NQTL REPORTING TEMPLATE INSTRUCTION GUIDE

The instructions in this Guide provide companies that offer health plans, insurance policies, and/or Medicaid and CHIP managed care benefits (collectively referred to in this document as "Plans") with an in-depth description of each step that is delineated for each non-quantitative treatment limit (NQTL) analysis for mental health and substance use disorder Parity ("Parity") compliance reports.

The purpose of federal and state Parity laws is to ensure that Plan benefit design and operations offer beneficiary access to mental health and substance use disorder ("MH/SUD") services that is comparable to and no more stringent than beneficiary access to medical/surgical ("M/S") services. Thus the guiding principle for NQTL compliance analyses and documentation should be to demonstrate the effect of the Plan design and operations on beneficiary access to services. In developing NQTL compliance analyses using these templates, Plans should focus on features of Plan design and operations for MH/SUD and M/S that ultimately impact beneficiary access to covered treatments services. Differences between Plan design and operations for MH/SUD and M/S that do not meaningfully impact beneficiary access are not a priority for enforcement and should not be a focus of compliance analyses.

For companies that offer multiple commercial health plans or products in Illinois, it is assumed that most policies and procedures that are relevant to most NQTLs are applied consistently across all of the company's product offerings. Where specific data are required, and/or where significant, substantive variations exist among the policies and procedures that are applied for an NQTL across different products, the company may limit its reporting to the required information for the top three largest plans by enrollment.

General Instructions

(a) Plans should develop a separate response for each step of each analysis that answers the specific instructions of the prompt for that step, as further explained in this guide. Prompts for each step are designed to be distinct and non-overlapping, and responses should generally avoid repeating information that was provided in a previous step.

(b) Information regarding plan design and operations analyzed in this report should be current, not retrospective. In other words, the Plan's analyses should reflect the Plan's current benefits, policies and procedures, operations, data, and related information as of the reporting date. Although operations measure data are by necessity retrospective, the interpretation of these data for the purposes of the compliance analysis should focus on the extent to which these data reflect the current plan design and operations. If changes to the plan design or operations mean that the operations measure data do not reflect the current plan design, this should be noted. Analyses should be maintained internally and updated on a periodic basis, such as annually.

(c) Responses may be supplemented by attachments as necessary. For example, Plans may attach lists of benefits subject to a given NQTL, policies and procedures containing full

details regarding the response to a given prompt, supporting evidence or operations data for a response, and/or other related information that may be useful for reference. However, a brief summary of the key information contained in the attachment should be provided within the relevant step response. All analyses should be wholly provided within the compliance report itself.

(d) Supporting documentation is generally not required to be attached or included in Parity compliance reports. Examples of supporting documentation include relevant policies and procedures, details about how policies and procedures were designed or applied, data used to apply factors/processes in the implementation of NQTLs, operations measure data, and/or any other analysis or documentation used by the Plan to sustain its basis for compliance with a given NQTL. However, Plans should be prepared to provide copies of all internal or public documentation of the factors, processes, evidentiary standards, or other information that is relied upon to implement, analyze, and demonstrate compliance with an NQTL upon request or in the event of a market conduct exam or other enforcement action. (As a best practice for compliance, Plans may find it useful to maintain internal crosswalks or indices of the specific Plan documents that are relevant for each analysis. This practice will create efficiency in keeping the analysis up to date and in responding to any need to provide such supporting documentation.)

(e) The term "benefits" is not defined in federal or state statute or regulation, and Plans have flexibility to determine the specificity with which to define benefits for their own coverage and operations. In general, Plans should align their use of the term "benefits" in their Parity analyses with the way this term is defined and applied in other Plan documents. An individual benefit may include a wide range of service codes, or it may be as narrow as a single service code. The analyses in this report do not require you to identify the logic used to define benefits, or to provide specific definitions for specific benefits. However, the logic for defining benefits should be consistent between MH/SUD and M/S coverage, and benefit definitions should be consistent across all Parity analyses.

(f) In any Step where the reporting template stipulates that it provides examples of factors, processes, or evidentiary standards, the provided examples are purely illustrative. For these Steps, the Plan is not required to respond or provide information with regard to any of the example factors, processes, or evidentiary standards that are listed, and may instead report on its own factors, processes, or evidentiary standards.

(g) Where specific operations measures are required, the plan may apply any technical specifications and/or data definitions that are reasonable and necessary to define and report on the identified measure. The technical specifications and data definitions must not conflict with the instructions in this Guide, but otherwise should be designed to align as well as possible with the Plan's coverage design and operations, including existing data collections. Plans may also choose to supplement these required operations measures with additional oversight factors, processes, and/or operations measures that provide further context and support for the Plan's determination of compliance for the NQTL.

