MEDICAL POLICY	Clinical Trials (All Lines of Business Except Medicare)
Effective Date: 9/1/2022  9/1/2022 Medical Officer Date	Medical Policy Number: 234 Medical Policy Committee approved Date: 11/09; 1/10; 4/12; 5/13; 10/14; 10/15; 9/16; 7/17; 12/18; 2/19; 3/2020; 08/2020; 8/2021; 3/2022; 8/2022

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business except Medicare (*unless otherwise directed by a Medicare medical policy. Note that investigational services are considered "**not medically necessary**" for Medicare members.)*

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

This policy is based on the following regulations:

- Oregon Revised Statutes 743A.192, *Clinical Trials*[1]
- Washington Administrative Code 284-43-5420, *Clinical Trials*[2]
- Section 2709 of the Public Health Service (PHS) Act, as amended by the Affordable Care Act (ACA), *Coverage for Individual Participating in Approved Clinical Trials*[3]

Note: Member benefits, which address coverage or non-coverage of out of network (OON) clinical trials, may vary by line of business. Member benefit contract language takes precedence over medical policy.

I. A health benefit plan:

A. Shall provide coverage for the **routine costs** of the care of patients (also referred to as a "**qualified individual**") enrolled in and participating in **approved clinical trials**; **and**
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**.

Note: Please see Policy Guidelines section below for use of in-network versus out-of-network providers.

II. As used in criterion I.A. above, "**qualified individual"** means an individual who is a participant or beneficiary in a health plan or with coverage described above in criterion I. and who meets the following conditions:
A. The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition; **and**
B. Either-
1. The referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in criterion II. A. above; **or**
2. The participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in criterion II.A. above.

III. As used in criterion I. above, "**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. Do not include:
1. The investigational item, device, or service being studied in the **approved clinical trial**; **or**
2. Items and services that are provided solely to satisfy the clinical trial's data collection and analysis needs and that are not used in the direct clinical management of the patient; **or**
3. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

IV. As used in criterion I. above, "**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 (**A. – H.**):

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 & Medicaid Services, the United States Department of Defense or the United States Department of Veterans Affairs; **or**
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; **or**
C. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants; **or**
D. Studies or investigations conducted by the Department of Veterans Affairs, the Department of Defense or the Department of Energy that have been reviewed and approved through a system of peer review and the Secretary determines that **both** of the following conditions (**1. and 2**.) are met:
    1. To be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, **and**
    2. Assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review; **or**
E. 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**
F. Exempt by federal law from the requirement to submit an investigational new drug application to the United States Food and Drug Administration; **or**
G. 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**
H. A qualified research entity that meets the criteria for NIH Center Support Grant eligibility.

V. 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.

VI. 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.

POLICY GUIDELINES

Coverage of Routine Patient Costs

Use of In-Network Providers: If one or more participating providers is participating in a clinical trial, nothing in criterion I. above shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

Use of Out-Of-Network: Criterion I. above shall also apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

CPT/HCPCS CODES

All Lines of Business Except Medicare	
Not Covered	
C9760	Non-randomized, non-blinded procedure for NYHA class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study
C9782	Blinded procedure for New York Heart Association (NYHA) class ii or iii heart failure, or Canadian Cardiovascular Society (CCS) class iii or iv chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study
C9783	Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catherization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved investigational device exemption (ide) study

DESCRIPTION

Coverage for the costs of standard medical care for patients enrolled in and participating in qualifying clinical trials.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. Oregon Revised Statutes 743A.192, Clinical trials. Chapter 743A — Health Insurance: Reimbursement of Claims https://www.oregonlegislature.gov/bills_laws/ors/ors743a.html. Accessed 6/30/2022.
2. Washington Administrative Code 284-43-5420, Clinical Trials. http://apps.leg.wa.gov/wac/default.aspx?cite=284-43-5420. Accessed 6/30/2022.
3. GovInfo. Title 42- The public health and welfare, public health service subchapter XXV, Coverage for individuals participating in approved clinical trials. Effective January 7, 2011. https://www.govinfo.gov/app/details/USCODE-2010-title42/USCODE-2010-title42-chap6A-subchapXXV-partA-subpart1-sec300gg-8. Accessed 6/30/2022.