Subject: Experimental and Investigational Services		Original Effective Date: 6/25/14
Guidance Number: MCG-184	**Revision Date(s):**	
Medical Coverage Guidance **Approval Date: 6/25/14**		

This Medical Guidance 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 exclusions 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 following website: http://www.cms.hhs.gov/center/coverage.asp.

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 drug, device, treatment or procedure that has not been recognized as having proven benefit in clinical medicine for any condition, illness, disease or injury being treated. A drug, device, procedure or service will be deemed, experimental, investigational or unproven by the Molina Health Care if any of the following criteria exist:

    - ❑ has not successfully completed a Phase III trial; *and*
    - ❑ has not been approved by the FDA; *and*
    - ❑ are not generally recognized as the accepted standard treatment for the disease or condition from which the patient suffers; *and*
    - ❑ 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) ; *and*

2. Fulfillment of the following five criteria is necessary to establish a treatment 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.