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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

MSQ1 – Executive Summary

Myers and Stauffer LC (Myers and Stauffer) is pleased to present our technical proposal in response to the State of Georgia in Conjunction with NASPO ValuePoint's *electronic Request for Proposals (eRFP) 41900-DCH0000136 – Pharmacy Benefit Services: Pharmacy Clinical Management Services* via the National Association of State Purchasing Officer's Organization (NASPO) in achieving its goals for improving pharmacy program claim integrity and fiscal stewardship through the provision of clinical pharmacy services. We have partnered with Medicaid programs throughout the country — programs with similar objectives committed to complying with federal requirements to combat fraud, waste, and abuse (FWA) and ensure responsible fiscal oversight of the Medicaid drug benefit.

Myers and Stauffer is nationally recognized as specialists in the support of Medicaid pharmacy programs providing clinical analysis, rate setting, and review of both prescription drug claims and

medical claims. We have decades of experience consulting for pharmacy-related programs, including monitoring for appropriate implementation of clinical policies by both managed care organizations and pharmacies; high-level consulting regarding states' use of unified preferred drug lists (PDLs); oversight and consulting relating to implementation of Medicaid drug rebates through both the federal Medicaid Drug Rebate Program (MDRP) and state supplemental rebates; pharmacy rate setting for drug ingredients and dispensing fees; development and maintenance of the National Average Drug Acquisition Cost (NADAC) pricing benchmark; performance of pharmacy benefit manager (PBM) audits; and other consulting services to address subjects such as specialty drugs, compound drugs, and 340B programs.

To further strengthen our team, Myers and Stauffer leverages our existing relationship with NorthStar HealthCare Consulting (NHC), a Georgia-domiciled, woman-owned business that specializes in pharmacy audits and pharmacy clinical management services (PCMS). NHC has worked as the clinical management vendor to the state of Georgia since 2006 via a subcontract relationship with the current Georgia Medicaid fee-for-service (FFS) program pharmacy claims processor, and is therefore the current incumbent for the proposed scope of work (SOW).

Myers and Stauffer and NHC share the common goal of supporting state Medicaid pharmacy programs, and based on our combined many years of experience, we have developed a deep understanding of the specialized needs that a Medicaid program has as compared to other payers. Our teams have learned to navigate the complex federal and state regulatory framework in which Medicaid programs operate and the unique needs of the populations served by Medicaid programs. Recognizing this common thread of serving state Medicaid programs, Myers and Stauffer has collaborated with NHC since 2021 in the support of other Medicaid programs. For example, Myers and Stauffer and NHC have partnered to support the Ohio Department of Medicaid with oversight of their Single PBM (SPBM) initiative, specifically collaborating regarding oversight of prior authorization (PA) and call center functions of the SPBM vendor. The combined knowledge, experience, and resources of Myers and Stauffer and NHC (collectively the Myers and Stauffer Team or the Team) make us an ideal candidate for Georgia and other states' PCMS needs.

Our Understanding of the SOW and Capability to Provide Services

Through the current procurement, the Georgia Department of Community Health (DCH) is seeking a vendor to provide clinical management services in support of the Medicaid pharmacy program. DCH requires that the clinical management services vendor be an active partner with the State to ensure the successful implementation and management of the clinical programs associated with administration of the pharmacy benefit. One of the primary roles of the Clinical Management Services vendor is to support the State Advisory Board (SAB) relative to the ongoing maintenance of the State's PDL and the physician-administered drug list (PADL) through coverage recommendations and the development of clinical monographs. The Clinical Management Services vendor provides drug information regarding new medications, as well as clinical and other updates regarding existing products, and participates in regular clinical meetings. In its role of supporting the State with the maintenance of the PDL, the Clinical Management Services vendor assists the State to meet its goals of utilizing cost-effective products, including the use of generic products. The Clinical Management Services vendor also performs retrospective review activities to monitor trends impacting patient safety and program cost and advises the State regarding appropriate utilization management (UM) criteria and edits to ensure the clinical and fiscal integrity of the pharmacy program.

The Myers and Stauffer Team recognizes that through this procurement, other states participating in the NASPO ValuePoint organization have an opportunity to leverage submitted proposals in support of similar programs within their respective state Medicaid organizations. While our proposal has been developed with a specific understanding of the needs of DCH, the Team has the depth of experience of operating within numerous Medicaid programs to recognize that our skill set, experience, and the tools we utilize have the potential to be transferable to other Medicaid programs. Our experience in providing service to multiple states has also reinforced to us the humility to recognize that each state Medicaid program brings a slightly different approach to the management of the pharmacy benefit, and that of necessity, we must adapt to those differences.

Corporate Background

Founded in 1977, Myers and Stauffer is a nationally based certified public accounting firm and is one of the most experienced government health care consulting firms in the nation. In addition to supporting Medicaid programs with clinical analysis, we are notably the most experienced Medicaid pharmacy rate methodology development and maintenance vendor in the country, having begun our practice in 1977 with pharmacy cost of dispensing (COD) studies which evolved over time to include pharmacy acquisition cost surveys. Our experience providing health care assurance and consulting services to state Medicaid programs, Medicare, the U.S. Department of Justice (DOJ), and other government health care agencies is unrivaled.

In addition to pharmacy clinical and reimbursement consulting, as a firm, Myers and Stauffer has performed managed care oversight and administration; program integrity; data aggregation and analytics; full- and limited-scope audits; claim reviews; minimum data set (MDS) reviews; fiscal analyses; cost settlements; and rate setting, encompassing nearly every provider type participating in the Medicaid program. We have represented and provided expert witness testimony on behalf of Medicaid and Medicare in various levels of appeals and judicial proceedings, and we have assisted the DOJ and state Medicaid Fraud Control Units in both civil and criminal actions related to health care fraud.

Since 2003, NHC has been providing clients with clinically appropriate customized cost initiatives that have improved quality, transparency, and cost outcomes. Since its inception, NHC has been a Georgia-domiciled, woman-owned, small business. It is independently owned and has no commercial holdings or contractual relationships with pharmacies that can cause an actual or perceived conflict of interest. With corporate headquarters located in Alpharetta, Georgia, more than 75% of NHC's revenue is retained within the state of Georgia through its locally based employees. Indeed, seven of NHC's eight employees are located within 60 miles of the Georgia DCH's offices.

Collectively, our staff of clinicians possess over 100 years of Medicaid, managed care, retail pharmacy, and fraud and abuse experience, with over 70 years specific to Georgia Medicaid.

Unlike many of our competitors, both Myers and Stauffer and NHC are free from conflicts of interest with Georgia and all other states. Notably for the Clinical Management Services vendor role, both Myers and Stauffer and NHC have no conflicts of interest associated with either pharmaceutical manufacturers or pharmacies. Myers and Stauffer avoid conflicts of interest, and circumstances that could create the appearance of a conflict of interest, by intentionally restricting our practice to government-sponsored health care programs and other social service engagements. We do not accept providers or health plans as clients; therefore, we do not have any conflicts of interest. NHC

is independently owned and has no commercial holdings or contractual relationships with pharmacies that can cause an actual or perceived conflict of interest. NHC operates in an FFS environment when possible to reduce any appearance of conflict.

Number of Employees. Myers and Stauffer has nearly 1,000 professionals, including 42 members/principals (partners), all of whom are fully engaged with our state and federal health care and human service clients. NHC was founded in 2003 and comprises nine individuals, including pharmacists and pharmacy technicians, with a combined total of more than 100 years of pharmacy experience and over 50 years of pharmacy audit experience.

Equal Employment Opportunity Policy and Current Key Position Percentages. Myers and Stauffer's diversity efforts are spearheaded by our Human Resources partner who manages all affirmative action/equal opportunity efforts and our Diversity and Inclusion Committee — consisting of partners and staff from across our firm — that proactively works to cultivate a workplace where people of all backgrounds and cultures want to spend their careers. We recognize that it is our shared duty to maintain an environment of respect for all employees, regardless of our differences. We know that diverse teams and viewpoints add to our cadre of creative problem solving skills, increase the quality and speed of innovation, and improve the level of engagement among our employees.

Myers and Stauffer stresses diversity and inclusion internally. We recognize the value of diverse teams and the positive impact people with different backgrounds and cultural experiences have on the outcome of project development and execution. We are an equal opportunity and affirmative action employer and have an Affirmative Action Plan on file that has been shared with firm leadership. This includes our hiring practice for women, minorities, and the disadvantaged. All of our open positions are posted across hundreds of websites, including many women- and minority-targeted platforms. These platforms include outreach networks with community agencies, websites, and social media networks, as well as university placement offices and organizations, such as the Association of Latino Professionals in Finance and Accounting and the National Association of Black Accountants. Through these methods, our recruiters are also able to identify qualified applicants who are individuals with disabilities, minorities, military members, LGBTQ+, women, and other candidates.

NHC also has established policies pertaining to equal employment opportunities in accordance with applicable federal, state, and local laws. They provide equal employment opportunities to all qualified persons and administer all aspects and conditions of employment without regard to race, religion, color, sex, gender, gender-based wage discrimination, sexual orientation, pregnancy, age, national origin, ancestry, physical or mental disability, severe/morbid obesity, medical condition, military or veteran status, genetic information, marital status, ethnicity, or alienage or any other protected classification, in accordance with applicable federal, state, and local laws.

The Myers and Stauffer Team takes allegations of discrimination, intimidation, harassment, and retaliation very seriously and promptly conducts investigations when warranted. Equal employment opportunity includes, but is not limited to, employment, training, promotion, demotion, transfer, leaves of absence, and termination.

Below, please find our breakdown of key positions within our firm.

Gender	American Indian/ Alaska Native	Asian	Black/African American	Hispanic or Latino	White	Total
Female	0.54%	1.09%	3.80%	1.63%	45.65%	52.72%
Male	0.00%	0.54%	2.72%	0.54%	43.48%	47.28%
Total	**0.54%**	**1.63%**	**6.52%**	**2.17%**	**89.13%**	**100.00%**

Office Locations

Myers and Stauffer has 20 offices nationwide, including in Atlanta, Georgia, and is currently contracted in all 50 states. In addition to Atlanta, our offices are located in the following locations: Albuquerque, New Mexico; Austin, Texas; Baltimore, Maryland; Boise, Idaho; Brentwood, Tennessee; Cranford, New Jersey; Denver, Colorado; Des Moines, Iowa; Frankfort, Kentucky; Harrisburg, Pennsylvania; Honolulu, Hawaii; Indianapolis, Indiana; Kansas City, Missouri; Raleigh, North Carolina; Glen Allen, Virginia; Salt Lake City, Utah; Topeka, Kansas; Windsor, Connecticut; and Tallahassee, Florida. We plan to perform the work under this master agreement primarily from our Atlanta office and from our headquarters in Kansas City, Missouri. In addition, NHC's office is located in Alpharetta, Georgia.

The Myers and Stauffer Team employs more than 80 Georgia residents, which has direct economic impact on the state.

Why Choose the Myers and Stauffer Team?

As subject matter experts (SMEs) in pharmacy clinical consulting, rate setting, and auditing of pharmacies and PBMs, the Myers and Stauffer Team offers this summary of our services:

- **Independent Pharmacy Consulting and Pricing Leader.** The Myers and Stauffer Team has been assisting states with a wide variety of pharmacy consulting analyses which include both clinical and financial issues. Operating as the current clinical management vendor to DCH, NHC is intimately familiar with the current needs of DCH and has been providing clinical management support for the past 18 years. The Team's clinical analyses have included monitoring managed care plans for compliance in implementing clinical policies, monitoring of pharmacies for compliance with clinical policies relating to hemophilia management, and numerous ad hoc analyses. Additionally, with more than 46 years of experience in Medicaid pharmacy ingredient and dispensing fee policy and pricing, our Team has an extensive understanding of drug pricing and pharmacy reimbursement methodologies used in both FFS and managed care Medicaid programs.
- **Extensive Experience Working with Claims Processors.** As a current contractor to 50 Medicaid and other public agencies, we have extensive experience working with all major Medicaid fiscal agents to support eligibility functions, PDLs, drug utilization reviews (DURs), point of sale, and more. We work with pharmacy claims processors on a daily basis, transferring files, loading and verifying rates, implementing new payment programs, and otherwise ensuring state pharmacy pricing policy is carried through to the claims processing level.
- **Right People, Right Experience.** Our Team includes former Centers for Medicare & Medicaid Services (CMS) and state government employees, pharmacists, pharmacy technicians, analysts, policy experts, health information specialists, medical doctors, registered nurses, and certified fraud examiners, as well as two former Georgia Medicaid

	pharmacy directors and Medicaid directors. Our multi-disciplinary staff work exclusively with state and federal agencies that operate public health care programs, dedicating their careers to health care improvement and compliance through continued engagement with a constantly growing knowledge base that best serves our state agency clients. Our long and highly successful Medicaid consulting and auditing practice is the result of focused services for our governmental clients; creative and competent staffing; extensive planning and training; and partnering with our clients to achieve their objectives. ▪ **Expert in Fiscal Analysis and Reporting.** We understand the importance of program monitoring, reliable fiscal projections, and cost containment, so we make it a priority to provide meaningful and customized reports that will provide our clients with exactly the information needed, on a timely basis, and without extraneous factors that otherwise distract from effective policymaking. ▪ **Quality Assurance (QA) and Contract Integrity.** We practice a rigorous protocol of QA that addresses every function we perform, every process we utilize, and every deliverable we provide. QA is built into our services and overseen by a QA manager who compares internal standard operating procedures with state contract requirements to validate that the highest quality services and products are being provided.
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

MSQ2 – State Advisory Board

Our Team has considerable experience supporting stakeholder groups similar to the SAB described in Attachment G of the eRFP. We have assisted clients in nearly all 50 states with stakeholder engagement across numerous initiatives including, but not limited to, strategic planning, program and benefit design, rate setting, program evaluation, and delivery system transformation.

Generally speaking, our approach to stakeholder engagement consists of the following:

- **Identification.** Successful stakeholder engagement demands meaningful inclusion of diverse groups. We leverage our experience and collaborate with clients to identify and recruit stakeholders for participation.
- **Planning.** The most effective means of gathering stakeholder input is a key element of a stakeholder engagement plan, which includes parameters for the frequency of stakeholder engagement
- **Communication.** Our professionals are skilled at stakeholder communication strategies designed to reinforce a client's strategic vision and goals, deliver clear and deliberate communications, and promote a transparent and collaborative environment.
- **Facilitation.** Our meeting facilitators are experienced in conducting effective in-person and online meetings.

Capabilities. The function of the SAB is to promote patient safety by reviewing outpatient drug prescribing and dispensing behaviors in service to the Medicaid patient population. Functions of the SAB can include DUR — including prospective, retrospective, and concurrent — as well as educational interventions in both the Managed Medicaid and FFS arenas. Additional responsibilities may include oversight in an advisory or binding capacity of the PDL and supplemental rebate programs, and by extension, UM programs including PA, quantity level limits (QLLs), and step edits (SEs). SABs are typically comprised of pharmacists, medical providers, and medical specialists who practice within the state and serve the Medicaid population. Other members of the board may include academicians, consumer advocates, and representatives of the Medicaid program. The SAB is critical in providing decision-making transparency and eliciting buy-in from key members of the community, including patients, prescribers, advocacy groups, legislators, and other stakeholders.

In their current role as the incumbent vendor for DCH, NHC is tasked with supporting the State and its Advisory Board in their mission to promote patient safety and to ensure fiscally prudent clinical decision-making. Approaches to supporting the SAB can vary in both form and function depending on the specific issue before the Board. In their current role, NHC leverages highly experienced clinicians with advanced training which is critical to NHC's approach to drug literature review and evaluation. This approach leads to clinically defensible recommendations that incorporate fiscal prudence. NHC comprehensively reviews medications, considering them both as individual agents and within their therapeutic classes. Furthermore, reviews also consider the place of medications in therapy across the clinical armamentarium of their respective disease states, paying close attention to clinical and safety data. Once this review is completed, NHC's efforts are focused on developing customized recommendations to the State while being cognizant that every state and its Medicaid program is unique. Once final decisions are made, NHC demonstrates its wealth of experience and consistency by providing detailed clinical literature reviews and program analytics.

Methods

Clinical Literature Review and Evaluation. Our Team's approach to clinical literature evaluation and analysis is comprehensive and guided by team members' advanced education and training in DUR. Prior to market approval, we track medications of particular interest to Medicaid programs via our internal drug pipeline report. While line extensions and new products within a mature drug class might be tangentially tracked, our primary focus is on first-to-market drugs, or new additions to drug classes that benefit from a competitor. In either case, we recognize that UM of all managed therapeutic classes should be subject to annual reevaluation as part of a QA initiative.

New chemical entities that are approved by the Food and Drug Administration (FDA) and are subject to coverage under the Medicaid program are tracked by approval date and date of market entry. Once a product has been identified, we begin our medication review process to develop a drug monograph or, as needed, a therapeutic class review. Our approach is based on post-doctoral training and is consistent with the guidance set forth by the American Society of Health-System Pharmacists (ASHP) and the Academy of Managed Care Pharmacy (AMCP). The overarching goal of this evaluation is to provide a comprehensive picture of the new product's place in therapy, within the current treatment paradigm, paying close attention to efficacy and safety data. As such, drug monographs are structured, evidence-based documents that are free from marketing influence or bias. They provide a thorough, accurate, and unbiased review developed from a critical analysis of the available primary literature — starting with randomized controlled clinical trials (RCTs) and progressing to nationally recognized clinical guidelines and expert consensus compendia. Any available meta-analyses and manufacturer dossiers may also be reviewed.

Monograph Development. Our Team's drug monographs follow a formulaic approach. We start by listing a summary of drug-specific indicators including brand and generic name, manufacturer name, FDA-approved indications as well as off-label indications supported by the compendia or primary literature, pharmacokinetic data, available formulations, routes of administration, and dosing. A disease state review is then presented, followed by a summary of the relevant data from the drug's pivotal clinical trial, including the number of enrollees, inclusion and exclusion criteria, a description of the intervention and its comparators, and the results of the primary and secondary endpoints along with their associated statistical and clinical significance. Finally, any notable product differentiators, safety data, and the drug's place in therapy is reviewed, culminating in a summary paragraph that presents our recommendations for PDL placement and UM criteria where applicable based on the reviewed clinical and safety data. For products that undergo an abbreviated review, such as new-to-market agents that are similar to other available agents or line extensions, an executive summary may be provided. Alternatively, a therapeutic class review may be provided if the entire drug class or disease state would benefit from a broader review.

Recommendations for UM Programs. We make recommendations for UM criteria (i.e., PAs, QLLs, and SEs) after the development of the drug monograph is complete. At the discretion of the State, this information can be provided to the State Board for consideration when a medication is reviewed for PDL placement. PA criteria are developed based on numerous factors and in consideration of study inclusion criteria, disease states, alternative agents, and the product's place in therapy based on available guidelines. Additionally, the net cost to the State after available rebates is considered, particularly with respect to any SEs or automated "fail first" edits. Lastly,

QLLs are often considered when there are strict upper limits to product dosing, when the product has abuse or diversion potential, or when tiered pricing is at play.

Manufacturer's Forum. Prior to each SAB meeting, our clinical team coordinates, schedules, and attends a manufacturer's forum for companies with drug products being reviewed at the upcoming meeting. The forum provides a venue for drug manufacturers to present their drug's clinical data and ensures that the most up-to-date clinical literature is incorporated and made available for Board review. During the forum, manufacturers are given the opportunity to submit a one-page product summary to be included in the presentation materials provided to the Board.

DUR. DUR is an effective and targeted approach to ensure medication safety in patient populations. DUR focuses on ensuring that medication use is consistent with predetermined, product-specific criteria. Deviations from the specified criteria are flagged for educational intervention. This review provides a comprehensive assessment of a patient's prescription and medical data prior (e.g., prospectively or ProDUR), during (e.g., concurrently or CDUR) or after (retrospectively or RetroDUR) dispensation to ensure patient-specific medication goals are achieved, and preventable or controllable adverse outcomes are avoided. As the focus is educational, DUR programs provide actionable information to prescribers for further review and response to the Medicaid program.

A comprehensive DUR program includes interventions at three points in time:

- **Prospectively.** The evaluation of a patient's drug therapy occurs before the medication is dispensed.
- **Concurrently.** The evaluation of a patient's drug therapy occurs at initiation or during the course of treatment.
- **Retrospectively.** The evaluation of a patient's drug therapy occurs after the patient has initiated therapy.

Prospective DUR. Prospective DUR (ProDUR) occurs prior to dispensation and gives the pharmacist an opportunity to prevent any adverse outcomes before therapy is initiated. ProDUR information is communicated to pharmacists in the form of either soft or hard edits within the real time point-of-sale claims adjudication system. These edits prompt a review of patient information for conflicts in dosing, drug interactions, and drug plus disease state contraindications. Common ProDUR edits include the following:

- Drug – Disease state contraindications.
- Drug – Drug interactions often associated with increasing levels of severity.
- Drug – Patient alerts that may be triggered based on age, gender, pregnancy status, allergies, etc.
- PDL edits that require therapeutic interchange, brand over generic, or generic substitutions.
- Drug abuse or misuse including exceeding morphine milligram equivalents (MMEs) or duplicative therapy.

Concurrent DUR. Concurrent DUR (CDUR) occurs at initiation or during medication therapy and seeks to optimize patient outcomes and prevent adverse effects. Pharmacists can provide prescribers with valuable information to enhance dose optimization and avoid drug-drug interactions or duplicative therapy. Ideally, CDUR should occur when a prescriber transmits an electronic prescription. However, pharmacists may also serve in this role as an additional check in

the system, particularly if they have access to all medication records and up-to-date allergy information. Common CDUR interventions include dose optimization, therapeutic interchange, and over/under utilization.

Retrospective DUR. Retrospective DUR (RetroDUR) occurs after medication dispensation or completion of therapy. The primary goal is to detect and intervene upon prescribing or dispensing patterns that may run counter to patient safety. Based on predetermined criteria of acceptable medication use, educational interventions are developed to provide actionable information to prescribers to improve patient care whether at the individual level or across patient populations. Common intervention types include abuse or misuse; inappropriate duration of treatment; or overutilization and underutilization, including lack of therapy when indicated.

SAB Presentation Materials. To facilitate review with the SAB, our clinical staff compiles a binder of presentation materials that is provided to Board members two weeks prior to each meeting via an encrypted electronic format. The binder contents vary for each meeting and may include meeting agenda, minutes from the previous meeting, product information solicited from drug manufacturers, documents submitted by the State or other stakeholders as allowed per policies, UM criteria recommendations, DUR intervention proposals, pipeline reports, and clinical newsletters. To foster discussion during drug reviews, our clinical staff develops and delivers a visual presentation summarizing the new drug monographs for Board review, including background information, clinical efficacy, place in therapy, and recommendations for UM criteria.

Administrative Services to SAB. In addition to providing clinical review materials, our Team supports the administration of the SAB in several ways. The proposed meeting agenda is sent to the State for approval and posted on the State's website prior to the corresponding Board meeting. We then draft and submit a document listing the new drugs under review for posting on the SAB website. After the drugs under review and agenda documents have been posted, we serve as an intermediary between key stakeholders, the State, and its Advisory Board via a dedicated email address monitored for all inquiries related to the Board meeting agenda. Our staff correspond directly with Board members regarding meeting dates, materials, and member attendance, and collect any relevant conflicts of interest disclosures from Board members to be forwarded to the State.

During the Board meeting, we prepare and distribute meeting handouts to Board members and public attendees and collects conflict of interest disclosure forms from any attendees wishing to speak during the designated time for consumer comment. The meeting minutes are submitted to the State for approval and posted to the State website in accordance with the State's preferred timelines.

Lastly, we can act on behalf of the State to recruit nominees for appointment to the Board pending approval from the State. A nominee may be considered when the State receives written or verbal communication containing the curriculum vitae or resume of a qualified candidate from individuals, representatives of various professional organizations, or academic institutions.

Myers and Stauffer Team member, NHC, has been the incumbent clinical vendor for the state of Georgia, having served its Advisory Board since 2006. This clinical team has 30 years of combined Georgia Medicaid-specific experience. NHC provides clinical leaders to support the State's program who have assisted more than 15 state Medicaid programs in various capacities. Emily Baker, PharmD, BCPS, President and CEO of NHC, has significant experience with Medicaid programs

and has accumulated over 23 years of experience as a clinical pharmacist, of which 17 years are specific to the state of Georgia. Chad Nicholson, PharmD, NHC's Director of Clinical Programs, has been assigned to service the Georgia Medicaid program and has been interfacing with the State's team for nine years. The team is further supported by additional clinical pharmacists with extensive Medicaid and SAB experience.

Additionally, we highlight below several other recent engagements that demonstrate the Team's experience supporting stakeholder groups comparable to the SAB:

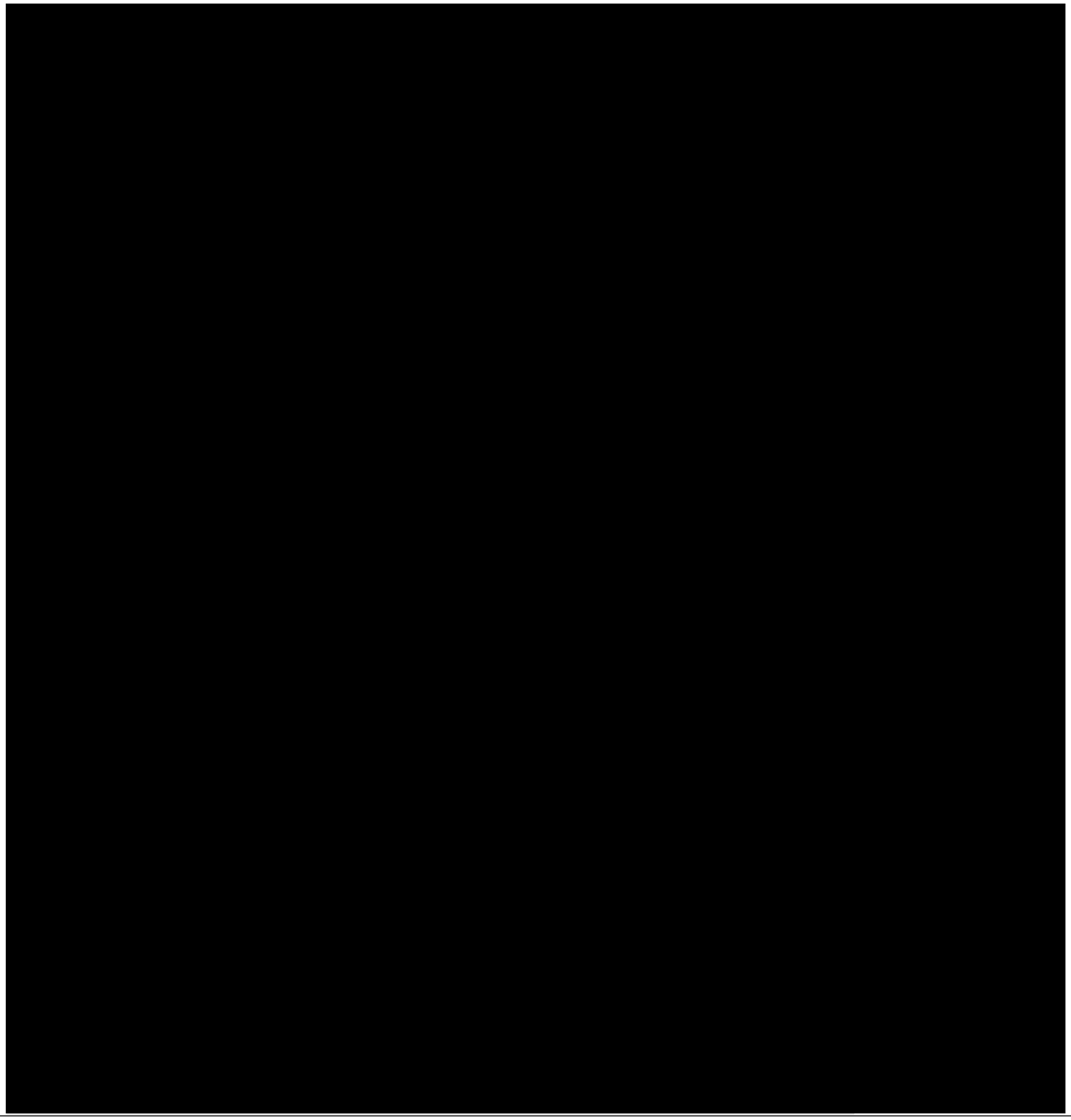
- Oregon Department of Consumer and Business Services (DCBS). Myers and Stauffer provides consultation, facilitates stakeholder engagement, and performs analytical services to assist the Oregon Prescription Drug Affordability Review Board in developing a plan to establish an upper payment limit for high-cost drugs in Oregon.
- North Dakota Department of Health and Human Services (DHHS). Myers and Stauffer developed a steering committee comprised of department directors for Medicaid, Aging Services, Children's Services, and Developmental Disabilities Services. The committee convened monthly throughout the engagement to advise on a home and community-based services (HCBS) rate study for Medicaid and the Children's Health Insurance Program (CHIP).
- Nebraska Department of Health and Human Services (DHHS). Myers and Stauffer are working with DHHS to create a comprehensive transformation of its service offerings, methodologies for tracking data, and ongoing QA measures. Stakeholders include cabinet members, department directors, division administrators, program chiefs, advocates, families, and recipients.

MSQ2.1 – Sample HIV Clinical Drug Monographs

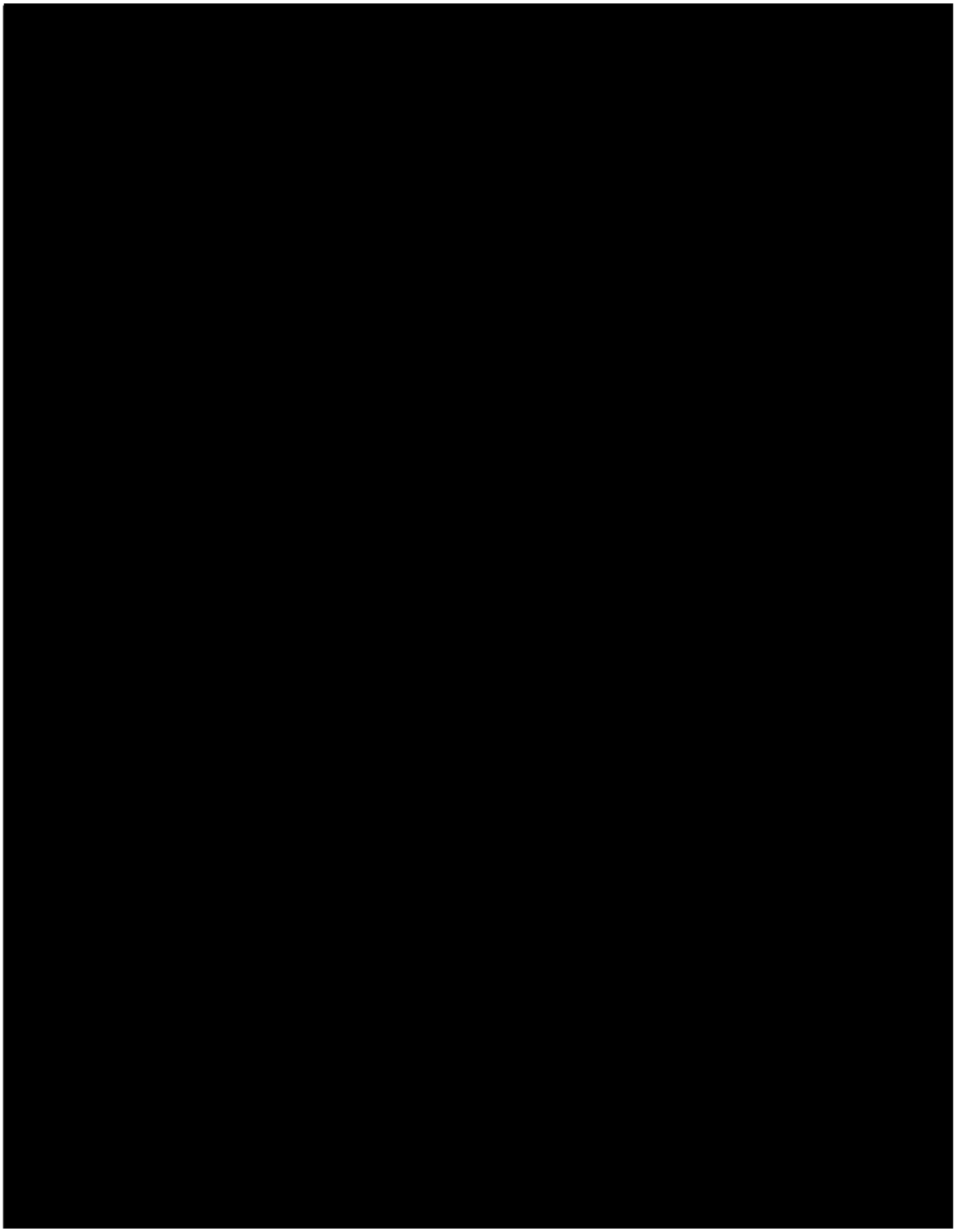
On the following pages, we have included two samples of HIV Monographs. Please note that these are confidential and should not be distributed publicly.

