NQTL: Medical Necessity

Classification: ALL

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding the NQTL and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Medical/Surgical:	MH/SUD:
UTILIZATION MANAGEMENT: Medically Necessary (Medical Necessity) A service or supply that is required to identify or treat your condition and is: • Appropriate and necessary for, and consistent with, the symptom or diagnosis and treatment or distinct improvement of an illness or injury. • Adequate and essential for the evaluation or treatment of a disease, condition, or illness. • Can reasonably be expected to improve your condition or level of functioning. • Conforms to standards of good medical practice, uniformly recognized and professionally endorsed by the general medical community at the time it is provided. • Not mainly for the convenience of the member, a physician or other provider. • The most appropriate medical service, supply or level of care that can safely be provided. When applied to inpatient care, it further means that your medical symptoms or conditions require that the services cannot be safely provided to you as an outpatient.	**UTILIZATION MANAGEMENT:** Same

PHARMACY: **Medically necessary drug:** A medically necessary drug is prescribed for treatment of an indication listed in the Food and Drug Administration (FDA) approved package insert, an indication studied in a well-designed clinical trial published in peer-reviewed literature, or an indication listed medical or drug compendia and meeting the defined level or strength of evidence. One of the following applies: medication provides clinically superior outcomes compared to all currently available agents based upon review of the published literature; documentation of trial and failure to all currently available formulary agents in the same therapeutic class is provided; documentation of allergic reactions or contraindication to all currently available formulary agents in the same therapeutic class is provided. Medications which fall under the following classifications are not considered medically necessary: drugs for cosmetic purposes; over-the-counter (OTC) medications (except for insulin, syringes, or items required as part of the Preventive Health or Women's Wellness Benefit); products classified as prescription medical devices or medical foods; drugs which have an OTC alternative; formulations of drugs that have an existing covered alternative, but which have been formulated to be convenient or cosmetically pleasing; formulations which are a combination of two or more existing drugs, with no additional clinical benefit; compounded products, including compounding kits, of two or more commercially available drugs that offer no additional clinical benefit compared to taking the individual components. *[See Documents: 1. Policy #425 Medical Necessity, 2. Policy #539 Drug Review Process, and 3. Policy #560 Excluded Drug List]*	**PHARMACY:** For MH/SUD drugs, criteria are less stringent in considering medical necessity of combination drugs or formulations of drugs that have an existing covered alternative. Instead of being outright excluded, the MH/SUD drug is often added to the formulary with step therapy or prior authorization. Example olanzapine/fluoxetine is available with step therapy, but naproxen/sumatriptan is currently excluded from the formulary.

Step 2 – Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits	
N/A	N/A
Step 3 – Identify any other source or evidence relied upon to design and apply the NQTLs to mental health or substance use disorder benefits and medical or surgical benefits.	
Medical/Surgical: **UTILIZATION MANAGEMENT:** InterQual, Medical Director reviews, Peer to Peer reviews with providers, external clinical consultants as needed, best practice or clinical guidelines published by a professional practice body, medical plans & benefits, Dashboard/AS400 (data warehouse) to determine in or out of network, extended health networks. **PHARMACY:**	MH/SUD: **UTILIZATION MANAGEMENT:** InterQual, Medical Director reviews, Peer to Peer reviews with providers, Prest and Associates clinical reviewers if needed American Society of Addiction Medicine (ASAM) treatment guidelines, medical plans & benefits, Dashboard/AS400 (data warehouse) to determine in or out of network, extended health networks. Prest and Associates and ASAM represent specific examples of resources for MH/SUD. This does not reflect a difference in practices between M/S and MH/SUD **PHARMACY:** Same

• Medispan Drug Data weekly reports to identify drugs newly approved by the FDA. • Drug manufacturer's website and/or insert to determine dosing, administration, formulations • Food and Drug Administration Website to determine dosing, administration, formulations • Requirements of the ACA • Requirements of 215 ILCS 134/45.1 • Pharmacy Policy #425: Illinois-Medical Exception Process • Pharmacy Policy #539: Drug Review Process • Pharmacy Policy #560: Excluded Drug List • Pharmacy Drug Policies • Treatment guidelines from professional organizations. • Drug compendia • Evidence published in peer-reviewed literature from well-designed randomized, controlled clinical trials. • Current Health Alliance drug formulary • Recommendations from Pharmacy and Therapeutics (P&T) subcommittee specialists and provider partners based on commonly accepted clinical practice	
Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification	
<u>Medical/Surgical</u>: **QUALITY:** ***Step 4(c):*** Health Alliance continuously monitors the consistency of the Medial Directors' utilization review decisions to improve consistency. To accomplish this, the following steps are taken:	<u>MH/SUD:</u> **QUALITY:** Same

• A quiz is developed by the Regional Medical Director. Questions are based on hypothetical cases. The questions are developed by examining appeals, issues that have been brought forward by staff, and questions/concerns of medical directors. • The quiz is administered through an electronic survey tool. • Each Medical Director receives a link to the quiz via email. • Scores are downloaded and shared with the CMO for action. • Goal is for all Medical Directors to achieve a score of 70% or better. • To promote consistency in review decisions by the Medical Directors. • To identify barriers to consistency in review decisions and determine and implement solutions. • To provide education as needed. • To identify additional resources appropriate to use for review decisions. The initial inter-rater reliability (IRR) was administered in January 2020. There were 4 medical directors that failed to meet the goal of 70% or better. A discussion of the IRR results was completed at the January 2020 Medical Director's meeting, to evaluate if understanding improved related to the testing process. Another IRR evaluation was completed in February. A follow up IRR was administered in February 2020. There were 4 medical directors that failed to meet the goal of 70% or better. Results were reviewed at the Medical Director's meeting to evaluate understanding and consistency. An IRR test was administered in June 2020. There were 8 medical directors that failed to meet the goal. The results were again reviewed at the Medical Director's meeting to evaluate understanding and consistency. A follow up IRR test was administered in Aug/Sept	

2020. There were 6 medical directors that failed to meet the goal. The results were reviewed at the Medical Director's meeting to evaluate understanding and consistency. **UTILIZATION MANAGEMENT:** ***Step 4(a)(i) & 4(b):*** Health Alliance uses nationally recognized and specialty peer reviewed, third-party policy criteria sets from eviCore and InterQual primarily for Medical/Surgical medical necessity determinations. Prest and Associates clinical reviewers, American Society of Addiction Medicine (ASAM), and InterQual criteria are used for Behavioral Health and Substance Use Disorder. These criteria provide medical necessity guidance for facility levels of care and length of stay, procedures, advanced imaging, molecular testing, physical/occupational therapy, chiropractic care, radiation therapy, oncology drug utilization, sleep medicine, spine/joint procedures, pain management, and DME authorization. Health Alliance has strategically identified our third-party vendor partners of medical necessity criteria to require that they be in the top quintile nationally by review volume of medical necessity review vendors. EviCore reviews 100 million covered lives, has over 570,000 engaged providers, and 100 clients; InterQual Guidelines are used by 4,308 Companies, including CMS contracts for Medicare audits; Prest and Associates uses InterQual Behavioral Health/Substance Use Disorder medical necessity criteria and the American Society of Addition Medicine (ASAM) medical necessity criteria. The ASAM Criteria is the most widely used and comprehensive set of guidelines for placement, continued stay, transfer, or discharge of patients with addiction and co-occurring conditions.	**UTILIZATION MANAGEMENT:** Same

