Instructions for Step Therapy

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. This 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: 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.

Guidance: This step requires that the plan/issuer identify all coverage terms, policies, and procedures related to step therapy. It is understood that step therapy only applies in the prescription drug classification of benefits. All medications subject to step therapy must be identified. Given that this may be a significant amount of medications, it is permissible to submit a separate attachment that lists every medication subject to step therapy.

Step 2: 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 whether step therapy will apply to M/S and MH/SUD medications. 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 step therapy for each medication.

Step 3: 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 for each factor. For example, quantitative factors such as value or projected costs savings must be defined in an appropriate manner and documentation and/or an illustration of the calculation provided as supporting information. 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 a evidentiary standard are given more weight or value than others and explain the basis to assert they are not weighted. That is, if

multiple factors are utilized to determine whether the NQTL will be applied, are any of them alone sufficient to determine the NQTL applies? Or are all or a combination of the factors required?

If a factor clearly involves some sort of threshold, such as "drug is considered low value either in terms of efficacy, safety or cost", the threshold must be clearly defined and articulated. In this example, at what point does "value" fall into the realm of "low" in terms of each of efficacy, safety, or cost? It is possible that there is a hard quantitative means of establishing this, but it is also understood that the parameters for the threshold could somewhat more qualitative (although no concept of "value" can ever be completely severed from a quantitative understanding).

In terms of other evidence relied upon to design step therapy, there obviously will be substantial amounts of evidence that the plan/issuer relies upon to inform both which medications are subject to step therapy and what the requirements are for each step therapy protocol. It is not necessary to detail and describe every piece of evidence and every source for the evidence. However, it is necessary for the plan/issuer to explain clearly and in detail how and why it was able to determine that the evidence relied upon when deciding whether to apply step therapy to MH/SUD medications—and the nature and degree of the step therapy protocols—was comparable to and applied nor more stringently than that used for medical/surgical medications. This should consist of more than merely stating that the process is "the same" or there is "no differentiation" between MH/SUD and medical/surgical when the P&T committee meets. Even when no differentiation or distinction is made between MH/SUD and medical/surgical it is certainly possible that more stringent application could have still occurred for some MH/SUD medications (this could occur through random variation alone).

Step 4: 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.

Guidance: This Step requires two distinct comparative analyses: a comparative analysis, as written, and a 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 operationalized in a no more stringent fashion. 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: Any written materials the plan/issuer relies upon to design step therapy protocols should be examined and evaluated. However, it is understood that most if not all plans/issuers (or their vendors) likely use an overall set of written policies and procedures to design step therapy and not separate ones for MH/SUD medications and medical/surgical medications (and that most if not all of this would be covered in step 3). Therefore, the emphasis for the plan/issuer in the as-written analysis of this step should be to look at samplings of actual written step therapy protocols for MH/SUD medications and medical/surgical medications. The plan/issuer should examine the written step therapy processes and compare MH/SUD processes to medical/surgical processes to determine comparability and application stringency. This does not mean the plan/issuer needs to exhaustively compare the as-written processes in place for every MH/SUD medication subject to step therapy with the as-written processes in place for every medical/surgical medication subject to step therapy.

A recommended approach is to identify the MH/SUD medications that appear to have the most lengthy, detailed, and difficult to achieve series of steps. The more steps involved, the more intricate the requirements of each step, and the more difficult it may be for a member to meet the all the steps and requirements, indicates a greater degree of stringency for these as-written processes. The plan/issuer could then look to identify medical/surgical medications that have similarly lengthy, detailed, and difficult to achieve series of steps. There is no requirement that the number of steps listed, or things required to meet each step aligns perfectly between these types of MH/SUD medications and medical/surgical medications; that is unrealistic. However, the plan/issuer should be able to explain clearly and convincingly how and why the examination has led the plan/issuer to conclude that the as-written step therapy processes in place for MH/SUD medications are in fact comparable and applied no more stringently.

It is important to note that just because a plan/issuer followed the same general design protocols, used the same assortment of factors, and relied on the same evidentiary standards, that does not mean that the actual final as-written processes in a step therapy protocol are automatically comparable and applied no more stringently to MH/SUD medications. The actual as-written processes that must be completed as part of step therapy protocols for MH/SUD medications must be comparable to and applied no more stringently than the actual as-written processes that must be completed as part of step therapy protocols for medical/surgical medications. These as-written processes certainly can and often are informed by factors, evidentiary standards, and even strategies, but as final products they are distinct components (as-written processes) that must adhere to the NQTL requirements of comparability and no more stringent application.

In operation: There are several areas that need exploration to demonstrate comparability and no more stringent application in operation. The first are the processes by which the plan/issuer decided which medications would be subject to step therapy and what the requirements would be for medications subject to step therapy.

It is understood that factors and evidentiary standards play a large role in determining which medications end up being subject to step therapy. And, if a plan/issuer can conclusively demonstrate that once the factors and evidentiary standards were established there was no further human decision-making at work in selecting the medications subject to step therapy then that would be an acceptable comparative analysis for this component of the in-operation exercise. However, if there is any decision-making that occurs that determines whether a drug will or will not be subject to step therapy then that must be demonstrated to be comparable and (especially) applied no more stringently for MH/SUD versus medical/surgical. For example, if members of a P&T committee ultimately make the decision for some or all medications under consideration, that is a process that is distinct from any factors or evidentiary standards. It certainly may be informed by factors and evidentiary standards, or even heavily rely on them, but if individuals are making the final call as to whether or not medications are subject to step therapy, that is a process that must be comparable and applied no more stringently.

The second area of exploration involves any plan/issuer decision-making as to whether required steps have been met for a particular member. For example, many step therapy as-written processes include requirements that the member has “tried and failed/not tolerated treatment” with another medication or medications. While there are many times when this will be obvious to a member, prescriber, and the plan/issuer, there certainly will be times when the plan/issuer has to examine the clinical information and make a determination as to whether the step has been met. This is an in-operation process that must be comparable and applied no more stringently.

Plans/issuers are not expected to perform an exhaustive examination of every instance this in-operation process takes place given that it likely occurs many, many times throughout a year for any given plan/issuer. Rather, the plan/issuer's comparative analysis must detail what it has done to examine the operationalization of this process how it has concluded that the process is applied no more stringently to MH/SUD than to medical/surgical. This detailing and concluding must clearly show evidence of no more stringent application and not merely describe that oversight occurs and flatly state that it showed no more stringent application without concrete proof.

Finally, plans/issuers may report on the overall percentages of medications subject to step therapy in a comparative manner between MH/SUD and medical/surgical. While these types of percentages are not dispositive of compliance or lack thereof, evidence that MH/SUD medications are subject to step therapy at similar or lower percentages versus medical/surgical medications may afford the plan/issuer more benefit of the doubt on other areas of the comparative analysis.

Step 5: 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 of the analyses described in this subparagraph that indicate that the plan or coverage 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 prescription drug 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 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.

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