Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Coverage of Routine Services Associated with Clinical Trials

Description/Background

Clinical trials, also referred to as research studies, are designed to examine and evaluate the safety and effectiveness of various aspects of medical care. Clinical trials are federally funded and are conducted to prevent, detect or to treat life-threatening diseases or conditions. A life threatening condition or disease includes any disease or condition where the likelihood of death is probable unless the course of the disease or condition is interrupted. Clinical trials test new types of medical care, new uses for existing drugs or treatments or compare the safety and effectiveness of different treatments for the same condition.

All clinical trials are based on a set of rules - a “protocol.” A protocol defines:

- Who can participate in the clinical trial
- The length of the clinical trial
- The frequency of tests and medication
- Other study details and requirements

While in a clinical trial, participants are regularly evaluated by the research staff to monitor their health, as well as the safety and effectiveness of their treatment.

Clinical trials of experimental drugs or treatments proceed through four phases:

- **Phase I:** Researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, to determine a safe dosage range and to identify side effects. Phase I trials do not determine efficacy and may involve significant risks as these trials represent the initial use in human patients.
- **Phase II:** The study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.

- **Phase III:** If a treatment has shown to be effective in Phase II, it is subjected to additional scrutiny in Phase III. In this phase, the sample size of the study population is increased to between 1,000 and 3,000 people. The goals in Phase III are to confirm the effectiveness noted in Phase II, monitor for side effects, compare the study treatment against current treatment protocols, and collect data that will facilitate safe use of the therapy or treatment under review.
- **Phase IV:** These studies are performed after the drug or treatment has been marketed or has become a standard component of patient care. These studies continue testing the study drug or treatment to collect information about the effect in various populations and any side effects associated with long-term use. Phase IV studies are required by the Food and Drug Administration (FDA) when there are any remaining unanswered questions about a drug, device or treatment.

The United States has strict guidelines and safeguards to protect people who choose to participate in clinical trials. Every clinical trial in the U.S. must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. An IRB is an independent committee of physicians, statisticians, community advocates and others that ensure that a clinical trial is ethical and the rights of study participants are protected. All institutions that conduct or support biomedical research involving people must, by federal regulation, have an IRB that initially approves and periodically reviews the research.

Clinical trials are sponsored by government agencies, such as the National Institutes of Health (NIH); pharmaceutical companies; individual physician investigators; health care institutions, such as health maintenance organizations (HMOs); and organizations that develop medical devices or equipment. Trials can take place in a variety of locations, including hospitals, university medical research centers, physician offices or community clinics.

Regulatory Status

U.S. Food and Drug Administration

The FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions, issued on December 5, 2017 states:

"2013 Amendment to 42 CFR 405 Subpart B

> CMS, with FDA's concurrence, published a final rule in the FR on December 10, 2013 (78 FR 74230, 74809) that, among other things, modified the definitions for Category A and Category B. These definitions can be found in the Code of Federal Regulations (CFR) at 42 CFR 405.201:
>
> *Category A (Experimental)*
> 42 CFR 405.201(b): "…a device for which 'absolute risk' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective."

Category B (Nonexperimental/investigational)
42 CFR 405.201(b): "…a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type."

Medical Policy Statement

The cost of routine services of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in approved clinical trials, will be covered. Covered clinical trials may include Phase II, III and IV.

The cost of routine services during Phase I clinical trials are covered only when the purpose is for therapeutic intent.

Inclusionary and Exclusionary Guidelines

Note: Refer to individual certificates for specific guidelines for clinical trials.

Inclusions:

- Costs of routine services associated with clinical trials include all items and services that are otherwise generally available to members receiving an established medical treatment. These include items or services, medical in nature, that are provided in either the experimental or the control arm of a clinical trial:
  - Items or services that are typically provided absent a clinical trial (eg, labs, x-rays, etc.)
  - Items or services required solely for the provision of the investigational item or service (eg, administration of a non-covered chemotherapeutic agent). The clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
  - Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service – in particular, for diagnosis or treatment of complications
  - Item or service that is an IDE device with Category B FDA approval
- For a clinical trial to qualify for coverage of routine costs the following requirements must be met:
  - The subject or purpose of the trial must be the evaluation of an item or service that falls within a benefit category (e.g., physicians' services, durable medical equipment, diagnostic tests) and is not normally excluded from coverage (eg, cosmetic surgery)
  - Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group

Note: The requirements above are insufficient by themselves to qualify a clinical trial for coverage of routine costs. Clinical trials should also have all the following characteristics:

- The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes and not just to test the item's safety

- The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use
- The trial does not unjustifiably duplicate existing studies
- The trial design is appropriate to answer the research question being asked in the trial
- The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully
- The trial complies with Federal regulations relating to the protection of human subjects.
- All aspects of the trial are conducted according to the appropriate standards of scientific integrity

All requests for member participation in a clinical trial must include the appropriate supporting documentation, including:

