

Approved by: Optum Medical and Pharmacy Subcommittee	Effective Date: 01/01/2026
Clinical Policy Document: Experimental and Investigational Services	Date Approved: 12/10/25
Reference #: MC/C001	Replaces Effective Clinical Policy Dated: 10/01/25

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PLANS IN SCOPE

Aspirus Health Plan

PURPOSE:

The intent of this policy is to provide coverage guidelines for experimental health care services rendered outside 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:

The health plan does not cover services deemed to be investigational or experimental.

The following criteria are used to determine if codes are investigational:

1. Current evidence-based guidance published in InterQual or another clinical decision support software
2. The procedure, service, or device is listed in Medicare Category A and Category B listings (<https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved>)

3. Procedures determined by other review organizations (ex. Hayes New Technology Summaries, ECRI Health Technology Assessment Information Services, etc.) to be investigational if the medication is listed as experimental on the FDA website (<https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases>)
4. A clinical review conducted by the Medical Policy Committee and approved by the health plan CMO has determined the service to be experimental

New medical and pharmacy codes are routinely reviewed by the health plan to determine if services are considered investigational. It is possible that new codes may be excluded from the listing until a review is conducted. In the case a code has been denied and a health plan member or customer believes it was in error, their ordering provider may submit a code for clinical review using the routine appeal procedure.

Exclusions

The following services are excluded from this policy:

- Routine services not specifically associated with the experimental service
- Other items and services that, in the plan's determination, meet specified criteria in accordance with the plan's medical and drug policies

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.

DEFINITIONS

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.

Experimental Services: A service wherein the procedure, service, or medication is not a safe or effective/proven treatment for the condition which it is ordered.

Investigational Services: A service wherein the procedure, service, or medication is not an effective or proven treatment for the condition which it is ordered.

InterQual: An evidence-based clinical decision support software designed to help determine medical-utilization decisions.

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.

Routine Patient Costs: All items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not receiving an experimental service

APPLICABLE CODES

Code listings are not provided outside NDC; however, a list is provided of current CMS IDE studies and for experimental devices to help guide reviews. Note: The lists below are provided for guidance. Not experimental and investigational listings will be found on these lists. Coverage will depend on coverage guidelines above. All experimental and/or investigational procedures and medication coverage requests will require medical review.

POLICY/REVISION HISTORY

Date	Summary of Changes	Approval By
06/26/25	Initial Policy Development	Optum Medical and Pharmacy Subcommittee
12/10/25	Addition of investigational review organizations; Repair of broken links	Optum Medical and Pharmacy Subcommittee

REFERENCES:

Centers for Medicare and Medicaid Services. (2025) Medicare coverage: Final national coverage decision. Accessed April 8, 2025. <https://www.cms.gov>.

Centers for Medicare and Medicaid Services. (2025). Approved IDE studies. <https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved>

Forward Health. (2025) Topic #567: Experimental services. www.forwardhealth.wi.gov.

National Committee for Quality Assurance (2025). HP standards and guidelines: Appendix 9, glossary, definition of medical necessity determination.

National Committee for Quality Assurance (2025) NCQA Standards and Guidelines for the Accreditation of Health Plans: UM10 Evaluation of New Technology

U.S. Food and Drug Administration. (May 2025) National Drug Code Directory: NDC unfinished drugs database. www.fda.gov

U.S. Food and Drug Administration (May 2025) Currently approved CDEB device premarket applications as of 31-May-2025. www.fda.gov

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 أعلى رقم الهاتف 1-800-332-6501 (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 zur Verfügung. 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 थ 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 numer 1-800-332-6501 (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 al 1-800-332-6501 (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 Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaue Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).