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PLANS IN SCOPE

Aspirus Health Plan

PURPOSE:

The intent of this policy is to provide coverage guidelines for health care services rendered in the scope of a clinical trial.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

COVERAGE INDICATIONS:

In accordance with Section 2709 of the Public Health Service Act (PHSA), as added by the Affordable Care Act (ACA) (42 U.S.C. §300gg-8), the Plan will not:

- Deny any "qualifying individual's" participation in an "approved clinical trial"
- Deny, (or limit or impose additional conditions on) the coverage of "routine patient costs" for items and services furnished in connection with participation in the approved clinical trial.

Discriminate against a qualifying individual based on their participation in an approved clinical trial

Routine vs Non-Routine Costs

Routine Patient Costs include items and services that are:

- Medically necessary for the direct clinical management of the member;
- Typically covered under the member's benefit plan if the member were not enrolled in a clinical trial; and
- Provided consistent with generally accepted standards of care.

Examples of routine patient costs may include, but are not limited to: • Office visits and professional services:

- Laboratory tests and imaging performed at standard frequencies
- Hospitalizations and facility services
- Management of complications arising from participation in the trial

Non-Routine (Protocol-Induced) Costs include items and services that are:

- Provided solely for data collection, analysis, or research purposes;
- Required exclusively by the clinical trial protocol and not part of standard clinical care; or
- Customarily provided by the trial sponsor at no cost

Non-routine costs are not eligible for coverage unless otherwise required by law or explicitly stated in the member's benefit plan.

Use of In Network Providers

If one or more participating providers is participating in a clinical trial, nothing 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 Providers

If no participating in-network provider is willing or able to accept the qualifying individual for participation in an approved clinical trial, the Plan will not deny coverage for routine patient costs provided by an out-of-network provider solely due to trial participation, subject to the following:

- Documentation demonstrating the unavailability of in-network trial participation;
- Medical review approval prior to initiation of out-of-network services; and
- Coverage limited to benefits otherwise available under the member's plan.

This section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage).

General Provisions

- Non-routine patient costs (costs determined to be directly associated with the clinical trial protocol) are not eligible for coverage.
- Routine patient costs are subject to standard plan prior authorization requirements. However, routine patient costs may not be denied solely because the member is enrolled in an approved clinical trial.

Exclusions

Investigational Service(s) or items that are used in the Clinical Trial are not covered, except for the following:

1. Certain “Category B Devices”. Only certain FDA-designated Category B Devices are covered. In order to be covered, all of the following criteria must be met:
    i. The device must be used within the context of an FDA-Approved Clinical Trial
    ii. The device must be used according to the Clinical Trial's approved protocols
    iii. Must fall under a covered benefit category and must not be excluded by law, regulation, or current Medicare coverage guidelines
    iv. The device is medically necessary for the member, and the amount, duration, and frequency of use or application of the service is medically appropriate
    v. The device is furnished in a setting appropriate to the member’s medical needs and condition
2. Certain promising interventions for members with terminal illnesses
3. Other items and services that, in the plan’s determination, meet specified criteria in accordance with the plan’s medical and drug policies
4. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the member; examples include, but are not limited to:
    i. Laboratory tests and imaging studies done at a frequency dictated by the study protocol and not consistent with signs and symptoms and other standards of care for that diagnosis or treatment type
5. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis
6. Items and services provided by the research sponsors free of charge for any person enrolled in the trial
7. Travel and transportation expenses are excluded from coverage; these include, but are not limited to:
    i. Transportation fees (e.g. personal vehicle, taxi, medical van, non-emergency medical transportation via ambulance, commercial airline, and train)
    ii. Rental car expenses
    iii. Mileage reimbursement for driving a personal vehicle
    iv. Lodging
    v. Meals

8. Routine patient costs obtained out-of-network where non-network benefits do not exist under the plan
9. Clinical trials that do not meet the definition of approved clinical trial

Medical Records Documentation

Benefit coverage is determined by review of member specific benefit plan information and all applicable laws. Medical records documentation may be required to assess if the member meets criteria; however, provision of records does not guarantee coverage.

