

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

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 اعلى 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) schwetzsch, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໄປ່ດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໄດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY:711).