Humanitarian Use Devices

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Medical Policy #: 10.01.14
Original Effective Date: April 2009
Reviewed: June 2022
Revised: December 2022

NOTICE: This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

A humanitarian use device (HUD) is a medical device intended to benefit individuals by treatment or diagnosis of a disease or condition that affects fewer than 4,000 individuals in the United States per year. The United States Food and Drug Administration (FDA) evaluates humanitarian use devices (HUDs) through the Humanitarian Device Exemption (HDE) process. A device that is granted an HDE indicates the device is approved for marketing, but the approval is based on evidence of safety and probable benefit rather than the higher standard of reasonable assurance and effectiveness.

In 1996, the Food and Drug Administration (FDA) issued a regulation to carry out provisions of the Safe Medical Devices Act of 1990 regarding HUDs. It creates an alternative pathway for getting market approval for medical devices that may help people with rare diseases or conditions. Because clinical investigation demonstrating a HUD's efficacy is not feasible (given the low prevalence of the disease in the population), an FDA-approved HDE grants manufacturers an exemption from the usual premarket

approval process and allows marketing of the device only for the FDA-labeled HDE indication(s). Under FDA requirements, a HUD may only be used after institutional review board (IRB) approval has been obtained for the use of the device in accordance with the FDA-labeled indication(s) under the HDE.

A comprehensive list of devices and their respective FDA-labeled HDE indication(s) is available at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm

PRIOR APPROVAL

Not applicable.

POLICY

Medically Necessary
Humanitarian use device (HUD) by the United States Food and Drug Administration (FDA) may be considered **medically necessary** when **all of the following** criteria are met:

- The coverage position described for a humanitarian use device (HUD) does not supersede Wellmark's medical policy on a specific device, technology, and/or procedure; **and**
- The device is being utilized in accordance with the Humanitarian Device Exemption (HDE) labeled indication(s) approved by the FDA; **and**
- Humanitarian use device (HUD) will only be covered in facilities that have an institutional review board (IRB) to oversee the clinical application of such device; **and**
- The IRB must approve the application of the device to ensure that it will be used in accordance with the FDA-labeled indication(s); **and**
- Documentation of the IRB approval is provided to ensure compliance with the FDA-labeled indication(s).

Investigational
Humanitarian use device (HUD) requested for off-label uses (i.e., outside of their FDA-labeled Humanitarian Device Exemption (HDE) indication[s]) are considered **investigational** and, therefore, not covered because their safety and/or effectiveness cannot be established by review of the available published peer reviewed literature.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- Coding is variable depending on the device being requested

SELECTED REFERENCES

- U.S. Department of Health and Human Services. Food and Drug Administration. Center for Devices and Radiological Health. Guidance for Industry and FDA Staff: Humanitarian Device Exemption (HDE) Regulation: Questions and Answers. July 18, 2006.
- Samuel FE Jr. Safe Medical Devices Act of 1990. Health Aff (Millwood), 1991 Spring; 10(1):192-5.
- U.S. Department of Health and Human Services. Food and Drug Administration, Medical Devices, Products and Medical Procedures, Devices Approvals and Clearance, Humanitarian Device Approvals and Exemption.
- U.S. Department of Health and Human Services. Food and Drug Administration Medical Devices HDE Approvals, Listing of CDRH Humanitarian Device Exemptions.
- U.S. Department of Health and Human Services Food and Drug Administration, Medical Devices Regulation and Guidance, Humanitarian Device Exemption.
- U.S. Department of Health and Human Services Food and Drug Administration, Guidance for Industry and Food and Drug Administration Staff Humanitarian Use Device (HUD) Designations.

POLICY HISTORY

Date	Reason	Action
December 2022	Interim Review	Policy Revised
June 2022	Annual Review	Policy Renewed
June 2021	Annual Review	Policy Revised
June 2020	Annual Review	Policy Renewed
June 2019	Annual Review	Policy Renewed
June 2018	Annual Review	Policy Renewed
June 2017	Annual Review	Policy Renewed
June 2016	Annual Review	Policy Renewed
July 2015	Annual Review	Policy Renewed
August 2014	Annual Review	Policy Revised
August 2013	Annual Review	Policy Renewed
September 2012	Annual Review	Policy Revised
September 2011	Annual Review	Policy Renewed
August 2010	Annual Review	Policy Renewed
June 2010	Interim Review	Prior Approval Removed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.