Molina Clinical Policy
Evaluation of New and Existing Technologies (UM 10)
Policy No. 000

Last Approval: 06/11/2025
Next Review Due By: June 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

PURPOSE

A 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 outpatient medical, surgical, and behavioral procedures, equipment, devices, laboratory tests, and pharmaceuticals. The MCP establishes medical necessity, investigational, experimental, unproven, or 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. Clinical policies are written to comprise a given condition applicable to most people without taking into consideration an individual’s unique, clinical circumstances. MCPs 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. The intent of a MCP is 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 update them when appropriate. If new scientific evidence is not available, the Medical Clinical Policy Committee (MCPC) or the Pharmacy and Therapeutics (P&T) Committee may determine if further review of a criterion is necessary.

OVERSIGHT

1. A Molina Clinical Policy (MCP) for new technology and new applications of existing technology is developed:
    a. To maintain compliance with Federal and State regulatory bodies/accrediting agencies (e.g., National Committee for Quality Assurance [NCQA] or Utilization Review Accreditation Commission [URAC])
    b. By the P&T Committee or the designated Corporate Medical Director in the Clinical Policy and Services team, in conjunction with Molina Healthcare Physicians serving on the MCPC or P&T Committee, including Behavioral Health physicians. External physicians will be consulted in the review process via ad hoc to provide input relevant to their specific area of expertise
    c. To provide Molina Healthcare State plans guidance in administering specific state plan benefits

2. After review and discussion, the MCPC or P&T Committee shall make a collective decision as to whether such new technology:
    a. Is still considered experimental or investigational

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

3. Medical topics for MCPs are selected by the Molina Corporate Medical Director overseeing the Molina Clinical Policy and Services Department and the MCPC. Topics related to pharmaceuticals are selected by the P&T Committee.

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:
   a. High volume, high-cost utilization
   b. Controversial technology regarding treatment options for managing care
   c. Knowledge deficit regarding a new procedure, medical device, medication, or therapeutic test
   d. Availability of scientific research to evaluate the technology
   e. Technologies that are of great interest to the public and provider communities
   f. Life-saving technologies
   g. Known or suspected overutilization or inappropriate usage
   h. Procedures previously designated as experimental or investigational which may be evolving into the standard of care
   i. Technology is found to have a high potential for harm

5. Topics that are excluded for development by MCPC include **ALL** the following examples of Corporate and Plan processes:
   a. Utilization Management or Health Care Services procedure and process including Care Access and Monitoring (CAM), Utilization Management or Health Care Services policies, clinical practice guidelines, and any other ancillary criteria
   b. Criteria specific to any state or federal mandate or regulation
   c. Benefit coverage, limitations and exclusions outlined in Plan documents
   d. Reimbursement or payment criteria
   e. Coding edits including temporary, or any other, codes configured in claims as not covered
   f. Claims and operational processes
   g. 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 the National Institute of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ). Where appropriate, the Corporate Medical Director overseeing the Clinical Policy and Services Department and P&T Committee 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 a MCP shall be weighed by the strength of the evidence and the effectiveness the strength of evidence is as follows (**weakest to strongest**):
   a. case reports
   b. textbooks
   c. small series
   d. large series
   e. systematic review (e.g., meta-analysis)
   f. clinical trials
   g. 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 insufficient.

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 robust evidence for coverage. The following key markers are necessary to determine high quality evidence:

a. Large numbers of study participants in at least two different studies suitable for statistical validity
b. Strongly similar comparison groups (randomized trials are best)
c. Comparison studies to best standard of care alternatives
d. Blinding or other assurances of independence of the findings from bias

9. The material outlined in the MCP includes but is not limited to a review of evidence-based information obtained from the following sources:
    a. Approval statements from governmental regulatory agencies such as the United States Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS)
    b. Review of technology assessments established by nationally accepted governmental agencies or physician specialty societies, associations, or academies
    c. FDA-approved manufacturer's labeling or manufacturer's literature regarding the usage of equipment, device, or pharmaceutical
    d. 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), Wolters Kluwer Lexi-Drugs (Lexicomp)
    e. Hayes, Inc. and Cochrane Library meta-analysis or systematic reviews evaluating scientific evidence published in peer-reviewed medical literature
    f. DynaMed and UpToDate for clinical content and decision support
    g. Well-controlled studies or cohort/comparison studies published and referenced in medical or scientific literature
    h. Ad hoc review of recommendations from medical specialists or professional experts obtained from independent review organizations
    i. **Applicable to transplant requests only:** Published transplantation registry data supporting increased patient survival rates is considered an established standard of medical practice

PROCEDURE

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

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 and Services Department and MCPC or P&T Committee according to the following:
    a. 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.
    b. 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 and 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 Committee 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 MCPC or P&T Committee on at least a quarterly basis. The documents are distributed in advance of the meeting to all committee invitees (e.g., State CMOs (Chief Medical Officers), Medical Directors, Pharmacists, and other corporate designee). 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 document's content. The designated MCPC and P&T Committee members will be the voting body for the final recommended motions. The MCPC or P&T Committee 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 and Services Department will list the approved policy for review and approval of the respective oversight Committee, MCPC, or P&T 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 conflict with the corporate policy recommendations. The State Plan guideline supersedes the guidance contained within the MCP.

8. The completed MCPs shall be placed on the agenda for review and approval at the next scheduled State Plan committee designated to make UM decisions.

9. Distribution to the UM 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 (annually) 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 MCPs will be available via internal access on the Molina Clinical Policy SharePoint site for State Plan access. Policies will also be posted on the external Clinical Policy website at www.molinaclinicalpolicy.com.

APPROVAL HISTORY

06/11/2025	Policy reviewed, no changes.
06/12/2024	Policy reviewed, no changes.
06/14/2023	Policy reviewed, updated review period from "every 3 years" to "annually."
06/08/2022	Policy reviewed, no changes.
06/09/2021	Policy reviewed, no changes.
06/17/2020	Policy reviewed, no changes.
09/18/2019	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.
12/19/2018	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.
07/10/2018	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.
03/08/2018	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 be involved with, specific member cases or appeals that may cause a potential conflict of interest in the development or maintenance of any policy (MCP).
06/22/2017	No changes.
06/15/2016	Changed the department name to Molina Clinical Policy and added the section about Molina Clinical Review (MCR).
04/30/2015	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”.
06/25/2014	Revised the Purpose, Oversight and Procedure sections based on new leadership department recommendations.
02/27/2013	No changes.
06/29/2012	No changes.
12/14/2011	No changes.
02/10/2011	No changes.
03/11/2010	No changes.
01/14/2010	No changes.
01/28/2009	No changes.
11/20/2008	No changes.
04/24/2007	New policy.