Experimental & Investigational Services
Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Experimental & Investigational Services		
MNG #: 010	**☒SCO ☒One Care** **☒ MA Medicare Premier** **☒ MA Medicare Value** **☒ RI Medicare Preferred** **☒ RI Medicare Value** **☒ RI Medicare Maximum**	**Prior Authorization Needed?** **☒ Yes (always required)** **☐ Yes (only in certain situations. See this MNG for details)** **☐ No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Benefit Type: **☐ Medicare** **☐ Medicaid**	**Approval Date:** 1/28/2019; 10/12/23; 11/9/23	**Effective Date:** 4/01/2019; 10/12/23; 11/9/23; 1/1/24
Last Revised Date: 1/29/2019; 08/05/2020, 10/16/2020; 11/05/2020; 04/01/2021; 05/13/2021; 05/18/2021; 08/04/2021; 08/19/2021; 9/2/2021; 6/2/2022; 1/11/2023; 4/13/2023; 7/13/2023; 10/12/2023; 11/9/23;	**Next Annual Review Date:** 08/05/2021; 11/05/2021; 04/01/2022; 05/13/2022; 05/18/2022; 08/04/2022; 08/19/2022; 9/2/2022; 6/2/2023; 1/11/2024; 4/13/2024; 7/13/2024; 10/12/2024; 11/9/24	**Retire Date:**

OVERVIEW:

Experimental, investigational, or unproven service (EIS) may refer to a service (e.g., treatment), procedure (e.g., test or intervention), or supply (e.g., drug, device, or equipment) that is not accepted by the professional medical community as the standard practice or therapy. Commonly, there is insufficient *authoritative or reliable evidence* for the EIS and its absolute risk (in terms of safety and effectiveness) to permit conclusions to be drawn for the effect of the treatment on health outcomes. As such, the EIS is part of ongoing studies to determine its safety, effectiveness, toxicity, maximum tolerated dose, and efficacy compared to a generally accepted means of diagnosis or treatment.

To make coverage determinations on EIS, Commonwealth Care Alliance (CCA) will utilize pertinent medical necessity guidelines; and review related information from government regulatory bodies, accrediting organizations, and scientific evidence. This may include guidance from the Center for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), MassHealth, InterQual, National Committee for Quality Assurance (NCQA), authoritative or reliable evidence, and actively practicing specialty physicians. This will ensure that the coverage of EIS is consistent and clinically appropriate (in terms of type, frequency, extent, site, and duration) for the prevention, diagnosis, and treatment of the condition (which includes disease, illness, or disability).

DEFINITIONS:

Authoritative or Reliable Evidence: Authoritative or reliable evidence refer to:

- Reports and articles that are derived from well-designed, well-conducted and scientifically valid studies that are published in credible, medical, and scientific research journals,
- Peer-reviewed publications that have been assessed by medical or scientific experts prior to publication,
- Evaluations of evidence that have considered the consistency of results and quality of published studies,

Experimental & Investigational Services
Medical Necessity Guideline

- Guidelines and recommendations made by national medical associations, reputable technology assessment bodies, and healthcare professionals with recognized clinical expertise in treating the medical condition and/or providing the treatment.
- Examples of acceptable sources of peer-reviewed medical literature include (this is not an exhaustive list):
  - American Journal of Medicine
  - Annals of Internal Medicine
  - Annals of Oncology
  - Annals of Surgical Oncology
  - Blood
  - British Medical Journal
  - The Journal of the American Medical Association
  - Journal of Clinical Oncology
  - Journal of the National Cancer Institute
  - Journal of Urology
  - Lancet
  - The New England Journal of Medicine
  - Annals of General Surgery

Experimental, Investigational or Unproven Services (EIS): Experimental, investigational, or unproven services may refer to but not limited to a drug, test, procedure, treatment, device, or equipment that remains under study as its absolute risk is unestablished. Further study is required to determine the safety, effectiveness, toxicity, maximum tolerated dose, and efficacy of the EIS. It is generally not the standard therapy, therefore, not accepted by the professional medical community.

