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MEDICAL POLICY – 10.01.504

Technology Review

		RELATED MEDICAL POLICIES / GUIDELINES:	
Effective Date:	Mar. 1, 2025	10.01.511	Medical Policy and Clinical Guidelines: Definitions and Procedures
Last Revised:	Feb. 24, 2025	10.01.520	Review for Coverage in the Absence of a Medical Policy, Pharmacy Policy, or Utilization Management Guideline
Replaces:	N/A		

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

To determine if a new technology may be covered, teams of doctors, pharmacists, and nurses review new drugs and medical services. The Medical Policy Committee reviews new technology and other medical or surgery services. The Pharmacy and Therapeutics Committee reviews new drugs and some therapies. These committees decide if a new drug or service will be covered. Their decisions are based on sound studies. Their decisions help protect against the use of treatments that are not proven or not safe. This policy describes how new technologies are reviewed and the resources used to determine coverage criteria.

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.

Policy Coverage Criteria

The Medical Policy Committee (MPC) members and Medical Directors evaluate new technology, including medical and behavioral health procedures, pharmaceuticals, and devices, to determine

whether the service(s) meet contractually defined coverage criteria. Behavioral Health, Dental, and Pharmacy Professionals are included in the Medical Policy Committee membership.

Review	Resources
Technology reviews occur in the context of the Medical Policy Committee or in determinations when an individual member or provider requests coverage of: • **A new technology** • **A change to an existing technology**	**The technology review process may include, but is not limited to, the following resources:** • Agency for Healthcare Research and Quality (AHRQ) • Blue Cross Blue Shield Association (BCBSA) Evidence Positioning System • Clinical trial data • Company Medical Policy Manual • Consultation with local physicians with expertise in the relevant field or specialty, including behavioral health and chemical dependency • Applicable medical scientific data or information found by an Internet search, including manufacturer's website, if available • Hayes, Inc. Knowledge Center a Symplr company (©2024 Hayes, a Symplr company) • Independent external advisory group or medical specialty association recommendations • Institute for Clinical Systems Improvement (ICSI) • National physician specialty society guidelines and recommendations • PUBMED or other scientific literature databases, with an emphasis on credible scientific evidence in peer-reviewed medical literature generally recognized by the relevant medical community • Regulatory rulings and publications (e.g., FDA status and State specific office of insurance commissioner (OIC) regulations) • Up-To-Date (Wolters Kluwer Health, ©2024, UpToDate, Inc.)

Coding

N/A

Related Information

Definition of Terms

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.

Experimental/Investigational Services:

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:

- A drug or device that cannot be lawfully marketed without the approval of the US Food and Drug Administration (FDA) 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.

Cosmetic Services:

Plans typically do not cover drugs, services, or supplies for cosmetic services. This includes services performed to reshape normal structures of the body in order to improve or alter an individual's appearance and not primarily to restore an impaired function of the body.

Evidence Review

Description

The Company regularly evaluates new and developing medical, behavioral health, dental, and pharmacy applications of technologies, drugs, and services to determine if published scientific evidence supports the safety, efficacy, and appropriate use of the proposed services. Using the general principles of research methodology as a consistent approach to evaluating new technologies promotes adherence to the standards of the National Committee for Quality Assurance (NCQA), a private, not-for-profit agency that maintains accreditation standards for health plans.

The Medical Policy Committee and Medical Directors use the five BCBSA Technology Evaluation Center (TEC) criteria listed below to assess new and evolving technology:

1. The technology must have final approval from the appropriate governmental regulatory bodies

- This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the FDA or any other federal governmental body with authority to regulate the technology.
- Any approval that is granted as an interim step in the FDA's or any other federal governmental body's regulatory process is not sufficient.
- The indications for which the technology is approved need not be the same as those which Blue Cross and Blue Shield Association's Technology Evaluation Center is evaluating.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
   - The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
   - The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.
   - Opinions and evaluations by national medical associations, consensus panels, or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.
3. The technology must improve the net health outcome.
   - The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
4. The technology must be as beneficial as any established alternatives.
   - The technology should improve the net health outcome as much as, or more than, established alternatives.
5. The improvement must be attainable outside the investigational settings.
   - When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy TEC criteria in numbers 3 and 4 above.

The above criteria are listed in the majority of member contracts as the threshold to define services that are investigational. A given technology, drug or service must meet all of the criteria listed above. Failure of a technology, drug, or service to meet any one of the criteria results in a designation of that service as investigational (or experimental and investigational) and therefore excluded by the member's contract.

