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BENEFIT COVERAGE GUIDELINE – 10.01.518

Clinical Trials

		RELATED MEDICAL GUIDELINES/POLICIES:
Effective Date:	Mar. 1, 2025	5.01.549 Off Label Use of Drugs and Biologic Agents
Last Revised:	Feb. 24, 2025	10.01.517 Non-covered Services and Procedures
Replaces:	N/A	10.01.533 Non-covered Experimental/Investigational Services

Select a hyperlink below to be directed to that section.

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RELATED INFORMATION | RATIONALE | REFERENCES | HISTORY

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Introduction

A clinical trial is a research study that uses human volunteers. These studies are designed to answer questions about how a treatment (drug, medical device, biologic agent, gene therapy or surgery) might work for a specific disease. Some studies also test new approaches to diagnosing, preventing or testing for diseases. Based on the specific plan you are covered under and where you live, the health plan will cover the usual medical costs when you decide to participate in certain clinical studies. The decision to participate in a clinical study is made by you and your doctor, based on your disease or condition, and what treatments are available to you. This policy provides background about different types of studies, outlines what services the plan covers when you participate in a study and includes references to laws that govern what types of studies are covered under your specific type of plan.

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 providers about when a service may be covered.

Coverage Guideline

This guideline includes requirements of the Patient Protection and Affordable Care Act (PPACA) for non-grandfathered plans and Washington and Alaska state mandates regarding clinical trial coverage. See **Mandate Information** for state-specific information.

This guideline does not apply to the BCBS Federal Employee Program (FEP). Please refer to BCBS Service Benefit Plan for FEP.

Service	Coverage Criteria
Clinical trial participation	**Routine patient care costs that occur during participation in an approved clinical trial for qualified individuals for treatment of cancer or other life-threatening disease or condition* are eligible for coverage when ALL of the following criteria are met:** • The individual meets the eligibility requirements of the approved clinical trial according to the trial protocol • The individual's participation in the approved clinical trial is appropriate for the treatment of cancer or other life-threatening disease* as documented by a referring health care professional **OR** by the medical and scientific information provided by the individual • The individual has provided signed **informed consent** **AND** • The study in which the individual requests participation is a **Phase I**, **Phase II**, **Phase III** or **Phase IV** clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition* and is funded or approved by ONE of the following: ○ National Institutes of Health (NIH) (includes National Cancer Institute [NCI]) ○ Centers for Disease Control and Prevention (CDC) ○ Agency for Healthcare Research and Quality (AHRQ) ○ Centers for Medicare and Medicaid Services (CMS) ○ A cooperative group or center of any of the entities noted above or the Department of Defense (DOD) or the Department of Veterans Affairs ○ A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants

Service	Coverage Criteria
	○ The Department of Veterans Affairs, the Department of Defense, or the Department of Energy if the study or investigation has been reviewed and approved through a system of peer review that the Secretary of Health and Human Services determines to be comparable to the system of peer review used by the NIH, and assures an unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review **OR** ○ The study is conducted under an investigational new drug (IND) (see **definition** below) application reviewed by the Food and Drug Administration **OR** ○ The study is a drug trial that is exempt from having an investigational new drug application **OR** ○ An **institutional review board (IRB)** of an institution in Washington state that has a multiple project assurance contract approval by the Office of Protection for the Research Risks of the NIH (see **Washington mandate** below) **Clinical trial or other study participation is considered investigational if the criteria above are not met.** **Note:** The clinical trial must have a written protocol that describes a scientifically sound study that has been approved by all relevant IRBs before participants are enrolled in the trial **Note:** A patient registry is not considered a clinical trial ***** "life-threatening disease or condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted (death need not be imminent for a disease or condition to be life-threatening) Search **www.ClinicalTrials.gov** for a registry of federally and privately supported clinical trials

Service	Coverage Criteria
Routine patient costs covered during a clinical trial	**Covered routine patient care costs for an enrolled member in an approved clinical trial at the time coverage of routine costs is requested include: (see Benefit Application)** • Items and services that are consistent with the coverage that applies to routine care for individuals not enrolled in clinical trials such as laboratory services, radiologic services, office visits, hospital services, etc. • Items or services that are needed for the reasonable and necessary care used to prevent, diagnose, and treat complications arising from participation in the approved clinical trial