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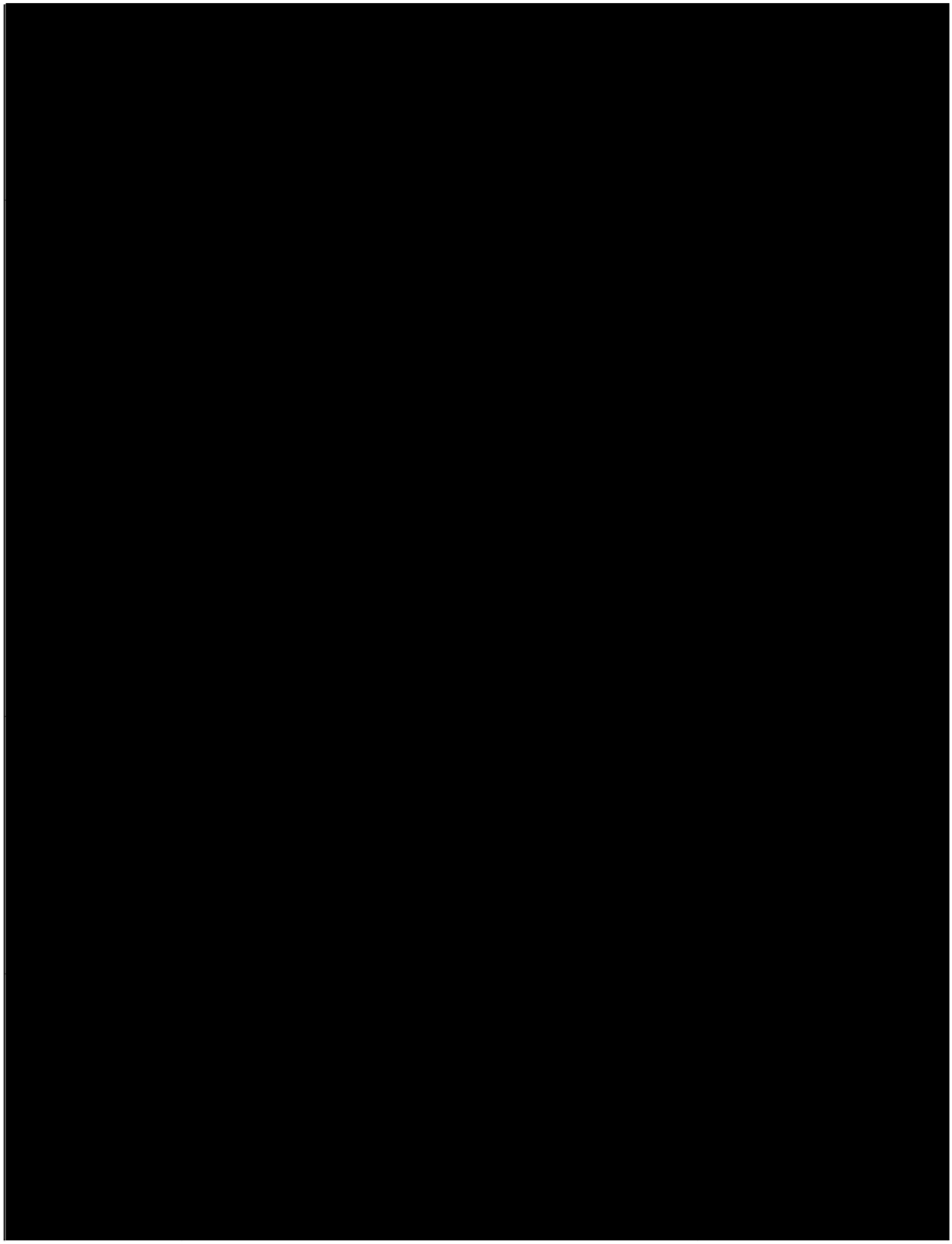
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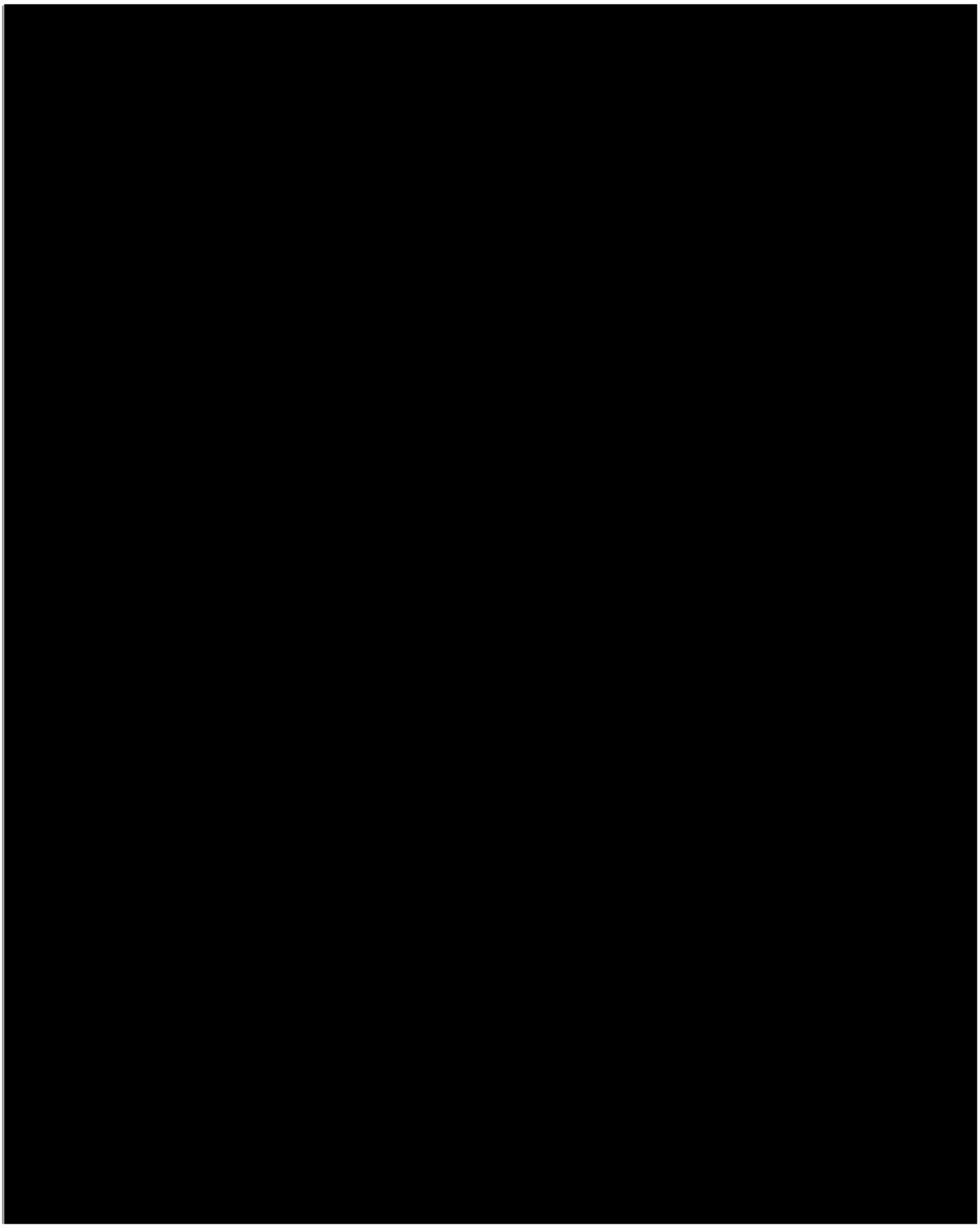
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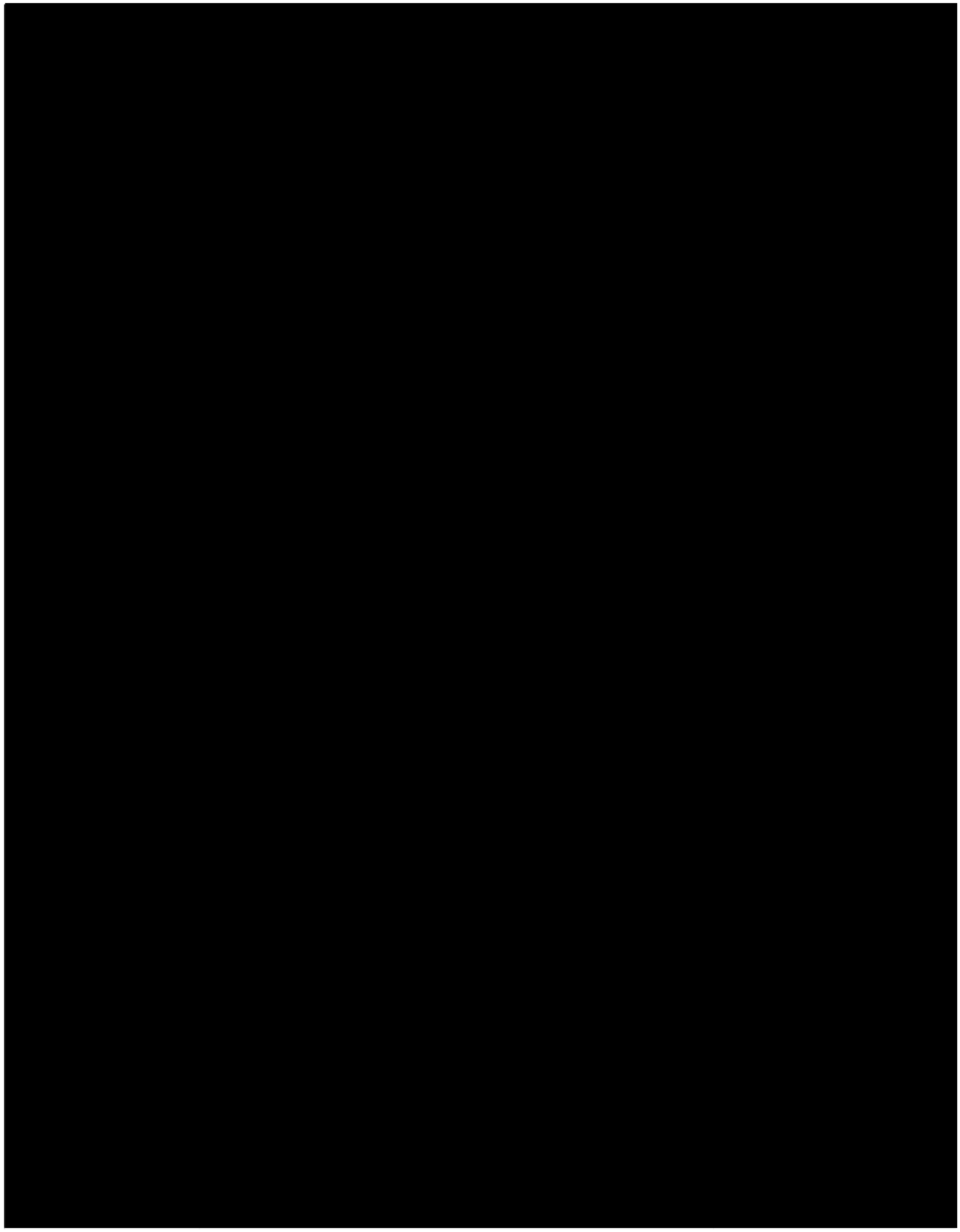
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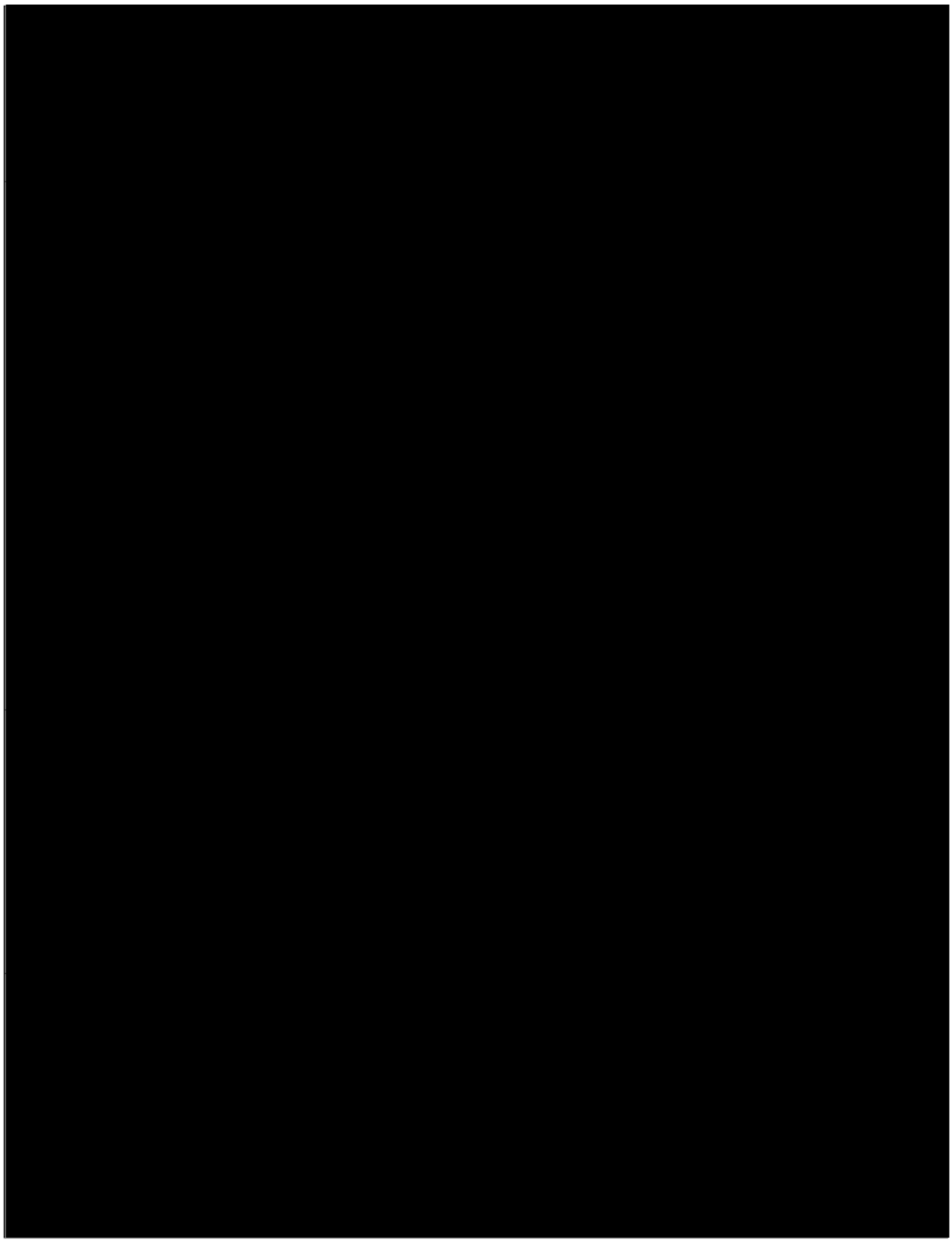
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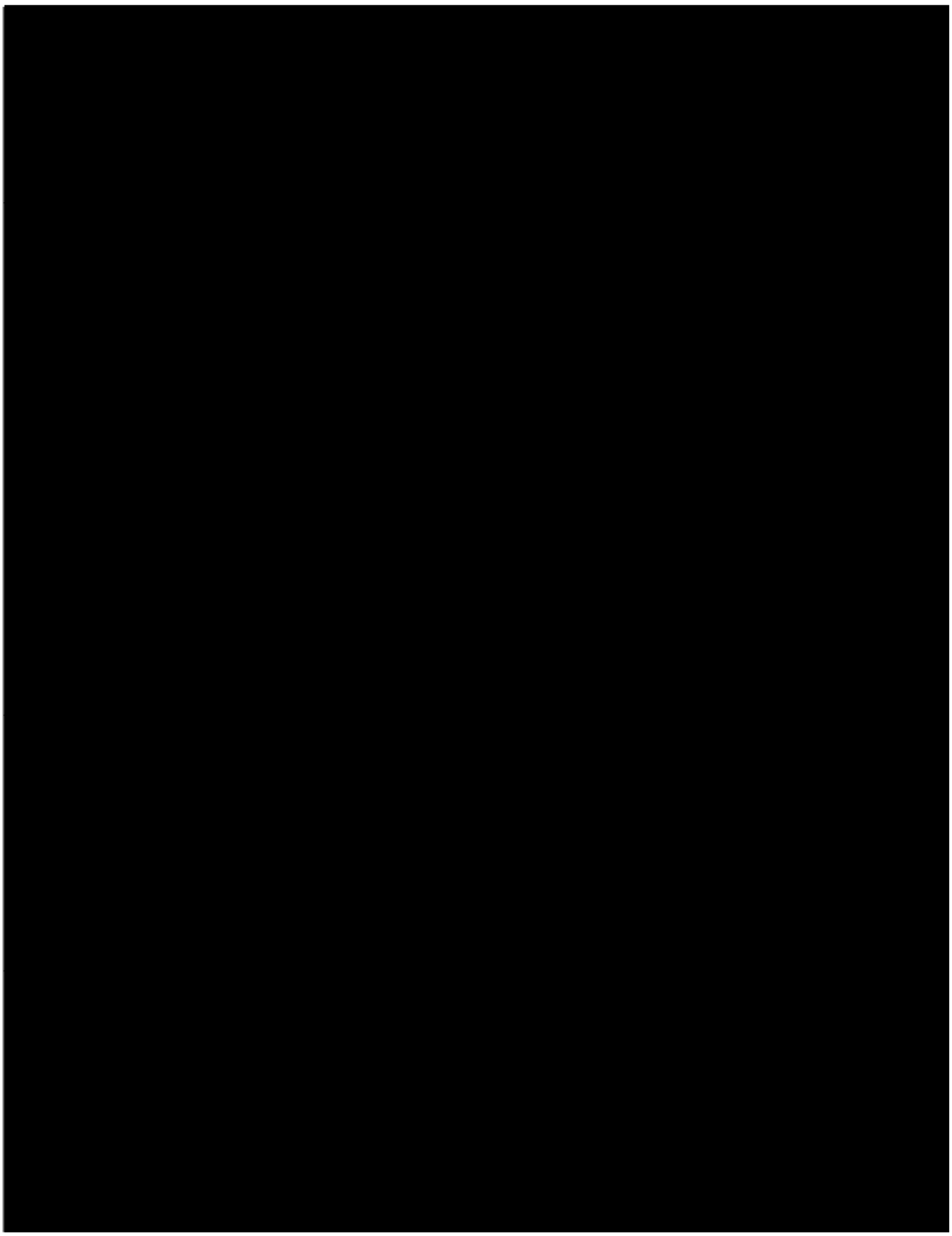
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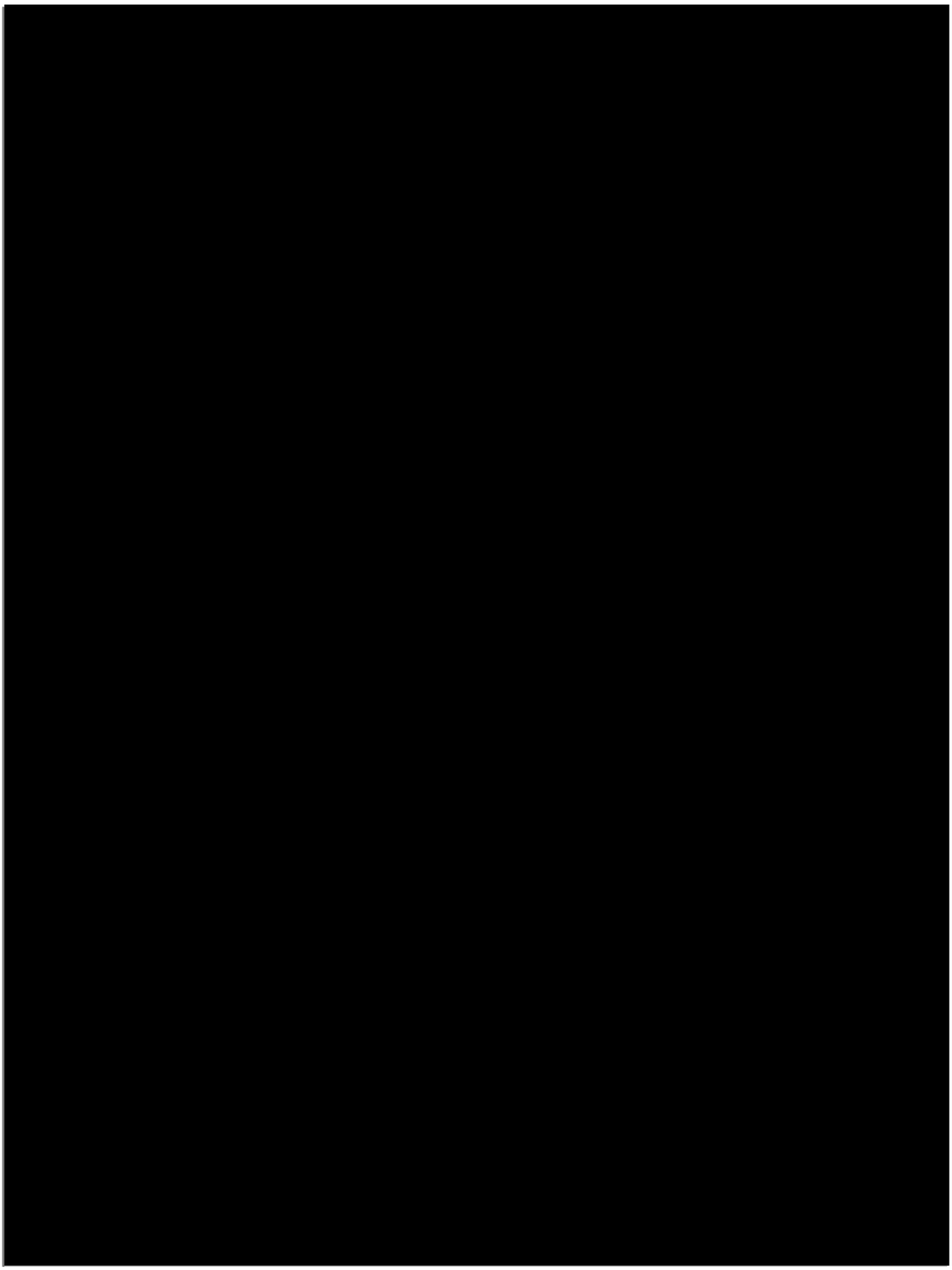
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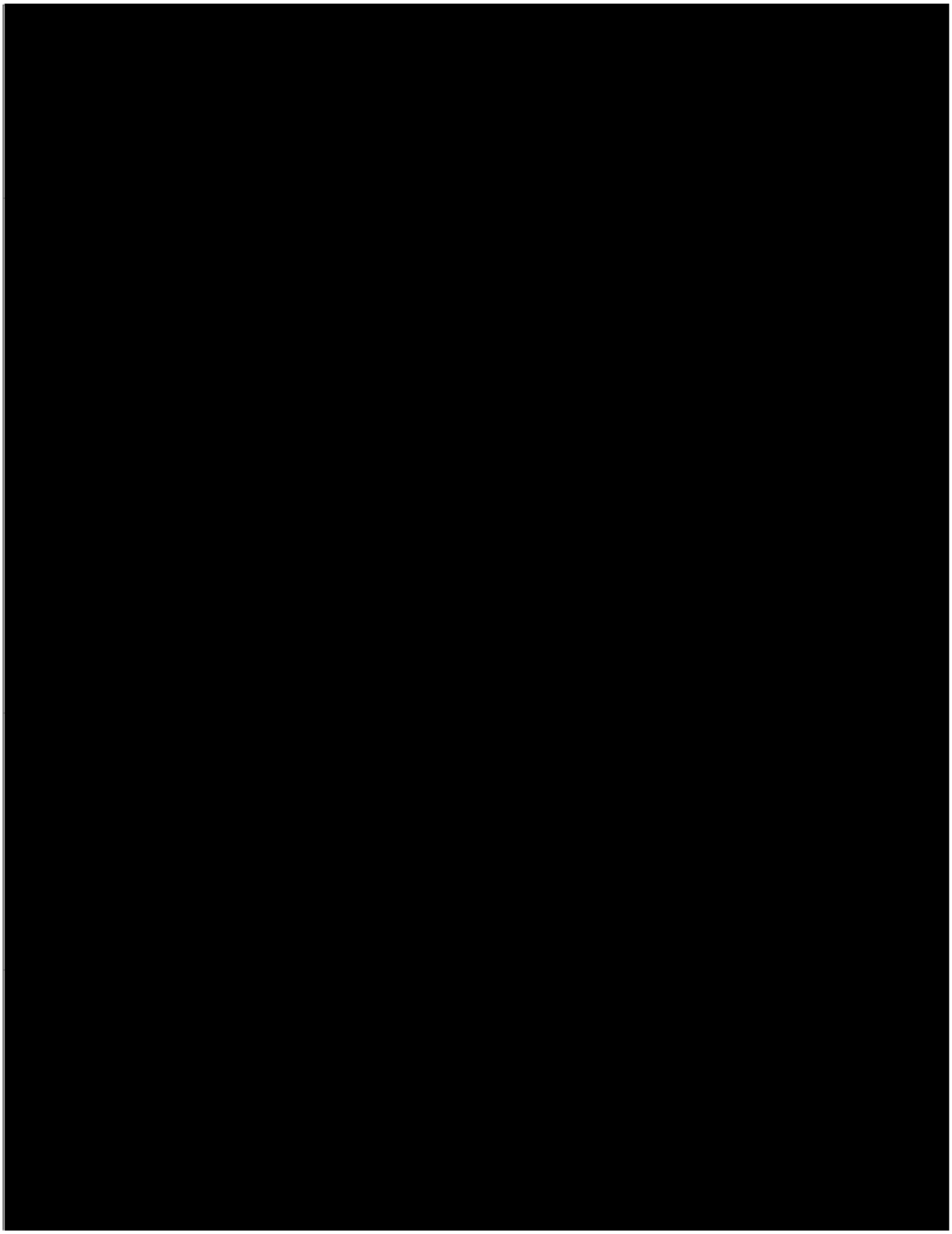
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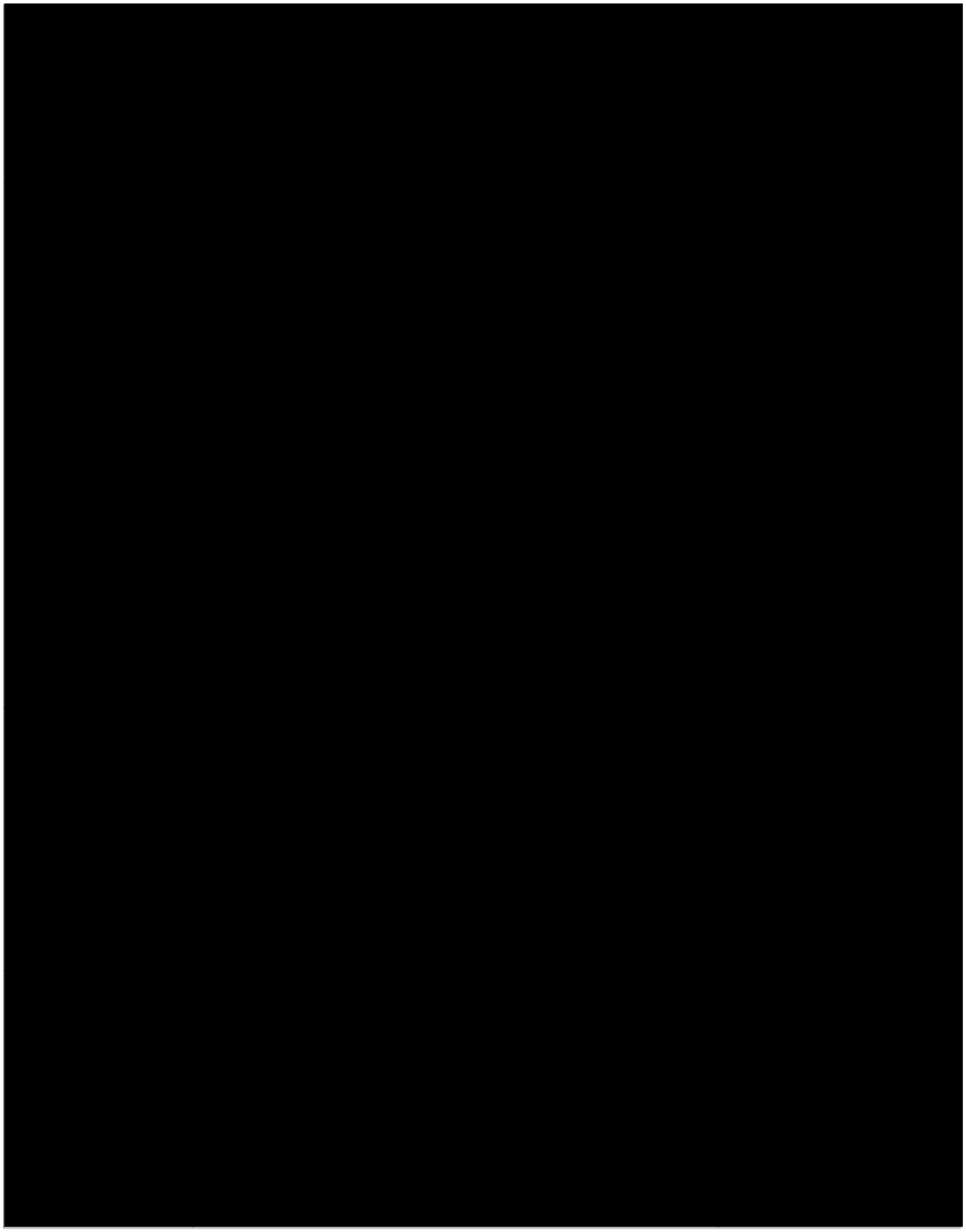
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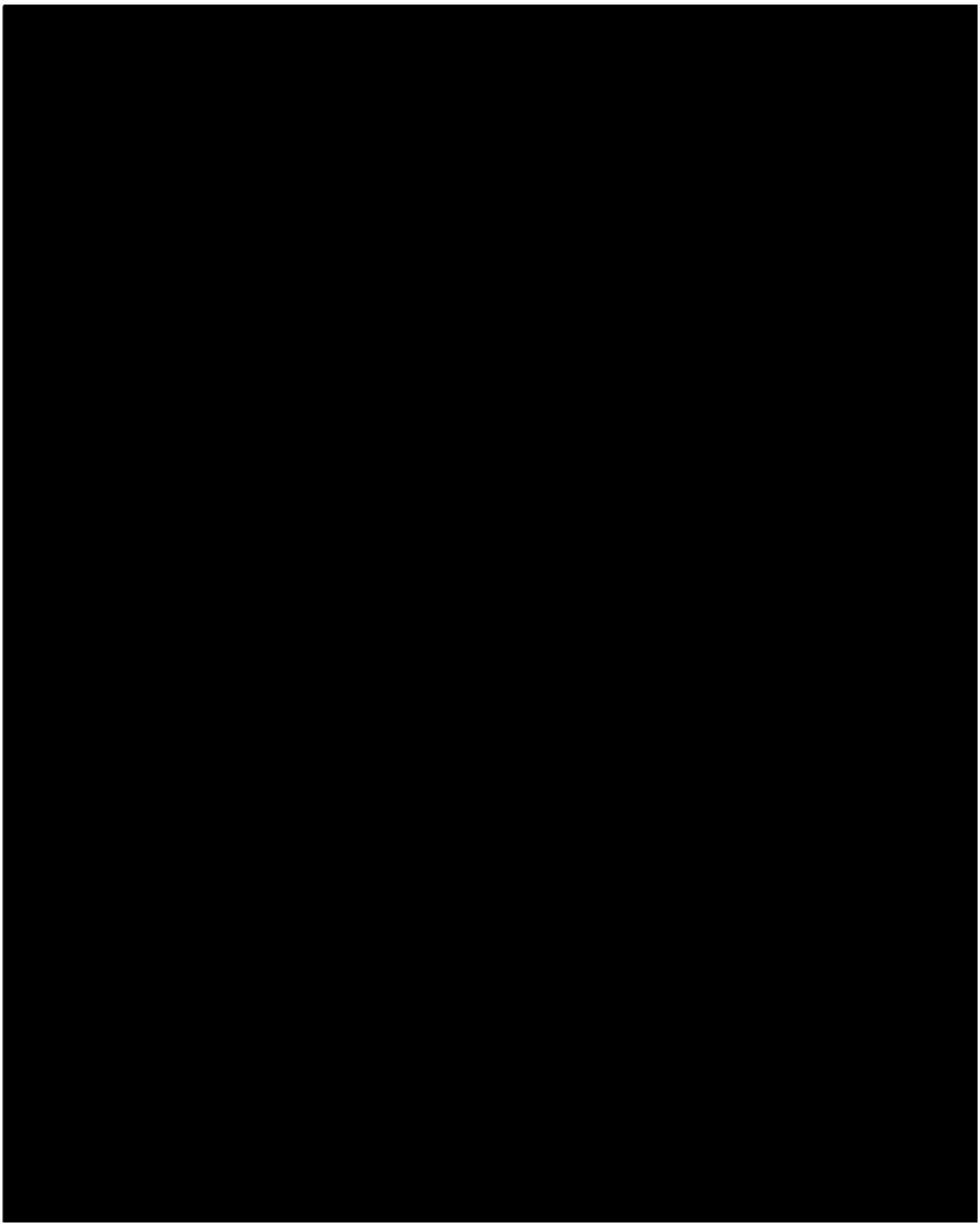


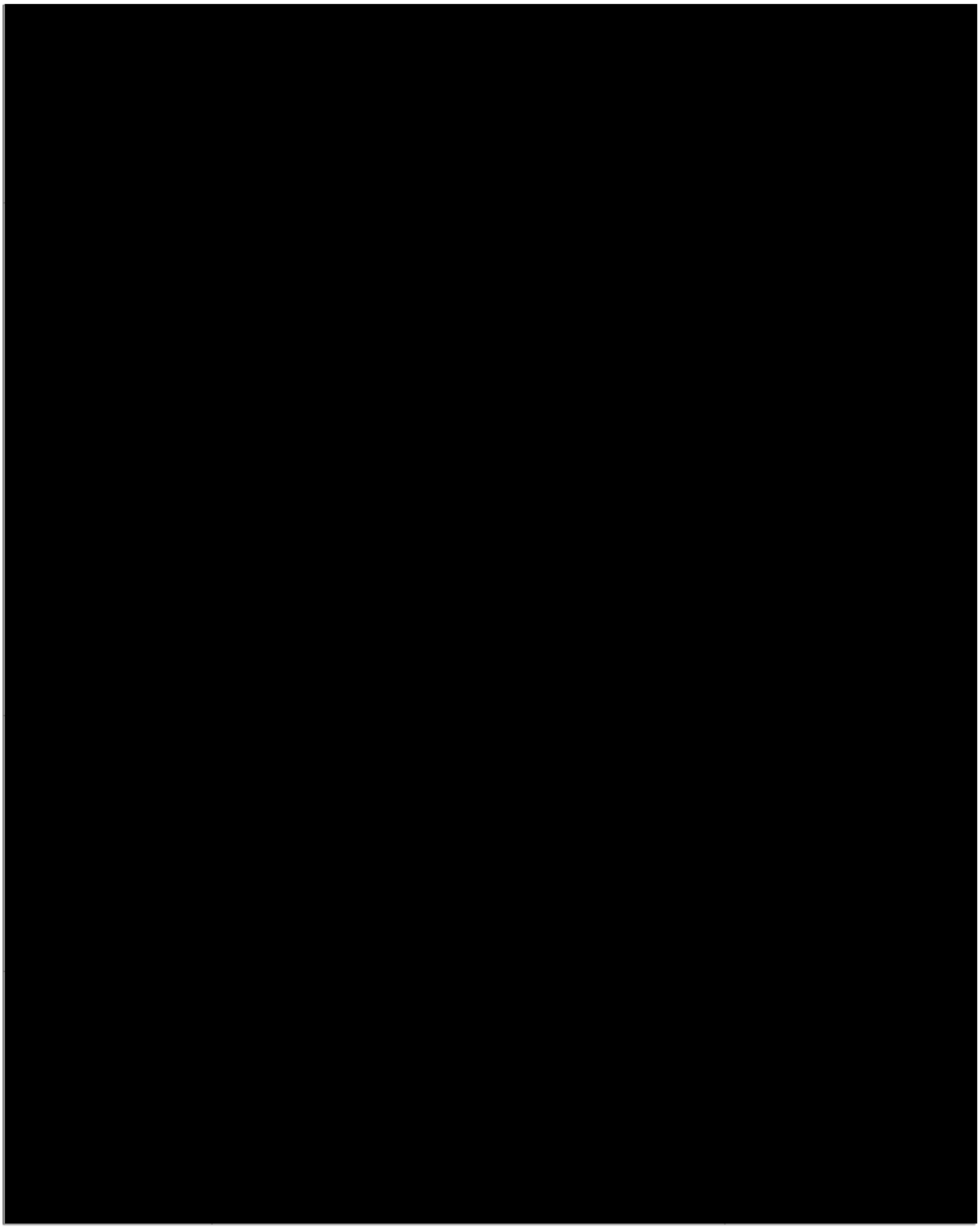
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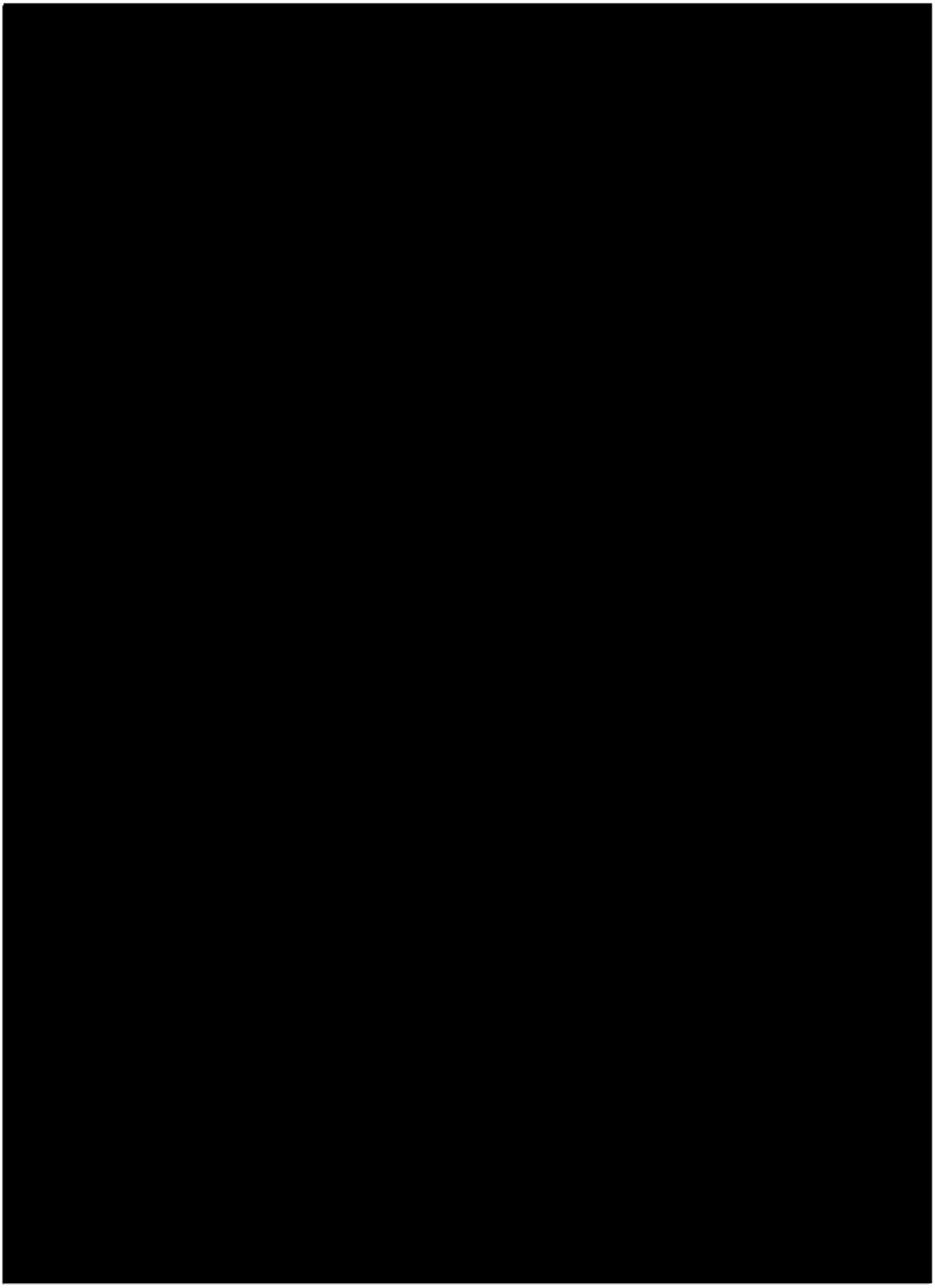
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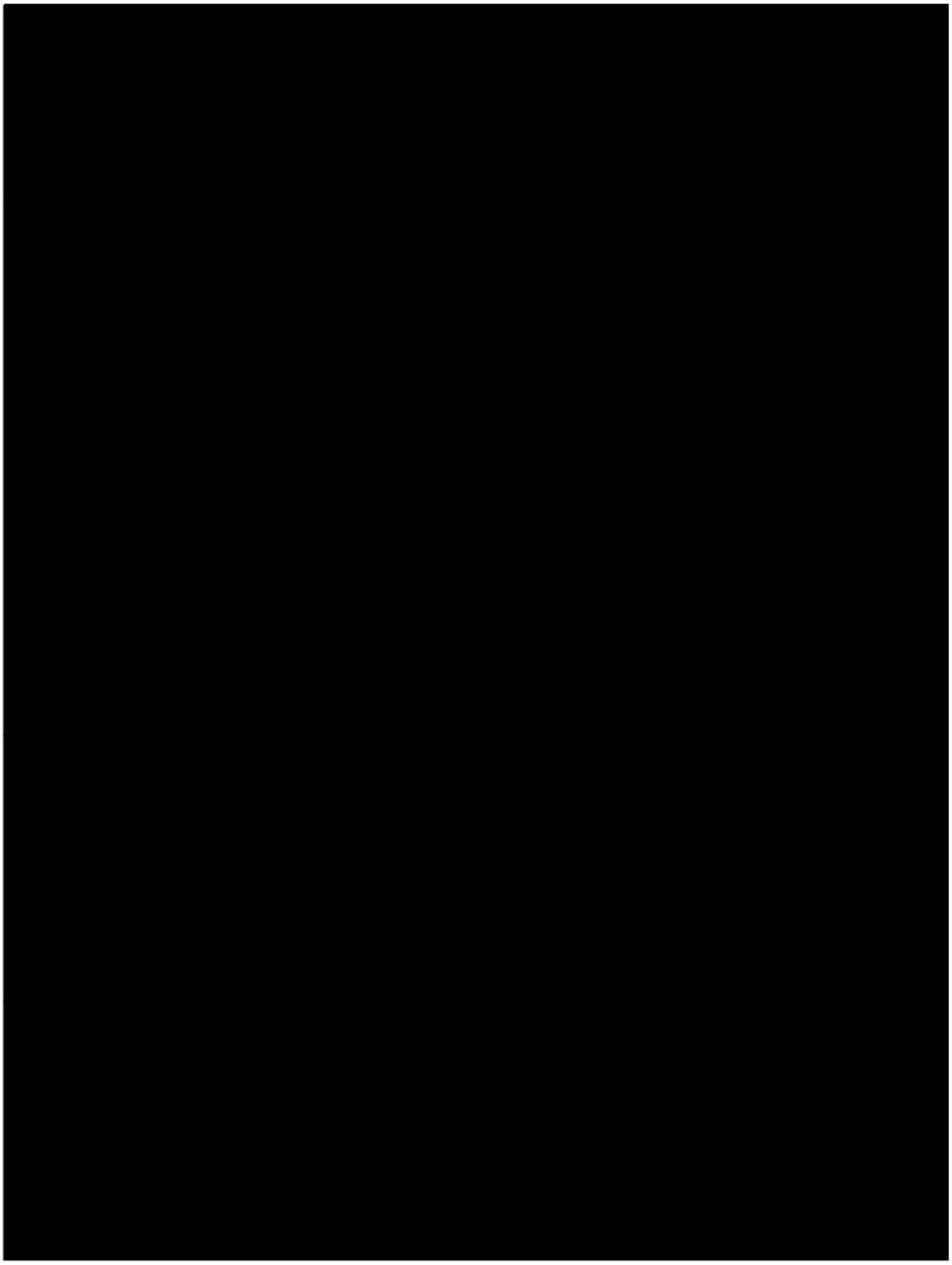
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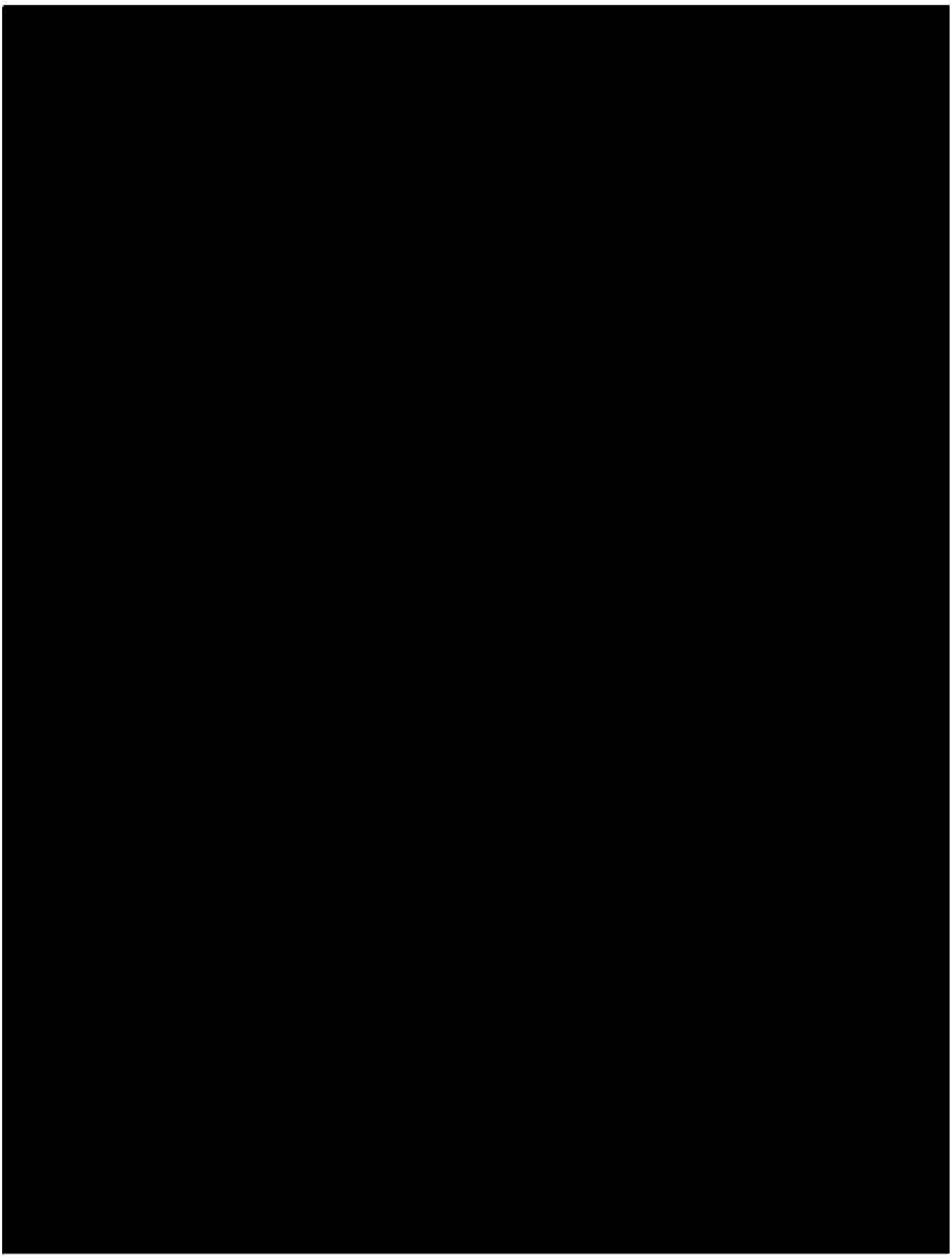
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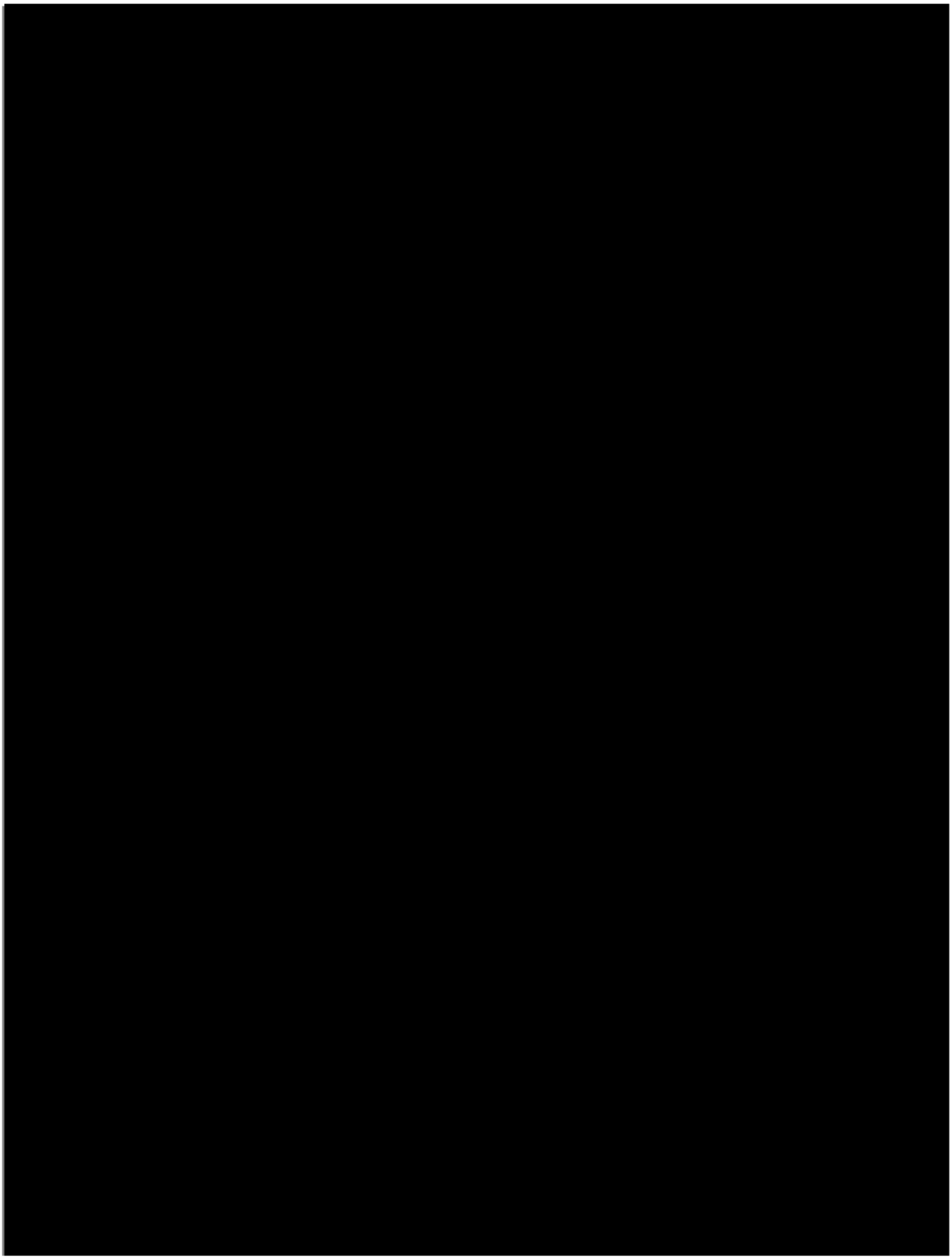


