Subject: Evaluation of New and Existing Technologies (UM 10)	Original Effective Date: 4/24/2007
Molina Clinical Policy (MCP)Number: MCP-000	**Revision Date(s):** 11/20/2008, 1/28/2009, 1/14/2010, 3/11/2010, 2/10/2011, 12/14/2011, 6/29/2012, 2/27/2013, 6/25/2014, 4/30/2015, 6/15/2016, 3/8/2018, 7/10/2018, 12/19/2018
Review Date: 6/22/2017, 12/19/2018, 9/18/2019, 6/17/2020, 6/9/2021	
MCPC Approval Date: 6/22/2017, 7/10/2018, 12/19/2018, 9/18/2019, 6/17/2020, 6/9/2021	

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DISCLAIMER

This Molina Clinical Policy 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 this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.

PURPOSE

I. PURPOSE

Molina Clinical Policy (MCP) is defined as a clinical policy that is based on the highest level of published peer reviewed scientific evidence available and addresses new or evolving technologies and new uses for existing technologies for specific "services". The term service herein applies to: out-patient medical, surgical, behavioral procedures, equipment, devices, laboratory tests and pharmaceuticals. The clinical policy establishes medical necessity, investigational, experimental, unproven and cosmetic status for the service being addressed. The purpose of a clinical policy is to provide guidelines for determining coverage

criteria and whether a service is medically necessary or not medically necessary for utilization management evidence based decision making. The goal is to develop objective, clinically supported coverage and non-coverage criteria. The clinical policies are written to comprise a given condition applicable to a majority of people without taking into consideration each individual's unique, clinical circumstances. Molina's clinical policies are not intended to direct the course of clinical care a physician provides to a member and do not replace a physician's independent professional clinical judgment.

Molina Clinical Policy (MCP) has been developed specifically with the intent to:

- ❑ Keep abreast of ongoing changes in technology
- ❑ Provide access to obtain safe, effective and evidence based care
- ❑ Review information from appropriate governmental regulatory bodies and from published scientific evidence
- ❑ Obtain input from specialists and professionals with unique knowledge about the specific technology reviewed
- ❑ Outline the variables used in making determinations including, but not limited to, experimental and investigational procedures
- ❑ Review the criteria in each specific MCP and procedures for applying them against current clinical and medical evidence and updates them when appropriate. If new scientific evidence is not available, the MCP Committee (MCPC) or the Pharmacy & Therapeutics committee (P&T) may determine if further review of a criterion is necessary

OVERSIGHT

II. OVERSIGHT

1. Molina Clinical Policy (MCP) for new technology and new applications of existing technology are developed:
   - ❑ To maintain compliance with all Federal and State regulatory bodies and Accrediting agencies such as NCQA or URAC.
   - ❑ By the Pharmacy & Therapeutics committee (P&T) or the designated and dedicated Corporate Medical Director in the Clinical Policy & Services team, in conjunction with Molina Healthcare Physicians serving on the MCPC or P&T, including Behavioral Health Physician. External physicians will be consulted in the review process ad hoc to provide input relevant to their specific area of expertise.
   - ❑ To provide Molina Healthcare State plans guidance in administering specific state plan benefits.

2. After review and discussion, the MCPC or P&T shall make a collective decision as to whether such New Technology:
   a. is still considered experimental or investigational (E/I),

   b. has been adopted as an accepted medical practice or community standard of care,

   c. has valid and substantial evidence supporting its appropriateness and effectiveness, and

   d. should be considered medically necessary by the state plans with or without limitations.

3. Molina Clinical Policy medical topics are selected by the Molina Corporate Medical Director overseeing the Molina Clinical Policy & Services Department and the Molina Clinical Policy Committee (MCPC). Molina Clinical Policy topics related to pharmaceuticals are selected by the By the Pharmacy & Therapeutics committee (P&T).
4. Appropriate topics are evaluated by review of the information in the NEW or REVISED MCP request form that details business need for policy development and prioritized according to the following information:
    - ❑ High volume, high cost utilization
    - ❑ Controversial technology regarding treatment options for managing care
    - ❑ Knowledge deficit regarding a new procedure, medical device, medication, or therapeutic test
    - ❑ Availability of scientific research to evaluate the technology
    - ❑ Technologies that are of great interest to the public and provider communities
    - ❑ Life-saving technologies
    - ❑ Known or suspected overutilization or inappropriate usage
    - ❑ Procedures previously designated as experimental or investigational that may be evolving into the standard of care
    - ❑ Technology found to have a high potential for harm

5. Topics that are excluded for development by MCPC include the following examples of Corporate and Plan processes: [ALL]
    - ❑ Utilization Management (UM) or Health Care Services (HCS) procedure and process including CAM, UM HCS policies, clinical practice guidelines and any other ancillary criteria,
    - ❑ Criteria specific to any state or federal mandate or regulation,
    - ❑ Benefit coverage, limitations and exclusions outlined in Plan documents
    - ❑ Reimbursement or payment criteria
    - ❑ Coding edits including temporary or any other codes configured in claims as not covered
    - ❑ Claims and operational processes
    - ❑ Government compliance rules