Patient costs NOT covered during a clinical trial	**Routine patient costs NOT eligible for coverage include:**
	• The drug, item, or service being studied (unless the drug, item or service is covered outside a clinical trial for other members)
	• Items and services provided solely for data collection and analysis needs that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition where one single scan is the standard of care for the diagnosis or treatment studied)
	• Items and services provided free of charge by the research sponsors for anyone enrolled in the trial
	• A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis
	• Travel and transportation expenses (unless otherwise covered by the plan) including, but not limited to, the following:
	  ○ Fees for personal vehicle, rental car, taxi, medical van, ambulance, commercial airline, or train
	  ○ Mileage reimbursement for driving a personal vehicle
	  ○ Lodging
	  ○ Meals
	
	Note: After a clinical trial ends, coverage is **not** provided for non-FDA approved drugs that were provided or made available to an individual during a covered clinical trial.

State	Mandate Information
Alaska fully insured (See below for self-funded groups)	Effective September 29, 2010, Alaska has a specific state statute (Senate Bill 10) that requires health care insurers to provide insurance coverage for medical care received by a patient during certain approved clinical trials designed to test and improve prevention, diagnosis, treatment, or palliation of cancer. More information regarding covered and non-covered services and other administrative criteria can be found at the following link: **http://www.akleg.gov/basis/Bill/Text/26?Hsid=SB0010Z**. Accessed January 30, 2025. **Note**: This state mandate addresses clinical trials related only to cancer.
Alaska self-funded groups	**The Alaska state mandate does not generally apply if the group is self-funded. However, some self-funded groups may elect to add state mandates or similar provisions to their contracts. If the member is in a self-funded group, please check the member contract for benefits regarding clinical trials or how the group defines experimental and investigational services. The provisions for clinical trials or definitions of what is considered experimental and investigational should be administered as outlined in the group's health plan contract.** **Note:** In the absence of contract language addressing clinical trials, the criteria of this policy should be applied to members covered by self-funded group health plan contracts.
Washington fully insured (see below for self-funded groups)	Effective November 8, 2012, Washington has a specific Washington Administrative Code (WAC284-43-850 recodified as WAC284-43-5420 effective 12/14/15) that mandates benefit coverage for the routine costs of patients enrolled in and participating in qualifying phase I, phase II, phase III, or phase IV clinical trials. More information regarding covered and non-covered services and other administrative criteria can be found at the following link: **http://apps.leg.wa.gov/WAC/default.aspx?cite=284-43-5420**. Accessed January 30, 2025. **Note:** This mandate addresses clinical trials related to cancer or other life-threatening disease or condition.
Washington self-funded groups	**The Washington state mandate does not generally apply if the group is self-funded. However, some self-funded groups may elect to add state mandates or similar provisions to their contracts. If the member is in a self-funded group, please check the member contract for benefits regarding clinical trials or how the group defines experimental and investigational services. The**

State	Mandate Information
	provisions for clinical trials or definitions of what is considered experimental and investigational should be administered as outlined in the group's health plan contract. **Note:** In the absence of contract language addressing clinical trials, the criteria of this policy should be applied to members covered by self-funded group health plan contracts.

Documentation Requirements
The individual's medical records submitted for review for participation in an approved clinical trial for the prevention, detection or treatment of cancer or other life-threatening disease or condition should document that these requirements are met. The record should include ALL of the following: • History and physical supporting the individual has cancer or a life-threatening condition that has a poor response to the most effective treatment currently available • Clinical trial name and the NCT number • The trial is phase I, II, III or IV and has been approved by the National Institutes of Health (NIH) or an organization affiliated with the NIH, or a Washington state institution institutional review board (IRB) or the departments of Veterans Affairs or Defense, or Energy • The individual's medical records demonstrate the member has signed consent to participate in a clinical trial • Or, if for an investigational new drug (IND) application reviewed by the FDA, the application number is given, or documentation is provided that indicates the study is exempt from an investigational new drug application

Coding

Code	Description
HCPCS	
S9988	Services provided as part of a Phase I clinical trial
S9990	Services provided as part of a Phase II clinical trial
S9991	Services provided as part of a Phase III clinical trial

Code	Description
ICD-10-Diagnosis	
Z00.6	Encounter for examination for normal comparison and control in clinical research program
Modifiers	
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study **Note:** Clinical trial claims are not limited to these modifiers.
Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study **Note:** Clinical trial claims are not limited to these modifiers.

