

Note regarding Federal members

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational for the purposes approved and thus these procedures, devices or laboratory tests may be assessed only based on their medical necessity.

Note regarding [Humanitarian Device Exemption \(HDE\)](#)

- [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. (Previously 4000 individuals; increased to 8000 on June 7, 2017)
- [Humanitarian Device Exemption \(HDE\)](#) — a marketing application for an HUD. An HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.

Note regarding Transplant Program Case Management

EmblemHealth's transplant program manages members with health care needs associated with having or preparing for a solid organ or bone marrow transplant. All transplant services are reviewed with the medical director assigned to support the transplant case management program. All requested transplant services are reviewed for medical necessity and evidence-based criteria are utilized to support the best care coordination and outcomes for EmblemHealth transplant members. To request transplant case management services for the EmblemHealth transplant program, members and providers may call 1-800-447-0768.

For additional information pertaining to experimental medical technologies please see [Medical Necessity Guidelines: Experimental, Investigational or Unproven Services](#)

EmblemHealth's Medical Guidelines are accessible through hyperlinks within the database or by [clicking here](#)

Key	N = No	Y = Yes	FFS = fee for service	HDE = humanitarian device exemption
	Denotes investigational unless indicated otherwise			

TECHNOLOGY	COMMERCIAL	MEDICARE	MEDICAID	LAST REVIEW
AbioCor® Implantable Replacement Heart Note: This investigational device is FDA-approved as a Humanitarian Device Exemption (HDE) for the treatment of severe biventricular end stage heart disease patients who are not cardiac transplant candidates and who are < 75 years old, require multiple inotropic support, are not treatable by LVAD destination therapy, and are not weanable from biventricular support if on such support. Pre certification requests when presented as such will be case by case reviewed for all LOBs EXCEPT for Medicare members, whose costs relating directly to the provision of services related to the National Coverage Determination (NCD) (that were non-covered services prior to the issuance of the NCD) will be paid by CMS intermediaries and carriers when beneficiaries are enrolled in a clinical study that meets the criteria put forth within the NCD. CPT (33927, 33928, 33929, L8698)	SEE NOTE	SEE NOTE	SEE NOTE	3/8/2024
Bioimpedance Spectroscopy (BIS) extracellular fluid analysis for breast cancer lymphedema assessment CPT (93702)	Y	Y	N	3/8/2024
Cooling devices for neuro/musculoskeletal conditions, pain conditions, post-surgical healing or as a prophylactic measure for hair loss secondary to chemotherapy Note RE device-use secondary to chemotherapy:	SEE NOTE	SEE NOTE	SEE NOTE	4/12/2024

