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# Clinical Trials (Clinical Trial Participation) MP9447

**Covered Service:** Yes

**Prior Authorization Required:** No

**Additional Information:** Self-funded plans (ASO) may require prior authorization. Please refer to the member's Summary Plan Description (SPD) or call the Customer Service number found on the member's card for specific prior authorization requirements.

A "life-threatening condition" is defined as any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

Section 1.2 only applies to members of the state of Wisconsin.

**Prevea360 Health Plan Medical Policy**:

1.0 Coverage of routine patient care costs for a qualified member participating in an approved clinical trial **does not require** prior authorization through the Health Services Division and may be approved when **ALL** of the following criteria are met:

1.1 Member is participating in 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 a life-threating condition, is not designed exclusively to test toxicity or disease pathophysiology, and meets **ONE** of the following criteria:

1.1.1 The study or investigation is approved or funded by **ONE** of the following:

1.1.1.1 National Institutes for Health (NIH) or one of its cooperative groups or centers, under the federal Department of Health and Human Services

1.1.1.2 Center for Disease Control and Prevention (CDC)

1.1.1.3 Agency for Health Care Research and Quality (AHCRQ)

1.1.1.4 Center for Medicare and Medicaid Services (CMS)

1.1.1.5 Cooperating group or center of any of the entities described in section 1.1.1.1 through 1.1.1.4

1.1.1.6 Cooperating group or center of the U.S. Department of Defense (DOD)

1.1.1.7 Cooperating group of the Department of Veterans Affairs (VA);

1.1.1.8 Qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants

1.1.1.9 Qualified non-governmental research entity identified in guidelines issued by the NIH for center support grants

1.1.1.10 The U.S. Department of Veterans Affairs (VA), Department of Defense(DOD), or the Department of Energy (DOE) (to the extent applicable to members in Illinois and Wisconsin) if the following conditions are met:

1.1.1.10.1 The study or investigation has been reviewed and approved through a system of peer review that the Secretary determines to be:

1.1.1.10.1.1 Comparable to the system of peer review of studies and investigations used by the NIH; **AND**

1.1.1.10.1.2 Provide an unbiased scientific review by qualified individuals who have no interest in the outcome of the review;

1.1.1.11 A cancer center that has been designated by the National Cancer Institute (NCI) as a Clinical Cancer Center or Comprehensive Cancer Center; **OR**

1.1.2 Trial is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration (FDA); **OR**

1.1.3 The study or investigation is a drug trial that is exempt from such an investigational new drug application; **AND**

1.2 For members of the state of Wisconsin a clinical trial must have a written protocol that describes a scientifically sound study and must have been approved by all relevant Institutional Review Boards (IRBs) before participants are enrolled in the trial. This information must be available upon request; **AND**

1.3 The trial tests **AT LEAST ONE** of the following in regards to treatment of the life threatening condition:

1.3.1 How to administer a health care service, item or drug;

1.3.2 Patient response to a health care service, item or drug;

1.3.3 Comparison of effectiveness of specific health care services, items or drugs;

1.3.4 New uses of health care services, items or drugs; **AND**

1.4 The subject or purpose of the trial is for the evaluation of an item or service that meets the definition of a Covered Expense and is not otherwise excluded under the Member Certificate or Summary Plan Description.

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2.0 In connection with an approved clinical trial and when the criteria of 1.0 are met, The Health Plan will cover routine or standard patient care related to clinical trials for life threatening diseases as described below:

2.1.1 "Routine or standard patient care" includes all health care services, items and drugs for the treatment of the life threatening disease that is consistent with the usual and customary standard of care, including professional services, hospital services, laboratory tests, x-rays and other imaging.

2.1.2 All health care services, items and drugs should be provided at a plan site or from a plan vendor whenever possible.

2.1.2.1 If The Health Plan site does not have the particular trial available, check to see if it can be opened in a timely manner to assume the member's care.

2.1.3 Specialized lab evaluations and medical images which are part of standard of care but cannot be performed at a plan site **require** prior authorization through the Health Services Division.

3.0 In connection with an approved clinical trial and when the criteria of 1.0 are met, the following items and services are **NOT COVERED**:

3.1 The investigational item, device, service or drugs that are the subject of the clinical trial.

3.2 Items and services that are provided solely to satisfy data collection and/or analysis needs that are not used in the direct clinical management of the member, including but not limited to, the costs of data collection and record keeping, research physician and/or clinician time, and result analysis costs.

3.3 A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

3.4 Testing only for the purpose of examining the value of the test (e.g. non-commercially available tests done only in academic labs)

3.5 Transportation, lodging, food, or other personal expenses for the patient or the family or companion of the patient that are associated with travel to or from a facility providing the clinical trial.

3.6 Any health care services, items or drugs provided by the clinical trial sponsors free of charge for any member.

3.7 Any health care services, items or drugs that is eligible for reimbursement by a person other than the insurer, including the sponsor of the clinical trial.

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