Step 4(a)(ii): When third-party medical necessity or Medicare guidance is not available, Health Alliance develops in-house medical policies using medical literature evidence of the highest evidentiary standards available as outlined in the E/I Section, Step 4 and obtained from the Review Sources in outlined in Step 2 of the E/I Section. This is performed by the Medical Policy Committee. This committee is composed of the health plan Associate Chief Medical Officer who is a psychiatrist, three family medicine physicians (two of which are senior medical directors), a pulmonary specialist, radiation oncologist, emergency medical system physician director, thoracic surgeon, compliance and government relations staff members, the Director of Utilization Management and Systems, UM nurse manager, third-party vendor coordinator, UM project coordinator (medical literature specialist). ***Step 4(b):*** Medical Necessity criteria efficacy and validity are assessed by many Health Alliance processes, obtained from multiple inputs. The Health Alliance Medical Policy Committee (MPC) reviews all active internal medical policies on a continuous basis at one year intervals. This yearly review includes: medical necessity criteria comparison with the criteria of several national payers for consistency and a medical literature review when indicated for more newly approved evolving technologies/services and new indications within existing technologies/service. All MPC decisions and any policy revisions require final review/approval by the full Medical Directors Committee (MDC) which is made up of ten physicians. Any MDC concerns or recommendations are sent back to MPC for re-review, reanalysis, policy changes, and resubmission to MDC.	

Also, any time a member, their provider, a Heath Alliance employee or Medical Director Reviewer expresses concern related to a medical necessity criteria, that concern can be reported to MPC staff for investigation, best practice medical literature review and full MPC consideration and determination. ***Step 4(c):*** The Quality Department of Health Alliance conducts regular inter-rater reliability case questions and discussions for the UM Nursing staff and Medical Director Reviewers to ensure that consistent review decisions are obtained related to the medical necessity criteria within various in house medical policies. The MPC reviews annually or as updated, all external third-party vendor criteria revisions and new vendor policies. Any policy or criteria concerns are expressed to the vendor for a response. If there are no concerns, the revisions are approved by MPC and MDC. Health Alliance performs a quarterly audit with our external UM partner, eviCore, on specific cases that the Medical Director reviewers or the providing physicians express concern related to the medical criteria involved. This process allows for the appropriate clinical specialist at eviCore to respond to our plan/provider concerns. The feedback and results of this process are revision of eviCore criteria when high-level medical literature supports reason to do so. Health Alliance has engaged the InterQual Chief Medical Officer in discussions when it is our belief that their medical necessity criteria are not consistent with best practice and high-level medical evidence. On an additional level, the Health Alliance's Vendor Management team (part of Corporate Compliance and	

Enterprise Risk Management) conducts initial and ongoing oversight activities to ensure that our Delegated Vendors comply with applicable federal and state laws, regulations, CMS guidelines, and contract provisions applicable to contracted FDRs in order to identify risk and assist in correcting any noted deficiencies; or when no risks have been identified, to confirm. The review of all practices, analysis, and listed sources above verifies the right guidelines are being used. If the plan finds outlier results or feedback through the processes described internal policies are updated to address those findings. **PHARMACY:** ***Step 4(a)(i):*** • Our internal Drug Review Process, Medical Necessity, and Excluded Drug List Policies are used to guide determination of a drug's medical necessity. The policies are reviewed and approved by the Pharmacy and Therapeutics (P&T) Committee yearly and are updated as needed to comply with state and federal regulations. • If a drug is not excluded by the Excluded Drug Policy, it may be considered medically necessary and included on the formulary • If a drug is determined to be clinically superior to other formulary drugs in the same therapeutic category based on published literature, the drug is considered medically necessary and will be added to the formulary. • If a new drug is for a condition which previously had no approved treatments, the drug will be added to the formulary. • If required by the ACA or by state law, a drug will be added to the formulary. • A drug must be used for indications listed in the FDA approved manufacturers labeling in order to be	**PHARMACY:** ***Step 4(a)(i):*** • Same, except we place heavier consideration on the inclusion of MH/SUD drugs which fall under the category of combinations or convenience formulations. These drugs are generally added with prior authorization or step therapy. MH/SUD subcommittee specialist is a practicing psychiatrist. This representative also routinely meets with and incorporates feedback from a substance use disorder treatment provider group. ***Step 4(a)(ii):*** Same ***Step 4(b):*** • If provider submits documentation that member is already stabilized on a MH/SUD medication prior to coming on the plan or medication is started during an inpatient treatment, trials and failures of formulary drugs will not be required.

considered medically necessary, OR if it is to be used for indications in accepted drug compendia with the following levels of evidence: o indication listed in DRUGDEX with a class IIb or higher strength of recommendation, a category B or higher strength of evidence and a class IIa or higher efficacy; o indication listed in Lexicomp with a Level of Evidence of B or higher • Recommendations of national provider practice association guidelines will be considered in the decision whether to add a drug to the formulary. • Recommendations of P&T subcommittee specialist physicians. We utilize the expertise of practicing physicians who are specialists in the treatment category being reviewed. • P&T Committee votes on final medical necessity decision. • A Medical Director will be engaged when needed to confirm medical necessity of a drug or drug regimen. ***Step 4(a)(ii):*** • The Medical Necessity and Excluded Drug List Policy were created with focus on providing safe, efficacious, and cost-effective care for patients. • Ensure a formulary with a range of drugs across a broad distribution of therapeutic categories and classes while limiting access to high cost, low value drugs. • Policies are reviewed at least annually by the Health Alliance P&T committee. If changes to state or federal regulations necessitate a change to the policies, they will be reviewed more frequently. • The Pharmacy and Therapeutics (P&T) Committee is made up of one Health Alliance Medical Director, a	***Step 4(c):*** Same • **Medical necessity review approvals: 3 out of 21 total MH/SUD medical necessity reviews = 12.5%** • **No appeals**

pharmacist from Health Alliance, representative physicians and pharmacists from the Health Alliance network, including at least one representative from Washington, one physician licensed to practice medicine in the state of North Carolina, and a pharmacist that practices in a geriatric setting and nonvoting subcommittee members (physician specialists and pharmacists). P&T Committee members must report any conflict of interest to the chairperson and other Committee members and will submit an annual conflict of interest statement. • Decisions by the Committee shall be made by consensus as much as possible. Voting by members may be necessary at times • The P&T Committee will report to Medical Directors Committee (MDC), directly through members who may also be members of MDC, and through the transmission of Committee minutes to MDC. Committee minutes will also be forwarded to department Directors who may be impacted by the decisions made by the committee. ***Step 4(b):*** • FDA labeled indications • indication listed in DRUGDEX with a class IIb or higher strength of recommendation, a category B or higher strength of evidence and a class IIa or higher efficacy • indication listed in Lexicomp with a level of evidence of B or higher • Professional practice association guidelines: guideline level of evidence corresponding to that representing adequately powered, well-conducted, randomized controlled trials • Provider documentation that a patient has tried and failed the alternative drugs or that a requested drug is best practice	

Step 4(c): • Policies are reviewed yearly and updated earlier if needed due to regulation changes. • We review feedback from internal and external appeals reviewers to monitor our policies' alignment with best practices. • Inter-rater reviews performed annually. • The CMS-Federally Funded Exchange (FFE) Formulary Review Suite tool shows 0 Failures for Clinical Appropriateness Review. • CMS-FFE Category and Class Drug Count Review Tool shows only one deficiency, and it was for an antibiotic previously withdrawn from the market. • **Medical necessity review approvals: 22 out of 302 total M/S medical necessity reviews = 20%** • **6 appealed decisions, all upheld.** *[Inter-rater reports available if needed]* *[2020 QHP non-discrimination tool and category class count tool available if needed]* **CUSTOMER SOLUTIONS:** Customer Solutions Policy #129, related to Member Complaints, is being provided as supporting documentation for data reporting for Step 4(c) *[See Document 4. [Policy #129 Member Complaint Documentation and Resolution]*	**CUSTOMER SOLUTIONS:** Same