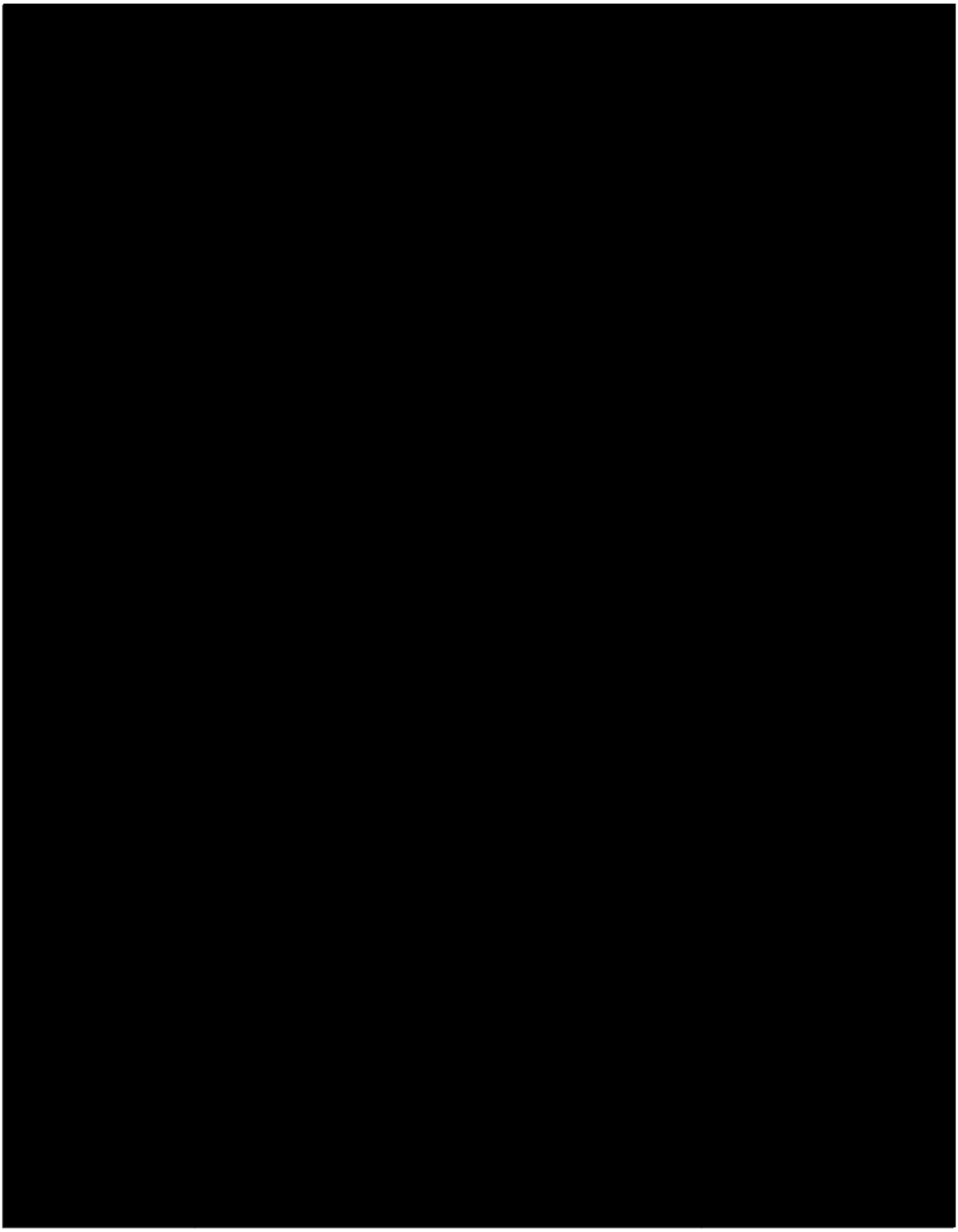
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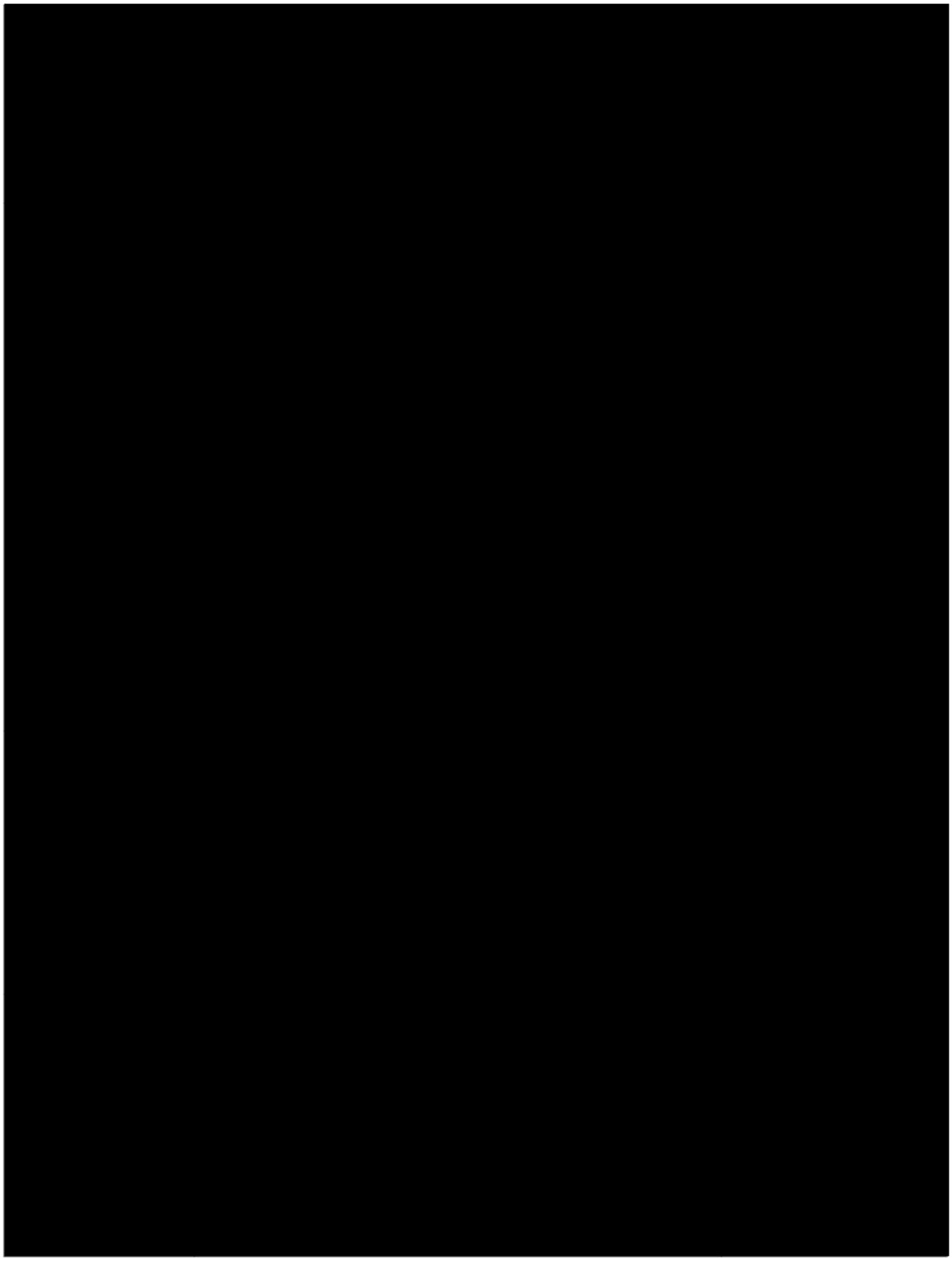


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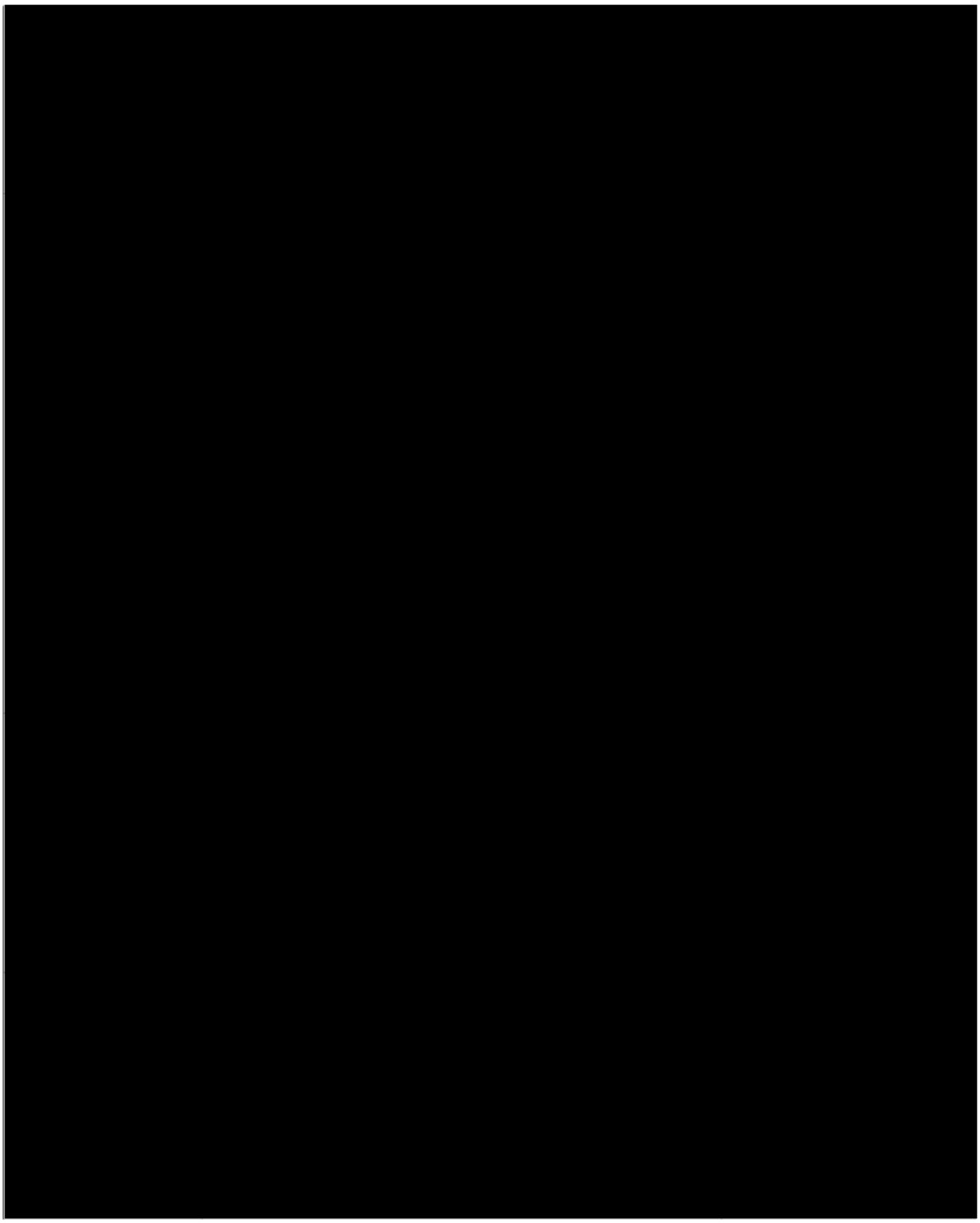


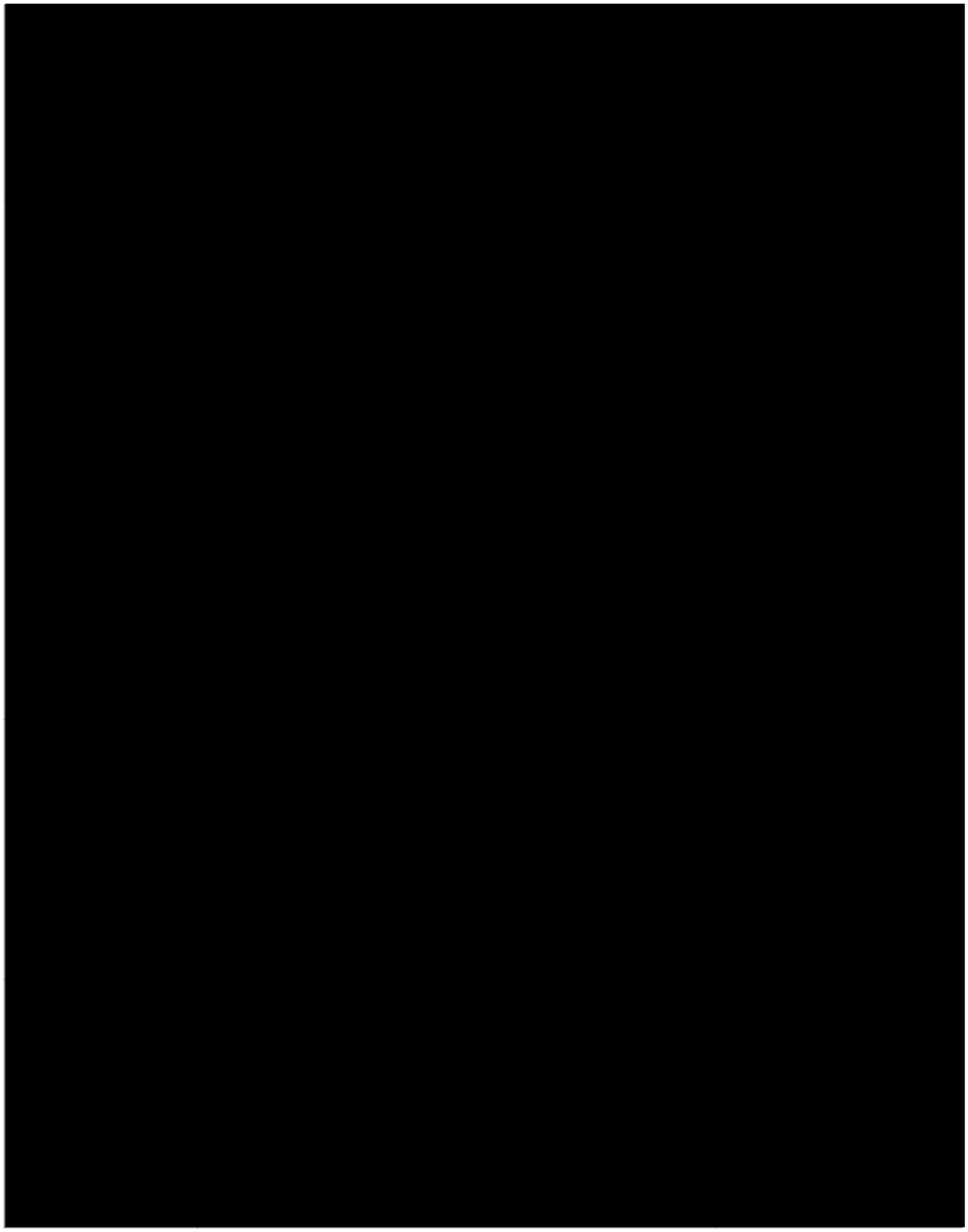




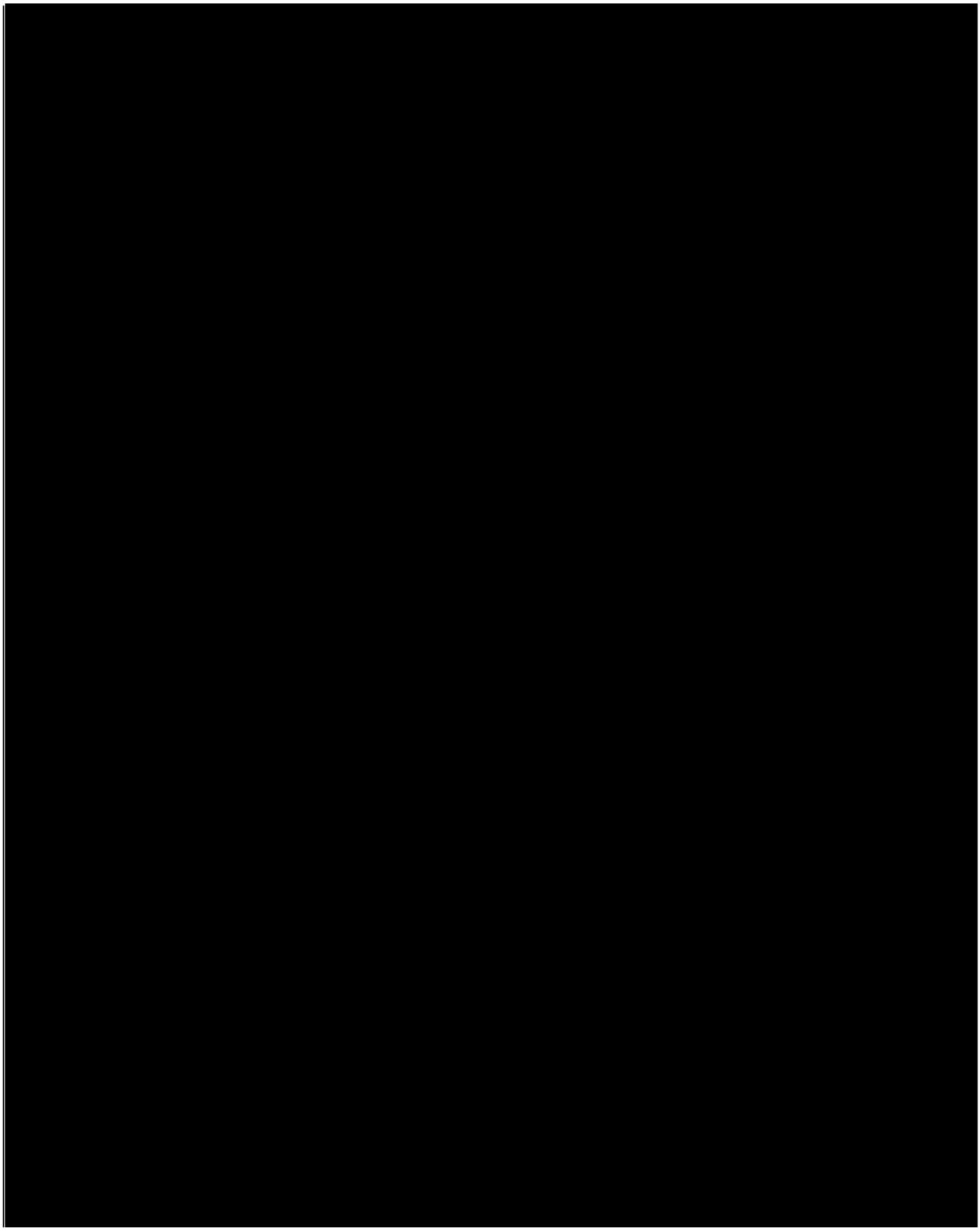


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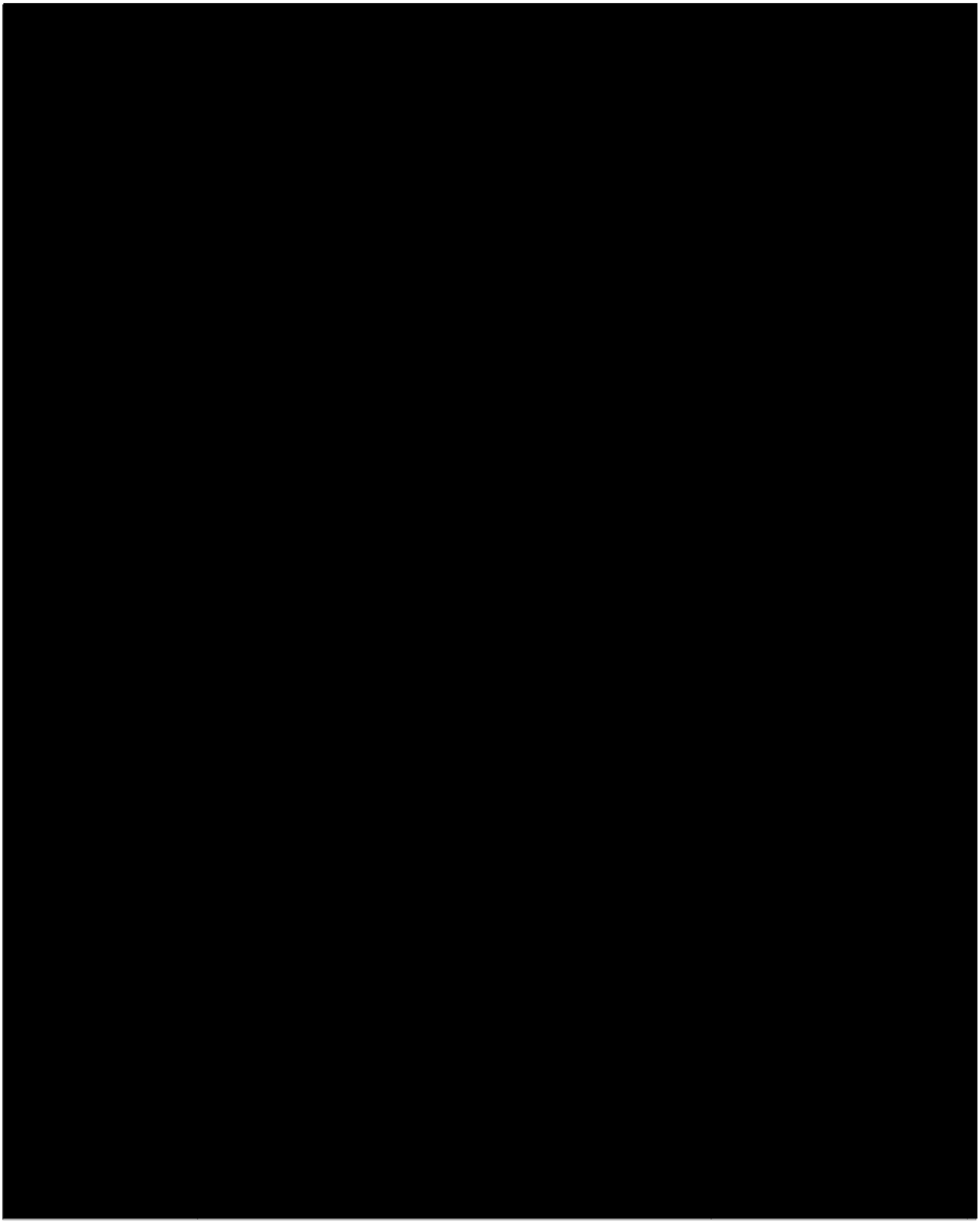
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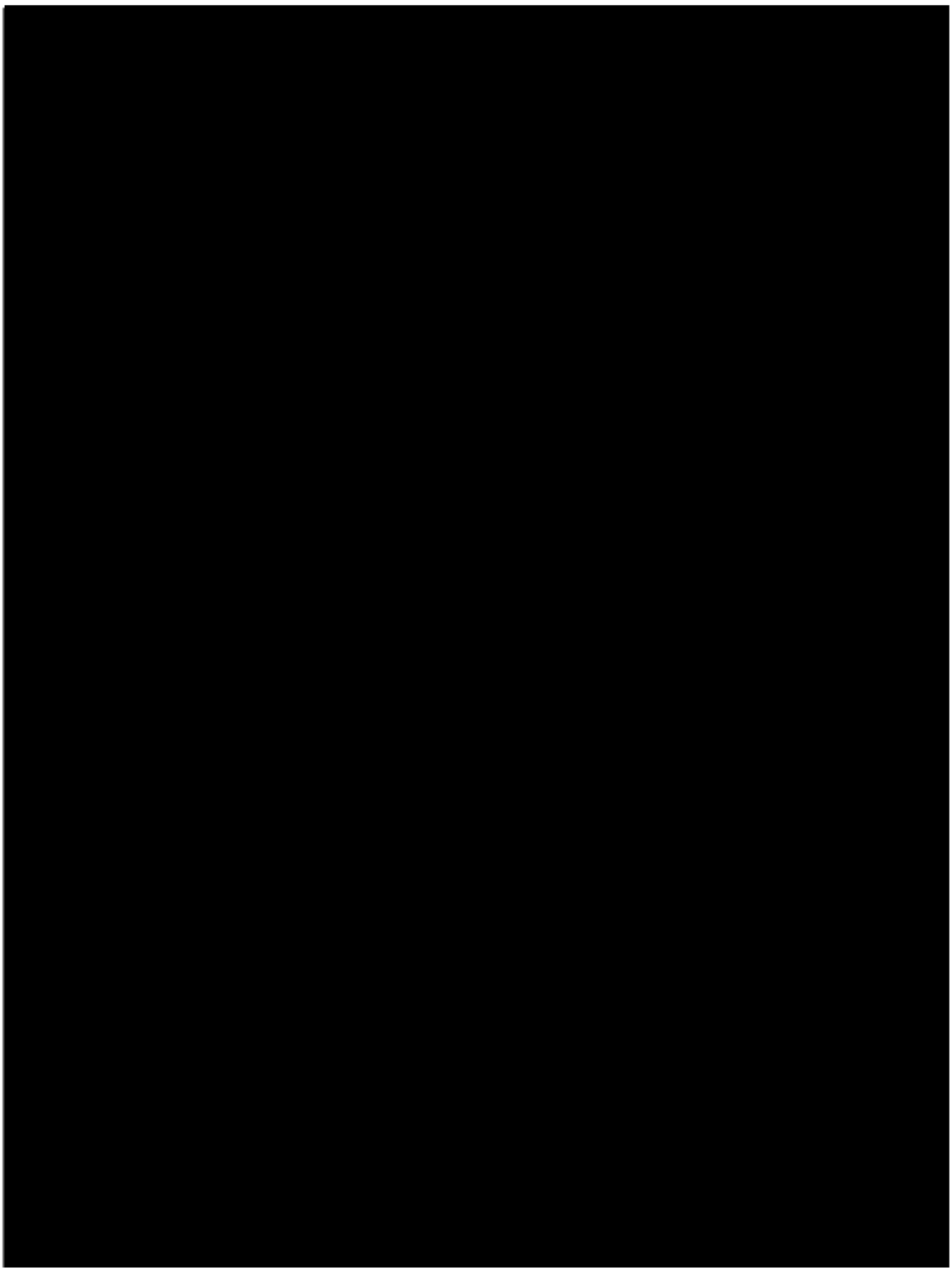
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3.	Bookmark Title: MSQ3 – Utilization Management Program Approach Bookmark Title for Supporting Material: MSQ3.1 – QLL Utilization Management Criteria Narrative description is limited to four (4) pages, not including the required supporting material. 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

MSQ3 – Utilization Management Program Approach

UM is a critical component of any Medicaid program. It requires both clinical knowledge and extensive experience to craft a customized solution to ensure appropriate prescribing and prevent excessive medication use within a State's unique provider and patient population. The Team's suite of UM offerings include: PA criteria, SEs, QLLs, and PDL development and maintenance. Each of these tools are designed to promote appropriate clinical usage, contain costs, and avoid waste and diversion.

The Team's robust clinical approach to UM criteria development starts with our team of experienced clinicians. Our development of a customized UM approach involves review and analysis of primary clinical literature, clinical trial design, prescribing information, product monographs, nationally recognized guidelines, expert consensus statements, and internal advisory relationships with State-approved specialists. We then draft clinically appropriate criteria for review by the State and the SAB based on our experience and clinical training. This process is performed for each new product, when new indications are approved for existing products, and often occurs concurrently with drug monograph development for PDL review and inclusion. Included in our review are QLLs, SEs, and PDL placement to ensure appropriate utilization when warranted.

The Team adheres to the State's policy regarding the length of time a product is required to be on the market prior to its eligibility for review by the SAB. For DCH, the Team will support the State's six-month eligibility requirement before SAB review; however, the process is adaptable to support any state agency's requirements. On a rolling annual basis, the Team will review and update criteria as needed and perform frequent reviews in response to significant developments within a drug class or disease state. Additionally, the Team has experience fostering collaborative relationships with states' rebate vendors and assisting the state with fiscal modeling, including break-even analyses. Partnering with a state's rebate vendor allows us to ensure criteria recommendations align with supplemental rebate contracting, thus ensuring recommendations to the State are prudent from both a clinical and a fiscal perspective. More recently, our Team member, NHC, has assisted the State with ensuring value-based contracting language, which was designed to be compatible current UM criteria. Additionally, through the Team's regular work in analyzing and developing state and federal drug pricing files, we are able to quickly identify products that provide only limited value. In such cases, the Team will recommend appropriate UM criteria that support the State's PDL process.

Once an in-depth product review has been completed, the Team will submit the proposed UM criteria to the State and the SAB if applicable. Included in the UM criteria proposals which we will submit to the State will be draft PA criteria which incorporates any FDA-approved indications as well as off label indications if applicable, clinical study results and inclusion criteria, and other pertinent clinical information that demonstrates the justification and rationale for our recommendation. All criteria and UM recommendations will be referenced when possible. If applicable, QLLs will be embedded within PA criteria or may be recommended even if a product does not require pre-approval. SEs may also be proposed and will be developed and detailed in a format similar to the creation of PA criteria. Depending upon the structure of the review and approval process for each state, the Team may present our recommendations during SAB meetings or directly to the State. To facilitate this portion of the process, the Team will utilize an automated workflow tool wherein the State conducts a review and provides final approval of any additions or updates to the UM program.

Once a final decision and approval of proposed UM criteria has been made by the State, we will draft PA criteria as applicable for posting to the State's website. The purpose of the web-based criteria is to provide a general overview of the clinical rationale and approval requirements. This high-level summary serves as a guide to stakeholders and providers to assist with optimization of therapy. Additionally, web posting of the UM criteria may serve as a contractual requirement for supplemental rebate purposes. The Team can also provide criteria in a decision tree format to assist with the decision-making process and to ensure consistency across PA reviewers. Any approved or updated QLLs and/or SEs will also be communicated to the pharmacy benefits administrator (PBA) for notation on the PDL and applicable system coding. Additionally, QLL criteria will be updated and included within a referential document for providers.

Our clinicians have experience with multiple Medicaid programs and are aware that all programs have unique characteristics reflective of the state and its population. As such, we will customize our approach to UM development and management to meet each state's requirements and will maintain and adhere to state-specific policies and procedures for the development, implementation, and execution of UM programs. Based on our efforts with other states, applying our methodology for UM program design has resulted in the successful implementation and execution of effective UM strategies for rebateable products typically covered under the outpatient drug benefit, including either existing products or products that are new to the pharmaceutical marketplace. The Team also offers additional experience and expertise in crafting effective UM strategies to address Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; physician-administered drugs (PADs); compliance with Early and Periodic Screening, Diagnosis, and Treatment requirements; and products that can be subject to "white bagging" or "brown bagging," both of which create an increased risk to the State for duplicative claims.

For example, the Team has successfully reviewed utilization data and available information in drafting proposed UM criteria for the following products:

- Continuous glucose monitors.
- Ventilation devices.
- Leg stretchers.
- Metabolic formulas.
- Gene therapies.

Our efforts continue beyond approval of a UM approach. As needed by the State, our Team will ensure the availability of qualified members of the Team who have been intimately involved in developing the UM criteria at any meetings as required by the State. We will further assist the State with responding to inquiries and complaints from stakeholders.

MSQ3.1 – QLL Utilization Management Criteria

The following document represents a summary of the process used to develop QLLs and to define clinical exceptions for exceeding established QLLs through a PA process.

