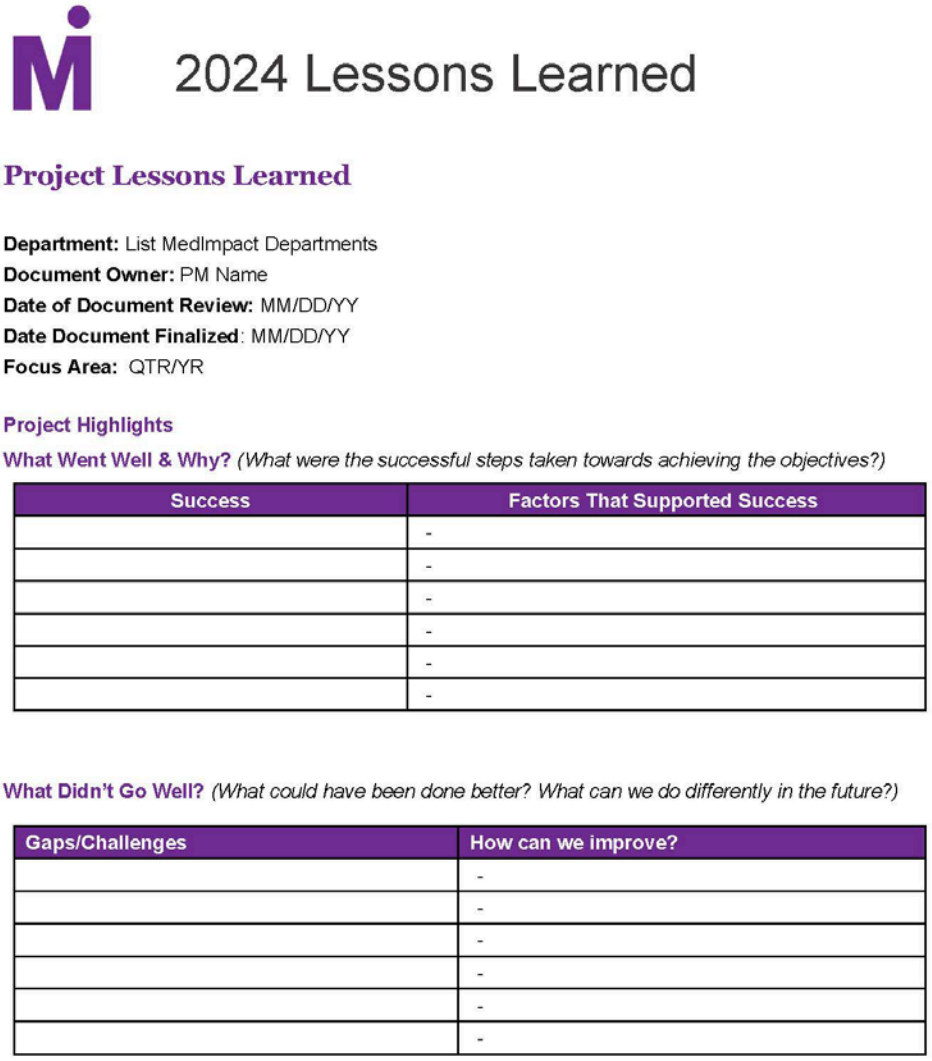


MSQ9.2 – Lessons Learned

At MedImpact, lessons learned is both project-based and global. Every DDI experience and project that occurs during the regular maintenance of business provides an opportunity for feedback, growth, and optimization that benefits the entire organization and our customers.

Project Learning

Project learning occurs during DDI and through projects that emerge during maintenance of business. The account manager leads project lessons learned for customers by distributing our lessons learned templates to the customer and other internal and external stakeholders involved in a given project. **Figure 11** provides a sample lessons learned template.



2024 Lessons Learned

Project Lessons Learned

Department: List MedImpact Departments
Document Owner: PM Name
Date of Document Review: MM/DD/YY
Date Document Finalized: MM/DD/YY
Focus Area: QTR/YR

Project Highlights

What Went Well & Why? *(What were the successful steps taken towards achieving the objectives?)*

Success	Factors That Supported Success
	-
	-
	-
	-
	-
	-

What Didn't Go Well? *(What could have been done better? What can we do differently in the future?)*

Gaps/Challenges	How can we improve?
	-
	-
	-
	-
	-
	-

Figure 11: Sample MedImpact Lessons Learned Template

All stakeholders provide feedback so that we can gather information from a diverse range of perspectives for any given project. After the information is gathered from all parties, the account manager works to analyze and report on the findings. This information will be presented to DCH to discuss and identify opportunities for growth that can be used for future projects.

Project-based lessons learned often provide a wealth of information and opportunities to create initiatives to continue to improve our projects. Examples of initiatives that emerged from project lessons learned include:

- Modifying project plans based on internal and external feedback
- Capturing more data in Salesforce
- Improving Salesforce dashboards for efficiencies and ease-of-use
- Updating DDI timelines, task lists, and project plans
- Optimizing documents for gathering requirements

The project-based lessons learned provides an opportunity to improve our business relationships with customers as we uncover ways to work together more effectively as well as offer opportunities to improve operations across the organization.

Global Learning

As a best practice, MedImpact holds annual BPI (business process improvement) reviews to determine areas for improvement and deploy findings prior to the next year's implementations. We solicit feedback from every business unit across organization to update and improve our implementation and maintenance of business practices.

After feedback is gathered, analyzed, and prioritized; MedImpact forms work groups across the organization to work on projects to improve our implementations and overall operations. Items with the highest priority that can make the biggest impact on future success are rolled out by early June in order to be ready for the next year's implementations.

MedImpact has made many of its innovative system enhancements as a direct result of this yearly process. DDI leadership consistently looks to identify opportunities to:

- Better define existing process
- Streamline DDI and business maintenance activities
- Integrate systems
- Improve processes and procedures
- Enhance technology solutions
- Improve internal and external communications
- Identify opportunities for organizational training and growth

MedImpact's approach to lessons learned is holistic rather than siloed in nature. Lessons learned initiatives and improvements are rolled out across the entire organization to create optimal outcomes both internally and externally during DDI and business maintenance.

We are an organization committed to continuous quality improvement and our project and global lessons learned approach is in alignment with that principle. We look forward to working with DCH during DDI and throughout business maintenance to identify opportunities to continue to fine-tune our processes and build positive customer relationships.

10.	**Bookmark Title: MSQ10 – Transition & Integration** Narrative description is limited to three (3) pages. Describe how you will handle the transition activities from the incumbent Clinical Management vendor. Include the value-add of your approach and techniques in terms of cost savings, quality improvement, and/or savings to the project schedule for the State. Describe your integration approach with the Pharmacy Benefit Administrator (PBA) vendor and its system.

Supplier Response

Transition and integration is an integral part of every project and MedImpact has over 30 years of experience transitioning customers from previous vendors. We have tried and true policies and procedures in place to make the transition and integration as seamless as possible. These include conversion management, integration management, integration testing, and quality management. Our approach to transition and integration focuses on efficiencies and continuous quality improvement to keep projects on time.

Conversion Management

MedImpact will develop a data conversion plan that includes data migration activities where no translation is required and different levels of ETL (extract, transform, and load) activities where simple, medium, or complex translations are required. Data to be migrated or converted includes all necessary information required to support the clinical program. The primary objective of the conversion strategy is to populate the core system tables with data from the current MMIS. The secondary objective is to successfully convert data required for operations, analytics, legislative/federal reporting, and fraud and abuse reduction.

Conversion Mapping

MedImpact is accustomed to accepting and converting historical data files in a variety of formats from states, PBMs, and vendors. Our experience has shown that even when MedImpact or industry standard formats are used, some level of data conversion is often necessary to capture system values and the supporting data necessary to facilitate a successful and seamless turnover. MedImpact has extensive experience developing and implementing data mapping and conversion strategies to migrate data from incumbent systems to our solutions. We will retain these data mapping specification for each file type and data source. These mapping documents will include all transformation steps and will be made available to DCH.

Integration Management

Alignment will drive successful integration of services. During the Planning Phase, our implementation team will finalize the plans and materials required for project delivery and conduct project kick-off meetings to help ensure they, DCH leadership, and all identified stakeholders are aligned with respect to project goals and objectives.

We consistently monitor identified risk indicators for evidence that a risk may be realized. In the event a risk progresses and becomes an issue, we activate remediation or contingency plans as appropriate.

Any identified issues and risks for mitigation are captured by the implementation team and are reviewed and prioritized during daily and weekly internal team meetings.

Integration Testing

Following completion of the System and Integration Test phase and during the implementation phase, MedImpact will work collaboratively with DCH and its incumbent contractor to perform the activities required for successful transition and validation of operational readiness. In preparation for go-live and transition to the Operations and Maintenance phase during the Transition and Operational Readiness phase, the work performed with the support of MedImpact, DCH, and incumbent contractor(s) will help ensure a successful transition and support ongoing management of the program with minimal disruption.

Quality Management

MedImpact employs rigorous quality control measures with every implementation to help ensure complete and accurate delivery of all services provided under the contract. We use a variety of tools and methodologies to help ensure traceability of any software development, business configuration, and requirements-gathering during the Requirements Definition phase of the project to applicable test cases. MedImpact will meet with the incumbent contractor to gain knowledge that may prove valuable in avoiding obstacles during implementation. We will work with the incumbent contractor to transfer all the written information specific to DCH and its operations.

MedImpact's Value-Add Approach

MedImpact works with customers to optimize cost efficiency and savings for pharmacy services through a variety of means including providing highly competitive pricing for our services, continuous quality improvement, automating processes, and recommending optimal PDL strategy and maximizing collection of supplemental rebates.

Cost Savings

MedImpact works to streamline and automate processes where it makes sense with the goal of increased efficiency and cost savings. For example, when allowed by our customers, we utilize targeted electronic fax in place of standard US mailings for our RetroDUR-related communications in an effort to maximize efficiency and promote participation. Our offering enables prescribers to reply electronically through a portal and offers follow-up options to increase response rates. MedInvoice, our proprietary rebate processing platform automates the rebate business process and streamlines the tracking of invoicing, payment reconciliation, and dispute resolution. This platform was purposefully designed to alleviate the flaws of the systems currently available on the market. MedContract, our supplemental rebate platform, enables customers to view the entire contracting process from start to finish with transparency and efficiency, including all bids and modeling.

Quality Improvement

MedImpact approaches implementation and operational management with a focus on finding opportunities to improve value and efficiency for all our customers. Our continuous quality improvement program helps customers solve a variety of problems such as improving rebate operations, clinical outcomes, and PBA operations. For example, through a rigorous quality control process, we worked with an FFS Medicaid customer to reduce pharmacy provider payment delays by

helping to increase pharmacy enrollment in the State's EFT payment program, reducing the administrative burden of denials on pharmacists by updating the process for exclusions. Other areas of improvement include reducing COB (Coordination of Benefit) call volume by up to 50% by recommending a clearer IVR message and reducing prescriber burden and medication delays by increasing provider participation in ePA by 15%.

MedImpact is ready to utilize our collective experience and modern solutions to identify specific areas of opportunity for improvement and efficiency unique to the DCH's program.