Generally Accepted Standards of Medical Practice: Standards that are based on credible scientific data, are published in peer-reviewed medical/scientific literature, are recognized by the relevant medical community, and align with physician specialty society recommendations and views of physicians practicing in the relevant clinical areas.

Medically Necessary: A service is "medically necessary" if:

(1) it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity; **and**

(2) There is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly. Services that are less costly or more conservative include, but are not limited to, health care reasonably known by the provider, or identified by CCA pursuant to a prior authorization request, to be available to the member through the requesting provider or from another provider who is available to treat the member.

Not Medically Necessary: A healthcare service or product is considered not medically necessary when it is provided primarily for the convenience of the patient, physician, or other healthcare provider, and is more costly than an alternative service or sequence of services that may produce equivalent therapeutic or diagnostic effect in the diagnosis or treatment of the member's specific illness or disease. These healthcare service or products may be in accordance with generally accepted standards of medical practice and/or be clinically appropriate.

DECISION GUIDELINES:

commonwealth care alliance®

Experimental & Investigational Services
Medical Necessity Guideline

Commonwealth Care Alliance will not cover services, procedures, and/or supplies that are considered experimental, investigational, or unproven AND *not medically necessary* according to the following criteria:

- The service, procedure, or supply does not have final and/or unrestricted market approval from the FDA or from any other governmental regulatory body,
- Further study is required to determine the safety, efficacy, toxicity, or maximum tolerated dose for the service, procedure, or supply,
- There is insufficient authoritative evidence to allow for the evaluation of the therapeutic value of the service, procedure, or supply,
- There is insufficient authoritative evidence to permit the evaluation of *net health outcomes*,
- There is insufficient authoritative evidence that the service, procedure, or supply has a beneficial effect on health outcomes or is as beneficial as other alternative interventions or therapies, when used in a non-investigational setting,
- The service, procedure, or supply is not as beneficial as established alternative interventions or therapies, AND
- The service, procedure, or supply is not in accordance with *generally accepted standards of medical practice* or not generally accepted by in the professional medical community as safe and effective in the setting and condition for which it is used.

Commonwealth Care Alliance may cover services, procedures, and/or supplies that are considered experimental, investigational, or unproven when they meet the following criteria:

- The service, procedure, or supply request is evaluated by a CCA medical director,
- The service, procedure, or supply is determined to be *medically necessary* in accordance with the definition, regulatory and professional standards, and authoritative evidence,
- The medical necessity for the service, procedure, or supply is substantiated by:
    - Documentation to support that the service, procedure, or supply is medically necessary, AND
    - Complete copies (in full-text) of supporting peer-reviewed literature to indicate that the service, procedure, or supply is,
        - Safe and efficacious,
        - Generally accepted by the professional medical community,
        - Regarded or accepted as a comparable treatment for the member's underlying disease, AND
        - The most conservative or least costly alternative

    OR

    - Documentation that indicates that the service, procedure, or supply is:
        - The best treatment choice for the member due to their specific unique clinical circumstances,
        - Standard therapies have been tried and not been effective OR have been determined to not be medically appropriate,
        - There is reason to believe that the intervention requested will be successful when other treatments have failed.
    - Complete copies (in full-text) of supporting peer-reviewed literature to indicate that the service, procedure, or supply is safe and efficacious.

The hierarchy of authoritative evidence that will be used to determine whether the service, procedure, or supply is safe and efficacious, generally accepted by the professional medical community, and regarded or accepted as a comparable treatment for the member's underlying disease, is:

- Published formal technology assessments and/or high-quality meta-analyses,
- Well-designed randomized studies published in credible, peer-reviewed literature,
- High quality case-control or cohort studies,
- Historical control studies, case reports, and/or case series,
- Reports of expert opinion from national professional medical societies or national medical policy organizations

LIMITATIONS/EXCLUSIONS:

Commonwealth Care Alliance limits coverage to EIS services, procedures, or supplies wherein medical necessity has been determined, safety and efficacy has been established, and therapeutic benefit is comparable with standard treatment, evidenced by authoritative evidence. Reports, articles or statements from providers that contain only abstracts, anecdotal evidence, or personal professional opinions is not considered authoritative evidence.