<p>EmblemHealth considers scalp cooling (e.g., using ice-filled bags/bandages, cryogel packs, or specially designed products (e.g., Chemo Cold Cap, DigniCap, ElastoGel, Paxman Scalp Cooling System and Penguin Cold Cap) medically necessary to prevent hair loss during chemotherapy.</p> <p>Cooling caps and other products for scalp cooling are considered incidental to the chemotherapy administration and are not separately reimbursed. Cooling caps and other scalp cooling products purchased by the member are considered supplies that are generally excluded from coverage under plans that exclude supplies.</p> <p>CPT (0662T, 0663T)</p> <p>HCPCS (E0218, E0236)</p>				
<p>Cryoablation — rhinitis, chronic</p> <p>(E.g., ClariFix)</p> <p>CPT (30999, 31299)</p>	N	N	N	3/8/2024
<p><u>Deep brain stimulation — obsessive compulsive disorder</u> (Reclaim™ DBS™ Therapy)</p> <p>Note: The Reclaim™ DBS™ Therapy is an investigational device that is FDA-approved as a humanitarian exemption (HDE) for bilateral stimulation of the anterior limb of the internal capsule, AIC, as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs). Therefore, pre-certification requests when presented as such will be reviewed on a case-by-case basis.</p> <p>CPT (21499, 61863, 61864, 61867, 61885, 61886, 61880, 61888, 95961, 95962)</p> <p>HCPCS (L8680, L8681, L8682, L8683, L8684, L8685, L8686, L8687, L8688, L8689)</p>	SEE NOTE	SEE NOTE	SEE NOTE	3/8/2024
<p>Gene expression profiling — acute myeloid leukemia (AML), therapeutic management</p> <p>(E.g., NPM1 nucleophosmin), CEBPA [CCAAT/enhancer binding protein [C/EBP], alpha [a], full gene sequence analysis FLT3 gene analysis)</p> <p>(See Also NGS Medicare LCD: Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases and Molecular Pathology Procedures LCD)</p> <p>CPT ([0046U, 0049U, 0050U, LabPMM], 81310 [NPM1, Commercial and Medicaid coverage eff. 9/12/2020], 81218 [CEBPA], 81245, 81246 [FLT3], 81450)</p> <p>Note: Proprietary lab analysis (PLA) codes (those ending with “U”) are not covered for Medicaid members, as they are not reimbursed by NYS Medicaid</p>	Y	Y	Y	5/17/2024
<p>Gene expression profiling — RUNX1 (runt related transcription factor 1) (e.g., acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy) to guide therapeutic decision-making</p> <p>(See also Gene Expression Profiling and Molecular Pathology Procedures LCD)</p> <p>CPT (81334)</p>	Y	Y	Y	8/9/2024
<p>Immunoglobulin heavy chain locus (IGH@) testing for acute lymphoblastic leukemia (ALL) and lymphoma, B-cell, to guide therapeutic decision-making</p> <p>CPT (81261, 81262, 81263, 81264)</p> <p>Note: Commercial coverage eff. 11/13/2021</p>	Y	Y	N	11/10/2023
<p>Laser — interstitial thermotherapy (LITT) for all indications other than epilepsy and intracranial lesions (as depicted in the row below)</p> <p>CPT (19499, 20999, 27599, 32999, 47399, 53899, 55899)</p>	N	N	N	4/12/2024
<p>Laser — interstitial thermotherapy (LITT) for intracranial indications (e.g., NeuroBlate®, Visualase®)</p>	Y	Y	N	4/12/2024

<p>Note: MRI-guided LITT for intracranial indications is covered for Commercial and Medicare members, either:</p> <ul style="list-style-type: none"> ▪ Epilepsy —disabling seizures despite the use of ≥ 2 tolerated antiepileptic drug regimens, and when there are ≤ 2 well delineated epileptogenic foci accessible by laser ▪ Recurrent brain metastases, recurrent glioblastoma, or radiation necrosis — poor surgical candidacy for craniotomy and resection when open surgery presents prohibitive surgical risk or tumor is surgically inaccessible <p>CPT (61736, 61737)</p>				
<p>Meniscus root repair using Arthrex Root Repair System/Arthrex PEEK SwiveLock Anchor CPT (29999)</p>	N	N	N	7/12/2024
<p>Microwave thermotherapy for chest wall recurrence of breast cancer CPT (19499)</p>	N	N	N	7/12/2024
<p>Nasal endoscopy, surgical; balloon dilation of eustachian tube (E.g., ACCLARENT AERA™ Eustachian Tube Balloon Dilation System, XprESS ENT Dilation System) (See also Experimental, Investigational or Unproven Services) CPT (69705, 69706)</p>	N	Y	Y	7/12/2024
<p>NeuRx DPS™, Diaphragm Pacing System for amyotrophic lateral sclerosis (ALS) Note: The NeuRX is an investigational device that is FDA-approved as a humanitarian device exemption (HDE) for use in patients 21 years of age or older with a stimulatable diaphragm (both right and left portions) as demonstrated by voluntary contraction or phrenic nerve conduction studies, and who are experiencing chronic hypoventilation (CH), but not progressed to an FVC less than 45% predicted. (percutaneous, intramuscular, diaphragm motor point stimulating device) Therefore, pre-certification requests when presented as such will be reviewed on a case-by-case basis. CPT (0674T, 0675T, 0676T, 0677T, 0678T, 0679T, 0680T, 0681T, 0682T, 0683T, 0684T, 0685T, 64575, 64580, 64585, 64590, 64595) HCPCS (C1778, C1816, L8680, L8681, L8682, L8683, L8684, L8685, L8686, L8687, L8688, L8689)</p>	SEE NOTE	SEE NOTE	SEE NOTE	7/12/2024
<p>Pharmacogenetic testing — genotyping for CYP2C19 polymorphisms for members who have been prescribed clopidogrel (Plavix) Note: One allowable per lifetime CPT (81225)</p>	Y	Y	Y	7/12/2024
<p>Pharmacogenetic testing — MGMT (O(6)-methylguanine-DNA methyltransferase) gene methylation assay for predicting response to temozolomide (Temodar) in members with glioblastoma (E.g., PredictMDx for Glioblastoma) CPT (81287)</p>	Y	Y	Y	5/17/2024
<p>PK Papyrus Covered Coronary Stent System Note: The PK Papyrus Covered Coronary Stent System is an investigational device that is FDA-approved as a humanitarian device exemption (HDE) for use in patients for the treatment of acute perforations of native coronary arteries and coronary bypass grafts in vessels 2.5 to 5.0 mm in diameter. Therefore, pre-certification requests when presented as such will be reviewed on a case-by-case basis. CPT (No specific code)</p>	SEE NOTE	SEE NOTE	SEE NOTE	11/10/2023
<p>Pudendal nerve decompression surgery (See also Experimental, Investigational or Unproven Services) CPT (64722)</p>	N	N	N	11/10/2023
<p>Pulmonary artery pressure monitoring — wireless</p>	N	Y	N	11/10/2023