The following documentation may be required to support coverage determinations:

- Clinical trial protocol summary
- Institutional Review Board (IRB) approval
- Confirmation of member eligibility and enrollment
- Identification of routine versus protocol-induced services
- Treating provider attestation of medical necessity

DEFINITIONS

"Approved" Clinical Trial: 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 meets any of the following criteria:

1. The study or investigation is federally 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 1 group or center of any of the entities described in clauses (i) through (iv)
    vi. The Department of Defense
    vii. The Department of Veterans Affairs.
    viii. The Department of Energy.
    ix. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants
2. The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration or is exempt from IND requirements.
3. . Approved by a recognized Institutional Review Board (IRB) and conducted by a qualified research entity using scientifically valid study methods and protocols.

In addition, the study or investigation must be reviewed and approved through a system of peer review wherein:

1. The system of peer review of studies and investigations is comparable to the National Institute of Health AND
2. An unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review

Category A Devices: An experimental device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B Devices: A non-experimental investigational device for which the incremental risk is the primary risk in questions (that is the questions of safety and effectiveness have been resolved) or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

Covered Services: Services or supplies that are provided by a licensed provider or clinic and covered by the Plan, subject to all of the terms, conditions, limitations and exclusions of the contract.

Life Threatening Condition: Any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

Investigational (Experimental) Services: A service wherein the procedure or service is not an effective or proven treatment for the condition which it is intended.

Protocol-Induced or Non-Routine Costs: Those costs incurred in the administration of any item or service that are:

1. Required exclusively for the completion of the *protocol treatment* but are not usual, customary, and appropriate for the patient's condition and would not typically be provided to that patient when cared for outside of a clinical trial
2. Incurred by performance of tasks directly related to data collection, reporting or analysis for purposes of the clinical trial
3. Provided solely for data collection, analysis, or research purposes
4. Provided by the trial administrator or performance site for purposes of the clinical trial
5. Provided by the trial administrator or performance site and not otherwise charged to the health plan
6. Customarily provided by the trial sponsor at no cost.

Non-routine costs are not eligible for coverage unless otherwise required by law or explicitly stated in the member's benefit plan.

Protocol Treatment: Those items, drugs, procedure, services and schedule for administration described in the approved protocol document. In the case of comparative studies, *protocol treatment* refers to all arms in the protocol document (e.g., the "standard" arm and the "experimental" arm).

Routine Patient Costs: include items and services that are:

- Medically necessary for the direct clinical management of the member;
- Typically covered under the member's benefit plan if the member were not enrolled in a clinical trial; and
- Provided consistent with generally accepted standards of care.

Examples of routine patient costs may include, but are not limited to:

- Office visits and professional services
- Laboratory tests and imaging performed at standard frequencies
- Hospitalizations and facility services

Routine patient costs remain subject to standard plan prior authorization requirements.

However, routine patient costs may not be denied solely because the member is enrolled in an approved clinical trial.

Qualifying Individual: An individual who is a participant or beneficiary in a health plan) and who meets the following conditions:

1. 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.
2. Either:
    i. 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 OR
    ii. 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

APPLICABLE CODES

Codes listed below are provided for informational purposes only and do not, by themselves, establish coverage. Coverage determinations are based on clinical criteria, benefit plan provisions, and applicable law

The code list below is provided for guidance. Not all clinical trials will contain these codes. Code coverage will depend on coverage guidelines above. All clinical trial coverage requests will require medical review.