Commonwealth Care Alliance will not cover the following EIS services, procedures, or supplies in the following list of procedure and/or diagnosis codes below. Information related to the list include:

- The following CPT/HCPCS procedure codes are considered as EIS and are generally not covered,
- The list is intended to be used as a reference and for informational purposes,
- When it states, there is “no specific code available” this indicates that it is an “unlisted code” or “miscellaneous code,”
- When it states, “EIU (experimental, investigational, or unproven)” in the third column of the list, non-coverage is implied, AND
    - Note: Codes of related therapy for similar conditions may be non-covered as an EIU
- The list is not all inclusive and may change as emerging evidence becomes available.

AUTHORIZATION:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the servicearea who are medical experts in the appropriate field, review of FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions. If at any time a CMS Local or National Coverage Determination (LCD or NCD) is published that conflicts with the criteria set forth herein, the NCD or LCD criteria shall supersede these criteria.

commonwealth care alliance®

Experimental & Investigational Services
Medical Necessity Guideline

Code	Description	Details	Last Review Date
19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroedenoma	EIU	2/21/2023
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures; image-less (MAKO Surgical Corp® (Stryker), RIO® Robotic Arm)	EIU	2/21/2023
22505	Manipulation Procedures on the Spine (Vertebral Column)	EIU	10/12/2023
22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level (IDET)	EIU	2/21/2023
22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; one or more additional levels (IDET)	EIU	2/21/2023
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace	EIU	2/21/2023
22857	Total disc arthroplasty (artificial disc), anterior approach, including diskectomy to prepare interspace (other than decompression); single interspace, lumbar	EIU	2/21/2023
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)	EIU	2/21/2023
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed	EIU	2/21/2023
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular	EIU	2/21/2023

33548	Surgical ventricular restoration procedure, includes prosthetic patch, when performed (e.g., ventricular remodeling, SVR, SAVER, Dor procedures)	EIU	2/21/2023
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated (e.g. "Clarivein")	EIU	2/21/2023
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (e.g. "Clarivein")	EIU	2/21/2023
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles){e.g.,Percutaneous Transcatheter Coil Embolization for Pelvic Congestion Syndrome}	EIU	2/21/2023
37790	Penile venous occlusive procedure	EIU	2/21/2023
41512	Tongue base suspension, permanent suture technique	EIU	2/21/2023
43206	Esophagoscopy, rigid or flexible, with optical endomicroscopy	EIU	2/21/2023
43252	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate, with optical endomicroscopy	EIU	2/21/2023
43257	Upper Gastrointestinal Endoscopy with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease, (e.g., Stretta procedure, the Bard® EndoCinch™ Suturing System, Plicator™ and Enteryx™)	EIU	2/21/2023
43497	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])	EIU	2/21/2023

53451	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance (ProAct (Uromedica))	EIU	2/21/2023
53452	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance (ProAct (Uromedica))	EIU	2/21/2023
53453	Periurethral transperineal adjustable balloon continence device; removal, each balloon (ProAct (Uromedica))	EIU	2/21/2023
53454	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume (ProAct (Uromedica))	EIU	2/21/2023
53860	Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence	EIU	2/21/2023
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance	EIU	2/21/2023
61736	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion	EIU	2/21/2023
61737	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)	EIU	2/21/2023
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array	EIU EXCEPT for G20, G21.4, G24.1, G25.0- G25.2, G40.011-G40.019; G40.111-G40.119; G40.211-G40.219, G40.311-G40.319, G40.813, G40.814, G40.A11, G40.A19	6/2/2022
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays	EIU EXCEPT for G20, G21.4, G24.1, G25.0- G25.2,G40.011-G40.019;G40.111-G40.119;G40.211-G40.219,G40.311-G40.319,G40.813, G40.814,G40.A11, G40.A19	6/2/2022