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

PHARMACY:

- MH/SUD criteria for medical necessity of excluded or non-formulary medications is less stringent than for med-surg in that a provider will not be required to show trial and failure or allergy or contraindication of all formulary alternatives if documentation is submitted showing that member is established on the medication. Further, MH/SUD combination formulations are more readily considered medically necessary than their M/S counterparts.
- Approval rates for MH/SUD formulary exceptions appears to be lower than that for M/S drugs, 12.5% versus 20%, though this calculation is based on a small denominator (21 MH/SUD medical necessity reviews).
    - Potential process improvement for MH/SUD and M/S: The care management platform does not currently allow medication determinations to be classified as non-medically necessary, excluded, or experimental. Currently, the platform only allows for specification of a review as prior authorization (PA), step therapy (ST), or a non-formulary determination. Within the non-formulary classification, we cannot further specify that a request was denied or approved on the basis of medical necessity, formulary exclusion, or experimental. This would be a helpful upgrade to the platform in performing future audits and analyses. We will work with our system vendor to explore the possibility of this enhancement.

CUSTOMER SOLUTIONS:

None

NQTL: Prior Authorization

Classification:

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding the NQTL and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Medical/Surgical:	MH/SUD:
UTILIZATION MANAGEMENT: ***Step 1(a):*** Prior Authorization definition: A decision by Health Alliance Utilization Management, made before the service is provided, that a non-emergent health care service, treatment plan, prescription drug, or durable medical equipment is medically necessary. Supporting documents: • *[Document 5. Prior authorization P&P Policy #2404]* • *[Document 6. Medical Criteria review P&P Policy #437]* ***Step 1(b):*** Standard PA Narrative list and DME Narrative list are used to identify the benefits and services for which Prior Authorization is required. Supporting documents: • *[Document 7. DME PA List – 2020]* • *[Document 8. DME PA List – 2021]* • *[Document 9. Standard PA List – 2020]* • *[Document 10. Standard PA List – 2021]*	**UTILIZATION MANAGEMENT:** To facilitate smooth transition to lower levels of MH/SUD care, during the concurrent review process, medical necessity is determined prior to a stepdown to lower level of care; otherwise process is the same as medical /surgical.

For planned admissions, prior authorization is needed for an HMO member to utilize out of network facilities, or for any member to receive out of network care reimbursed at the in network benefit level. No prior authorization is required for inpatient admissions; however, notification is required within 24 hours of admission. **PHARMACY:** Prior Authorization: A review process requested by a provider prior to member obtaining a drug or service. Prior authorization review is a determination made by the insurer that certain requirements have been met which indicate medical necessity of the drug or service. Supporting document: • *[Document 11. Excel sheet-List of PA_TIER_ST. Blue highlight = MH/SUD]*	**PHARMACY:** Same
Step 2 – Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits	
<u>Medical/Surgical:</u> **UTILIZATION MANAGEMENT:** Factors used to assign NQTL prior authorization requirements include all of the following: 1. An annual analysis of utilization patterns for all nationally recognized procedure codes, including recommendations for prior authorization program changes; 2. The CPT/HCPCS/Revenue code classification in our benefits system;	<u>MH/SUD:</u> **UTILIZATION MANAGEMENT:** Same

3. Internal committees comprised of medical and coding subject matter experts, such as the Code Review Committee, Code Review Workgroup, and Medical Policy Committee; 4. State or federal regulations; 5. Evidence-based concerns about fraud, waste, abuse, overuse, or clinical effectiveness; 6. Narrative NQTL categories on the Standard Prior Authorization List and DME Prior Authorization List. **PHARMACY:** 1. Urgency of treatment; route of administration 2. Potential for critical adverse effects likely to outweigh benefits in some cases 3. Need for complex monitoring 4. Clinical concerns about overuse (e.g. antibiotic resistance) 5. Potential for significant use that is deemed not to be clinically effective, or lacking long-term clinical effectiveness 6. Concern for sub-optimal use in terms of dose or off-label prescribing 7. Availability of formulary alternatives and NQTL status of formulary alternatives 8. State or federal regulations	**PHARMACY:** Same, except SUD medications may not have prior authorization per Illinois law.
Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.	
<u>Medical/Surgical:</u> **UTILIZATION MANAGEMENT:** We base the decision to PA on several factors, such as if a procedure is a new and expensive technology, if internal claims or data analyses show excessive utilization, and if there are standard of care criteria to be met for these procedures to be deemed appropriate using a preponderance of the medical literature and adherence to identified national standards.	<u>MH/SUD:</u> **UTILIZATION MANAGEMENT:** Same

All of our PA decisions are based on in-depth data analyses that factor in approval rates, denial rates, appeal rates, and overturned appeal rates for two calendar years' worth of data. The intent of the analysis is to reduce member and provider friction, particularly when requiring prior authorization would not result in an adequate return on investment or would result in excessive burden to members and providers. An organizational review is done with decisions made to add or take procedures off the list, based on that analysis. We look for overutilization of a procedure based on Milliman benchmarks, an increasing utilization trend, and the percent of denials. The analysis is done to ensure we are prior authorizing procedures appropriately and not inconveniencing providers and members unnecessarily. We also take that time to ensure there is no qualitative or quantitative difference in how we select MH/SUD vs Med/Surg procedures for PA. **PHARMACY:** Urgency of treatment; route of administration are defined by manufacturer's package insert, FDA website. Evidentiary standard is FDA recommendation and requirements for use and administration. Medications likely to be used in emergent or urgent situations in which a delay in therapy would have significant harmful consequences will not have prior authorization. Potential for adverse effects or need for complex monitoring: Drugs for which the FDA requires Black box warnings to be included within the manufacturer's packaging would generally have prior authorization. Drugs for which FDA requires REMS program to ensure that benefits outweigh risks will generally have prior authorization Clinical concerns about overuse: Recommendations of national organizations (CDC, AAP, ACC, NIH) and/or national practice association guidelines; recommendations from P&T subcommittee specialists. Potential for significant use that is deemed not to be cost-effective, such as for non-FDA approved indications. Prior auth would be applied to ensure appropriate use for: • FDA labeled indication	**PHARMACY:** Same; with the exception that drugs for SUD must not have prior auth per Illinois regulation.

• An indication listed in DRUGDEX with a class IIb or higher strength of recommendation, a category B or higher strength of evidence and a class IIa or higher efficacy. • An indication listed in Lexicomp with a level of evidence of B or higher. • Input from P&T subcommittee specialists and provider partners based on common clinical practice. 7) Prior auth status of formulary alternatives: • Prior auth required for other meds in the same therapeutic category—apply PA • Prior auth not required for other meds in the same therapeutic category, and new medication is no more effective but significantly more costly—apply PA 8) P&T committee will vote on final PA status 9) State regulations prohibit prior auth from being applied to certain classes of medications. Supporting Document: • *[Document 12. Policy #540-Prior Approval Guidelines]*	
Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification	
Medical/Surgical: **UTILIZATION MANAGEMENT:** ***Step 4(a):*** Supporting Document: • *[Document 13. Utilization Management PA Factor Comparative Analysis Grid]* ***Step 4(b):***	MH/SUD: **UTILIZATION MANAGEMENT:** Same. Tables containing MH/SUD denial rates, appeal rates, overturned appeal rates, and claims data are provided in the M/S section for easier visual analysis and parity comparison.

