Instructions for Prior Authorization (PA)

~~**General guidance applicable to all NQTL analyses:** Every comparative analysis for each classification of benefits should be self-contained. In other words, it should not be necessary for the regulator to read through attachments or other separate policy documents to determine if the comparative analysis is sufficient. For any relevant document such as utilization management manuals, clinical policy bulletins, guidelines, criteria, etc., it is the responsibility of the plan/issuer to examine those documents and determine if there is comparability and no more stringent application between MH/SUD and medical/surgical. The is the fundamental expectation of comparative analysis: the plan/issuer examines all relevant materials and data, compares, contrasts, probes, and analyzes them and then explains what was revealed and how or why everything examined did or did not reveal compliance. Attachments and other documents may be submitted so that the regulator can corroborate the plan/issuer's findings and conclusions, but the plan/issuer should avoid responding to any step with "see attachments X, Y, and Z for proof of compliance". There will be select instances when the instructions for a particular step allow for the submission of attachments in lieu of analysis text.~~

Step 1: Identify ~~T~~the specific plan or coverage terms or other relevant terms regarding the NQTL and a description of all mental health or substance use disorder (MH/SUD) and medical or surgical benefits to which each such term applies in ~~each respective~~the benefits classification. 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.

Guidance: This Step requires that the plan/issuer provide the specific coverage terms and policies and procedures regarding the PA NQTL and a definitive identification of all MH/SUD and medical/surgical benefits to which each such term applies in each of the respective benefit classifications or subclassifications. PA includes review of clinical information on a case-by-case basis to ~~determine if coverage will be provided for~~ authorize the delivery of requested services prior to service delivery ~~of requested services~~based on a determination of medical necessity.

~~It is possible that the plan/issuer utilizes various forms of and/or processes for PA, which include, but may not be limited to, the following:~~

- ~~coverage approval that requires only provider notification and clinical review is not performed for coverage approval;~~
- ~~a request for coverage is reviewed and approved by nonclinical personnel according to predetermined criteria (or not approved and referred on to clinical personnel for a coverage determination); and/or~~
- ~~a "fast certification" process.~~

The plan/issuer should clearly define PA ~~provide precise definitions for the terms for all of the forms of PA~~ that it and/or its delegates utilize in Step 1, ~~along with documenting any applicable plan/policy language, and ensure these different forms of PA are accounted for throughout the subsequent steps of the analysis~~. ~~This process includes explaining any differences in design and application and demonstrating comparability in each classification/subclassification between MH/SUD and medical/surgical benefits. The plan/issuer must explain, for example, why some benefits are subject to only notification, why some benefits require clinical review, and why some benefits are eligible for review by nonclinical personnel.~~

The plan/issuer should provide a list for the services in each classification as follows:

- ~~Services that require PA, including a description of the service.~~

- ~~Services that require notification of admission or the service.~~
- ~~Services that may be eligible for coverage approval by nonclinical personnel.~~
- Services that are provided in connection with both MH/SUD and M/S conditions (e.g., physical therapy, speech therapy, and occupational therapy) that may be subject to any PA requirements.

~~The plan/issuer should also describe and explain any case or care management processes that are utilized in connection with the PA and coverage approval process. If these are utilized, provide details regarding whether this is required or optional for the enrollee and if there are different reimbursement or patient cost sharing outcomes if refused or not elected by the enrollee.~~

The plan/issuer should indicate and identify any delegate/vendor involvement with MH/SUD benefits. This includes if there are separate operating departments or divisions in the plan/issuer responsible for the management of covered MH/SUD benefits and any contractual arrangements with external entities. The issuer should specifically provide the PA requirements that are specific to the delegate or vendor and reference their policies and procedures.

Step 2: Identify ~~T~~the factors used to determine that the NQTL will apply to MH/SUD benefits and medical or surgical benefits.

Guidance: The plan/issuer should provide an all-inclusive list of the factors it utilizes to decide that the ~~notification or~~ PA requirement will apply to medical/surgical and MH/SUD services. The plan/issuer should avoid using phrases such as "factors include…" or "factors may include…". The standard for this step is reporting the factors used to determine that the NQTL **will** apply. Phrasing that uses "include" or "may include" introduces uncertainty as to whether the listed factors actually were used or that there may be unlisted factors used to determine the NQTL will apply. It is recommended, but not required, that the plan/issuer have a grid or chart indicating which factor or factors led to the imposition of PA for each benefit.

