Clinical Trials

Policy Number: BIP028.K
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➲ Instructions for Use

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Federal/State Mandated Regulations

Oregon

Oregon Revised Statutes (ORS) Section 743A.192, Clinical Trials

https://www.oregonlaws.org/ors/743A.192

1) A health benefit plan, as defined in ORS 743B.005 (Definitions):
   a) Shall provide coverage for the routine costs of the care of patients enrolled in and participating in approved clinical trials;
   b) May not exclude, limit or impose additional conditions on the coverage of the routine costs for items and services furnished in connection with participation in an approved clinical trial; and
   c) May not include provisions that discriminate against an individual on the basis of the individual's participation in an approved clinical trial.
2) As used in this section, "routine costs":
   a) Means all medically necessary conventional care, items or services consistent with the coverage provided by the health benefit plan if typically provided to a patient who is not enrolled in a clinical trial.
   b) Does not include:
      (A) The drug, device or service being tested in the approved clinical trial unless the drug, device or service would be covered for that indication by the health benefit plan if provided outside of an approved clinical trial;
      (B) Items or services required solely for the provision of the drug device or service being tested in the clinical trial;
      (C) Items or services required solely for the clinically appropriate monitoring of the drug, device or service being tested in the clinical trial;
      (D) Items or services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient;
      (E) Items or services customarily provided by a clinical trial sponsor free of charge to any participant in the clinical trial; or
      (F) Items or services that are not covered by the health benefit plan if provided outside of the clinical trial.
3) As used in this section, approved clinical trial means a clinical trial that is:
   a) Funded by the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the United States Department of Defense or the United States Department of Veterans Affairs;
   b) Supported by a center or cooperative group that is funded by the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the United States Department of Defense or the United States Department of Veterans Affairs;
   c) Conducted as an investigational new drug application, an investigational device exemption or a biologics license application subject to approval by the United States Food and Drug Administration; or
   d) Exempt by federal law from the requirement to submit an investigational new drug application to the United States Food and Drug Administration.

4) The coverage required by this section may be subject to provisions of the health benefit plan that apply to other benefits within the same category, including but not limited to copayments, deductibles and coinsurance.
5) An insurer that provides coverage required by this section is not, based upon that coverage, liable for any adverse effects of the approved clinical trial.
6) This section is exempt from ORS 743A.001 (Automatic repeal of certain statutes on individual and group health insurance). [2009 c.274 §2; 2013 c.681 §34]

Texas

Sec. 1379.051 Coverage for Routine Patient Care Costs – Clinical Trials (SB 39, Applies to policies issued or renewed on or after 01/01/2010)

Section 1379.051, Routine Patient Care Costs

https://statutes.capitol.texas.gov/DocViewer.aspx?DocKey=IN%2fIN.1379&Phrases=1379.051&HighlightType=1&ExactPhrase=False&QueryText=1379.051

For purposes of this chapter, routine patient care costs means the costs of any medically necessary health care service for which benefits are provided under a health benefit plan, without regard to whether the enrollee is participating in a clinical trial. Routine patient care costs do not include:
(1) The cost of an investigational new drug or device that is not approved for any indication by the United States Food and Drug Administration, including a drug or device that is the subject of the clinical trial;
(2) The cost of a service that is not a health care service, regardless of whether the service is required in connection with participation in a clinical trial;
(3) The cost of a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis;
(4) A cost associated with managing a clinical trial; or
(5) The cost of a health care service that is specifically excluded from coverage under a health benefit plan.

Section 1379.052, Coverage Required

https://statutes.capitol.texas.gov/DocViewer.aspx?DocKey=IN%2fIN.1379&Phrases=1379.052&HighlightType=1&ExactPhrase=False&QueryText=1379.052

A health benefit plan issuer shall provide benefits for routine patient care costs to an enrollee in connection with a phase I, phase II, phase III, or phase IV clinical trial if the clinical trial is conducted in relation to the prevention, detection, or treatment of a life-threatening disease or condition and is approved by:
(1) The Centers for Disease Control and Prevention of the United States Department of Health and Human Services;
(2) The National Institutes of Health;
(3) The United States Food and Drug Administration;
(4) The United States Department of Defense;
(5) The United States Department of Veterans Affairs; or
(6) An institutional review board of an institution in this state that has an agreement with the Office for Human Research Protections of the United States Department of Health and Human Services.