11. **Bookmark Title: MSQ11 - Project Management**

Bookmark Title for Supporting Material:

- MSQ11.1 - Project Schedule/Project Work Plan (Sample)
- MSQ11.2 - WBS tasks and Project Outputs (Sample)
- MSQ11.3 - Implementation Plan (Sample)
- MSQ11.4 - Quality Management Plan (Sample)
- MSQ11.5 - Requirements Management Plan (Sample)
- MSQ11.6 - Change Management Plan (Sample)
- MSQ11.7 - Risk Management Plan (Sample)
- MSQ11.8 - Communications Management Plan (Sample)
- MSQ11.9 - Integration Plan(Sample)
- MSQ11.10 - Operations & Maintenance Plan (Sample)
- MSQ11.11 - Training Plan (Sample)
- MSQ11.12 - Cost Management Plan (Sample)
- MSQ11.13 - Stakeholder Management Plan (Sample)

Narrative description is limited to five (5) Pages, not including the required supporting material.

Provide a description of the project management approach, including, but not limited to, the methodology and implementation of the system to be used for monitoring and control of scope, schedule, and cost. Additionally, describe any previous experience managing similar projects using the Project Management Lifecycle (PMLC) and Project Management Book of Knowledge (PMBOK) throughout the life of the contract.

Refer to Attachment C - Common Scope Requirements and Security Standards, Section 2 Project Organization and Management.

In the Supporting Material, include a draft or sample project management plan representative of this project. In your narrative response, explicitly identify any differences between the State's project management approach from your proposed approach, including all responsibilities.

Supplier Response

Following the contract award, our proposed methodology will be submitted to DCH for approval. All methodology plans, schedules, and documents will be considered required MedImpact deliverables and will be subject to approval by DCH. MedImpact will provide DCH with an initial Project Work Breakdown Schedule draft for its approval within the agreed upon timeframe after contract execution.

For all PBA implementations, including Georgia's, we are committed to quality project management grounded in the PMI's PMBOK principles, which represent the leading standard for defining project management processes, tools, techniques, and plans. These principles align directly with the SEI (Software Engineering Institute's) CMMI (Capability Maturity Model Integration), ISO 9000x standards, and Lean Six Sigma continuous improvement methods.

Project Management Methodology

Our project management framework provides a strong foundation based on clear standards, automated processes, and measured controls to manage activities, tasks, Deliverables, work plans,

staffing, issues, risks, and milestones for projects in an enterprise solution like our PBMS. Benefits of this framework include:

- Reducing project risk by avoiding deviations from DCH-approved requirements and reinforcing agreed-upon project standards and disciplines.
- Promoting a common language, effective communication, efficient linkages, asset reuse, and information-sharing.

We follow industry standard SDLC methodology to achieve optimal outcomes. We support both Waterfall and Agile development frameworks. Waterfall is used for the distinct phases within the larger scope of the project while Agile is used to facilitate iterative and incremental system development where sprints are most effective.

We use the Scrum methodology to facilitate early and frequent releases of system functionality. Led by certified Scrum Masters, our teams work in sprints (time-boxed system development iterations) to facilitate the continual delivery of quality operational system functionality in the shortest time possible. It allows our teams to collaborate effectively with our customers and engage as a well-organized, cross-functional team.

Activities throughout the SDLC and its phases are analyzed, and we determine the best method to move through each sprint and phase efficiently and effectively while upholding the schedule outlined in the Project WBS. Following PMBOK, our project management model referred to as IPECC (Initiating, Planning, Executing, Controlling, Closing), encompasses the phases depicted in **Figure 12**.

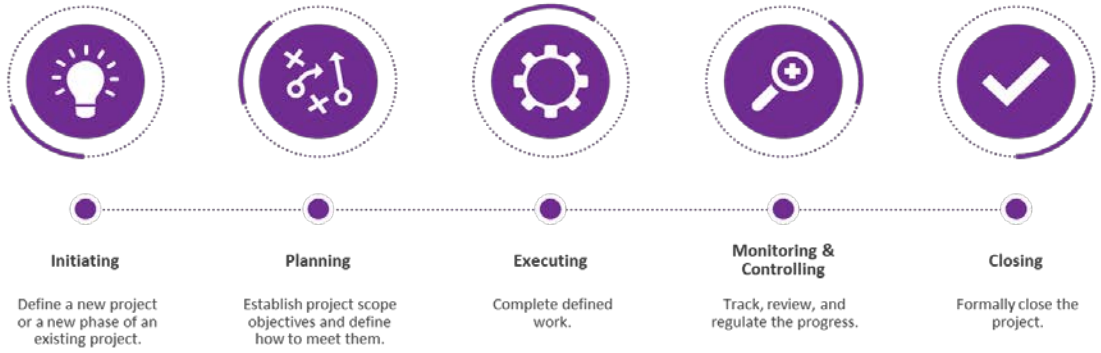


Figure 12: IPECC Project Management Model

All phases of our project management activities focus on carefully managing and reporting on DCH's project scope, schedule, quality, performance, risk/issues/opportunities, and staffing. MedImpact will coordinate with DCH and other stakeholders whose participation is necessary to help ensure the successful delivery of the PBM FFS program.

Project Schedule

MedImpact will establish the project schedule following key project management practices. We employ industry best practices, project management tools, and methodologies to help ensure seamless project management and leadership. We are committed to delivering quality project oversight and management grounded in the PMI's PMBOK principles, which represent the leading

standard for defining project management processes, tools, techniques, strategies, schedules, and plans.

Leveraging these principles helps to ensure MedImpact's ability to successfully manage large-scale implementations like DCH's across multiple markets, customer types, and lines of business. Our teams strive to meet and exceed DCH expectations with its solution as well as with its project management and collaboration.

A sample Project Work Plan is included with the proposal as **MSQ11.1.**

WBS Tasks

During the Implementation Phase, we develop the Project WBS for all Contract tasks and activities. The WBS will be the outcome of requirements gathering process, collaborative working sessions with DCH's implementation team and SMEs (Subject Matter Experts). We deliver it in the form of a Gantt chart, incorporating significant detail on every area, milestones, and task.

A sample WBS is included with the proposal as **MSQ11.2**

Implementation

In accordance with DCH requirements and our organizational policy, the project team determines the appropriate technologies and organizational policies and standards required during operations and maintenance. At contract award, we create a collaborative group of our teams, IT, and the implementation team to achieve the following:

- Create a smooth transition from outgoing FFS Vendor to MedImpact Operations (including all Implementation Activities)
- Meet with SMEs and the State of Georgia DCH's team members involved in the effort
- Treat all data confidentiality
- Deliver on requirements

A sample Implementation Plan is included with the proposal as **MSQ11.3**

Quality Management

MedImpact develops a Quality Management Plan to be utilized throughout the life of the contract after go-live. This plan summarizes the quality assurance control and quality management process, quality management program, analysis, findings, recommendations, and continuous improvement projects for business areas associated with this contract. This plan is updated twice a year.

Methodology for Maintaining Quality

MedImpact has a deep understanding of the importance of defining clear objectives to maintain quality of code, project schedule and deliverables, tasks, and work product. Our commitment to consistent stakeholder communication and monitoring helps assure the quality and accuracy of our work while being mindful of scope creep. MedImpact performs continuous analysis based on industry best practices to ensure deliverables are accurate and we remain focused on fulfilling the stated requirements. Post project lessons learned are used to improve the performance of our functions.

These methods, along with our defined processes for continuous quality improvement, demonstrate our dedication to maintaining quality from the DDI phase through operations.

A sample Quality Management Plan is included with the proposal as **MSQ11.4.**

Requirements Management

Our business and technical analysts will schedule and participate in targeted detailed requirements and validation sessions with their counterparts at DCH to validate and refine requirements. Throughout other phases of the SDLC, we anticipate additional requirements will be uncovered. Requirements uncovered following its approval will be processed through our change order process.

RTM (Requirements Traceability Matrix)

For every PBMS implementation, MedImpact develops and then relies on accurate, detailed, and complete requirements documented in an RTM (Requirements Traceability Matrix) to define activities during the Configuration/Customization phase. We also use the RTM during testing to help ensure there is testing coverage for all requirements. Finally, we use the RTM to demonstrate to DCH that, upon implementation (go-live), all requirements (functional and non-functional) are met by MedImpact.

A sample Requirements Management Plan is included with the proposal as **MSQ11.5**.

Change Management

MedImpact applies rigorous change control protocols for projects following the change control process. To guide this process, MedImpact collaborates with DCH to establish a change management plan that aligns with DCH change management processes. This includes defining how we collaborate with DCH to define procedures for assembling the CCB (change control board) and conducting CCB meetings to make decisions regarding change requests. The resulting change management plan documents our approach, strategies, and methods used for identifying, assessing, reviewing, and implementing (upon DCH approval) changes to the solution, scope, timeline, or deliverables.

We will implement the Change Management Plan once approved, after which we will adhere to the processes included in the plan. A sample Change Management Plan is included with the proposal as **MSQ11.6**.

Risk Management

Risk and Issue Management Plans are critical to each successful PBMS Implementation. The MedImpact Project team documents any identified issues for mitigation, reviews, and prioritizes them daily and in weekly internal team meetings. If it is determined a risk or issue requires a change request, we develop the required change request documentation and initiate our change management process. The Project team monitors the risk issue log on an ongoing basis, determines probability impact, initiates contingency and mitigation plans, when necessary, reviews and removes risks from the log when appropriate, prioritizes and communicates new risks, collaborates with DCH to review and adjust the risk management process, and provides continuous improvement recommendations based upon quarterly analysis of the Risk Management approach built upon Lean Six Sigma principles.

A sample Risk Management Plan is included with the proposal as **MSQ11.7**

Communications Management

The DDI Manager provides the necessary information about the project-to-project stakeholders in accordance with the communications strategy as agreed-upon with DCH. The DDI Manager drives the agenda for status meetings based on the reports generated by the implementation team. We escalate risks and issues to stakeholders using established escalation mechanisms and status meetings. This ensures risks and issues receive the appropriate visibility and are addressed in a timely manner.

A sample Communications Management Plan is included with the proposal as **MSQ11.8**.

Integration

The system integration plan supports industry standard integration points for an interconnected MMIS. MedImpact's solution is architected to support and interconnect to the MMIS. Requirements for data exchange methods are defined during the Requirements Definition phase and documented in the design documents. The integration plan is updated and used during the Integration and Test phase. The final version is provided in the Implementation phase for approval by DCH. Additionally, the plan outlines various types of internal Integrator software integration tests conducted to help ensure the POS is designed and operating in accordance with the RFP and the other contract documents.

A sample Integration Plan is included with the proposal as **MSQ11.9.**

Operations and Maintenance

We establish the staffing, policies, procedures, processes, and systems with step-by-step instructions required to change any parts of the system with minimal disruption to DCH's members, providers, and other stakeholders. This System Operations and Maintenance plan establishes the key activities involved during operations and maintenance.

A sample Operations and Maintenance Plan is included with the proposal as **MSQ11.10.**

Training

We will develop and implement a training plan tailored to the needs of DCH. Our training management approach will provide subject-specific information to the following:

Authorized DCH staff in a classroom-style setting or virtual webinars to prepare them for the transition of operations including ongoing changes implemented during operations.

Documentation, including layouts and a data dictionary to support the receipt, processing, and application of historical program data.

Claim and provider payment details required to support successful implementation.

Our training management approach will include a training plan, training preparation, documentation, status, and progress reporting on training tasks. This approach addresses and includes operational components of the contract. Our approach has been informed by our extensive experience, lessons learned, and industry best practices.