(E.g., CardioMEMS HF System) (See also Experimental, Investigational or Unproven Services) CPT (33289)				
Shoulder resurfacing (E.g., Copeland™ Extended Articulating Surface [EAS]™ Resurfacing Heads, DePuy Global CAP™ CTA Resurfacing Shoulder Humeral Head, Axiom Shoulder Resurfacing System, HemiCAP® [also referred to as Contoured Articular Prosthetic [CAP] Humeral Head Resurfacing Prosthesis]) (See also Experimental, Investigational or Unproven Services) CPT (23470, 23472, 23929)	N	N	N	11/10/2023
Spinal — vertebral stapling for idiopathic scoliosis CPT (22899)	N	N	N	11/10/2023
Surgical decompression for peripheral polyneuropathy CPT (28035, 64702, 64704, 64708, 64712, 64714, 64722, 64726, 64727) Note: The above CPT codes are not covered when rendered for non-compressive peripheral neuropathy syndromes due to insufficient evidence of therapeutic value.	N	N	N	11/10/2023
Surgical interventions for the prevention of lymphedema (E.g., microsurgery for the prevention of lymphedema in breast cancer [lymphatic microsurgical preventing healing approach —LYMPHA], simplified lymphatic microsurgical preventive healing approach [SLYMPHA], reverse lymphatic mapping) CPT (38999)	N	N	N	11/10/2023
Tele-retinal imaging/digital photography computer programs (i.e., algorithms) to automatically detect or diagnose diabetic retinopathy when administered by nonspecialists (E.g., DigiScope Diabetic Retinal Evaluation Service, Inoveon Diabetic Retinopathy Evaluation Service) Note: Diabetic retinopathy telescreening systems are considered medically necessary for diabetic retinopathy screening when administered by an ophthalmologist or optometrist CPT (92227)	N	Y	N	11/10/2023
Tinnitus retraining therapy (TRT) CPT (No specific code; evaluation and management codes may be used or possibly physical medicine and rehabilitation codes. TRT may also be billed as physical or speech therapy using V5299, 97039, E1399)	N	N	N	11/10/2023
Transcatheter mitral valve repair (TMVR) (aka mitral valve transcatheter edge-to-edge repair [TEER]) (E.g., MitraClip®) Note: Medicare members, whose costs relating directly to the provision of services related to the Decision Memo for Transcatheter Mitral Valve Repair (TMVR) (that were non-covered services prior to the issuance of the NCD) will be paid by CMS intermediaries and carriers, as part of the Coverage with Evidence Development (CED) program, when beneficiaries are enrolled in a clinical study that meets the criteria put forth within the NCD for the treatment of significant symptomatic degenerative mitral regurgitation when furnished according to an FDA approved indication and when the conditions put forth within the NCD are met. CPT (0345T, 33418, 33419, 93590, 93592) CPT (0483T, 0484T, [0543T, NeoChord], [0544T, Cardioband™ Mitral Valve Reconstruction System]) Note: These “T” codes are considered experimental and investigational for all members.	Y	SEE NOTE	Y	2/9/2024
Transcranial magnetic stimulation for neurologic or psychological indications other than depression (E.g., migraines [e.g., Cerena Single-Pulse Transcranial Magnetic Stimulator], strokes, obsessive compulsive disorder [e.g., Brainsway Deep Transcranial Magnetic Stimulation System], Parkinson's disease, dystonia, tinnitus, and auditory hallucinations) (See also Experimental, Investigational or Unproven Services)	N	N	N	11/10/2023