6. The literature review of appropriate topics is initiated with a query of an electronic Medline database. While the database is comprised of thousands of journals worldwide, an initial query encompasses a search of the general topic and is limited to peer-reviewed journals and articles dealing with human studies in the English language. Reviews of the articles meeting these qualifications are reviewed by the Molina Clinical Policy staff. Consideration is given to any applicable published statements issued by a recognized national assessment authority such as, but not limited to, the National Institute of Health, and the Agency for Healthcare Quality and Research. Where appropriate, the Corporate Medical Director of the Clinical Policy & Services department and P&T or the clinical staff may contact specialists, researchers, or institutions who specialize in the condition involved.

7. The evaluation of the sources used to produce Molina Clinical Policy shall be weighed by the strength of the evidence and the effectiveness the strength of evidence is as follows (weakest to strongest):
    - ❑ case reports
    - ❑ text books
    - ❑ small series
    - ❑ large series

- ❑ systematic review- e.g. meta-analysis
- ❑ clinical trials
- ❑ randomized, controlled double-blinded clinical trials

8. There must be sufficient evidence from medical or scientific literature to identify the therapeutic value, the improvement or beneficial effect on health outcomes, or to establish the therapeutic advantages over established alternatives.

   Insufficient evidence may be defined as: evidence obtained from studies other than good quality randomized-control trials or minimally biased prospective cohort/comparison studies. Opinion statements, case studies, abstracts, and retrospective studies are not considered high quality evidence and are not sufficient.

   Evidence summaries from published reports or articles located in authoritative medical and scientific literature regarding the drug, device, treatment or procedure recommending further studies or clinical trials are required to determine, safety, efficacy, or toxicity when compared with standard treatments or diagnoses shall be noted and are not considered strong evidence for coverage.

   The following key markers are necessary to determine high quality evidence:
   - ❑ Large numbers of study participants in at least two different studies suitable for statistical validity
   - ❑ Strongly similar comparison groups (randomized trials are best)
   - ❑ Comparison studies to best standard of care alternatives; and
   - ❑ Blinding or other assurances of independence of the findings from bias

9. The material outlined in the Molina Clinical Policy includes but is not limited to a review of evidence based information obtained from the following sources:
   - ❑ Approval statements from governmental regulatory agencies such as the Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS)
   - ❑ Review of technology assessments established by nationally accepted governmental agencies or physician specialty societies, associations or academies
   - ❑ FDA-approved manufacturer's labeling or Manufacturer's literature regarding the usage of equipment, a device or pharmaceutical
   - ❑ American Hospital Formulary Service-Drug Information (AHFS-DI); National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium; Truven Health Analytics Micromedex DrugDEX (DrugDEX); Elsevier Gold Standard Clinical Pharmacology Compendium (Clinical Pharmacology)]
   - ❑ Hayes Inc. and Cochrane Library Meta-analysis or systematic reviews evaluating scientific evidence published in peer reviewed medical literature
   - ❑ Well-controlled studies or cohort/comparison studies published and referenced in medical or scientific literature
   - ❑ Ad Hoc review of recommendations from medical specialists or professional experts obtained from independent review organizations
   - ❑ Applicable to transplants requests only: Published transplantation registry data supporting increased patient survival rates is considered an established standard of medical practice

PROCEDURE

III. PROCEDURE

1. Molina Clinical Policies (MCPs) are developed by the Clinical Policy & Services Department for the review and evaluation of the Molina Clinical Policy Committee (MCPC) and P&T through the formal corporate mechanism as outlined in this policy. In order to achieve and maintain high standards of integrity, impartiality, and objectivity in this process, the Medical/Pharmacy Director shall not review/advise, or have involvement with, specific member cases or appeals that may cause a potential conflicts of interest in the development or maintenance of any policy (MCP).

2. Appropriate topics are evaluated by review of the information in the NEW or REVISED MCP request form that details business need for policy development and are prioritized by the Molina Corporate Medical Director overseeing the Molina Clinical Policy & Services Department and MCPC or P&T according to the following:
   - ❑ If the request is for a medical, surgical, behavioral procedure, equipment, device, laboratory test or a pharmaceutical in response to an active prior authorization request the MCP will be developed in a timely manner once the request is received and all pertinent information is submitted.
   - ❑ If the request is for a medical, surgical, behavioral procedure, equipment, device, laboratory test or a pharmaceutical that is NOT in response to a prior authorization request the Clinical Policy department will review the request and determine if a MCP document is appropriate based upon the need for guidance within a Plan

3. The Clinical Policy & Services department will perform a literature search and develop the draft content for each document.

4. Documents will be reviewed by an external review organization when appropriate. A specialist with expertise and credentials appropriate for the topic will be chosen to review each document on an ad hoc basis and the MCPC or P&T meeting minutes will reflect whether the specific policy was reviewed and by what specialist if applicable.