A sample Training Plan is included with the proposal as **MSQ11.11**

Cost Management

The Cost Management plan details the processes for managing project financial resources that are to be followed through all stages of the project. Managing cost focuses on tracking costs for all resource types needed to complete the activities of the project such as people, equipment, hard goods, soft goods, and facilities.

The Project Management Book of Knowledge (PMBOK) defines the three project cost management processes as follows:

- Estimate Costs - Estimation of the monetary resources needed to complete the project
- Determine Budget - Aggregation of costs and activities to determine a cost baseline
- Control Costs - Monitoring project status to update budget and manage changes to the cost baseline

As the DCH/ValuePoint contract would be a fixed price, the Cost Management Plan summary included as **MSQ11.12** is an example of how MedImpact would manage an alternative project.

Stakeholder Management

Understanding of roles and agreement around how to communicate are key to effective collaboration between MedImpact and DCH, incumbent contractors, and module contractors. To facilitate the PBMS project, MedImpact will develop the Communication Management and Stakeholder Engagement Plan and deliver it to DCH for approval, as a part of the Project WBS.

Effective project control is a result of effective communication throughout the project team. Our DDI Manager and the Executive Sponsor, as the key representative to DCH from MedImpact and as the Program Sponsor, will encourage open and honest communication throughout the project team about what is being worked on and what the status is.

Open communication does not preclude the need for every project team member and leader to use good judgment in communications. Incomplete information can create chaos and information that has sensitive implications must be communicated only to those team members that have a need for the information.

A sample Stakeholder Management Plan is included with the proposal as **MSQ11.13**.

MSQ11.1 - Project Schedule/Project Work Plan (Sample Summary)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Project Management Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) Implementation.

Purpose

The purpose of the Project Management Plan is to define the plans, standards, and templates that collectively describe the approach and activities for managing projects. The Project Management Plan also defines the tools and technologies that will be used for program/project management, including, but not limited to, program and project status reporting, dashboards, schedule maintenance, issue management, and risk management.

Overview

MedImpact implements an established Project Management Framework (PMF) that includes standardized processes and templates, coordinates plans, schedules, and integration of projects, coordinates overall budget and quality assurance activities for the program, and facilitates communication and reporting for all levels of governance. Additionally, MedImpact monitors and controls scope, time, quality, and cost along with providing structure, organization, and consistent reporting across projects.

The Project Management Plan is developed for the purpose of planning the project and provides a consistent, coherent document that is used to guide both project execution and project control. The Project Management Plan also serves as a summary document that outlines the supporting plans and components of the PMF. This document is a quick reference that defines each plan and outlines the templates and tools that will be used to manage PMF processes. Sections include, but are not limited to, the following:

- Goals and Objectives
- Assumptions and Constraints
- Risk and Mitigation Strategies
- Reports and Dashboards
- Project Schedule/Work Breakdown Structure (WBS)
- Issue and Risk Management Plans
- Quality Management Plan
- Project Staffing Plan
- Change Management Plan
- Communication Management Plan
- Facilities and Equipment Plan
- SharePoint Project Repository
- Project Status Report Template

MSQ11.2 - WBS Tasks and Project Outputs (Sample)

Please see important notes on the last page.

ID	Attachment F - Ref	Task Name	Duration	Start	Finish	Predecessors	Resource Names
1		**1 Pre-Initiation Phase**	**21 days**	**Tue 7/23/24**	**Tue 8/20/24**		
2		1.1 Contract Start Date	1 day	Tue 7/23/24	Tue 7/23/24	11FS-30 days	MedImpact,Client
3		1.2 Request PMO Templates from Client	1 day	Tue 8/20/24	Tue 8/20/24	11FS-10 days	MedImpact
4		1.3 Cyber Insurance Bond	1 day	Tue 7/23/24	Tue 7/23/24	11FS-30 days	MedImpact
5		1.4 Business Associate Agreement and HIPPA Confidentiality Compliance	1 day	Tue 7/23/24	Tue 7/23/24	11FS-30 days	MedImpact
6		1.5 Information Agreement Form for External Vendors	1 day	Tue 7/23/24	Tue 7/23/24	11FS-30 days	MedImpact,Client
7		**2 Initiation Phase**	**42 days**	**Tue 8/13/24**	**Thu 10/10/24**		
8		**2.1 Client Kick-off**	**17 days**	**Tue 8/13/24**	**Thu 9/5/24**		
9		2.1.1 Schedule Client Kick-off	1 day	Tue 8/13/24	Tue 8/13/24	11SS-14 days	MedImpact
10		2.1.2 Prepare Agenda 2 Business Days Prior Kick-off	1 day	Thu 8/29/24	Thu 8/29/24	11SS-2 days	MedImpact
11		2.1.3 Hold Client Kick-off	1 day	Tue 9/3/24	Tue 9/3/24		Client,MedImpact
12		2.1.4 Prepare Meeting Notes 2 Business Days After Kick-off	1 day	Thu 9/5/24	Thu 9/5/24	11SS+2 days	MedImpact
13		**2.2 Stakeholder Management Plan**	**27 days**	**Wed 9/4/24**	**Thu 10/10/24**		
14		2.2.1 Draft and Compile Stakeholder Management Plan	10 days	Wed 9/4/24	Tue 9/17/24	11	MedImpact
15		**2.2.2 Review Deliverable**	**15 days**	**Wed 9/18/24**	**Tue 10/8/24**		
16		2.2.2.1 Client reviews Deliverable	10 days	Wed 9/18/24	Tue 10/1/24	14,20	Client
17		2.2.2.2 Revise Deliverable based on Client's latest review	5 days	Wed 10/2/24	Tue 10/8/24	16,22	MedImpact
18		2.2.3 Obtain approval of deliverable	2 days	Wed 10/9/24	Thu 10/10/24	17,23	MedImpact
19		**2.3 Create Responsible, Accountable, Informed, Consulted (RACI) matrix**	**27 days**	**Wed 9/4/24**	**Thu 10/10/24**		
20		2.3.1 Draft and Compile RACI Matrix	10 days	Wed 9/4/24	Tue 9/17/24	11	MedImpact
21		**2.3.2 Review Deliverable**	**15 days**	**Wed 9/18/24**	**Tue 10/8/24**		
22		2.3.2.1 Client reviews Deliverable	10 days	Wed 9/18/24	Tue 10/1/24	14	Client
23		2.3.2.2 Revise Deliverable based on Client's latest review	5 days	Wed 10/2/24	Tue 10/8/24	16	MedImpact
24		2.3.3 Obtain approval of deliverable	2 days	Wed 10/9/24	Thu 10/10/24	17	MedImpact
25		**2.4 Project Management Tools**	**6 days**	**Wed 9/11/24**	**Wed 9/18/24**		
26		2.4.1 Identify Georgia PM Tools	1 day	Wed 9/11/24	Wed 9/11/24	11FS+5 days	MedImpact
27		2.4.2 Complete training	5 days	Thu 9/12/24	Wed 9/18/24	26	MedImpact
28		**3 Project Planning Phase**	**83 days**	**Wed 9/4/24**	**Thu 1/2/25**		
29		**3.1 Requirement Specification Document / Implementation Questionnaire (IQ)**	**47 days**	**Tue 9/10/24**	**Wed 11/13/24**		
30		**3.1.1 Clinical Operations IQ JAD Sessions**	**47 days**	**Tue 9/10/24**	**Wed 11/13/24**		
31		3.1.1.1 Complete IQ JAD Sessions	30 days	Tue 9/10/24	Mon 10/21/24	11FS+4 days	Client,MedImpact
32		**3.1.1.2 Review Deliverable**	**15 days**	**Tue 10/22/24**	**Mon 11/11/24**		
33		3.1.1.2.1 Client reviews Deliverable	10 days	Tue 10/22/24	Mon 11/4/24	31	Client
34		3.1.1.2.2 Revise Deliverable based on Client's latest review	5 days	Tue 11/5/24	Mon 11/11/24	33	MedImpact
35		3.1.1.3 Obtain approval of deliverable	2 days	Tue 11/12/24	Wed 11/13/24	34	MedImpact
36		**3.2 Requirement Management Plan**	**27 days**	**Tue 9/10/24**	**Wed 10/16/24**		
37		3.2.1 Requirement Management Plan Compile and Deliver	10 days	Tue 9/10/24	Mon 9/23/24	11FS+4 days	MedImpact
38		**3.2.2 Review Deliverable**	**15 days**	**Tue 9/24/24**	**Mon 10/14/24**		
39		3.2.2.1 Client to review Plan	10 days	Tue 9/24/24	Mon 10/7/24	37	Client
40		3.2.2.2 Revise Deliverable based on Client's review	5 days	Tue 10/8/24	Mon 10/14/24	39	MedImpact
41		3.2.3 Obtain approval of deliverable	2 days	Tue 10/15/24	Wed 10/16/24	40	MedImpact

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Please see important notes on the last page.