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Benefit Application

Benefit determinations will be made in accordance with the following:

- All applicable plan limitations for coverage of out-of-network care will apply to routine patient care costs in clinical trials. (For example, plans are not required to provide benefits for routine patient care services provided outside of the network area unless out-of-network benefits are otherwise provided under the plan)
- All utilization management guidelines and coverage policies that apply to routine care for members not in clinical trials will also apply to routine patient care for members in clinical trials.
- Members must meet all applicable plan requirements for preauthorization, eligibility, and referrals.
- In the event a claim contains charges related to covered clinical trial services, but those charges have not been or cannot be separated from costs related to non-covered services, benefits will **NOT** be provided.

- Services may be approved for coverage as part of a qualifying clinical trial when they would typically be covered by the health plan for a member who is not enrolled in a clinical trial. The services will be provided under the applicable benefit category (e.g., pharmacy, durable medical equipment, medical care, etc.). Services may not be covered by the plan if they are fully funded by another source and are provided as part of the clinical trial.

Definition of Terms

Informed consent: The process of learning the risks and potential benefits, and any alternatives of a clinical trial before an individual decides to participate. An individual signs an informed consent prior to enrolling in a study, acknowledging they have been given this information and with the understanding that the individual can withdraw from a study at any time, even if the study has not been completed.

Institutional Review Board (IRB): An IRB is a panel of scientists and non-scientists in hospitals and research institutions that oversees clinical research. IRBs approve the clinical trial protocols, which describe the type of people who may participate in the clinical trial, the schedule of tests and procedures, the medications, and dosages to be studied, the length of the study, the study's objectives and other details. IRBs make sure the study is acceptable, that participants have given consent and are fully informed of their risks, and that researchers take appropriate steps to protect individuals from harm.

Investigational New Drug (IND):** In an IND application, sponsors - companies, research institutions, and other organizations that take responsibility for marketing a drug - must show the FDA results of pre-clinical testing they've done in laboratory animals and what they propose to do for human testing. At this stage, the FDA decides whether it is reasonably safe to move forward with testing the drug on humans. Drug studies in humans can begin only after an IND is reviewed by the FDA and a local IRB. Drugs with a treatment IND may not be marketed.

**drug as defined by the Food, Drug, and Cosmetic (FD&C) Act (section 201 [g][1]) includes, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease…"and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Biological products subject to licensure under the Public Health Service Act (section 351 42 USC 262) may also be considered drugs within the meaning of the FD&C Act. A biological product is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a

disease or condition of human beings. Biological products include, among other products, bacterial vaccines, allergenic extracts, gene therapy products, growth factors, cytokines, and monoclonal antibodies."[4]

Phase of clinical trial: The progress of a clinical trial is categorized by the "phase" category assigned. Most trials can be categorized into one of four phases. A generally accepted categorization follows. Note that the cohort size is not absolute and there are exceptions.

Note: In any phase of a treatment clinical trial, the FDA can impose a clinical hold if the treatment is found to be unsafe or if the protocol is clearly deficient in design in meeting its stated objectives. **Institutional Review Boards (IRBs)** also may cause a trial to be suspended if some aspect of the study is found to be unsafe.

Phase I clinical trial: The therapeutic intervention is tested in a small group of people (20-80) for the first time to evaluate its safety and effectiveness. Phase I studies may determine the metabolic mechanism of action of the treatment in humans. In the case of drug trials, the side effects associated with increasing doses, drug metabolism and structure-activity relationships may be examined. The primary focus is on safety.

Phase II clinical trial: The treatment is applied to a larger group of people (100-300) to further evaluate effectiveness and safety. In drug studies, this phase often consists of pilot studies which may be open label, single or double blind.

Phase III clinical trial: The treatment is applied to large groups of people (1000-3000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow safe use of the treatment.

Phase IV clinical trial: The treatment continues to be tested after marketing approval of the device or drug has been given by the Food and Drug Administration (FDA). This testing is performed to collect information about the effect in various populations and any side effects associated with long-term use.

Registry: "A registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes."[3]

NIH definition of a clinical trial: A research study in which one or more human subjects are prospectively assigned* to one or more interventions** (which may include placebo or other control) to evaluate the effects of those interventions on health-related*** biomedical or behavioral outcomes.

* "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

** "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and diagnostic strategies.

***A "health-related biomedical or behavioral outcome" is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and positive or negative changes to quality of life.

Source: https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm Accessed January 24, 2025

US Food and Drug Administration (FDA) approval: Clinical trials may investigate drugs or devices that have received different types of FDA approval or clearance. Some approvals may allow marketing of drugs or devices; some may approve their use only in investigational settings.

