

Approved by: Optum Medical and Pharmacy Subcommittee	Effective Date: 10/01/25
Clinical Policy Document: Hierarchy of Evidence in the Evaluation of Healthcare Services	Date Approved: 09/10/25
Reference #: MC/H001	Replaces Effective Clinical Policy Dated: N/A

TABLE OF CONTENTS

Plans In Scope	1
Purpose:	1
Coverage Indications:.....	1
Exclusions.....	2
Medical Records Documentation	3
Definitions.....	3
Applicable Codes.....	3
Policy/Revision History	3
References:	3

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.

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.

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
- National Institutes of Health (NIH) Clinical Statements
- United States Preventive Task Force (USPSTF) Recommendations
- Hayes New Technology Summaries
- 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).

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.

DEFINITIONS

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
07/22/2025	Initial Policy Development	Optum Medical and Pharmacy Subcommittee

REFERENCES:

Agency for Healthcare Research and Quality (AHRQ). Methods guide for effectiveness and comparative effectiveness reviews. Content last reviewed October 2022. Effective Health Care Program, Agency for Healthcare Research and Quality, Rockville, MD. Available at:

<https://effectivehealthcare.ahrq.gov/products/collections/cer-methods-guide>. Accessed June 2, 2025.

AHRQ. Methods guide for medical test reviews. Content last reviewed August 2021. Effective Health Care Program, Agency for Healthcare Research and Quality, Rockville, MD. Available at:

<https://effectivehealthcare.ahrq.gov/products/collections/methods-guidance-tests>. Accessed June 2, 2025.

Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011 Apr;64(4):401-6. Reviewed June 2, 2025.

Berkman ND, Lohr KN, Ansari M, et al. Methods Guide – Chapter: Grading the strength of a body of evidence when assessing health care interventions for the effective health care program of the Agency for Healthcare Research and Quality: an update. Content last reviewed November 2017. Effective Health Care Program, Agency for Healthcare Research and Quality, Rockville, MD. Available at: <https://effectivehealthcare.ahrq.gov/products/methods-guidance-grading-evidence/methods>. Accessed June 2, 2025.

Burns, P. B., Rohrich, R. J., & Chung, K. C. (2011). The levels of evidence and their role in evidence-based medicine. *Plastic and reconstructive surgery*, 128(1), 305–310. <https://doi.org/10.1097/PRS.0b013e318219c171>

Centre for Evidence-Based Medicine (CEBM). Levels of evidence. 2009 and 2011. Available at: <https://www.cebm.ox.ac.uk/resources/levels-of-evidence>. Accessed June 2, 2025.

Guyatt G, Oxman AD, Akl EA, et al. GRADE guidelines: 1. Introduction - GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol*. 2011 Apr;64(4):383-94. Reviewed June 2, 2025.

Halperin JL, Levine GN, Al-Khatib SM, et al. Further evolution of the ACC/AHA clinical practice guideline recommendation classification system: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2016 Apr 5;133(14):1426-8. Reviewed June 2, 2025.

Higgins JPT, Thomas J, Chandler J, et al. (editors). *Cochrane handbook for systematic reviews of interventions* version 6.5 (last updated August 2024). Cochrane, 2024. Available at: <https://training.cochrane.org/handbook>. Accessed June 2, 2025.

National Academy of Medicine. 2011. *Finding what works in health care: standards for systematic reviews*. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/13059>. Accessed June 2, 2025.

U.S. Preventive Services Task Force (USPSTF). *Procedure manual*. Current as of April 2023. Available at: <https://uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/procedure-manual>. Accessed June 2, 2025.

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 mitaus 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).