Status
Active

Medical and Behavioral Health Policy
Section: Surgery
Policy Number: IV-11
Effective Date: 03/26/2014

HUMANITARIAN USE DEVICES

Description: As defined by the Food and Drug Administration (FDA), a humanitarian use device is "a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4000 individuals in the United States per year." In 1996, the FDA developed a specific approval process and designation for devices used in the treatment or diagnosis of diseases affecting these populations. This type of FDA approval is designated as a "Humanitarian Device Exemption."

Policy: All humanitarian use devices that have received a Humanitarian Device Exemption (HDE) from the FDA will be reviewed on an individual basis.

Examples of devices with an HDE designation include:

- Enterra™ Therapy System [formerly named Gastric Electrical Stimulation (GES) System]
- Acticon™ Neosphincter
- VOCARE® Bladder System
- Activa® Dystonia Therapy System

To see a complete listing of devices that have received a Humanitarian Device Exemption from the FDA, please select the following:

FDA list of Humanitarian Device Exemptions

Coverage: Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan

description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding: *The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

Coding is variable depending on the procedure being requested

Policy History: **Developed February 14, 2001**

Most recent history:
Reviewed February 9, 2011
Reviewed February 8, 2012
Reviewed February 13, 2013
Reviewed March 12, 2014

Cross Reference:
Bone Morphogenetic Protein (BMP), IV-85
Durable Medical Equipment (DME), VII-07
Endovascular Procedures (Angioplasty and/or Stenting) for Intracranial Arterial Disease (Atherosclerosis and Aneurysms), II-48
Ventricular Assist Devices and Total Artificial Hearts, IV-86