Rationale

Background

The Company may be asked to cover services that are provided within the context of clinical trials. These requests often represent relatively new technology, therapies, or the application of established therapies to treat new or rare diagnoses.

Clinical trials are performed to determine if new treatments and procedures, new drugs, and combinations of drugs, or new devices are clinically safe and effective, and if they should be considered as standard care for individuals in the future. Clinical trials help determine whether a new treatment works as well or better than an existing treatment. Participation in a clinical trial is often considered when standard therapies have failed. Sponsorship of clinical trials can come from federal agencies such as the National Institutes of Health, pharmaceutical and medical device companies, or individual or hospital-based researchers.

Clinical trials are designed and used to research one or more interventions for treating a disease, syndrome, or condition before they are made available to the general public. Examples of these interventions, though not all-inclusive, are new medical products, drugs, devices, radiation

therapy, or surgical procedures. Services, supplies, and drugs that are a standard of care throughout the medical community may have a clinical trial designed to demonstrate their efficacy for a different diagnosis or when they are used in combination with other therapeutic agents. Many clinical trials are designed to study and report therapeutic effectiveness over a prolonged period of time.

Some life-threatening malignant conditions are the subject of clinical trials when the currently available treatments are not known to be effective. During the consecutive phases of some clinical trials, evidence emerges which strongly suggests that the services under study may be as effective, or more effective, than conventional treatment.

In addition, there may be important quality-of-life considerations if preliminary data from clinical trials show medical outcomes that are at least comparable to standard treatment. These quality-of-life issues may include reduction of treatment side effects and simpler treatment strategies.

By providing coverage for members who choose to participate in qualifying trials, the member benefits from having access to new technology that has early evidence of efficacy, often in circumstances where no effective alternative treatments are available.

Clinical trials aid in the advancement of medicine and the improvement of individual outcomes in many areas of healthcare. Whether testing a new therapy or exploring a new way to use an existing therapy, clinical trials measure care and are responsible for breakthroughs in science, as well as key information about treatment risks to different populations.

References

1. Patient Protection and Affordable Care Act; Section 2709. Coverage for individuals participating in approved clinical trials. 2010.. **https://www.dpc.senate.gov/healthreformbill/healthbill53.pdf** Accessed January 24, 2025.
2. Center for Medicare and Medicaid Services (CMS). Routine costs in clinical trials. NCD 310.1, version 2. Effective 07/09/2007. **https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA** Accessed January 24, 2025.
3. Gliklich R, Dreyer N. Registries for Evaluating Patient Outcomes: A User's Guide. Rockville, MD: Agency for Healthcare Research and Quality; 2010. AHRQ Publication No. 10-EHC049.
4. US Food and Drug Administration (FDA). Guidance for clinical investigators, sponsors, and IRBs. investigational new drug applications (INDs)-determining whether human research studies can be conducted without an IND. **https://www.fda.gov/downloads/drugs/guidances/ucm229175.pdf.** Published September 2013. Accessed January 24, 2025.

5. National Cancer Institute (NCI). Cancer clinical trials at the National Institutes of Health clinical center. **https://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/where/clinical-center**. Updated September 6, 2019. Accessed January 24, 2025.
6. National Institutes of Health (NIH). NIH clinical research trials and you.**https://www.nih.gov/health-information/nih-clinical-research-trials-you**. Last reviewed October 3, 2022. Accessed January 24, 2025.
7. US National Library of Medicine National Institutes of Health (NLM-NIH). Clinical Trials.gov Learn about clinical studies. **https://clinicaltrials.gov/ct2/about-studies/learn**. Last reviewed June 10, 2024. Accessed January 24, 2025.
8. National Institutes of Health (NIH). National Institute on Aging. What are clinical trials and studies?. Content last reviewed March 22, 2023. **https://www.nia.nih.gov/health/clinical-trials-and-studies/what-are-clinical-trials-and-studies**. Accessed January 30, 2025.