(h) A brief comparability and stringency analysis should be provided for each data point, factor, or process that is reported in the "in operation" analyses in Step 6 of each analysis. If the data provided for a given measure appear to indicate a more stringent design or application of the NQTL to MH/SUD benefits relative to M/S benefits, the Plan should provide an explanation for the disparity in the data or justification for the difference in approach, including the reasons for which it determined that the underlying factors, processes, and evidentiary standards were in fact comparable and no more stringent. For example, a very small denominator or sample size for a given metric may lead to results that are heavily skewed by a small number of idiosyncratic instances or circumstances.

(i) A Plan may wish to include, but is not required to provide, a discussion of actions that it is taking to amend processes or outcomes for MH/SUD benefits and services, especially in Step 6 of any given analysis. Such disclosures or actions may not be interpreted to indicate or imply non-compliance with Parity. However, should the State make a determination of non-compliance based on other information provided in a given analysis, the State may decide to consider the Plan's existing improvement actions as a mitigating factor for any resulting non-compliance penalty, requirement for corrective action, or other enforcement action.

(j) Although these templates do not require Plans to submit definitions for MH, SUD, and M/S conditions, definitions for benefit classifications, or lists of MH/SUD and M/S benefits by classification, Plans should be prepared to submit such documentation to regulators in instances where such documentation may be necessary to determine compliance.

(k) For all analyses of the prescription drugs classification, Plans should identify the evidentiary standard used to classify drugs as M/S drugs or MH/SUD drugs for the purpose of this analysis.

Filling out the Template

(l) For each step, the instructions below should be applied separately to the response for M/S benefits and the response for MH/SUD benefits.

- If the information for MH/SUD benefits is substantively identical to the response that is provided for M/S benefits within a given step, write "same" in the MH/SUD box and "N/A" in the comparability and stringency analysis box for that step.

- If there are any differences between the information for MH/SUD benefits and the information for M/S benefits for a given step, provide an analysis of the comparability and stringency of the responses for that step.

- The comparability and stringency analysis and conclusion provided in step 6 may include a discussion of the weight or probative value that should be given to

individual factors, processes, or operations measures that are used to monitor and evaluate compliance. For NQTLs for which certain specific operations measures are required, the Plan's comparability and stringency analysis in step 6 may include a discussion of the reasons why a Plan has determined that any additional factors, processes, or operations measures that it applies should be given more weight or probative value than the operations measures that are required.

- Discussion should be provided to explain why any apparent disparity in operations measure data or other oversight factor or process is misleading or not truly indicative of noncompliance. This discussion should conclusively explain the Plan's rationale and substantive basis for determining that compliance has been achieved.

(m) Although the instructions below are not duplicated for each classification, separate reporting must be provided for each classification as set forth in the reporting templates.

- If the NQTL is not applied to any MH/SUD benefits within a classification, stop and do not complete the analysis for that benefit classification. (However, Plans may find it useful to complete and maintain an NQTL analysis for internal purposes as a best practice for compliance.)

- If the NQTL is applied to one or more MH/SUD benefit(s) within a classification but does not apply to any medical/surgical benefits within that classification, the NQTL does not comply with MHPAEA.[1]

- If the NQTL is applied to all MH/SUD benefits within a classification but does not apply to all medical/surgical benefits within that classification, the NQTL is unlikely to comply with MHPAEA.[2]

- Plans that sub-classify Outpatient benefits into Outpatient-Office Visit and Outpatient-All Other may create additional templates as needed to reflect these subclassifications.

- Plans that provide benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of all other participating providers) may create additional templates as needed to reflect these provider network tiers.

- Medicaid and CHIP managed care organizations (MCOs) and health plans that do not offer out-of-network benefits (e.g. an Exclusive Provider Organization) can omit all out-of-network classification templates, since the Parity rules for

[1] *See* 78 FR 68240, 68245 (Nov. 13, 2013). *See also* FAQs About Affordable Care Act Implementation (Part VII) and Mental Health Parity Implementation (November 17, 2011) at Q&A-2.
[2] *See* 78 FR 68240, 68245 (Nov. 13, 2013). *See also* FAQs About Affordable Care Act Implementation (Part VII) and Mental Health Parity Implementation (November 17, 2011) at Q&A-5.

Medicaid and CHIP do not distinguish between in-network and out-of-network classifications.