Policy and Procedure: Quantity Level Limit (QLL) Exception

Requestor:	State
Creation Date:	December 22, 2022
Last Reviewed:	January 2023
Approved Date:	February 2023
Created By:	Lead Pharmacist

Policy Type: Prior Authorization Criteria
Policy Name: Quantity Level Limit (QLL) Exception
Requestor: State Fee-For-Service Medicaid
Length of Authorization: 12 months; 3 months for loading dose or titration
Description:
Quantity Level Limits (QLL) are established based on: • **Dosage recommendations from FDA-approved product labeling or CMS-approved compendia for off-label use** • **Commercially available dosage strengths and duration of therapy in clinical practice** • **Dose efficiency, which advises the use of a single higher strength drug rather than multiple lower strength drugs** **The prior authorization process allows prescribers to submit exception requests for review if there is sufficient clinical justification to exceed established quantity limits. These requests will be reviewed based on the criteria below.**
Criteria for Exceeding Quantity Level Limit (QLL):
❖ **Requests to exceed established Quantity Level Limits (QLL) are approvable when *all* of the following conditions are met:** i. **The patient has an FDA-labeled indication or an off-label indication that is supported in CMS approved compendia for the requested medication** ii. **<u>One</u> of the following:** a. **The requested dose cannot be achieved with a lower quantity of a higher strength that does not exceed the plan quantity limit** b. **The patient is being prescribed a drug dosed by weight or body surface area and requires a greater quantity to achieve the appropriate dose** c. **The patient has a documented history of treatment failure with the requested drug being prescribed within plan quantity limits** d. **The request is for continuation of therapy on the requested dose where patient is stable and not experiencing any adverse side effects**

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e. The request is for a temporary loading dose or dose titration
iii. The prescriber has provided clinical literature in support of therapy with a higher dose for the requested indication

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

MSQ4 – Utilization Management Criteria Structure

As a part of the Team's approach to the UM Program, the structure of the UM criteria provides a foundational guideline for the provision of the most appropriate utilization of included products. Our approach was crafted based on post-doctoral training in drug literature evaluation and formulary management coupled with decades of experience working with Medicaid FFS and managed care programs. Encompassed within Team members' training were principles derived from Primers in Formulary Management from the American AMCP and the Principles of a Sound Drug Formulary System from the ASHP. As such, our approach to UM criteria development and presentation is stepwise and incremental, and is presented to our clients in a logical format that has been standardized over the years based on best practices derived from our clinical engagements from other Medicaid programs.

The development of UM criteria commences with the identification of new medications or new indications of existing products. These discussions typically occur during weekly meetings with the PBA vendor and the client.

Upon identification, new products will be evaluated comprehensively to provide a robust and inclusive recommendation to the State and the SAB regarding the product's place in therapy and its appropriate utilization. As a part of our evaluation, the Team will conduct a total class review to assess comparator products for efficacy, medical appropriateness, quality of life, safety, and cost.

After completing this assessment, the Team will develop a new drug monograph. The monograph will be presented to the State and SAB to facilitate discussions and inform decisions regarding PDL placement, physician-administered drug list (PADL) placement, QLLs, SEs, and UM criteria. The structure of our drug monographs, and by extension any resulting UM criteria, follows a stepwise

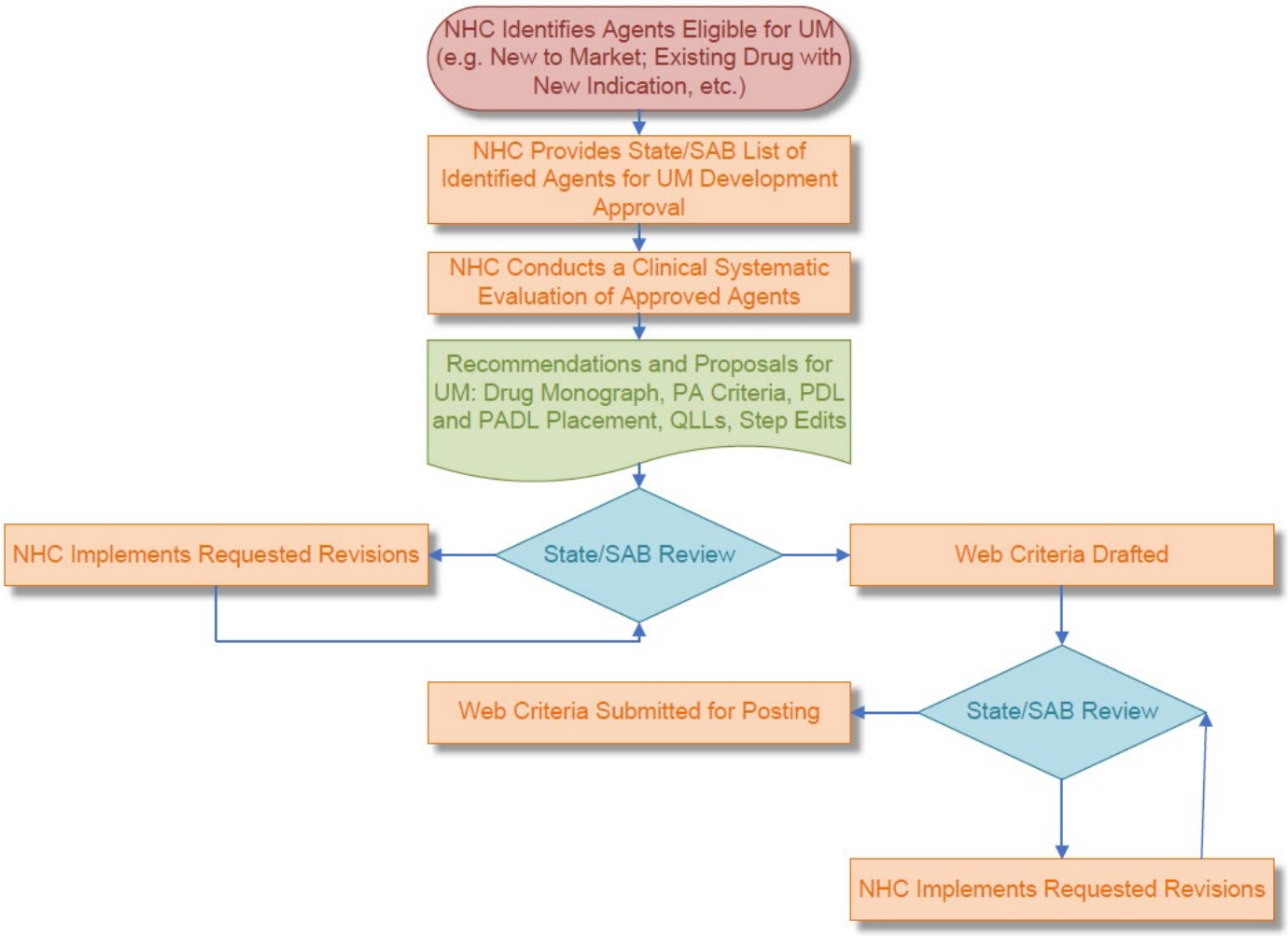
approach. This structure includes three main sections: background information, safety and clinical efficacy, and interpretation and application of the available data to the covered patient population.

Background information contained in a drug monograph may include the brand and generic name of the product, FDA approval and market availability dates, the manufacturer, indication, and the available strengths and formulations. The second section focuses on clinical and safety data and typically begins with a disease state review followed by safety data which is often summarized from package labeling and pivotal trials. The clinical efficacy is presented in a tabular format and relies on primary literature that meet the pre-determined criteria for monograph inclusion. Summaries of selected RCTs will focus on study design including primary outcomes and statistical outcomes. Finally, the third section will focus on interpretation and application of the previous information, including place in therapy, recommendations for UM criteria (PA criteria, QLLs, SEs), and a summary paragraph referencing PDL placement.

As UM criteria is determined for new products, existing criteria for comparator products will be simultaneously reevaluated and updated as needed. All UM criteria will be developed and submitted for approval to the State in two formats. One version will be formatted for posting on the State's website to provide stakeholders with a general idea of how the product is managed by the State. A second version will be formatted as an algorithm-based criteria for use in coverage determinations by the PBA vendor's call center.

Throughout the life of the contract, the Team will review all UM criteria on a rolling annual basis. As needed, the annual review will include updating UM algorithm criteria for each therapeutic class, any UM form, and web-based UM criteria. Any resulting updates will be finalized and submitted to the State for review, approval, and posting.

MSQ4.1 – Utilization Management Process Visual



MSQ4.2 – Utilization Management Algorithm Examples

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PA Criteria Category/Drug: HIV-AIDS

Length of authorization: Varies

Medications

PDL Status	
Preferred (may not be all inclusive)	**Non-Preferred**
Abacavir generic	Abacavir/lamivudine/zidovudine generic
Abacavir/lamivudine generic	Aptivus (tipranavir)
Atazanavir capsules generic	Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)
Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)	Fuzeon (enfuvirtide)
Cimduo (lamivudine/tenofovir disoproxil fumarate)	Intelence (etravirine)
Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate)	Invirase (saquinavir)
Descovy (emtricitabine/tenofovir alafenamide)	Lexiva (fosamprenavir)
Dovato (dolutegravir/lamivudine)	Nevirapine extended-release generic
Edurant (rilpivirine)*	Norvir Solution (ritonavir)
Efavirenz tablets generic	Pifeltro (doravirine)
Efavirenz/emtricitabine/tenofovir disoproxil fumarate generic	Reyataz Powder (atazanavir)
Emtriva (emtricitabine)	Rukobia (fostemsavir)
Epivir solution (lamivudine)	Selzentry (maraviroc)
Evotaz (atazanavir/cobicistat)*	Stavudine generic^
Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide)	Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate)
Isentress and Isentress HD (raltegravir)*	Sunlenca tablets (lenacapavir)
Juluca (dolutegravir/rilpivirine)	Symfi (efavirenz 600 mg/lamivudine/tenofovir disoproxil fumarate)
Lamivudine generic	Symfi Lo (efavirenz 400 mg/lamivudine/tenofovir disoproxil fumarate)
Lamivudine/zidovudine generic	Temixys (lamivudine/tenofovir disoproxil fumarate)
Lopinavir/ritonavir generic	Viracept (nelfinavir)
Nevirapine immediate-release tablets generic	
Norvir Powder (ritonavir)	
Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide)*	
Prezcobix (darunavir/cobicistat)*	
Prezista (darunavir)*	
Ritonavir tablets generic	
Sustiva capsules (efavirenz)	
Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide)	
Tenofovir disoproxil fumarate generic	
Tivicay (dolutegravir tablets)	

Tivicay PD (dolutegravir tablets for oral suspension)*	
Triumeq (dolutegravir/abacavir/lamivudine)	
Triumeq PD (dolutegravir/abacavir/lamivudine tablets for oral suspension)	
Trizivir (abacavir/lamivudine/zidovudine)	
Emtricitabine/tenofovir disoproxil fumarate generic	
Tybost (cobicistat)*	
Viramune Suspension (nevirapine)	
Viread Powder and Tablets 150 mg, 200 mg, 250 mg (tenofovir disoproxil fumarate)	
Ziagen Solution (abacavir)	
Zidovudine generic	

*preferred but requires PA; ^non-preferred but does not require PA

- **Note:** Edurant, Evotaz, Isentress, Odefsey, Prezcobix, Prezista, Tivicay PD and Tybost are preferred but require prior authorization.
- **Grandfathering:** For all prior authorized products except Isentress chewable (25 mg and 100 mg) for patients 12 years of age and older and Sunlenca tablets, look back 365 days in claims history for same product (not specific to strength) to bypass reject 75.
- **Step Edit:** Aptivus, Invirase and Viracept - For ages 2 years and older, look back 365 days for 2 protease inhibitor claims to bypass reject 75.
- **Step Edit:** Evotaz and Prezcobix – For ages 12 years and older, look back 365 days for a claim from the antiretroviral drug class to bypass reject 75.
- **Step Edit:** Fuzeon - For ages 6 years and older, look back 365 days for 2 claims from the antiretroviral drug class to bypass reject 75.
- **Step Edit:** Intelence – For ages 6 years and older, look back 365 days for 2 non-nucleoside transcriptase inhibitor claims to bypass reject 75.
- **Step Edit:** Lexiva - For ages 6 months and older, look back 365 days for 2 protease inhibitor claims to bypass reject 75.
- **Step Edit:** Prezista - For ages 3 years and older, look back 365 days for a protease inhibitor claim to bypass reject 75.
- **Step edit:** Tybost – For ages 18 years and older, look back 365 days for a claim for atazanavir or darunavir to bypass reject 75.
- **Note:** Emergency override allowed for generic abacavir/lamivudine/zidovudine if brand Trizivir is unavailable—go to the following criteria: Emergency Override for Non-Preferred Generics.

Criteria

Abacavir/Lamivudine/Zidovudine Generic

1. Inform the caller that brand Trizivir is preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred product, brand Trizivir, is not appropriate for the member.

Aptivus

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 2 years or older = Go to next question. If less than 2 years = DENY and refer to RPH.
3. Is the member resistant to at least 2 other protease inhibitors (PIs)? *Resistance may be determined by HIV drug-resistance testing prior to initiation of therapy or prior to changing antiretroviral regimen. Other protease inhibitors may include but not limited to atazanavir (Reyataz, Evotaz), darunavir (Prezista, Prezcobix), fosamprenavir (Lexiva), lopinavir/ritonavir (Kaletra), nelfinavir (Viracept), and saquinavir (Invirase).*
If YES = Go to next question. If NO = DENY and refer to RPH.
4. Will the medication be used with ritonavir [Kaletra, Norvir] and one or more other antiretroviral medications but will not be used in combination with etravirine (Intelence)? *Etravirine concentration may be significantly reduced by ritonavir-boosted tipranavir and coadministration is not recommended in the DHHS guidelines.*
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Complera

1. What is the member's age?
If 12 years or older = Go to next question. If less than 12 years = DENY and refer to RPH.
2. What is the member's weight in kilograms (kg)?
If 35 kg or greater = Go to next question. If less than 35 kg = DENY and refer to RPH.
3. Is the member using this medication for prophylaxis following exposure to HIV?
If YES = APPROVE for 1 month. If NO = Go to next question.
4. Is the member HIV treatment-naïve (has not used other antiretrovirals previously)?
If YES (treatment-naïve) = Go to next question. If NO (treatment-experienced) = Go to question 7.
5. What is the member's baseline HIV-RNA level?
If less than or equal to 100,000 copies/ml = Go to next question. If greater than 100,000 copies/ml = DENY and refer to RPH.
6. What is the member's baseline CD4+ cell count?

If less than 200 cells/mm³ = DENY and refer to RPH. If greater than or equal to 200 cells/mm³ = Go to question 8.
7. Has the member experienced consistent viral suppression (HIV RNA <50 copies/mL) for ≥6 months with no history of virologic failure?
If YES = Go to next question. If NO = DENY and refer to RPH.
8. In all calls, inform caller that Odefsey and Edurant taken with Descovy or emtricitabine/tenofovir disoproxil fumarate generic are preferred.
If caller agrees = CANCEL this request and APPROVE Odefsey or Edurant (Descovy and emtricitabine/tenofovir disoproxil fumarate generic do not require PA) for 1 year. If caller disagrees = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred products, Odefsey and Edurant taken with Descovy or emtricitabine/tenofovir disoproxil fumarate generic, are not appropriate for the member.

Edurant

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 12 years or older = Go to next question. If less than 12 years = DENY and refer to RPH.
3. What is the member's weight in kilograms (kg)?
If 35 kg or greater = Go to next question. If less than 35 kg = DENY and refer to RPH.
4. Is the member using this medication for prophylaxis following exposure to HIV in combination with one or more antiretroviral medications?
If YES = APPROVE for 1 month. If NO = Go to next question.
5. Is the member HIV treatment-naïve (has not used other antiretrovirals previously)?
If YES (treatment-naïve) = Go to next question. If NO (treatment-experienced) = Go to question 8.
6. What is the member's baseline HIV-RNA level?
If less than or equal to 100,000 copies/ml = Go to next question. If greater than 100,000 copies/ml = DENY and refer to RPH.
7. What is the member's baseline CD4+ cell count?
If less than 200 cells/mm³ = DENY and refer to RPH. If greater than or equal to 200 cells/mm³ = Go to question 9.
8. Has the member experienced consistent viral suppression (HIV RNA <50 copies/mL) for ≥6 months with no history of virologic failure?
If YES = Go to next question.

If NO = DENY and refer to RPH.
9. Will the medication be used in combination with one or more antiretroviral medications?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Evotaz and Prezcobix

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 12 years or older = Go to next question. If less than 12 years = DENY and refer to RPH.
3. Will the medication be used in combination with one or more antiretroviral medications?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH

Fuzeon and Intelence

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 6 years or older = Go to next question. If less than 6 years of age = DENY and refer to RPH.
3. Has the member used antiretroviral medications previously (i.e. Is the member treatment-experienced)?
If YES = Go to question 5. If NO = Go to next question.
4. Is the member using this medication for prophylaxis following exposure to HIV in combination with one or more antiretroviral medications?
If YES = APPROVE for 1 month. If NO = DENY and refer to RPH.
5. Which medication is being requested?
If Fuzeon = Go to next question. If Intelence = Go to question 8.
6. Is the member resistant to at least 2 HIV treatments?
If YES = Go to next question. If NO = DENY and refer to RPH.
7. Will the medication be used in combination with one or more antiretroviral medications?

If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.
8. Is the member resistant to at least 2 other non-nucleoside reverse transcriptase inhibitors (NNRTIs)? *Other NNRTIs may include but not limited to delavirdine (Rescriptor), efavirenz (Sustiva, Atripla), nevirapine (Viramune, Viramune XR), rilpivirine (Edurant, Complera, Odefsey).*
If YES = Go to next question. If NO = DENY and refer to RPH.
9. Will the medication be used in combination with one or more antiretroviral medications but will not be used in combination with tipranavir (Aptivus), atazanavir (Reyataz) or fosamprenavir (Lexiva)? *Concentrations of etravirine, tipranavir, atazanavir or fosamprenavir may be altered when etravirine is used in combination with tipranavir, atazanavir or fosamprenavir and coadministration is not recommended in the DHHS guidelines.*
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Invirase

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 2 years or older = Go to next question. If less than 2 years = DENY and refer to RPH.
3. Is the member resistant to at least 2 other protease inhibitors (PIs)? *Resistance may be determined by HIV drug-resistance testing prior to initiation of therapy or prior to changing antiretroviral regimen. Other protease inhibitors may include but not limited to atazanavir (Reyataz, Evotaz), darunavir (Prezista, Prezcobix), fosamprenavir (Lexiva) lopinavir/ritonavir (Kaletra), nelfinavir (Viracept), and tipranavir (Aptivus).*
If YES = Go to next question. If NO = DENY and refer to RPH.
4. Will the medication be used with ritonavir [Kaletra, Norvir] and one or more other antiretroviral medications?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Isentress, Isentress HD and Selzentry

1. Are Isentress chewable tablets (25 mg or 100 mg) or powder being requested?
If YES = Go to question 10. If NO = Go to next question.
2. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?

If YES = APPROVE for 1 year. If NO = Go to next question.
3. Is the member using this medication for prophylaxis following exposure to HIV in combination with one or more antiretroviral medications?
If YES = APPROVE for 1 month. If NO = Go to next question.
4. Which medication is being requested?
If Isentress 400 mg tablets = Go to question 6. If Isentress HD 600 mg tablets = Go to question 16. If Selzentry = Go to next question.
5. What is the member's age?
If 12 years or older = Go to question 7. If 2 to 11 years = Go to question 7. If less than 2 years = DENY and refer to RPH.
6. What is the member's age?
If 6 years or older = Go to question 9. If less than 6 years = DENY and refer to RPH.
7. Does the member have CCR5-tropic HIV-1 as indicated by tropism testing?
If YES = Go to next question. If NO = DENY and refer to RPH.
8. Will the medication be used in combination with one or more antiretroviral medications?
If YES = Go to question 13. If NO = DENY and refer to RPH
9. Will the medication be used in combination with one or more antiretroviral medications?
If YES = APPROVE Isentress 400 mg tablets for 1 year. If NO = DENY and refer to RPH.
10. What is the member's age?
If 12 years or older = Go to next question. If less than 12 years = Go to question 12.
11. Inform the caller that Isentress 400 mg Tablets should be used based on age-appropriate dosing.
If caller agrees = CANCEL this request and PROCEED to question 9. If caller refuses = DENY and refer to RPH. Inform prescriber that in addition to meeting the criteria for Isentress 400 mg Tablets above, a written letter of medical necessity must be submitted stating the reason(s) that Isentress 400 mg Tablets cannot be used.
12. Will the medication be used in combination with one or more antiretroviral medications?
If YES = APPROVE Isentress chewable tablets or powder for 1 year. If NO = DENY and refer to RPH.
13. Which formulation is being requested?
If tablets = APPROVE for 1 year. If oral solution and member is aged 2 to 11 years (provided in question 5) = APPROVE for 1 year. If oral solution and member is aged 12 years or older (provided in question 5) = Go to next question.
14. Is the member unable to swallow solid oral dosage formulations (i.e., capsules, tablets)?
If YES = APPROVE for 1 year.

If NO = Go to next question.
15. Inform the caller that Selzentry tablets should be used.
If caller agrees = CANCEL this request and APPROVE Selzentry tablets for 1 year. If caller refuses = DENY and refer to RPH. Inform prescriber a written letter of medical necessity must be submitted stating the reason(s) that Selzentry tablets are not appropriate for the member.
16. What is the member's age?
If 18 years or older = Go to question 18. If less than 18 years = Go to next question.
17. What is the member's weight?
If 40 kg or greater = Go to next question. If less than 40 kg = DENY and refer to RPH.
18. Is the member treatment-naïve or virologically suppressed on Isentress 400 mg twice daily?
If YES = Go to next question. If NO = DENY and refer to RPH.
19. Will the medication be used in combination with one or more antiretroviral medications?
If YES = APPROVE Isentress HD 600 mg tablets for 1 year. If NO = DENY and refer to RPH.

Lexiva

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 6 months or older = Go to next question. If less than 6 months = DENY and refer to RPH.
3. Is the member using this medication for prophylaxis following exposure to HIV in combination with one or more anti-HIV medications?
If YES = APPROVE for 1 month. If NO = Go to next question.
4. Is the member resistant to at least 2 other protease inhibitors (PIs)? *Resistance may be determined by HIV drug-resistance testing prior to initiation of therapy or prior to changing antiretroviral regimen. Other protease inhibitors may include but not limited to atazanavir (Reyataz, Evotaz), darunavir (Prezista, Prezcobix), lopinavir/ritonavir (Kaletra), nelfinavir (Viracept), saquinavir (Invirase), and tipranavir (Aptivus).*
If YES = Go to next question. If NO = DENY and refer to RPH.
5. Will the medication be used with ritonavir [Kaletra, Norvir] and one or more other antiretroviral medications but will not be used in combination with etravirine (Intelence)? *Etravirine may alter the concentration of fosamprenavir and coadministration is not recommended in the DHHS guidelines.*

If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Nevirapine ER Generic

1. Inform the caller that generic nevirapine immediate-release is preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred product, generic nevirapine immediate-release, is not appropriate for the member.

Norvir Solution

1. Is the member unable to swallow solid oral dosage formulations (i.e., tablets) and requires a dose that cannot be obtained by generic ritonavir tablets and brand Norvir Powder?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred products, generic ritonavir tablets and brand Norvir Powder, are not appropriate for the member.

Odefsey

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 12 years or older = Go to next question. If less than 12 years = DENY and refer to RPH.
3. What is the member's weight in kilograms (kg)?
If 35 kg or greater = Go to next question. If less than 35 kg = DENY and refer to RPH.
4. Is the member using this medication for prophylaxis following exposure to HIV?
If YES = APPROVE for 1 month. If NO = Go to next question.
5. Is the member HIV treatment-naïve (has not used other antiretrovirals previously)?
If YES (treatment-naïve) = Go to next question. If NO (treatment-experienced) = Go to question 8.
6. What is the member's baseline HIV-RNA level?
If less than or equal to 100,000 copies/ml = Go to next question. If greater than 100,000 copies/ml = DENY and refer to RPH.
7. What is the member's baseline CD4+ cell count?
If less than 200 cells/mm^3 = DENY and refer to RPH.

If greater than or equal to 200 cells/mm³ = APPROVE for 1 year.
8. Has the member experienced consistent viral suppression (HIV RNA <50 copies/mL) for ≥6 months with no history of virologic failure?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Pifeltro

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 18 years or older = Go to next question. If less than 18 years = DENY and refer to RPH.
3. Is the member antiretroviral treatment-naïve or is the member virologically suppressed (HIV RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the requested medication?
If YES = Go to next question. If NO = DENY and refer to RPH.
4. Will the medication be used in combination with strong CYP 3A inducers? *Strong CYP 3A inducers may include but not limited to carbamazepine, oxcarbazepine, phenobarbital, phenytoin, enzalutamide, rifampin, rifapentine, mitotane and St John's wort.*
If YES = DENY and refer to RPH. If NO = Go to next question.
5. Will the medication be used in combination with one or more antiretroviral medications?
If YES = Go to next question. If NO = DENY and refer to RPH.
6. Is the member resistant to bictegravir, emtricitabine or tenofovir alafenamide (Biktarvy)? *The DHHS HIV guidelines recommend HIV drug-resistance testing at entry into care for persons with HIV to guide selection of the initial antiretroviral therapy (ART) regimen.*
If YES = Go to question 8. If NO = Go to next question.
7. Does the member have an allergy, contraindication, drug-drug interaction or intolerable side effect to bictegravir, emtricitabine or tenofovir alafenamide (Biktarvy)?
If YES = Go to next question. If NO = DENY and refer to RPH. Inform prescriber that a written letter of medication necessity must be submitted stating the reasons the preferred product, Biktarvy, is not appropriate for the member.
8. Is the member resistant to lamivudine or tenofovir disoproxil fumarate (in Delstrigo)?
If YES = APPROVE for 1 year. If NO = Go to next question.
9. Does the member have an allergy, contraindication, drug-drug interaction or intolerable side effect to

lamivudine or tenofovir disoproxil fumarate (in Delstrigo)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH. Inform prescriber that a written letter of medication necessity must be submitted stating the reasons the preferred product, Delstrigo, is not appropriate for the member.

Prezista

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 3 years or older = Go to next question. If less than 3 years = DENY and refer to RPH.
3. Will the medication be used with ritonavir [Kaletra, Norvir] and one or more other antiretroviral medication(s)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Reyataz Powder

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 3 months or older = Go to next question. If less than 3 months = DENY and refer to RPH.
3. What is the member's weight?
If 5 kg to less than 25 kg = APPROVE for 1 year. If 25 kg or more = Go to next question. If less than 5 kg = DENY and refer to RPH.
4. Is the member unable to swallow solid oral dosage formulations (i.e., capsules, tablets)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Rukobia

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.

2. What is the member's age?
If 18 years or older = Go to next question. If less than 18 years = DENY and refer to RPH.
3. Is the member heavily-treatment experienced with multidrug-resistant HIV-1 infection?
If YES = Go to next question. If NO = DENY and refer to RPH.
4. Is the member failing their current antiretroviral regimen due to resistance, intolerance or safety considerations?
If YES = Go to next question. If NO = DENY and refer to RPH.
5. What is the member's viral load?
If ≥400 copies/mL = Go to next question. If <400 copies/mL = DENY and refer to RPH
6. How many classes of antiretroviral medications are remaining that the member can take?
If ≤2 classes = Go to next question. If >2 classes = DENY and refer to RPH.
7. Will the medication be used in combination with one or more other antiretroviral medications?
If YES = Go to next question. If NO = DENY and refer to RPH
8. Will the medication be coadministered with strong CYP3A inducers? *Strong CYP3A inducers may include but not limited to enzalutamide, carbamazepine, phenytoin, rifampin, mitotane and St John's wort.*
If YES = DENY and refer to RPH. If NO = APPROVE for 1 year.

Stribild

1. Inform the caller that Genvoya is preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred product, Genvoya, is not appropriate for the member.

Sunlenca

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 8 days. If NO = Go to next question.
2. Has the member been on Sunlenca injection, and it has been more than 28 weeks since the last injection?
If YES = APPROVE for 8 days.

If NO = Go to next question.
3. What is the member's age?
If 18 years or older = Go to next question. If less than 18 years = DENY and refer to RPH.
4. Is the member heavily-treatment experienced with multidrug-resistant HIV-1 infection?
If YES = Go to next question. If NO = DENY and refer to RPH.
5. Is the member failing their current antiretroviral regimen due to resistance, intolerance or safety considerations?
If YES = Go to next question. If NO = DENY and refer to RPH.
6. What is the member's viral load?
If ≥400 copies/mL = Go to next question. If <400 copies/mL = DENY and refer to RPH
7. How many classes of antiretroviral medications are remaining that the member can take?
If ≤2 classes = Go to next question. If >2 classes = DENY and refer to RPH.
8. Will the medication be used in combination with one or more other antiretroviral medications?
If YES = Go to next question. If NO = DENY and refer to RPH
9. Will the medication be coadministered with strong CYP3A inducers? *Strong CYP3A inducers may include but not limited to enzalutamide, carbamazepine, phenytoin, rifampin, mitotane and St John's wort.*
If YES = DENY and refer to RPH. If NO = APPROVE for 8 days.

Symfi and Symfi Lo

1. Inform the caller that the individual products, efavirenz generic, lamivudine generic and tenofovir disoproxil fumarate generic, are preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred products, efavirenz generic, lamivudine generic and tenofovir disoproxil fumarate generic, are not appropriate for the member.

Temixys

1. Inform the caller that Cimduo and lamivudine generic with tenofovir disoproxil fumarate generic are preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred products, Cimduo and lamivudine generic with tenofovir disoproxil fumarate generic, are not appropriate for the member.

Tivicay PD

1. What is the member's age?
If 4 weeks to <18 years = Go to next question. If younger than 4 weeks = DENY and refer to RPH. If 18 years or older = DENY and refer to RPH.
2. What is the member's weight?
If 3 kg to <20 kg = APPROVE for 1 year. If 20 kg to <25 kg = Go to next question. If less than 3 kg = DENY and refer to RPH. If 25 kg or more = DENY and refer to RPH.
3. Is the member unable to swallow solid oral dosage formulations (i.e., tablets, capsules)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Tybost

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 18 years or older = Go to next question. If less than 18 years = DENY and refer to RPH.
3. Will the medication be used in combination with atazanavir or darunavir?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH

Viracept

1. Has the member been started on medication through another insurance plan or ADAP (AIDS Drug Assistance Program) program?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's age?
If 2 years or older = Go to next question. If less than 2 years = DENY and refer to RPH.
3. Is the member resistant to at least 2 other protease inhibitors (PIs)? *Resistance may be determined by HIV drug-resistance testing prior to initiation of therapy or prior to changing antiretroviral regimen. Other protease inhibitors may include but not limited to atazanavir (Reyataz, Evotaz), darunavir*

(Prezista, Prezcobix), fosamprenavir (Lexiva), lopinavir/ritonavir (Kaletra), saquinavir (Invirase), and tipranavir (Aptivus).
If YES = Go to next question. If NO = DENY and refer to RPH.
4. Will the medication be used with other antiretroviral medications?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

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7. Centers for Disease Control and Prevention. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV – United States, 2016. U.S. Department of Health and Human Services. Available at http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf. Last accessed November 2, 2023.
8. Centers for Disease Control and Prevention. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis – United States, Updated May 23, 2018. U.S. Department of Health and Human Services. Available at https://stacks.cdc.gov/view/cdc/20711. Last accessed November 2, 2023.

In the event of a denial, advise all callers of appeal rights and the reason for denial.

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PA Criteria Category/Drug: Atypical Antipsychotics

Length of authorization: 1 year

Medications

PDL Status	
Preferred	**Non-Preferred**
Oral Agents	
Aripiprazole tablets, oral solution generic Asenapine sublingual tablets generic Clozapine tablets generic Fanapt (iloperidone) Lurasidone generic Olanzapine tablets, ODT generic Paliperidone generic Risperidone generic Quetiapine IR and ER generic Vraylar (cariprazine) Ziprasidone generic	Abilify MyCite (aripiprazole tablets with sensor) Aripiprazole ODT generic Caplyta (lumateperone) Clozapine ODT generic Lybalvi (olanzapine and samidorphan) Nuplazid (pimavanserin) Olanzapine/fluoxetine generic Rexulti (brexpiprazole) Secuado (asenapine transdermal patch) Versacloz (clozapine oral suspension)
Injectable Agents	
Abilify Asimtufii (aripiprazole extended-release injection)* Abilify Maintena (aripiprazole extended-release injection)* Aristada and Aristada Initio (aripiprazole lauroxil extended-release injection)* Geodon (ziprasidone short-acting injection) Invega Hafyera (paliperidone extended-release injection)* Invega Sustenna (paliperidone extended-release injection)* Invega Trinza (paliperidone extended-release injection)* Olanzapine short-acting injection generic Perseris (risperidone extended-release injection)* Risperdal Consta (risperidone long-acting injection)* Uzedy (risperidone extended-release injection)* Zyprexa Relprevv (olanzapine extended-release injection)*	n/a

*Preferred injectable agents that require PA. ^Non-preferred agent that does not require PA. IR=immediate-release; ER=extended-release; ODT=orally disintegrating tablets

- **Grandfathering:** Grandfathering in place for Abilify Asimtufii, Abilify Maintena, Aristada, Caplyta, Lybalvi, Invega Sustenna, Invega Trinza, Invega Hafyera, Nuplazid, Perseris, Rexulti, Risperdal Consta, Uzedy, Vraylar and Zyprexa Relprevv for patients within FDA-approved age indications, look back 365 days in claims history for same product (not specific to strength) to bypass reject 75.
- **Note:** For ziprasidone generic, PA is not required for members ≥18 yo. For risperidone/risperidone ODT/risperidone oral solution generic, PA is not required for members ≥5 yo with pervasive developmental disorders/autism or irritability associated with autism/PDD or for members ≥10 yo with other diagnoses. For quetiapine IR and ER generic, PA is not required for members ≥10 yo. For olanzapine/olanzapine ODT generic and lurasidone generic, PA is not required for members ≥13 yo. For clozapine generic, PA is not required for members ≥18 yo. For aripiprazole tablets and oral solution generic, PA is not required for members ≥6 yo with pervasive developmental disorders/autism, irritability associated with autism/PDD or Tourette's disorder or for members ≥10 yo with other diagnoses. For Fanapt, PA is not required for members ≥18 yo. For paliperidone generic, PA is not required for ≥12 yo
- **Automated PA Approval Process:** Risperidone/ODT/Oral Solution – Look for ages 5-9 years and diagnosis of pervasive developmental disorder (PDD)/autism or irritability associated with autism/PDD

to approve for 1 year. Vraylar – For 18 and older, look for Schizophrenia or Bipolar diagnosis to approve for 1 year OR look for MDD diagnosis and 1 antidepressant in the past 30 days to approve for 1 year.

- **Note: PAs for all atypical antipsychotics should be wildcarded at the GPI-12 EXCEPT Invega Sustenna, Invega Trinza, and Invega Hafyera.**
  - **Invega Sustenna, Invega Trinza, and Invega Hafyera should be approved at the PA GPI List Level.**
    - **For Invega Sustenna approvals, use PA GPI List: GAMINVSUST**
    - **For Invega Trinza approvals, use PA GPI List: GAMINVTRIN**
    - **For Invega Hafyera approvals, use PA GPI List: GAMINVHAFY**
- **Note:** The Atypical Antipsychotic Prior Authorization (PA) Request Form is located on the State's website.

Criteria

Automated PA Approval Process Protocols

Drug Name	GPI	MSC
RISPERIDONE (tabs/tbdp/soln)-does not include microspheres	5907007000****	Y
VRAYLAR	5940001810****	n/a

Automated PA Approval Process CRITERIA QUESTIONS for Risperidone/ODT/oral solution generic

System Check 1: Age between 5 and 9 years (i.e. ≥5 to ≤9)
Yes = Go to SC2 No (all other ages) = Go to Manual Question 1
System Check 2: One of the following diagnosis codes: ICD-9 (299, 299.0, 299.00, 299.01, 299.1, 299.10, 299.11, 299.8, 299.80, 299.81, 299.9, 299.90, 299.91) or ICD-10 (F84.0, F84.3, F84.5, F84.8, F84.9)
Yes = APPROVE for 1 year No = Go to Manual Question 1

Initial vs. Reauthorization Request for Aripiprazole tablets and oral solution generic (not ODT, Abilify MyCite, Abilify Maintena or Aristada), Caplyta, Clozapine generic, Clozapine ODT generic, Fanapt, Lurasidone generic, Lybalvi, Olanzapine/ODT generic (not Zyprexa Relprevv), Olanzapine/Fluoxetine generic, Paliperidone generic (not Invega Sustenna or Invega Trinza), Rexulti, Risperidone/ODT/oral solution generic (not Perseris or Risperdal Consta), Quetiapine IR and ER generic, Secuado, Versacloz, Vraylar, Ziprasidone generic

1. Is this an initial or reauthorization request? *Call center rep: Verification of prior authorization history required.*
If initial = Go to appropriate criteria below based on drug being requested. If reauthorization = Go to next question.

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1. For PA Rep Only: Was the most recent prior authorization approved for a duration of therapy of 6 months or longer? *Check for duration of therapy of most recent prior authorization required.*
If YES = Go to next question. If NO = Go to appropriate criteria below based on drug being requested.
3. Have the member's symptoms improved on therapy?
If YES = Go to next question. If NO = DENY and refer to RPH.
4. Will the member continue to be routinely monitored for safety and effectiveness while on therapy?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Criteria for Oral Agents

Aripiprazole Tablets and Oral Solution Generic, Asenapine Sublingual Tablets Generic, Fanapt, Lurasidone Generic, Olanzapine/ODT Generic (not short-acting injection), Paliperidone Generic, Risperidone/ODT/Oral Solution Generic, Quetiapine IR Generic, Quetiapine ER Generic, Ziprasidone Generic

1. Which medication is being requested?
If ziprasidone generic = Go to next question. If risperidone/ODT/oral solution generic = Go to question 4. If quetiapine IR/ER generic = Go to question 3. If olanzapine/ODT generic or lurasidone generic = Go to question 6. If aripiprazole tablets or oral solution generic = Go to question 9. If Fanapt = Go to next question. If paliperidone generic = Go to question 11. If asenapine sublingual tablets = Go to question 12.
2. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = APPROVE (PA is not required). If Ziprasidone QLL exceeds request is needed, go to the QLL criteria section for Ziprasidone below.
3. What is the member's age?
If less than 10 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 10 years or older = APPROVE (PA is not required). If a QLL exceeds or QLL low dose request is needed, go to the QLL criteria section for Quetiapine QLL Exceeded or Quetiapine Low Dose below.
4. What is the member's age?
If less than 5 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the

Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 5 to 9 years = Go to next question. If 10 years or older = APPROVE (PA is not required). If a QLL exceeds request is needed, go to the QLL criteria section for Risperidone below
5. What is the member's diagnosis?
If pervasive developmental disorder (PDD)/autism or irritability associated with autism/PDD = APPROVE (PA is not required). Please inform caller that the pharmacy can submit the claim with ICD-10 F84.0, F84.3, F84.5, F84.8, F84.9. If a QLL exceeds request is needed, go to the QLL criteria section for Risperidone below. If other diagnosis = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
6. What is the member's diagnosis?
If depressive episodes associated with bipolar disorder (bipolar depression) = Go to next question. If other diagnosis = Go to question 8.
7. What is the member's age?
If less than 10 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 10 years or older = APPROVE for 1 year. If a QLL exceeds request is needed, go to the QLL criteria section for Olanzapine or Olanzapine ODT below.
8. What is the member's age?
If less than 13 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 13 years or older = APPROVE (PA is not required). If a QLL exceeds requests needed, go to the QLL criteria section for Olanzapine or Olanzapine ODT below.
9. What is the member's age?
If less than 6 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 6 to 9 years = Go to next question. If 10 years or older = APPROVE (PA is not required).
10. What is the member's diagnosis?
If pervasive developmental disorder (PDD)/autism or irritability associated with autism/PDD = APPROVE (PA is not required). Please inform caller that the pharmacy can submit the claim with ICD-10 F84.0, F84.3, F84.5, F84.8, F84.9. If Tourette's disorder = APPROVE (PA is not required). Please inform caller that the pharmacy can submit the claim with ICD-10 F95.2. If other diagnosis = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.
11. What is the member's age?