62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar	EIU	2/21/2023
64505	Injection, anesthetic agent; sphenopalatine ganglion	EIU	2/21/2023
64553	Percutaneous implantation of neurostimulator electrodes; cranial nerve	EIU	2/21/2023
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed	EIU when submitted with the following codes: M53.3, M54.16, M54.17, M54.18, M54.40, M54.41, M54.42, M54.50, M54.51, M54.59, M54.9	2/21/2023
64568	Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator	EIU EXCEPT for G40.011-G40.019; G40.211-G40.219, G40.311-G40.319, G40.813, G40.814, G40.A11, G40.A19	6/2/2022
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling	EIU for K59.00, R10.2, R33.9, N39.3, G62, G64, G90, 356.9, E10.43, K31.84, Z4542, M54.81, R51, G43, G44	6/2/2022
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	EIU for K59.00, R10.2, R33.9, N39.3, G62, G64, G90, 356.9, E10.43, K31.84, Z4542, M54.81, R51, G43, G44	6/2/2022
64640	Destruction by neurolytic agent; other peripheral nerve or branch (when requested as iovera)	EIU for M17.0-M17.9	1/4/2023
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed (when requested as iovera)	EIU for M17.0-M17.9	1/4/2023
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	EIU	2/21/2023
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral (Intacept)	EIU	2/21/2023

64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure) (Intacept)	EIU	2/21/2023
68841	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each	EIU	2/21/2023
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral	EIU	2/21/2023
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral	EIU	2/21/2023
76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method	EIU	2/21/2023
76982	Ultrasound, elastography, first target lesion	EIU	2/21/2023
76983	Ultrasound, elastography, each additional target lesion (List separately in addition to code for primary procedure)	EIU	2/21/2023
77089	Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual Xray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture-risk	EIU	2/21/2023
80145	Adalimumab	EIU	2/21/2023
80230	Infliximab	EIU	2/21/2023
80280	Vedolizumab	EIU	2/21/2023
81490	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score, (e.g., Vectra® DA)	EIU	2/21/2023
81500	Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score, (e.g., Risk of Ovarian Malignancy Algorithm (ROMA™))	EIU	2/21/2023
81503	Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin and prealbumin), utilizing serum, algorithm reported as a risk score (OVA1™, Vermillion, Inc.)	EIU	2/21/2023
81506	Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbA1c, insulin, hs-CRP, adiponectin, ferritin, interleukin 2-	EIU	2/21/2023

	receptor alpha), utilizing serum or plasma, algorithm reporting a risk score, (e.g., PreDx™ Diabetes Risk Score)		
81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination, (ChemoFx, Helomics)	EIU	2/21/2023
81536	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure), (ChemoFx, Helomics)	EIU	2/21/2023
81538	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival, (VeriStrat, Biodesix, Inc.)	EIU	2/21/2023
81560	Transplantation medicine (allograft rejection, pediatric liver and small bowel), measurement of donor and third-party-induced CD154+Tcytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score (Pleximmune test)	EIU	2/21/2023
82777	Galectin-3	EIU	2/21/2023
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)	EIU	2/21/2023
83631	Lactoferrin, fecal, quantitative	EIU	2/21/2023
83987	pH; exhaled breath condensate	EIU	2/21/2023
84145	Procalcitonin (PCT)	EIU	2/21/2023
86152	Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood); (e.g., CellSearch Circulating Tumor Cell (CTC) Kit for monitoring Metastatic Breast Cancer)	EIU	2/21/2023
86153	Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood); physician interpretation and report, when required, (e.g., CellSearch Circulating Tumor Cell (CTC) Kit for monitoring Metastatic Breast Cancer)	EIU	2/21/2023