(n) Within each step, please present paragraphs on the same topic for MH/SUD and M/S starting on the same line or row of the page.

- As a general rule, short paragraphs with narrowly-defined topics are preferred, as long narrative paragraphs often sacrifice clarity of thought or ease of analysis. However, the response must sufficiently respond to the step's prompt.

NQTL: Medical Necessity

Classification(s): if the same responses are applicable for all benefit classifications, then a single analysis may be submitted

Step 1 - In Writing: Define Medical Necessity

Define "Medical Necessity" (or "medically necessary" or other such related term that may be used by the Plan) *as applied to medical or coverage policies, benefit authorizations, or payment determinations* for benefits delivered under the Plan.

This is generally a single, basic definition of "Medical Necessity" that is applied to all benefits and services.

Note that this step does NOT ask you to provide a list of all medical, coverage, or payment policies that may be applied to specific benefits or services.

Step 2 - In Writing: Identify all sources of the standards, criteria, or guidelines that are used to determine Medical Necessity for specific benefits and services in this classification

Examples of the types of sources for such tools include:

- *Plan-created standards, definitions, or guidelines*
- *Third-party vendor algorithms or guidelines*
- *Level of care or service intensity criteria and instruments*
- *National provider practice association position statements or guidelines*
- *Medicare National and Local Coverage Determinations*
- *State regulations or sub-regulatory guidance*

The focus of this step is on the types of sources; it is not necessary to provide a comprehensive list of the specific sources for Medical Necessity standards. For example, it is sufficient to state that national provider practice association position statements or guidelines are a type of source that is used for the for medical or coverage policies that are used to determine the Medical Necessity of a service. It is not necessary to name each and every such position statement or guideline that is cited in any medical or coverage policy, nor is it necessary to provide the medical or coverage policies themselves.

Step 3 - In Writing: Identify and define the processes and strategies used to select Medical Necessity standards, definitions, or guidelines

These strategies and processes should include, but are not limited to:

Commented [A1]: Comment to the Illinois Workgroup: Throughout the document, instructions in italics are the language that has already been approved by the state workgroup members. Non-italicized language in this document provides further explanation and discussion of the intended instructions.

- *The hierarchy of the sources cited in Step 2 that are used to define Medical Necessity for a given service*
- *The factors applied to select the primary source for guidelines (e.g. third-party vendor)*
- *The factors applied to determine when to select from a secondary (or tertiary, quaternary, etc.) source or develop internally*

This response should describe the step-by-step decision-making process that leads to the selection or creation of any Medical Necessity standard or clinical coverage guideline. For example, a Plan's primary source for guidelines might be a set of third-party vendor's clinical criteria or guidelines. The Plan should briefly discuss the factors used to select that source to be the primary source. If some of the vendor's guidelines are not adopted, the Plan should identify the factors used to determine which vendor guidelines (if any) to exclude. The Plan's secondary source (to supplement or fill gaps left by the primary source) might be Medicare National and Local Coverage Determinations. The Plan should then briefly discuss the factors used to identify this as the secondary source, and the factors used to determine which of these guidelines (if any) to exclude. Similar discussion should be provided to explain when and how each source of guidelines is selected and used, including the factors used to determine when to develop internal criteria or guidelines for determinations of Medical Necessity.

If the hierarchy of sources varies based on context (e.g. if certain steps in the decision-making process differ by treatment setting or specialty), these differences should be identified and the rationale for these differences should be explained. If any exceptions exist to the general rules described then those exceptions should be identified and explained.

Step 4 - In Writing: Identify and define the processes and strategies used to develop internal Medical Necessity guidelines or modifications to external guidelines that are created by the Plan

This Step applies to Medical Necessity guidelines that are developed by the Plan. It is not necessary to discuss the processes and strategies used by any external sources of guidelines.

The discussion of Plan strategies and processes to develop Medical Necessity guidelines ~~should~~ may include, but is not limited to, brief discussions of:

- *The composition of the committee used to develop the internal standards*
- *The selection and use of external or independent experts*
- *Key steps in the process for developing the standards*

If the Plan uses its own clinical criteria, guidelines, or related standards to determine the Medical Necessity of certain treatments or services, the Plan must identify and define the processes and strategies that are used to develop these guidelines. This includes guidelines that are wholly created by the Plan as well as deviations from or modifications to any external guidelines that are used.

Commented [A2]: Comment to the Illinois Workgroup: The word "should" is ambiguous as guidance. IAMHP and ILHIC recommend this be changed to "may".