All medical necessity reviews must be completed following regulatory timeframes of 72 hours for medically urgent and 15 days for standard requests, with one extension period of 45 day for standard requests if not enough clinical documentation is submitted. Preauthorization requests must include a clear statement of what service is being reviewed and supporting clinical documentation including clinical notes, lab and imaging test results, and any relevant surgical documentation. All medical necessity reviews are conducted by RNs who may approve the request if the documentation submitted meets medical necessity criteria (InterQual, internal medical policies, eviCore guidelines). Reviews that do not appear to meet established criteria are passed to a Medical Director for final review. Only Medical Directors may issue a denial based on not meeting medical necessity criteria. RNs and Medical Directors may apply professional discretion to approve services if strictly following the criteria would cause harm to the member physically, or if there are socio-economic reasons that show the deviation is in the best interest of the member. The discretionary reason must be clearly documented in the nurse or Medical Director review notes. In the absence of medical and coverage policies or guidelines the requests default to medical necessity requests described in the medical necessity section of this template Individual reviews may depart from written policies and procedures when making a determination when the total of the member's medical history, provider statement, and proposed clinical course is believed to provide the best clinical care. Supporting documents: • *[Document 13. Referrals: Tertiary and Out of Network Referrals Policy #451]* • *[Document 14. Coverage Determination Review Process: Medical Necessity Reviews Policy #410]* • *[Document 15. Coverage Determination Review Process: Benefit Policy #1002]* Our organization treats post-service requests as claims appeals, so post-service denial rates are captured within the appeals data. Pre-service denial rates, internal appeal rates, external appeal rates, and overturned appeal rates are provided below. There are 26 experimental and investigational M/S prior authorizations included in the	

overall summary data, and these will also be broken out separately in the experimental and investigational section.

Step 4(c):

All appeals regardless of whether it is Med/Surg or MH/SUD is reviewed following the regulatory timeframes of 24/72 hours for expedited and 15/30 days for standard reviews. All medical necessity appeals are reviewed by a Medical Director/Clinical Peer.

A comparison of business year 2020 appeal data indicates there were more appeals on MH drugs (10) than on the Med/Surg (4). The appeal reviews were conducted the same by using the appropriated criteria for the request being reviewed and by a Medical Director. Upon an adverse determination the member/authorized representative was afforded their right to a voluntary level of appeal with an external reviewer via a request through the Illinois Department of Insurance. The regulation does not indicate that the health plan is to call out whether the review is for MH/SUD or Med/Surg, however it does indicate we have to acknowledge if the review is experimental/investigational.

The Inter-rater Reliability testing serves as a random audit process of our decisions and application of prior authorization to a given benefit.

Pre-Service Denial Rates:

Category	Prior Authorization Denials (#)	Total Prior Authorizations (#)	Percentage Denied (%)
MH/SUD	15	852	2%
M/S	6,613	96,190	7%

Internal and External Appeal Rates and Overturned Appeal Rates:

Category	Prior Authorization Denials (#)	Internal Appeals (#)*	External Appeals (#)	Denials Appealed (%)	Overturned Appeals (#)	Overturned Appeals (%)
MH/SUD	15	3	0	20%	0	0%
M/S	6,613	627	30	10%	279	42%

*Until mid-March 2020, internal and external appeals were captured together. After a new care management system was launched in mid-March, internal and external appeals could be automatically distinguished in appeals reporting.

Proportions of covered MH/SUD and M/S claims that are subject to prior authorization:

Category	Number of Claims that Contain a Procedure Code with an NQTL	Total Number of Claims, Including NQTL and Non-NQTL	Percentage of Claims by Category with an NQTL (%)
M/S	285,645	1,559,429	18%
MH/SUD	1,340	154,182	1%
Grand Total	286,985	1,713,611	17%

QUALITY:

It is the policy of Health Alliance to consult a Clinical Peer when appropriate at the time of initial determinations and appeals for potential denials of coverage based on medical necessity criteria. A Clinical Peer is a health care professional who is in the same profession and the same or similar specialty as the health care provider who typically manages the medical condition, procedures and treatment under review. A Medical Director qualifies as same or similar if he/she would treat the condition in his/her own practice. If the Medical Director cannot act as a Clinical Peer, he/she will

QUALITY:

Same

refer for a clinical peer review with a Health Alliance-contracted external review organization. The medical director may also contact a clinical peer they know of the same or similar specialty. If Medical Director contacts a clinical peer whom he/she knows instead of a reviewer with a contracted external review organization, he/she will document the conversation with Clinical Peer and include in the documentation the clinical peers initials, date and major points of discussion in the Appeal Tracking System. The Chief Medical Officer is available to advise the Medical Director on any case under review.

Member/Provider Resolution Coordinator prepares all cases for external review organizations and attaches the case information submitted into the Appeals Tracking System. Member/Provider Resolution Coordinator informs the Medical Director/RN of external review organization clinical peer decisions and documents it in the Appeals Tracking System. Medical Management staff will finalize the review based on the clinical peer decision.

Step 4(c):

The following summarizes the Medical Director inter-rater reliability scores of 2020.

Respondent	Final Score	Date Finished
PA	77%	1/16/20
JB	92%	1/13/20
SB	54%	1/15/20
SB	92%	1/16/20
JB	85%	1/15/20
TD	92%	1/16/20
RH	92%	1/10/20
MJ	69%	1/17/20
CL	77%	1/20/20
KS	54%	1/17/20
MS	85%	1/16/20
JZ	69%	1/11/20

- **February 2020**

Respondent	Final Score	Date Finished
JB	75%	2/12/20
SB	25%	2/10/20
SB	50%	2/9/20
JB	25%	2/14/20
TD	50%	2/12/20
RH	100%	2/4/20
MJ	100%	2/17/20
CL	100%	2/4/20
MS	75%	2/15/20

- **June 2020**

Respondent	Final Score	Date Finished
JB	67%	6/18/20
SB	33%	6/16/20
JB	100%	6/17/20
RH	33%	6/17/20
MJ	33%	6/17/20
CL	67%	6/12/20
KS	33%	6/17/20
MS	50%	6/17/20
JZ	67%	6/15/20

- **Aug/Sept 2020**

Respondent	Final Score	Date Finished
JB	75%	9/9/20
SB	38%	9/14/20
JB	50%	9/2/20
TD	38%	9/15/20
RH	38%	9/8/20
MJ	75%	9/13/20
CL	25%	8/29/20
HM	63%	9/2/20
MS	75%	8/25/20
JZ	88%	8/29/20

The following summarizes the RN inter-rater reliability scores of 2020.

