EmblemHealth

Clinical Trials/Experimental/Investigational Procedure/Treatments/Rare Disease Treatment — Commercial and Medicaid

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Background

Section 10103 (c) of Patient Protection and Affordable Care Act (PPACA) requires group health plans and health insurance issuers offering individual and group health insurance products to provide coverage for routine patient costs associated with approved clinical trials as stated within the law. The costs of clinical trials are not covered however; EmblemHealth is responsible for the coverage of other routine medical costs for the members that would be covered if the member was not in a clinical trial.

EmblemHealth is prohibited from:

1. Denying the member participation in an approved clinical trial.
2. Denying or limiting, or imposing additional conditions on, the coverage of routine patient costs for items or services furnished in connection with participation in the approved clinical trial.
3. Discriminating against the member on the basis of the member's participation in the approved clinical trial.

Definitions

Experimental Treatment	A treatment that has not been tested in human beings; or that is being tested but has not yet been approved for general use; or that is subject to review or approval by an institutional review board.
Investigational Treatment	A treatment that includes, but is not limited to services or supplies which are under study or in a clinical trial to evaluate their toxicity, safety, and efficacy for a particular diagnosis or set of indications.
Qualified Individual	An individual who is enrolled or participating in EmblemHealth and who is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or another life-threatening disease or condition.

	To be a qualified individual, there is an additional requirement that a determination be made that the individual's participation in the approved clinical trial is appropriate to treat the disease or condition. That determination can be made based on the referring health care professional's conclusion during the prior approval process or based on the provision of medical and scientific information to EmblemHealth for review by the individual member
Rare Disease Treatment	A life threatening or disabling condition that is, or was, subject to review by the NIH Rare Disease Council, or affects < 200,000 U.S. residents per year. There is no standard health service or treatment more beneficial than the requested health service or treatment. This provision requires certification by an outside physician specialized in an area appropriate to treat the disease in question

Coverage Statement

Qualified Commercial and Medicaid individuals are covered for other routine medical costs (i.e., those costs that would otherwise be covered if the member was not participating in a clinical trial).

All experimental/investigational clinical trial or rare disease treatments will be reviewed for medical necessity; however, no prior approval is required for a member to enroll in a qualified clinical trial as defined by TITLE XXVII-PUBLIC HEALTH SERVICE ACT Sec. 2709.

Covered Costs

Routine costs generally include all items and services consistent with the coverage provided under the plan (or coverage) for a qualified individual (viz. for treatment of cancer or another life threatening disease or condition) who is not enrolled in a clinical trial.

Covered routine costs:

1. Items or services that are typically provided absent a clinical trial (e.g., medically necessary conventional care).
2. Items and services required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent).
3. Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications).
4. Items and services that is medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

See Limitations/Exclusions for noncovered costs.

Approved Clinical Trial (See full descriptive in APPENDIX — TITLE XXVII-PUBLIC HEALTH SERVICE ACT Sec. 2709)

The term "approved clinical trial" is defined in the statute as 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 one of the following:

1. A federally funded or approved trial.
2. A clinical trial conducted under an FDA investigational new drug application.

3. A drug trial that is exempt from the requirement of an FDA investigational new Drug (IND) application.

Network Providers

EmblemHealth may require the individual to participate in the approved clinical trial through a participating provider if the provider will accept the individual as a participant in the trial. However, this authority granted by the plan does not preclude a qualified individual from participating in an approved clinical trial conducted outside the state in which the individual resides. These requirements are not intended to require a plan or issuer to provide benefits for routine patient services out of network unless out of network benefits are otherwise provided under the plan or coverage.

Limitations/Exclusions

The costs of clinical trials are not covered.

Routine costs do not include any of the following:

1. The investigational item or service, itself.
2. Items and services for which there is no benefit category.
3. Items and services which are statutorily excluded.
4. Items and services that fall under a state/federal non-coverage policy.
5. Items and services furnished solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient (e.g. monthly CAT scans for a condition usually requiring only a single scan).
6. Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.
7. Items and services provided solely to determine trial eligibility.

APPENDIX

TITLE XXVII-PUBLIC HEALTH SERVICE ACT Sec. 2709

Approved Clinical Trial Defined

(I) IN GENERAL.—In this section, the term ‘‘approved clinical trial’’ means 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 described in any of the following subparagraphs:

(A) **Federally Funded Trials** —the study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

(i) The National Institutes of Health.

(ii) The Centers for Disease Control and Prevention.

(iii) The Agency for Health Care Research and Quality.

(iv) The Centers for Medicare & Medicaid Services.

(v) cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.

(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(vii) Any of the following if the conditions described in paragraph (2) are met:

(I) The Department of Veterans Affairs.

(II) The Department of Defense.

(III) The Department of Energy.

(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

(A) To be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

(B) Assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) LIFE-THREATENING CONDITION DEFINED.—in this section, the term ‘‘life-threatening condition’’ means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

(f) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan’s or issuer’s coverage with respect to clinical trials.