EmblemHealth

Medical Technologies Database

April 2024

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 on the basis of 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 — Denotes investigational unless indicated otherwise | **Y** = Yes | **FFS** = fee for service | **HDE** = humanitarian device exemption

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**
Argus II Retinal Prosthesis System for advanced retinitis pigmentosa **Note: The Argus II is an investigational device that was FDA-approved as a Humanitarian Device Exemption (HDE) for use in adults, age 25 years or older, with severe to profound RP who have bare light perception. The device has since been removed from marketplace.** **CPT (0100T, 0472T, 0473T)**	**N**	**N**	**N**	**3/8/2024**

Bioengineered skin/tissue products for reconstruction **(E.g., abdominal, breast) (See also Experimental, Investigational or Unproven Services)** SurgiMend® — No specific code XenMatrix™ — No specific code	**N**	**N**	**N**	**11/10/2023**
Bioimpedance Spectroscopy (BIS) extracellular fluid analysis for breast cancer lymphedema assessment **CPT (93702)**	**Y**	**Y**	**N**	**3/8/2024**
Cardiac — VADs pediatric (Berlin Heart EXCOR® Pediatric Ventricular Assist Device) **Note: The EXCOR is an investigational device that is FDA-approved as a humanitarian device exemption (HDE), as a bridge to transplant, for severe isolated left ventricular or biventricular dysfunction; therefore, pre-certification requests when presented as such will receive case-by-case review for all LOBs.** **CPT (33975, 33976, 33977, 33978, 33979, 33980, 33981, 33982, 33983, 33990, 33991, 33992, 33993, 33995, 33997)** **HCPCS (Q0478–Q0506)**	**SEE NOTE**	**SEE NOTE**	**SEE NOTE**	**3/8/2024**
Carotid sinus baroreflex activation device — all aspects **(E.g., Barostim™ neo™ Legacy System ([CVRx Inc.])** **(See also Experimental, Investigational or Unproven Services)** **Note: The Barostim is an investigational device that is FDA-approved as a Humanitarian Device Exemption (HDE) for use in patients with resistant hypertension who have had bilateral implantation of the Rheos Carotid Sinus Leads (Models 1010R, 1010L, 1014L and 1014R) which have been discontinued and are obsolete and were determined to be responders in the Rheos pivotal clinical study. The approved implantable pulse generator (IPG) will replace an existing IPG in a patient whose battery is depleted and needs to be replaced and/or electrode lead repair procedures are necessary. Therefore, pre-certification requests when presented as such will be reviewed on a case-by-case basis.** **CPT (0266T, 0267T, 0268T, 0269T, 0270T, 0271T, 0272T, 0273T)**	**N**	**N**	**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:** **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.** **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.** **CPT (0662T, 0663T)** **HCPCS (E0218, E0236)**	**SEE NOTE**	**SEE NOTE**	**SEE NOTE**	**4/12/2024**
Cryoablation — rhinitis, chronic **(E.g., ClariFix)** **CPT (30999, 31299)**	**N**	**N**	**N**	**3/8/2024**
Deep brain stimulation — obsessive compulsive disorder (Reclaim™ DBS™ Therapy) **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.**	**SEE NOTE**	**SEE NOTE**	**SEE NOTE**	**3/8/2024**

