

Department of Origin: Integrated Healthcare Services	Effective Date: 11/11/24
Approved by: Chief Medical Officer	Date Approved: 10/17/24
Clinical Policy Document: Clinical Policy Application, Development, Oversight and Distribution	Replaces Effective Clinical Policy Dated: 09/12/23
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PURPOSE:

The intent of this policy is to outline the processes for clinical policy application, development, oversight and distribution.

POLICY:

Clinical policies do not constitute or substitute for medical treatment or advice, nor do they constitute or substitute for the exercise of independent medical judgment in member-specific matters. They are intended to promote objectivity and consistency in the health care medical necessity determination process and are necessarily general in their approach; therefore, medical discretion must be exercised in their application. All practitioners will have ready access to peer reviewers and criteria to discuss specific member circumstances that do not fall within the stated criteria.

Clinical policies meet the requirements of regulating and accrediting bodies. State and federal mandates are addressed when appropriate.

I. Application

- A. Clinical policy documents are used by Medical Management staff to promote objectivity and consistency in determining the medical appropriateness of health care services.
- B. When information obtained does not meet medical necessity requirements, cases are referred to peer review for consideration of special circumstances, on a case-by-case basis, before a determination is rendered. Appropriate characteristics that will be considered when applicable, include but are not limited to the following:
 1. Age
 2. Comorbidities
 3. Complications
 4. Progress of treatment
 5. Psychosocial situation
 6. Home environment, when applicable
 7. Geographic location/local delivery system when it impacts available services required by the member, such as, but not limited to, the following:
 - a. Availability of mental health, substance use and medical-surgical inpatient, outpatient, residential and transitional facilities.
 - b. Availability of outpatient services in lieu of inpatient services such as -
 - 1) Infusion centers or home infusion versus inpatient hospital; or
 - 2) Intensive outpatient mental health or substance use treatment versus inpatient; or
 - 3) Surgicenters versus inpatient hospital.
 - c. Availability of highly specialized services, such as transplant facilities or cancer centers.
 - d. Availability of skilled nursing facilities, subacute care facilities, or home care in the organization's service area to support the patient after hospital discharge.

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- e. Local hospitals' ability to provide all recommended services within the estimated length of stay.

II. Development

- A. Need for clinical policy is identified based on the following:
 1. Variation in practice: There is variation in medical practice and/or complex clinical decision making is required for determining treatment options.
 2. Evidence: Clinical evidence exists that defines appropriate member selection or exclusion criteria.
 3. Utilization patterns: Clinical diagnosis or treatment occurs frequently in medical practice, involves a large population, and/or is associated with high costs.
 4. External organizations' policies: Concerns for quality or coverage result in criteria or guideline development by governmental agencies (such as, but not limited to, Advisory Committee on Immunization Practices [ACIP] Agency for Healthcare Research and Quality [AHRQ], United States Preventive Services Task Force [USPSTF], regulatory bodies, and/or professional societies.
 5. Unclear benefit language where further direction is required
 6. State or federal mandates need clarification or direction
- B. Drafting, sources, annual review, revision and adoption
 1. Health plan staff (such as, but not limited to, Medical Policy, Medical Management, Pharmacy, Chief Medical Officer, Medical Directors and other appropriate physicians) may draft new clinical policy documents.
 - Health plan staff from other departments (such as, but not limited to, Claims, Coding, Compliance, Legal, Network Management, Sales, etc.) are consulted as needs are identified.
 2. Sources for content include, but are not limited to, the following:
 - a. Medical/surgical (including behavioral health [mental health/substance related disorders]) clinical policies are based on available scientific literature, including but not limited to, government agencies, expert professional practice guidelines, specialty/professional society guidelines, technology assessment bodies, point of care synthesized resources, peer-reviewed journal articles, and/or expert consensus opinion.
 - b. Pharmacy clinical policies (including step therapy protocols) are based on U.S. Food and Drug Administration (FDA) approved labeling, contracted pharmacy benefit manager's (PBM) drug class reviews, government agencies, medical associations, national commissions, peer-reviewed journals, authoritative compendia, scientific literature, expert professional practice guidelines, specialty/professional society guidelines, technology assessment bodies, point of care synthesized resources, and/or expert consensus opinion.
 3. Annual review and/or revision
 - a. Clinical policies are reviewed annually, or more frequently when a need is identified, for continued usefulness and appropriateness.