Section 1379.053, Research Institution

https://statutes.capitol.texas.gov/DocViewer.aspx?DocKey=IN%2fIN.1379&Phrases=1379.053&HighlightType=1&ExactPhrase=False&QueryText=1379.053

(a) A health benefit plan issuer is not required to reimburse the research institution conducting the clinical trial for the cost of routine patient care provided through the research institution unless the research institution, and each health care professional providing routine patient care through the research institution, agrees to accept reimbursement under the health benefit plan, at the rates that are established under the plan, as payment in full for the routine patient care provided in connection with the clinical trial.
(b) A health benefit plan issuer is not required to provide benefits under this section for services that are a part of the subject matter of the clinical trial and that are customarily paid for by the research institution conducting the clinical trial.

Section 1379.054, Limitations on Coverage

https://statutes.capitol.texas.gov/DocViewer.aspx?DocKey=IN%2fIN.1379&Phrases=1379.054&HighlightType=1&ExactPhrase=False&QueryText=1379.054

a) Notwithstanding Section 1379.053, this chapter does not require a health benefit plan issuer to provide benefits for routine patient care services provided outside of the plan's health care provider network unless out-of-network benefits are otherwise provided under the plan.
b) This chapter does not require a health benefit plan issuer to provide benefits for health care services provided outside this state unless the health benefit plan otherwise provides benefits for health care services provided outside this state.

Section 1379.055, Deductible, Coinsurance, and Copayment Requirements

https://statutes.capitol.texas.gov/DocViewer.aspx?DocKey=IN%2fIN.1379&Phrases=1379.055&HighlightType=1&ExactPhrase=False&QueryText=1379.055

The benefits required under this chapter may be made subject to a deductible, coinsurance, or copayment requirement comparable to other deductible, coinsurance, or copayment requirements applicable under the health benefit plan.

Washington

Washington Administrative Code (WAC) Section 284-43-5420, Clinical Trials

https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-5420

A carrier must not restrict coverage of routine patient costs for enrollees who participate in a clinical trial. "Routine costs" means items and services delivered to the enrollee that are consistent with and typically covered by the plan or coverage for an enrollee who is not enrolled in a clinical trial. A carrier may continue to apply its limitations and requirements related to use of network services.

(1) A carrier may require enrollees to meet the eligibility requirements of the clinical trial according to the trial protocol. While not required to impose such a condition, a carrier may refuse coverage under this section if the enrollee does not provide medical and scientific information establishing that the individual's participation in such trial would be appropriate based on the individual meeting the eligibility requirements for the clinical trial, unless the enrollee is referred to the clinical trial by a health care provider participating in the carrier's network.
(2) This includes the cost of prescription medication used for the direct clinical management of the enrollee, unless the trial is for the investigation of the prescription medication or the medication is typically provided by the research sponsors free of charge for any enrollee in the trial.
(3) The requirement does not apply to:
    (a) A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis;
    (b) For items and services provided solely to satisfy data collection and analysis needs;
    (c) Items and services that are not used in the direct clinical management of the enrollee; or
    (d) The investigational item, device, or service itself.
(4) 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, funded or approved by:
    (a) One of the National Institutes of Health (NIH);
    (b) An NIH cooperative group or center which is a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group including, but not limited to, the NCI Clinical Cooperative Group and the NCI Community Clinical Oncology Program;
    (c) The federal Departments of Veterans Affairs or Defense;
    (d) An institutional review board of an institution in this state that has a multiple project assurance contract approval by the Office of Protection for the Research Risks of the NIH; or
    (e) A qualified research entity that meets the criteria for NIH Center Support Grant eligibility.

    "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.

State Market Plan Enhancements

None

Covered Benefits

Important Note: Covered benefits are listed in *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits* sections. Always refer to the *Federal/State Mandated Regulations* and *State Market Plan Enhancements* sections for additional covered services/benefits not listed in this section.

Refer to the member's Evidence of Coverage (EOC)/Schedule of Benefits (SOB) for specific information on what is covered.

Note: Reviews for clinical trials can be submitted through clinical coverage review at phone number 877-842-3210 and/or contact member services.

Not Covered

Refer to the member's EOC/SOB for specific information on what is covered.

Policy History/Revision Information

Date	State(s) Affected	Summary of Changes
09/01/2024	All	• Routine review; no change to coverage guidelines • Archived previous policy version BIP028.J

Instructions for Use

Covered benefits are listed in three (3) sections: *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits*. All services must be medically necessary. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the member's Evidence of Coverage (EOC)/Schedule of Benefits (SOB). If there is a discrepancy between this policy and the member's EOC/SOB, the member's EOC/SOB provision will govern.