ACUTE ADULT TEAM

Respondent	Final Score	Pass/Fail	Times Taken	Action between attempts	Date Finished
CN	92%	Pass	1	Na	5/22/20
JF	88%	Pass	1	Na	6/4/20
KM	84%	Pass	1	Na	5/21/20
LW	92%	Pass	1	Na	6/9/20
ME	84%	Pass	2	Education with Educator	5/27/20
SB	88%	Pass	1	Na	6/12/20

- Average Adult Team 88%

ACUTE PEDIATRIC TEAM

Respondent	Final Score	Pass/Fail	Times Taken	Action between attempts	Date Finished
EC	80%	Pass	1	Na	6/2/20
KM2	92%	Pass	1	Na	6/10/20
LF	92%	Pass	1	Na	6/5/20
NG	84%	Pass	1	Na	6/11/20
TW	96%	Pass	1	Na	5/29/20

Average Pediatric Team 88%

DME TEAM

Respondent	Final Score	Pass/Fail	Times Taken	Action between attempts	Date Finished
EW	100%	Pass	2	Education with Educator	6/11/20
JL	84%	Pass	1	Na	6/3/20

KG	84%	Pass	1	Na	6/3/20
KW	84%	Pass	1	Na	6/9/20
LR	88%	Pass	1	Na	5/20/20
LR2	92%	Pass	1	Na	6/9/20
TF	80%	Pass	1	Na	6/10/20
VP	80%	Pass	1	Na	6/17/20
VR	80%	Pass	1	Na	6/11/20

Average DME Team 85%

BH TEAM

Respondent	Final Score	Pass/Fail	Times Taken	Action between attempts	Date Finished
JL2	100%	Pass	1	Na	6/1/20
SB	88%	Pass	1	Na	6/10/20

Average BH Team 94%

Health Alliance continuously monitors the consistency of the UM Coordinator's utilization review decisions to improve consistency with the UM Coordinator approving requests to identify issues. To accomplish this, the follow steps are taken:

- The InterQual Inter-rater Reliability (IRR) tool is used.
- The tool generates questions and administers custom tests to each coordinator to reduce the possibility of consulting on answers.
- Each UM Coordinator is sent a link for a quiz customized to their area of specialization.
- Test scores are reviewed. For Coordinators with a score of less than 80%, additional education and retesting will be completed. Failure to achieve a passing score on the second attempt may result in a corrective action plan.
- Goal is for all coordinators to achieve a score of 80% or better in two attempts or less.
- To promote consistency in review decisions by the UM Coordinators.
- To identify barriers to consistency in review decisions and determine and implement solutions.
- To provide education as needed.

PHARMACY:

• To identify additional resources appropriate to use for review decisions.
 	
The test was administered throughout the months of May/June 2020.
 	
PHARMACY:
 	
Step 4(a):
 	
Supporting Document:
• *[Document 14. Prescription Drug PA Factor Comparative Analysis Grid]*
 	
Step 4(b): Briefly describe the processes by which prior authorization is applied.
• A registered pharmacist reviews the request within the appropriate state or NCQA timeframes (For Illinois: 24 hours for urgent request, 72 hours for a non-urgent request, or 30 days for a retroactive request) and according to the relevant Drug Policy.
• A provider or their representative may submit a request via the provider portal or by fax using the Health Alliance Prior Authorization form.
• When all information is received, the pharmacist will refer to the applicable drug policy and make the determination to approve or deny the request based on documentation submitted by provider.
• In cases where a request does not meet Drug Policy criteria due to complex disease state or member factors, a Medical Director will be requested to review the provided information before a determination is made. Certain drug policies for very high cost drugs or drugs for diseases requiring complicated or nuanced diagnosis also require a Medical Director's review.
• A fax will be sent to notify the provider of the decision. In the case of a denial, the member will also receive a letter which details the specific unmet criteria which resulted in the denial.
• Provider may request a peer-to-peer conference in which provider may discuss the denial with the reviewing pharmacist and present additional information.
• Provider may request to appeal the denial. Appeal request will be routed to Member Relations and will receive a second level review by a Medical Director.
Exceptions:
	Step 4(a):
	
	Supporting Document:
	• *[Document 14. Prescription Drug PA Factor Comparative Analysis Grid]*
	
	Step 4(b):
	Same
	
	Step 4(c) :
	Same
	
	• **MH/SUD formulary drugs with PA: 27/276 = 9.8%**
	• (count is of drug names only, strengths and formulations were not included in count)
	• **MH/SUD Prior auth requests: 582 approvals/731 requests = 81%**
	• (no data on pre- vs post-service; criteria would be the same for both)
	• **Total MH/SUD appealed prior auth decisions: 10**
	  ○ **0 to ERO**
	  ○ **2 overturned denials**

• Requests for Oncology medications are submitted through Evicore who review the request based upon National Comprehensive Cancer Network (NCCN) algorithms.
 	
Step 4(c) :
 	
The Inter-rater Reliability testing serves as a random audit process of our decisions and application of prior authorization to a given benefit.
 	
• Inter-rater reliability is performed once per year, 50 events; 100% for 2020.
• Health Alliance formulary and prior authorization criteria meet the standards of a number of commercial and government programs, including the State of Illinois Employees and Federal Employees Health Benefit.
 	
• **M/S formulary drugs with PA: 743/3152 =23.6%**
• (count is of drug names only, strengths and formulations were not included in count)
• **M/S Prior Auth requests: 6183 approvals/7826 requests = 79%**
• (no data on pre- vs post-service; criteria would be the same for both)
• **Total M/S appealed prior auth decisions: 180**
  ○ **13 to ERO**
  ○ **34 overturned denials**
 	
ALL DEPARTMENTS:
 	
Step 4(c):
 	
Health Alliance does not have any defined corrective action plan process for results of inter-rater reviews. The information is used for educational purposes and results are meant to foster discussion on interpretation or decision differences. Results are shared and discussed with the appropriate parties and when needed policies and procedures are updated to decrease ambiguity and variances in decisions.	

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

UTILIZATION MANAGEMENT:

- PA requests are approved at a higher rate for MH/SUD than M/S
- The number of MH/SUD appeals is only 3, so it's difficult to make any statistically significant assumptions on that volume

Possible process improvements for both M/S and MH/SUD:

1. Health Alliance will add the Prior Authorization definition to current Prior Authorization Policy #2404.

PHARMACY:

- PA requests are approved at a similar rate for M/S and MH/SUD: 79% and 81%
- Though the number of appeals for both M/S and MH/SUD is low, the calculated proportions of overturned decisions would be similar: M/S: 19% and MH/SUD: 20%

Possible process improvements for both M/S and MH/SUD:

1. We have a written policy in place for developing prior authorization criteria, but there is no policy outlining the steps a pharmacist takes to review prior authorization requests. This policy would clarify the steps in the process for new and continuing pharmacists and ensure uniformity of all determinations.
2. Perform inter-rater audit more frequently and with a greater proportion MH/SUD reviews; or create a separate inter-rater focusing exclusively on MH/SUD reviews.
3. Create a central written repository of peer to peer discussions to monitor the alignment of policy criteria with current best practice and provider concerns with findings to be taken forward for P&T review as needed.
4. Initiate pharmacist discussion of MH/SUD determinations with at the standing pharmacist meetings

NQTL: Experimental and Investigational

Classification:

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding the NQTL and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Medical/Surgical:	MH/SUD:
PHARMACY: Experimental and investigational are defined as relating to medications which are still the subject of ongoing Phase I, Phase II, or Phase III trials to establish the medication's effectiveness, optimal dosage, toxicity, and side-effects, or to establish the medication's maximum tolerated dose, it's toxicity, it's safety, it's effectiveness, or its effectiveness as compared with the standard means of treatment or diagnosis. Reliable evidence shows that experts agree that further studies or clinical trials are needed to test the safety and effectiveness of the treatment compared to other accepted treatments. Experimental medications may be medications that have not been approved by the FDA or may be medications that have usages which are not approved by the FDA. Supporting document: *[Document 16. Policy #561-Experimental Medications Policy]* **UTILIZATION MANAGEMENT:** Definition of Experimental from IL SPDs: Treatments/Procedures/Drugs/Devices/Transplants Unless otherwise stated in this Policy, such as coverage for Approved Clinical Trials, the Plan does not pay benefits for any charges incurred for or related to any medical treatment, procedure, drug, device or transplant that is determined by a Medical Director to meet one or more of the following standards or conditions:	**PHARMACY:** Same **UTILIZATION MANAGEMENT:** Same