ID	Attachment F - Ref	Task Name	Duration	Start	Finish	Predecessors	Resource Names
42	3.0	3.3 Requirements Review, Planning, & Analysis	59 days	Tue 10/8/24	Thu 1/2/25		
43		3.3.1 Requirement Traceability Matrix (RTM)	32 days	Thu 10/17/24	Tue 12/3/24		
44		3.3.1.1 Complete Functional Requirements	15 days	Thu 10/17/24	Wed 11/6/24	41	MedImpact
45		3.3.1.2 Complete Technical Requirements (TBD)	15 days	Thu 10/17/24	Wed 11/6/24	41	MedImpact
46		**3.3.1.3 Review Deliverable**	**15 days**	**Thu 11/7/24**	**Wed 11/27/24**		
47		3.3.1.3.1 Client reviews Deliverable	10 days	Thu 11/7/24	Wed 11/20/24	44,45	Client
48		3.3.1.3.2 Revise Deliverable based on Client's latest review	5 days	Thu 11/21/24	Wed 11/27/24	47	MedImpact
49		3.3.1.4 Obtain approval of deliverable	2 days	Mon 12/2/24	Tue 12/3/24	48	MedImpact
50		3.3.2 Business Requirements Document (BRD)	59 days	Tue 10/8/24	Thu 1/2/25		
51		3.3.2.1 Gap Analysis and Create Enhancement Request	10 days	Tue 10/8/24	Mon 10/21/24	31FF	
52		3.3.2.2 Complete BRD	20 days	Thu 11/7/24	Fri 12/6/24	45,51FF	MedImpact
53		**3.3.2.3 Review Deliverable**	**15 days**	**Mon 12/9/24**	**Mon 12/30/24**		
54		3.3.2.3.1 Client reviews Deliverable	10 days	Mon 12/9/24	Fri 12/20/24	52	Client
55		3.3.2.3.2 Revise Deliverable based on Client's latest review	5 days	Mon 12/23/24	Mon 12/30/24	54	MedImpact
56		3.3.2.4 Obtain approval of deliverable	2 days	Tue 12/31/24	Thu 1/2/25	55	MedImpact
57		3.4 Project Schedule/Work Breakdown Structure (WBS)	27 days	Wed 9/4/24	Thu 10/10/24		
58		3.4.1 Draft WBS and Deliver	10 days	Wed 9/4/24	Tue 9/17/24	11	MedImpact
59		**3.4.2 Review WBS**	**15 days**	**Wed 9/18/24**	**Tue 10/8/24**		
60		3.4.2.1 Client to review WBS	10 days	Wed 9/18/24	Tue 10/1/24	58	MedImpact
61		3.4.2.2 Revise Deliverable based on Client's review	5 days	Wed 10/2/24	Tue 10/8/24	60	Client
62		3.4.3 Obtain approval of deliverable	2 days	Wed 10/9/24	Thu 10/10/24	61	MedImpact
63		3.5 Project Management Plan	27 days	Fri 10/11/24	Mon 11/18/24		
64		3.5.1 Project Management Plan Compile and Deliver	10 days	Fri 10/11/24	Thu 10/24/24	18,24,27,61,62	MedImpact
65		**3.5.2 Review Deliverable**	**15 days**	**Fri 10/25/24**	**Thu 11/14/24**		
66		3.5.2.1 Client to review Plan	10 days	Fri 10/25/24	Thu 11/7/24	64	Client
67		3.5.2.2 Revise Deliverable based on Client's review	5 days	Fri 11/8/24	Thu 11/14/24	66	MedImpact
68		3.5.3 Obtain approval of deliverable	2 days	Fri 11/15/24	Mon 11/18/24	67	MedImpact
69		3.6 Security Policies and Procedures (STANDARD DOCUMENT)	3 days	Wed 9/4/24	Fri 9/6/24		
70		3.6.1 Security Policies and Procedures Deliver and Approve	3 days	Wed 9/4/24	Fri 9/6/24	11	MedImpact
71	2.4	3.7 Utilization Management Program Policies and Procedures	3 days	Wed 9/4/24	Fri 9/6/24		
72		3.7.1 Utilization Management Program Policies and Procedures Deliver and Appr	3 days	Wed 9/4/24	Fri 9/6/24	11	MedImpact
73	2.2	3.8 State Advisory Board Policies and Procedures	3 days	Wed 9/4/24	Fri 9/6/24		
74		3.8.1 State Advisory Board Program Policies and Procedures Deliver and Approve	3 days	Wed 9/4/24	Fri 9/6/24	11	MedImpact
75		3.9 System Security Plan	27 days	Mon 9/9/24	Tue 10/15/24		
76		3.9.1 System Security Plan (SAR) Compile and Deliver	10 days	Mon 9/9/24	Fri 9/20/24	70	MedImpact
77		**3.9.2 Review Deliverable**	**15 days**	**Mon 9/23/24**	**Fri 10/11/24**		
78		3.9.2.1 Client reviews Deliverable	10 days	Mon 9/23/24	Fri 10/4/24	76	Client
79		3.9.2.2 Revise Deliverable based on Client's latest review	5 days	Mon 10/7/24	Fri 10/11/24	78	MedImpact
80		3.9.3 Obtain approval of deliverable	2 days	Mon 10/14/24	Tue 10/15/24	79	MedImpact
81		3.10 Disaster Recovery Plan (STANDARD DOCUMENT)	5 days	Tue 11/19/24	Mon 11/25/24		
82		3.10.1 Disaster Recovery Plan Compile and Deliver	5 days	Tue 11/19/24	Mon 11/25/24	68	MedImpact

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Please see important notes on the last page.

ID	Attachment F - Ref	Task Name	Duration	Start	Finish	Predecessors	Resource Names
83		**3.11 Communication Plan**	27 days	Tue 11/19/24	Mon 12/30/24		
84		3.11.1 Communication Plan Compile and Deliver	10 days	Tue 11/19/24	Wed 12/4/24	68	MedImpact
85		**3.11.2 Review Deliverable**	**15 days**	**Thu 12/5/24**	**Thu 12/26/24**		
86		3.11.2.1 Client to review Plan	10 days	Thu 12/5/24	Wed 12/18/24	84	Client
87		3.11.2.2 Revise Deliverable based on Client's review	5 days	Thu 12/19/24	Thu 12/26/24	86	MedImpact
88		3.11.3 Obtain approval of deliverable	2 days	Fri 12/27/24	Mon 12/30/24	87	MedImpact
89		**3.12 Risk and Issue Management Plan**	27 days	Tue 11/19/24	Mon 12/30/24		
90		3.12.1 Risk and Issue Plan Compile and Deliver	10 days	Tue 11/19/24	Wed 12/4/24	68	MedImpact
91		**3.12.2 Review Deliverable**	**15 days**	**Thu 12/5/24**	**Thu 12/26/24**		
92		3.12.2.1 Client to review Plan	10 days	Thu 12/5/24	Wed 12/18/24	90	Client
93		3.12.2.2 Revise Deliverable based on Client's review	5 days	Thu 12/19/24	Thu 12/26/24	92	MedImpact
94		3.12.3 Obtain approval of deliverable	2 days	Fri 12/27/24	Mon 12/30/24	93	MedImpact
95		**3.13 Quality Management Plan**	27 days	Tue 11/19/24	Mon 12/30/24		
96		3.13.1 Quality Management Plan Compile and Deliver	10 days	Tue 11/19/24	Wed 12/4/24	68	MedImpact
97		**3.13.2 Review Deliverable**	**15 days**	**Thu 12/5/24**	**Thu 12/26/24**		
98		3.13.2.1 Client to review Plan	10 days	Thu 12/5/24	Wed 12/18/24	96	Client
99		3.13.2.2 Revise Deliverable based on Client's review	5 days	Thu 12/19/24	Thu 12/26/24	98	MedImpact
100		3.13.3 Obtain approval of deliverable	2 days	Fri 12/27/24	Mon 12/30/24	99	MedImpact
101		**3.14 Change Management Plan**	27 days	Tue 11/19/24	Mon 12/30/24		
102		3.14.1 Change Management Plan Compile and Deliver	10 days	Tue 11/19/24	Wed 12/4/24	68	MedImpact
103		**3.14.2 Review Deliverable**	**15 days**	**Thu 12/5/24**	**Thu 12/26/24**		
104		3.14.2.1 Client to review Plan	10 days	Thu 12/5/24	Wed 12/18/24	102	Client
105		3.14.2.2 Revise Deliverable based on Client's review	5 days	Thu 12/19/24	Thu 12/26/24	104	MedImpact
106		3.14.3 Obtain approval of deliverable	2 days	Fri 12/27/24	Mon 12/30/24	105	MedImpact
107		**3.15 Implementation Plan**	27 days	Tue 11/19/24	Mon 12/30/24		
108		3.15.1 Implementation Plan Compile and Deliver	10 days	Tue 11/19/24	Wed 12/4/24	68	MedImpact
109		**3.15.2 Review Deliverable**	**15 days**	**Thu 12/5/24**	**Thu 12/26/24**		
110		3.15.2.1 Client reviews Deliverable	10 days	Thu 12/5/24	Wed 12/18/24	108	Client
111		3.15.2.2 Revise Deliverable based on Client's latest review	5 days	Thu 12/19/24	Thu 12/26/24	110	MedImpact
112		3.15.3 Obtain approval of deliverable	2 days	Fri 12/27/24	Mon 12/30/24	111	MedImpact
113		**3.16 Cost Management Plan**	27 days	Tue 11/19/24	Mon 12/30/24		
114		3.16.1 Cost Management Plan Compile and Deliver	10 days	Tue 11/19/24	Wed 12/4/24	68	MedImpact
115		**3.16.2 Review Deliverable**	**15 days**	**Thu 12/5/24**	**Thu 12/26/24**		
116		3.16.2.1 Client reviews Deliverable	10 days	Thu 12/5/24	Wed 12/18/24	114	Client
117		3.16.2.2 Revise Deliverable based on Client's latest review	5 days	Thu 12/19/24	Thu 12/26/24	116	MedImpact
118		3.16.3 Obtain approval of deliverable	2 days	Fri 12/27/24	Mon 12/30/24	117	MedImpact
119		**3.17 State Advisory Board Plan**	27 days	Tue 11/19/24	Mon 12/30/24		
120		3.17.1 Compile and Deliver Integration Plan	10 days	Tue 11/19/24	Wed 12/4/24	68	MedImpact
121		**3.17.2 Review Deliverable**	**15 days**	**Thu 12/5/24**	**Thu 12/26/24**		
122		3.17.2.1 Client reviews Deliverable	10 days	Thu 12/5/24	Wed 12/18/24	120	Client
123		3.17.2.2 Revise Deliverable based on Client's latest review	5 days	Thu 12/19/24	Thu 12/26/24	122	Client,MedImpact

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Please see important notes on the last page.

ID	Attachment F - Ref	Task Name	Duration	Start	Finish	Predecessors	Resource Names
124		3.17.3 Obtain approval of deliverable	2 days	Fri 12/27/24	Mon 12/30/24	123	MecImpact
125		**4 Execution**	**176 days**	**Wed 9/4/24**	**Thu 5/15/25**		
126		4.1 Design	27 days	Wed 12/4/24	Tue 1/14/25		
127		4.1.1 Data Migration/Conversion Plan	27 days	Wed 12/4/24	Tue 1/14/25		
128		4.1.1.1 Data Migration and Conversion Plan Compile and Deliver	10 days	Wed 12/4/24	Tue 12/17/24	49	MecImpact
129		**4.1.1.2 Review Deliverable**	**15 days**	**Wed 12/18/24**	**Thu 1/9/25**		
130		4.1.1.2.1 Client reviews Deliverable	10 days	Wed 12/18/24	Thu 1/2/25	128	Client
131		4.1.1.2.2 Revise Deliverable based on Client's latest review	5 days	Fri 1/3/25	Thu 1/9/25	130	MecImpact
132		4.1.1.3 Obtain approval of deliverable	2 days	Fri 1/10/25	Tue 1/14/25	131	MecImpact
133		4.1.2 Test Management Plan	27 days	Wed 12/4/24	Tue 1/14/25		
134		4.1.2.1 Test Management Plan Compile and Deliver	10 days	Wed 12/4/24	Tue 12/17/24	49	MecImpact
135		**4.1.2.2 Review Deliverable**	**15 days**	**Wed 12/18/24**	**Thu 1/9/25**		
136		4.1.2.2.1 Client reviews Deliverable	10 days	Wed 12/18/24	Thu 1/2/25	134	Client
137		4.1.2.2.2 Revise Deliverable based on Client's latest review	5 days	Fri 1/3/25	Thu 1/9/25	136	MecImpact
138		4.1.2.3 Obtain approval of deliverable	2 days	Fri 1/10/25	Tue 1/14/25	137	MecImpact
139		4.2 Establish connectivity to the Client	20 days	Wed 9/4/24	Tue 10/1/24		
140		4.2.1 Approve and Sign Connectivity Form	10 days	Wed 9/4/24	Tue 9/17/24	11	Client
141		4.2.2 Establish Connectivity	5 days	Wed 9/18/24	Tue 9/24/24	140	MecImpact
142		4.2.3 Test Connectivity	5 days	Wed 9/25/24	Tue 10/1/24	141	MecImpact
143		4.3 Configuration	62 days	Thu 11/14/24	Fri 2/14/25		
144		4.3.1 Data Conversion	20 days	Wed 1/15/25	Tue 2/11/25		
145		**4.3.1.1 Inbound**	**10 days**	**Wed 1/15/25**	**Tue 1/28/25**		
146		4.3.1.1.1 Member Clinical Data/Medical Claims	10 days	Wed 1/15/25	Tue 1/28/25	132,142	MecImpact
147		4.3.1.1.2 Eligibility	10 days	Wed 1/15/25	Tue 1/28/25	132,142	MecImpact
148		4.3.1.1.3 Provider	10 days	Wed 1/15/25	Tue 1/28/25	132,142	MecImpact
149		4.3.1.1.4 Patient Attributes	10 days	Wed 1/15/25	Tue 1/28/25	132,142	MecImpact
150		4.3.1.1.5 Other	10 days	Wed 1/15/25	Tue 1/28/25	132,142	MecImpact
151		**4.3.1.2 Outbound**	**10 days**	**Wed 1/15/25**	**Tue 1/28/25**		
152		4.3.1.2.1 Clinical Criteria Documents	10 days	Wed 1/15/25	Tue 1/28/25	132,142	MecImpact
153	2.5	4.3.1.2.2 Retro-DUR Data Files	10 days	Wed 1/15/25	Tue 1/28/25	132,142	MecImpact
154	2.5	4.3.1.2.3 Retro-DUR Letter Templates	10 days	Wed 1/15/25	Tue 1/28/25	132,142	MecImpact
155		4.3.1.2.4 Other	10 days	Wed 1/15/25	Tue 1/28/25	132,142	MecImpact
156		**4.3.1.3 Historical**	**20 days**	**Wed 1/15/25**	**Tue 2/11/25**		
157		4.3.1.3.1 Member Clinical Data/Medical Claims	10 days	Wed 1/15/25	Tue 1/28/25	132,142	MecImpact
158		4.3.1.3.2 Eligibility	10 days	Wed 1/29/25	Tue 2/11/25	157	MecImpact
159		4.3.1.3.3 Provider	10 days	Wed 1/29/25	Tue 2/11/25	157	MecImpact
160		4.3.1.3.4 Patient Attributes	10 days	Wed 1/29/25	Tue 2/11/25	157	MecImpact
161		4.3.1.3.5 Other	10 days	Wed 1/29/25	Tue 2/11/25	157	MecImpact
162		4.3.2 Interface Configuration/Development	30 days	Fri 1/3/25	Fri 2/14/25		
163		**4.3.2.1 Interface Development**	**30 days**	**Fri 1/3/25**	**Fri 2/14/25**		
164		4.3.2.1.1 Sprint 1 - Complete Interface Development	10 days	Fri 1/3/25	Fri 1/17/25	56	MecImpact

