Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP312

Section: Medical Benefit Policy

Subject: Routine Care in Clinical Trials

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**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.

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

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

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