


ADMINISTRATIVE GUIDELINE – 10.01.511

Medical Policy and Clinical Guidelines: Definitions and Procedures

Effective Date:	Sept. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Aug. 12, 2024	10.01.504 Technology Review
Replaces:	N/A	

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Introduction

This document provides an overview of how medical policies and clinical guidelines are created, approved, and updated. The Plan clinical review staff use medical policies, clinical guidelines, and member contract language to make clinical coverage decisions on certain services. This document defines some of these terms.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Administrative Guideline

Services	Specifics
Medical Surgical Behavioral health Dental	This document defines terminology and outlines the processes used to develop, approve, and modify the Plan medical policies and clinical guidelines used by staff to make clinical and benefit coverage decisions. Medical policies and clinical

Services	Specifics
Pharmacy Ancillary care Level or site of care	<p>guidelines may address any of the types of services listed in the column to the left.</p> <p>Medical policies may also provide additional clarification of contract language regarding benefits or administrative guidelines.</p> <p>Many of the Plan's medical policies are adopted or modified from the Blue Cross Blue Shield Association (BCBSA) Evidence Positioning System. When evidence-based medical outcomes, new peer-reviewed medical literature, local medical standards, or state or federal mandates warrant, the Plan may create a new policy or modify an existing policy.</p> <p>Note: The use of medical policies is always secondary to member contract provisions, restrictions and exclusions. The member contract always supersedes clinical review criteria the Plan adopts.</p>

Coding

N/A

Related Information

Definition of Terms

Administrative guideline: A document that supports or explains administrative functions related to medical policies, clinical guidelines, or benefit language. The guideline may support clinical decision-making.



Benefit coverage guideline: A benefit coverage guideline generally begins with contract language and provides coding or administrative examples to assist clinical reviewers in consistent decision making.

Experimental or investigational: Experimental or investigational services include a treatment, procedure, equipment, drug, drug usage, medical device, or supply that meets one or more of the following criteria as determined by the Company:

- A drug or device that cannot be lawfully marketed without the approval of the U. S. Food and Drug Administration and has not been granted such approval on the date the service is provided.
- The service is subject to oversight by an Institutional Review Board.
- No reliable evidence demonstrates that the service is effective in clinical diagnosis, evaluation, management, or treatment of the condition.
- The service is the subject of ongoing clinical trials to determine its maximum tolerated dose, toxicity, safety, or efficacy.
- Evaluation of reliable evidence indicates that additional research is necessary before the service can be classified as equally or more effective than conventional therapies.

Reliable evidence includes but is not limited to reports and articles published in authoritative peer-reviewed medical and scientific literature and assessments and coverage recommendations published by the Blue Cross and Blue Shield Center for Clinical Effectiveness.

Medical necessity/medically necessary: Those covered services and supplies that a physician, exercising prudent clinical judgment, would provide to an individual for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease, or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the individual's illness, injury, or disease; and
3. Not primarily for the convenience of the individual, physician, or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that individual's illness, injury, or disease.



For these purposes, “generally accepted standards of medical practice” means standards that are based on reliable scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and the views of physicians practicing in relevant clinical areas and any other relevant factors. The fact that services were furnished, prescribed, or approved by a physician or other qualified provider does not in itself mean that services were medically necessary.

Medical policy: A medical policy is generally based on the highest level of evidence available and addresses new or evolving technologies, drugs, services, or supplies. The policy usually establishes medical necessity or investigational status for the service, drug or device being addressed.

Utilization management guideline: A utilization management guideline is generally based on evidence, professional guidelines, clinical effectiveness data, and best practices.

Note: A small number of member contracts may contain differing definitions of investigational or medically necessary services. The member booklet should be consulted for the definitions of investigational and/or medically necessary for that group.

Administrative Review

Description

Development and Approval Process

Medical policies are Plan documents used to support coverage decisions for specific medical, surgical, or dental procedures, and behavioral health services, drugs, other ancillary services, or devices. Medical policies frequently address medical necessity or investigational status based on the contract definitions.