Step 5 - In Writing: Identify and describe the evidentiary standards relied upon for Medical Necessity guidelines, or modifications to external guidelines that are created by the Plan

Evidentiary standards are used to define the level and types of evidence the Plan considers in designing ~~and applying~~ its Medical Necessity criteria. Specific types of evidentiary standards that a Plan may consider include recognized medical literature, professional standards and protocols (including comparative effectiveness studies and clinical trials), published research studies, treatment guidelines created by professional guild associations or other third-party entities, publicly available or proprietary clinical definitions, and outcome metrics from consulting or other organizations.

In this step, the Plan should identify and describe the types of evidentiary standards that relevant committees use to develop the Plan's own Medical Necessity guidelines. It may include criteria or factors used to determine whether to consider and/or how much weight to assign to a given research study or publication. It is NOT necessary to list the actual evidence consulted for specific Medical Necessity guidelines.

Step 6 - In Operation: Identify and define the factors and processes that are used to monitor and evaluate the efficacy and validity of Medical Necessity guidelines

This analysis should include a discussion of the quality assurance and oversight processes and metrics that the plan applies to the adoption and development of its Medical Necessity guidelines.

As with steps 1-5, this discussion should focus primarily on the adoption and development of the Plan's Medical Necessity guidelines. For this step, how does the Plan know that it has adopted or developed the right guidelines? (The implementation of these guidelines through various utilization management processes, such as prior authorization and retrospective review, will be analyzed separately.)

Plans have full discretion to select factors and processes for oversight that are efficient and effective to monitor the adoption and development of Medical Necessity definitions within their own operations. Quantitative measures should be listed to the extent that they are used, and specific data should be provided for such measures. However, quantitative measures are not required, and qualitative factors and processes may be used as well. A brief analysis of the relevance of each data point, factor, or process to the Plan's overall determination of Parity compliance should be provided.

Factors, processes, and operations measures that may be considered include:

- *Process for oversight of third-party guideline vendors*
    - This could include a brief narrative discussion of the process that the Plan uses to monitor a specific vendor's strategy and processes for Parity compliance.

Commented [A3]: Comment to the Illinois Workgroup: The reference to "applying" medical necessity standards may cause confusion about overlap with NQTL analyses for prior authorization, concurrent review, retrospective review, or other utilization management processes. This analysis should focus on the design or creation of the medical necessity standards.

    - This could also include a brief narrative description of the process to re-evaluate the quality, utility, suitability, and/or hierarchy of use of third-party sources of Medical Necessity guidelines.
- *Annual policy reviews or Parity compliance audits by relevant staff or committees*
    - This could include a brief narrative discussion of the process to select and review specific Medical Necessity guidelines for Parity or other quality control purposes.
- *Consumer and provider complaints or appeals with regard to the content or substance of Medical Necessity guidelines*
    - This could include a quantification and analysis of any consumer or provider complaints about Medical Necessity guidelines, and/or a narrative discussion of the process used to monitor, consider, and respond to any such complaints.
- *Analyses of inter-rater reliability*
    - This could include inter-rater reliability and/or other operations measures data used to ensure that specific utilization management processes (such as prior authorizations or retrospective review) are compliant with Parity.
    - Interpretation of such data should focus on their relevance to the validity, utility, or quality of the underlying guidelines themselves.
    - Note that these measures may duplicate or overlap with measures used for other NQTLs. This is permissible but is not required.

A brief comparability and stringency analysis should be provided for each factor, process, and/or operations measure.

NQTL: Prior Authorization

Classification(s): separate analyses should be submitted for each classification of benefits for which Prior Authorization is applied

Step 1 - In Writing: Define Prior Authorization

Define "Prior Authorization" as applied by the Plan to benefits in this classification. The Plan's definition should focus on strategies that impact claims adjudication and payment or may otherwise serve to limit access and utilization.

The Plan's definition of prior authorization may implicitly or explicitly distinguish among several related concepts or functions that may be required prior to the delivery of the services, including a determination or certification of Medical Necessity by the Plan, notification to the Plan that the service or admission has been scheduled or ordered, and/or other related policies and processes. For example, if a Plan requires prior notification of inpatient admissions but does not require a determination of Medical Necessity prior to admission, then the Plan could determine that this prior notification requirement is a separate NQTL and exclude it from the definition and analysis of prior authorization. The present analysis should focus specifically on Prior Authorization, as defined by the Plan in this Step, and does not require analyses of other related concepts that do not meet the Plan's definition.

