

Department of Origin: Integrated Healthcare Services	Effective Date: 11/21/23
Approved by: Chief Medical Officer	Date Approved: 11/10/23
Clinical Policy Document: FDA-Approved Humanitarian Use Devices (HUD)	Replaces Effective Clinical Policy Dated: 10/18/22
Reference #: MP/H008	Page: 1 of 3

PURPOSE:

The intent of this clinical policy is to provide coverage guidelines for *Humanitarian Use Devices* (HUD).

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:

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. *Humanitarian Use Devices (HUDs)* must be used according to the indication/s for which the FDA granted the *Humanitarian Device Exemption (HDE)*.
- II. When a device is being used in a clinical investigation (ie, collection of safety and effectiveness data) for its *HDE*-approved indication(s), or for a different indication, both of the following apply:
 - A. It must be used in a facility that has an established a local *institutional review board (IRB)* to supervise the clinical testing of the devices.
 - B. The facility *IRB* must approve the use of the device to treat or diagnose a specific disease.

Access the following for an up-to-date list of FDA/Center for Devices and Radiological Health (CDRH) Humanitarian Device Exemptions:
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm>.

Access the following for up-to-date information regarding clinical trials associated with HDE/HUD
<https://www.clinicaltrials.gov/>.

DEFINITIONS:

Humanitarian Use Device (HUD):

Device that intends to benefit patients by treating or diagnosing diseases or conditions that affect fewer than 8,000 individuals in the United States per year. The HUD provision provides an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting small patient populations.

Humanitarian Device Exemption (HDE):

For a device to obtain *HUD* approval, a *HDE* application must be submitted to the FDA. This is similar to a premarket approval application, but is exempt from the effectiveness requirements of a premarket approval. Application for *HDE* is not required to contain results of scientifically valid clinical investigations that demonstrate the device's effectiveness for its indication. The application must contain enough information for FDA to determine that the devices do not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. The applicant must also demonstrate that there are no comparable devices available to treat or diagnose the disease or condition, and that the applicant could not otherwise bring the device to market.

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Institutional Review Board (IRB):

Formally designated board, committee, or other group tasked to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects in accordance with 21 CFR 56. The IRB's purpose is to assure the protection of the rights, safety, and welfare of the human subjects.

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Prior Authorization: Yes, per network provider agreement

CODING:

Coding is variable depending on the procedure being requested.

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines (MP/C009)
3. Clinical Policy: Investigative Services (MP/I001)
4. Clinical Policy: Levels of Evidence and the Evaluation of Health Care Services (MP/L004)
5. Food and Drug Administration (FDA). Guidance Document Humanitarian Device Exemption (HDE) Program. Guidance for Industry and Food and Drug Administration Staff. September 2019. Retrieved from <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf>. Accessed 10-19-23.
6. Food and Drug Administration (FDA): IDE Definitions and Acronyms. Current as of 12/22/2017. Retrieved from <http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/investigationaldeviceexemptionide/ucm046698.htm>. Accessed 10-19-23.
7. Food and Drug Administration (FDA): Humanitarian Device Exemption. Current as of 10/03/2022. Retrieved from <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/HumanitarianDeviceExemption/default.htm>. Accessed 10-19-23.
8. Food and Drug Administration (FDA): HDE Approvals. Current as of 08/24/2018. Retrieved from <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/default.htm>. Accessed 10-19-23.
9. Food and Drug Administration. Listing of CDRH Humanitarian Device Exemptions. Content current as of: 02/18/2021. Retrieved from <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/hdeapprovals/ucm161827.htm>. Accessed 10-19-23.

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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).