If less than 12 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 12 years or older = APPROVE (PA is not required).
12. What is the member's age?
If less than 10 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 10 to 17 years = Go to next question. If 18 years or older = APPROVE (PA is not required).
13. What is the member's diagnosis?
If bipolar I disorder = APPROVE (PA is not required). If other diagnosis = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review.

Abilify MyCite

1. What is the member's diagnosis?
If mixed or manic episodes associated with bipolar disorder = Go to question 3. If schizophrenia or schizoaffective disorder = Go to question 3. If adjunctive therapy for major depressive disorder (MDD, depression) = Go to question 4. If other diagnosis = Go to next question.
2. What is the member's age?
If less than 18 years of age = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 6.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to next question.
5. Is the member receiving another antidepressant to be used concurrently with Abilify MyCite? *Other antidepressants may include the following (list may not be all inclusive): SSRIs (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), SNRIs (desvenlafaxine, duloxetine, venlafaxine), vortioxetine, bupropion,*

mirtazapine, or trazodone.
If YES = Go to next question. If NO = DENY and refer to RPH.
6. Inform the caller that generic aripiprazole tablets are preferred over Abilify MyCite.
If caller agrees = CANCEL this PA request and inform caller that aripiprazole tablets generic is preferred and does not require PA. If caller refuses = Go to next question.
7. Please submit a letter of medical necessity stating the reasons generic aripiprazole tablets are not appropriate for the member.
If reasons are valid in letter of medical necessity = APPROVE for 1 year. If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Aripiprazole ODT Generic

1. Inform the caller that generic aripiprazole tablets are preferred over aripiprazole ODT generic.
If caller agrees = CANCEL this PA request and inform caller that aripiprazole tablets generic is preferred and does not require PA. If caller refuses = Go to next question.
2. Please submit a letter of medical necessity stating the reasons generic aripiprazole tablets are not appropriate for the member.
If reasons are valid in letter of medical necessity = APPROVE for 1 year. If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Caplyta

1. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If depressive episodes associated with bipolar disorder (bipolar depression) = Go to question 9. If other diagnosis = Go to question 3.
2. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
4. How long (if any time) has the member been taking the requested medication? *Faxed documentation of antipsychotic form is required.*
If 2 weeks or more = Go to question 8 upon review of faxed antipsychotic form. If <2 weeks = Go to next question.

If patient has not started requested medication = Go to question 6.
5. Have the member's symptoms improved on therapy? *Faxed documentation of antipsychotic form is required.*
If YES = Go to question 8 upon review of faxed antipsychotic form. If NO = Go to next question.
6. Were any of the following: aripiprazole, Fanapt, lurasidone, olanzapine/ODT, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, Vraylar, OR ziprasidone capsules (preferred products for same age group/diagnosis) ineffective in treating the member's condition?
If YES = Go to question 8. If NO = Go to next question.
7. Did the member have an allergic reaction, contraindication, drug-drug interaction, or intolerable side effects to at least 6 of the following: aripiprazole, Fanapt, lurasidone, olanzapine/ODT, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, Vraylar, OR ziprasidone capsules (preferred products for same age group/diagnosis)?
If YES = Go to next question. If NO = DENY and refer to RPH.
8. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

9. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to next question.
10. How long (if any time) has the member been taking the requested medication? *Faxed documentation of antipsychotic form is required.*
If 2 weeks or more = Go to question 8 upon review of faxed antipsychotic form. If <2 weeks = Go to next question. If patient has not started requested medication = Go to question 12.
11. Have the member's symptoms improved on therapy? *Faxed documentation of antipsychotic form is required.*
If YES = Go to question 8 upon review of faxed antipsychotic form. If NO = Go to next question.
12. Was olanzapine given concurrently or in combination with fluoxetine, lurasidone, quetiapine, OR Vraylar ineffective in treating the member's condition?
If YES = Go to question 8. If NO = Go to next question.
13. Did the member have an allergic reaction, contraindication, drug-drug interaction, or intolerable side effect to olanzapine, fluoxetine, lurasidone, quetiapine, OR Vraylar?
If YES = Go to question 8. If NO = DENY and refer to RPH.

Clozapine Tablets Generic, Clozapine ODT Generic, Versacloz

1. What is the member's diagnosis?
If suicidal behavior associated with schizophrenia or schizoaffective disorder = Go to next question. If treatment-resistant (refractory) schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 3.
2. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
4. Which medication is being requested?
If generic clozapine tablets = APPROVE (PA is not required). If a QLL exceeds request is needed, go to the QLL criteria section below. If generic clozapine ODT or Versacloz = Go to next question.
5. Inform the caller that generic clozapine tablets are preferred over generic clozapine ODT and Versacloz.
If caller agrees = CANCEL this PA request and inform caller that clozapine tablets generic is preferred and does not require PA. If caller refuses = Go to next question.
6. Please submit a letter of medical necessity stating the reasons generic clozapine tablets are not appropriate for the member.
If reasons are valid in letter of medical necessity = APPROVE for 1 year. If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Lybalvi

1. What is the member's diagnosis?
If manic or mixed episodes associated with bipolar disorder = Go to next question. If schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 3.
2. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the

Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
4. How long (if any time) has the member been taking the requested medication? *Faxed documentation of antipsychotic form is required.*
If 2 weeks or more = Go to question 10 upon review of faxed antipsychotic form. If <2 weeks = Go to next question. If patient has not started requested medication = Go to question 6.
5. Have the member's symptoms improved on therapy? *Faxed documentation of antipsychotic form is required.*
If YES = Go to question 10 upon review of faxed antipsychotic form. If NO = Go to next question.
6. Is the member currently established on olanzapine/ODT as confirmed by claims history?
If YES = DENY and refer to RPH. Current evidence base for Lybalvi is limited to reduction of weight gain in people who are starting olanzapine as opposed to producing weight loss in people who have already gained weight on olanzapine. If NO = Go to next question.
7. Is the member expected to experience undesirable weight gain attributable to treatment with olanzapine/ODT?
If YES = Go to next question. If NO = DENY and refer to RPH.
8. Were ANY of the following: aripiprazole, Fanapt, lurasidone, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, OR ziprasidone capsules (preferred products for same age group/diagnosis), as confirmed by claims history, ineffective in treating the member's condition?
If YES = Go to question 10. If NO = Go to next question.
9. Did the member have an allergic reaction, contraindication, drug-drug interaction, or intolerable side effect (such as weight gain) to ANY of the following: aripiprazole, Fanapt, lurasidone, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, OR ziprasidone capsules (preferred products for same age group/diagnosis)?
If YES = Go to next question. If NO = DENY and refer to RPH.
10. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Nuplazid

1. Has the member been started and stabilized on the requested medication from outside the plan (samples do not count)?
If YES = APPROVE for 1 year. If NO = Go to next question.
2. What is the member's diagnosis?
If hallucinations and/or delusions associated with Parkinson's disease psychosis = Go to next question. If dementia-related psychosis = DENY and refer to RPH. If other diagnosis = DENY and refer to RPH.

3. What is the member's age?
If 40 years or older = Go to next question. If less than 40 years = DENY and refer to RPH.
4. Does the member have QT prolongation or is the member taking a medication that can prolong the QT interval? *Drugs known to prolong QT interval include Class 1A antiarrhythmics (e.g., quinidine, procainamide), Class 3 antiarrhythmics (e.g., amiodarone, sotalol), certain antipsychotic medications (e.g., ziprasidone, chlorpromazine, thioridazine) and certain antibiotics (e.g., gatifloxacin, moxifloxacin).*
If YES = DENY and refer to RPH. If NO = Go to next question.
5. Has the prescribing physician attempted to adjust Parkinson's disease medications in order to reduce psychosis without worsening motor symptoms?
If YES = Go to next question. If NO = DENY and refer to RPH.
6. Will the member be on a concomitant antipsychotic while taking Nuplazid? *Concomitant indicates that Nuplazid will be taken continuously with another antipsychotic medication. If an antipsychotic medication will be taken continuously with Nuplazid, the answer should be 'YES' and the PA request should be denied. If an antipsychotic medication is being tapered for discontinuation while starting Nuplazid, the answer should be 'NO.'*
If YES = DENY and refer to RPH. If NO = Go to next question.
7. Is the medication being prescribed by or in consultation with a geriatrician, neurologist or psychiatrist?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Olanzapine/Fluoxetine Generic

1. Inform the caller to use a preferred atypical antipsychotic and a preferred antidepressant as two separate products.
If caller agrees = CANCEL this PA request and inform caller that several atypical antipsychotics and antidepressants (including olanzapine and fluoxetine) are preferred and do not require PA. If caller refuses = Go to next question.
2. Please submit a letter of medical necessity stating the reasons a preferred atypical antipsychotic and a preferred antidepressant, used as two separate products, are not appropriate for the member.
If reasons are valid in letter of medical necessity = APPROVE for 1 year. If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Rexulti

1. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If adjunctive therapy for major depressive disorder (MDD, depression) = Go to question 9. If agitation associated with dementia due to Alzheimer's disease = Go to question 13. If other diagnosis = Go to question 3.
2. What is the member's age?

If less than 13 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 13 years or older = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
4. How long (if any time) has the member been taking the requested medication? *Faxed documentation of antipsychotic form is required.*
If 2 weeks or more = Go to question 8 upon review of faxed antipsychotic form. If <2 weeks = Go to next question. If patient has not started requested medication = Go to question 6.
5. Have the member's symptoms improved on therapy? *Faxed documentation of antipsychotic form is required.*
If YES = Go to question 8 upon review of faxed antipsychotic form. If NO = Go to next question.
6. Were ANY of the following medications: aripiprazole, Fanapt, lurasidone, olanzapine/ODT, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, OR ziprasidone capsules (preferred products for same age group/diagnosis) ineffective in treating the member's condition?
If YES = Go to question 8. If NO = Go to next question.
7. Did the member have an allergic reaction, contraindication, drug-drug interaction, or intolerable side effect to ANY of the following medications: aripiprazole, Fanapt, lurasidone, olanzapine/ODT, paliperidone, quetiapine IR/ER, risperidone/ODT/oral solution, OR ziprasidone capsules (preferred products for same age group/diagnosis)?
If YES = Go to next question. If NO = DENY and refer to RPH.
8. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If a QLL exceeds request is needed, go to the QLL criteria section for Rexulti below. If NO = DENY and refer to RPH.
9. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to next question.
10. Has the member had an inadequate response to at least 1 antidepressant, aripiprazole or quetiapine extended release (preferred products for same age group/diagnosis)? *Antidepressants may include the following (list may not be all inclusive): SSRIs (citalopram, escitalopram, fluoxetine,*

fluvoxamine, paroxetine, sertraline), SNRIs (desvenlafaxine, duloxetine, venlafaxine), vortioxetine, bupropion, mirtazapine, or trazodone.
If YES = Go to next question. If NO = DENY and refer to RPH. Note: A prescriber may wish to submit an appeal (with letter of medical necessity, medical history, PA form, etc) to PBA vendor for a new member or a recently discharged (from inpatient care) member on a non-preferred medication for less than 2 weeks who is responding well and not appropriate for conversion.
11. Is the member receiving another antidepressant to be used concurrently with Rexulti? *Other antidepressants may include but not limited to the following (list may not be all inclusive): SSRIs (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), SNRIs (desvenlafaxine, duloxetine, venlafaxine), vortioxetine, bupropion, mirtazapine, or trazodone.*
If YES = Go to next question. If NO = DENY and refer to RPH.
12. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If a QLL exceeds request is needed, go to the QLL criteria section for Rexulti below. If NO = DENY and refer to RPH.
13. What is the member's age?
If 40 years or older = Go to next question. If less than 40 years = DENY and refer to RPH.
14. Did the member have an inadequate response, allergy, contraindication, drug-drug interaction or intolerable side effect to at least one selective serotonin reuptake inhibitor (SSRI) or one preferred atypical antipsychotic (see table above)? *SSRIs may include but not limited to citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and sertraline,*
If YES = Go to next question. If NO = DENY and refer to RPH.
15. Is the medication being prescribed by or in consultation with a geriatrician, neurologist or psychiatrist?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Secuado

1. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 3.
2. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the

Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
4. Inform the caller that generic asenapine sublingual tablets are preferred over Secuado.
If caller agrees = CANCEL this PA request and inform caller that asenapine sublingual tablets generic are preferred and do not require PA. If caller refuses = Go to next question.
5. Please submit a letter of medical necessity stating the reasons generic asenapine sublingual tablets are not appropriate for the member.
If reasons are valid in letter of medical necessity = APPROVE for 1 year. If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Vraylar

1. What is the member's diagnosis?
If manic or mixed episodes associated with bipolar disorder = Go to next question. If schizophrenia or schizoaffective disorder = Go to next question. If depressive episodes associated with bipolar disorder (bipolar depression) = Go to question 4. If adjunctive therapy for major depressive disorder (MDD, depression) = Go to question 5. If other diagnosis = Go to question 3.
2. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = APPROVE (PA is not required if Automated PA Approval Process criteria is met).
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = APPROVE (PA is not required if Automated PA Approval Process criteria is met).
5. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to next question.
6. Has the member had an inadequate response to at least 1 antidepressant, aripiprazole, OR quetiapine extended-release (preferred products for same age group/diagnosis)? *Other antidepressants may include the following (list may not be all inclusive): SSRIs (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), SNRIs (desvenlafaxine, duloxetine, venlafaxine), vortioxetine, bupropion,*

mirtazapine, or trazodone.
If YES = Go to next question. If NO = DENY and refer to RPH. Note: A prescriber may wish to submit an appeal (with letter of medical necessity, medical history, PA form, etc) to PBA vendor for a new member or a recently discharged (from inpatient care) member on a non-preferred medication for less than 2 weeks who is responding well and not appropriate for conversion.
7. Is the member receiving another antidepressant to be used concurrently with Vraylar? *Other antidepressants may include but not limited to the following (list may not be all inclusive): SSRIs (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), SNRIs (desvenlafaxine, duloxetine, venlafaxine), vortioxetine, bupropion, mirtazapine, or trazodone.*
If YES = Go to next question. If NO = DENY and refer to RPH.
8. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Criteria for Injectable Agents

- **Note:** For a listing of Community Service Board health centers, go to the website.

Abilify Asimtufii and Abilify Maintena

1. Where is the medication being administered?
If medication will be administered in the home = Go to next question. If medication will be administered in a long-term care facility = Go to next question. If medication will be administered in a CSB (community service board health center) = Go to next question. If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and Refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)
2. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If bipolar disorder = Go to next question. If other diagnosis = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 5.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.

5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?
If medication is being prescribed by or in consultation with a psychiatrist = Go to next question. If other provider specialty = DENY and refer to RPH.
6. Has the member been started and stabilized on the requested medication?
If YES = Go to question 10. If NO = Go to next question.
7. Has the member been noncompliant after a trial of oral aripiprazole?
If YES = Go to question 10. If NO = Go to next question.
8. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets (ODT)?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?
If YES = DENY and refer to RPH. If NO = Go to next question.
10. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Aristada and Aristada Initio

1. Where is the medication being administered?
If medication will be administered in the home = Go to next question. If medication will be administered in a long-term care facility = Go to next question. If medication will be administered in a CSB (community service board health center) = Go to next question. If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and Refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)
2. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 5.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the

Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?
If medication is being prescribed by or in consultation with a psychiatrist = Go to next question. If other provider specialty = DENY and refer to RPH.
6. Has the member been started and stabilized on Aristada?
If YES = Go to question 12. If NO = Go to next question.
7. Has the member been noncompliant after a trial of oral aripiprazole?
If YES = Go to question 10. If NO = Go to next question.
8. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets (ODT)?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?
If YES = DENY and refer to RPH. If NO = Go to next question.
10. Which product is being requested?
If Aristada = Go to question 14. If Aristada Initio = Go to next question.
11. Is Aristada being initiated?
If YES = APPROVE Aristada Initio for one dose only. If NO = DENY and refer to RPH.
12. Which product is being requested?
If Aristada = Go to question 14. If Aristada Initio = Go to next question.
13. Is Aristada being re-initiated following a missed dose of Aristada?
If YES = APPROVE Aristada Initio for one dose only. If NO = DENY and refer to RPH.
14. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE Aristada only for 1 year. If NO = DENY and refer to RPH.

Invega Hafyera, Invega Sustenna and Invega Trinza

1. Where is the medication being administered?
If medication will be administered by a trained healthcare professional in the home, in a long-term care facility or other outpatient pharmacy setting = Go to next question. If medication will be administered in a CSB (community service board health center) = Go to next question.

If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and Refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)
2. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 5.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?
If medication is being prescribed by or in consultation with a psychiatrist = Go to next question. If other provider specialty = DENY and refer to RPH.
6. Which medication is being requested?
If Invega Sustenna = Go to next question. If Invega Trinza = Go to question 11. If Invega Hafyera = Go to question 12.
7. Has the member been started and stabilized on Invega Sustenna?
If YES = Go to question 13. If NO = Go to next question.
8. Has the member been noncompliant after a trial of oral paliperidone (Invega) or oral risperidone (Risperdal)?
If YES = Go to question 13. If NO = Go to next question.
9. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets (ODT)?
If YES = Go to next question. If NO = DENY and refer to RPH.
10. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?
If YES = DENY and refer to RPH. If NO = Go to question 13.
11. Has Invega Sustenna been established as adequate treatment for the member for at least 4 months? *The member's last 2 doses of Invega Sustenna must be the same dosage strength to substantiate established, adequate treatment.*
If YES = Go to question 13. If NO = DENY and refer to RPH.

12. Has Invega Sustenna been established as adequate treatment for the member for at least 4 months or has Invega Trinza been established as adequate treatment for the member for at least 3 months? *The member's last 2 doses of Invega Sustenna must be the same dosage strength to substantiate established, adequate treatment.*
If YES = Go to next question. If NO = DENY and refer to RPH.
13. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Perseris and Uzedy

1. Where is the medication being administered?
If medication will be administered by a trained healthcare professional in the home, in a long-term care facility or other outpatient pharmacy setting = Go to next question. If medication will be administered in a CSB (community service board health center) = Go to next question. If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)
2. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 5.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?
If medication is being prescribed by or in consultation with a psychiatrist = Go to next question. If other provider specialty = DENY and refer to RPH.
6. Has the member been started and stabilized on Perseris?
If YES = Go to question 10. If NO = Go to next question.
7. Has the member been noncompliant after a trial of oral risperidone (Risperdal) or oral paliperidone (Invega)?
If YES = Go to question 10. If NO = Go to next question.

8. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets (ODT)?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?
If YES = DENY and refer to RPH. If NO = Go to next question.
10. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Risperdal Consta

1. Where is the medication being administered?
If medication will be administered by a trained healthcare professional in the home, in a long-term care facility or other outpatient pharmacy setting = Go to next question. If medication will be administered in a CSB (community service board health center) = Go to next question. If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)
2. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If bipolar disorder = Go to next question. If other diagnosis = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 5.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?
If medication is being prescribed by or in consultation with a psychiatrist = Go to next question. If other provider specialty = DENY and refer to RPH.
6. Has the member been started and stabilized on Risperdal Consta?
If YES = Go to question 10. If NO = Go to next question.

7. Has the member been noncompliant after a trial of oral risperidone (Risperdal) or oral paliperidone (Invega)?
If YES = Go to question 10. If NO = Go to next question.
8. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?
If YES = DENY and refer to RPH. If NO = Go to next question.
10. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Zyprexa Relprevv

1. Where is the medication being administered?
If medication will be administered in the home = DENY and refer to RPH. If medication will be administered in a REMS-certified long-term care facility = Go to next question. If medication will be administered in a REMS-certified CSB (community service board health center) = Go to next question. If medication WILL be administered in a physician's office or clinic (except a CSB) = DENY and Refer to RPH (Caller should be informed that this should be billed through the Medicaid physician's services program and not the outpatient pharmacy program.)
2. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question. If other diagnosis = Go to question 4.
3. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = Go to question 5.
4. What is the member's age?
If less than 18 years = Let caller know that the PA request will need to be reviewed by a healthcare professional. Ask caller to complete the Atypical Antipsychotic PA Request Form if not already done so and CANCEL this request. Once the Atypical Antipsychotic PA Request Form is received, PEND to healthcare professional for off label review. If 18 years or older = DENY and refer to RPH.
5. What is the specialty of the prescriber who is either prescribing the medication or being consulted with?
If medication is being prescribed by or in consultation with a psychiatrist = Go to next question. If other provider specialty = DENY and refer to RPH.

6. Has the member been started and stabilized on Zyprexa Relprevv?
If YES = Go to question 10. If NO = Go to next question.
7. Has the member been noncompliant after a trial of oral olanzapine (Zyprexa)?
If YES = Go to question 10. If NO = Go to next question.
8. Is the member unable to swallow oral dosage forms of medication (ex. tablets, solution) or use orally disintegrating tablets (ODT)?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. PA rep assess the following (question not directly asked to caller): Does it appear the member is currently taking oral dosage forms of medication (ex. tablets, ODT, solution) as confirmed by claims history (oral claims of today's date or within last week or so)?
If YES = DENY and refer to RPH. If NO = Go to next question.
10. Is there a monitoring plan or will the member be monitored for evaluating safety and effectiveness of the medication (via follow-up office visits, phone calls or other evaluation methods)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Quantity Level Limit Criteria

Clozapine Tablets Generic, Clozapine ODT Generic, Rexulti or Versacloz Quantity Level Limit (QLL) Criteria

1. Is the member's dose being titrated due to initiation of therapy?
If YES = APPROVE enough for initial titration only (one month authorization only). If NO = DENY and refer to RPH. Offer higher tablet strength if available.

Ziprasidone (Geodon) Quantity Level Limit (QLL) Criteria

1. Is the member's dose being titrated due to initiation of therapy?
If YES = APPROVE enough for initial titration only (one month authorization only). If NO = DENY and refer to RPH. Offer higher capsule strength if available.

Risperidone (Risperdal) Tablet or Risperidone ODT tablet (Risperdal M-Tablet) Quantity Level Limit (QLL) Criteria

1. Is the member's dose being titrated due to initiation of therapy?
If YES = APPROVE enough for initial titration only (one month for all diagnoses except pervasive developmental disorder

(PDD)/autism or irritability associated with autism/PDD in which QLL authorization may be for two months if necessary). If NO = DENY and refer to RPH. Offer higher tablet strength if available.

Quetiapine IR (Seroquel IR) Quantity Level Limit (QLL) Criteria

- **Note:** Use of low dose quetiapine IR (Seroquel) 25mg (at doses of 1 or 2 tablets per day) or quetiapine IR (Seroquel) 50 mg (at dose of 1 tablet per day) not in conjunction with another strength of quetiapine (Seroquel), an antidepressant or other antipsychotic will be reviewed upon appeal only (see below).

Quetiapine IR (Seroquel) Low Dose - 25 mg (at doses of 1 or 2 tablets per day) or 50 mg (at dose of 1 tablet per day) (see below for max quantity limits exceeded)

In all calls, DENY and refer to RPH. Inform caller of the appeals process and that the prescriber must submit a written letter of medical necessity for the use of quetiapine IR (Seroquel) 25mg (one or two tablets per day) or 50 mg (one tablet per day) without the concomitant use of another strength of quetiapine IR (Seroquel), an antidepressant or other antipsychotic.

Quetiapine IR (Seroquel) Max Quantity Limits Exceeded – All Strengths

1. What formulation of quetiapine (Seroquel) is being requested?
Quetiapine immediate release generic (Seroquel) = Go to next question. Quetiapine extended release generic(Seroquel XR) = DENY and refer to RPH.
2. Is the member's dose being titrated due to initiation of therapy?
If YES = APPROVE enough for initial titration only (one month authorization only). If NO = DENY and refer to RPH. Offer higher tablet strength if available.

Olanzapine (Zyprexa) or Olanzapine ODT (Zyprexa Zydis) tablets Quantity Level Limit (QLL) Criteria

1. What strength of medication is being requested?
If 2.5 mg = Go to next question. If 5 mg = Go to question 3. If 20 mg = Go to question 4. If other strength = DENY and refer to RPH. QLL of 60 tablets/30 days applies. Offer higher tablet strength if available.
2. Is the member's dose being titrated due to initiation of therapy?
If YES = APPROVE enough for up to 10 mg/day for the first month of therapy (initiation of therapy) only. If NO = DENY and refer to RPH. QLL of 60 tablets/30 days applies.
3. Is the member's dose being titrated due to initiation of therapy?
If YES = APPROVE enough for up to 20 mg/day for the first month of therapy (initiation of therapy) only. If NO = DENY and refer to RPH. QLL of 60 tablets/30 days applies.
4. What is the member's diagnosis?
If schizophrenia or schizoaffective disorder = Go to next question.

If other diagnosis = DENY and refer to RPH. QLL of 30 tablets/30 days applies.
5. Is this an initial or reauthorization QLL request?
If initial = Go to next question. If reauthorization = Go to question 7.
6. Does the member have refractory schizophrenia (failure of 2 or more antipsychotics at adequate doses for at least 6 weeks)?
If YES = Go to next question. If NO = DENY and refer to RPH. QLL of 30 tablets/30 days applies.
7. Is the member being monitored for increases in weight, blood glucose, and lipid panel?
If YES = APPROVE up to 90 tablets per 30 days for 3 months (renewals may be approved for 1 year). If NO = DENY and refer to RPH. QLL of 30 tablets/30 days applies.

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In the event of a denial, advise all callers of appeal rights and the reason for denial.

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PA Criteria Category/Drug: GLP-1 Agonists
Length of authorization: 1 Year Unless Otherwise Noted

Medications

PDL Status	
Preferred	**Non-Preferred**
Byetta (exenatide) Victoza (liraglutide)	Adlyxin (lixisenatide) Bydureon BCise (exenatide ER) Mounjaro (tirzepatide) Ozempic (semaglutide injection) Rybelsus (semaglutide tablets) Trulicity (dulaglutide)

Criteria

Adlyxin

1. Is this an initial or reauthorization request?
If initial = Go to next question. If reauthorization = Go to question 11.
2. What is the member's diagnosis?
If Type 2 diabetes mellitus = Go to next question. If other diagnosis = DENY and refer to RPH.
3. What is the member's age?
If 18 years or older = Go to next question. If less than 18 years = DENY and refer to RPH.
4. Does the member have ESRD (end-stage renal disease)?
If YES = DENY and refer to RPH. If NO = Go to next question.
5. Does the member have a history of pancreatitis or gastroparesis?
If YES = DENY and refer to RPH. If NO = Go to next question.
6. Has the member tried the preferred medications, Byetta AND Victoza, for 3 months EACH and failed therapy (i.e., hemoglobin A1c [HbA1c] not lowered to goal)?
If YES = Go to next question. If NO = Go to question 8.
7. What is the member's hemoglobin A1c (HbA1c) level after therapy with Byetta AND Victoza?
If 7% or higher = Go to question 10. If less than 7% = DENY and refer to RPH.
8. Does the member have allergies, contraindications, drug-drug interactions or intolerable side effects to the preferred medications, Byetta AND Victoza, which are not expected to occur with Adlyxin?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. What is the member's hemoglobin A1c (HbA1c) level prior to therapy?

If 7% or higher = Go to next question. If less than 7% = DENY and refer to RPH.
10. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione? *For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.*
If YES = APPROVE for 6 months. If NO = DENY and refer to RPH.
11. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione? *For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.*
If YES = Go to next question. If NO = DENY and refer to RPH.
12. Is the member receiving clinical benefit (i.e., improvement in HbA1c levels) from the requested medication?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Bydureon BCise

1. What is the member's age?
If 10 to 17 years = Go to next question. If 18 years or older = Go to question 3. If less than 10 years = DENY and refer to RPH.
2. Inform the caller that Victoza is preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred product, Victoza, is not appropriate for the member.
3. Inform the caller that Byetta and Victoza are preferred.
If caller agrees = CANCEL the PA request. If caller refuses = DENY and refer to RPH. Inform prescriber that a written letter of medical necessity must be submitted stating the reasons the preferred products, Byetta and Victoza, are not appropriate for the member.

Mounjaro and Ozempic

1. Is this an initial or reauthorization request?
If initial = Go to next question. If reauthorization = Go to question 15.
2. What is the member's diagnosis?
If Type 2 diabetes mellitus = Go to next question. If other diagnosis = DENY and refer to RPH.
3. What is the member's age?
If 18 years or older = Go to next question.

If less than 18 years = DENY and refer to RPH.
4. What is the member's hemoglobin A1c (HbA1c) level prior to therapy?
If 7% or higher = Go to next question. If less than 7% = DENY and refer to RPH.
5. Does the member have a personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN2)?
If YES = DENY and refer to RPH. If NO = Go to next question.
6. Does the member have a history of pancreatitis?
If YES = DENY and refer to RPH. If NO = Go to next question.
7. Which product is being requested?
If Mounjaro = Go to question 11. If Ozempic = Go to next question.
8. Does the member have established cardiovascular disease (history of coronary artery disease, stroke, cerebrovascular disease or peripheral artery disease)?
If YES = Go to next question. If NO = Go to question 11.
9. Has the member tried the preferred medication, Victoza, for 3 months and failed therapy?
If YES = APPROVE for 1 year. If NO = Go to next question.
10. Does the member have an allergy, contraindication, drug-drug interaction or intolerable side effect to the preferred medication, Victoza, which is not expected to occur with the requested medication?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.
11. Has the member tried the preferred medications, Byetta AND Victoza, for 3 months EACH and failed therapy (i.e., hemoglobin A1c [HbA1c] not lowered to goal) as confirmed by claims history?
If YES = Go to next question. If NO = Go to question 13.
12. What is the member's hemoglobin A1c (HbA1c) level after therapy with Byetta AND Victoza?
If 7% or higher = Go to question 14. If less than 7% = DENY and refer to RPH.
13. Does the member have allergies, contraindications, drug-drug interactions or intolerable side effects to the preferred medications, Byetta AND Victoza, which are not expected to occur with the requested medication?
If YES = Go to next question. If NO = DENY and refer to RPH.
14. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione as confirmed by claims history? *For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table.*
If YES = APPROVE for 6 months. If NO = DENY and refer to RPH.
15. Does the member have established cardiovascular disease (history of coronary artery disease, stroke, cerebrovascular disease or peripheral artery disease)?
If YES = APPROVE for 1 year.

If NO = Go to next question.
16. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione? *For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.*
If YES = Go to next question. If NO = DENY and refer to RPH.
17. Is the member receiving clinical benefit (i.e., improvement in HbA1c levels)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Rybelsus

1. Is this an initial or reauthorization request?
If initial = Go to next question. If reauthorization = Go to question 11.
2. What is the member's diagnosis?
If Type 2 diabetes mellitus = Go to next question. If other diagnosis = DENY and refer to RPH.
3. What is the member's age?
If 18 years or older = Go to next question. If less than 18 years = DENY and refer to RPH.
4. Does the member have a personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN2)?
If YES = DENY and refer to RPH. If NO = Go to next question.
5. Does the member have a history of pancreatitis?
If YES = DENY and refer to RPH. If NO = Go to next question.
6. Has the member tried the preferred medications, Farxiga, Jardiance or Invokana AND Byetta or Victoza, for 3 months EACH and failed therapy (i.e., hemoglobin A1c [HbA1c] not lowered to goal)?
If YES = Go to next question. If NO = Go question 8.
7. What is the member's hemoglobin A1c (HbA1c) level after therapy with Farxiga, Jardiance or Invokana AND Byetta or Victoza?
If 7% or higher = Go to question 10. If less than 7% = DENY and refer to RPH.
8. Does the member have allergies, contraindications, drug-drug interactions or intolerable side effects to the preferred medications, Farxiga, Jardiance, Invokana, Byetta and Victoza, which are not expected to occur with the requested medication?
If YES = Go to next question. If NO = DENY and refer to RPH.
9. What is the member's hemoglobin A1c (HbA1c) level prior to therapy?
If 7% or higher = Go to next question.

If less than 7% = DENY and refer to RPH.
10. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione? *For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.*
If YES = APPROVE for 6 months. If NO = DENY and refer to RPH.
11. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione? *For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.*
If YES = Go to next question. If NO = DENY and refer to RPH.
12. Is the member receiving clinical benefit (i.e., improvement in HbA1c levels)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

Trulicity

1. Is this an initial or reauthorization request?
If initial = Go to next question. If reauthorization = Go to question 16.
2. What is the member's diagnosis?
If Type 2 diabetes mellitus = Go to next question. If other diagnosis = DENY and refer to RPH.
3. Does the member have a personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN2)?
If YES = DENY and refer to RPH. If NO = Go to next question.
4. Does the member have a history of pancreatitis?
If YES = DENY and refer to RPH. If NO = Go to next question.
5. What is the member's age?
If 10 to 17 years = Go to question 7. If 18 years or older = Go to next question.
6. Does the member have established cardiovascular disease (history of coronary artery disease, stroke, cerebrovascular disease or peripheral artery disease)?
If YES = Go to question 9. If NO = Go to question 11.
7. Has the member tried the preferred medication, Victoza, for 3 months and failed therapy?
If YES = APPROVE for 1 year. If NO = Go to next question.
8. Does the member have an allergy, contraindication, drug-drug interaction or intolerable side effect to the preferred medication, Victoza, which is not expected to occur with the requested medication?

If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.
9. Has the member tried the preferred medications, Victoza and Ozempic (NP/PA), for 3 months each and failed therapy?
If YES = APPROVE for 1 year. If NO = Go to next question.
10. Does the member have allergies, contraindications, drug-drug interactions or intolerable side effects to the preferred medications, Victoza and Ozempic (NP/PA), which is not expected to occur with the requested medication?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.
11. Has the member tried the preferred medications, Byetta, Victoza and Ozempic (NP/PA), for 3 months EACH and failed therapy (i.e., hemoglobin A1c [HbA1c] not lowered to goal)?
If YES = Go to next question. If NO = Go to question 13.
12. What is the member's hemoglobin A1c (HbA1c) level after therapy with Byetta, Victoza and Ozempic?
If 7% or higher = Go to question 15. If less than 7% = DENY and refer to RPH.
13. Does the member have allergies, contraindications, drug-drug interactions or intolerable side effects to the preferred medications, Byetta, Victoza and Ozempic (NP/PA), which are not expected to occur with the requested medication?
If YES = Go to next question. If NO = DENY and refer to RPH.
14. What is the member's hemoglobin A1c (HbA1c) level prior to therapy?
If 7% or higher = Go to next question. If less than 7% = DENY and refer to RPH.
15. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione? *For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.*
If YES = APPROVE for 6 months. If NO = DENY and refer to RPH.
16. Does the member have established cardiovascular disease (history of coronary artery disease, stroke, cerebrovascular disease or peripheral artery disease)?
If YES = APPROVE for 1 year. If NO = Go to next question.
17. Is the member currently on metformin, sulfonylurea, or thiazolidinedione therapy or combination therapy with metformin + sulfonylurea or metformin + thiazolidinedione? *For examples of metformin, sulfonylurea and thiazolidinedione therapies, see medication table above.*
If YES = Go to next question. If NO = DENY and refer to RPH.
18. Is the member receiving clinical benefit (i.e., improvement in HbA1c levels)?
If YES = APPROVE for 1 year. If NO = DENY and refer to RPH.

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MSQ4.3 – QLL Override Criteria

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PA Criteria Category/Drug: Antimigraine Agents, Triptans

Length of authorization: 1 year

Medications

PA Status	
Preferred	**Non-Preferred**
Rizatriptan tablet, ODT generic Sumatriptan nasal spray, tablet generic Zomig Nasal Spray (zolmitriptan)	Almotriptan generic Cafergot (ergotamine with caffeine 1/100 mg tablet)* Dihydroergotamine (DHE) nasal spray generic Eletriptan generic Ergomar (ergotamine sublingual) Frova (frovatriptan) Migergot (ergotamine with caffeine 2/200 mg suppository) Migranal Nasal Spray (dihydroergotamine) Naratriptan generic Onzetra Xsail (sumatriptan nasal powder) Sumatriptan injection generic Tosymra (sumatriptan nasal spray) Treximet (sumatriptan/naproxen) Trudhesa (dihydroergotamine nasal spray) Zembrace SymTouch (sumatriptan for injection) Zolmitriptan tablet, ODT generic Zomig (zolmitriptan tablet) Zomig ZMT (zolmitriptan ODT)

ODT=orally disintegrating tablets; *non-preferred but does not require PA

- **Note:** The triptan tablets are limited to 9 total tablets per 30 days. See quantity level limit (QLL) authorization criteria below for QLL requests.
- **Step Edit:** For generic almotriptan, generic eletriptan, brand Frova, generic naratriptan and brand Zomig, look back 60 days in claims history for two of the following: rizatriptan tablet/orally disintegrating tablet and sumatriptan tablet to bypass reject 75.
- **Step Edit:** For Ergomar and Zomig ZMT, look back 60 days in claims history for rizatriptan orally disintegrating tablet and sumatriptan tablet to bypass reject 75.
- **Note:** If brand Migranal Nasal Spray is approved, notify the caller that the generic is preferred over the brand and the PA is approved for generic dihydroergotamine nasal spray.
- **Note:** If generic zolmitriptan is approved, notify the caller that the brand is preferred over the generic and the PA is approved for brand Zomig; enter the PA for brand Zomig at the NDC level.
- **Note:** If generic zolmitriptan ODT is approved, notify the caller that the brand is preferred over the generic and the PA is approved for brand Zomig ZMT; enter the PA for brand Zomig ZMT at the NDC level.

Quantity Level Limit Authorization Criteria

Triptans

1. How many moderate to severe headache days does the member experience each month?
If >8 days per month = Go to next question. If ≤8 days per month = DENY and refer to RPH.
2. Is the triptan being used for migraine prophylaxis?
If YES = DENY and refer to RPH. If NO = Go to next question.

3. Is the member receiving prophylactic (preventative) therapy for migraine headaches such as an anticonvulsant, antidepressant, beta-blocker, calcium channel blocker, or NSAID? *Examples of prophylactic therapy may include but not limited to the medications in Table 1 below.*
If YES = Go to next question. If NO = DENY and refer to RPH.
4. Is the member taking this triptan in combination with another triptan or an ergotamine (ex. Migranal, dihydroergotamine, Cafergot, Ergomar, Migergot)?
If YES = DENY and refer to RPH. If NO = APPROVE for 1 year.

