Molina Clinical Policy
Experimental and Investigational Services: Policy No. 184

Last Approval: 6/12/2024
Next Review Due By: June 2025

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.

OVERVIEW

This policy specifies the conditions under which a service is considered experimental and investigative for all indications.

Experimental and investigational is defined as the use of a service that is not recognized by the Plan as standard medical care for the condition, disease, illness, or injury being treated. A service includes, but is not limited to any treatments, diagnostics, procedures, drugs, vaccines, facilities, equipment, devices, or supplies. **Any service for which the safety and efficacy have not been established and proven is considered investigational (unproven), is therefore not medically necessary and is not covered.**

This policy applies when there is NO existing applicable state and federal requirements or definition in the member's benefit plan. Members and providers should consult the member's health benefit plan for information. If there is a discrepancy between this policy and the member's coverage benefit document, the member's benefit plan will govern.

Experimental and investigational services may be covered when:

1. Mandated by the state or federal law (Refer to the Federal/State Mandated Regulations and/or State Health Plan regulations)
2. Covered by member's benefit plan as defined in the benefit coverage document or schedule of benefits

This policy does not imply that Molina Healthcare is responsible for experimental or investigational technology not covered by the Benefit Plan Contract or relevant state and federal regulations.

RELATED POLICIES

MCP-183: Clinical Trials and Rare Disease – apply if the proposed plan of care includes participation in a clinical trial and **ALL** criteria below must be met

MCP-000: Evaluation of New Technology (UM-10)

MCP-332: Medically Necessary Services

COVERAGE POLICY

Molina Health Care considers a health care service to be experimental, investigational, or unproven if **ONE** or more of the following criteria are met:

1. FDA approval has **not** been granted for unrestricted marketing at the time of request or proposed use:
   a. Interim regulatory approval is not a replacement for final, unrestricted market authorization
   b. New device application on file with the FDA and approval is not yet granted

c. Drugs granted orphan drug status that have not yet received approval by the FDA

2. The technology has not been demonstrated to be as safe or effective, or not of proven benefit for the particular diagnosis or treatment of a particular condition

3. Peer-reviewed, evidence-based medical literature indicates the service requested is not generally recognized as the accepted standard treatment for the disease or condition from which the patient suffers

4. Peer-reviewed, evidence-based medical literature does not support the safety and effectiveness of the requested service, or insufficient or inconclusive data exists to assess the therapeutic value or positive effects on health outcomes.

   Refer to **'Supplemental Information' section of policy OR MCP-000: Evaluation of New and Existing Technologies (UM 10)** for evidence-based references.

5. Requested service or technology has received FDA or appropriate regulatory approval for marketing and meets **ONE** of the following:
   a. Usage as a part of a treatment or service that has not been FDA approved (e.g., use of an FDA approved drug, device or procedure for an off-labeled use in a novel medical procedure)
   b. Utilization of the requested service or technology is contingent upon a drug, device, therapy, or operation that is investigational or experimental

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUPPLEMENTAL INFORMATION

A service meeting **ALL** the following criteria is **not** defined as experimental/investigational:

1. Device/service must have received final approval from the appropriate regulatory agency (e.g., FDA)

2. Scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the service or technology indicates the following:
   a. Proven beneficial impact of the service/technology on health outcomes for the specified indication
   b. The technology is as effective as established technology for the specified indication

3. The outcomes for the specified indication must be attainable outside investigational or experimental settings

Peer-reviewed scientific/medical literature: The most recent peer-reviewed scientific studies published or accepted for publication by nationally recognized medical journals or biomedical compendia such as The American Hospital Formulary Service-Drug Information (AHFS-DI), The National Comprehensive Cancer Network Drugs & Biologics Compendium (NCCN), The Thomson Micromedex® DRUGDEX®, The Elsevier Gold Standard's Clinical Pharmacology) or any other authoritative compendia as recognized periodically by the United States Secretary of Health and Human Services.

APPROVAL HISTORY

06/12/2024	Policy reviewed. No changes to coverage criteria.
06/14/2023	Policy reviewed. No changes to coverage criteria.
06/08/2022	Policy reviewed. Rewrote and added verbiage to overall policy for clarity, including the Overview section; added Related Policies section; rewrote Coverage Policy section; updated Supplemental Information; added References section.
06/09/2021	Policy reviewed. No changes to coverage criteria.
06/17/2020	Policy reviewed. No changes to coverage criteria.
06/19/2019	Policy reviewed. 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.
07/10/2018	Policy reviewed. No changes to coverage criteria.
06/22/2017	Policy reviewed. No changes to coverage criteria.
06/15/2016	Policy reviewed. No changes to coverage criteria.
12/16/2015	Policy reviewed. No changes to coverage criteria.
06/25/2014	New policy.

REFERENCES

1. Centers for Medicare and Medicaid Services. Medicare coverage: Final national coverage decision. Accessed April 8, 2024. https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/Downloads/finalnationalcoverage.pdf.
2. National Committee for Quality Assurance (NCQA). HP standards and guidelines: Appendix 9, glossary, definition of medical necessity determination. “A decision about coverage for a requested service based on whether the service is needed, based on a member's circumstances, or clinically appropriate. A medical necessity review and appropriate practitioner review of experimental or investigational requests are required unless the requested services or procedures are specifically excluded from the benefits plan.” The term “requested service, services or supplies” applies to medical and behavioral healthcare procedures, pharmaceuticals, and devices.