CPT (21499, 61863, 61864, 61867, 61885, 61886, 61880, 61888, 95961, 95962) **HCPCS (L8680, L8681, L8682, L8683, L8684, L8685, L8686, L8687, L8688, L8689)**				
Electrical stimulation/diathermy (pulsed) — knee osteoarthritis **(E.g., BioniCare®BIO-1000, OrthoCor Active Knee System)** **(See also Medicare LCD: Transcutaneous Electrical Joint Stimulation Devices)** **HCPCS (No specific code)**	**N**	**N**	**N**	**5/12/2023**
Electrical stimulation — transcutaneous electrical nerve stimulation [TENS) of the trigeminal nerve for pediatric attention deficit hyperactivity disorder (ADHD) **(Monarch External Trigeminal Nerve Stimulation [eTNS] System)** **(See also Experimental, Investigational or Unproven Services)** **HCPCS (K1016, K1017)**	**N**	**N**	**N**	**4/12/2024**
Gene expression profiling — acute myeloid leukemia (AML), therapeutic management **(E.g., NPM1 nucleophosmin], CEBPA [CCAAT/enhancer binding protein [C/EBP], alpha [a], full gene sequence analysis FLT3 gene analysis)** **(See Also NGS Medicare LCD: Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases and Molecular Pathology Procedures LCD)** **CPT ([0046U, 0049U, 0050U, LabPMM], 81310 [NPM1, Commercial and Medicaid coverage eff. 9/12/2020], 81218 [CEBPA], 81245, 81246 [FLT3], 81450)** **Note: Proprietary lab analysis (PLA) codes (those ending with "U") are not covered for Medicaid members, as they are not reimbursed by NYS Medicaid**	**Y**	**Y**	**Y**	**5/12/2023**
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 **(See also Gene Expression Profiling and Molecular Pathology Procedures LCD)** **CPT (81334 [coverage added for Commercial and Medicaid members eff. 11/14/2020])**	**Y**	**Y**	**Y**	**8/11/2023**
Immunoglobulin heavy chain locus (IGH@) testing for acute lymphoblastic leukemia (ALL) and lymphoma, B-cell, to guide therapeutic decision-making **CPT (81261, 81262, 81263, 81264)** **Note: Commercial coverage eff. 11/13/2021**	**Y**	**Y**	**N**	**11/10/2023**
Insulin — insulin potentiation therapy (IPT) for all indications **(E.g., arthritis, cancers, infectious diseases)** **(See also Experimental, Investigational or Unproven Services)** **CPT (82948, 96365, 96366, 99070)** **HCPCS (J1817, J7030, J7040, J7050)** **Coding note: No specific CPT; the following series of CPT and HCPCS J codes are used to describe the various IPT components. Some codes (i.e., code for glucose testing) may be used more than once during a single session of IPT.**	**N**	**N**	**N**	**8/11/2023**
Intracranial angioplasty — atherosclerotic post stroke/vasospasm post aneurysmal subarachnoid hemorrhage **Atherosclerotic stenosis secondary to stroke**	**SEE NOTE**	**SEE NOTE**	**SEE NOTE**	**8/11/2023**

(E.g., NEUROLINK® System, including NEUROLINK® Stent & Delivery Catheter and NEUROLINK® Balloon Dilatation Catheter; Wingspan&Trade Stent System with Gateway&Trade PTA Balloon Catheter) **Vasospasm post aneurysmal subarachnoid hemorrhage** **(E.g., NeuroVasx cPAX Aneurysm Treatment System, ENTERPRISE Vascular Reconstruction Device and Delivery System, Low-Profile Visualized Intraluminal Support Device, Onyx® Liquid Embolic System [Onyx® HD-500])** **Note: These devices are FDA-approved as Humanitarian Device Exemptions (HDEs); therefore, pre certification requests when presented as such will receive case-by-case review for all LOBs EXCEPT for Medicare members with atherosclerotic disease ONLY, whose costs relating directly to the provision of services related to the Intracranial Stenting and Angioplasty NCD (that were non-covered services prior to the issuance of the NCD) will be paid by CMS intermediaries and carriers for cerebral artery stenosis (≥ 50% in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA- approved protocols governing Category B [Investigational Device Exemption] IDE clinical trials). (Medicare does not provide vasospasm coverage)** **NEUROLINK®** **Indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with > 50% stenosis and that are accessible to the stent system** **Wingspan** **Indicated for patients between 22 and 80 years old AND who meet all the following criteria:** **≥ 2 strokes despite aggressive medical management most recent stroke occurred > 7 days prior to planned treatment with Wingspan 70-99 % stenosis due to atherosclerosis of the intracranial artery related to the recurrent strokes have made good recovery from previous stroke and have a modified Rankin score of 3 or less prior to Wingspan treatment. The Rankin scale is used to measure the degree of disability in stroke patients. Lower scores indicate less disability.** **cPax Aneurysm Treatment System** **Indicated for adults (≥ 22 years of age) for wide-necked large and giant-sized cerebral aneurysms (>10) mm that require use of adjunctive assist-devices such as stents or balloons** **ENTERPRISE Vascular Reconstruction Device and Delivery System** **Indicated for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of >= 3 mm and <= 4 mm** **Low-Profile Visualized Intraluminal Support Device** **For use with bare platinum embolic coils for the treatment of unruptured, wide-neck (neck ≥ 4 mm or dome to neck ratio < 2 mm), intracranial, saccular aneurysms arising from a parent vessel with a diameter ≥ 2.5 mm and ≤ 4.5 mm** **Onyx® Liquid Embolic System (Onyx® HD-500)** **Treatment of intracranial, saccular, sidewall aneurysms that present with a wide neck (>= 4 mm) or with a dome-to-neck ratio < 2 that are not amenable to treatment with surgical clipping** **CPT (61630, 61635, 61640, 61641, 61642)**				
Laser — interstitial thermotherapy (LITT) for all indications other than epilepsy and intracranial lesions (as depicted in the row below) **CPT (19499, 20999, 27599, 32999, 47399, 53899, 55899)**	**N**	**N**	**N**	**4/12/2024**
Laser — interstitial thermotherapy (LITT) for intracranial indications (e.g., NeuroBlate®, Visualase®) **Note: MRI-guided LITT for intracranial indications is covered for Commercial and Medicare members, either:** ▪ **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** **CPT (61736, 61737)**	**Y**	**Y**	**N**	**4/12/2024**