Table 1

Prophylactic Drug Class	Example of medication
Anticonvulsants	Divalproex sodium/sodium valproate, gabapentin, topiramate (Topamax)
Tricyclic Antidepressants	Amitriptyline, nortriptyline, protriptyline, doxepin, imipramine
Selective serotonin reuptake inhibitors (caution: co-administration with triptans can cause serotonin syndrome)	fluoxetine, fluvoxamine, paroxetine, sertraline
Other antidepressants (caution: co-administration of venlafaxine with triptans can cause serotonin syndrome)	Bupropion, mirtazapine, trazodone, venlafaxine
Beta Blockers	Atenolol, metoprolol, nadolol, propranolol, timolol
Calcium Channel Blockers	Diltiazem, nimodipine, verapamil
NSAIDs	Aspirin, fenoprofen, flurbiprofen, mefenamic acid, ibuprofen, ketoprofen, naproxen

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PA Criteria Category/Drug: Diabetic supplies, Insulin pens or cartridges

Length of authorization: 1 year

Medications

PA Status	
Preferred	**Non-Preferred**
Apidra pens/cartridges (insulin glulisine)*	Basaglar pens/cartridges (insulin glargine 100 units/mL)
Baqsimi (glucagon nasal powder)	Fiasp pens/cartridges (insulin aspart with niacinamide)
Glucagon injection generic EXCEPT kit by Fresenius (NDC 63323-0582-82)*	Gvoke (glucagon injection)
Glucagen (glucagon injection)*	Humalog 200 units/mL pens/cartridges (insulin lispro)
Humalog 100 units/mL pens/cartridges (insulin lispro)	Humulin N pens/cartridges (insulin NPH)
Humalog Mix 50/50 pens/cartridges (insulin lispro/lispro protamine)	Insulin lispro/lispro protamine mix 75/25 pens/cartridges generic
Humalog Mix 75/25 pens/cartridges (insulin lispro/lispro protamine)	Lyumjev pens/cartridges (insulin lispro-aabc)
Humulin 70/30 pens/cartridges Humulin R U-500 pens/cartridges (insulin regular concentrate)	Novolin 70/30 pens/cartridges (insulin NPH/regular)
Insulin aspart pens/cartridges generic	Semglee pens/cartridges (insulin glargine 100 units/mL)
Insulin glargine 100 units/mL pens/cartridges generic*	Toujeo pens/cartridges (insulin glargine 300 units/mL)
Insulin aspart/aspart protamine mix 70/30 pens/cartridges generic	Tresiba pens/cartridges (insulin degludec)
Insulin lispro 100 units/mL pens/cartridges generic	Zegalogue (dasiglucagon)
Insulin syringes	
Ketone test strips	
Lancet devices and lancets	
Lantus pens/cartridges (insulin glargine 100 units/mL)*	
Levemir pens/cartridges (insulin detemir)*	
Novolin N pens/cartridges (insulin NPH)	
Novolin R pens/cartridges (insulin regular)	
Novolog pens/cartridges (insulin aspart)	
Novolog Mix 70/30 pens/cartridges (insulin aspart/aspart protamine)	
Pen needles	
True Metrix blood glucose test strips	

*Does not require PA; The drug names above include all available pen/cartridge/syringe formulations under the same primary name unless otherwise stated.

- **Note:** Please refer to the covered diabetic supplies listing for covered NDCs located at the State's website
- **Note:** Please see end of document for quantity level limit (QLL) criteria for test strips, lancets, pen needles and insulin syringes.
- **Note:** Glucagon, Glucagen, Lantus and Levemir pens/cartridges do not require PA. Other preferred insulin pens/cartridges do not require PA for members younger than 21 years of age. Non-preferred insulin pens/cartridges require PA for all ages.
- **Note:** All lancet devices, lancets, pen needles and insulin syringes will be covered at a flat MAC rate.
- **Note:** For True Metrix Test Strips, enter approvals at the PA list level using the following: PA NDC list-TRUE and PA Reason Code-XC. Do not enter approvals at NDC-9 level.
- **Grandfathering:** For all preferred and non-preferred products, look back 365 days for same product to bypass reject 75.
- **Step Edit:** Preferred test strips and lancets: Claims history reviewed for 1 antidiabetic medication in the past 90 days to bypass reject 75. Claims history also reviewed for 1 prenatal vitamin in the past 90 days or an ICD-10 code submitted on claim for gestational diabetes (O24.410, O24.414, O24.419, O24.420, O24.424, O24.429, O24.430, O24.434, O24.439, O99.810, O99.814, or

O99.815) to bypass reject 75. Insulin syringes: Claims history reviewed for desmopressin/DDAVP vial, insulin vial, enoxaparin/Lovenox vial, Epogen, Granix, Leukine, Neupogen, Nivestym or growth hormone vial claim in the past 90 days to bypass reject 75. Pen needles: Claims history reviewed for 1 claim of insulin pen/cartridge, Forteo, Byetta, Victoza, SymlinPen or growth hormone pen/cartridge in the past 90 days to bypass reject 75. Baqsimi: Claims history reviewed for 1 claims of generic glucagon injection in the past 90 days to bypass reject 75.

Quantity Level Limit Criteria

Quantity Level Limit (QLL) Criteria for Blood Glucose Test Strips and Lancets

1. On average, how many times per day does the member test his or her blood glucose?
If >5 = Go to next question. If ≤5 = DENY and refer to RPH.
2. What is the member's hemoglobin A1C (HbA1c)?
If ≥7 = APPROVE for 1 year. If <7 = Go to next question.
3. Please submit a letter of medical necessity stating the reasons that testing blood glucose more than 5 times per day is required.
If reasons are valid in letter of medical necessity = APPROVE for 1 year. If reasons are not valid or letter of medical necessity is not received = DENY and refer to RPH.

Quantity Level Limit (QLL) Criteria for Insulin Syringes

1. How many insulin syringes does the member use each day?
If >4 = APPROVE for 1 year. If ≤4 = DENY and refer to RPH.

Quantity Level Limit (QLL) Criteria for Pen Needles

1. How many pen needles does the member use each day?
If >4 = APPROVE for 1 year. If ≤4 = DENY and refer to RPH.

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PA Criteria Category/Drug:	Biologic Immunomodulators
Length of authorization:	Varies

Medications

PA Status	
Preferred	**Non-Preferred**
Adbry (tralokinumab)	Actemra subcutaneous (tocilizumab)
Arcalyst (rilonacept)	Amjevita (adalimumab-atto)
Dupixent (dupilumab)	Cibinqo (abrocitinib)
Enbrel (etanercept)	Cimzia (certolizumab)
Fasenra Pen (benralizumab autoinjector)	Cosentyx (secukinumab)
Humira (adalimumab)	Enspryng (satralizumab-mwge)
Ilaris (canakinumab)	Kineret (anakinra)
Kevzara (sarilumab)	Olumiant (baricitinib)
Nucala Pen (mepolizumab autoinjector)	Orencia subcutaneous (abatacept)
Otezla (apremilast)	Rezurock (belumosudil)
Taltz (ixekizumab)	Rinvoq (upadacitinib)
Xeljanz (tofacitinib tablets)	Siliq (brodalumab)
Xeljanz Oral Solution (tofacitinib)	Simponi (golimumab)
Xeljanz XR (tofacitinib extended-release tablets)	Skyrizi (risankizumab)
	Sotyktu (deucravacitinib)
	Stelara (ustekinumab)
	Tremfya (guselkumab)

The drug names above include all available oral or subcutaneous formulations under the same primary name unless otherwise noted.

- **Note:** All preferred and non-preferred agents require prior authorization. Intravenous (IV) formulations of the biologic immunomodulators are not covered under Pharmacy Services. Only Fasenra and Nucala autoinjector pen formulations are covered under Pharmacy Services.
- **Note:** If the provider is calling for authorization for administration in a physician's office or clinic, please instruct them to go to the State website to request coverage from Physician Services.
- **Note:** PAs for Enbrel should be entered at the GPI-10 (6629003000****)
- **Note:** All starter or titration kits/packs/packages should be approved one time only – one per lifetime limit.
- **Step Edit:** For Kineret and Cimzia, look back 365 days for 3 months use of each Enbrel and Humira to bypass reject 75.
- **Grandfathering:** For Arcalyst, Ilaris and Otezla, look back 180 days in claims history for same product (not specific to strength) to bypass reject 75.

QLL Criteria

Quantity Level Limit (QLL) Criteria for Cimzia

1. Is the patient initiating therapy with Cimzia for any diagnosis below or renewing therapy with Cimzia for Plaque Psoriasis?

Crohn's Disease
• 400 mg initially and at weeks 2 and 4. If response occurs, follow with 400 mg every four weeks.
Rheumatoid Arthritis
• 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week; for maintenance dosing, 400 mg every 4 weeks can be considered.
Psoriatic Arthritis
• 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week; for maintenance dosing, 400 mg every 4

weeks can be considered.
Ankylosing Spondylitis
• 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks.
Non-Radiographic Axial Spondyloarthritis
• 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks.
Plaque Psoriasis
• 400 mg every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week may be considered.

If YES = May APPROVE 2 kits (400 mg each) per 30 days for the initial month of therapy only. For Plaque Psoriasis, may APPROVE 2 kits (400 mg each per 30 day for initial requests and renewal requests if member is dosing 400 mg every other week.
If NO = DENY and refer to RPH (max of 1 kit [400 mg each] per 30 days allowed for maintenance dosing).

Quantity Level Limit (QLL) Criteria for Humira

1. What is the member's diagnosis?

Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis
• Adults: 40 mg every other week. Some patients with rheumatoid arthritis not receiving methotrexate may benefit from increasing the dosage to 40 mg every week or 80 mg every other week.
Juvenile Idiopathic Arthritis or Pediatric Uveitis
• Pediatric Patients 2 Years of Age and Older: Depending on weight, 10 mg, 20 mg or 40 mg every other week.
Crohn's Disease
• Adults: 160 mg on Day 1 (given in one day or split over two consecutive days), 80 mg on Day 15, followed by 40 mg every other week starting on Day 29.
• Pediatric Patients 6 Years of Age and Older: Depending on weight, 80 mg or 160 mg (single dose or split over two consecutive days) on Day 1, 40 mg or 80 mg on Day 15, followed by 20 mg or 40 mg every other week starting on Day 29.
Ulcerative Colitis
• Adults: 160 mg on Day 1 (given in one day or split over two consecutive days), 80 mg on Day 15, followed by 40 mg every other week starting on Day 29. Discontinue in patients without evidence of clinical remission by eight weeks (Day 57).
• Pediatric Patients 5 Years of Age and Older: Depending on weight, 80 mg or 160 mg (single dose or split over two consecutive days) on Day 1, 40 mg or 80 mg on Day 8, 40 mg or 80 mg on Day 15, followed by 40 mg or 80 mg every other week or 20 mg or 40 mg every week starting on Day 29.
Plaque Psoriasis and Adult Uveitis
• 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose.
Hidradenitis Suppurativa
• Adults: 160 mg (given in one day or split over two consecutive days) on Day 1, 80 mg on Day 15, followed by 40 mg every week or 80 mg every other week starting on Day 29.
• Adolescents 12 Years of Age and Older: Depending on weight, 80 mg on Day 1 followed by 40 mg every other week starting on Day 8 or 160 mg (given in one day or split over two consecutive days) on Day 1, 80 mg on Day 15, followed by 40 mg every week or 80 mg every other week starting on Day 29.

If plaque psoriasis = May APPROVE 4 syringes per 28 days for the initial month of therapy only or may APPROVE one psoriasis starter pack per lifetime.
If uveitis = May APPROVE 4 syringes per 28 days for the initial month of therapy only.
If Crohn's disease = May APPROVE 6 syringes per 28 days for the initial month of therapy only or may APPROVE one Crohn's disease starter pack per lifetime.
If ulcerative colitis = May APPROVE 6 syringes per 28 days for the initial month of therapy only.
If hidradenitis suppurativa = May APPROVE 6 syringes per 28 days for the initial month of therapy only and APPROVE 4 syringes per 28 days thereafter.
If rheumatoid arthritis = Go to next question.
If other diagnosis = DENY and refer to RPH (max of 2 syringes per 28 days allowed for other diagnoses).

2. Is the member currently taking or will the member begin taking methotrexate?

The dosing for rheumatoid arthritis is 40 mg every other week. Patients not taking concomitant methotrexate may benefit from a dosage of 40 mg every week.
If YES = DENY and refer to RPH (max of 2 syringes per 28 days allowed). If NO = May APPROVE 4 syringes per 28 days.

Quantity Level Limit (QLL) Criteria for Enbrel

1. What is the member's diagnosis? *The dosing for plaque psoriasis is: 50 mg dose given twice weekly for 3 months, followed by a reduction to a maintenance dose of 50 mg weekly.*
If plaque psoriasis = APPROVE a maximum of 8 syringes per 28 days for 3 months only. If other diagnosis = DENY and refer to RPH.

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In the event of a denial, advise all callers of appeal rights and the reason for denial.

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PA Criteria Category/Drug: Hepatitis C Agents

Length of authorization: Varies

Medications

PA Status	
Preferred	**Non-Preferred**
Direct Inhibitors	
Mavyret (glecaprevir/pibrentasvir)* Sofosbuvir/velpatasvir 400/100 mg tablets generic* Vosevi (sofosbuvir/velpatasvir/voxilaprevir)*	Epclusa Paks (sofosbuvir/velpatasvir 200/50 mg, 150/37.5 mg pellets) Harvoni 45/200 mg and Paks (ledipasvir/sofosbuvir) Ledipasvir/sofosbuvir 90/400 mg generic Sovaldi (sofosbuvir) Zepatier (elbasvir/grazoprevir)
Ribavirin	
Ribavirin generic	n/a)
Pegylated Interferons	
Pegasys (peginterferon alfa-2a)	
Interferons	
Intron-A (interferon alfa-2b)	

*Preferred but requires PA

- **Note:** Mavyret, sofosbuvir/velpatasvir 400/100 mg generic and Vosevi are preferred but require prior authorization.
- **Note:** For all repeat authorization/retreatment requests, faxed documentation of the Hepatitis C Retreatment Form is required. The Hepatitis C Retreatment Form must be completed and signed by the physician to be accepted. This Form is located at the State website

Table 1: Quantity of Medication for Sofosbuvir/Velpatasvir 400/100 mg Generic Therapy

Patient Population	Treatment	Total Quantity (Duration)
Without cirrhosis or with compensated cirrhosis (Child-Pugh A)	sofosbuvir/velpatasvir	84 tablets (for 12 weeks)
With decompensated cirrhosis (Child-Pugh B or C) who are ribavirin ineligible	sofosbuvir/velpatasvir	168 tablets (for 24 weeks)
With decompensated cirrhosis (Child-Pugh B or C) who are ribavirin eligible	sofosbuvir/velpatasvir + ribavirin	84 tablets (for 12 weeks)

Table 2: Quantity of Medication for Harvoni 45/200 mg and Pak and Ledipasvir/Sofosbuvir 90/400 mg Generic Therapy

Patient Population	Treatment	Total Quantity (Duration)
Genotype 1 treatment-naïve adults without cirrhosis who have pre-treatment HCV RNA < 6 million IU/mL	Harvoni/ledipasvir-sofosbuvir	56 tablets (for 8 weeks)
Genotype 1 treatment-naïve adults without cirrhosis who have pre-treatment HCV RNA ≥ 6 million IU/mL	Harvoni/ledipasvir-sofosbuvir	84 tablets (for 12 weeks)
Genotype 1 treatment-naïve adults who have HIV or compensated cirrhosis (Child-Pugh A), or treatment-naïve	Harvoni/ledipasvir-sofosbuvir	84 tablets (for 12 weeks)

adolescents without cirrhosis or with compensated cirrhosis (Child-Pugh A)		
Genotype 1 treatment-experienced adults without cirrhosis and without liver transplant or adolescents without cirrhosis	Harvoni/ledipasvir-sofosbuvir	84 tablets (for 12 weeks)
Genotype 1 treatment-experienced adults with compensated cirrhosis (Child-Pugh A) and without liver transplant who are ribavirin ineligible or adolescents with compensated cirrhosis (Child-Pugh A)	Harvoni/ledipasvir-sofosbuvir	168 tablets (for 24 weeks)
Genotype 1 treatment-experienced adults with compensated cirrhosis (Child-Pugh A) and without liver transplant who are ribavirin eligible	Harvoni/ledipasvir-sofosbuvir + ribavirin	84 tablets (for 12 weeks)
Genotype 1, 4, 5 or 6 adults with decompensated cirrhosis (Child-Pugh B or C) without liver transplant who are ribavirin ineligible	Harvoni/ledipasvir-sofosbuvir	168 tablets (for 24 weeks)
Genotype 1, 4, 5 or 6 adults with decompensated cirrhosis (Child-Pugh B or C) without liver transplant who are ribavirin eligible	Harvoni/ledipasvir-sofosbuvir + ribavirin	84 tablets (for 12 weeks)
Genotype 1, 4, 5 or 6 adults with liver transplant	Harvoni/ledipasvir-sofosbuvir + ribavirin	84 tablets (for 12 weeks)
Genotype 4, 5 or 6 treatment-naïve or treatment-experienced adults or adolescents without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni/ledipasvir-sofosbuvir	84 tablets (for 12 weeks)
Genotype 1, 4, 5 or 6 treatment-naïve or interferon/peginterferon-experienced pediatrics without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni/ledipasvir-sofosbuvir	84 tablets (for 12 weeks)

Table 3: Quantity of Medication for Sovaldi Therapy

Patient Population	Treatment	Total Quantity
Genotype 1 treatment-naive without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + PEG/RBV	84 tablets (for 12 weeks)
Genotype 1 treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	168 tablets (for 24 weeks)
Genotype 2 without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	84 tablets (for 12 weeks)
Genotype 3 without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin	168 tablets (for 24 weeks)
Genotype 3 peginterferon/ribavirin-experienced with compensated cirrhosis (Child-Pugh A)	Sovaldi + Zepatier	84 tablets (for 12 weeks)
Genotype 4 treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + PEG/RBV	84 tablets (for 12 weeks)
Hepatocellular carcinoma awaiting liver transplantation	Sovaldi + ribavirin	Up to 336 tablets (for up to 48 weeks) or until liver transplantation, whichever occurs first

PEG/RBV=peginterferon/ribavirin

Table 4: Quantity of Medication for Zepatier Therapy

Patient Population	Treatment	Duration
Genotype 1a treatment-naïve or peginterferon/ribavirin-experienced	Zepatier	84 tablets (for 12 weeks)

without baseline NS5A polymorphisms		
Genotype 1a treatment-naïve or peginterferon/ribavirin-experienced with baseline NS5A polymorphisms	Zepatier + ribavirin	112 tablets (for 16 weeks)
Genotype 1b treatment-naïve or peginterferon/ribavirin-experienced	Zepatier	84 tablets (for 12 weeks)
Genotype 1a without baseline NS5A polymorphisms	Zepatier + ribavirin	84 tablets (for 12 weeks)
Genotype 1a with baseline NS5A polymorphisms	Zepatier + ribavirin	112 tablets (for 16 weeks)
Genotype 4 treatment-naïve	Zepatier	84 tablets (for 12 weeks)
Genotype 4 peginterferon/ribavirin-experienced	Zepatier + ribavirin	112 tablets (for 16 weeks)
Genotype 3 peginterferon/ribavirin-experienced with compensated cirrhosis	Zepatier + Sovaldi	84 tablets (for 12 weeks)

Table 5: Quantity of Medication for Mavyret Therapy

Patient Population	Treatment	Total Quantity (Duration)
Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Mavyret	168 tablets (for 8 weeks)
Treatment-naive with liver transplant or kidney transplant without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Mavyret	252 tablets (for 12 weeks)
Genotype 1, 2, 4, 5 or 6 treatment-experienced following interferon, peginterferon and/or ribavirin regimen without cirrhosis	Mavyret	168 tablets (for 8 weeks)
Genotype 1, 2, 4, 5 or 6 treatment-experienced following interferon, peginterferon and/or ribavirin regimen with compensated cirrhosis (Child-Pugh A), liver transplant or kidney transplant	Mavyret	252 tablets (for 12 weeks)
Genotype 3 treatment-experienced following interferon, peginterferon and/or ribavirin regimen without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Mavyret	336 tablets (for 16 weeks)

Table 6: Quantity of Medication for Vosevi Therapy

Patient Population	Treatment	Total Quantity (Duration)
Genotype 1, 2, 3, 4, 5 or 6 treatment-experienced	Vosevi	84 tablets (for 12 weeks)
Genotype 3 treatment-naive	Vosevi	84 tablets (for 12 weeks)

References

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3. Epclusa [prescribing information]. Foster City, CA: Gilead Sciences, Inc; Revised June 2021.
4. Harvoni [prescribing information]. Foster City, CA: Gilead Sciences, Inc; Revised March 2020.
5. Mavyret [prescribing information]. North Chicago, IL: AbbVie Inc; Revised June 2021.
6. Sovaldi [prescribing information]. Foster City, CA: Gilead Sciences, Inc; Revised March 2020.
7. Vosevi [prescribing information]. Foster City, CA: Gilead Sciences, Inc; Revised November 2019.
8. Zepatier [prescribing information]. Whitehouse Station, NJ: Merck Inc: December 2021.
9. American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) Guidance Panel. Hepatitis C Guidance 2020 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Last updated September 29, 2021. Available at https://www.hcvguidelines.org. Last accessed March 17, 2022.

In the event of a denial, advise all callers of appeal rights and the reason for denial.

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

MSQ5 – RetroDUR

Since 1993, CMS has required states to develop a comprehensive DUR program to ensure appropriate patient care and to address safety concerns. States are allowed significant flexibility in the administration of their programs, but there are two standard requirements:

1. States must prospectively review drug utilization against pre-determined criteria to identify and prevent potential safety issues.
2. States must retrospectively identify questionable prescribing patterns and target them for educational intervention.

More recently, CMS has provided guidance on specific DUR requirements including atypical anti-psychotic use in pediatric patients and opioid utilization from the perspective of fraud, misuse, or unnecessary medical care. These targeted directives underscore the need for a robust DUR program to rely on additional resources beyond pharmacy claims data.

Our Team member, NHC, brings proprietary software for utilization in DUR: *Compass*DUR, which addresses the complexity of increasingly specific CMS requirements as well as the unique needs of individual State programs. The software allows customizable clinical analytics in order to review both medical and pharmacy populations to identify and address suboptimal behaviors. *Compass*DUR provides prescribers with feedback on their individual prescribing behaviors as compared to program-specific criteria, accepted standards of practice, and treatment guidelines established by professional medical associations (e.g., the American College of Cardiology), as well as national and global health institutes (e.g., the Centers for Disease Control and Prevention [CDC] or the World Health Organization). The platform provides support and reinforcement when states plan to implement policy or coverage changes.

At the most basic level, the RetroDUR program our Team will provide to the State is based on initiatives to identify and monitor medical practices and medication usage for potential fraud, abuse, misuse, and inappropriate utilization or care among prescribers, pharmacies, and members.

A RetroDUR program starts with identification of an area of concern, resulting in a set of predetermined criteria the State intends to review against claims data to identify areas for educational focus and intervention. The Team will support the claims analysis function using *Compass*DUR. Areas of concern can come from multiple sources, including clinical literature, standard reporting and claims review, governmental and legislative authorities, State Board recommendations, pharmacy audit findings, and relevant, exemplary issues identified by peers in other state programs.

In addition to claims analysis, the importance of being able to create customized criteria that is defensible, referenced, targeted, and pre-determined, specifically for a State Medicaid program, cannot be understated. Our robust RetroDUR program is staffed with experienced pharmacists who are well trained to develop and deliver effective educational interventions and work under the direction of a clinical pharmacist; this is paramount in eliciting provider review and action.

Most RetroDUR interventions are classified based on problem type or area of concern. The interventions below are available to the State and include, but are not limited to, using preset standards (although the specifics of the intervention can vary) to examine:

- Overutilization and underutilization.
- Therapeutic appropriateness and duplication.
- Appropriate use of generics and formulary medications.
- Inappropriate duration of treatment.
- Inappropriate or medically unnecessary care.
- Overuse, misuse, abuse, and fraud.
- Incorrect dosage.
- Drug-drug interactions.
- Drug-disease contraindications.
- Drug-induced illness.
- Drug-pregnancy risk indicators.
- Use of high-cost prescription drugs.
- Polypharmacy.
- Agents of abuse.

As an additional resource for issue identification, our clinical team is a member of the American Drug Utilization Review Society. Our membership allows us to stay abreast of best practices on a national scale. Finally, our role and experience as a pharmacy audit and Medicaid program integrity vendor allows us to remain on the forefront of issue identification at the prescriber, pharmacy, and member level.

Intervention Development and Proposal Submission

Our Team develops criteria for each intervention based on a multi-step process reflective of the issue at hand. First, based on the results of the analyses performed during issue identification, we determine parameters against which claims data and member and/or provider behaviors are measured. Then we build algorithms leveraging those parameters to find potential targets of the planned intervention.

Typically, intervention rationale is created to determine a standard or threshold by which claims data and member and/or provider behavior is measured. Intervention rationale may be based on clinical literature, FDA-approved labeling, or expert consensus statements and are specific to the State and its patient population. Regardless of the origination, the criteria set forth are focused, referenced, and defensible.

We then create a sample of the intervention's educational material, or 'interventional collateral,' which typically includes the following documents:

- A provider letter that details the utilization problem and recommended corrective action.

- Report cards and/or patient profiles that demonstrate the provider's prescribing patterns.
- A survey, questionnaire, or other tool to capture provider feedback.

A summary of the issue identified, which includes a preliminary projection of the problem's scope and reach (based on claims data), is packaged along with the sample interventional collateral to create a formal RetroDUR proposal that is submitted to the State, the State Board, or both for review, refinement, and approval. Once approved, we identify the final provider targets for intervention and implement and execute the intervention via a method agreed upon by the State.

Our RetroDUR process is described in more detail below.

Experience and Knowledge is Key. Compulsory data analytics of RetroDUR interventions can present a conundrum. While the power to leverage data feeds from multiple sources has increased our ability to identify complex cases, the automation has also led to identification of extensive data sets, which results in information overload to providers. The Team will meet this challenge by exclusively staffing experienced clinical pharmacists with advanced education who are intimately involved in the RetroDUR process — especially criteria development and resultant case identification. For certain cases, we will conduct an additional review by an experienced clinician, in the specified field, who can gauge provider response and provide us with valuable feedback on ways to mitigate perceived informatics burden to the provider community.

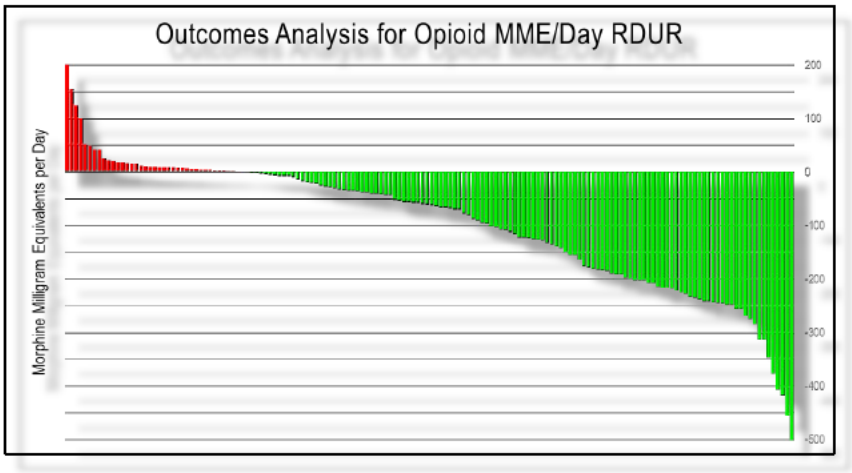
RetroDUR Intervention Process. Upon identification of the area of interest or problem type, the Team compares optimal medical practice or medication use with the State's actual medical practice or medication use utilizing claims data and provides a written proposal to the State detailing (1) the rationale for the RetroDUR intervention, (2) member and/or provider selection criteria with necessary data fields to conduct the evaluation, (3) intervention, and (4) analysis plan.

Identification and Initiation. Medical claims data provided by the State or its medical vendor and pharmacy claims data provided by the State's PBA vendor are reviewed. We build an algorithm and review the claims data to identify targeted members and/or providers for the intervention based on the RetroDUR proposal which delineates acceptable thresholds (e.g., percent of members or providers meeting the indicator) needed to evaluate the intervention. As a final step, the RetroDUR pharmacist then assesses the claims data to measure the State's actual medical practice or medication use and compares the findings to optimal medical practice or medication use. Irregular practice patterns, inappropriate medication use, and causes for any differences between actual and optimal usages are identified and interpreted. Rather than rely solely on system-generated letters, our Team also employs pharmacist review to ensure the approach and intervention are appropriately and specifically targeted and stratified. While a systematic approach will generate letters that meet the identified targets and is highly efficient, the process also must employ pharmacist review to ensure the appropriateness of the intervention and avoid burdening providers with unnecessary or irrelevant interventions.

The next step in the process is the actual intervention itself. We implement the educational intervention via methods agreed upon by the State. Letters are drafted detailing the rationale for the intervention with recommended corrective action. The confidential communications are mailed and/or faxed to corresponding members and/or providers highlighting the changes needed to optimize outcomes based on the intervention. The number of members and providers identified, along with the drafted prescriber, member, or pharmacy letters, are provided to and approved by the State prior to distribution to the targeted population. Generally, the letters are targeted at

providers, but member letters can be employed if the State desires to perform an intervention specific to compliance or PDL changes.

Intervention Evaluation, Measurement, and Reporting. Depending upon the timeline of the intervention, within approximately three to six months, the Team will evaluate the effectiveness of RetroDUR interventions by comparing claims data three months prior to the intervention to claims data three months after the intervention. The pre- and post-intervention findings are then compared to national standards or to the standards reported in other states as available. Clinical outcomes and financial impact of RetroDUR interventions are assessed, the rationale and reasons for positive and negative results are documented, and these results are reported to the State and its DUR Board quarterly and to CMS annually. Findings are reported to providers at the State's discretion. Finally, any findings of FWA are communicated to the appropriate program integrity division or vendor of the State.



A recent example of a RetroDUR intervention and the resulting outcomes data over a 12-month review period included activities for which the goal was to encourage prescribers to gradually taper total daily MME doses, where possible. In this intervention, letters were sent to prescribers whose patients were receiving high MME doses. The letters included CDC resources for opioid tapering. The post-intervention analysis revealed that 76% of the patients included in the intervention had decreased their baseline average daily MME. A positive impact such as this highlights the utility and importance of our *Compass*DUR solution.

Customizable to Meet Our Clients' Unique Needs

The Team's RetroDUR program, *Compass*DUR, is fully customizable. The platform intelligently incorporates the State's medical claims with its pharmacy claims to identify and address differences across the state, such as regional variations in health care access and utilization, distribution of disease states and seasonality in medication usage, as well as State utilization differences as compared to national standards. While the Team's goal is to guide and assist our clients, all intervention criteria and collateral are subject to review and refinement at the State's discretion. The Team agrees to make any updates to the RetroDUR files and criteria tables as recommended by the SAB within 10 business days of the State's approval.

The Team stands at the ready to provide the State with an intelligent and customizable RetroDUR program staffed by seasoned clinical pharmacists. As your dedicated clinical vendor, the State can be assured that the Team will not recycle canned interventions across multiple clients. Our pledge to our clients is to provide a customizable RetroDUR program that is specific to a given state, program, and population.

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 UM 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

MSQ6 – Approach to Appeals

The Team recognizes that the impact of a Clinical Management program is not limited to the quality of health care provided through the State's program but may also include inquiries and concerns from various stakeholders. As such, we are committed to responding to feedback from providers, patient advocates, manufacturers, and others affected by the program and its UM criteria. We propose several methods by which interested parties can raise concerns regarding the structure and functioning of the State's drug management policies. Our approach is designed to promote goodwill and collaboration among all participants.

With respect to Georgia Medicaid, new drug entities are not eligible for presentation to the SAB until the product has been on the market for six months. Prior to this review, there must be a pathway to coverage consistent with guidance from CMS. Manufacturers, advocacy groups, providers, and other interested parties have opportunities to provide input at an SAB meeting for consideration in the development and approval process for UM criteria as discussed below. Prior to review by the SAB, interested parties may seek information regarding the general process by contacting a dedicated email inbox for Georgia Medicaid, currently monitored by NHC. Those with patient-specific inquiries will be referred to the PBA's call center for further follow-up.

Generally, manufacturers may contact the Team at any time with product-specific inquiries. However, when a product is up for review or discussion by the State, manufacturers may request an appointment to present relevant information to our clinicians followed by a question and answer session. This forum allows manufacturers to present clinical information on a new drug, as well as clinical information relating to other drugs within the same therapeutic class. For drugs already available in the marketplace, manufacturers may present information that has become available since previous evaluations of the drug by the SAB. This information should emphasize any changes in the drug's place in therapy and highlight comparisons with other drugs in the same therapeutic class. Prior to the forum, the manufacturer must submit a one-page, factual summary of the drug in an electronic format to be provided to the State and SAB members.

Although the State employs a process by which a manufacturer can appeal an adverse recommendation by the SAB directly to the State, outside of this process, a manufacturer can submit an inquiry at any time to the Team regarding general concerns with respect to UM criteria. Questions unrelated to UM criteria, such as rebate questions, will be referred to the appropriate vendor for follow-up and resolution. Otherwise, we will review the manufacturer's concerns and follow up directly with the manufacturer with any questions and information. If we are able to resolve the issue after speaking with the manufacturer, then no further action is necessary. If we are unable to resolve the manufacturer's concerns, the issue is further researched, reviewing any available information and contacting experts within the state, if needed, for further input and recommendations. An analysis will be drafted and provided to the State with a summary of the

issue(s) raised and recommendations, if any, for next steps by the State. Upon a determination by the State, we can also convey this information to the manufacturer on behalf of the State. All inquiries and complaints will be logged and tracked so that a historical record is maintained for future reference.

In addition to manufacturers, advocacy groups and providers with general questions may contact us through a dedicated email inbox, specific to the State, regarding concerns with the UM program. Alternatively, the State may forward inquiries directly to the Team for handling and disposition. If the inquiry is unrelated to a product being reviewed and discussed at the next SAB, the process that will be followed is nearly identical to the process that applies to manufacturers. These inquiries will be triaged and assessed by the Team, and either resolved directly (as allowed by the State) or forwarded to the State for review and direction. We will research and provide the State with a summary of the issue(s) and recommendations, if applicable. For inquiries unrelated to UM or the FFS Medicaid program, we will direct the inquirer to an alternative resource, if known. For inquiries tangentially related to UM, such as claims processing, call center, or patient-specific issues, we may forward the inquiry to the PBA for follow-up and resolution. Any inquiries from the media will be referred directly to the State.

Interested parties of medications being reviewed at the next SAB, other than manufacturers, their agents, or care management organization enrollees, may contact the Team to submit consumer comments, or the like, for review by the SAB. This information can be forwarded directly to Board members and may also be included in the meeting binder for discussion at the meeting. An additional opportunity is available to non-manufacturer stakeholders to provide testimony directly to the SAB in the form of consumer comments via a signup sheet at the meeting. Presenters are required to disclose any conflicts of interest, including any payments or gifts in kind from manufacturers, whether directly or indirectly.

If, for any reason, the State is contacted directly by a stakeholder, the State may forward the pertinent information at its discretion to the Team for review and follow up. Once contacted, our clinical team will evaluate the communication for any clinical concerns and the PBA vendor as needed for any administrative or operational concerns. We may also collaborate with the rebate vendor to confirm that any recommendations made have taken into consideration both rebate contracting and the net cost to the State. Our feedback, along with relevant clinical and economic recommendations and suggestions for revision to UM criteria, if any, will be logged and forwarded to the State for review and determination. The State may decide to maintain the UM criteria as it currently stands or make subsequent changes to reflect their consideration of the issues presented.

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.

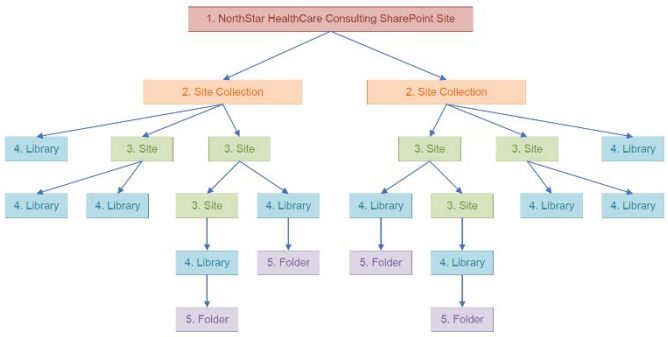
Supplier Response

MSQ7 – Document Repository

The secure management of sensitive data is an intrinsic component of a PCMS Program. We are committed to maintaining industry standards for data management. To meet the document repository requirements outlined in Attachments C and G of this eRFP, we propose leveraging Microsoft SharePoint to create and maintain a state-specific site, as outlined below.

SharePoint Design. Among its numerous features, SharePoint offers solutions for access control, storage, organization, tracking, dissemination, and mobile access.

- **RBAC:** Its **R**ole-**B**ased **A**ccess **C**ontrol feature allows for permissions to be based on roles (e.g., project team members, stakeholders). Permissions for viewing, editing, and managing documents can be controlled throughout the contract's duration.
- **Storage, Organization, and Tracking:** SharePoint's Document Libraries provide space where project-related documents may be stored, organized, and tracked. Additionally, its Version Control feature maintains a version history, ensuring proper control over document changes.



- **Dissemination and Interface:** SharePoint's Web Pages serve as interfaces wherein project team members and stakeholders may access project information, view the latest documentation, and submit issues or comments to the project team. The discussion boards, notifications, and alerts enhance collaboration.
- **Mobile Access:** A mobile access feature is available to authorized users, which affords access to the document repository.

Account Manager Oversight and Authorized Users. SharePoint allows the Contractor to assign an Account Manager to oversee the document repository, ensuring smooth operations and adherence to guidelines. Permissions may be assigned at the library level. If desired, the State can own and manage access to project documentation.

In addition to its mobile device accessibility, SharePoint ensures that users who have the authorization and appropriate credentialing have 24/7 access, upload capabilities, and document linking. Users may attach new or revised versions of electronic documents and images in various formats. SharePoint may be accessed by authorized users' mobile devices, allowing real-time communication with the centralized data repository. Additionally, users may link uploaded documents or images to other system documents or cases.

Document Organization, Creation, and Tracking Features. SharePoint's Document Libraries can be used to store detailed project documentation, including process documents, procedures, and guidelines. To aid in document creation and editing of projects, SharePoint supports templates, as well as collaborative editing wherein multiple team members can work on the same document simultaneously. A version history is maintained, allowing users to track changes and updates over the lifetime of a project. Additionally, metadata columns can be leveraged to categorize and organize documents by project activity or process.

Review, Modification, and Approval of Document Deliverables. SharePoint workflows can be set up to manage document approval processes. For example, when a document is modified, it can trigger an approval request and allow for designated approvers to review, modify, and approve document deliverables. Additionally, SharePoint can help manage deadlines by setting reminders and notifications, ensuring timely submission of records, documentation, reports, and data as specified in the State-approved Turnover Plan.