• The medical treatment, procedure, drug, device or transplant is the subject of ongoing phase I, phase II, phase III or phase IV clinical trial or is otherwise under study to determine its safety, efficacy or its efficacy as compared with the standard means of treatment or diagnosis for the Member's condition, disease or illness. • The consensus of opinion among experts regarding the medical treatment, procedure, drug, device or transplant is that further studies or clinical trials are necessary to determine its safety, efficacy or its efficacy as compared with the standard means of treatment or diagnosis for the Member's condition, disease or illness. • The drug or device cannot be lawfully marketed for your condition, disease or illness without the approval of the FDA, and approval for marketing has not been given at the time the drug or device is prescribed or furnished. • The medical treatment, procedure, drug, device or transplant for the treatment or diagnosis of your condition, disease or illness does not conform to standards of good medical practice, and is not uniformly recognized and professionally endorsed by the general medical community at the time it is to be provided. • The medical treatment, procedure, drug, device or transplant for the treatment or diagnosis of your condition, disease or illness is determined by a Medical Director to be experimental or investigational. • Organ Transplants will be deemed experimental or investigational if the Office of Healthcare Technology Assessment within the Agency for Healthcare Policy and Research, as part of the federal Department of Health and Human Services (HHS), determines that such procedures are either experimental or investigational, or that there is insufficient data or experience to determine whether an organ transplantation procedure is clinically acceptable. • If Health Alliance has made a written request, or had one made on its behalf by a national organization, for determination by HHS as to whether a specific organ transplant procedure is clinically acceptable, and the organization fails to respond to such a request within a period of 90 days, the failure to act may be deemed a determination that the procedure is deemed to be experimental or investigational.	

In making his or her determination that a medical treatment, procedure, drug, device or transplant for the treatment or diagnosis of your condition, disease or illness is excluded from coverage under this subsection, a Medical Director will use current medical literature and discussion with medical experts and other technological assessment bodies designated by Health Alliance. Each review will be on a case-by-case basis regarding coverage of a requested medical treatment, procedure, drug, device or transplant for the treatment or diagnosis of your condition, disease or illness. Services meeting ANY of the following are considered to be Experimental and/or Investigational: • The intervention does not have unrestricted Food and Drug Administration (FDA) approval to be marketed in the US for the member's specific medical condition and diagnosis, however, FDA approval by itself does not ensure that Health Alliance will consider it as standard of care and not investigational; OR • The intervention is not proven to be as safe or effective in achieving an outcome equal to or exceeding the outcome of alternative standard therapies; OR • The available scientific evidence does not permit conclusions concerning the effect of the intervention on health outcomes; OR • The intervention is not proven to be applicable outside the research setting; OR • The consensus of opinion in peer-reviewed, high-level, evidence based medical literature is that further studies or clinical trials are necessary to determine long-term safety and effectiveness; OR • The intervention does not conform to standards of good medical practice and is not uniformly recognized and professionally endorsed by the general medical community at the time it is to be provided.	
Step 2 – Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits	

N/A	N/A
Step 3 – Identify any source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.	
Medical/Surgical: **PHARMACY:** • Medline • FDA publications • Peer-reviewed medical or pharmacy articles published in medical and scientific literature • Pharmaceutical manufacturer literature • Proprietary drug review literature • Expert opinion and consultation • The written protocol(s) used by the treating facility or the protocol(s) of another facility studying the same treatment, procedure, device, drug, or medicine • The written informed consent used by the treating facility or by another facility studying the same treatment, procedure, device, drug, or medicine • The standard of care in the medical community • State or federal regulations **UTILIZATION MANAGEMENT:** Health Alliance will assess new medical and behavioral health/substance use disorder technologies/devices/procedures and their coverage based on high-level, evidence-based, peer-reviewed medical literature database searches, which may include, but are not limited to: • PubMed-US National Library of Medicine, National Institutes of Health	MH/SUD: **PHARMACY:** Same **UTILIZATION MANAGEMENT:** Same

• The Cochrane Collaboration • Hayes, Inc. – includes Hayes Medical Technology Directory, Hayes Technology Briefs, and Genetic Testing Evaluations. • Agency for Healthcare Research and Quality (AHRQ) • Governmental Regulatory Agencies, including CMS National Coverage Determinations and Medicare Intermediary Local Coverage Determinations • Specialty Society Guidelines supported by a literature strength ranking system • National Comprehensive Cancer Network • Expert Medical Opinion • Major National Health Insurance Plans Policy Statements • External Review Organizations board-certified, peer consultants	
Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to medical or surgical benefits in the benefits classification	
Medical/Surgical: **QUALITY:** ***Step 4(a)(ii):*** It is the policy of Health Alliance to consult a Clinical Peer when appropriate at the time of initial determinations and appeals for potential denials of coverage based on medical necessity criteria. A Clinical Peer is a health care professional who is in the same profession and the same or similar specialty as the health care provider who typically manages the medical condition, procedures and treatment under review. A Medical Director qualifies as same or similar if he/she would treat the condition in his/her own practice. If the Medical Director cannot act as a Clinical Peer, he/she will refer for a clinical peer review with a Health Alliance-contracted external review organization. The medical director may also contact a clinical peer they know of the same or similar specialty. If Medical Director contacts a clinical peer whom he/she knows instead of a reviewer with a contracted external review organization, he/she will document the conversation with Clinical Peer and include in the documentation the clinical peers initials, date and major points of discussion in the Appeal Tracking System. The Chief Medical Officer is available to advise the Medical Director on any case under review.	MH/SUD: **QUALITY:** Same

Member/Provider Resolution Coordinator prepares all cases for external review organizations and attaches the case information submitted into the Appeals Tracking System. Member/Provider Resolution Coordinator informs the Medical Director/RN of external review organization clinical peer decisions and documents it in the Appeals Tracking System. Medical Management staff will finalize the review based on the clinical peer decision.	
PHARMACY: ***Step 4(a)(i):*** Medications used in an approved clinical cancer phase I through phase IV trial are not considered experimental. A drug that is approved by the FDA for treatment of a type of cancer and is being prescribed for the treatment of another type of cancer will be covered so long as the drug has been proven effective and accepted for the treatment of the specific type of cancer for which the drug has been prescribed in any one of the following: • The National Comprehensive Cancer Network Drugs and Biologics Compendium • The Thomson Micromedex DrugDex • American Hospital Formulary Service-Drug Information • The Elsevier Gold Standard's Clinical Pharmacology • Any other authoritative compendia as recognized periodically by the United States Secretary of Health and Human Services ***Step 4(a)(ii):*** The Experimental and Investigational Drug Policy is reviewed at least once per year by the Health Alliance P&T Committee. The Committee consists of voting members (one Health Alliance Medical Director, a pharmacist from Health Alliance, representative physicians and pharmacists from the Health Alliance network, including at least one representative from Washington, one physician licensed to practice medicine in the state of North Carolina, and a pharmacist that practices in a geriatric setting) and nonvoting subcommittee members (physician specialists and pharmacists). Meetings	**PHARMACY:** ***Step 4(a)(i):*** Same ***Step 4(a)(ii):*** Same ***Step 4(b):*** Same ***Step 4(c):*** Same