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

References

N/A

History

Date	Comments
03/12/96	Add to Managed Care Policy Manual - Initial documentation of process
10/06/98	Revise and Update - Transfer to Premera Medical Policy Manual Introduction Section
10/05/99	Add to Administrative Section - Formatted as a Policy and removed from Introduction Section of Manual
07/10/01	Replace Policy - Scheduled review; revised for clarity.
12/10/02	Replace Policy - Policy reviewed; no criteria changes.
12/09/03	Replace Policy - Scheduled review; no criteria changes.
09/01/04	Replace Policy - Policy renumbered from PR.10.01.104. No date changes.
12/14/04	Replace Policy - Scheduled review; no criteria changes.
11/11/05	Replace Policy - Scheduled review; no criteria changes.
05/26/06	Scope and Disclaimer language update only. No other changes.
12/12/06	Replace Policy - Scheduled review, revised for clarity. No change to the policy statement.

Date	Comments
07/10/07	Replace Policy - Policy updated with BCBSA TEC criteria added to Description section and inclusion of information on Physician Specialty Society review board.
06/10/08	Replace Policy - Scheduled review; no criteria changes.
12/16/08	Replace Policy - Policy updated to include BCBSA and Premera policies to description section.
11/10/09	Replace Policy - Scheduled review; no criteria changes.
12/14/10	Replace Policy - Scheduled review; no criteria changes.
12/13/11	Replace Policy – Scheduled review. Policy updated with language to include behavioral health procedures, pharmaceuticals and devices, to address whether the services meet contractually defined coverage criteria.
09/11/12	Replace policy. Scheduled review; no criteria changes.
07/08/13	Replace policy. MCG™ and Up-To-Date added as resources. Guideline description of review process reformatted. Clarification added regarding differing member contract definitions of investigational service.
06/13/14	Annual Review. Added the full name for the acronym "ICSI" to Policy Guidelines. Moved resources from Description to Policy Guidelines. Reformatted list of resources in Policy Guidelines to alphabetical order. Expanded Description section to include NCQA reference as a health plan accreditation provider.
09/08/14	Interim review. Notation added within Policy section to indicate that MPC membership includes Behavioral Health Professionals; Policy Guidelines updated in support of this change.
12/22/14	Interim update. MCG™ removed from the list of possible technology sources used in policy development.
07/14/15	Annual Review. Added dental and pharmacy professionals as members of the Medical Policy Committee (MPC) to the Policy section. Added the full name for the acronym "BCBSA". Minor edits for readability. Policy section revised as noted.
02/09/16	Annual Review. No changes.
02/01/17	Annual Review, approved January 10, 2017. Policy moved into the new format. Current copyright dates now reflected, no other changes.
02/01/18	Annual Review, approved January 9, 2018. Policy edited for clarity. No other changes.
02/01/19	Annual Review, approved January 4, 2019. Policy reviewed. Updated applicable copyright dates. Replaced the term "Medical Policy Reference Manual" with "Evidence Positioning System" in guideline statement. Added BCBSA Evidence Street to list of resources and removed BCBSA Technology Evaluation Center Assessments.
03/01/20	Annual Review, approved February 4, 2020. Policy reviewed. ECRI Institute added to list of resources; otherwise policy remains unchanged.

Date	Comments
02/01/21	Annual Review, approved January 21, 2021.Policy reviewed Applicable copyright dates updated; otherwise policy unchanged.
06/01/21	Interim Review, approved May 4, 2021. Added definition of terms: medically necessary, experimental/investigational, and cosmetic for clarity.
03/01/22	Annual Review, approved February 7, 2022. Policy reviewed. Updated applicable copyright dates; otherwise policy remains unchanged.
02/01/23	Annual Review, approved January 9, 2023. Policy reviewed. ECRI Institute removed from the list of resources used in review of new technology. Updated applicable copyright dates. Changed the wording from "patient" to "individual" throughout the policy for standardization.
03/01/24	Annual Review, approved February 12, 2024. Policy reviewed. The listed resource MEDLINE scientific literature database changed to PUBMED scientific literature database. Updated applicable copyright dates.
03/01/25	Annual Review, approved February 24, 2025. Policy reviewed. Policy remains 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).

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 applies to all Company lines of business except Medicare Advantage.