86343	Leukocyte histamine release test (LHR)	EIU	2/21/2023
88375	Optical endomicroscopic image(s), interpretation and report, realtime or referred, each endoscopic session	EIU	2/21/2023
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report (Pillcam 2 (medtronic)	EIU	2/21/2023
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report	EIU	2/21/2023
92512	Nasal function studies	EIU	2/21/2023
92548	Computerized dynamic posturography	EIU	2/21/2023
92549	Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report; with motor control test (MCT) and adaptation test (ADT)	EIU	2/21/2023
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional	EIU	2/21/2023
93278	Signal-averaged electrocardiography (SAECG), with or without ECG	EIU	2/21/2023
93356	Myocardial strain imaging using speckle tracking-derived assessment of myocardial mechanics (List separately in addition to codes for echocardiography imaging)	EIU	2/21/2023
93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)	EIU	2/21/2023
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral	EIU	2/21/2023
95060	Ophthalmic mucous membrane tests	EIU	2/21/2023
95065	Direct nasal mucous membrane test	EIU	2/21/2023
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording	EIU	2/21/2023
96904	Whole body integumentary photography, for monitoring of high-risk patients with dysplastic	EIU	2/21/2023

	nevus syndrome or a history of dysplastic nevi, or patients with a personal or familial history of melanoma (e.g., MelaFind®)		
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)	EIU for N39, R32, R15; ALLOWED for N32.81, N39.15, N39.41, R35.0	6/2/2022
97610	Low frequency, non-contact, nonthermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	EIU	2/21/2023
A2001	InnovaMatrix AC, per sq cm	EIU	2/21/2023
A2002	Mirragen Advanced Wound Matrix, per sq cm	EIU	2/21/2023
A2004	XCelliStem, per sq cm	EIU	2/21/2023
A2005	Microlyte Matrix, per sq cm	EIU	2/21/2023
A2006	NovoSorb SynPath dermal matrix, per sq cm	EIU	2/21/2023
A2007	Restrata, per sq cm	EIU	2/21/2023
A2008	TheraGenesis, per sq cm	EIU	2/21/2023
A2009	Symphony, per sq cm	EIU	2/21/2023
A2010	Apis, per sq cm	EIU	2/21/2023
A2011	Supra SDRM, per sq cm	EIU	2/21/2023
A2012	SUPRATHEL, per sq cm	EIU	2/21/2023
A9272	Wound suction, disposable, includes dressing, all accessories and components, any type, each, (e.g., PICO™ Single Use Negative Pressure Wound Therapy System) (NPWT)	EIU	2/21/2023
A9291	Prescription digital cognitive and/or behavioral therapy, FDAcleared, per course of treatment	EIU	2/21/2023
C1818	Integrated Keratoprosthesis	EIU	6/2/2022
C1821	Interspinous process distraction device (implantable)	EIU	2/21/2023
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads	EIU	2/21/2023
C1824	Generator, cardiac contractility modulation (implantable)	EIU	2/21/2023
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)	EIU	2/21/2023
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components (e.g., CardioMEMSTM HF System)	EIU	2/21/2023

C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	EIU	2/21/2023
C9755	Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed	EIU	2/21/2023
C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar	EIU	2/21/2023
C9758	Blinded procedure for NYHA Class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, transesophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	EIU	2/21/2023
C9760	Nonrandomized, nonblinded procedure for NYHA Class II, III, IV heart failure, transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, transesophageal echocardiography	EIU	2/21/2023

	(TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study		
C9771	Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral	EIU	2/21/2023
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	EIU	2/21/2023
C9783	Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catherization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved investigational device exemption (IDE) study	EIU	2/21/2023
E0218	Fluid circulating cold pad with pump, any type	EIU	7/13/2023
E0221	Infrared heating pad system	EIU	2/21/2023
E0236	Pump for water circulating pad	EIU	2/21/2023
E0746	Electromyography (EMG), biofeedback device (when used for SPEAC System)	EIU	2/21/2023
E0749	Osteogenesis stimulator, electrical, surgically implanted	EIU	2/21/2023
E0761	Nonthermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device	EIU	2/21/2023
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories	EIU	2/21/2023
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting	EIU	2/21/2023