are chaired by the Health Alliance Director of Pharmacy and decisions shall be made by consensus as much as possible. Voting by members may be necessary at times. ***Step 4(b):*** 1) A registered pharmacist reviews a request within the appropriate state or NCQA timeframes (For Illinois: 24 hours for urgent request, 72 hours for a non-urgent request, or 30 days for a retroactive request). 2) A requested treatment will be considered experimental if the treatment is being used for an indication other than: the indication for which it was approved by the FDA; an indication listed in DRUGDEX with a class IIb or higher strength of recommendation, a category B or higher strength of evidence and a class IIa or higher efficacy; or an indication listed in Lexicomp with a level of evidence of B or higher. 3) If the treatment is not being used for one of these categories of indications, it will be considered experimental. 4) Coverage will be considered if the treatment has been the subject of at least two well-designed, controlled clinical trials, the results of which have been published in a peer-reviewed journal. 4) If it is unclear that the available literature supports the use of the requested drug for the treatment for which it is being requested, the request will be forwarded to a Medical Director for final review and decision. 5) A fax will be sent to notify the provider of the decision. In the case of a denial, the member will also receive a letter which explains the specific evidence supporting the denial, or the lack of evidence for the treatment. 6) Provider may request to appeal the denial. Appeal request will be routed to Member Relations and will receive a second level review by a Medical Director. 7) If denial is upheld, the member is given the right to a voluntary external review level of appeal. ***Step 4(c):*** • E/I determinations for medications are not differentiated from medical necessity determinations in the management platform. Any requests reviewed as E/I would be classified as medical necessity requests and therefore cannot be counted separately.	

• Experimental/Investigational Medications Policy is reviewed by the P&T Committee annually. **UTILIZATION MANAGEMENT:** ***Step 4(a)(i):*** Health Alliance does not cover any services that are determined to be E/I, however, if the E/I service is the investigational item of a Clinical Trial, Health Alliance will cover the Standard of Care services in the Trial if the member elects to participate. ***Step 4(a)(ii):*** Using the Evidentiary sources in Step 3 above, Health Alliance ranks the Evidentiary sources of evidence-based medical information by their type and hierarchical Strength of Evidence with the strongest level of evidence and study design assigned the greatest decisional weight and ranking of other study designs with progressive lesser precision lower in the decisional hierarchy as follows: 1. Systemic Review/Meta-Analysis 2. Randomized Controlled Trials 3. Non-randomized Controlled Trials 4. Cohort Studies 5. Case Control Studies 6. Case Series/Reports 7. Expert Medical Opinion When sufficient data are collected, the assigned Medical Director forwards the information to the Medical Policy Committee (MPC) for review and discussion based upon this hierarchy of medical evidence. Considering the Definition of Experimental and/or Investigational Services above in Step 1, and available literature the Committee then discusses and votes to deny coverage of the service as Investigational or to cover the service.	**UTILIZATION MANAGEMENT:** Same

Services/items that are determined to be E/I are entered into the PolicyTech electronic policy data base, alphabetically filed in the Technology Topic Grid for easy access if a request for the E/I item is received.

Step 4(b):

If a medical director receives a request for an E/I item/service and the Tech Topics was reviewed by MPC within the past one year, the reviewer performs a brief review of current literature and if the item continues to not be standard of care, the request is denied. If the current Tech Topic has not been reviewed by MPC within the past one year, the reviewer completes their literature review and with case adjudication and passes the item to the full MPC for re-review. If at any time the reviewer determines that there is new literature establishing the item as standard of care they also refer that information on to the MPC.

The 26 experimental and investigational M/S prior authorizations shown below are also included in the overall NQTL Prior Authorization summary data.

Step 4(c):

Pre-Service Denial Rates:

Category	Prior Authorization Denials (#)	Total Prior Authorizations (#)	Percentage Denied (%)
MH/SUD	0	0	NA
M/S	19	26	73%

Internal and External Appeal Rates and Overturned Appeal Rates:

Category	Prior Authorization Denials (#)	Internal Appeals (#)*	External Appeals (#)	Denials Appealed (%)	Overturned Appeals (#)	Overturned Appeals (%)
MH/SUD	0	0	0	NA	0	NA
M/S	19	3	0	16%	1	33%

*Until mid-March 2020, internal and external appeals were captured together. After a new care management system was launched in mid-March, internal and external appeals could be automatically distinguished in appeals reporting.

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section
PHARMACY: Experimental/Investigational is less strictly defined for oncology medications because of Illinois law. Possible process improvements for both M/S and MH/SUD: • Develop a written policy outlining the steps a pharmacist takes to review Experimental/Investigational requests. This policy would clarify the steps in the process for new and continuing pharmacists and ensure better uniformity of all determinations. Create a central repository of Pharmacy Experimental/Investigational reviews and determinations for future reference and tracking. • If possible, implement enhancements to care management platform, Guiding Care, to include a method of classifying determinations as Experimental/Investigational. Given current platform constraints there is not an easily reportable way to determine E/I reviews and rely on a manual review and bucketing of events for discussion purposes.

NQTL: Prescription Drug Formulary Tiering

Classification:

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding the NQTL and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Medical/Surgical:	MH/SUD:
PHARMACY: ***Step 1(a): Define Formulary Tiers*** **Tier 1** Preferred generics: Lowest out-of-pocket cost **Tier 2** Non-preferred generics: Higher out-of-pocket cost than Tier 1 **Tier 3** Preferred brands: Higher out-of-pocket cost than Tier 2 **Tier 4** Non-preferred brands: Higher out-of-pocket cost than Tier 3 **Tier 5** Preferred specialty: Higher out-of-pocket cost than Tier 4 **Tier 6** Non-preferred specialty: Highest out-of-pocket cost No Tier 1 drugs require prior authorization or step therapy. Otherwise, all policies may apply to all tiers Supporting document: *[Document 11. Excel sheet-List of PA_TIER_ST. Blue highlight = MH/SUD]*	**PHARMACY:** ***Step 1(a): Define Formulary Tiers*** Same ***Step 1(b): Identify all drugs covered in each Formulary Tier*** Same

Step 2 – Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits

Medical/Surgical:	MH/SUD:
PHARMACY: • Drug availability as brand, generic, or biosimilar • Specialty vs non-specialty status of drug (specialized procurement, administration, complex management) • Narrow therapeutic index drugs • State regulations (ex. Drugs for SUD are on lowest generic or brand tier) • Cost • Tier placement of formulary alternatives	**PHARMACY:** Same
Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.	

Medical/Surgical:
 	
PHARMACY:
 	
Drug's brand or generic status via FDA Orange Book
• Generic drugs will be placed in Tier 1-- preferred generic or Tier 2-- non-preferred generic tiers.
  o Tier 1 drugs are the very lowest cost maintenance generics for a handful of chronic conditions, similar to retail pharmacy chains' $4 drug lists. These are assigned based on cost and current formulary placement of their therapeutic alternatives.
  o New generics which do not fall into tier 1 automatically are placed into tier 2.
• Brand drugs will be placed in Tier 3-- preferred brand tier or Tier 4-- non-preferred brand tier
	MH/SUD:
	
	PHARMACY:
	
	Same
	-Medications for the treatment of SUD are placed on the preferred generic or brand tier per Illinois law.