5. The MCP document will be presented to the Molina Clinical Policy Committee (MCPC) or P&T on at least a quarterly basis. The documents are distributed in advance of the meeting to all committee invitees (e.g., State CMOs, Medical Directors, Pharmacists, and other corporate designees). The MCPC chair, committee member or internal reviewer will present the specific policy document to the MCP or P&T committee. All attendees present at the committee meeting will have input into the content of the document. The designated MCPC and P&T members will be the voting body for the final recommended motions. The MCPC or P&T meeting minutes will reflect the status of each specific MCP as approved or not. Once the MPC has been approved and distributed, there shall be no additional "wordsmith" or changes until the MCP is scheduled for review and revision.

6. The Clinical Policy & Services Department will list the approved policy for review and approval of the respective oversight Committee, Molina Clinical Policy Committee or P&T Pharmacy Committee.

7. The State Health Plan Chief Medical officer or their designee will be responsible for review of specific contractual, Federal, or state guidelines that may be in conflict with the corporate policy recommendations. The State Plan guideline supersedes the guidance contained within the MCP.

8. The completed Molina Clinical Policy document(s) shall be placed on the agenda for review and approval at the next scheduled state plan committee designated to make Utilization Management decisions.

9. Distribution to the Utilization Management staff for each state Plan is the responsibility of the plan following revision and approval of the document. The meeting minutes from the state Plan committee should reflect approval or non-approval of all documents. States that are not responsible for reimbursement of technology such as pharmacy or transplants will note in their committee minutes a notation such as "This benefit or pharmaceutical agent is not covered under the plan's state contract and a full review of these technologies is not required."

10. Each specific MCP shall include the original approval date, and the date of each review and revision

11. Each MCP shall be reviewed against current clinical and medical evidence and updated when appropriate (every 3 years) or may be reviewed prior to their scheduled review date if there is any new scientific evidence published that would change or impact the policy criteria as appropriate.

12. All corporate approved MCP's will be available via access on the Molina Clinical Policy SharePoint site for state Plan access.

IV. Molina Clinical Review (MCR)

1. MCR documents are a set of clinical guidelines to assist the clinical utilization management (UM) staff in making appropriate medical necessity decisions for services that require medical review and prior authorization and available via access on the Molina Clinical Policy SharePoint site for state Plan access.
2. MCR guidelines address the medical necessity of existing, generally accepted standard of care medical and behavioral health services, technologies and drugs.
3. MCR documents follow the above outlined policy and procedure with the following exceptions:
   - ❑ MCR documents may not be scheduled for revisions as determined by the MCPC since they outline stable processes and the guidelines are not likely to change
   - ❑ MCR documents may not contain or be based on evidence based medical information as the criteria is considered standard of care and generally accepted in the medical community

REVIEW/REVISION HISTORY

4/24/07: New Policy
11/20/08, 1/28/09, 1/14/10, 3/11/10, 2/10/11, 12/14/11, 6/29/12 & 2/27/13: No changes.
6/25/14: Revised the Purpose, Oversight and Procedure sections based on new leadership department recommendations.
4/30/15: Added the following sentence from Page 5, number 7: "The State Health Plan is responsible for revision of the document to incorporate any state specific regulations".
6/15/16: Changed the department name to Molina Clinical Policy and added the section about Molina Clinical Review (MCR).
6/22/17: No changes.
3/8/18: Changed department name to Clinical Policy & Services. The following sections were updated: The purpose section was updated with current NCQA UM 10 criteria for annual reviews required when appropriate. The oversight section was updated with new dept. name (Clinical Policy & Services), changed "reimbursement" to medically necessary, added that requests for new or revised MCP's need to be submitted using a request form that details the business need for the policy, outlined topics that are excluded from development. The procedure section was updated to indicate that the department does not review/advise, or have involvement with, specific

member cases or appeals that may cause a potential conflicts of interest in the development or maintenance of any policy (MCP).
7/10/18: Oversight section: Added the following bullet on page 4, number 8: CMS approved compendia [American Hospital Formulary Service-Drug Information (AHFS-DI); National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium; Truven Health Analytics Micromedex DrugDEX (DrugDEX); Elsevier Gold Standard Clinical Pharmacology Compendium (Clinical Pharmacology)]. Procedure section: Removed the following sentence from Page 5, number 7: The State Health Plan is responsible for revision of the document to incorporate any state specific regulations.
12/19/18: Added definition of MCP in the Purpose section and added that the Pharmacy & Therapeutics committee (P&T) reviews and approved pharmacy MCP's in the purpose, oversight and procedure sections.
9/18/19: Changed department name to Clinical Policy & Services. On page 5, numbers 4 & 5 added that the meeting minutes will reflect approval and whether the policy was reviewed by a specialist.
6/17/20, 6/9/21: Policy reviewed, no changes.