MEDICARE COVERAGE ON HUMANITARIAN USE DEVICES (HUD) WITH FDA APPROVED HUMANITARIAN DEVICE EXEMPTION (HDE)

OVERVIEW

HDE/HUD Coverage Varies According to Local MAC Policies and Medical Necessity:

Medicare coverage and claims processing for procedures that involve a humanitarian use device (HUD) that has received or is in the process of receiving FDA approval of its humanitarian device exemption (HDE) is determined by the local Medicare Administrative Contractor (MAC). FDA and Medicare want to support patient access to these devices, which involve small patient populations for which there are typically no other alternative treatments. CMS does not have a national coverage determination (NCD) for HDEs/HUDs. Thus, there is variation in how local Medicare Administrative Contractors (MACs) review and process claims. Some MACs require a pre-approval process in which supporting documentation is required prior to billing. Others do not require a pre-approval process, and medical necessity requirements apply. You should always check and follow the procedures provided by the MAC that processes your claims.

MAC PROCESSES FOR HDE

MAC	Jurisdiction	Pre-Approval	Billing Instructions (if available)
Cahaba Government Benefit Administrators, LLC	AL, GA, TN	Not Published	N/A
CGS Administrators, LLC	KY, OH	Yes	CGS will consider case-by-case coverage for a Humanitarian Use Device. Upon receipt of the required documentation, CGS will review the submission and respond as soon as possible. Again, while there is no prior approval process in traditional Medicare, the process outlined above will help ensure Medicare beneficiaries are receiving covered services and have adequate access to care.
First Coast Service Options, Inc (FCSO)	FL, Puerto Rico, U.S. Virgin Islands	No	No prior approval will be provided for these devices even if the patient is a participant in a clinical trial. Documentation, if requested, supporting the medical necessity of the procedure/device for the beneficiary must be made available upon request.
National Government Services, Inc (NGS)	CT, IL, NY, ME, MN, MA, NH, RI, VT, WI	No	N/A
Noridian Healthcare Solutions, LLC	AL, AZ, CA, HI, ID, MT, NV, ND, OR, SD, UT, WA, WY	Yes	Pre-approval of the device for a specific indication speeds the process of individual consideration. If pre-approved, when the provider has a patient whose condition matches the specific clinical indication (noted in both the FDA and Contractor approvals), the provider only needs to submit the patient information (by mail or fax), verifying the patient's clinical situation is consistent with the approved indication. If pre-approval of an HDE has not occurred, the entire HDE and patient reviews must be completed before use of the device. If the provider follows the instructions in the approval letter, the provider may use the device in advance of our patient-specific approval with an expectation of approval. However, the provider will want approval notification per patient in the event of claim denial and/or later review by any entity. Applications for HDE approvals are submitted in accordance with the instructions found on our Web site.
Novitas Solutions, Inc	AR, CO, DE, District of Columbia, LA, MS, MD, NM, NJ, OK, PA, TX, VI**	No	No prior approval will be provided for these devices even if the patient is a participant in a clinical trial. Documentation, if requested, supporting the medical necessity of the procedure/device for the beneficiary must be made available upon request.
Palmetto GBA, LLC	NC, SC, VI**, WV	Yes, required	HDE requests are submitted similar to the Investigational Device Exemption (IDE) request. Documentation must be furnished to Palmetto GBA prior to submission of a claim for payment. HDEs do not have a specific/distinct benefit category for coverage under Medicare but the service being provided may fall into a benefit category. Approval of coverage may also follow the policies for coverage of 'Routine Services'.
Wisconsin Physicians Service Insurance Corporation (WPS)	IN, IA, KS, MI, MO, NE	Not Published	N/A

***Note: Novitas serves as the Part B MAC authority for Arlington and Fairfax counties, along with the city of Alexandria, in Virginia. Palmetto is the Part B MAC authority for the remaining counties in Virginia.*

References

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3. Novitas Website http://www.novitas-solutions.com/webcenter/faces/oracle/webcenter/page/scopedMD/sad78b265_6797_4ed0_a02f_81627913bc78/Page57.jspx;jsessionid=QmpbWMYQSQR1jpmqpBPhGcky1pyv0yp1XxMx18t1LtCJ6lxJ1pn6!-1817591945!-569303007?contentId=00080348&_afrLoop=96133348891000#!%40%40%3F_afrLoop%3D96133348891000%26contentId%3D00080348%26_adf.ctrl-state%3D6zgq1wt29_4
4. CGS Website http://www.cgsmedicare.com/parta/pubs/news/2012/1212/cope20731.html
5. Cahaba Website https://www.cahabagba.com/
6. Noridian Website https://www.noridianmedicare.com/cgi-bin/coranto/viewnews.cgi?id=EkZkyyVuAlzCkoTMqL&tmpl=part_b_viewnews&style=part_ab_viewnews
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8. FDA http://www.fda.gov/RegulatoryInformation/Guidances/ucm110194.htm
9. Medicare Coverage Database https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=humanitarian+device&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAAAAAAAAAA%3d%3d&=&
   Article A52590 (Humanitarian Use Device and Humanitarian Device Exemptions; FCSO)
   Article A52936 (Humanitarian Use Devices and Exemptions; Noridian)
   LCD L36238 (Humanitarian Use Device and Humanitarian Device Exemptions; FCSO)

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