Note that this step does NOT ask you to define "Medical Necessity," which is analyzed as a separate NQTL.

Step 2 - In Writing: Identify the benefits/services for which Prior Authorization is required

List all benefits in this classification that are subject to Prior Authorization.

This list may be provided as a link or attachment if desired. For prescription drug benefits, a copy of the Plan's formulary that indicates which covered drugs are subject to PA may be provided as a link or attachment.

In general, no analysis of comparability and stringency is required for this Step. However:

- If the Plan applies Prior Authorization to <u>all</u> MH/SUD benefits but <u>not all</u> M/S benefits in the classification, then discussion should be provided about how the Plan has determined that this benefit structure complies with Parity.
- If the Plan applies Prior Authorization to <u>some</u> MH/SUD benefits but <u>not to any</u> M/S benefits in the classification, then federal guidance indicates that this benefit structure does not comply with Parity.

Step 3 - In Writing: Identify and define the factors used to determine which benefits are subject to Prior Authorization

Each factor must be defined with sufficient precision to determine whether a given benefit does or does not meet the definition.

Plans have broad discretion to select and define factors for determining whether to apply Prior Authorization to a given benefit. *Examples of selection factors and definitions include:*

- *Excessive utilization*
- *Recent medical cost escalation*
- *Lack of adherence to quality standards*
- *High levels of variation in length of stay*
- *High variability in cost per episode of care*
- *Clinical efficacy of the proposed treatment or service*
- *Provider discretion in determining diagnoses*
- *Claims associated with a high percentage of fraud*
- *Severity or chronicity of the MH/SUD condition*

Definitions may or may not include a quantitative threshold, but each definition should include a clearly-identified evidentiary standard and/or data source that is used to evaluate or measure the factor and determine whether or not the factor is met. Plans have broad discretion to select these data sources and evidentiary standards. *Examples of data sources include:*

- *Internal claims or data analyses*
- *Internal quality standard studies*
- *Preponderance of the medical literature*
- *Adherence to identified national standards*

For example, a Plan could decide to apply Prior Authorization to all benefits for which there is "excessive utilization." The Plan could define "excessive utilization" to mean benefits for which utilization exceeds some pre-defined benchmark, and then identify this benchmark as the data source for that factor.

If "clinical efficacy of the proposed treatment or service" is used as a factor, then the evidentiary standard could be a "preponderance of the medical literature." In this case, the Plan should provide the definition of "clinical efficacy" that is used and identify the committee that determines whether a preponderance of the literature meets this definition.

Note that this step does NOT require Plans to analyze the development process or evidence base for the Medical Necessity guidelines for the Prior Authorized services. Instead, this step focuses on the factors, data sources, and evidentiary standards that were used to decide to require Prior Authorization for the service.

Step 4 - In Writing: For each benefit subject to Prior Authorization, identify which of the factor(s) in Step 3 were met

Include a brief summary description of the data or evidence relied upon to determine that the benefit met each factor that it was determined to meet, in addition to a breakdown of which factors apply to each benefit that is subject to Prior Authorization on a benefit-by-benefit basis. A sample grid is provided below, but any format can be used. This grid or list may be provided as an attachment if necessary. One or more factors may be indicated for a given benefit. No factors should be applied that are only met by MH/SUD benefits. For the prescription drugs classification, the Plan may indicate that this factor-level analysis for a given MH/SUD drug, formulation, or dosage level is available to regulators upon request in the event of a complaint or suspicion of noncompliance, including a non-comprehensive set of examples of M/S drugs or drug classes that meet the identified factors.

The grid must include all benefits subject to prior authorization. *It is not necessary to provide the actual data or evidence relied upon to determine that the benefit met the indicated factors*. It is sufficient to provide a brief summary of the data types and/or sources of evidence that are used to apply or implement the factors listed in Step 3. *The underlying data or evidence should be collected and documented internally and may be required by the state, including in the case of an audit or investigation.*

	Excessive utilization	Recent medical cost escalation	Lack of adherence to quality standards	High variability in length of stay/treatment	High variability in cost per episode
MH/SUD benefits					
Electroconvulsive therapy					X
Transcranial magnetic stimulation	X			X	
Psych testing	X		X		X
Intensive outpatient		X	X		
Etc.					
M/S benefits					
~~Home health~~Cardiac rehab	X		X	X	
~~Pain mgt~~X-ray		X	X	X	
Genetic testing	X	X			
Non-emerg CT scan					X
Etc.					

Step 5 - In Operation: Briefly describe the processes by which prior authorization is applied.

