

Policy: MP312

Section: Medical Benefit Policy

Subject: Routine Care in Clinical Trials

Applicable line of business:

Commercial	x	Medicaid	x
Medicare	x	ACA	x
CHIP	x		

I. Policy: Routine Care in Clinical Trials

II. Purpose/Objective:

To provide a policy of coverage regarding Routine Care in Clinical Trials

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Routine care during participation in an approved clinical trial is defined as being those items and services that are consistent with the coverage typically provided to a qualified member who is not otherwise enrolled in a clinical trial. Coverage is consistent with Centers for Medicare & Medicaid Services policy and Patient Protection and Affordable Care Act requirements.

INDICATIONS:

The routine care while a member is participating in a qualifying Phase II, III, or IV clinical trial for the treatment of cancer or another life-threatening disease or condition is covered.

Qualifying clinical trials are defined as those:

- Funded by National Institutes of Health (NIH), National Cancer Institute (NCI), The Center for Disease Control and Prevention (CDC), The Agency for Health Care Research and Quality (AHRQ), The Centers for Medicare & Medicaid Services (CMS), Department of Defense (DOD), Veterans Administration (VA) or supported by centers and/or cooperative groups which are funded by one of those agencies; or
- Conducted under an Investigational New Drug (IND) application reviewed by the Food and Drug Administration (FDA) (e.g., drugs that have not been approved for marketing by the FDA, or FDA-approved drugs being tested for uses that are not approved by the FDA); or
- Meet the criteria for exemption from IND regulations

Routine costs in clinical trials include those items and services that:

- are typically considered to be conventional care and provided absent the clinical trial; and
- are required for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service and the prevention of complications; and
- are needed for necessary care for the diagnosis or treatment of complications.

EXCLUSIONS:

Costs which are not routine care costs, including, but not limited to, the following are excluded:

- The investigational item, device, drug or service (unless otherwise covered outside of the clinical trial);
NOTE: For Medicare, Routine care items and services in CMS-approved Category A and B IDE studies are approved; however, the Category A devices are statutorily excluded, while Category B devices are reimbursable
- Services, drugs or items specifically excluded in the member's benefit plan document;
- Products and services provided by the research sponsors free of charge for any person enrolled in the trial;

- Services that are provided for the sole purpose of data collection and analysis, and not used in the direct clinical management of the patient;
- Any service that is inconsistent with generally accepted and established standards of care for the treatment of a particular diagnosis;
- Travel and transportation expenses;
- Lodging;
- Meals

MEDICARE BUSINESS SEGMENT: please also see NCD310.1 Routine Costs in Clinical Trials

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Clinical Trial

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

S9988 Services provided as a part of a phase I clinical trial

S9990 Services provided as a part of a phase II clinical trial

S9991 Services provided as a part of a phase III clinical trial

G0293 Non-covered surgical procedure(s) using conscious sedation, regional, general or spinal anesthesia in a Medicare qualifying clinical trial, per day

G0294 Non-covered surgical procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day

Modifier Q0 Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Modifier Q1 Routine clinical service provided in a clinical research study that is in an approved clinical research study

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Centers for Medicare and Medicaid Services, National Coverage Determination (NCD) – No. 310.1 - Routine Costs in Clinical Trials. Publication 100-3

Centers for Medicare and Medicaid Services (CMS), Medicare Learning Network (MLN), MLN Matters No. MM3548 - Coverage of Routine Costs of Clinical Trials Involving Investigational Device Exemption (IDE) Category A Devices

U.S. Department of Labor (DOL). Employee Benefits Security Administration (EBSA). FAQs about the Affordable Care Act Implementation Part XV. Coverage for Individuals Participating in Approved Clinical Trials - Q3.

PA Dept of Human Services. MAB 99-23-10

This policy will be revised as necessary and reviewed no less than annually.

Devised: 12/16

Revised: 11/18 (clarification of conventional care); 11/23 (clarify exclusion)

Reviewed: 11/17, 11/19, 11/20, 11/21, 11/22, 11/24

CMS UM Oversight Committee Approval: 12/23 ,12/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.