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Please see important notes on the last page.

ID	Attachment F - Ref	Task Name	Duration	Start	Finish	Predecessors	Resource Names
165		4.3.2.1.2 Sprint 2 - Complete Interface Development	10 days	Mon 1/20/25	Fri 1/31/25	164	MedImpact
166		4.3.2.1.3 Sprint 3 - Complete Interface Development	10 days	Mon 2/3/25	Fri 2/14/25	165	MedImpact
167		4.3.3 Software Application Configuration	60 days	Thu 11/14/24	Wed 2/12/25		
168		**4.3.3.1 Client Setup in Retro-Dur Application**	**30 days**	**Thu 11/14/24**	**Mon 12/30/24**		
169	3.0	4.3.3.1.1 Coding	30 days	Thu 11/14/24	Mon 12/30/24	35	MedImpact
170	3.0	4.3.3.1.2 QA	30 days	Thu 11/14/24	Mon 12/30/24	35	MedImpact
171	2.4	**4.3.3.2 Utilization Management Application**	**30 days**	**Tue 12/31/24**	**Wed 2/12/25**		
172		4.3.3.2.1 Coding	30 days	Tue 12/31/24	Wed 2/12/25	35,169	MedImpact
173		4.3.3.2.2 QA	30 days	Tue 12/31/24	Wed 2/12/25	35,170	MedImpact
174		4.4 Account Receivable Setup	10 days	Thu 11/14/24	Wed 11/27/24		
175		4.4.1 Accounting System Setup	10 days	Thu 11/14/24	Wed 11/27/24		
176		4.4.1.1 Setup AR	10 days	Thu 11/14/24	Wed 11/27/24	35	MedImpact
177	2.3 & 2.5	4.5 Retro-DUR Survey Portal	46 days	Tue 10/22/24	Fri 12/27/24		
178		4.5.1 Account Provisioning	5 days	Tue 10/22/24	Mon 10/28/24	31	MedImpact
179		4.5.2 Development	20 days	Tue 10/29/24	Mon 11/25/24	178	MedImpact
180		4.5.3 QA	20 days	Tue 11/26/24	Thu 12/26/24	179	MedImpact
181		4.5.4 Grant User Access	1 day	Fri 12/27/24	Fri 12/27/24	180	MedImpact
182	2.2 & 2.5	4.6 Reporting	45 days	Wed 12/4/24	Fri 2/7/25		
183		4.6.1 Reporting Development and QA	45 days	Wed 12/4/24	Fri 2/7/25		
184		4.6.1.1 Standard Suite Review and Approval	10 days	Wed 12/4/24	Tue 12/17/24	49	MedImpact,Client
185		4.6.1.2 New Report Development	20 days	Wed 12/18/24	Fri 1/17/25	184	MedImpact
186		4.6.1.3 New Report QA	10 days	Mon 1/20/25	Fri 1/31/25	185	MedImpact
187		4.6.1.4 New Report Review and Approval by Client	5 days	Mon 2/3/25	Fri 2/7/25	186	Client
188		4.7 Testing	81 days	Mon 12/30/24	Thu 4/24/25		
189		4.7.1 Interface Testing	20 days	Tue 2/18/25	Mon 3/17/25		
190		4.7.1.1 Interface Testing	20 days	Tue 2/18/25	Mon 3/17/25	49,166	MedImpact
191		4.7.2 Application Testing	71 days	Wed 1/15/25	Thu 4/24/25		
192		4.7.2.1 Security	20 days	Wed 1/15/25	Tue 2/11/25	138,80	MedImpact
193		4.7.2.2 Software Application Testing	25 days	Thu 2/13/25	Thu 3/20/25	173,172	MedImpact
194		4.7.2.3 Data Migration Conversion Testing	25 days	Fri 3/21/25	Thu 4/24/25	192,193,146,147,148,	MedImpact
195		4.7.3 Retro-DUR Portal Testing	20 days	Mon 12/30/24	Tue 1/28/25		
196		4.7.3.1 Security	20 days	Mon 12/30/24	Tue 1/28/25	181	MedImpact
197		4.7.3.2 Retro-Dur Portal Testing	20 days	Mon 12/30/24	Tue 1/28/25	181	MedImpact
198		4.8 Communications/Materials	31 days	Thu 3/27/25	Thu 5/8/25		
199		4.8.1 Provider Communications (Prescriber)	31 days	Thu 3/27/25	Thu 5/8/25		
200		**4.8.1.1 Appleals Notification Letter(s) (Prescriber)**	**16 days**	**Thu 4/17/25**	**Thu 5/8/25**		
201		4.8.1.1.1 Draft PA Notification Letter(s) (Prescriber)	10 days	Thu 4/17/25	Wed 4/30/25	49FS+92 days	MedImpact
202		4.8.1.1.2 Client Review and approve PA Notification Letter(s) (Prescriber)	5 days	Thu 5/1/25	Wed 5/7/25	201	MedImpact
203		4.8.1.1.3 Distribute Notification	1 day	Thu 5/8/25	Thu 5/8/25	202	MedImpact,Client
204		**4.8.1.2 P&T Notification (Prescriber)**	**16 days**	**Thu 4/17/25**	**Thu 5/8/25**		
205		4.8.1.2.1 Draft PDL Change Notification (Prescriber)	10 days	Thu 4/17/25	Wed 4/30/25	49FS+92 days	MedImpact

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Please see important notes on the last page.

ID	Attachment F - Ref	Task Name	Duration	Start	Finish	Predecessors	Resource Names
206		4.8.1.2.2 Client Review and approve PDL Change Notification (Prescriber)	5 days	Thu 5/1/25	Wed 5/7/25	205	MedImpact
207		4.8.1.2.3 Distribute Notification	1 day	Thu 5/8/25	Thu 5/8/25	206	MedImpact,Client
208		**4.8.1.3 UM Criteria Distribution (Prescriber)**	**16 days**	**Thu 4/17/25**	**Thu 5/8/25**		
209		4.8.1.3.1 Draft PDL Distribution (Prescriber)	10 days	Thu 4/17/25	Wed 4/30/25	49FS+92 days	MedImpact
210		4.8.1.3.2 Client Review and approve PDL Distribution (Prescriber)	5 days	Thu 5/1/25	Wed 5/7/25	209	MedImpact
211		4.8.1.3.3 Distribute Notification	1 day	Thu 5/8/25	Thu 5/8/25	210	MedImpact,Client
212		**4.8.1.4 Prescriber Communication**	**16 days**	**Thu 3/27/25**	**Thu 4/17/25**		
213		4.8.1.4.1 Draft Prescriber Communication	10 days	Thu 3/27/25	Wed 4/9/25	49FS+77 days	MedImpact
214		4.8.1.4.2 Client Review and approve Prescriber Communication	5 days	Thu 4/10/25	Wed 4/16/25	213	MedImpact
215		4.8.1.4.3 Distribute Notification	1 day	Thu 4/17/25	Thu 4/17/25	214	MedImpact,Client
216		4.8.2 Member Communications	16 days	Thu 4/17/25	Thu 5/8/25		
217		**4.8.2.1 Appleals Notification Letter(s)**	10 days	Thu 4/17/25	Wed 4/30/25	49FS+92 days	MedImpact
218		4.8.2.2 Client Review and approve Consumer Portal Member Letter	5 days	Thu 5/1/25	Wed 5/7/25	217	MedImpact
219		4.8.2.3 Distribute Notification	1 day	Thu 5/8/25	Thu 5/8/25	218	Client
220		4.9 Data Migration/Conversion - Initial Files	10 days	Fri 5/2/25	Thu 5/15/25		
221		4.9.1 Conduct Initial Prod Data Migration	10 days	Fri 5/2/25	Thu 5/15/25	244,194,196,197	MedImpact
222		4.10 Data Migration/Conversion - Subsequent Files	10 days	Fri 5/2/25	Thu 5/15/25		
223		4.10.1 Conduct Initial Prod Data Migration	10 days	Fri 5/2/25	Thu 5/15/25	244	MedImpact
224		5 Operational Readiness Review (ORR)	116 days	Tue 12/31/24	Mon 6/16/25		
225		5.1 ORR Documentation	95 days	Tue 12/31/24	Thu 5/15/25		
226		**5.1.1 Certification Metric Intake Form**	**27 days**	**Tue 12/31/24**	**Fri 2/7/25**		
227		5.1.1.1 Complete Intake Form with client	10 days	Tue 12/31/24	Wed 1/15/25	112	Client
228		5.1.1.2 Gather Metric Documentations	10 days	Thu 1/16/25	Wed 1/29/25	227	MedImpact
229		5.1.1.3 Obtain Metric Documentation approval from Client	5 days	Thu 1/30/25	Wed 2/5/25	228	Client
230		5.1.1.4 Client Provides Intake Form and Metric Documentations to CMS	2 days	Thu 2/6/25	Fri 2/7/25	229	Client
231		**5.1.2 ORR Artifacts**	**94 days**	**Tue 12/31/24**	**Wed 5/14/25**		
232		5.1.2.1 Review List with Client	10 days	Tue 12/31/24	Wed 1/15/25	112	MedImpact
233		5.1.2.2 Gather Artifact Documentations	10 days	Fri 4/25/25	Thu 5/8/25	188,232	MedImpact
234		5.1.2.3 Bundle and Submit Documentation to Client	2 days	Fri 5/9/25	Mon 5/12/25	233	MedImpact
235		5.1.2.4 Client submits to CMS	2 days	Tue 5/13/25	Wed 5/14/25	234	Client
236		**5.1.3 CMS Presentation**	**5 days**	**Fri 5/9/25**	**Thu 5/15/25**		
237		5.1.3.1 Draft and Compile PowerPoint presentation with Client	5 days	Fri 5/9/25	Thu 5/15/25	233	MedImpact,Client
238		5.2 ORR Session with Client and CMS	1 day	Mon 6/2/25	Mon 6/2/25		
239		5.2.1 ORR Meeting	1 day	Mon 6/2/25	Mon 6/2/25	237FS+10 days,235,23	CMS,Client,MedImpact
240		5.3 Client provides System Acceptance Letter to MedImpact	10 days	Tue 6/3/25	Mon 6/16/25	239	Client
241		6 ORR Readiness Date	0 days	Fri 4/25/25	Fri 4/25/25	188FS+1 day,42,175,1	
242		7 Go-Live Readiness	17 days	Fri 4/25/25	Mon 5/19/25		
243		7.1 Go-Live Prep	10 days	Fri 4/25/25	Thu 5/8/25		
244		7.1.1 Promote Code and Maps to PROD	5 days	Fri 4/25/25	Thu 5/1/25	190,192,193,197,196,	MedImpact
245		7.1.2 Validate PROD Environment	5 days	Fri 5/2/25	Thu 5/8/25	244	MedImpact
246		7.2 Final Go-Live Checklist	6 days	Fri 5/9/25	Fri 5/16/25		