Provide a brief description of each step of the processes by which the prior authorization request is submitted, Medical Necessity and any other factors for authorization are evaluated, and authorizations are approved or denied. The analysis should focus on processes that lead to the approval or denial of the authorization. This should include descriptions and *analyses of any documented policies and procedures for the processes used to make a determination* ("as written"), as well as any additional details, including common exceptions or deviations from the documented policies and procedures, regarding *the processes that are used in practice to make a determination ("in operation")*. As noted in the general instructions, the underlying policies and procedures and related Plan documents should be identified but do not have to be attached to this report. Instead, key details from these documents should be summarized and analyzed here.

Clearly identify and provide comparative analyses of relevant:

- *Timelines and deadlines*
- *Forms and/or other information required to be submitted by the provider*
- *Utilization management manuals and any other documentation of UM processes that are relied upon to make a determination*
- ~~*In-operation processes in place to make a determination such as distinctions between first and second-level reviews or between administrative and clinical reviews, peer-to-peer reviews, and the use of medical discretion or administrative protocol applied in comparison to, lieu of or in the absence of written criteria and guidelines*~~
- *Review processes, such as administrative reviews, clinical reviews, peer-to-peer reviews, and second-level reviews or sign-offs*
- *Processes applied in the absence of medical or coverage policies or guidelines*
- *Reviewer's discretion in departing from written policies and procedures, including medical and coverage policies or guidelines*
- ~~*Minimum qualifications for reviewers*~~
- *Minimum standards to issue a denial (e.g. sign-off from a physician with relevant board certification)*

Information provided for these items should be ordered and formatted to facilitate direct comparisons between M/S and MH/SUD benefits. Discussion of these items should be brief, not comprehensive, but sufficient to enable a high-level comparison between key aspects of PA processes for MH/SUD relative to M/S benefits.

Note that this step focuses on the process by which Medical Necessity and/or other factors are evaluated and treatment is authorized. The design and adoption of the Medical Necessity guidelines themselves is analyzed as a separate NQTL.

Step 6 - In Operation: Identify and define the factors and processes that are used to monitor and evaluate the application of Prior Authorization

This analysis should include a discussion of the quality assurance and oversight processes and metrics that the plan applies to its Prior Authorization program.

The analysis must include, at minimum, data for the following operations measures:

- *Pre- and/or post-service denial rates*
- *Internal and/or external appeal rates*
- *Appeal overturn rates*
- *Inter-rater reliability scores*
- *Pass/fail results of an internal audit of the adherence of peer-to-peer reviews to the plan's inpatient admissions policies and Medical Necessity criteria, and key steps of any internal corrective action plan.*

The analysis may also include information on other quality assurance or oversight processes and metrics, such as:

- The rough percentages or proportions of covered MH/SUD and M/S benefits and/or claims that are subject to Prior Authorization
- Comparisons to government programs or other publicly-available formularies
- Quantitative data or narrative descriptions of random audit processes for decisions to apply Prior Authorization to a given benefit ("in writing")
- Quantitative data or narrative descriptions of random audit processes for Prior Authorization denials and/or appeals ("in operation")

A brief comparability and stringency analysis should be provided for each factor, process, and/or operations measure that is identified.

NQTL: Experimental and Investigative Treatments

Classification(s): if the same responses are applicable for all relevant benefit classifications, then a single analysis may be submitted. If the Plan's coverage for Experimental or Investigational drugs is based solely on FDA approval, it may indicate "N/A" for this NQTL for the prescription drug classification.

Step 1 - In Writing: Define "Experimental or Investigational" (E/I) Treatments

Define "Experimental or Investigational" (or other such related term that may be used by the Plan) *as applied to* medical or *coverage* policies, benefit authorizations, or payment *determinations for benefits* delivered under the *Plan*.

This is generally a single, basic definition of "Experimental or Investigational" that is applied to all benefits and services.

Step 2 - In Writing: Identify the evidentiary standards for determining that a treatment or service meets the definition for E/I Treatments

Evidentiary standards are used to define the level and types of evidence the Plan considers in designing ~~and applying~~ its E/I criteria. Specific types of evidentiary standards that a Plan may consider include completion of a Phase III trial, approval by the FDA or other relevant regulatory agency, *recognized medical literature, recognition by a professional guild association as the accepted standard treatment, professional standards and protocols (including comparative effectiveness studies and clinical trials), published research studies, treatment guidelines created by professional guild associations or other third-party entities, publicly available or proprietary clinical definitions, and outcome metrics from consulting or other organizations.*

In this step, the Plan should identify and describe the types of evidentiary standards that relevant committees use to develop the Plan's E/I criteria. It may include criteria or factors used to determine whether to consider and/or how much weight to assign to a given research study or publication. It is NOT necessary to list the actual evidence consulted for specific E/I determinations.