History

Date	Comments
03/18/05	Add to Administrative Section - New Policy
05/10/05	Replace Policy and move to Medicine, sub-section Oncology - Policy title and policy number changed for clarification purposes.
05/09/06	Replace Policy - Policy reviewed; no change to policy statement.
05/08/07	Replace Policy - Policy reviewed; no changed to policy statement.
01/08/08	Replace Policy - Policy updated with literature review. Policy statement clarified for ease of use, but no substantial change to criteria. Criteria for devices added. Description and Rationale revised. HCPCS codes added.
06/10/08	Cross Reference Update - No other changes.
01/13/09	Replace Policy - Policy statement and guidelines clarified to define routine costs eligible for coverage and costs not eligible for coverage. Intent of policy statement unchanged.
10/13/09	Replace Policy - Benefit Application revised to include Oregon mandate to provide coverage for all clinical trials and links to AZ and OR mandates.
01/12/10	Minor update - Note added at the top of the description section regarding Arizona and Oregon Members to view benefit application.
08/10/10	Replace Policy - Benefit Application revised to add Alaska mandate for cancer clinical trials and delete Arizona mandate.
10/12/10	Minor update - Benefit Application clarified regarding AK and OR mandates and self-funded groups.
09/15/11	Replace Policy – Policy reviewed; no change in policy statements.
10/19/11	Related Policies updated; new title for 5.01.01.

Date	Comments
03/23/12	Replace Policy. Policy reviewed; no change in policy statements.
11/13/12	Replace policy. Policy title changed to "Clinical Trials". All references to "oncology" clinical trials changed to "Clinical Trials". Policy statements revised to meet Washington state specific mandates, which require coverage of routine costs of all qualifying clinical trials phases I-IV when criteria are met. (The prior policy related only to clinical trials phase II-III). Used the PPACA definition of "life threatening condition". Added statement about the PPACA to the benefit application section. Reference 1 added. Added code V70.7. Policy moved to the UM section of the Medical Policy classification index and renumbered; previously 2.03.503, the policy is now 11.01.503.
08/16/13	Replace policy. Policy reviewed; no change in policy statements.
11/20/13	Update Related Policies. Delete 5.01.01 and replace with 5.01.549.
06/24/14	Update Related Policies. Add 8.01.530 and 8.01.531.
09/03/14	Annual Review. Policy reviewed. Literature search through June 2014 did not prompt addition of new references. In Benefit Application section, the hyperlink to Oregon State law is revised. Policy Statement unchanged.
10/23/14	Update Related Polices. Add 10.01.517.
03/10/15	Annual Review. Search through January 2015 did not prompt addition of new references. Policy statement unchanged. Converted to Benefit Coverage Guideline, renumbered from 11.01.503 to 10.01.518.
01/12/16	Annual Review. Policy reviewed. No references added. Guidelines statements unchanged.
06/01/16	Interim Review, approved May 10, 2016. Policy updated to address coverage of complications resulting from participation in a clinical trial.
08/09/16	Policy converted to new policy format; no changes in content or coverage.
01/01/17	Annual Review Policy reviewed, reference added. Coverage statements unchanged.
06/01/17	Minor update. Reformatted Coding section for clarification.
08/01/17	Interim update, approved July 11, 2017. Policy clarification made; requirement for member consent form replaced with records demonstrating member agrees to participate in a clinical trial. No other changes.
05/01/18	Annual Review, approved April 10, 2018. Updated policy with ACA requirements for clinical trials. Deleted CMS requirements and related definitions.
03/01/19	Annual Review, approved February 25, 2019. References 4-8 added. Minor edits made for clarity; otherwise guideline statements unchanged. Added Q0 and Q1 modifier details.
04/12/19	Minor update. Added note that this policy does not apply to the Federal Employee Program (FEP).

Date	Comments
03/01/20	Annual Review, approved February 4, 2020. Benefit coverage guideline reviewed. References updated. Guideline statement added for clarity: "Individual provides informed consent"; otherwise guideline statements remain unchanged. Removed HCPCS codes S9992, S9994, and S9996.
02/01/21	Annual Review, approved January 21, 2021. Benefit coverage guideline reviewed. Guideline statements unchanged.
02/01/22	Annual Review, approved January 24, 2022. Benefit coverage guideline reviewed. Guideline statements unchanged.
02/01/23	Annual Review, approved January 10, 2023. Benefit coverage guideline reviewed. References updated. Added the term "signed" to criteria statement "the individual has provided signed informed consent." Changed the wording from "patient" to "individual" throughout the policy for standardization.
03/01/24	Annual Review, approved February 26, 2024. Benefit coverage guideline reviewed. References updated. Guideline statements unchanged.
03/01/25	Annual Review, approved February 24, 2025. Benefit coverage guideline reviewed. Reference added and updated. Guideline statements unchanged.

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.