CPT (90867, 90868, 90869)				
Transendoscopic therapies for dysphagia and gastrointestinal reflux disease (GERD) (E.g., Bard EndoCinch™ Suturing System, Enteryx™, EsophyX™, LINX Reflux Mgmt. System, Stretta® radiofrequency ablation) (See also Medicare LCD: Select Minimally Invasive GERD Procedures) Natural orifice transoral endoscopic surgery (NOTES) for bariatric surgery/transoral gastroplasty (TOGA) (E.g., Apollo OverStitch endoscopic suturing system, StomaphyX™ endoluminal fastener and delivery system, etc.) (See also Bariatric Surgery) CPT (43210, 43257, 43284, 43285, 43289, 43499, 43999, 49999) Note: CPTs 43210 and 43285 are covered for Medicare eff. 10/12/19	N	N	N	11/10/2023
Transpupillary thermotherapy for retinoblastoma CPT (67299)	Y	Y	Y	4/12/2024
Tremor analysis device (E.g., Physiologic recording of tremor using accelerometers) CPT (95999)	N	N	N	11/10/2023
Unicondylar interpositional spacer for joint pain (e.g., osteoarthritis) (E.g., UniSpacer™ Knee System) CPT (27599)	N	N	N	11/10/2023
Vagus nerve stimulation — multiple conditions (E.g., Addictions, Alzheimer disease, anxiety disorders, atrial fibrillation, autism spectrum disorders, back pain, bipolar disorder, cerebral palsy, chronic pain syndrome, eating disorders, headaches, cognitive impairment associated with Alzheimer’s disease, coma, depression, essential tremor, fibromyalgia, heart failure, hemicrania continua, impaired glucose tolerance, morbid obesity [aka nerve blocking therapy, i.e., vBloc® Maestro® System], mood disorders, narcolepsy, neck pain, obsessive compulsive disorder, paralysis agitans, sleep disorder, stroke, tinnitus, Tourett’s syndrome, traumatic brain injury [TBI] including post-TBI pneumonia, etc.) (See also Experimental, Investigational or Unproven Services) Note: Vagus nerve stimulation is considered investigational for all indications except: <ul style="list-style-type: none"> ▪ Epilepsy (see MCG #A-0424) ▪ Treatment resistant depression (covered for Medicare members per NCD: Vagus Nerve Stimulation [VNS] for Treatment Resistant Depression [TRD] through Coverage with Evidence Development [CED]) CPT (0312T, 0313T, 0314T, 0315T, 0316T, 0317T, 61885, 61886, 61888, 64553, 64568, 64569, 64570, 64585, 64590, 64595, 95970) HCPCS ([E1399, report for gammaCore Sapphire], K1020, L8680, L8681, L8682, L8683, L8684, L8685, L8686, L8687, L8688, L8689)	SEE NOTE	SEE NOTE	SEE NOTE	2/9/2024
Venoplasty for relapsing remitting multiple sclerosis (See also Experimental, Investigational or Unproven Services) CPT (36901, 36902, 36903, 36904, 36905, 36906)	N	N	N	11/10/2023