E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified	EIU	2/21/2023
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified	EIU	2/21/2023
E2001	Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system (when requested as PureWick)	EIU	1/1/24
E2120	Pulse generator system for tympanic treatment of inner ear endolymphatic fluid	EIU	2/21/2023
G0255	Current perception threshold/sensory nerve conduction test, (SNCT) per limb, any nerve	EIU	2/21/2023
G0282	Electrical stimulation, (unattended), to one or more areas, for wound care	EIU	2/21/2023
G0295	Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses	EIU	2/21/2023
G0327	Colorectal cancer screening, bloodbased biomarker	EIU	2/21/2023
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)	EIU	2/21/2023
J2001 **J3490** **96365** **96366** **96374**	IV Infusions of anesthetics (e.g., ketamine or lidocaine) for the management of: (1) Chronic pain (including but not limited to chronic neuropathic pain, chronic daily headache, and fibromyalgia) Behavioral health conditions (including but not limited to depression, bipolar disorder, post-traumatic stress disorder, autism spectrum disorder, and obsessive-compulsive disorder)	EIU	6/2/2022
K1007	Powered exoskeletons for ambulation in patients with lower limb disabilities.	EIU	6/2/2022
K1016	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve	EIU	2/21/2023
K1017	Monthly supplies for use of device coded at K1016	EIU	2/21/2023
K1018	External upper limb tremor stimulator of the peripheral nerves of the wrist	EIU	2/21/2023
K1019	Replacement supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist	EIU	2/21/2023

K1020	Noninvasive vagus nerve stimulator	EIU	2/21/2023
K1021	Exsufflation belt, includes all supplies and accessories	EIU	2/21/2023
K1023	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm	EIU	2/21/2023
K1024	Nonpneumatic compression controller with sequential calibrated gradient pressure	EIU	2/21/2023
K1025	Nonpneumatic sequential compression garment, full arm	EIU	2/21/2023
K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment	EIU	2/21/2023
K1028	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application	EIU	2/21/2023
K1029	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply	EIU	2/21/2023
K1030	External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only	EIU	2/21/2023
L2006	Knee-ankle-foot (KAF) device, any material, single or double upright, swing and/or stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated	EIU	2/21/2023
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)	EIU	2/21/2023
L6880	Electric Hand, Switch Or Myolelectric Controlled, Independently Articulating Digits, Any Grasp Pattern Or Combination Of Grasp Patterns, Includes Motor(s)	EIU	6/2/2022
L8605	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies, e.g., SOLESTA® (hyaluronicacid/dextranomer)	EIU	2/21/2023

L8607	Injectable bulking agent for vocal cord medialization, 0.1 ml, includes shipping and necessary supplies	EIU	2/21/2023
L8608	Miscellaneous external component, supply or accessory for use with the Argus II Retinal Prosthesis System	EIU	2/21/2023
L8701	Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated.	EIU	6/2/2022
L8702	Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated.	EIU	6/2/2022
M0076	Prolotherapy	EIU	2/21/2023
M0300	IV chelation therapy (chemical endarterectomy)	EIU	2/21/2023
S1091	Stent, noncoronary, temporary, with delivery system (Propel)	EIU	2/21/2023
S2080	Laser-assisted uvulopalatoplasty (LAUP)	EIU	2/21/2023
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar	EIU	2/21/2023
S3900	Surface electromyography (EMG)	EIU	2/21/2023
S8080	Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical	EIU	2/21/2023
S8092	Electron beam computed tomography (also known as ultrafast CT, Cine CT)	EIU	2/21/2023
S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with patient (e.g., PSTIM™)	EIU	2/21/2023
S9024	Paranasal sinus ultrasound	EIU	2/21/2023
S9090	Vertebral axial decompression, per session	EIU	2/21/2023
~~**Q4121**~~	~~Theraskin, per square centimeter~~	~~EIU~~	~~2/21/2023~~
Q4134	hMatrix, per sq cm	EIU	2/21/2023
Q4135	Mediskin, per sq cm	EIU	2/21/2023
Q4136	E-Z Derm, per sq cm	EIU	2/21/2023
Q4140	BioDFence® and BioDFence® G3 human amniotic allograft products	EIU	2/21/2023
Q4148	NEOX 1k, per square centimeter	EIU	2/21/2023