Operations Training and Retention. We will make available to the State comprehensive on-site training that may also be provided in a web-based format on SharePoint delivered by a certified professional. Additionally, an end-user operations manual specific to the State will be provided as reference material. The manual will address the requirements in Attachment C section 2.14.1 Document Repository and will include modules on system functionality, accessing the application, role-based access, interfacing and navigating within the application, and security protocols. Further training is available from SharePoint's official website. To familiarize new users with the site, SharePoint provides instructions on using the document repository effectively via its Operations Manual feature. Additionally, its web-based tutorial training sessions cover role-based access, navigation, document download, viewing, and confidentiality protocols. Lastly, SharePoint supports retention policies to ensure compliance with applicable ownership requirements.

SharePoint Maintenance Plan. SharePoint will be the primary access point for collaboration between our Team and the State. As such, it will be configured to meet the specific business needs of both organizations. It is imperative to this engagement that the application be well maintained and that outages be limited to planned downtime.

The SharePoint operational functionality plan will include support for updates and routine maintenance to maintain a healthy environment. Critical to maintenance of the application is communication between the end user and the project manager. All users will have the ability to submit tickets when issues arise. Further, the SharePoint project manager will review user logs to identify any unreported issues with access and functionality.

Any security enhancements to SharePoint will be assessed as they are provided. Upon assessment, the enhancements will be promptly implemented where applicable. SharePoint is regularly updated by Microsoft. Security patches to SharePoint published by Microsoft will be installed automatically and immediately upon availability.

Our Team will work with the State to determine document retention policies to facilitate the removal of obsolete content stored within the application.

The project manager will review site permissions regularly to remove or delete obsolete users or immediately upon receipt of notice of termination of a user, and to add or change permission settings at the user level as needed to limit access to the application's content.

The solution can be managed by our Team, and we will ensure that data stored within the site will not be located outside of the United States. The SharePoint maintenance plan will include routine backups and scheduled backup testing to ensure disaster recovery.

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:

a. 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.

b. Roles and responsibilities of staff.

c. Job titles and the requisite qualifications, skills, and credentials, including clinical licensures relevant to this Contract.

If Subcontractors will be used, provide the following:

a. Subcontractor's name and address.

b. Roles and responsibilities to be delegated to the Subcontractor for purposes of this Contract.

c. Subcontractor's qualifications to perform these roles and responsibilities.

d. 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

MSQ8 – Staffing

The Myers and Stauffer Team includes highly skilled specialists with significant knowledge and expertise in PCMS within a Medicaid program. All staff assigned to this master agreement have past experience providing direct services for CMS and state Medicaid agencies. At contract onset, we will implement a Staff Management Plan in accordance with eRFP requirements and adhere to that plan. Following, we present an overview of plan elements.

Organizational Chart (a)

We are pleased to present our organizational chart below, which shows the specific staff structure proposed to accomplish the requirements of the PCMS scope and includes our subcontractor, NHC. We understand that if there are changes to our staff plan, we must update the organizational chart within five business days prior to the change/vacancy. The team, as depicted in the organizational chart below, includes individuals with an intimate understanding of Medicaid programs including Georgia and firsthand experience in other Medicaid pharmacy programs.

[redacted]

Roles and Responsibilities of Staff (b)/Job Titles, Qualifications, Skills, and Credentials (c)

The table below presents our proposed staff, their credentials, roles and responsibilities, and qualifications/skills. The adequacy of our staffing plan is evidenced by the quality of our Team's historical clinical management experience — meeting and exceeding contract requirements.

Myers and Stauffer: Proposed Staff	
Staff Name/Role/Responsibilities	**Qualifications**
[redacted] **Role: Project Leader** Provides direct project governance. Maintains alignment with identified project goals and supports the Project Manager and Team by providing timely decisions, sets priorities and strategy, communicates any issues, and provides resources. **FTE:** 0.10	• More than 30 years of professional experience with over 20 in Medicaid pharmacy rate setting and reimbursement. • A principal of the firm and co-partner-in-charge of our national pharmacy engagement team. • Oversees Myers and Stauffer's contract with CMS to develop and maintain the NADAC benchmark. • Has managed and provided QA on a variety of projects including pharmacy consulting, pharmacy reimbursement, program integrity, litigation support, and rate setting.
[redacted] **Role: Clinical Management Team Manager**	• More than 11 years of experience in pharmacy and PCMS. • Prior experience includes Medicaid FFS government health care, as well as Medicare, commercial, and exchange health plans, supporting program and pharmacy management. Served in roles of RetroDUR

Provides overall management to the PCMS Team. **FTE:** 0.50	Product Manager and Clinical Account Manager for several states. • PharmD, Albany College of Pharmacy and Health Sciences.
[redacted] **Role: NHC Oversight** Serves as a resource regarding Medicaid FFS Programs, Clinical Management, and Policy Interpretation **FTE:** 0.20	• Founder of NHC and serves as President and CEO. • Over 25 years of experience working with Medicaid programs in both the FFS and managed care spaces; former Interim Medicaid Pharmacy Director for Georgia Medicaid. • Experience includes PA management; FWA; formulary, and PDL development. • PharmD, University of Georgia, College of Pharmacy.
[redacted] **Role: NHC Clinical Management Team Lead; Clinical Program Director** Oversees the PCMS Team's work in medication therapy management and DUR programs; supports the State's DUR Board. **FTE:** 1	• Eight years of experience supporting Georgia's PCMS Program. • Provide hands-on clinical management services and oversees the team's work in medication therapy management, DUR programs including RetroDUR, medication PA, pharmacy claim data analysis, and support of the State's DUR Board. • Three years of prior experience in retail pharmacy as a pharmacist and pharmacy manager. • PharmD, University of Georgia, College of Pharmacy.
[redacted] **Role: Clinical Pharmacist** Supports the Clinical Program Director and ensures PA decisions and criteria are consistent with covered benefits, quality of care, and medical necessity. **FTE:** 1	• Twelve years of experience providing clinical management services for Georgia's program. • Ensures PA decisions are consistent with covered benefits, quality of care, and medical necessity. • Provides independent evaluations and recommendations for appropriate therapeutic solutions and communicates clinical decisions to providers and patients. • Prior experience in a clinical capacity for a pharmacy benefit management company and was also a dispensing pharmacist for 14 years. • PharmD, University of Georgia, College of Pharmacy.
[redacted] **Role: Clinical Pharmacist** Supports the Clinical Program Director and ensures PA decisions	• Six years of experience working with PBAs, designing and providing clinical support for Medicaid programs involving RetroDURs, PAs, and the creation of new drug monographs.

are consistent with covered benefits, quality of care, and medical necessity. **FTE:** 1	• Eight years of clinical pharmacy hospital experience and served 11 years as a preceptor and/or professor to pharmacy students. • PharmD, Duquesne University.
Additional Clinical Pharmacist Senior Advisor* and SMEs (FTE: 0.10, each) [redacted] **Senior Advisor* [redacted] [redacted] [redacted] [redacted]	The combined group of the clinical pharmacist senior advisor and clinical pharmacist SMEs have extensive experience in pharmacy clinical management, including the following qualifications, and they will provide Medicaid-specific pharmacy perspectives to support the clinical management team: • Former Medicaid Director, state of Georgia. • Former Medicaid Pharmacy Director for Georgia. • Previous experience for the state of Connecticut Medicaid program as Medicaid drug rebate manager, PA call center supervisor, and Medicaid Management Information System SME. • Previous experience supporting the DUR Board for the state of Mississippi. • Each has extensive backgrounds involving Medicaid FFS and managed care programs including evaluation and reimbursement recommendations for pharmacy claims and PADs, 340B program evaluation, cost/benefit analyses of PDL/PA programs, specialty drugs, pharmacy claims analysis, Medicaid drug rebates, and cost containment opportunity evaluations.

Key Staff. Per eRFP Attachment C, Section 3.2, Contractor Key Staff, we acknowledge that staff designated as key staff following contract award will be committed to the project 100% of the time or as agreed upon by the State. We will work in partnership with the State to ensure staffing levels and time commitments meet the needs of the program throughout the contract term. The Myers and Stauffer Team has sufficient staff on for all key staff positions for this engagement and a fully staffed Team will be ready to begin upon contract start. For key staff, we understand that we must notify the State within two business days of the date a key staff position resigns; obtain the State's written consent before key staff and other proposed project staff can be reassigned or replaced; name a temporary replacement acceptable to the State when key staff resigns or is reassigned and must do so within five business days of the position's vacancy; name a temporary replacement acceptable to the State prior to periods of planned leave for key staff positions; and ensure a permanent replacement is working on the project within 60 calendar days of the date a key staff position becomes vacant. We acknowledge that the State may request reassignment/replacement of key staff at any point throughout the life of the contract.

Meeting Federal and State Requirements. Our Team is committed to being fully compliant with all federal and state requirements relative to our workforce. Each Team member has equal employment opportunity policies and procedures in place to ensure fair employment and treatment of all employees without regard race, color, religion, national origin, or physical disability. Team members adhere to all federal and state laws regarding social security registration and legal work status of all their employed or contracted staff. We complete criminal background checks for all employed or contracted staff prior to project participation and we commit to using State-accepted background check criteria and submit results to the State for review. Both Myers and Stauffer and NHC are located within the United States and will not perform any work related to this contract outside of the United States for the duration of the contract. Both Myers and Stauffer and NHC associates are subject to the guidelines stipulated in their respective employee handbooks, including requirements to disclose any potential areas of conflict. Once approved by the State, we understand it is our responsibility to maintain compliance with the Staff Management Plan for the duration of the contract.

Subcontractor Information

Myers and Stauffer will utilize the services of NHC throughout the contract. We understand that we are responsible for all work performed by NHC and that State approval is required, in writing, prior to any agreement between Myers and Stauffer and any subcontractor.

Subcontractor Name and Address (a). NorthStar HealthCare Consulting; 4080 McGinnis Ferry Road; Alpharetta, GA 30005

Subcontractor Roles and Responsibilities (b)/Tasks the Subcontractor will Perform. NHC will collaborate with Myers and Stauffer to comprehensively provide pharmacy clinical management as described in Attachment G of the eRFP to include SAB support services, DUR services, UM program services and RetroDUR services.

Subcontractor Qualifications (c). NHC specializes in clinical cost containment strategies for government-sponsored health care, commercial programs, and fraud and abuse. Founded by clinicians, their extensive staff expertise comprises over 30 years of Medicaid, managed care, and fraud and abuse experience. Their clinicians have personal experience in over 16 Medicaid states assisting with formulary management, prior authorization programs, and retrospective drug utilization review programs among others.

Subcontractor Letter of Agreement (d).

NorthStar HealthCare Consulting
Let Us Be Your Guide

April 19, 2024

Mike Johnson, CPA, CFE
Myers and Stauffer
1349 W Peachtree Street NE, Ste. 1600
Atlanta, GA 30309

Dear Mr. Johnson:

NorthStar Healthcare Consulting (NHC) is pleased to serve as a subcontractor to Myers and Stauffer LC (Myers and Stauffer) in response to the Electronic Request for Proposals (eRFP), Event Number 41900-DCH0000136 – Pharmacy Benefit Services.

We are a Georgia-based Tier I small business and we are a 100% female-owned consulting services firm that specializes in clinical services and pharmacy audits. NHC has worked as the clinical management and fraud, waste, and abuse vendor to the state of Georgia since 2006 via a subcontract relationship with the current Georgia Medicaid fee-for-service program pharmacy claims processor. As the incumbent for the clinical management and fraud, waste, and abuse scopes of work for the lead state, NHC possess the qualifications to perform these roles and responsibilities.

NHC's extensive staff expertise comprises over 30 years of Medicaid, managed care, and fraud and abuse experience. Our clinicians have personal experience in over 16 Medicaid states and numerous commercial clients assisting with formulary management, prior authorization programs, and retrospective drug utilization review programs among others. Our fraud and abuse staff have performed audits in every state of the country and has added expertise in Bill of Right states.

As required in RFP Sections Attachment U Pharmacy Clinical Management Services MSQ8 and Attachment W Pharmacy Fraud, Waste, and Abuse Audit Services MSQ12, we have provided this letter of agreement to conduct the following activities for this engagement:

- *Pharmacy Clinical Management Services.*
  - *"Pharmacy Clinical Management Services" as described in Attachment G of the eRFP, to include:*
    - *State Advisory Board support.*
    - *Drug Utilization Review Services.*
    - *Utilization Management Program.*
    - *Retrospective Drug Utilization Review.*

- *Pharmacy Fraud, Waste, and Abuse.*
  - *"Pharmacy Fraud, Waste, and Abuse (FWA) Audit Services" as described in Attachment H of the eRFP, to include:*
    - *Audits.*
    - *Concurrent Review.*
    - *Reporting.*
    - *Pharmacy Lock-In Program.*

I, Emily Baker, President and CEO, am authorized to contractually obligate our company and negotiate a contract on behalf of NHC. My contact information is:

Emily Baker, PharmD, BCPS, MBA, MHA
NorthStar HealthCare Consulting
4080 McGinnis Ferry Road
Alpharetta, GA 30005
Phone: (678) 672-4210
E-mail: ebaker@nhc-llc.com

Thank you for providing us with the opportunity to participate in this bidding process.

Sincerely,

Emily Baker

Emily Baker, PharmD, BCPS, MBA, MHA
President and CEO

Additional Staff Management Plan Details/General Requirements

Subcontractor Management. We understand we are responsible for all work performed by our subcontractor and that the State must approve all subcontractors in writing prior to any agreement between Myers and Stauffer and NHC. Myers and Stauffer's approach to using subcontractors on engagements is to seamlessly integrate the staff of the subcontractor with our staff. Our subcontracting staff work alongside the Myers and Stauffer staff and are involved in planning, meetings, and any project team communications and receive consistent training.

Estimated Subcontractor Percentage of Total Contract Dollars. The estimated utilization of the subcontractor is 49% of total contract dollars.

Staff Training. We will cross-train our staff to ensure someone is always available for our clients. New staff members are provided with additional training commensurate with their experience and work assignments. We also maintain an electronic learning management training system through which staff complete required and on-demand learning modules to increase their knowledge base.

Escalation Paths. Myers and Stauffer will provide and maintain a Responsible, Accountable, Consulted, and Informed contact list for both routine and emergency situations.

Resources Calendar. During our kick-off call for each project phase, we will present a resource calendar including staff names, time commitment, location, and other relevant details. This will be a living document and updated/reported weekly.

Secure Communications. Myers and Stauffer is able to provide a variety of tools to accommodate secure communications including the use of secure email, portals, and secure file transfer protocol methods.

Implementation Phase Interaction. Although our Team member, NHC, is the incumbent vendor for PCMS for the state of Georgia's Medicaid FFS program, we understand that some project implementation will still be necessary to coordinate with other potential changes being implemented by the State. The Team will develop a Communication Plan (see response to MSQ11.8) and an Implementation Plan (see response to MSQ11.3) to address appropriate during the Implementation Phase.

Staff Retention. We strive to maintain staffing consistency on all of our engagements to ensure project continuity and maintain the highest levels of client satisfaction. In the event of staff turnover, we will offer replacement personnel of equal or greater credentials and experience and will comply with the State's requirements for the replacement of key staff (see *Key Staff* section above).

Additional Contractor Duties, Responsibilities, and Requirements. The Myers and Stauffer Team will maintain the level of staff described in the plan through the life of the contract unless the State agrees to a change in advance; obtain State approval prior to changes to staffing and/or skill levels; increase staffing levels if requirements or standards are not being met based on the discretion of the State and at no additional cost to the State; ensure Myers and Stauffer Team staff only perform work under the contract which has been approved by the State; comply with all other State staffing requirements, including but not limited to, those pertaining to security, health, and safety issues; commit key staff to the project 100% of the time or as determined/agreed upon by the State; only allow key staff to serve in one role, unless approved by the State in writing; ensure key staff have experience with health care and Medicaid program operation; be available after normal work hours as required by the State.

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

MSQ9 – Project Stages and Phases

Our Team recognizes the State's commitment to a stepwise incremental project management approach during this engagement while acknowledging that not all of the project stages and phases are applicable to service-related scopes of work. As our Team includes the incumbent PCMS vendor for the lead State, we do not plan to deviate from the outline which recognizes two project stages: Design, Development, and Implementation (DDI); and Operations and Maintenance (O&M). Although the clinical management services SOW is largely service-related, the implementation or enhancement of our *Compass*DUR program will follow the State's outline, where applicable.

DDI Stage

As will be described in a Communications Management Plan to be developed by the Team, the DDI stage will begin with a joint project planning kick-off meeting with the State. The Project Manager will disseminate a meeting agenda to identified stakeholders and participants to facilitate the kick-off meeting. The overarching goal of the kick-off meeting is to define the SOW and document requirements analysis for the DDI stage. During the meeting, our plans and processes for Project Schedule/Project Work, Communications Management, Risk and Issue Management, Project Change Management, and Quality Assurance and Control will be reviewed and discussed. These plans will have been drafted based on our existing knowledge of the state's programs combined with any new functionality as described within this solicitation. Further, we will collaborate with the State to agree on a conflict resolution process and escalation procedure. The members of the Project Core Team (PCT) will be identified, and roles and responsibilities will be discussed and memorialized. The Team's fundamental approach to this engagement and resulting protocols (i.e., those for communication via electronic mail, live meetings, or phone; production of meeting minutes; team member availability; etc.) will also be established. Time will also be allowed for questions and answers, as well as any other related items. Finally, a summary of the discussion will be provided to the PCT, including any decisions, actionable items, and risks. Key milestones will be included for State approval of the suggested timeline for implementation and approval of submitted project management plans.

The project will then transition into the Design, Development, and Testing (DDT) phase. In this phase, we will modify or enhance the functionality of the *Compass*DUR system identified during the project planning phase. Key activities in this phase will include:

- Confirmation of project scope and detail via a Requirements Analysis Document (RAD).
- Initiation of any system enhancements or modifications as needed for the *Compass*DUR system or external processes based on information contained within the RAD.
- Draft and submit for approval RetroDUR-related collateral, including provider communication letters.
- Capture and subsequently draft for approval standard operating procedures for all clinical services modules.
- Collaborate with the State to determine a claims file format, frequency, and transmission method.
- Conduct QA and data cleansing of claims file for ingestion.
- Initiate clinical management activities in a test environment for user acceptance testing (UAT).

Our Team will seek client approval of the DDI plan prior to moving into a testing environment. Upon approval of the DDI approach, UAT will be initiated. Once the State has approved the DDI process and completed UAT, the key milestones for this phase will have been completed and the transition to phase III will commence.

Immediately after the conclusion of the DDI phase, we will enter the Operational Readiness and Production Cutover phase. Our *CompassDUR* system will be stress tested to confirm the successful ingestion of final production claims data and generation of State-approved RetroDUR collateral provider communication letters. The system will then be migrated into the production environment for cut-over. The technical architecture will receive final validation while the project management staff and operations manual will be validated for operational readiness. Upon completion of parallel testing and the State's acceptance of the results is received, the final milestone for this phase of the project will be complete. We will submit an implementation letter to the State indicating readiness for implementation. Once approval from the State is secured, the operations as outlined in the letter will be deployed.

Design, Development, and Implementation Project Stage			
Project Phase	**Project Phase I** Project Planning and Startup	**Project Phase II** Design, Development, and Testing	**Project Phase III** Operational Readiness and Production Cutover
Purpose	• Project planning kick-off meeting. • Presentation of the Myers and Stauffer Team's plans and processes for Project Schedule, Communications,	• Completion of RAD. • Initiate system modifications /enhancement. • State approval of RetroDUR collateral.	• Final testing to confirm successful ingestion of claims data/generation of communication letters. • Validate technical architecture.

	Risk/Issue Management, Change Management, and QA/Control. • Define conflict resolution process/ escalation procedure. • Clarify expectations for the PCT. • Establish protocol for communications.	• Memorialization of standard operating procedures. • Myers and Stauffer Team/State determine claims file format, transmission method, and frequency. • Conduct QA and data cleansing of claims file for ingestion. • User acceptance of activities in test environment.	• Validate operational readiness of staff and operating manual. • State approval of implementation plan. • Operations as outlined in letter deployed.
Key Milestones	• State approval of implementation timeline and project management plans.	• State approval of DDI process. • UAT.	• State acceptance of parallel testing.

O&M Stage

The project's O&M stage will be next to launch with its first phase of Initial Operations. Although the clinical management SOW is largely service-related by design, there are go-live milestones to be obtained. Given the cyclical nature of some of the State's programs (e.g., RetroDUR, SAB) and their established schedule, we recommend a rolling initiation of the clinical management services including DUR, UM, SAB administration, and RetroDUR. Assuming a July 1, 2025 go-live date, it is anticipated that UM efforts, particularly weekly review of new additions to the drug file and drugs to market, will commence immediately. Depending on where the state is in its work flow cycle, SAB support and RetroDUR initiation will commence to avoid or minimize interruption or delay to the State's schedule for these programs. It is expected that all services will be in operational phase within three months of go-live with the possible exception of RetroDUR outcome reporting, which generally spans a period of six months.

Phase V marks the continuation of clinical management services through the operations phase, with expected functionality enhancements that will evolve over time. O&M will incorporate the execution of reporting tasks and management of State-approved change orders as needed, including program requirements modification and any system improvements. During the final phase of the O&M stage, our Team will commence tasks involving the project's turnover and contract close-out. Unless directed otherwise by the State, we will focus efforts into wrapping up open or ongoing clinical management initiatives and the provision of historical documentation and records to the incoming vendor in the final time period of this engagement. New initiatives of clinical management services that run on a quarterly or other cyclical schedule will cease unless otherwise directed by the client after the last full cycle has been completed under the contract. At that time, efforts will be focused on closing out any remaining active initiatives and transitioning services to the incoming vendor. Included in our transition efforts will be the provision of reporting and historical

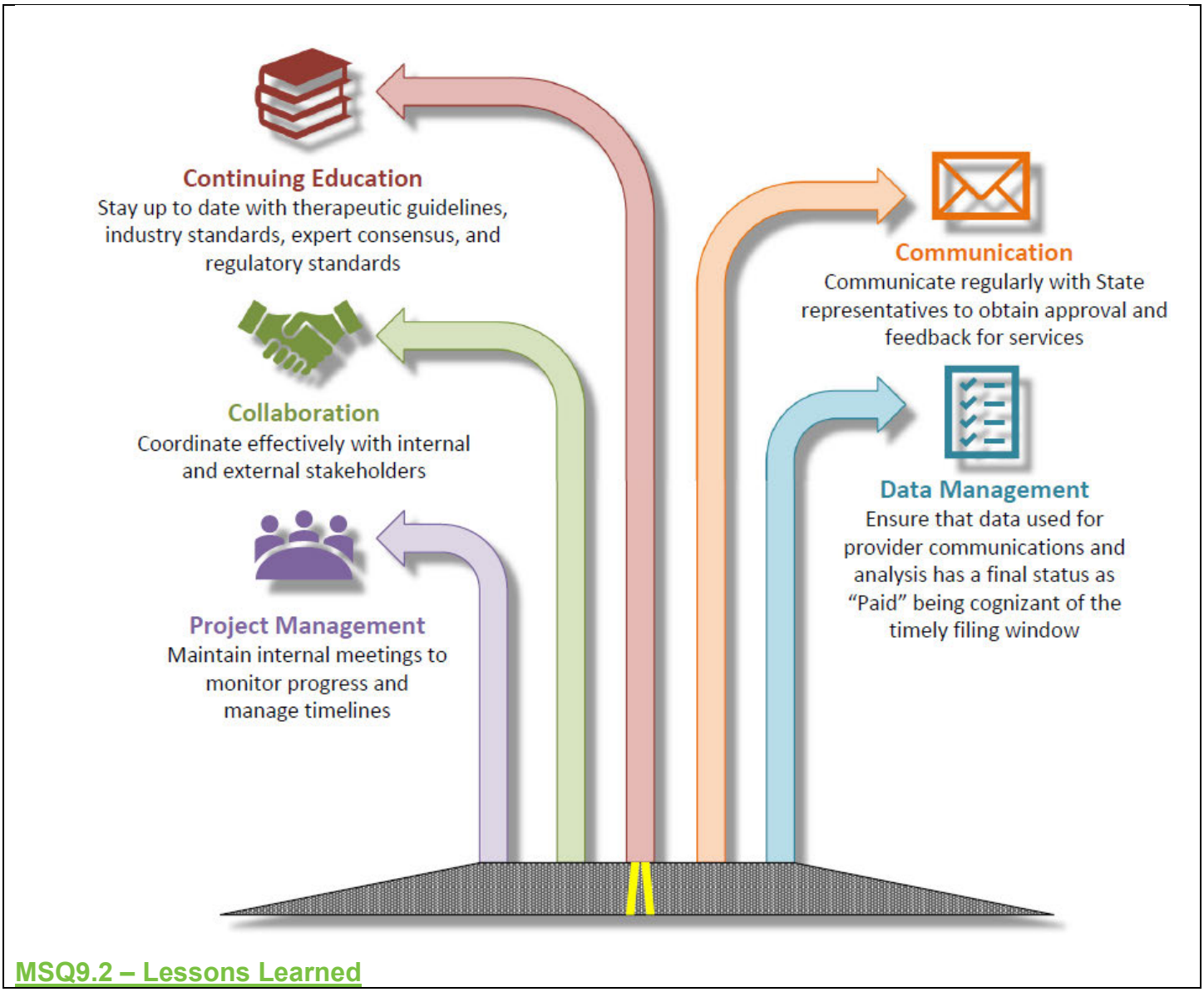
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data to the client or their designee as mutually agreed upon and at least as far back as necessary to facilitate the filing of the next CMS annual DUR report. Any data or documentation not transferred will be destroyed and the client will be provided with a certificate of destruction. Turnover readiness will be demonstrated with the closing out and transitioning of all clinical management services to the incoming vendor, and the performance of other tasks, as needed, to transition to the incoming vendor as outlined above.

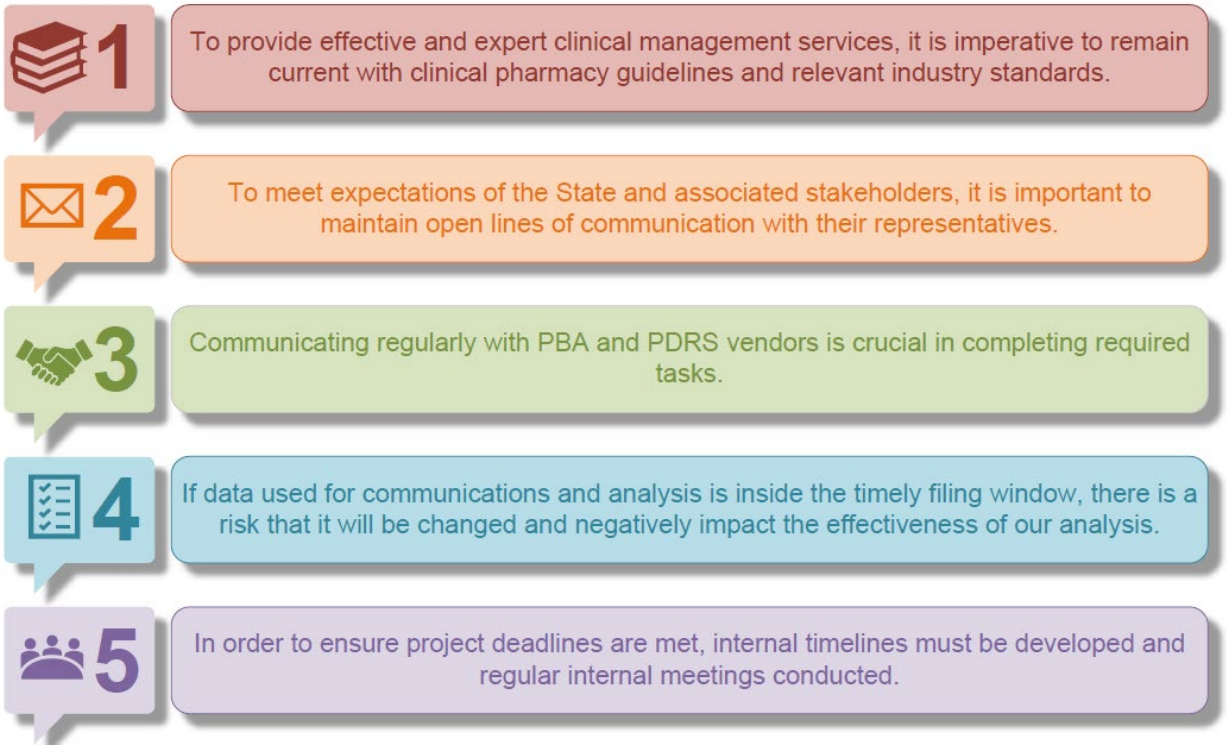
O&M Stage Summary

Operations and Maintenance Project Stage			
Project Phase	**Project Phase IV** Initial Operations and CMS Certification	**Project Phase V** Operations Project	**Phase VI** Turnover and Contract Closeout
Purpose	• Initiation of PCMS: DUR, UM, SAB, RetroDUR.	• Incorporate execution of reporting tasks. • Manage change orders.	• Changeover of PCMS to incoming vendor. • Other tasks as needed for transition.
Key Milestones	• Go-Live of Solution.	• O&M.	• Service turnover. • Project end.

MSQ9.1 – Best Practices



MSQ9.2 – Lessons Learned



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

MSQ10 – Transition & Integration

The Myers and Stauffer Team has years of experience working with other vendors in successfully transitioning services, both as the incumbent and as the newly selected vendor. Specifically, our Team has significant experience working with all of the leading Medicaid pharmacy claims processors and drug rebate administrators. We understand all the transition steps that must be taken and the timelines that must be met to ensure the continuation of services, and we are fully committed to ensuring that all contract requirements are met.

Transition from Incumbent. Because we are working with the current incumbent, NHC, the Myers and Stauffer Team does not anticipate needing a complex transition in period, and therefore, would result in minimal implementation. However, we acknowledge the potential for transition and the need for integration should there be a change in other suppliers, including the PBA and/or Pharmacy Drug Rebate Services (PDRS) vendors, or contract award from a participating state.

For states in which we are not the incumbent, the transition will initially focus on data receipt and ingestion. This may also be true for the lead state should there be a change in how we access the data from today. The initial transition will start by collaborating with identified stakeholders, including any outgoing PCMS vendor and the State, to assume clinical management services, as well as the designated source of claims data feed for integration into our data systems. To initiate transition efforts, we will ingest historical clinical services data as needed from the outgoing PCMS vendor, either directly or indirectly via a conduit with or authorized by the State. Our Team takes data security very seriously and is positioned to receive this data in a secure manner agreed to by the State. Any data received by the Myers and Stauffer Team will be subject to QA procedures to identify and address any data inconsistencies. After a thorough QA process, data will be mapped for ingestion into our database.

While data integration is being conducted, review of prior efforts on behalf of the State will commence. As such, previous SAB meeting minutes will be reviewed, as well as prior RetroDUR interventions and CMS annual reports. Current policy manuals, UM criteria, SEs, QLLs, PADL, and PDL placement will also be examined. This information, coupled with our current knowledge of the State and its programs, will be incorporated into our approach and commitment to delivery of a comprehensive PCMS program. Once this has been completed, we will propose an individualized PCMS program tailored to and reflective of the needs of the State. The culmination of our Team's experienced approach to PCMS services is minimal disruption and limited effort and cost to the State and its stakeholders.

Integration with PBA. Our Team acknowledges and understands the necessity of integrating with the PBA and other vendors when implementing a successful PCMS program. Such integration is crucial for data access surrounding clinical management services, provider relations, member communications, and other PCMS functions. Indeed, open communication will be paramount as the PBA will be reliant upon the clinical management supplier to provide final UM decisions, and we will be reliant upon metrics provided by the PBA for completion of the CMS annual DUR report. To ensure this integration is completed in a timely manner, we will leverage a detailed Integration Plan, outlining the coalescence of multiple factors into a cohesive, functional program. Scope, cost, time, quality, and communications must all be expertly assessed, addressed, and monitored for a successful integration.

Scope. Our Team works with the State and any other assigned vendors to define and refine the functions and features of the PCMS Program and program objectives. A clearly defined SOW that satisfies the needs of the State is key to successful integration. Any changes to the scope will be identified and implemented in accordance with our Change Management Plan that we will develop, ensuring stakeholder satisfaction.

Open communication and documentation of policy and processes will be paramount as the PCMS contractor will be the supplier of final UM decisions including PDL status, SEs, QLLs, and PA criteria, which is critical information for the PBA. Further, the PBA will serve as the source of several metrics such as call center statistics and reporting on DUR edits required for the completion of the CMS annual DUR report.

We anticipate collaboration with the PDRS vendor in order to make the most appropriate recommendations for the State, particularly with designation of PDL status and development of PA criteria as these efforts can have downstream effects on supplemental rebates and value-based contracting. Additionally, the PBA vendor should be aware of potential RetroDUR interventions as these initiatives may result in provider contact to the call center.

Cost. Because a Medicaid FFS program has a significant economic impact on the State, the cost of a project of such importance must be carefully managed to avoid wasting resources. The Myers and Stauffer Team understands the budget constraints under which many state Medicaid programs operate, and as such, are committed to providing our clients value. We will develop and adhere to a Cost Management Plan for State review. The Cost Management Plan will focus on the avoidance of misallocation or waste of funds during the process of integration with other vendors and throughout the life of the contract.

Time. Confusion and delay in the implementation of the program only serves to decrease the confidence of providers and stakeholders in the PCMS program. Time goes hand-in-hand with cost on a task with high-level consequence. In accordance with the Communications Management Plan that we will develop, we will coordinate with PBA and rebate vendors, along with the State, to link functionality and provide efficient PCMS services, ensuring integration is completed in a timely manner.

Quality. Both Myers and Stauffer and NHC have had the privilege of providing quality services to the Georgia Medicaid program for many years. We are committed to maintaining the highest standards not only in our services but also in our professionalism when interacting with providers, stakeholders, and clients.

With respect to quality improvement in our processes and by extension the State's programs, our clinical team will meet regularly with all team members assigned to the project to review operations and assess any opportunities for improvements.

Communications. Good communication is the foundation of any successful endeavor. It is crucial to ensure all involved share the same understanding of the PCMS program's form and functions, that any proposed changes are accepted and integrated, and are prepared for implementation. We will leverage a detailed project Communications Management Plan to make certain that all project stakeholders have the information they need to perform their roles throughout the project. The finalized communication plan will include an outline for a kick-off meeting to facilitate a successful integration process and progresses to project end and contract run out.

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

MSQ11 – Project Management

The Myers and Stauffer Team understands that the driver to good project management is a robust but realistic plan which clearly identifies activities and milestones and includes accountability for both the project manager and the entire team. We utilize features of the Project Management Body of Knowledge (PMBOK) to customize our approach and meet the specific needs of our clients. Paramount to effective project management is an agreed-upon Project Plan to guide the execution and control of the implementation, as well as monitoring of all aspects of the SOW post go-live. Our approach provides a solid foundation for customizing and tailoring the schedule to optimally chart the needed tasks for the State.

Once the Project Plan is finalized, it will be used as the mechanism to report project status for tasks, deliverables, and milestones. In addition to the project schedule, the detailed project plan outlines a structure for handling changes, communication methods, risk and issue monitoring and mitigation, and stakeholder engagement activities, as well as a baseline for the project including scope and schedule. Our project management approach includes, but is not limited to, tracking

project status and deliverables; engaging stakeholders at key points of the project; consulting and advising on best practices during project development and design; and providing operational support once projects have been implemented.

The detailed project schedule will be finalized using Microsoft Project. The schedule utilizes a work breakdown structure (WBS) which keeps subtasks uniquely identified within hierarchical task structures. Tasks, deliverables, and milestones are identified, and their dependencies are created based on requirements. Additionally, assigned resources are identified at the task level. Each task or subtask line contains at a minimum the following elements: line number, WBS number, task description, duration (in working days), start/end date, and assigned resource. The Project Plan is a living document and will be updated throughout the life cycle of the project as events change and priorities are shifted. Our team's approach to creating and updating the Project Plan takes into account several characteristics, as detailed below.

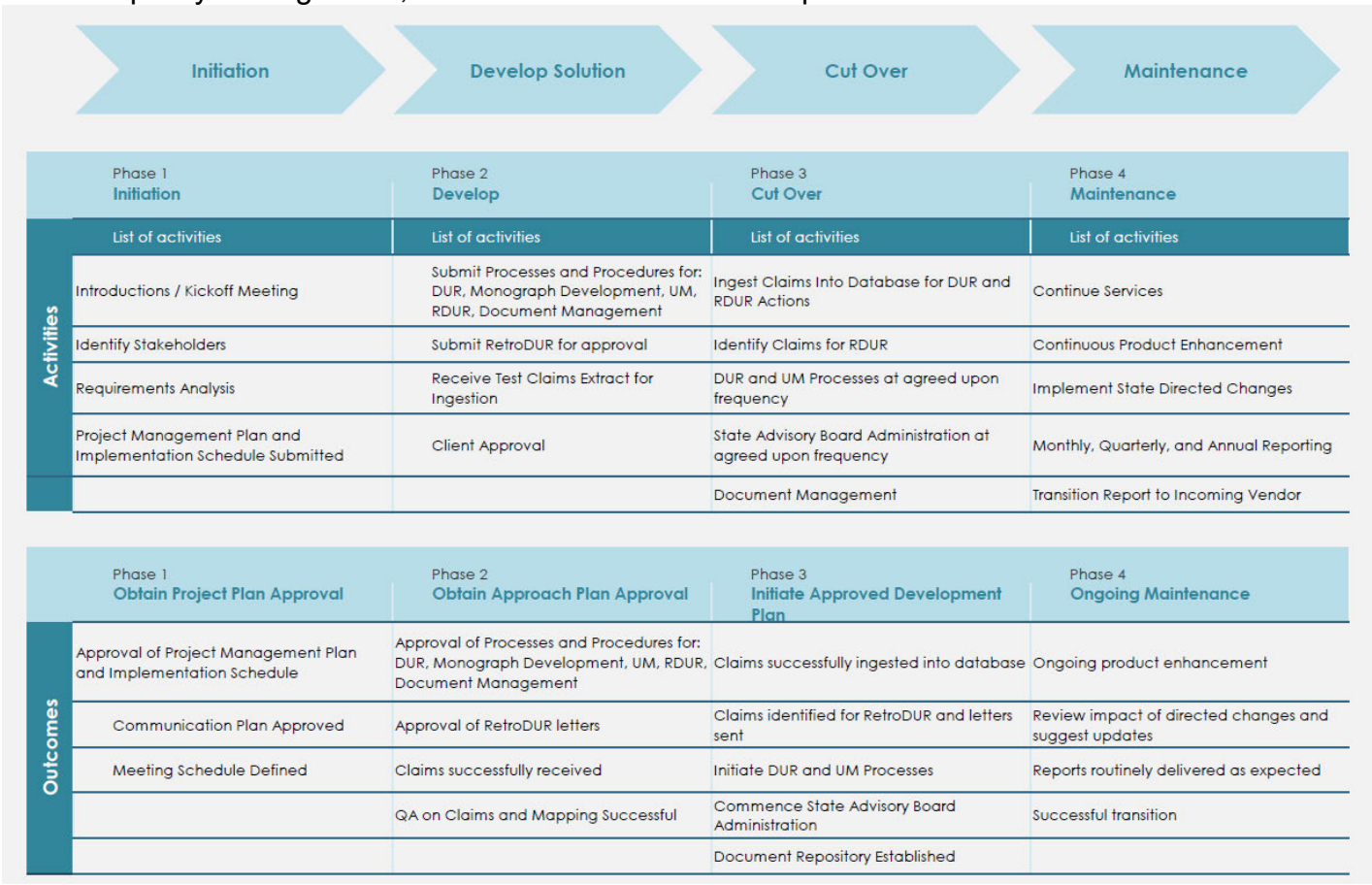
Project Plan Characteristics	
Leveraging Existing Tools	The project begins by leveraging Myers and Stauffer's experience and assets to quickly stand up project management processes.
Clear Communication Channels	Quickly establish a stakeholder map and related communication process that facilitates rapid and timely information sharing, collaboration, escalation, and efficient decision-making, founded on the overarching principle of "no surprises."
Transparency	Provide the State with a clear and timely picture of how the project is progressing, who is responsible for each activity, who to contact to resolve questions and issues, what decisions have been made, and risk mitigation strategies.
Joint Management	Establish and promote a strong working relationship between the State and the Myers and Stauffer Team, which is especially important given the involvement of multiple agencies and outside stakeholders.
Measuring Progress	Most activities do not get done, or done properly, unless they are measured and monitored. Our methodology establishes meaningful metrics based on past experience that are tailored for this project. We report progress and issues through dashboards and weekly status meetings, coupled with a well-defined escalation process for critical issues and dependencies.
Standard Methods	Create predictability and then reliability. We use demonstrated project management methods and tools that support consistent, effective planning and control for the project through all phases.