<table>
<tr><td>

Tier 3 contains narrow therapeutic index brand name drugs (blood thinners, anti-rejection, seizure meds); brand name drugs which are lower cost or receive rebating; brand name drugs for the treatment of substance use disorders (per Illinois regulations).
All other brand name, non-specialty drugs will be placed in tier 4.

A drug may be identified as a Specialty medication via the Medispan file, drug compendia, informational bulletins from the Specialty pharmacy, or manufacturer’s website.
Specialty drugs will be placed in Tier 5-- preferred specialty or Tier 6-- non-preferred specialty.

Tier 5, preferred specialty drugs are usually generic or biosimilar as determined by FDA website.
Tier 6 are the highest cost specialty drugs or specialty drugs which have a generic or biosimilar on the Preferred specialty tier.

</td><td></td></tr>
<tr><td colspan="2">Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to medical or surgical benefits in the benefits classification</td></tr>
<tr><td>Medical/Surgical:

PHARMACY:

Step 4(a) :
New drugs are identified by the weekly Medispan reports
If a new drug which shares a GPI with a current formulary drug is introduced, the PBM has coding to automatically place it into the same tier as the current formulary drug.</td><td>MH/SUD:

PHARMACY:

Step 4(a)
Same

Step 4(b):
Formulary MH/SUD drugs on:</td></tr>
</table>

• The clinical pharmacist makes the rest of the tier placements based on factors and evidence listed in steps 2 and 3. • If a new generic drug becomes available, the corresponding brand drug may be moved to a higher tier with proper notice to members. • Tier placement for all new drugs is reviewed by the Pharmacy & Therapeutics committee • P&T committee votes to approve tier placement and tier changes. ***Step 4(b):*** **Formulary M/S drugs on:** **Tier 1:** 34 = **1.1%** **Tier 2:** 997 = **31.6%** **Tier 3:** 165 = **5.2%** **Tier 4:** 1156 = **36.7%** **Tier 5:** 115 = **3.6%** **Tier 6:** 685 = **21.7%** **Total = 3152 formulary M/S drugs** **(count is of drug names only, strengths and formulations were not included in count)** Tier lowering requests: 30 approvals/43 requests = 70%	**Tier 1:** 12 = **4.3%** **Tier 2:** 143 = **51.8%** **Tier 3:** 9 = **3.2%** **Tier 4:** 94 = **34.4%** **Tier 5:** 9 = **3.2%** **Tier 6**: 8 = **2.9%** **Total = 276 formulary MH/SUD drugs** **(count is of drug names only, strengths and formulations were not included in count)** Tier lowering requests: 4 approvals/6 requests = 67%
Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section	

PHARMACY:

Any parity findings are in favor of MH/SUD benefits. All SUD drugs are required by Illinois law to be in the preferred applicable tier (preferred generic, preferred brand, preferred specialty). The majority of both classifications of drugs fall within the non-preferred generic or non-preferred brand tiers.
The proportion of

Potential process improvement for MH/SUD and M/S:

- Develop written internal policy outlining the process by which drugs are placed on each tier, including cost benchmarks for each tier.

NQTL: Step Therapy

Classification:

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding the NQTL and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Medical/Surgical:	MH/SUD:
PHARMACY: ***Step 1(a) - Define Step Therapy as applied to Prescription Drug benefits*** • Step therapy limitations require a trial with a more cost-effective formulary drug or drugs before the requested drug will be covered. The prerequisite drug will be at least as safe and effective than the requested drug in addition to being less costly. • Some prior auth policies have steps within their requirements. ***Step 1(b) - Identify the drugs or drug classes to which Step Therapy is applied and define the Step Therapy requirements*** Supporting document: *[Document 11. Excel sheet-List of PA_TIER_ST. Blue highlight = MH/SUD]*	**PHARMACY:** ***Step 1(a) - Define Step Therapy as applied to Prescription Drug benefits*** Same ***Step 1(b) - Identify the drugs or drug classes to which Step Therapy is applied and define the Step Therapy requirements*** Same except less stringent for SUD. No step therapy may be applied to drugs for treating SUD.

Step 2 – Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits

Medical/Surgical: **PHARMACY:** • Professional practice association treatment guidelines • Brand and generic alternative availability • Drug cost • Rebating status	MH/SUD: **PHARMACY:** Same except no step therapy on drugs to treat SUD.
Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.	
Medical/Surgical: **PHARMACY:** • Manufacturer's package insert; FDA Website, Medical and drug compendia to assess efficacy and safety • Recommendations of national organizations and professional practice association reports to ensure that step therapy requirements adhere to recognized treatment guidelines. • Head to head trials when available • Internal claims review and cost analysis for comparison to current formulary alternatives • Recommendations from P&T subcommittee specialists and provider partners based on commonly accepted clinical practice • State regulations where necessary (ex. No step therapy for drugs to treat SUD)	MH/SUD: **PHARMACY:** Same
Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, as written and in operation, are	

comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to medical or surgical benefits in the benefits classification	
Medical/Surgical: **PHARMACY:** • Health Alliance formulary and its step therapy requirements meet the standards of a number of commercial and government programs, including the State of Illinois Employees and Federal Employees Health Benefit • Review of feedback from peer-to-peer interviews and internal and external reviewers is used to update step therapy criteria when necessary. M/S drugs subject to Step, percentage of formulary ***(counts steps within a prior authorization policy):*** **1 step:** 116 = **3.7%** **2 steps:** 63 = **2%** **3 steps**: 27 = **0.8%** **4 steps:** 3 = **0.1%** **5 or 6 steps:** 12 = **0.4%** **Total w/step:** 221 = **7%** **(count is of drug names only, strengths and formulations were not included in count)** M/S Step Therapy requests: 1971 approvals/2162 requests= 91% Approval rate 191 denials/ 2162 requests = 9% Denial rate	MH/SUD: **PHARMACY:** Same MH drugs subject to Step, percentage of formulary ***(counts steps within a prior authorization policy):*** **1 step:** 2 = **0.8%** **2 steps:** 10 = **4%** **3 steps**: 5 = **2%** **4 steps:** 2 = **0.8%** **5 or 6 steps:** 0 = **0%** **Total w/steps:** 19 = **6.8%** **(count is of drug names only, strengths and formulations were not included in count)** MH/SUD Step Therapy requests: 2 approvals/2 requests = 100% Approval rate 0 denials/2 requests = 0% Denial rate

M/S Appeals: 0 Appeals for Step Therapy decisions	MH/SUD Appeals: 0 Appeals for Step Therapy decisions

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

PHARMACY:

SUD drugs have no step therapy requirements per Illinois law. The proportion of MH/SUD drugs with step is 7.5% versus 7% for M/S drugs. A number of M/S drugs have 5 or 6 steps, while the most steps MH/SUD drugs is 4 (Spravato).

Possible process improvements for MH/SUD and M/S:

- Develop written policy outlining the process and decision by which step therapy is applied to drugs, similar to the Drug Review and Prior Authorization policies.

- Many drugs have required steps that are listed within a prior authorization policy. For example, brand name antidepressants, anti-psoriatic meds, acne meds will be listed on the formulary as requiring prior authorization, and determinations are classified as PA approvals or PA denials. However, the request may have been denied based on unmet steps within the prior authorization policy. Therefore, the calculated proportion of step therapy approvals/denials only reflects medications where a step therapy is the only criteria needing to be satisfied.

Supporting documents available upon request.
Contact Us (healthalliance.org)