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Clinical Policy Document: Hierarchy of Evidence in the Evaluation of Healthcare Services	**Date Approved:** 06/10/26
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PLANS IN SCOPE

Aspirus Health Plan

PURPOSE:

The intent of this policy is to outline the hierarchy of clinical evidence that is used to determine which health services are safe and effective and, therefore, eligible for benefit coverage. This hierarchy is applied in conjunction with structured certainty and strength frameworks (e.g., GRADE) to document confidence in the evidence and support transparent, consistent determinations.

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:

Optum routinely assesses medical guidelines and literature to determine if new technology or application of existing technology associated with a health care service is proven safe and effective by reliable evidence. This includes medical literature reflecting a high level of evidence showing safety and effectiveness and positive effects on health outcomes.

Evidence Sufficiency

Reliable evidence generally includes good-quality randomized controlled trials and minimally biased prospective cohort and comparison studies. Case reports, retrospective studies alone, and abstracts alone are not sufficient to establish safety and effectiveness for coverage determinations.

Coverage Source Precedence (when applicable)

- Rapid reviews may be used for time-sensitive coverage decisions when methods are transparent and limitations are documented; a full systematic review may be completed as appropriate.
- For Medicare/Medicare Advantage determinations, apply CMS coverage manuals and resources, then National Coverage Determinations (NCD), then Local Coverage Determinations/Local Coverage Articles (LCD/LCA); when criteria are not fully established, use evidence-based internal and/or external criteria as applicable.
- For Medicaid determinations, apply applicable state Medicaid coverage policy first; if not instructive, use evidence-based external criteria and/or internal criteria as applicable.
- In the event of a conflict, the member's benefit plan document and applicable law govern.

Guideline usage is preferred with Grade A or B recommendations (see definitions section). Some common national guidelines and consensus statements include:

- Advisory Committee on Immunization Practices
- Agency for Healthcare Research and Quality (AHRQ) Clinical Statements
- Centers for Disease Control (CDC) Guidelines
- Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations (NCD)
- CMS Local Coverage Determinations (LCD)
- National Comprehensive Cancer Network (NCCN) Guidelines (when NCCN evidence categories are used, Category 2A or higher is preferred)
- National Institutes of Health (NIH) Clinical Statements
- United States Preventive Task Force (USPSTF) Recommendations
- Hayes New Technology Summaries (ratings of B or better may be considered generally supportive; ratings of C or below generally indicate unproven or uncertain benefit)
- ECRI Health Technology Assessment Information Service
- UpToDate,

In the absence of published guidelines, Optum will use the level of evidence hierarchy for therapeutic studies level 1A-2A (see table 1 below). Non-randomized and observational studies may also contribute to coverage decisions when assessed using structured risk-of-bias tools (e.g., ROBINS-I) and when results are sufficiently robust and consistent.

Table 1: Level of evidence

Level	Type of evidence
1A	Systematic review (with homogeneity) of randomized control trials (RCT) or meta-analysis
1B	Individual RCT (with narrow confidence intervals)
1C	All or none study
2A	Systematic review (with homogeneity) of cohort studies
2B	Individual cohort study (including low quality RCT e.g. < 80% follow-up)
2C	Outcomes research : Ecological studies
3A	Systematic review (with homogeneity) of case control studies
3B	Individual case control study
4	Case series (and poor quality cohort and case-control study)
5	Expert opinion without critical appraisal or based on physiology bench research or "first principles"

In addition to meeting safety and effectiveness criteria, coverage requires:

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

Exclusions

Investigational treatments are not covered as part of this policy. For information on clinical trials or investigational treatments, please refer to policies MC/CLINT01 and MC/I001 respectively.

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. Submitted documentation should be sufficient to link the request to the applicable guideline and/or coverage-source precedence used and to support the evidence level and strength applied in the determination, as applicable.

DEFINITIONS

Strength of Recommendation: Degree to which benefits outweigh harms and other considerations (e.g., as described in GRADE methodology).

Certainty of Evidence: Confidence that the estimated effects are close to the true effects (e.g., as described in GRADE methodology).

Levels of Evidence (Hierarchy): Ranks study designs by typical risk of bias (as reflected in Table 1).

Grade A Practice Recommendation: Strong Recommendation- Level I evidence or consistent findings from multiple studies of levels II, III, or IV. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Grade B Practice Recommendation: Recommendation- Level II, III, or IV evidence and findings are generally consistent. Generally clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences.

Grade C Practice Recommendation: Option- Level II, III, or IV evidence but findings are inconsistent. Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preferences should have a substantial influencing role.

Grade D Practice Recommendation: Option- Level V evidence little or no systematic empirical evidence. Clinicians should consider all options in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

APPLICABLE CODES

Not applicable for this policy

POLICY/REVISION HISTORY

Date	Summary of Changes	Approval By
09/10/2025	Initial Policy Development	Optum Medical and Pharmacy Subcommittee
06/10/2026	Annual review update: added coverage-source precedence (Medicare/Medicaid); added evidence sufficiency language and rapid review allowance; clarified observational evidence assessment (structured bias tools); updated guideline thresholds (NCCN/Hayes); updated references.	Optum Medical and Pharmacy Subcommittee

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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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