

Department of Origin: Integrated Healthcare Services	Effective Date: 03/06/24
Approved by: Chief Medical Officer	Date Approved: 02/29/24
Clinical Policy Document: Investigative Services	Replaces Effective Clinical Policy Dated: 09/12/23
Reference #: MP/I001	Page: 1 of 2

PURPOSE:

The intent of this clinical policy is to provide coverage guidelines for investigative health care services.

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.

POLICY:

Health care services that are considered investigative are not eligible for coverage when current *reliable evidence* does not permit conclusions concerning its safety, effectiveness, or effect on health outcomes.

The Plan maintains a list of services considered to be *investigative*. This list is not all-inclusive. Additions and deletions to the list will be made as new issues arise or the *investigative* status of a service changes. The list can be found on the Plan's website.

Benefits must be available for *health care services*. *Health care services* must be ordered by a provider. *Health care services* must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

COVERAGE:

- I. All *health care services* listed on the *Investigative* List are excluded from coverage.
- II. New FDA-approved drugs and clinical indications for provider-administered medications, newly released CPT and HCPCS codes for emerging technology, services, and procedures, such as but not limited to Category III and other temporary codes may be designated as excluded, until the Plan has determined if *reliable evidence* permits conclusions concerning its safety, effectiveness, or effect on health outcomes.
- III. An *investigative* determination will be made for all *health care services* that lack *reliable evidence* (see MP/L004 Levels of Evidence and the Evaluation of Health Care Services)
 - Includes, but not limited to, *health care services* designated by the CMS Medicare program as Coverage with Evidence Development (CED)
- IV. Methods of distribution of *Investigative* List to members and providers
 - A. Available on the internet on the Plan's web site
 - B. Revisions are published in provider newsletters
 - C. The List is available on request

DEFINITIONS:

Health Care Service:

Medical or behavioral services including pharmaceuticals, devices, technologies, tests, treatments, therapies, supplies, procedures, hospitalizations, or *provider* visits.

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Investigative:

As determined by the Plan, a drug, device or medical treatment or procedure is investigative if reliable evidence does not permit conclusions concerning its safety, effectiveness, or effect on health outcomes.

Reliable evidence:

The Plan considers the following categories of reliable evidence, none of which shall be determinative by itself:

1. Whether there is a final approval from the appropriate government regulatory agency, if required. This includes whether a drug or device can be lawfully marketed for its proposed use by the FDA; or if the drug, device or medical treatment or procedure is under study or if further studies are needed to determine its maximum tolerated dose, toxicity, safety or efficacy as compared to standard means of treatment or diagnosis; and
2. Whether there are consensus opinions or recommendations in relevant scientific and medical literature, peer-reviewed journals, or reports of clinical trial committees and other technology assessment bodies. This includes consideration of whether an oncology treatment is included in the applicable National Comprehensive Cancer Network (NCCN) guideline, as appropriate for its proposed use, or whether a drug is included in any *authoritative compendia* as identified by the Medicare program such as, the National Comprehensive Cancer Network Drugs and Biologics Compendium, as appropriate for its proposed use; and
3. Whether there are consensus opinions of national and local health care providers in the applicable specialty as determined by a sampling of providers, including whether there are protocols used by the treating facility or another facility, studying the same drug, device, medical treatment or procedure.

REFERENCES:

1. Integrated Healthcare Services Utilization Process Manual: UR009 Referral to Medical Policy
2. Integrated Healthcare Services Utilization Process Manual: UR015 Use of Medical Policy and Criteria
3. Integrated Healthcare Services Medical Policy Process Manual: MP001 Medical Policy Process for Research Related to Potentially Investigative Healthcare Services
4. Integrated Healthcare Services Medical Policy Process Manual: MP002 Investigative List Oversight
5. Clinical Policy: Clinical Trials (MP/C008)
6. Clinical Policy: Clinical Policy Application, Development, Oversight, and Distribution (MP/C014)
7. Clinical Policy: Levels of Evidence and the Evaluation of Health Care Services (MP/L004)
8. Clinical Policy: New/ Emerging Technology/ Health Care Services, Omnibus Code List (MP/N003)
9. Pharmacy Policy: Off-Label Drug Use (PP/O001)
10. Pharmacy Policy: Off-Label Drug Use (PP/O002)
11. Pharmacy Policy: Review of New FDA-Approved Drugs and Clinical Indications (PP/R001)
12. 2023 NCQA Standards and Guidelines for the Accreditation of Health Plans
- UM10 Evaluation of New Technology

DOCUMENT HISTORY:

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Nondiscrimination & Language Access Policy

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, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

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

Provide free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

If you believe that we have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, you can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
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>.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (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 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (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 1.866.631.5404 (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 1.866.631.5404 (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 1.866.631.5404 (TTY: 711).

Lao: ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).