If all benefits in a classification are subject to PA, it is not necessary to list any factors. Simply state that all benefits are subject to PA and that no additional factors were relied upon.

As it is understood that all services must be medically necessary, medical necessity or clinical appropriateness does not need to be noted as a factor. Medical Necessity is a separate and distinct NQTL.

Step 3: Identify ~~T~~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 MH/SUD benefits and medical or surgical benefits.

Guidance: The plan/issuer must define each factor set forth in Step 2 and identify the applicable evidentiary standard and source(s) for each factor. For example, if the plan/issuer applies ~~quantitative~~ factors such as ~~value or~~ projected costs savings in a quantitative manner, the plan/issuer must ~~be~~ define~~d~~ these factors in an appropriate manner and provide documentation and/or an illustration of the calculation ~~provided~~ as supporting information. Alternatively, the analysis may stipulate that projected cost savings are not estimated in a quantitative manner and instead are informed by whatever data are available but are ultimately evaluated in broad, qualitative terms (such as "some," "great," "growing," "unlikely," etc.). When defining a qualitative factor, it is not sufficient to indicate a factor or component of an evidentiary standard such as "opportunity to improve quality" without explaining specifically what that means or how it is determined. In addition, the plan/issuer should identify whether or not certain factors or components of an evidentiary standard are given more weight or value than others and explain the basis to assert they are not weighted. ~~That is~~For example, if multiple factors are utilized to determine whether the NQTL will

be applied, the analysis may stipulate that ~~are~~ any of them alone are sufficient to determine the NQTL applies, ~~? Or are~~or that all or a combination of the factors is required.~~?~~ Alternatively, the analysis may stipulate that a conclusion is reached according to a synthesis of the findings across all factors pursuant to the professional judgment of the committee members.

If a factor ~~clearly~~ involves some sort of threshold, such as "excessive utilization" or "high-cost admission", those thresholds must be defined and demonstrated to be comparable between MH/SUD and medical/surgical. For example, the analysis should identify the point at which ~~at what point does~~ utilization reaches the point of being "excessive," ~~? At what~~ or the dollar amount at which ~~does~~ a stay becomes "high cost." ~~? Please note that t~~There is no expectation that these threshold values must be or should be exactly the same for MH/SUD versus medical/surgical in order to be comparable. However, the plan/issuer must explain how and why the disparate values are in fact comparable.

Examples of data sources include:

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

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: Provide ~~T~~the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD 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.

Guidance: This Step requires two distinct comparative analyses: a comparative analysis, as written, and comparative analysis, in operation. The first analysis concerns the plan/issuer's demonstration that its written protocols are comparable and applied no more stringently. The second analysis concerns the plan/issuer's demonstration that the NQTL is applied no more stringently in operation. The reporting must clearly address these two components separately and should not merely provide a conclusory statement that the plan/issuer has done an assessment and determined that the NQTL complies without providing the analysis and explanation as to how and why the plan/issuer has concluded it has met the tests of comparability and no more stringent application.

As Written: ~~The comparative analysis concerning the "as written" component should be inclusive of all the plan/issuer's written policies, procedures, and utilization management manuals regarding the PA processes for MH/SUD and M/S services. These standards determine the basis for application of the NQTL are comparable and applied no more stringently with respect to MH/SUD and medical/surgical services.~~

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
- 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.

~~The plan/issuer's analysis should also account for how decisions rendered during the PA process are categorized and monitored by the plan/issuer because they may relate to the in-operation analysis for both MH/SUD and medical/surgical services. That is, denial rates may have at least two categories–denials recorded as denials based on medical necessity and denials recorded as administrative which can be due to a variety of reasons, e.g., provider failed to provide information deemed essential to the coverage decision. There is a related question as to how coverage modifications are recorded (e.g., the provider submits for an inpatient service and the coverage approved is negotiated down to approval for partial hospitalization) and whether coverage modifications are counted as denials. The plan/issuer must demonstrate through an analysis that these are defined and recorded comparably between MH/SUD and medical/surgical services.~~ The plan/issuer's analysis should also stipulate the categories of reasons for denials that it applies, such as denials based on medical necessity, failure to provide information deemed essential to the coverage decision, or approval of a service that differs from the original requested service (such as a lower level of care). The analysis must either stipulate that the same set of reasons for denials are used for both M/S and MH/SUD services or must analyze any difference in the sets of reasons that are used for M/S and MH/SUD services.