- A complete description of the clinical trial, including the phase of the trial
- Name of the sponsoring organization (NIH, CDC, etc.)
- Patient selection criteria
- Protocol guidelines
- Patient history including previous treatment therapies
- Appropriate supporting medical literature

Exclusions:

- Routine services for clinical trials that do not meet policy guidelines as defined above
- Services that are not covered in an applicable member benefit certificate or rider
- The investigational item or service, itself
- IDE device with Category A FDA approval
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for condition usually requiring only a single scan)
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial
- Phase I clinical trials whose primary purpose is not for therapeutic intent (eg. prolongation of life, shrinkage of tumor, or improved quality of life, even in absence of cure or dramatic improvement of a condition)
- Travel and transportation expenses. This includes transportation, mileage reimbursement, lodging or meals.
- Use of Transition Technologies in a Clinical Trial

Transition Technologies in Clinical Trials

Transition Technologies are services that meet the following criteria:

1. Represents a new, unique, very different approach to diagnosis or treatment.
2. Has been approved for marketing for five years or less.
3. Has been approved for a very narrow range of indications and/or
4. Represents an extreme, catastrophic level of cost: > than or = 250,000.00 for a course of therapy or one standard use.

Note: Phase IV clinical trials are performed after the product is released. A specific product or service is covered unless there is a medical policy to the contrary. Data collection, data analysis and other costs for the phase IV trial are not covered.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

multiple

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Medicare has approved the costs of routine services associated with qualifying clinical trials since 2000, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.

Under the Public Health Service Act section 2709(a), as added by the Affordable Care Act, if a group health plan or health insurance issuer in the group and individual health insurance market provides coverage to a qualified individual (as defined under PHS Act section 2709(b)), then such plan or issuer: (1) may not deny the qualified individual participation in an approved clinical trial with respect to the treatment of cancer or another life-threatening disease or condition; (2) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and (3) may not discriminate against the individual on the basis of the individual's participation in the trial.

Government Regulations

National:

CMS National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)
Effective Date of this Version 7/9/2007, Implementation Date 5/27/2024

Indications and Limitations of Coverage
Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;

- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, for the diagnosis or treatment of complications.

This policy does not withdraw Medicare coverage for items and services that may be covered according to Local Coverage Determinations (LCDs) or the regulations on category B investigational device exemptions (IDE) found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare Administrative Contractor local policies.

For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in Pub. 100-03, National Coverage Determination (NCD) Manual, and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.

A. Requirements for Medicare Coverage of Routine Costs

Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;

2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

B. Qualification Process for Clinical Trials

Using the authority found in §1142 of the Act (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to CMS.

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.

Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare

coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

The CMS, through the national coverage determination (NCD) process, through an individualized assessment of benefits, risks, and research potential, may determine that certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination, are only reasonable and necessary when provided in a clinical trial that meets the requirements defined in that NCD.

Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified, have certified that they meet the qualifying criteria, or are required through the NCD process, unless CMS's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

Should CMS find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act. In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §§1879, 1842(l), or 1834(j) (4) of the Act, as applicable. Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial's principal investigator may be pursued.

Medicare regulations require Medicare + Choice (M+C) organizations to follow CMS's national coverage decisions. This NCD raises special issues that require some modification of most M+C organizations' rules governing provision of items and services in and out of network. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. M+C organizations therefore must cover these services regardless of whether they are available through in-network providers. M+C organizations may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members' care, but cannot require prior authorization or approval.

Medicare Managed Care Manual
Chapter 4 - Benefits and Beneficiary Protections
Effective: 04-22-16; Implementation: 04-22-16

10.7 – Clinical Trials
(Rev. 120, Issued: 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)
10.7.1 – Payment for Services
(Rev. 121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

For clinical trials covered under the Clinical Trials National Coverage Determination 310.1 (NCD) (NCD manual, Pub. 100-03, Part 4, section 310), original Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, including those enrolled in MA plans, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials. All other original Medicare rules apply.

Refer to the Medicare Clinical Trial Policy at: NCD - Routine Costs in Clinical Trials (310.1) (cms.gov)
and for more information on the definition of routine costs and the clinical trial Medicare qualification process. This policy does not withdraw Medicare coverage for items and services that may be covered according to Local Coverage Determinations (LCDs) or the regulations on category B investigational device exemptions (IDE) found in 42 CFR 405, Subpart B, 411.15, and 411.406. MAOs may contact the Medicare Administrative Contractor (MAC) for information about qualification and payment for clinical trial items and services.

MAOs pay the enrollee the difference between original Medicare cost-sharing incurred for qualified clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services. This cost-sharing reduction requirement applies to all qualifying clinical trials as defined in the NCD manual, Pub. 100-03, Part 4, section 310.1. MAOs may not choose the clinical trial or clinical trial items and services to which this policy applies. The MAO owes the difference even if the enrollee has not yet paid the clinical trial provider. Additionally, the enrollee's in-network cost-sharing portion also must be included in the plan's out-of-pocket maximum calculation.