Meniscus root repair using Arthrex Root Repair System/Arthrex PEEK SwiveLock Anchor **CPT (29999)**	**N**	**N**	**N**	**7/14/2023**
Microwave thermotherapy for chest wall recurrence of breast cancer **CPT (19499)**	**N**	**N**	**N**	**7/14/2023**
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)**	**N**	**Y**	**Y**	**7/14/2023**
Near-infrared guidance for vascular access requiring real-time digital visualization of subcutaneous vasculature for evaluation of potential access sites and vessel patency **(E.g., AccuVein AV300 or VeinViewer)** **CPT (No specific code)**	**N**	**N**	**N**	**7/14/2023**
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)**	**SEE NOTE**	**SEE NOTE**	**SEE NOTE**	**7/14/2023**
Patient Specific Talus Spacer **Note: The Patient Specific Talus Spacer 3D-printed talus implant is an investigational device that is FDA-approved as a Humanitarian Device Exemption (HDE) for use in adults with avascular necrosis (AVN) of the ankle joint. Therefore, pre-certification requests when presented as such will be reviewed on a case-by-case basis.** **CPT (No specific code)**	**SEE NOTE**	**SEE NOTE**	**SEE NOTE**	**3/8/2024**
Pharmacogenetic testing — FDA cleared or approved companion diagnostics for targeted pharmacotherapeutic management (click on companion diagnostics link to view entire list. (Note: The FDA's list of tests approved for use in conjunction with specific drugs may be searched in its entirety by selecting "All" in the "Show entries" drop down menu) **(See also Gene Expression Profiling, Related drug-specific Medical Policies are also available on EmblemHealth's Medical Policy page.** **The member's Pharmacy benefit should be checked for formulary inclusion at emblemhealth.com. Examples of companion diagnostics associated with the safe use of therapeutics per drug labeling include:** ▪ **Guardant360® CDx (Note: The Guardant360 CDx [CPT 0242U] is an FDA-approved companion diagnostic [CDx] to Tagrisso (osimertinib), Rybrevant (amivantamab-vmjw) and Lumakras (sotorasib) for the treatment of non-small cell lung cancer [NSCLC]. The labels of these drugs stipulate the use of an FDA approved test for patient selection. The Guardant360 CDx differs from the Guardant360 lab developed test [LDT] [CPT 0326U eff. 07/01/2022], as the LDT is not FDA approved as a CDx. The Guardant360 LDT is covered for Commercial and Medicare members when the criteria in the Gene Expression Profiling policy are met)**	**Y**	**Y**	**SEE NOTE**	**11/10/2023**