The as written analysis should specifically account for any differences where the plan/issuer has delegated review functions for MH/SUD services to a third-party vendor or when a separate unit within the plan/issuer is responsible for the MH/SUD NQTL. The plan/issuer documentation here should provide a clear, logical, and comprehensive analysis which illustrates comparability as to the written policies and procedures where the review function is actually conducted by separate parties.

In Operation: The plan/issuer must also demonstrate that the NQTL is being applied in a comparable and no more stringent manner. The required comparative analysis must account for what happens when PA is operationalized in real time.

Merely explaining that certain processes exist and that those processes are "the same" for MH/SUD and medical/surgical may demonstrate that there is comparability, but it does not demonstrate no more stringent application. For example, it may be the case that only a licensed physician or a medical director can make a determination that a request is not medically necessary when a first-level reviewer cannot approve it. This process may be exactly the same for MH/SUD and medical/surgical. However, further analysis is required to demonstrate that these identical, in-operation processes are applied no more stringently to MH/SUD than to medical/surgical.

Comparative analyses of coverage denial rates, if offered as evidence of no more stringent application, which resulted from the PA process must be specific and broken down by benefits classification and service type. Plan/issuer reporting on denial rates should not be provided on an aggregate basis. Moreover, denial rates by themselves are not a sufficient basis to demonstrate no more stringent application in operation (nor are they sufficient basis to demonstrate more stringent application, e.g. noncompliance).

Commented [DS1]: What does "aggregate" refer to here?

Reporting on interrater reliability (IRR) as evidence that criteria are applied consistently and as the sole basis to demonstrate comparability and no more stringent application in operation is also not a sufficient basis to demonstrate in operation compliance. IRR results are derived from a testing situation and are not necessarily reflective of what happens as the PA process is operationalized.

In order to demonstrate no more stringent application of the operationalization of the processes, the comparative analysis should account for several other pertinent operational metrics. These may include matters such as ~~the percentage of cases that are referred for second level (physician) review~~, the ~~frequency of peer-to-peer reviews~~, and others. Comparative analyses offered to demonstrate compliance in operation should provide information beyond denial rates and IRR results to demonstrate that everything was comparable and applied no more stringently in operation. ~~**Also, please note** that greater frequency of peer-to-peer reviews for MH/SUD is not necessarily problematic as it is understood that some plans/issuers offer peer-to-peer to MH/SUD providers upon an initial denial as a matter of routine whereas that may not be the case for medical/surgical. If this is the case an explanation as such should alleviate any concerns that greater frequency is indicative of more stringent application.~~

The plan/issuer should incorporate as part of its analysis, quality assurance oversight reports which include review of the PA processes, including generalized audits. This includes the results of any internal audits involving the first-level review process, the physician review process, the peer-to-peer process, and consultations with expert review process (if applicable) excluding IRR testing reports.

Step 5: Provide t~~T~~he specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results of the analyses described in this step that indicate that the plan or issuer is or is not in compliance with this section.

Guidance: The plan/issuer should provide a reasoned discussion of its findings and conclusions identified in Steps 1 through 4 within the affected classification, including any citations to specific evidence considered and results of analyses which demonstrate that the issuer is or is not in compliance with MHPAEA. ~~Note that it is not valid to present summary conclusions as to compliance if the required information in the preceding steps is insufficient.~~

The required information in Step 5 is inclusive of a summary and conclusion. The summary should be a concise statement or account of the principal information and results of the analyses offered to demonstrate compliance. It should not introduce new information or analyses not presented in the foregoing Steps. The conclusion provided should not merely be a summary of the principal supporting information or a re-statement of the plan/issuer's analysis; it should be a synthesis of the basis from the above required information and analyses which ~~definitively~~ demonstrates compliance as written and in operation. Where all information provided for a given step is identical for M/S and MH/SUD services, the plan is presumptively determined to be in compliance for that step. Where any differences are identified, the plan should identify and explain such differences and provide a brief justification for its conclusion regarding comparability and stringency.

If the plan/issuer has decided that it is not in compliance, it should describe any plan it has for corrective action.