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- b. Revisions are based on any of the following:
 - 1) An abbreviated search of scientific literature, expert professional practice guidelines, and specialty/professional society organizations; to assess for changes to previous positions.
 - 2) A change in status of medications, such as, but not limited to, FDA approvals, FDA withdrawals, FDA warnings or instructions.
 - 3) A PBM drug class review.
 - 4) A change in expert consensus opinion.
 - 5) Health plan medical/surgical (including behavioral health [mental health/substance related disorders]) and pharmacy impact and utilization data may also be incorporated.
 - 6) Benefit language and state and federal mandates are assessed to determine if any changes to clinical policies are required.
4. Adoption of external criteria or guidelines based on sound medical evidence and reviewed and approved by the appropriate physician or provider specialty may be adopted for health plan medical necessity decision making. This includes, but is not limited to, the following:
 - a. Centers for Medicare and Medicaid Services (CMS) or National Committee for Quality Assurance (NCQA) accredited health plans' criteria or guidelines.
 - b. Delegated entities' criteria or guidelines.
 - c. Expert professional practice guidelines or specialty/professional society guidelines. This includes, but is not limited to, local and national physician associations, National Comprehensive Cancer Network (NCCN), or American College of Radiology (ACR).
 - d. NCQA or Utilization Review Accreditation Commission (URAC) accredited or contracted PBM criteria or guidelines.

III. Oversight by expert review and approval

- A. Health plan internally developed clinical policies
 1. All action (newly developed, annual review, and revision) on health plan internally developed clinical policies require approval from the Chief Medical Officer or appropriate physician. Clinical Policy documents that have been approved by the Chief Medical Officer or appropriate physician may be used as a reference for medical necessity determinations until the policy is approved by the applicable oversight entity. This includes mid-cycle revision of a pharmacy clinical policy due to a change in status or availability of medications.
 2. Medical necessity determination elements within the policy documents (newly developed, annual review and clinical revision) are brought to the applicable oversight entity for expert review and approval.
 - a. A quorum of 50% must be present and greater than 50% of "Yes" votes are required for approval.
 - b. As an alternative to a formal presentation, a ballot process may be utilized for approval of newly developed or revised clinical policies.
 - 1) Ballot process is being used in place of a formal meeting
 - a) A quorum of 50% of ballots must be received and unanimous "Yes" votes are required for approval
 - b) If less than a quorum response, or any "No" votes are received, the policy is not accepted via ballot and is brought to the next formal meeting for discussion and action

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- c) Minutes reflecting the ballot process are generated and submitted to the oversight entity for review and action.
- 2) Ballot process is being used as an adjunct to a formal meeting
 - a) A quorum of 50% of ballots must be received and unanimous “Yes” votes are required for approval
 - b) If less than a quorum response, or any “No” votes are received, the policy is not accepted via ballot. The policy is discussed at the oversight entity meeting for discussion and action
 - c) The ballot process is reflected in the meeting minutes
- 3. Benefit coverage determination elements within the policy documents are brought to the applicable oversight entity for informational purposes.
- 4. Retirement of clinical policies are brought to the applicable oversight entity for informational purposes and are based on any of the following:
 - a. Benefit language changes
 - b. Change in a law or mandate
 - c. Utilization pattern changes, such as but not limited to:
 - 1) Minimal requests for the health care service over the past year.
 - 2) Utilization of health care service has become community standard, there is no longer a variation in practice and members are being selected appropriately as evidenced by the absence of any denials over the past year.

[Note: Retired clinical policies may be re-adopted following the applicable processes outlined above.]

- B. Adopted external criteria or guidelines for medical necessity determination
 - 1. If the health plan adopts external criteria or guidelines that are based on sound medical evidence and reviewed and approved by the expert specialty service practitioners, health plan oversight entity voting action is not required.
 - 2. Notice of adoption of external criteria or guideline is bought to the applicable oversight entity for informational purposes.

IV. Methods of distribution to members and providers

- A. Available on internet on health plan web site
- B. Notice of newly approved clinical policies and revisions are published in the provider newsletter
- C. Clinical policies are available upon request

REFERENCES:

- 2024 NCQA Standards and Guidelines for the Accreditation of Health Plans
 - UM 2: Clinical Criteria for UM Decisions
 - UM 11: Procedures for Pharmaceutical Management

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