▪ Abbott RealTime IDH1 and RealTime IDH2 tests, Vysis ALK Break Apart FISH and CLL FISH Probe Kits, PathVysion HER-2 DNA Probe Kit (Abbott Molecular Inc.) ▪ KIT D816V Mutation Detection by PCR for Gleevec Eligibility in Aggressive Systemic Mastocytosis (ASM), PDGFRB FISH for Gleevec Eligibility in Myelodysplastic Syndrome / Myeloproliferative Disease (MDS/MPD) (ARUP Laboratories, Inc.) ▪ InSite Her-2/neu KIT (Biogenex Laboratories, Inc.) ▪ THXID BRAF Kit (bioMérieux Inc.) ▪ HER2 CISH and FISH pharmDx tests, HercepTest (Dako Denmark A/S) ▪ Dako c-KIT and EGFR pharmDx tests, PD-L1 IHC 22C3 pharmDx and PD-L1 IHC 28-8 pharmDx tests (Dako North America, Inc.) ▪ FoundationOne CDx, FoundationFocus CDxBRCA, FoundationOne Liquid CDx (Foundation Medicine Inc.) ▪ Praxis Extended RAS Panel (Illumina, Inc.) ▪ LeukoStrat CDx FLT3 Mutation Assay (Invivoscribe Technologies, Inc.) ▪ Bond Oracle HER2 IHC System (Leica Biosystems) ▪ Oncomine Dx Target Test, SPOT-LIGHT HER2 CISH Kit (Life Technologies Corp.) ▪ MRDx BCR-ABL Test (MolecularMD Corporation) ▪ BRACAnalysis CDx, Myriad myChoice® CDx (Myriad Genetic Labs.) ▪ therascreen BRAF V600E and PIK3CA RGQ kits (QIAGEN GmbH) ▪ therascreen EGFR, FGFR and KRAS RGQ kits (Qiagen Manchester Ltd.) ▪ FerriScan (Resonance Health Analysis Services Pty Ltd.) ▪ cobas BRAF, EGFR, EZH2 and KRAS mutation tests (Roche Molecular Systems, Inc.) ▪ INFORM HER2 Dual ISH DNA Probe Cocktail and INFORM HER-2/neu tests, VENTANA ALK (D5F3) CDx and PD-L1 (SP142) tests, PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems Inc.) ▪ VENTANA MMR RxDx Panel ▪ pharmDX ▪ DetectCDx™ **CPT (81120, 81170, 81206, 81207, 81208, 81210, 81222, 81227, 81235, 81245, 81246, 81275, 81276, 81301, 81401, 81403, 81404, 81445, 81479, 88271, 88184, 88185, 88272, 88273, 88274, 88275, 88291, 88341, 88342, 88361, 88363, 88381)** **Proprietary Lab Analyses (PLA) codes ([0022U Oncomine Dx Target]), [0023U LeukoStrat CDx FLT3], [0037U FoundationOne CDx], [0040U, MRDx BCR- ABL Test], [0154U therascreen FGFR RGQ RT-PCR Kit], [0155U therascreen PIK3CA RGQ PCR Kit, tumor tissue], [0172U myChoice® CDx], [0177U, therascreen PIK3CA RGQ PCR Kit, plasma], [0239U, FoundationOne Liquid CDx] [0242U, Guardant360 CDx], [0111U Praxis Extended RAS Panel])** Note: Proprietary lab analysis (PLA) codes (those ending with "U") are not covered for Medicaid members, as they are not reimbursed by NYS Medicaid.				
Pharmacogenetic testing — IFNL3/IFNL4 gene analysis for drug response (interferon) **(See also MCG #A-0783 and Medicare Molecular Pathology Procedures LCD)** **CPT (81283)**	**N**	**N**	**N**	**2/9/2024**
Pharmacogenetic testing — genotyping for CYP2C19 polymorphisms for members who have been prescribed clopidogrel (Plavix) Note: One allowable per lifetime **CPT (81225)**	**Y**	**Y**	**Y**	**7/14/2023**
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)**	**Y**	**Y**	**Y**	**5/12/2023**

CPT (81287)				
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)**	**SEE NOTE**	**SEE NOTE**	**SEE NOTE**	**11/10/2023**
Placental rapid immunoassay for detection of fetal membrane rupture • **The AmniSure® ROM Test (AmniSure International, LLC) detects the placental alpha microglobulin-1 (PAMG-1) protein marker of the amniotic fluid** • **The ROM Plus® Test (Clinical Innovations, LLC) detects alpha-fetoprotein (AFP) and placental protein 12 (PP12)** • **The Actim® PROM Test (Medix Biochemica) detects insulin growth factor binding protein-1 (IGFBP-1)** **(See also Experimental, Investigational or Unproven Services)** **CPT ([0066U, PartoSure], 84112)**	**N**	**N**	**N**	**7/14/2023**
Pudendal nerve decompression surgery **(See also Experimental, Investigational or Unproven Services)** **CPT (64722)**	**N**	**N**	**N**	**11/10/2023**
Pulmonary artery pressure monitoring — wireless **(E.g., CardioMEMS HF System)** **(See also Experimental, Investigational or Unproven Services)** **CPT (33289)**	**N**	**Y**	**N**	**11/10/2023**
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)	**N**	**N**	**N**	**11/10/2023**

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)				
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)** **CPT (90867, 90868, 90869)**	**N**	**N**	**N**	**11/10/2023**
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:**	**SEE NOTE**	**SEE NOTE**	**SEE NOTE**	**2/9/2024**

▪ 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, L6868, L8689)**				
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**