



Section: 800– Office of Research Administration

Subject: Humanitarian Use Devices (HUD) & Humanitarian Use Device Exemption (HDE) at JHS Facilities

## I. Purpose

To implement an approval workflow at Jackson Health System (JHS) for Humanitarian Use Devices (HUDs) and Humanitarian Use Device Exemption (HDEs) by following First Coast Service Options Guidelines last updated January 20, 2020 which is still in effect after CMS retired Local Coverage Determination (LCD) (L36238) in December 2022.

## II. Definitions

**Centers of Medicare and Medicaid Services (CMS):** previously known as the Health Care Financing Administration (HCFA), agency of HHS that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and Health Insurance Portability and Accountability Act (HIPAA) standards.

**First Coast Service Options, Inc. (FCSO):** Medicare Part A and B Medicare Administrative Contractors (MAC) for (Florida, Puerto Rico, and the U.S. Virgin Islands).

**Food and Drug Administration (FDA)** of Health and Human Services (HHS) responsible for protecting and promoting public health through the regulation and supervision of medical device safety (as well as drugs and other products with medical applications). FDA definitions: <http://www.fda.gov/MedicalDevices/default.htm>.

**Humanitarian Use Device (HUD):** a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year (21 CFR 814.3(n)).

**Humanitarian Use Device Exemption (HDE):** a premarket approval application submitted pursuant to this subpart seeking a humanitarian device exemption from the effectiveness requirements of sections 514 and 515 of the act as authorized by section 520(m)(2) of the act (21 CFR 814.3(n)).

**Local Coverage Determination (LCD):** means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A).

**Medicare Administrative Contractors MACs:** Medicare Administrative Contractors entities contracted with CMS to administer various aspects of the Medicare program and specifically claims payment for medically reasonable and necessary services.

## III. Procedure

### A. HUD and HDE Approval Process

1. Physician seeks approval for each new device via email communication from Facility Chief Medical Officer (CMO) who in turn may communicate with the Chief Financial Officer (CFO), and the Chief Operations Officer (COO).
  - a. The JHS Office of Research Administration (ORA) Office Director will be copied in the email.
2. Institutional Review Board (IRB) submission will trigger JHS ORA Review:



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- a. If a HUD and HDE is used as an Emergency, the physician shall submit to the IRB Chair within 5 days after the use of the device.
  - b. The following is as outlined below by FDA criteria
    - i. The patient has a life-threatening or serious disease or condition that needs immediate treatment;
    - ii. No generally acceptable alternative treatment for the condition exists; and
    - iii. Because of the immediate need to use the device, there is no time to use existing procedures to obtain FDA approval for the use.
  3. Once JHS Director of ORA receives communication from IRB (if applicable) and approval from leadership, JHS approval will be granted through the IRB system for single use only.
  4. Only Physicians/(Principal Investigators) qualified by training and experience to implant these devices are allowed to perform the procedure using an IRB approved Informed Consent Form which outlines payment responsibilities.
  5. The HUD and HDE proposals will be reviewed to assess on-label and off-label uses of the device.
  6. The HUD and HDE approval process flow will be followed, and the business unit will engage strategic sourcing in the event the device needs to meet vendor requirements.
- B. Documentation Requirements
1. First Coast Service Options, Inc. (FCSO) will consider coverage for a humanitarian use device when documentation supporting the medical necessity of the procedure/device for the beneficiary is made available:
    - a. Device details, including the device number and documentation that the device is classified by the FDA as a humanitarian use device (HUD) and has been approved by the FDA under a humanitarian device exemption (HDE).
    - b. A description of the clinical indications for the patient and why the device is needed.
      - i. Medical records should document why the benefits of use of the device outweigh the risks, considering both other available devices and other available therapies.
    - c. A copy of the institution's IRB approval letter for each individual patient.
      - i. This means for each claim that documentation is requested, a copy of the institution's IRB letter must be included with the documentation submitted.
    - d. Informed Consent Form) required for each individual patient when it is still under a HUD designation.
- C. Billing & Coding Guidelines
1. The JHS ORA will communicate with the Corporate Billing Office to provide necessary documentation that will aid in reimbursement.
  2. Each FDA-approved HUD is assigned an identification code by the FDA, which enables Medicare contractors to establish special claims processing procedures as per First Coast Service Options guidelines: Humanitarian Use Device (fcsso.com).
- D. Special Request
- If the physician/investigator makes a clinical determination that the HUD and/or HDE merits to be used off-label, the same process will follow to contact senior leadership for approval as mentioned in Section III.A.
- E. General Policy for Ongoing HUDs
1. All HUDs and HDEs should follow the same process of approval as described above.
  2. For HUDs and HDEs approved by JHS ORA prior to the year 2016, there will not be a case-by-case approval.



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3. Only those HUDs and HDEs after 2016 will be considered to follow the approval on a case-by-case basis until further review and assessment.
4. The JHS ORA will work with the physicians to determine approval process.

F. Monitoring Requirements

1. The JHS ORA will maintain all documentation of the HUD/HDE application packet, including FCSO's past response to the Medicare coverage request.
2. The JHS ORA will, on occasion, perform a follow-up billing audit to ensure that JHS is being adequately reimbursed for the HUD and facility charges billed to Medicare.
  - a. Whenever the JHS ORA determines that payments are not being received or the amount is inadequate, the Director will notify the PI and work with him/her to ensure future billings are properly coded and reimbursed.

IV. **References**

1. CMS Retired LCD (L36238): <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=36238&Ctrctr=All&UpdatePeriod=797>
2. FDA Humanitarian Use Device (HUD) Designation Program: <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/DesignatingHumanitarianUseDevicesHUDS/default.htm>
3. In the House of Representatives, U. S: EC. 3052. Humanitarian Device Exemption: <https://www.congress.gov/114/bills/hr34/BILLS-114hr34eah.pdf>
4. <https://medicare.fcso.com/lcd/active/l36238.pdf>
5. [https://medicare.fcso.com/Clinical\\_trials/137306.asp](https://medicare.fcso.com/Clinical_trials/137306.asp)

**Responsible Party:** Director, Clinical Research  
Office of Research Administration

**Reviewing Committee(s):** JHS Policy and Procedure Committee

**Authorization:** CEO, Jackson Health System