Code Type	Code	Description
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
HCPCS	C9758	Blind procedure for NYHA Class III/IV heart failure; transcatheter implantation of interatrial shunt including right heart catheterization, transesophageal 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
HCPCS	C9760	Nonrandomized, nonblinded procedure for NYHA Class II, III, IV heart failure; transcatheter implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, transesophageal 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

HCPCS	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
HCPCS	C9792	Blinded or nonblinded procedure for symptomatic New York Heart Association (NYHA) Class II, III, IVA heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., transesophageal echocardiography (TTE), intracardiac echocardiography (ICE), fluoroscopy), performed under general anesthesia in an approved investigational device exemption (IDE) study
HCPCS	G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial
HCPCS	G0293	Noncovered surgical procedure(s) using conscious sedation, regional, general, or spinal anesthesia in a Medicare qualifying clinical trial, per day
HCPCS	G0294	Noncovered procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day
HCPCS	G2000	Blinded administration of convulsive therapy procedure, either electroconvulsive therapy (ECT, current covered gold standard) or magnetic seizure therapy (MST, noncovered experimental therapy), performed in an approved IDE-based clinical trial, per treatment session
HCPCS	G8968	Documentation of medical reason(s) for not prescribing an FDA-approved anticoagulant (e.g., present or planned atrial appendage occlusion or ligation or patient being currently enrolled in a clinical trial related to AF/atrial flutter treatment)
HCPS	G9057	Oncology; practice guidelines; management differs from guidelines as a result of patient enrollment in a clinical trial
HCPCS	G9537	Imaging needed as part of a clinical trial; or other clinician ordered the study
HCPCS	M1396	Patients on a therapeutic clinical trial
HCPCS	M1404	Patients on a therapeutic clinical trial
HCPCS	S9988	Services provided as part of a phase I clinical trial
HCPCS	S9990	Services provided as part of a phase II clinical trial
HCPCS	S9991	Services provided as part of a phase III clinical trial

HCPCS	S9992	Transportation costs to and from trial location and local transportation costs (e.g. fares for taxicab or bus) for clinical trial participant and one caregiver/companion
HCPCS	S9996	Meals for clinical trial participant
HCPCS	S9994	Lodging costs (e.g., hotel charges) for clinical trial participants and one caregiver/companion
ICD-10	Z00.6	Encounter for examination for normal comparison and control in clinical research program

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POLICY/REVISION HISTORY

Date	Summary of Changes	Approval By
06/26/2025	Initial Policy Development	Optum Medical and Pharmacy Subcommittee
06/10/2026	Annual review updates clarify statutory authority, expand qualifying clinical trial definitions, strengthen protections for routine patient costs, enhance network and prior authorization guidance, improve documentation requirements, and align exclusions, coding, and references with national payer standards and ACA requirements.	Optum Medical and Pharmacy Subcommittee

REFERENCES:

Centers for Medical & Medicaid Services (CMS). National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1). Effective 7/9/2007. Retrieved from NCD - Routine Costs in Clinical Trials (310.1) Accessed April 24, 2026.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Article: Clinical Trials – Medical Policy Article (A52840) Effective 10/01/2015. Retrieved from: Article - Clinical Trials – Medical Policy Article (A52840). www.cms.gov Accessed April 24, 2026.

Centers for Medicare & Medicaid Services (CMS). (October 2014). Medicare coverage investigational device exemption (IDE) study criteria crosswalk table. www.cms.gov. Accessed April 24, 2026.

Centers for Medicare and Medicaid (CMS). (November 6, 2014). MLN Matters. Medicare coverage of items and services in category A and B investigational device exemption studies. www.cms.gov. Accessed April 24, 2026.

Code of Federal Regulations. (June 13, 2025). Title 42 (June 03, 2025). Title 42 U.S.C. 300gg-8 - Coverage for individuals participating in approved clinical trials 42 U.S.C. 300gg-8 - Coverage for individuals participating in approved clinical trials - Document in Context - USCODE-2015-title42-chap6A-subchapXXV-partA-subpart1-sec300gg-8 (Accessed April 24, 2026).

National Institutes of Health (NIH). (October 3, 2022). NIH Clinical Research Trials and You. The Basics. Retrieved from The Basics | National Institutes of Health (NIH).
Public Health Service Act §2709, 42 U.S.C. §300gg□8. Accessed April 24, 2026.

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).

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