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| Department of Origin: Integrated Healthcare Services | Effective Date: 10/09/24 |
| Approved by: Chief Medical Officer | Date Approved: 09/12/24 |
| Clinical Policy Document: Coverage Determination Guidelines | Replaces Effective Clinical Policy Dated: 06/23/23 |
| Reference #: MP/C009 | Page: 1 of 3 |

PURPOSE:

The intent of this clinical policy is to provide guidelines to aid in coverage 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.

POLICY:

- I. Benefits must be available for *health care services*.
- II. *Health care services* must be proven effective by *reliable evidence*.
- III. *Health care services* designated by the CMS Medicare program as Coverage with Evidence Development (CED) are considered *investigative*.
- IV. *Health care services* must be ordered by a *provider*, unless otherwise pre-empted by law.
- V. *Health care services* must be *medically necessary*, applicable conservative treatments must have been tried, the most cost-effective alternative must be requested for coverage consideration, and not provided specifically for the convenience of the member or provider.
- VI. Services, drugs, or supplies must be rendered in the most cost-efficient setting or manner appropriate for the condition.
- VII. *Health care service* must be based on medical standards and accepted practice parameters of the community and provided at a frequency that is accepted by the medical community as medically appropriate. Based on this, unnecessary tests and treatments are not-covered, such as but not limited to the following:
 - A. Routine use of preoperative diagnostic testing and imaging in low-risk members for low-risk surgeries
 - B. Low-value medical procedures including diagnostic imaging and disease screening, including health care services that:
 1. Are not supported by evidence
 2. May be duplicative of other procedures
 3. May provide harm
 4. Are truly unnecessary
- VIII. Where applicable, *outcome measures* and/or pre-determined treatment goals that are *specific, measurable, and/or functional* must be employed and clearly defined in the medical record, including the degree of change over time. The documentation must also provide evidence of lasting, sustainable, progress with treatment.
- IX. When *standardized tests and measures* are used, the most *current edition/version* of the testing instrument is employed.
- X. For continuation of *health care services*, effectiveness or measurable improvement/progress must be documented and objectively quantified. Absence of placement and/or availability at a lower level of care does not constitute medical necessity for continuation of care at the current level of care.
- XI. There are no documentation irregularities or inconsistencies regarding such condition or *health care service* in the medical record.

EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description

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DEFINITIONS:

Activities of Daily Living (ADL):

Activities related to personal self-care and independent living, which include eating, bathing, dressing, transferring, walking/mobility, and toileting/continence

Cosmetic:

Services, medications and procedures that improve physical appearance but do not correct or improve a physiological function, or are not medically necessary

Health Care Service:

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

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.

Medically Necessary:

Any *health care services*, preventive health care services, and other preventive services that the Plan, in its discretion and on a case by case basis, determines are appropriate and necessary in terms of type, frequency, level, setting, and duration, for a diagnosis or condition; and the care must:

1. Be consistent with the medical standards and generally accepted practice parameters of providers in the same or similar general specialty as typically manages the condition, procedure or treatment at issue; and
2. Help restore or maintain health; or
3. Prevent deterioration of a condition; or
4. Prevent the reasonably likely onset of a health problem or detect an incipient problem.

Outcome Measures:

Objective, measurable, assessments to determine progress with treatment. The use of standardized tests and measures at the onset of care establishes the baseline status of the member, providing a means to quantify change in the patient's functioning. Outcome measures, along with other standardized tests and measures used throughout the episode of care, as part of periodic reexamination, provide information about whether predicted outcomes are being realized.

Provider:

A health care professional, physician, clinic or facility licensed, certified, or otherwise qualified under applicable state law to provide health care services

Reconstructive:

Refer to member's plan document for applicable reconstructive definition

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

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needed to determine its maximum tolerated dose, toxicity, safety or efficacy as compared to standard means of treatment or diagnosis; and

- 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
- 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.

Specific, Measurable, and Functional Goals:

Clearly defined goals of treatment that allow measurement of the amount and/or degree of meaningful change over time. These goals are often determined by the use of functional outcome assessment tools.

Standardized tests/measures current edition/version:

Standardized tests, scales and outcome measures must meet recognized standards for validity, reliability and precision. Providers must administer, score and interpret standardized tests, scales and outcome measures in accordance with test manuals and/or descriptions in the medical literature. The most current edition/version of standardized tests, scales and outcome measures must be administered.

REFERENCES:

- Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
- Clinical Policy: Clinical Policy Application, Development, Oversight, and Distribution MP/C014
- Clinical Policy: Investigative Services MP/I001
- Clinical Policy: Levels of Evidence and the Evaluation of Health Care Services MP/L004
- 2024 NCQA Standards and Guidelines for the Accreditation of Health Plans
- American Physical Therapy Association. Outcomes Measurement. Retrieved from: <http://www.apta.org/OutcomeMeasures/>. Accessed 09-11-24.
- American Occupational Therapy Association (AOTA). Quality Toolkit. Retrieved from <https://www.aota.org/practice/practice-essentials/quality/quality-toolkit>. Accessed 09-11-24.
- American Speech-Language-Hearing Association (ASHA). Assessment Tools, Techniques, and Data Sources. Retrieved from <https://www.asha.org/practice-portal/resources/assessment-tools-techniques-and-data-sources/>. Accessed 09-11-24.
- Joint Committee on the Standards for Educational and Psychological Testing of the American Educational Research Association, the American Psychological Association, and the National Council on Measurement in Education. Standards for Educational and Psychological Testing. 2014. Retrieved from https://www.testingstandards.net/uploads/7/6/6/4/76643089/standards_2014edition.pdf.

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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 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).