To be eligible for reimbursement, an enrollee (or providers acting on the enrollee's behalf) must notify their plan that the enrollee received a qualified clinical trial service and provide documentation of the cost-sharing incurred, such as a provider bill. MAOs also are permitted to seek the MA enrollee's original Medicare cost-sharing information directly from clinical trial providers.

MA enrollees are free to participate in any qualifying clinical trial that is open to beneficiaries in original Medicare. If an MAO conducts its own clinical trial, the MAO can explain to its enrollees the benefits of participating in its clinical trial; however, the MAO may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial, even if the MAO believes it is sponsoring a clinical trial of a similar nature. Examples of impediments to an enrollee's participation include, but are not limited to, requiring enrollees to pay the original Medicare cost-sharing amount for routine care services before being compensated by the MAO for the difference or unduly delaying any required cost-sharing refund. Enrollees retain the right to choose the clinical trial(s) in which they wish to participate. However, an MAO may request, but not require, enrollees to notify the plan in advance when they choose to participate in Medicare-qualified clinical trials.

10.7.2 – Payment for Investigational Device Exemption (IDE) Studies (Rev. 121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

MAOs are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered by the MAC with jurisdiction over the MA plan's service area. The MAO is responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies. The MAO is also responsible for CMS-approved Category B devices. CMS will not approve Category A devices because they are statutorily excluded from coverage.

CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015. A listing of all CMS-approved Category A IDE studies and Category B IDE studies will

be posted on the CMS Coverage webpage site located at: http://www.cms.hhs.gov/center/coverage.asp and published in the Federal Register.

10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED)
(Rev. 120, Issued: 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

In National Coverage Determinations (NCDs) requiring CED, Medicare covers items and services in CMS-approved CED studies. MAOs are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service (see 42 CFR 422.109). Approved CED studies are posted on the CMS Coverage with Evidence Development webpage (see http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html Billing instructions are issued for each NCD.

Local:

Wisconsin Physicians Service Insurance Corporation (WPS) does not have an LCD on the topic of routine services during clinical trials.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Transition Technologies in Clinical Trials (Interim Medical Policy)

References

1. Affordable Care Act, Section 2709. https://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf Accessed 5/2/24
2. Centers for Medicare and Medicaid Services (CMS). Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, Rev. 121, Issued 04-22-16. Accessed MCM Chapter 4 (hhs.gov) 5/2/24
3. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1). Medicare Coverage Database, 7/9/2007.
4. National Institute of Health. Learn About Clinical Studies. Clinical Trials.Gov., January 2017. https://clinicaltrials.gov/ct2/about-studies/learn Accessed 3/18/24.
5. U.S. Food and Drug Administration (FDA). Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions. December 5, 2017. https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm504091.pdf 5/2/24.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/2/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/14	4/8/14	4/15/14	Joint policy established
3/1/16	12/10/15	12/10/15	Routine maintenance
3/1/17	12/13/16	12/13/16	Routine maintenance
3/1/18	12/12/17	12/12/17	Routine maintenance
5/1/18	2/20/18	2/20/18	Addition under inclusion of item or service that is an IDE device with Category B FDA approval; regulatory section updated.
9/1/18	6/19/18	6/19/18	Addition under exclusions: travel expenses. Related policy deleted
9/1/19	6/18/19		Routine maintenance
9/1/20	6/16/20		Routine maintenance
9/1/21	6/15/21		Routine maintenance
9/1/22	6/21/22		Routine maintenance
9/1/23	6/13/23		Routine maintenance (jf) Vendor managed: NA
9/1/24	6/11/24		Routine maintenance (jf) Vendor managed: NA Addition to exclusions: Added • Use of Transition Technologies in a Clinical Trial *Transition Technologies in Clinical Trials* Transition Technologies are services that meet the following criteria: 1. Represents a new, unique, very different approach to diagnosis or treatment. 2. Has been approved for marketing for five years or less. 3. Has been approved for a very narrow range of indications and/or

			4. Represents an extreme, catastrophic level of cost: > than or = 250,000.00 for a course of therapy or one standard use.

Next Review Date: 2nd Qtr, 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	
4/19/02	Medical Policy established
1/18/06	Routine maintenance
10/27/07	Routine maintenance
10/19/2011	Routine maintenance
11/28/12	Routine maintenance, added FEP guidelines to BCN benefit page
1/1/14	Replaced with JUMP policy, title changed from Coverage of Routine Services Associated with Oncology Clinical Trials to Coverage of Routine Services Associated with Clinical Trials
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: COVERAGE OF ROUTINE SERVICES ASSOCIATED WITH CLINICAL TRIALS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, criteria apply
BCNA (Medicare Advantage)	See Government Regulations Section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.