Q4150	Allowrap DS or dry, per sq cm	EIU	2/21/2023
Q4152	Dermapure, per sq cm	EIU	2/21/2023
Q4153	Dermavest, per sq cm	EIU	2/21/2023
Q4154	Biovance, per sq cm	EIU	2/21/2023
Q4155	Neoxflo or clarixflo 1 mg	EIU	2/21/2023
Q4156	Neox 100, per sq cm	EIU	2/21/2023
Q4157	Revitalon, per sq cm	EIU	2/21/2023
Q4158	Kerecis Omega3, per sq cm	EIU	2/21/2023
Q4159	Affinity, per sq cm	EIU	2/21/2023
Q4160	Nushield, per square centimeter	EIU	2/21/2023
Q4165	Keramatrix, per sq cm	EIU	2/21/2023
Q4166	Cytal, per square centimeter	EIU	2/21/2023
Q4167	Truskin, per square centimeter	EIU	2/21/2023
Q4169	Artacent wound, per square centimeter	EIU	2/21/2023
Q4170	Cygnus, per square centimeter	EIU	2/21/2023
Q4171	Interfyl, 1 mg	EIU	2/21/2023
Q4173	Palingen or palingen xplus, per square centimeter	EIU	2/21/2023
Q4174	Palingen or promatrx, 0.36 mg per 0.25 cc	EIU	2/21/2023
Q4175	Miroderm, per square centimeter	EIU	2/21/2023
Q4176	NeoPatch, per sq cm	EIU	2/21/2023
Q4177	FlowerAmnioFlo, 0.1 cc	EIU	2/21/2023
Q4178	FlowerAmnioPatch, per sq cm	EIU	2/21/2023
Q4179	FlowerDerm, per sq cm	EIU	2/21/2023
Q4180	Revita, per sq cm	EIU	2/21/2023
Q4181	Amnio Wound, per sq cm	EIU	2/21/2023
Q4183	Surgigraft, per sq cm	EIU	2/21/2023
Q4184	Cellesta, per sq cm	EIU	2/21/2023
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc	EIU	2/21/2023
Q4188	AmnioArmor, per sq cm	EIU	2/21/2023
Q4189	Artacent AC, per sq cm	EIU	2/21/2023
Q4191	Restorigin, per sq cm	EIU	2/21/2023
Q4192	Restorigin, 1 cc	EIU	2/21/2023
Q4193	Coll-e-Derm, per sq cm	EIU	2/21/2023
Q4194	Novachor, per sq cm	EIU	2/21/2023
Q4195	PuraPly, per sq cm	EIU	2/21/2023
Q4196	PuraPly AM, per sq cm	EIU	2/21/2023
Q4197	PuraPly XT, per sq cm	EIU	2/21/2023
Q4198	Genesis Amniotic Membrane, per sq cm	EIU	2/21/2023
Q4199	Cygnus matrix, per sq cm	EIU	2/21/2023
Q4200	SkinTE, per sq cm	EIU	2/21/2023