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Please see important notes on the last page.

ID	Attachment F - Ref	Task Name	Duration	Start	Finish	Predecessors	Resource Names
247		7.2.1 Complete Go-Live Checklist	5 days	Fri 5/9/25	Thu 5/15/25	245	MedImpact
248		7.2.2 Verify contact list with the Client	1 day	Fri 5/16/25	Fri 5/16/25	247	MedImpact
249		7.2.3 Verify contact list with Client	1 day	Fri 5/16/25	Fri 5/16/25	247	MedImpact,Client
250		7.3 Client Go-Live Approval	1 day	Mon 5/19/25	Mon 5/19/25		
251		7.3.1 Client Approves Go-Live	1 day	Mon 5/19/25	Mon 5/19/25	247,248,249,187	Client
252		8 Go-Live Day	0 days	Mon 6/2/25	Mon 6/2/25	203,207,211,215,219,	
253		9 Certification	386 days	Thu 2/6/25	Wed 8/5/26		
254		9.1 Initial Operational Report Workbook Creation & Delivery	10 days	Thu 2/6/25	Thu 2/20/25		
255		9.1.1 Client Provides Operational Report Workbook for MedImpact Review	10 days	Thu 2/6/25	Thu 2/20/25	229	Client
256		9.2 MedImpact provides Certification reports	197 days	Tue 7/15/25	Wed 4/15/26		
257		9.2.1 Month 1 Reporting	1 day	Tue 7/15/25	Tue 7/15/25	255,252FS+28 days	MedImpact
258		9.2.2 Month 2 Reporting	1 day	Fri 8/15/25	Fri 8/15/25	257SF+24 days	MedImpact
259		9.2.3 Month 3 Reporting	1 day	Mon 9/15/25	Mon 9/15/25	258SF+22 days	MedImpact
260		9.2.4 Month 4 Reporting	1 day	Thu 10/16/25	Thu 10/16/25	259SF+24 days	MedImpact
261		9.2.5 Month 5 Reporting	1 day	Fri 11/14/25	Fri 11/14/25	260SF+22 days	MedImpact
262		9.2.6 Month 6 Reporting	1 day	Mon 12/15/25	Mon 12/15/25	261SF+22 days	MedImpact
263		9.2.7 Month 7 Reporting	1 day	Thu 1/15/26	Thu 1/15/26	262SF+24 days	MedImpact
264		9.2.8 Month 8 Reporting	1 day	Fri 2/13/26	Fri 2/13/26	263SF+22 days	MedImpact
265		9.2.9 Month 9 Reporting	1 day	Fri 3/13/26	Fri 3/13/26	264SF+21 days	MedImpact
266		9.2.10 Month 10 Reporting	1 day	Wed 4/15/26	Wed 4/15/26	265SF+24 days	MedImpact
267		9.3 Certification Documentation Preparation for Certification Review	45 days	Thu 2/26/26	Wed 4/29/26		
268		9.3.1 Client completes the Intake Form and submits to CMS	10 days	Thu 4/16/26	Wed 4/29/26	270,271,266	Client
269		9.3.2 Client submits the completed Operational Report Workbook to CMS	10 days	Thu 4/16/26	Wed 4/29/26	270,271,266	Client
270		9.3.3 Client submits the Official Certification Request Letter to CMS	10 days	Thu 2/26/26	Wed 3/11/26	275FS-60 days	Client
271		9.3.4 Client submits a copy of System Acceptance Letter to CMS	10 days	Thu 2/26/26	Wed 3/11/26	275FS-60 days	Client
272		9.4 Certification Review	115 days	Thu 2/26/26	Wed 8/5/26		
273		9.4.1 Client schedules certification review	1 day	Thu 2/26/26	Thu 2/26/26	275FS-60 days	Client
274		9.4.2 Client Give CMS access to artifacts and evidence	1 day	Thu 5/7/26	Thu 5/7/26	275FS-10 days,268,26	Client
275		9.4.3 Client conducts certification review	5 days	Thu 5/14/26	Wed 5/20/26	266FS+20 days	Client
276		9.4.4 CMS issues certification decision letter	15 days	Thu 7/16/26	Wed 8/5/26	275FS+40 days	CMS
277		10 Certification Complete	0 days	Wed 8/5/26	Wed 8/5/26	276	
278		11 Closeout	40 days	Tue 6/3/25	Wed 7/30/25		
279		11.1 Update and Finalize Project Documentation	30 days	Tue 6/3/25	Wed 7/16/25	252	MedImpact
280		11.2 Lessons Learned	10 days	Thu 7/17/25	Wed 7/30/25	279	Client,MedImpact

Each module WBS was created to be a standalone, independent project. Should more than one module be awarded, project WBSs will be combined into a comprehensive, cohesive project plan integrating various vendors as applicable. MedImpact will work collaboratively with all stakeholders to determine the most effective and efficient implementation timeline. The certification criteria are based on the "Streamline Modular Certification for Medicaid Enterprise System Certification Guidance Version 1.0 April 2022". Please note that any updates by CMS could impact each WBS.
The certification process consists of a minimum of 6 months of metrics reporting which includes 2 quarters of Rebates reporting. The Rebates program invoices in arrears which causes the certification process to be extended beyond the 6 months reporting window. Additionally, the WBS accounts for two months for CMS to issue the formal certification review decision letter.

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MSQ11.3 - Implementation Plan (Sample Summary)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Implementation Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) Implementation.

Purpose

The purpose of the Implementation Plan is to systematically execute the deployment of the FFS Pharmacy Benefit Management (PBM) program, ensuring a smooth transition from planning to design, development and implementation (DDI) to the Operations and Maintenance phase. This plan aims to coordinate resources, activities, and timelines to achieve project milestones, deliverables, and objectives effectively.

Overview

This plan is to provide a structured approach for implementing the FFS program, encompassing activities such as system integration, process optimization, stakeholder training, and performance testing. By outlining roles, responsibilities, and timelines, this plan seeks to minimize disruptions, mitigate risks, and ensure successful project execution.

The Implementation Plan outlines the step-by-step approach for implementing the FFS program, from initiation to full-scale operation. It includes the following key components:

Initiation Phase: Establishes project governance structure, including project team roles, responsibilities, and communication channels. Conducts a kickoff meeting to align stakeholders, define scope, clarify objectives, and determine implementation priorities.

Planning Phase: Develops a detailed implementation schedule, outlining tasks, dependencies, milestones, and timelines. Identifies resources required for implementation, including personnel, technology, and infrastructure needs. Conducts risk assessment and develops mitigation strategies to address potential implementation challenges.

Execution Phase: Implements system configurations and enhancements, data interfaces, and historical data migrations necessary for deployment. Conducts stakeholder training sessions to familiarize users with new processes, systems, and procedures. Executes performance testing and quality assurance activities to ensure system functionality and data integrity.

Monitoring and Control: Monitors project progress against the implementation schedule, identifying any deviations or delays. Conducts regular status meetings to review project metrics, address issues, and adjust as needed. Implements change

control procedures to manage scope changes and mitigate potential impacts on project timelines and deliverables.

Operations and Maintenance Phase: Prepares for the transition to full-scale operation, including final data validation, user acceptance testing, and operational readiness assessments. Coordinates the deployment of support resources, including call center services, information technology support, document management solutions and training materials. Executes a phased rollout, ensuring a smooth transition and minimal disruption to ongoing operations.

Closeout: Conducts a post-implementation review to evaluate project success, identify lessons learned, and capture best practices for future implementations. Solicits feedback from stakeholders to assess satisfaction with the implementation process and outcomes. Documents implementation outcomes, including achievements, challenges, and recommendations for continuous improvement.

MSQ11.4 - Quality Management Plan (Sample Summary)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Quality Management Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) Implementation.

Purpose

The purpose of the Quality Management Plan encompasses the management and execution of operations during the Operations and Maintenance (O&M) phase of the contract. It delineates the procedures for day-to-day operational support tasks, including adherence to SLAs, Key Performance Indicators (KPIs), and contractual requirements. Additionally, the plan addresses the monitoring and auditing processes essential for maintaining compliance with SLA criteria and contractual obligations.

Overview

Quality management is a systematic approach to ensuring that products, services, and processes meet or exceed expectations. It involves planning, assurance, control, and improvement of quality throughout all stages of the project engagement. For MedImpact, implementing a robust quality management process is essential to deliver high-quality services to the State of Georgia. Quality management is conducted throughout the life of the contract and all MedImpact team members take an active role to support and meet the contract requirements.
The quality management process involves Quality Planning, Quality Assurance and Quality Control as defined below:

Quality Planning:

- **Objective:** Establish clear quality objectives that align with the goals of the contract and the expectations of the State of Georgia.
- **Process:** This involves identifying quality requirements, defining measurable quality objectives, and determining the resources and processes needed to achieve those objectives.
- **Integration:** Quality planning is integrated into the overall program planning process to ensure alignment with program goals and objectives.

Quality Assurance:

- **Objective:** Ensure that all deliverables and activities meet the specified quality standards.
- **Process:** Quality assurance focuses on preventing defects by implementing processes, standards, and guidelines to monitor and evaluate performance against predetermined criteria.
- **Integration:** Quality assurance procedures are implemented throughout the O&M phase to continuously monitor and improve the quality of deliverables and activities.

Quality Control:

- **Objective:** Monitor and control the quality of deliverables and activities to ensure compliance with SLAs, contractual requirements, and regulatory standards.
- **Process:** Performance and quality control involve measuring, analyzing, and verifying the quality of outputs against predefined criteria, identifying any deviations or non-conformities, and implementing corrective actions as necessary.
- **Integration:** Performance and quality control processes are integrated into day-to-day operations to detect and address quality issues in real-time, minimizing risks and ensuring adherence to quality standards.

