Instructions for Experimental/Investigational

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: 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 benefits classification.

Guidance: This Step requires that the plan/issuer provide a definition of what constitutes an experimental or investigational use of a service, procedure, item, or medication for a particular condition, conditions, or all conditions. It is understood that some services, procedures, items, or medications may be designated experimental or investigational under all circumstances (example), while others may be considered experimental or investigational for the treatment of certain conditions but medically appropriate for the treatment of other conditions (example). There need not be a distinction in the definition of experimental or investigational between these two different instances.

For example, a treatment may be considered experimental or investigational under all circumstances for any conditions *because the safety and/or effectiveness of the service cannot be established by review of the available published peer-reviewed literature*. Or, a treatment may be considered medically appropriate for several conditions, but experimental or investigational for any other conditions *because the safety and/or effectiveness of this service cannot be established by review of the available published peer-reviewed literature*.

Even though these are different scenarios where one treatment is always considered experimental or investigational use under all circumstances, while the other is considered medically appropriate for some conditions but experimental or investigational for all other conditions, the definition for what constitutes experimental or investigational use is the same.

However, if there is a difference in the definition of what constitutes experimental or investigational use under any circumstances and what constitutes experimental or investigational use under some or most circumstances, please specify and provide the different definitions.

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

Guidance: N/A. Plans/issuers do not need to complete this step for this NQTL.

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: For this step the plan/issuer should establish what the evidence threshold is for the use of a treatment to be considered experimental or investigational. For example, take the definition provided above: because the safety and/or effectiveness of this service cannot be established by review of the available published peer-reviewed literature. The plan/issuer should specify what the threshold is for it being determined that the available published peer-review literature does not establish safety and/or effectiveness. Hypothetically, maybe the standard is if there are less than two randomized controlled trials demonstrating effectiveness of a treatment for a particular condition, it is considered experimental or investigational. Whatever the standard may be, it should be clearly explained in this step.

Also, if there is an and/or type situation in play with safety/effectiveness, the plan/issuer should specify what the standard is for when one of the two outweighs the other (likely safety outweighing effectiveness). For example, maybe a medication has demonstrated through multiple RCTs that it is effective in reducing blood pressure to a clinically-significant degree but it frequently causes dangerous fainting spells and is therefore deemed unsafe and considered experimental or investigational by the plan/issuer. The plan/issuer should specify what the threshold is for safety concerns to outweigh evidence of effectiveness in deeming a treatment experimental/investigational.

Step 4: 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:

As written: For this NQTL, the as-written component should consist of demonstrating that MH/SUD treatments that were considered experimental/investigational for some or all conditions and circumstances received this designation in a fashion that was comparable to and no more stringently applied than how medical/surgical treatments received the experimental/investigational designation.

This does not need to entail exhaustive examinations of every service, procedure, item, or medication that is considered experimental/investigational for all or some conditions and circumstances. Rather, the plan/issuer must simply explain how and why it is sure that the way this process transpires for MH/SUD passes the NQTL tests compared to medical/surgical. Of course, this should entail examining actual MH/SUD treatments for which use is considered experimental/investigational and ensuring that the evidence relied upon to reach those conclusions is comparable to and applied no more stringently than that relied upon to deem medical/surgical treatments as experimental/investigational, broadly speaking.

One possible, but not required, way of doing this would be to identify some MH/SUD treatments that are considered experimental/investigational in some or all circumstances (like ECT or deep-brain stimulation) and demonstrate that there are medical/surgical treatments that received the experimental/investigational designation with similar evidence bases (or lack thereof) on effectiveness and safety.

In operation: To meet the in operation requirements, the plan/issuer should examine any requests for coverage of treatments deemed experimental/investigational and determine if such requests were handled for MH/SUD were comparable and applied no more stringently than those for medical/surgical. A simple metric of approval rates should suffice. If MH/SUD requests were approved less frequently than

medical/surgical requests that may be fine as long as the plan/issuer provides a persuasive explanation as to why that was the case.

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 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, 3, and 4 within the affected classification, including any citations to specific evidence considered and results of analyses which demonstrate that the plan/issuer is or is not in compliance with MHPAEA.

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.

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