

Subject: Experimental and Investigational Services		Original Effective Date: 6/25/2014
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.

PURPOSE

To define experimental, investigational and unproven services for the following: medical and behavioral healthcare procedures, pharmaceuticals and devices. **This definition applies when NO existing definition exists in the member benefit or health plan contract documents.**

PROCESS

1. Molina Healthcare defines the terms “experimental” or “investigational” or “unproven” (E/I/U) as the use of a technology defined as: medical, surgical, behavioral procedures, equipment, devices, laboratory tests and pharmaceuticals, that has not been recognized as having proven benefit in clinical medicine for

any condition, illness, disease or injury being treated. A technology will be deemed, experimental, investigational or unproven by the Molina Health Care if one or more of any the following criteria exist:

- has not successfully completed a Phase III trial; *or*
- has not been approved by the FDA; *or*
- are not generally recognized as the accepted standard treatment for the disease or condition from which the patient suffers; *or*
- E/I/U treatments may also include off-label therapies (medical therapies that use a FDA approved drug or procedure for a non-indicated use)

2. Fulfillment of the following five criteria is necessary to establish a technology as **not** experimental/investigational:

- The device/service must have received final approval from the appropriate regulatory agency (e.g., FDA), **and**
- Published peer-reviewed literature must demonstrate the proven beneficial impact of the service/procedure on health outcomes for the given indication, **and**
- Published peer-reviewed literature must demonstrate that the technology must be at least as effective as established technology for the given indication, **and**
- Published peer-reviewed literature must demonstrate evidence that the technology improves health outcomes over time for the given indication, **and**
- The outcomes for the given indication must be obtainable outside investigational settings within the medical community defined as the outcomes must show improvement outside the investigational settings.

REVIEW/REVISION HISTORY

6/25/14: *New Policy*

12/16/15, 6/15/16, 6/22/17, 7/10/18: *Policy reviewed, no changes.*

6/19/19: *Policy reviewed and the following revisions were added: Process section #1: defined the word technology based on NCQA UM 10 definition as medical, surgical, behavioral procedures, equipment, devices, laboratory tests and pharmaceuticals; Changed the word treatment to technology and Added the word “or” after all 4 bullets. Clarified Process section #2, bullet #5 by adding a definition.*

6/17/20, 6/9/21: *Policy reviewed, no changes.*