Step 3 - In Writing: Identify the conditions or factors, if any, under which E/I treatments or services are covered

Each factor must be defined with sufficient precision to permit an objective determination of whether a given treatment or benefit does or does not meet the factor, including identification of the relevant measure or evidentiary standard for the criterion.

If there are no exceptions to the E/I exclusion, write N/A.

Commented [A4]: Comment to Illinois working group: The phrasing of this instruction has been revised to align with Step 1 of the Medical Necessity NQTL analysis

Step 4 - In Writing: Briefly describe the processes by which Treatments are determined to be E/I

Provide a brief description of each step of the processes by which a Treatment is determined to be E/I. The discussion of *relevant Plan processes may include, but is not limited to,* brief discussions of:

- The establishment of a Plan committee to make E/I determinations
- Consultation with expert reviewers
- The identification and scheduling of treatments or services for evaluation (e.g. for new technologies, or upon request by a beneficiary)
- The selection of information deemed reasonably necessary to make an E/I determination

Step 5 - In Operation: Briefly describe the processes by which coverage determinations or exceptions are made for E/I Treatments

If coverage is provided for E/I Treatments under certain conditions or criteria, provide a brief description of each step of the processes by which a coverage determination or exception is made for E/I Treatments.

The discussion of Plan strategies and processes to make coverage determinations or exceptions for E/I Treatments may, but are not required to, include, for example, brief discussions of:

- Timelines and deadlines
- Review committees, including roles and minimum qualifications for members
- Policies and procedures and/or manuals relied upon
- Next steps if coverage for the E/I Treatment is denied

If there are no exceptions to the E/I exclusion, write N/A.

Step 6 - In Operation: Identify and define the factors and processes that are used to monitor and evaluate the application of E/I Treatment policies

This analysis should include a discussion of the quality assurance and oversight processes that the plan applies to its E/I Treatment policies. The analysis should address the monitoring and evaluation of determinations of whether a treatment or service meets the E/I Treatment criteria as well as the monitoring and evaluation of any exceptions process.

Examples of relevant factors, processes, and operations measures may include:

- The number and outcomes of E/I determinations within a defined period
- The number and outcomes of E/I exceptions within a defined period
- Timelines and processes for re-evaluating the E/I Treatment policy

- Quantitative data or narrative descriptions of random audit processes for E/I determinations

A brief comparability and stringency analysis should be provided for each factor, process, and/or operations measure that is identified.

NQTL: Prescription Drug Formulary Tiering

If Formulary Tiers are not used, or if the formulary is determined by a State agency, then this NQTL analysis may be marked N/A.

Classification(s): this analysis is only completed for the Prescription Drug benefits classification

Step 1 - In Writing: Define Formulary Tiers

Identify and define each separate Formulary Tier applied by the plan to Prescription Drug benefits. For each tier, define all relevant coverage policies and limits that are applied to drugs in that tier, including, ~~at minimum,~~ any financial requirements and/or any utilization management requirements or other coverage limits.

Commented [A5]: Comment to Illinois working group: "At minimum" is confusing if a plan does not apply all of the listed limit types to all drugs within the formulary tier

If the specific levels of financial requirements vary across products or benefit packages offered by a Plan, it is not necessary to identify all specific levels of the financial requirement that may be applied within a given tier. Instead, it may simply be indicated whether the financial requirement type (co-pay and/or coinsurance) is applied to all drugs within the tier, whether the same level of the financial requirement type is applied to all drugs within the tier, and whether the level applied for a given product or benefit package is the same or higher than the preceding tier.

If Formulary Tiers are not used, or if the formulary is determined by a State agency, then all other rows may be marked N/A.

Step 2 - In Writing: Identify all drugs covered in each Formulary Tier

This information may be provided in a separate attachment.

Step 3 - In Writing: Identify and define the factors used to assign drugs to a Formulary Tier

Each factor must be defined with sufficient precision to determine whether a given drug does or does not meet the definition, including identification of the relevant measure or evidentiary standard for the factor. The response should indicate the general hierarchy or sequence in which these factors and evidentiary standards are applied in assigning a drug to a formulary tier, along with any criteria for determining whether/when to deviate from the general hierarchy or sequence. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

Step 4 - In Writing: N/A

N/A

Step 5 - In Operation: Briefly describe the processes by which drugs are assigned to a Formulary Tier.