We will also leverage a number of proven project management techniques from PMBOK to support the Project Plan. Our team, led by a Project Manager, will work with the State to tailor these to the following Project Plan components and tools to best fit the needs of the project:

MSQ11.1 – Project Schedule/Project Work Plan

We will develop a Project Work Plan documenting all project activities necessary to achieving project goals, as well as each activity's corresponding level of effort and cost estimates, schedule and resulting duration, and resource requirements. The Plan will be used as the basis to monitor

the progress and control the project, and will include all project management activities related to risk and quality management, as well as deliverables acceptance.



	Phase 1 Initiation	Phase 2 Develop	Phase 3 Cut Over	Phase 4 Maintenance
Activities	List of activities	List of activities	List of activities	List of activities
	Introductions / Kickoff Meeting	Submit Processes and Procedures for: DUR, Monograph Development, UM, RDUR, Document Management	Ingest Claims Into Database for DUR and RDUR Actions	Continue Services
	Identify Stakeholders	Submit RetroDUR for approval	Identify Claims for RDUR	Continuous Product Enhancement
	Requirements Analysis	Receive Test Claims Extract for Ingestion	DUR and UM Processes at agreed upon frequency	Implement State Directed Changes
	Project Management Plan and Implementation Schedule Submitted	Client Approval	State Advisory Board Administration at agreed upon frequency	Monthly, Quarterly, and Annual Reporting
			Document Management	Transition Report to Incoming Vendor

	Phase 1 Obtain Project Plan Approval	Phase 2 Obtain Approach Plan Approval	Phase 3 Initiate Approved Development Plan	Phase 4 Ongoing Maintenance
Outcomes	Approval of Project Management Plan and Implementation Schedule	Approval of Processes and Procedures for: DUR, Monograph Development, UM, RDUR, Document Management	Claims successfully ingested into database	Ongoing product enhancement
	Communication Plan Approved	Approval of RetroDUR letters	Claims identified for RetroDUR and letters sent	Review impact of directed changes and suggest updates
	Meeting Schedule Defined	Claims successfully received	Initiate DUR and UM Processes	Reports routinely delivered as expected
		QA on Claims and Mapping Successful	Commence State Advisory Board Administration	Successful transition
			Document Repository Established	

Our Team member, NHC, is the incumbent vendor for PCMS for the state of Georgia's Medicaid FFS program. We will undertake the development of a PCMS program by first collaborating with the State in a comprehensive planning effort to assess the SOW and institute, initialize, and anticipate the administration and management of the Project. We will assess and make proposals for a successful program that complies with all state and federal laws and regulations and encompasses support of the SAB, as well as a robust approach to management of the DUR and UM functions.

Previous Experience. Members of our Team have been a party to many implementations for Medicaid clients. Large projects, such as the implementation of a RetroDUR system, typically follow project management best practices for DDI. Continuing into the O&M phase, many of the core processes of project management are found in our daily client initiatives, including SAB presentations and DUR projects.

RetroDUR System. Phase 1 of the implementation of a RetroDUR system begins with project initiation. Details of the project goal are gleaned from the request for proposal, our past experience, and during the kick-off meeting. For an implementation with the size and scale of a RetroDUR program, a project charter would be created which details:

- Project constraints.
- Goals, including high-level SOW.

- Budget.
- Expected timeline.
- Stakeholder identification.

Phase 2, or project planning, involves defining the SOW through an RAD involving comprehensive planning efforts between the client and vendor. Primary tasks are then defined via a work breakdown schedule and would likely include the source, frequency, method of transfer, file layout, and ingestion of claims data feeds utilized in interventions. Technical requirements would include the standardization of file formats and methods and systems used to access the data transfers. A detailed project schedule will then be formulated with incremental steps and milestones identified. The completion of the project schedule assists in developing the communication plan and identifying stakeholders so that project status information can be communicated.

Moving on to Phase 3, execution, the project will commence implementation of the provision of services. Claims data files will be created and provided to the receiving vendor for data ingestions. The RetroDUR system will be queried for test interventions once the data has been scrubbed and ingested. Letter generation often serves as one of the final milestones in the implementation. While the work is being done, project progress will be monitored and communication with stakeholders becomes critical. Often, weekly, if not daily, meetings occur as go-live approaches. Use acceptance testing, if applicable, should occur as the implementation reaches selected milestones and deliverables. Phase 3 often occurs simultaneously to Phase 4, project monitoring and controlling.

During Phase 4, previously identified critical success factors and key performance indicators are consistently monitored (and controlled) as they can serve as early signals of potential issues. The identified indices should be tied to a successful project implementation to provide value towards the attainment of goal completion. Falling short on any of these indices may be an early signal of project delay and derailment. For instance, timely file transfer via the appropriate medium is a critical success factor for all data-driven programs. The ability to review and ingest the data serves as a key performance indictor of a successful implementation. Internally, efforts and expenditures will also be tracked to address any budgetary concerns.

Phase 5 is project closure, whereby lessons learned and best practices are documented for future implementations. The project monitoring and controlling that occurred in Phase 4 are reviewed and documented in the project closure report, which may serve as a historical record of how the implementation was guided. Finally, participating staff are thanked for their efforts and any records with potential historical value are archived.

The use of PMBOK principles also has value in smaller projects, such as a single RetroDUR intervention.

Phase 1 or Project Initiation of a RetroDUR intervention begins with the identification of a clear goal of the intervention, while detailed initiative information will be found in Phase 2. For instance, the client may wish to address the number of patients who are seen for asthma exacerbations in the emergency room as a goal for the intervention. The SOW would include the number of providers and patients (stakeholder identification) targeted and the method of contact. Any project constraints, such as lag in medical data, will be identified. Finally, a timeline for intervention and outcomes will be determined.

Moving on to Phase 2 in the project management process, the Team will drill down in the process to define the SOW. While the goal of the project is to improve outcomes in patients with asthma exacerbations, the SOW provides further details of the initiative. The population for intervention is defined as providers of patients with asthma who have had a recent emergency room visit for exacerbation, but who lack a controller medication for asthma. The primary tasks are outlined in this phase and, in this case, would include initiation and selection from claims data, identification of cohort for intervention, collateral development, and client approval. A detailed project schedule is formulated, which facilitates the development of a communication plan for identified stakeholders.

Phase 3 involves project execution, or more simply, getting the work done. Upon receiving client approval, we will commence work toward project completion. Since the stepwise process has been previously defined, we will monitor project progress and maintain collaboration and communication with stakeholders.

Phase 4 runs concurrently with Phase 3 and involves project monitoring and control. Critical success factors (e.g., client approval of intervention collateral) and key performance indicators (e.g., number of cases eligible for intervention) are identified and established to ensure the ultimate goal of the project is achieved. Because RetroDUR interventions are heavily dependent on timelines, deliverables and milestones (e.g., mailings) will also be monitored. The ultimate goal of monitoring and controlling is to prevent small problems from developing into much larger problems that derail the project entirely.

Finally, Phase 5 brings about project closure whereby the team meets to discuss successes and failures. The intervention's final outcomes will be provided in a pre- and post-intervention report. If the results of the intervention are generally positive, future enhancements to the RetroDUR process will be captured. Interventions with less than expected outcomes will undergo further analyses to identify "soft spots" in the process. These "soft spots" may be examined to determine if there are alternative approaches or enhancements that can be made to improve outcomes.

MSQ11.2 – Work Breakdown Structure (WBS) & Project Outputs

The above project schedule will utilize a WBS that keeps subtasks uniquely identified within hierarchical task structures. Tasks, deliverables, and milestones are identified and their dependencies are created based on requirements. Additionally, assigned resources are identified at the task level. Each task or subtask line contains at a minimum the following elements: line number, WBS number, task description, duration (in working days), start/end date, and assigned resource.

1. Pharmacy Clinical Management Services
    - 1.1. Initiation
        - 1.1.1. Project Kick-off Meeting
        - 1.1.2. Requirements Analysis
        - 1.1.3. Develop Project Plan
        - 1.1.4. Submit Project Plan
        - *1.1.5. Milestone: Project Plan Approval*
    - 1.2. Planning
        - 1.2.1. Create Approach Plan
            - 1.2.1.1. Policy and Procedures
                - 1.2.1.1.1. ProDUR and RetroDUR Management
                - 1.2.1.1.2. Utilization Management

1.2.1.1.3. State Advisory Board Administration
1.2.1.1.4. Document Management
1.2.1.2. Communications
1.2.1.2.1. Develop Provider Notification Letters
1.2.1.2.2. Develop Member Notification Letters
1.2.1.2.3. Educational Outreach
1.2.1.2.4. External Stakeholder Introductions
1.2.2. Submit Approach Document
1.2.3. *Milestone:* Approach Plan Approval
1.3. Execution
1.3.1. Receive Test Claim File
1.3.1.1. Scrub Data
1.3.1.2. Data Mapping and Ingestion
1.3.2. Testing Phase
1.3.2.1. Analytics
1.3.2.2. Letter Generation
1.3.2.3. Document Repository
1.3.3. Install Live System
1.3.4. User Training
1.3.5. Go-Live
1.4. Control
1.4.1. Project Management
1.4.2. Project Status Meetings
1.4.3. Risk Management
1.4.4. Update Project Management Plan
1.5. Closeout
1.5.1. Pharmacy Clinical Management Services Procurement
1.5.2. Document Lessons Learned
1.5.3. Update Files/Records
1.5.4. Gain Formal Acceptance
1.5.5. Transfer Archive Files/Documents

MSQ11.3 – Implementation Plan

We will create a discrete, streamlined plan to support the implementation efforts of key team members participating in the project execution phase. We will work with the State to determine its preferred implementation plan components; however, we anticipate including project goals and objectives, success criteria, deliverables, scope, resources, risk analysis, implementation timeline and milestones, roles and responsibilities, and implementation plan metrics.

Task	Assigned To	Start	End
Gather Requirements			
Identify Key Stakeholders	Clinical Management Team	7/1/24	7/1/24
Kickoff Meeting with Stakeholders	Clinical Management Team	7/2/24	7/2/24
Requirements Analysis	Clinical Management Team	7/3/24	7/18/24

Develop the Schedule			
List Tasks	Clinical Management Team	7/18/24	7/18/24
Set Task Priorities	Clinical Management Team	7/19/24	7/19/24
Determine Timeline	Clinical Management Team	7/19/24	7/19/24
Assign Resources	Clinical Management Team	7/22/24	7/22/24
Plan for Communication (DCH, PBA, PDRS)	Clinical Management Team	7/23/24	7/23/24
Identify Customer Security Requirements	Clinical Management Team	7/24/24	7/25/24
Implement Identified Security Measures	Clinical Management Team	7/26/24	8/9/24
Design the Solution			
Develop Approach Document	Clinical Management Team	8/9/24	8/12/24
Create Solution Design Document	Clinical Management Team	8/13/24	8/26/24
Define Product Specifications	Clinical Management Team	8/27/24	9/5/24
Update the Schedule	Clinical Management Team	9/6/24	9/6/24
Build the Solution			
Configure Features	Clinical Management Team	9/6/24	9/13/24
Customize RetroDUR System	Clinical Management Team	9/16/24	9/20/24
Perform System Testing	Clinical Management Team	9/23/24	9/24/24
Document Issues Found	Clinical Management Team	9/25/24	9/25/24
Correct Issues Found	Clinical Management Team	9/26/24	10/14/24
Test Corrections	Clinical Management Team	10/15/24	10/15/24
Integrate the Solution			
Receive Claim File	Clinical Management Team	10/15/24	10/15/24
Set up the Customer Database	Clinical Management Team	10/16/24	10/17/24
Migrate Data	Clinical Management Team	10/18/24	10/21/24
Integrate the Desktop (Internal)	Clinical Management Team	10/22/24	10/25/24
Monitor the Solution			
Define Success Metrics	Clinical Management Team	10/28/24	10/28/24
Review Business Performance	Clinical Management Team	10/29/24	10/31/24
Provide Training			
Schedule Training	Clinical Management Team	10/28/24	10/28/24
Train End Users	Clinical Management Team	10/29/24	10/31/24
Create User Documentation	Clinical Management Team	11/1/24	11/4/24

MSQ11.4 – Quality Management Plan

Our firm's rigorous QA protocol addresses every function we perform, every process we utilize, and every deliverable we provide. We will work with the State to develop a Quality Management Plan that describes the policies, procedures, and guidelines that will be implemented to achieve high quality project outcomes. The Plan will include, at a minimum, project and deliverable quality metrics, how quality metrics will be met, and all associated QA and quality control activities. The

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table below provides a summary of the types of content to be incorporated into the Quality Management Plan.

PCMS Area	Tasks	Deliverables with Established Frequencies	Quality Assurance and Control Methods
DUR	• Develop and maintain SEs, QLLs, PDL, PADL. • Develop recommendations for enhancement.	• Quarterly evaluations of ProDUR and RetroDUR criteria and interventions. • Report findings from literature reviews on a frequency determined by the State. • Monthly and quarterly DUR summary reports as required. • Annual report of DUR activities.	• Clinical pharmacists remain current with industry standards, therapeutic guidelines, expert consensus, regulatory changes, active in DUR societies. • Conduct regular internal meetings to assess adherence to timelines.
UM	• Develop and maintain criteria for covered products. • Develop and maintain protocols for all products, including those involving State-specific requirements. • Provide the State with an automated workflow tool.	• On annual basis: review, update, and provide the State with UM algorithm criteria for each therapeutic class and UM forms.	• Clinical pharmacists remain current with industry standards, therapeutic guidelines, expert consensus, regulatory changes, active in DUR societies. • Clinical pharmacists conduct therapeutic class reviews, develop monographs on new drug entities. • Conduct regular internal meetings to assess adherence to timelines. • Perform user access maintenance on

			automated workflow tool.
SAB	• Oversee, implement, direct SAB meetings. • Prepare, provide materials for presentation. • Post agendas to State website. • Make recommendations regarding UM services. • Record meeting minutes. • Recruit SAB members as directed by the State.	• Schedule meetings at an interval determined by the State. • Provide minutes of meetings to the State within three business days.	• Conduct internal meetings to plan for SAB meetings. • Coordinate with PBA and PDRS vendors to prepare for SAB meetings.
RetroDUR	• Identify, monitor drug usage for potential abuse/misuse and fraud assessments. • Notify providers via letter of potential drug therapy concerns.	• Within 10 business days of State approval, update RetroDUR files and criteria tables as recommended by SAB.	• Clinical pharmacists remain current with industry standards, therapeutic guidelines, expert consensus, regulatory changes, active in DUR societies. • Conduct regular internal meetings to assess adherence to timelines.
Document Management	• Maintain document repository supporting no less than 2GB per file.	• Must be accessible 24/7.	• Conduct periodic internal audits to confirm and maintain standard operating procedure.

MSQ11.5 – Requirements Management Plan

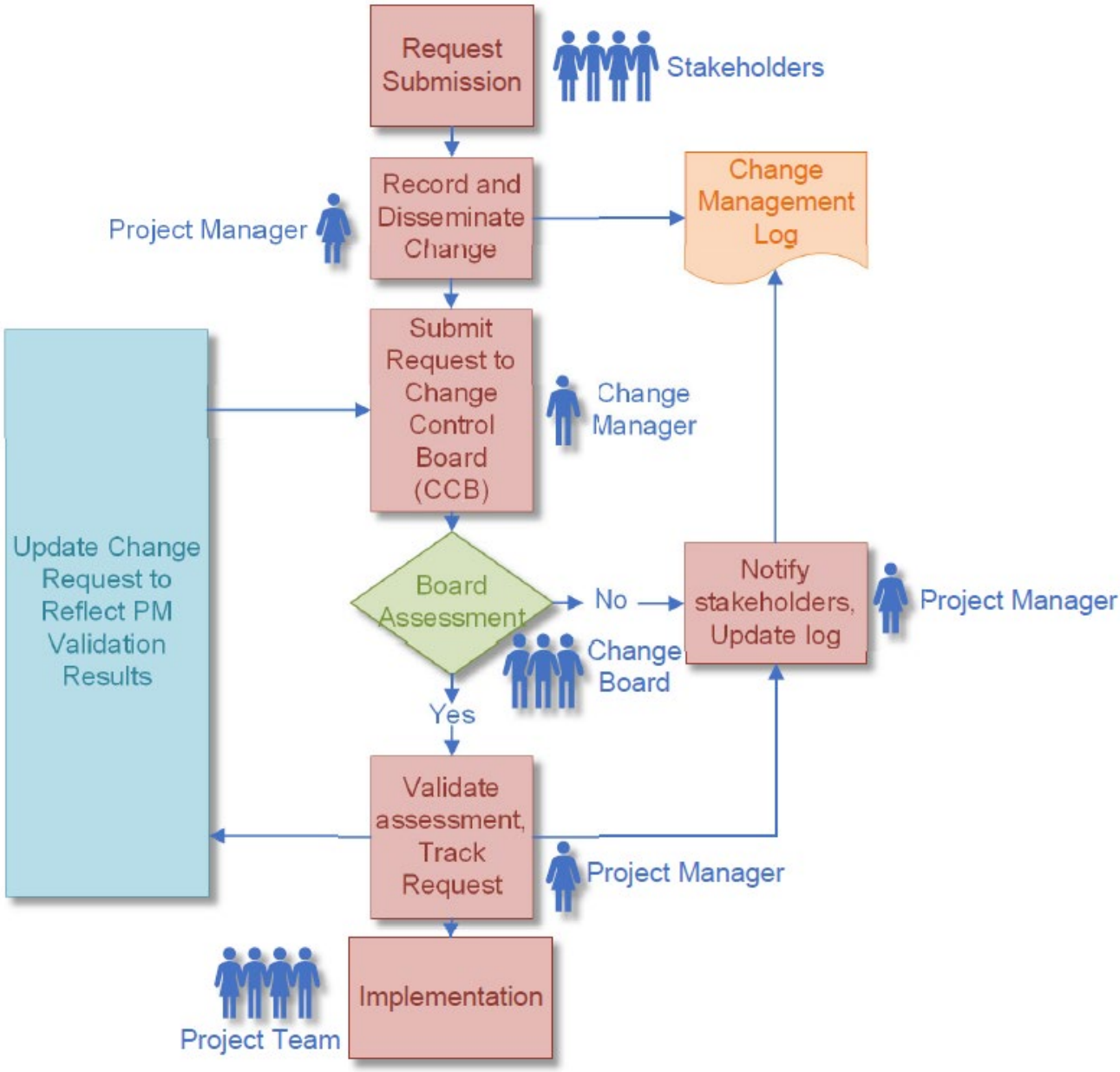
Ineffective requirements management processes are one of the most common causes of project failure. As such, we will develop a Requirements Management Plan describing all tasks or conditions (i.e., functional and non-functional) that must be completed to ensure a successful project. Specifically, the Plan will document how stakeholder needs are identified, categorized,

prioritized, and tracked throughout the project life cycle; the process by which requirements will change as stakeholder needs change; and how our project team will verify that all requirements have been met.

					Changes		
Requirement	Stakeholders	Priority-based on Resource Intensity	Responsible Party(s)	Traceability	Reason for Changes	Who Authorizes Changes	How to Make Changes
State Advisory Board (SAB)	the State, Myers and Stauffer Team, SAB	1	Clinical Pharmacists	Reports	Reports identify opportunity(s) for program enhancements; regulatory changes; the need to remain current with industry standards; State-requested changes; SAB-requested changes	the State, Myers and Stauffer Team, and SAB in collaboration	Myers and StaufferTeam system enhancements and process updates
Drug Utilization Review (DUR)	the State, Myers and Stauffer Team	3	Clinical Pharmacists	Reports	Reports identify opportunity(s) for program enhancements; regulatory changes; the need to remain current with industry standards; State-requested changes	the State and Myers and StaufferTeam, in collaboration	Myers and StaufferTeam system enhancements and process updates
Utilization Management Plan	the State, Myers and Stauffer Team	2	Clinical Pharmacists	Reports	Reports identify opportunity(s) for program enhancements; regulatory changes; the need to remain current with industry standards; State-requested changes	the State and Myers and Stauffer Team, in collaboration	Myers and Stauffer Team system enhancements and process updates
Retrospective DUR Services	the State, Myers and Stauffer Team	5	Clinical Pharmacists	Reports	Reports identify opportunity(s) for program enhancements; regulatory changes; the need to remain current with industry standards; State-requested changes	the State and Myers and Stauffer Team, in collaboration	Myers and Stauffer Team system enhancements and process updates
Common Requirements	the State, Myers and Stauffer Team	4	Operations Manager	Assessments	The need to remain current with industry standards; State-requested changes	the State and Myers and Stauffer Team, in collaboration	Conduct annual risk assessments to identify opportunities for enhancement of security protocols and implement identified enhancements; Implement letter changes by obtaining approval of updated draft letters and replacing outgoing template in our central repository with updated and approved letters

MSQ11.6 – Change Management Plan

To support change management processes associated with the project, we will develop a Change Management Plan specifying how project changes should be requested; the process and criteria for evaluating such requests; the process and mechanism for recording change request outcomes; and the process for incorporating an approved change into the delivery of the project. All approved changes will be documented in the Project Plan to accommodate any impacts to resources, budget, and deliverables. The graphic below includes key concepts that will be incorporated into the Change Management Plan.



MSQ11.7 – Risk Management Plan

Risk Management Plan. It is normal business practice for organizations to have uncertainty with the start of any new project. The organizations take chances, which results in risk playing a part in any project, especially during the early stages. The purpose of the Risk Management Plan is to establish the framework in which the project team will identify risks and develop strategies to mitigate or avoid those risks.

Risk Management Approach. Risks will be managed by the Project Director through a process which identifies the risks, assesses the likelihood of occurrence and impact if those risks were to occur, documents the risks, their impact, and mitigation strategy, and, finally, monitors the project for risks occurring. Most of this occurs during the early stage of the project; however, risks can be

identified at any time during the project life cycle. Risks are reviewed on a routine basis by the project team during internal project meetings. Once the project team has a good understanding of the risks, they will be presented to the State during routine status meetings. Full assessments are conducted on all risks no matter when they were identified. It is during this process where the decision of ranking and prioritization is started.

Risk Identification. Risk identification is the requirement of all project team members, the State, and its stakeholders. At times, the project team may have discussions with SMEs to discuss what types of risks might be encountered during a similar project. Additionally, the project team will research any previous similar projects to determine the types of risks identified.

Risk Qualification and Prioritization. We qualify risk by the likelihood of occurrence and the impact the risk can have to the project if it does occur. Each of the two separate categories are ranked with an L-Low, M-Medium, or H-High. Depending on the two selections, a color code for the risk is given (i.e., green means lower impact and lower likelihood, yellow is for average impact and medium level of likelihood, and red means very impactful and high likelihood). Red risks will be addressed first, followed by yellow and then green.

Risk Monitoring. The entire project team is required to monitor risks. The Project Director may assign risk managers to some risks to have a closer review of what is occurring. Project team members will address risks at the internal project meetings and with the client during status meetings. Only those risks that may occur during the current period should be discussed to allow for increased focus.

Risk Mitigation and Avoidance. The classification of the risk will determine the amount of details required for the risk mitigation and avoidance strategy. Risks with a red category will require a full risk mitigation strategy, which has a full work plan and specifies the tasks required to mitigate the risk; yellow category risks will require a listing of strategies and/or avoidance techniques which can be implemented to avoid escalation; green category risks will not require a mitigation strategy, but will be closely monitored. If any risk is escalated, the risk will require a new assessment based on the new color category.

MSQ11.8 – Communications Plan

A major component of project management is proactively managing the project to ensure deliverables are of a high quality and completed on time. Communication with the State, its stakeholders, and the project team is essential to ensure this outcome. Key activities involve managing communications to satisfy the needs of the State and resolve any issues that arise. The ultimate goal is to achieve efficient and effective collaboration between all key stakeholders of the project.

A project team directory will be developed to provide contact information for all team members directly involved in these tasks. This document will require updates or changes which will be made as the project progresses or changes are approved. Changes or updates may be required as the project matures due to changes in project resources and/or if additional requirements are needed. Once a change is approved, the Communications Management Plan will be updated and will be distributed to the State, its stakeholders, and the project team.

Communications Management Approach. Communications happen at every level of the project, and the Project Director, as well as key personnel, will take a proactive approach to communication.

Even though the Project Director is responsible for the overall effectiveness and efficiency of communications during the project, each of the team members will provide communications for their respective tasks and activities. Either the Project Director or other key staff will serve as the primary point of contact for engagement level communications. They will be available by telephone and/or email during regular business hours and, when necessary, a temporary back-up point of contact will be designated in advance. Either the Project Director or an appropriate designee will provide regular updates during project status meetings and/or at a frequency requested by the State, and will include other applicable State-contracted vendors. During these updates/meetings, they will review and provide updates on each major task, function, or activity in the project plan. Key events or outcomes will also be reviewed to inform the State of progress on relevant deliverables. They will also alert the State to any project risks and proposed mitigation strategies and will continually update the State on the impact of these strategies to deliverables and associated timelines. Upon request, our project team will also be available for recurring and/or ad-hoc meetings with the State and/or other contracted vendors.

Escalation Path. During the life of a project, there are times when escalation of an issue is necessary. Escalation procedures should be enacted when any issue is not being addressed by the primary contact. By invoking escalation procedures, the individual wants to use additional influence from project leadership to resolve a situation. The project leadership to contact for escalating an issue includes the Project Director and State-designated leadership. If a project team member has an issue or concern that is not being addressed, a written communication, usually by email, should be made to the Project Director. This communication should include the parties involved, the issue or concern, the response from the primary contact, and recommended paths to ensure compliance. It is recommended that the project team member try to resolve the issue or concern through open discussions with the primary contact. If all avenues of negotiation for resolution to the issue or concern have been exhausted, it is then appropriate to begin the escalation of the matter.

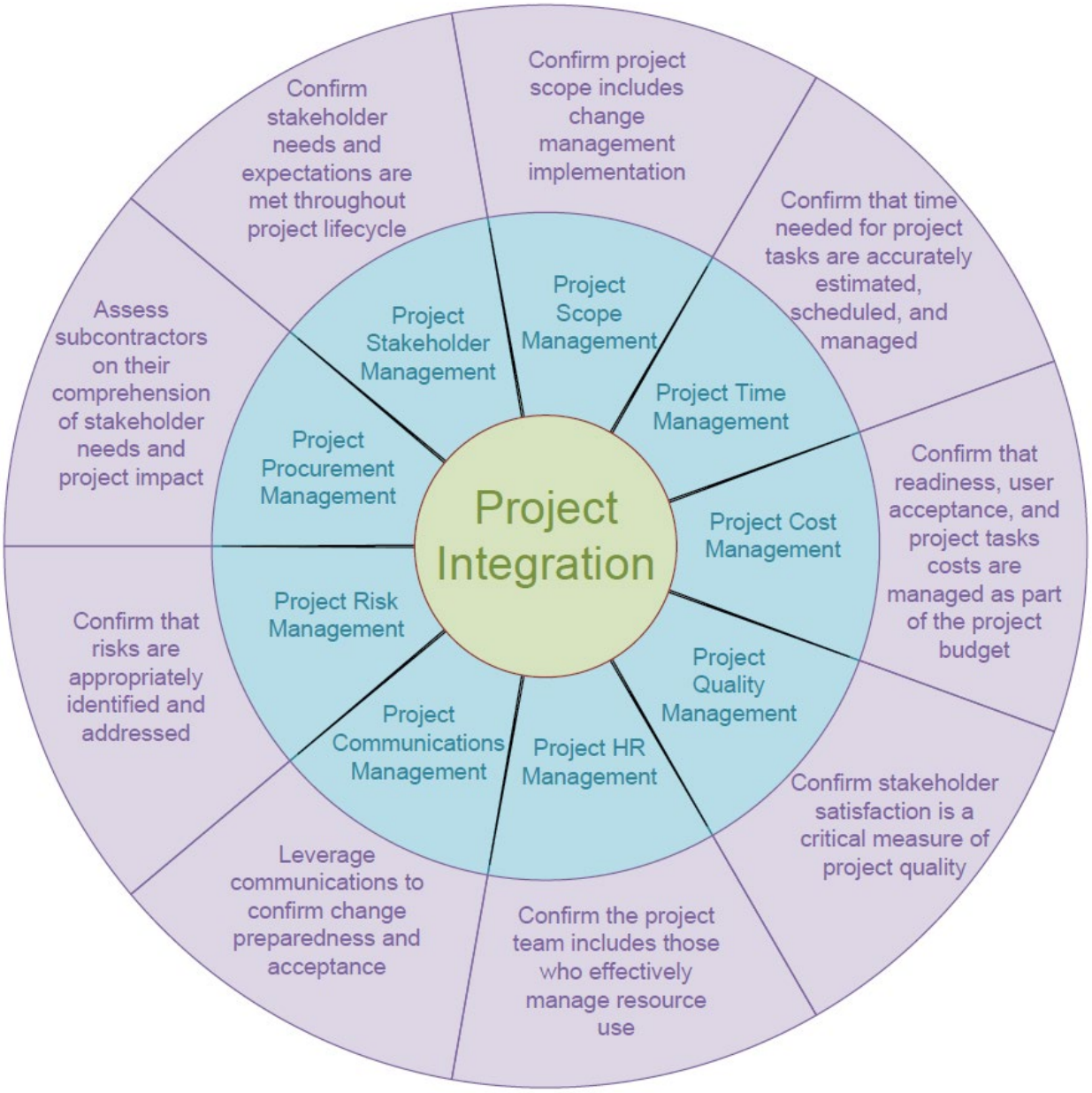
Project Management Reporting. Communications and reporting are two of the top responsibilities of project management. It is important that information is shared timely from the project team so the information is available for project status updates with the State.

Routine Status Meetings. We encourage regularly scheduled weekly or bi-weekly status meetings with the State through teleconference to discuss progress and any identified issues or risks that need to be solved together. These meetings will also be used to discuss upcoming deliverables, and any other topics identified by either the project team or the State. The project team will send the State an agenda for the meeting in advance, and a summary of the meeting will be sent within five business days following the meeting date. During the meeting, any changes to the project and/or the Project Work Plan will be drafted as an official change request and will go through the regular procedures to implement a change. If the Project Director and the State both agree to the change during the status meeting, the approval will be noted and included in the final notes.

MSQ11.9 – Integration Plan

Aligning work across cross-functional teams, managing schedules, and tracking resources is critical to achieving common project goals. To ensure that all project activities are synchronized and executed efficiently, we will develop an Integration Plan that outlines how various project components will be brought together, inclusive of strategies, timelines, resource allocation, communication plans, and other necessary steps. Integration Plan activities will be monitored and

controlled through regular progress assessments and comparisons with planned objectives, and any deviations will be addressed.



MSQ11.10 – Operation and Maintenance Plan

As necessary, we will develop an Operation and Maintenance Plan describing any information technology-related systems components, and outlining the operation, inspection, and maintenance activities necessary to ensure dependability of the system. The Plan will address normal operating conditions and recommended actions for emergency conditions. Copies of operations log sheets and maintenance checklists will also be included.

MSQ11.11 – Training Plan

To the extent that project team members and/or key stakeholders do not have the required competencies to support the project, we will develop a project Training Plan. At a minimum, the Plan will describe how we will train individuals during implementation of the project management process, including identification of existing and needed resources, individuals to be trained, and training requirements.

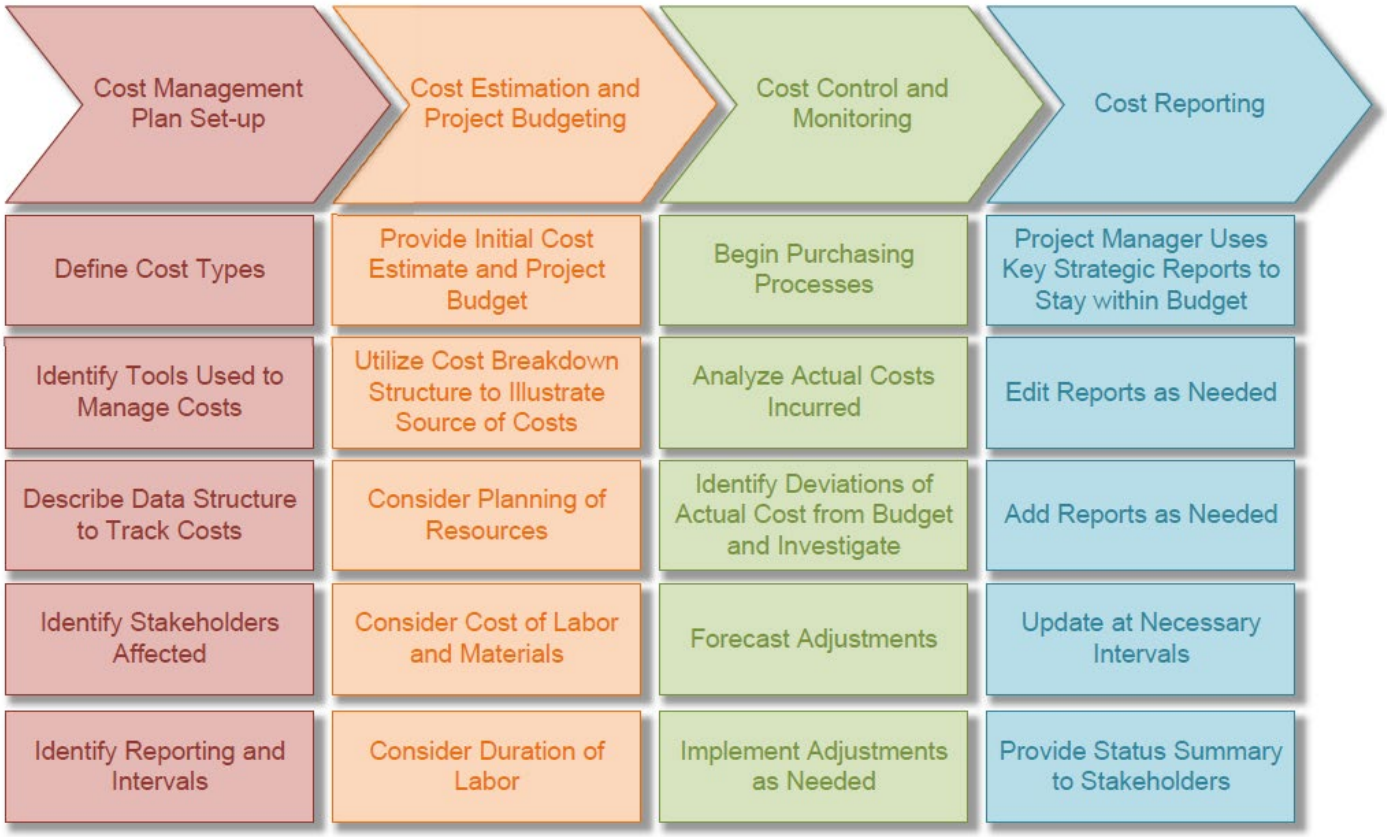
At the State's request, our Team will provide PCMS training to State staff either virtually or in-person on a schedule agreed upon by the State. Training material may include but not be limited to:

- DUR Management.
  - Development of Program Materials, Review, and Monitoring.
- UM Services.
  - Development of Program Materials, Review, and Monitoring.
- RetroDUR Management Services.
  - Preparation, Provider/Member Communications, and Review and Analysis.
- SAB Administration.
  - Development of Program Materials, Recruiting of Members, Coordination, Oversight, and Reporting of Meetings.
- Document Management.
  - Storage, Organization, Tracking, and Access Control.

Additionally, we will cross-train our Clinical Management Services staff in performing duties relating to DUR management, UM services, RetroDUR management, SAB administration, and document management.

MSQ11.12 – Cost Management Plan

Effective cost management requires adherence to established processes for estimating, budgeting, and controlling costs. We will work with the State to develop a Cost Management Plan that clearly articulates how project costs will be planned, structured, and controlled. The Plan will establish, at a minimum, units of measurement, level of precision, level of accuracy, control accounts and thresholds, rules for performance measurement, reporting formats, and corresponding organizational processes and procedures.



MSQ11.13 – Stakeholder Management Plan

Stakeholder engagement is critical to solicit buy-in, identify concerns and/or competing objectives, and ensure transparency and equity throughout the project life cycle. In collaboration with the State, we will develop a Stakeholder Management Plan that identifies relevant internal and external stakeholders impacted by or having influence on the project direction and success. It will also identify and document strategies that will be used to solicit stakeholder participation (e.g., focus groups, interviews, etc.), and will describe methods that will be used to communicate with stakeholders and escalate findings to the State, as appropriate.



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

MSQ12 – Role Understanding

Our Team member, NHC, has successfully provided PCMS and Pharmacy Fraud, Waste, and Abuse (PFWA) Services to the state of Georgia for 18 years. Since our team member is the incumbent for these services and is intimately familiar with the roles and responsibilities associated

with this SOW, we believe that we understand the intended SOW for the lead State more than other competitors. Over the course of providing these services, NHC has collaborated with both internal and external stakeholders, providing support and robust solutions leveraging a broad range of experience. Our Team recognizes that successful programs require ongoing collaboration among interested parties while also recognizing that ultimately, we are here to serve the State's interests.

While working together toward the realization of the State's goals, both Myers and Stauffer and NHC have developed substantive relationships with DCH. These working relationships have led to services that are tailored specifically to meet the needs of the State and its Medicaid population.

The Myers and Stauffer Team avoids any conflicts of interest and circumstances that could create any real or perceived conflict of interest. We have limited our practice exclusively to partnering opportunities with local, state, and federal government agencies. To the best of our knowledge, we have no real or perceived conflicts of interest. We have never experienced any unmitigated real or perceived conflict of interest in providing services, and we are exceptionally sensitive to public scrutiny, performance expectations, and the high levels of accountability and integrity that are expected of government agencies and policymakers.