Sources used in creating medical policies include but are not limited to the following:

- Blue Cross and Blue Shield Association (BCBSA) Evidence Positioning System
- Hayes Inc. Knowledge Center
- National Comprehensive Cancer Network (NCCN)



- UpToDate
- Recommendations or guidelines from national physician specialty organizations
- Reliable scientific evidence published in peer-reviewed scientific literature is generally recognized by the relevant medical, pharmacy, and dental communities.
- Input from practicing physicians
- Materials from independent review organizations and any other clinically relevant factors
- Legal statutes, or state, or federal mandates

Plan medical policies are developed, reviewed, and revised by registered nurses, physicians, dentists, and/or pharmacists. This work is done with the support of Plan Medical Directors. The Plan Medical Policy Committee, composed of licensed health care professionals, approves the medical policies. The Medical Policy Committee reviews all new and revised medical policies during the Medical Policy Committee meeting or by electronic vote.

Medical policies are reviewed at least once per year but may have more frequent reviews based on changes in the scientific literature or clinical practice standards.

The Medical Policy Committee meets as needed to fulfill its mandate, at least nine times a year. The Medical Policy Committee is part of the Plan's quality improvement program, overseen by the Chief Medical Officer.

Publication Process

After approval of a new or revised medical policy, it will be available in an electronic format on the effective date, the first day of the month following approval.

References

N/A



History

Date	Comments
06/06/09	Policy numbered to allow listing as an Administrative Policy.
06/08/10	Added National Comprehensive Cancer Network to development and approval process section.
08/19/11	Replace Policy. Policy converted to new policy format, policy sections rewritten and reordered to support the new format, electronic voting, Pharmacist involvement in policy updates/development, and ICD-10 codes added to coding section.
08/14/12	Replace Policy. Minor edits made for clarity. No change to the intent of the policy.
10/10/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
07/08/13	Replace policy. MCG™ and Up-To-Date added as resources. Clarification added regarding differing member contract definitions of investigational and medically necessary services. Information on medical policy formatting and sample medical policy format deleted. Other minor edits made.
05/05/14	Annual Review. Clarification added on other sources used in revising or creating medical policy. "On occasion, Medical Policies may be developed and revised based solely on legal statute, state or federal mandates in lieu of the resources described above".
10/23/14	Update Related Policies. Add 10.01.517.
12/22/14	Interim update. Description section updated by removing MCG™ from the list of sources utilized in developing and adopting medical policies; clarifying statement added that medical policies with updates related to formulary changes, and not on the basis of evidence of new literature, do not require MPC approval.
07/14/15	Annual review. Edits and formatting changes to improve readability; intent is unchanged. Added DynaMed to the list of sources. Added definitions of benefit coverage guideline, medical policy, and utilization management guideline. Title changed to Medical Policy and Clinical Guidelines: Definitions and Procedures.
02/09/16	Annual Review. Minor editing: intent is unchanged.
04/01/16	Interim Review, approved March 8, 2016. Policy updated to reflect effective and publication date now the first day of the month following approval.
02/01/17	Annual Review, approved January 10, 2017. Moved to new format, no change in statements. Definition of administrative guideline added to Definition of Terms. Removed DynaMed from the list of sources.
02/01/18	Annual Review, approved January 9, 2018. Policy edited for clarity. No change to policy statement.



Date	Comments
05/19/18	Minor update. Corrected Technology Evaluation Center (TEC) to Blue Cross and Blue Shield Center for Clinical Effectiveness. No other changes.
02/01/19	Annual Review, approved January 4, 2019. Administrative guideline reviewed. Replaced the term "Medical Policy Reference Manual" with "Evidence Positioning System" in guideline statement.
06/01/20	Annual Review, approved May 21, 2020. Guideline reviewed. Guideline statements unchanged.
03/01/21	Annual Review, approved February 2, 2021. Administrative guideline reviewed. Guideline statements unchanged.
03/01/22	Annual Review, approved February 7, 2022. Administrative guideline reviewed. Guideline statements unchanged. Removed ECRI from the resource list.
08/01/23	Annual Review, approved July 24, 2023. Administrative guideline reviewed. Guideline statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
09/01/24	Annual Review, approved August 12, 2024. Administrative guideline reviewed. Sources updated. Oversight officer updated. Guideline statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