Provide a brief description of each step of the processes by which drugs are assigned to Formulary Tiers.

~~*Relevant processes may include, but are not limited to, peer clinical review, consultations with expert reviewers, the availability and exercise of reviewer discretion, adherence to criteria hierarchy, and the selection of information deemed reasonably necessary to make a Formulary Tier determination.*~~

The discussion of Plan strategies and processes to assign drugs to Formulary Tiers may, but are not required to, include brief discussions of:

- The composition of and member qualifications for the Pharmacy and Therapeutics and/or other relevant committees
- The selection and use of external or independent experts
- The identification and scheduling of drugs for tiering (e.g. for new drugs, or upon request by a beneficiary)
- Key steps in each relevant committee process

Commented [A6]: Comment to Illinois working group: Revised to better reflect the specific processes relevant to formulary tiering. Further edits are welcomed.

Step 6 - In Operation: Identify and define the factors and processes that are used to monitor and evaluate the Formulary Tiering program

This analysis should include a discussion of the quality assurance and oversight processes and metrics that the plan applies to its Formulary Tiering program.

Examples of relevant information may include:

- The percentages of covered MH/SUD and M/S drugs that are assigned to each tier
- Comparisons to government programs or other publicly-available formularies
- Quantitative data or narrative descriptions of random audit processes for tier assignments

A brief comparability and stringency analysis should be provided for each factor, process, and/or operations measure that is identified.

NQTL: Step Therapy

Classification(s): this analysis may only need to be completed for the Prescription Drug benefits classification. However, if Step Therapy policies are applied to MH/SUD benefits in any other benefit classifications, such as physician-administered MH/SUD drugs that are classified as inpatient or outpatient benefits, then Parity compliance analyses should be provided for all such classifications.

Step 1 - In Writing: Define Step Therapy as applied to Prescription Drug benefits

Define "Step Therapy" or fail first policies as applied to Prescription Drug benefits. This definition may implicitly or explicitly distinguish and exclude certain related concepts such as Prior Authorization (which should be analyzed and reported separately), Medical Necessity, exclusions for failure to complete a course of treatment, and other related policies and processes. If the Plan determines that all aspects of its Step Therapy, fail first, and/or related requirements are designed and implemented through its Prior Authorization program (and/or other related NQTLs), then the Step Therapy analysis may be marked N/A.

Step 2 - In Writing: Identify the drugs or drug classes to which Step Therapy is applied and define the Step Therapy requirements

List all drugs or drug classes to which Step Therapy is or may be applied and define the Step Therapy requirements that are applied to each drug or drug class. If multiple "steps" are required to be fulfilled before gaining access to a given drug or drug class, each step should be separately defined.

An attachment may be used if necessary.

Step 3 - In Writing: Identify and define the factors used to determine which drugs or drug classes are subject to Step Therapy

Each factor must be defined with sufficient precision to determine whether a given drug does or does not meet the definition. Each definition should include a clearly-identified evidentiary standard and/or data source that is used to evaluate or measure the factor and determine whether or not the factor is met.

Also identify the factors used to determine the number of "steps" that are required for each drug or drug class. Plans have broad discretion to define and select these factors, data sources, and evidentiary standards.

Note that this step does NOT require you to submit the evidence base for specific determinations of whether to apply Step Therapy to a given drug.

Commented [A7]: Comment to Illinois working group: some drugs are subject to ST only under certain conditions. (In this case, the conditions are identified and defined in Step 3.)

Step 4 - In Writing: N/A

N/A

Step 5 - In Operation: N/A

N/A

Step 6 - In Operation: Identify and define the factors and processes that are used to monitor and evaluate the application of Step Therapy

This analysis should include a discussion of the quality assurance and oversight processes and metrics that the plan applies to its Prior Authorization program.

The analysis must include, at minimum, data for the following factors:

- *Denial rates for failure to complete the required steps*
- *Internal and/or external appeal rates*
- *Appeal overturn rates*

The analysis may also include information on other quality assurance or oversight processes and metrics, such as:

- The percentages of covered MH/SUD and M/S drugs that are subject to Step Therapy
- The numbers or percentages of covered MH/SUD and M/S drugs that are subject to multiple "steps" of Step Therapy
- Comparisons to government programs or other publicly-available formularies
- Quantitative data or narrative descriptions of random audit processes for Step Therapy assignments

A brief comparability and stringency analysis should be provided for each factor, process, and/or operations measure that is identified.