MSQ11.5 - Requirements Management Plan (Sample Summary)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Requirements Management Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) Implementation.

Purpose

The purpose of the Requirements Management Plan is to document the project team's approach to collecting, monitoring, and controlling change for each requirement. It is a reference document that details all approaches and procedures the team will use to execute the requirement management activities.

Overview

MedImpact understands the importance of requirements gathering and documentation in building the foundation for other DDI activities. Accurate, detailed, and complete requirements documented in a Requirements Trackability Matrix (RTM) are used to drive the activities of the Configuration phase to verify that the MedImpact Pharmacy Benefit Administration (PBA) solution aligns with the State of Georgia's defined requirements.

The RTM is used to provide tracing forward from requirements to test cases, documentation, demonstrations, or a combination of these validation types. Finally, the RTM is used to demonstrate to the State of Georgia that, upon implementation (go-live), all requirements (functional and non-functional) are met by MedImpact and have been fully tested and validated.

The requirements management process is broken out into four phases: requirements identification, requirements analysis, requirements documentation, and ongoing requirements management. A description of each phase is described below.

Requirements Identification: The MedImpact (MI) team collects and gathers the project requirements via various project documentations and/or meetings (i.e., RFP, requirements listings, etc.). The team uses the information from this phase as the primary input to all other requirements processes.

Requirements Analysis: The MI team will analyze requirements to determine where in the Work Breakdown Structure (WBS) the requirements will fall or what work activities correspond to certain requirements. The RTM will be created as part of this analysis and will be reviewed and approved by all applicable stakeholders.

Requirements Documentation: After requirements have been identified and analyzed, they will be assigned to accountable personnel. These requirements will be added to the WBS, as applicable, and the project team will determine what methodology the accountable personnel will use to track and report on the status of

each requirement. The requirements documentation compiled will be used to validate that requirements have been met as it relates to this implementation.

Ongoing Requirements Management: Throughout the project lifecycle, the project manager will ensure all team members are reporting requirement status and raising any issues or concerns with their assigned requirements as appropriate. As the project matures there may be situations in which requirements must change or be altered in some way. The project team will follow the agreed upon change control process to propose any changes to requirements and receive approval from the appropriate stakeholders and the change control board, as applicable.

MSQ11.6 - Change Management Plan (Sample Summary)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Change Management Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) Implementation.

Purpose

The purpose of the Change Management Plan is to document MedImpact's approach and methods used for identifying, assessing, reviewing, and implementing (upon applicable stakeholders' approval) changes to the scope, timeline, requirements, or deliverables for the implementation.

Overview

MedImpact will follow a formal change control process, mutually defined, and agreed to with the State of Georgia, before implementing any change to the implementation. MedImpact will work together with the State of Georgia to establish the Change Control Board (CCB) to manage the change control process. MedImpact will document the approach to change control along with specific, executable change control protocols and procedures in the change management plan, which is a component of the Project Management Plan (PMP). The change management plan will define the processes and steps for identifying and logging a change request, performing change impact analysis, conducting change review with the State of Georgia's CCB, and executing approved changes accordingly.

Change Requests will be submitted to the Project Team for approval. The Project Team will evaluate the scope change and conduct an estimate and impact to schedule and effort. Upon official approval of scope changes, the related project documents will be updated. Change Requests are tracked and maintained in the mutually agreed upon location using the 'Change Request' identifier. Status of Change Requests will be reported via regular status reporting channels as agreed upon by all stakeholders.

MSQ11.7 - Risk Management Plan (Sample Summary)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Risk Management Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) Implementation.

Purpose

The purpose of the Risk Management Plan is to describes MedImpact's (MI) strategy for identifying, assessing, controlling, monitoring, and mitigating risk throughout the State of Georgia Pharmacy Benefit Administration System (PBA) implementation. This document describes the processes by which implementation risks are recorded, communicated, and tracked throughout the project.

Overview

The goal of the MedImpact Risk Management Plan is to implement processes and tools to successfully prevent negative influences from threatening the success of the State of Georgia PBA implementation. It is MI's intent to proactively identify risk and allow the implementation team to execute avoidance and mitigation strategies to prevent risks from becoming issues. Should a risk become an issue, it will be handled through the communication escalation process described in the Communication Management Plan. This process allows for collaborative engagement to develop a remediation plan for resolving risks and issues.

The Risk Management Plan ensures procedures are in place to foster proactive risk mitigation and ensure the involvement of the State of Georgia through transparent communication. MI's communication practices ensure all stakeholders are consulted and involved with making risk mitigation decisions. These practices also ensure all stakeholders remain informed as risks evolve and are tracked by the Project Implementation team. The Risk Management Plan will include but is not limited to the following sections. A description is provided for each section:

- **Risk Identification:** An implementation risk can be defined as any threat to the success and satisfaction of the State of Georgia PBA implementation. MI relies on its subject matter experts to identify areas of concern and communicate those concerns to the MI implementation team. Risks that are identified will be entered into the agreed upon risk register (i.e. Project SharePoint site) to be reviewed during scheduled status meetings or ad-hoc meeting, if warranted. Upon entry of the risk, all applicable information is completed to accurately describe the noted risk.
- **Risk Assessment:** During agreed upon status meetings or ad-hoc meeting, if warranted, the risk(s) identified and logged will be reviewed with all applicable stakeholders to discuss description, a decision to accept or mitigate the risk, an initial acceptance or mitigation plan, a risk score, an assigned risk owner, an identification

date, and an initial risk status. This allows for collaborative risk assessment by all stakeholders.

- **Risk Recording and Monitoring:** Each implementation risk is assigned a risk owner, and it is the responsibility of the owner to act on the mitigation plan and keep the risk register up to date. The risk owner might be the project manager, the functional area subject matter expert, or anyone else who is most knowledgeable of the risk. Weekly reviews of the risk register ensure the most current information is obtained, the risk is being managed and the risk owner is making progress toward successfully mitigating the risk.
- **Risk Closure:** The main goal is to drive toward the successful closure of any identified risks. Risks may be closed due to successful remediation, due to a requirement change, thus removing the risk from scope, or due to a risk being deemed as not applicable after further research by applicable stakeholders. When it is agreed upon by all stakeholders that a risk can be closed, the risk register will be updated accordingly by the risk owner.

MSQ11.8 - Communications Management Plan (Sample Summary)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Communications Management Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) Implementation.

Purpose

The purpose of the Communications Management Plan is to provide a process for managing and coordinating a wide variety of formal and informal communications for projects. The process guides projects in delivering timely, accurate, and consistent information to stakeholders throughout the project life cycle. The Communications Management Plan is to be used by Program/Project Managers and defines the program's structure and methods for collecting, screening, formatting, and distributing project information.

Overview

Organized and efficient communication among all relevant project stakeholders is a critical factor in successful implementation and operations. MedImpact develops and follows the communication plan throughout the project to coordinate communications with the State of Georgia, our solution interface partners, and all other applicable stakeholders.

Beginning in the project startup phase and continuing throughout all phases of the project, the MedImpact Team collaborates with all stakeholders for project governance and communication. MI includes all applicable stakeholders as appropriate within regular project status meetings and other formal and informal discussions for escalation of critical project changes, risks, or issues and joint problem solving.

The Communication Management Process involves an integrated approach to (bi-directionally) collect, generate, and disseminate relevant project information to all interested parties. Templates, matrices, and other associated artifacts will support the process outlined in the plan. Three phases occur in the Communication Management Process as outlined below:

- **Plan Communications** – This phase involves the development of an approach and plan for all program and project communication activities. Outputs of this phase are the stakeholder registry, the stakeholder assessment, and the communication matrix.
- **Manage Communications** – This phase involves ensuring timely and appropriate collection, creation, distribution, storage, retrieval, management, monitoring, and the ultimate dissemination of project information. One of the primary outputs of this phase is status reporting. Other artifacts from this phase include standardized templates, communication standards, guidelines, and tools used to manage communication.
- **Monitor Communications** – This phase involves the continual monitoring of the communication process to ensure that the information needs of the program, project, and applicable stakeholders are met. Additionally, this phase includes the practice of identifying lessons learned to further improve future communications.

MSQ11.9 - Integration Plan (Sample Summary)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Integration Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) implementation.

Purpose

The purpose of the Integration Plan is to ensure appropriate data exchange across required channels in a way that optimizes interoperability and satisfies the state requirements, methods, and standards. This plan captures information and data sharing, functionality, and efficiency of the various systems by integrating into the FFS program. This integration aims to streamline operations, improve data accuracy, and facilitate informed decision-making for the FFS program.

Overview

The Integration Plan encompasses the following key components:

Assessment and Requirements Gathering: Assess existing systems and processes to identify integration requirements and dependencies. Gather stakeholder input to define specific integration goals and objectives.

Interface Identification and Prioritization: Identify the interfaces that need to be integrated with the FFS program. Prioritize modules based on their criticality and impact on business operations.

Data Mapping and Transformation: Develop data mapping and transformation strategies to ensure seamless integration of data between the client's data and the FFS system. Define data formats, standards, and protocols for data exchange.

ETL Process Design and Implementation: Design and implement Extract, Transform, and Load (ETL) processes to extract data from various sources, transform it according to business rules, and load it into the target system. Ensure data integrity, consistency, and security throughout the ETL process.

Testing and Validation: Conduct thorough testing of the integrated system to verify data accuracy, functionality, and performance. Validate the integration against predefined acceptance criteria and user requirements.

Deployment and Rollout: Plan and execute the deployment of the integrated system into production environment. Coordinate with stakeholders to ensure a smooth rollout with minimal disruption to business operations.

Monitoring and Optimization: Implement monitoring tools and processes to track the performance of the integrated system. Continuously optimize integration processes and address any issues or challenges that arise during operation.

MSQ11.10 - Operations & Maintenance Plan (Sample Summary)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Operations and Maintenance Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) implementation.

Purpose

The purpose of the Operations and Maintenance Plan is to ensure the effective and efficient delivery of services for the Georgia FFS program. This plan aims to outline the strategies, procedures, and responsibilities necessary for sustaining high-quality service delivery and optimizing operational efficiency.

This plan is developed to establish clear guidelines and protocols for the ongoing operation and maintenance phase of the FFS program. By defining roles, responsibilities, and processes, this plan aims to minimize disruptions, identify, and mitigate risks, and ensure continuous high quality service delivery through the life of the contract. Additionally, it seeks to establish and foster collaboration among stakeholders, promote program transparency, and ensure compliance with regulatory standards.

Overview

The Operations and Maintenance Plan encompasses a comprehensive framework for managing the day-to-day operations and maintenance of the FFS program. The final plan includes the following key components:

Service Delivery Processes: Monitoring the end-to-end processes for the FFS program, including but not limited to claims processing, formulary management, member services, and provider relations.

Risk Management: Identifies potential risks and vulnerabilities in service delivery and outlines strategies for risk mitigation, contingency planning, and disaster recovery to minimize disruptions and ensure business continuity

Resource Management: Identifies the human, financial, and technological resources required to support service delivery and outlines strategies for resource allocation and optimization.

Stakeholder Communication and Engagement: Facilitates open communication channels with clients, partners, and stakeholders to address concerns, solicit feedback, and foster collaborative relationships in delivering value-added services.

Training and Development: Provides ongoing training and development programs for staff to enhance their skills, knowledge, and capabilities in delivering quality services and adapting to evolving market dynamics.

Compliance and Regulatory Requirements: Ensures compliance with regulatory standards, accreditation requirements, and industry best practices to uphold the highest standards of integrity, confidentiality, and security in service delivery.

Quality Assurance and Performance Monitoring: Establishes mechanisms for monitoring and evaluating service quality, performance metrics, and key performance indicators (KPIs) to ensure adherence to service level agreements (SLAs) and continuous improvement.

MSQ11.11 - Training Plan (Sample Summary)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Training Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) Implementation.

Purpose

The purpose of the training plan is to ensure all authorized State of Georgia personnel, and end users (pharmacies, billing agents, and prescribers) have the information they need to work effectively with MedImpact systems and processes.

Overview

The goal and objective of MedImpact's training is to help all stakeholders who work with our processes and systems understand the underlying concepts and principles and will be able to perform their work with a high level of proficiency. MedImpact will help ensure all training materials are accessible for all trainees in accordance with the Americans with Disabilities Act. The training plan includes the following topics:

- Audiences for Training: Identifies the primary audiences for training and their general informational needs.
- Schedule for Training: This information will come from the project Work Breakdown Structure (WBS).
- Scope of Training (Curriculum): Defines the set of training classes that MedImpact will produce and deliver during the coming year.
- Organization and Staffing: Defines the organization and staffing of the training group, which is responsible for production and delivery of the training materials.
- Training Modes: Description of the modes through which MedImpact will deliver training.
- Training Tools and Materials: Specifies the training tools MedImpact will use to create and manage training.
- Evaluation: Describes the tools and processes MedImpact will use to evaluate the effectiveness of training materials and training delivery.
- Tracking of Training: MedImpact uses the Events Registration Database to track available courses, schedule, mode, registrations, actual attendance, and evaluation results.

MSQ11.12 - Cost Management Plan (Sample Summary)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Cost Management Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) Implementation.

Purpose

The purpose of this Cost Management Plan is to define the methodology by which costs associated with the Georgia FFS Implementation will be managed throughout the project lifecycle. To ensure the successful completion of the project within the allotted budget, this plan sets the format and standards by which the project costs are measured, reported and controlled. Several cost components are associated with this project. Metrics, cost variance considerations, and reporting activities will be outlined in this plan. To complete this project successfully, all key project members and stakeholders must adhere to and work within this Cost Management Plan and the overall project plan it supports.

Overview

This Cost Management Plan will:

- Outline the overall project cost management approach
- Outline how the project cost, budget and source of funding will be determined
- Identify who is responsible for managing costs, including who has the authority to approve changes to the project, its budget or sources of funding
- Identify the methods to be used for quantitatively measuring and reporting on cost performance
- Identify the reporting formats, frequency and to whom they are presented

MSQ11.13 - Stakeholder Management Plan (Sample)

Deliverable Description

Objective

The objective of this document is to provide a summary of the Stakeholder Management Plan that will be utilized as part of the State of Georgia in conjunction with NASPO ValuePoint Medicaid Fee-for-Service (FFS) Implementation.

Purpose

The purpose of the Stakeholder Management Plan is to effectively identify, engage, and manage collaborative service delivery with stakeholders involved in the Georgia FFS implementation. This plan aims to establish proactive communication channels, cultivate positive relationships, and address stakeholder expectations to ensure project success and stakeholder satisfaction.

The plan outlines strategies and approaches for identifying, analyzing, and engaging stakeholders throughout the project lifecycle. By understanding their interests and potential impact on the project, this plan seeks to mitigate conflicts, leverage stakeholder support, and maximize project outcomes.

Overview

The Stakeholder Management Plan encompasses a structured approach for managing stakeholder relationships and ensuring their active involvement and support throughout the project. It includes the following key components:

Stakeholder Identification and Analysis: Identifies all internal and external stakeholders, including clients, partners, regulatory bodies, end-users, and affected communities. Assesses their interests, expectations, and potential influence on the project. Analyze stakeholders and create Responsible, Accountable, Consulted, and Informed (RACI) matrix.

Stakeholder Engagement Strategy: Defines strategies for engaging stakeholders throughout the project lifecycle, including communication methods, frequency, and level of engagement. Tailors' communication approaches to meet the needs and preferences of different stakeholder groups.

Communication Plan: Outlines a communication plan that includes regular updates, progress reports, and feedback mechanisms to keep stakeholders informed and engaged. Identifies key messages, communication channels, and responsible parties for delivering information to stakeholders.

Stakeholder Management: Develops strategies for managing stakeholder expectations, addressing concerns, and resolving conflicts to maintain positive relationships and stakeholder support. Anticipates potential challenges and proactively addresses them to minimize disruptions to the project.

Stakeholder Feedback and Evaluation: Establishes mechanisms for soliciting feedback from stakeholders and incorporating their input into project decision-making processes. Identify areas for improvement and refine stakeholder engagement strategies.

12.	**Bookmark Title: MSQ12 – Role Understanding** Narrative description is limited to five (5) pages. Describe your understanding of your role and responsibilities in the project, your relationship to the other resources and stakeholders involved, including the State's Project Management Office (PMO), or equivalent office, PBA vendor, and Fraud Waste and Abuse vendor. Describe how you will collaborate and provide leadership among the various resources and stakeholders and provide examples of past successes in a similar environment. Refer to Attachment C: Common Scope Requirements and Security Standards.

Supplier Response

MedImpact offers a customer-centric approach to service excellence and a commitment to operating as a performance-based organization, MedImpact is proposing a modern process-oriented PBM solution built on a unified information technology platform that enables MedImpact and DCH's Medicaid staff to perform job functions necessary to administer all aspects of the Medicaid FFS program. Our goal is to provide improved ways to address the current and future challenges in FFS Medicaid. This is accomplished by leveraging our existing processes and making sound investments in new technology to enhance automation, accountability, and transparency.

MedImpact's responses and staffing are formulated to specifically address DCH's requirements and bring value to the program. We value an innovative, flexible, and forward-thinking approach to the administration of pharmacy benefits. Our mission is to use our in-depth clinical expertise, high-touch account management, advanced technology, and a proactive holistic approach to engage and empower individuals to lead healthier lives.

MedImpact's objectives for DCH are to:

- Provide an integrated approach to managing Medicaid programs by closing gaps and inefficiencies seen in competitor FFS contractors' technology and processes.
- Deliver an improved approach to managing FFS populations in compliance with Georgia and federal regulations, the MECT (Medicaid Enterprise Certification Toolkit), and OBC (Outcomes-Based Certification).
- Improve the customer, member, prescriber, and pharmacy provider experience through automation, innovation, accountability, and access to exceptional care.

MedImpact is fully committed to meeting the performance and scope requirements detailed in the eRFP and stands ready to provide a comprehensive staffing plan composed of dedicated resources, hands-on support from executive leadership and the account team, and leading technology that continually advances as DCH modernizes its Medicaid enterprise system.

MedImpact offers Georgia a better way to manage their PBMS. We distinguish ourselves from our competitors through:

- A new perspective to PBM in the FFS market utilizing expert committed staff.
- The unique offering of a partner with the characteristics of a smaller corporation coupled with the resources and assets necessary to help ensure successful delivery of the pharmacy program.

- A conflict free, transparent business model. We are a PBM, not a health plan or other entity with a conflicting agenda or competing priorities.

DCH will be afforded increased flexibility regarding the ways in which our solution integrates with Georgia MEST, including:

- **High visibility within the MedImpact organization**: De'Lona Davis-Jones, Vice President of Government Programs, will be actively engaged in this program to help ensure we meet and exceed all expectations.
- **Proven FFS Medicaid leadership**: Dean Beuglass, Managing Principal, FFS Medicaid has proven implementation and operations experience and is highly familiar with Georgia Medicaid and is positioned as DCH's executive sponsor
- **Highly configurable, flexible POS capabilities**: We configure the PBM using tools such as our EFS tool which allows for configuration of the PDL and the ECS tool which allows for benefit configuration.
- **Automation**: MedImpact has heavily invested in areas that improve efficiencies through automation. These capabilities include an automated PA solution, ePA, IVR, and OCR, which provide automatic or self-services capabilities to providers, which streamlines the decisioning processes.
- **Service-oriented architecture**: Our interfaces utilize common communication standards enabling rapid incorporation into new applications without having to perform deep integration each time.
- **MITA-aligned**: We utilize national data standards, common business processes, componentized business applications, business rules engines, web-based services, alternate delivery models, and platform independence.

MedImpact's DUR system meets all applicable State and federal requirements and regulations, including those identified in the OBRA '90 and eRFP specifications. In addition, MedImpact will prepare all CMS-required DUR reports. Our ProDUR system response times meet NCPDP performance standards, and we will continue to meet those standards over the contract period, including future edit changes, as identified by DCH.

Since the release of regulatory requirements on January 2, 1993, with federal mandates for Medicaid RetroDUR programs, we have assisted states in administering their programs. MedImpact's RetroDUR process is strengthened by federal regulations Title 42, Part 456, Subpart K. These regulations, entitled DUR Program and Electronic Claims Management System for Outpatient Drug Claims, Section 456.709, provide a foundation for our teams to monitor prescription drug claims. Within the final rule, modifications for the inclusion of over-the-counter medications enables us to enhance the review to include these products and their therapeutic effects on members.

Our process is strengthened by federal regulations Title 42, Part 456, Subpart K. These regulations, entitled, DUR Program and Electronic Claims Management System for Outpatient Drug Claims, Section 456.709, provide a foundation for our teams to monitor prescription drug claims. Additionally, we have modified our process with federal regulations Title 42, Part 438.3, Subpart S(4).

Collaborative Support

MedImpact will provide consultative services and collaborate with DCH staff to use the current

MedImpact PDL workflow and business process. We will modify our process where appropriate to meet DCH's goals to implement, maintain, and modify/enhance the DCH PDL. We will provide support and clinical consultation to partner on reviews of medication quantity limits and rules on medications based upon package size, units of measurement, and FDA maximum dosing. The pharmacist will review the quantity limits to help ensure they align with package size, units of measurement, FDA maximum dosing, and guideline / market recommendations.

MedImpact will follow the plans and processes defined by the State and the DCH project management team when performing contract management activities. In addition to normal implementation activities, we understand there may be additional meetings, requirements, testing, and data integration activities required to support the successful alignment with DCH's vision for a successful project. Our FFS Medicaid team brings a wealth of knowledge and experience in implementing pharmacy solutions in advance of and concurrent to a multi-module MMIS deployment, as well as a deep understanding of the level of coordination and cooperation required to help ensure program success.

MedImpact will assume responsibility for the activities listed in this eRFP, as well as the eRFP attachments. We understand that failure to fulfill these responsibilities may result in financial penalties and/or the assessment of financial damages, as defined in eRFP Attachment E - Service Level Agreements.

MedImpact applies our knowledge of Pharmacy Benefit Administration Services, Pharmacy Clinical Management Services, Pharmacy Fraud Waste and Abuse Audit Services, and Pharmacy Drug Rebate Services along with the information provided in this eRFP to establish the roles and responsibilities necessary to provide an expert level of support for DCH. In alignment with MedImpact's executive support model, DCH will have access to our leadership team and executive support personnel that will execute their identified roles and responsibilities in their areas of expertise