Q4201	Matrion, per sq cm	EIU	2/21/2023
Q4202	Keroxx (2.5 g/cc), 1 cc	EIU	2/21/2023
Q4203	Derma-Gide, per sq cm	EIU	2/21/2023
Q4204	XWRAP, per sq cm	EIU	2/21/2023
Q4205	Membrane Graft or Membrane Wrap, per sq cm	EIU	2/21/2023
Q4206	Fluid Flow or Fluid GF, 1 cc	EIU	2/21/2023
Q4208	Novafix, per sq cm	EIU	2/21/2023
Q4209	SurGraft, per sq cm	EIU	2/21/2023
Q4210	Axolotl Graft or Axolotl DualGraft, per sq cm	EIU	2/21/2023
Q4211	Amnion Bio or AxoBioMembrane, per sq cm	EIU	2/21/2023
Q4212	AlloGen, per cc	EIU	2/21/2023
Q4213	Ascent, 0.5 mg	EIU	2/21/2023
Q4214	Cellesta Cord, per sq cm	EIU	2/21/2023
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg	EIU	2/21/2023
Q4216	Artacent Cord, per sq cm	EIU	2/21/2023
Q4217	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm	EIU	2/21/2023
Q4218	SurgiCORD, per sq cm	EIU	2/21/2023
Q4219	SurgiGRAFT-DUAL, per sq cm	EIU	2/21/2023
Q4220	BellaCell HD or Surederm, per sq cm	EIU	2/21/2023
Q4221	Amnio Wrap2, per sq cm	EIU	2/21/2023
Q4222	ProgenaMatrix, per sq cm	EIU	2/21/2023
Q4224	Human Health Factor 10 Amniotic Patch (HHF10-P), per sq cm	EIU	2/21/2023
Q4225	AmnioBind, per sq cm	EIU	2/21/2023
Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm	EIU	2/21/2023
Q4227	AmnioCoreTM, per sq cm	EIU	2/21/2023
Q4229	Cogenex Amniotic Membrane, per sq cm	EIU	2/21/2023
Q4230	Cogenex Flowable Amnion, per 0.5 cc	EIU	2/21/2023
Q4231	Corplex P, per cc	EIU	2/21/2023
Q4232	Corplex, per sq cm	EIU	2/21/2023
Q4233	SurFactor or NuDyn, per 0.5 cc	EIU	2/21/2023
Q4234	XCellerate, per sq cm	EIU	2/21/2023
Q4235	AMNIOREPAIR or AltiPly, per sq cm	EIU	2/21/2023
Q4237	Cryo-Cord, per sq cm	EIU	2/21/2023
Q4238	Derm-Maxx, per sq cm	EIU	2/21/2023
Q4239	Amnio-Maxx or Amnio-Maxx Lite, per sq cm	EIU	2/21/2023
Q4240	CoreCyte, for topical use only, per 0.5 cc	EIU	2/21/2023
Q4241	PolyCyte, for topical use only, per 0.5 cc	EIU	2/21/2023
Q4242	AmnioCyte Plus, per 0.5 cc	EIU	2/21/2023

Q4244	Procenta, per 200 mg	EIU	2/21/2023
Q4245	AmnioText, per cc	EIU	2/21/2023
Q4246	CoreText or ProText, per cc	EIU	2/21/2023
Q4247	Amniotext patch, per sq cm	EIU	2/21/2023
Q4248	Dermacyte Amniotic Membrane Allograft, per sq cm	EIU	2/21/2023
Q4249	AMNIPLY, for topical use only, per sq cm	EIU	2/21/2023
Q4250	AmnioAmp-MP, per sq cm	EIU	2/21/2023
Q4251	Vim, per sq cm	EIU	2/21/2023
Q4252	Vendaje, per sq cm	EIU	2/21/2023
Q4253	Zenith Amniotic Membrane, per sq cm	EIU	2/21/2023
Q4254	Novafix DL, per sq cm	EIU	2/21/2023
Q4255	REGUaRD, for topical use only, per sq cm	EIU	2/21/2023
Q4256	MLG-Complete, per sq cm	EIU	2/21/2023
Q4257	Relese, per sq cm	EIU	2/21/2023
Q4258	Enverse, per sq cm	EIU	2/21/2023
Q4260	Signature APatch, per sq cm	EIU	2/21/2023
Q4261	TAG, per sq cm	EIU	2/21/2023
0042T	Cerebral perfusion analysis using computed tomography with contrast administration, including post-processing of parametric maps with determination of cerebral blood flow, cerebral blood volume, and mean transit time	EIU	2/21/2023
0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (List separately in addition to code for primary procedure)	EIU	2/21/2023
0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images (List separately in addition to code for primary procedure)	EIU	2/21/2023
0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue	EIU	2/21/2023
0072T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue	EIU	2/21/2023
0075T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s),	EIU	2/21/2023

	including radiologic supervision and interpretation, percutaneous; initial vessel		
0076T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; each additional vessel	EIU	2/21/2023
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy	EIU	2/21/2023
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy	EIU	2/21/2023
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle	EIU	2/21/2023
0106T	Quantitative sensory testing (QST), testing and interpretation per extremity; using touch pressure stimuli to assess large diameter sensation	EIU	2/21/2023
0107T	Quantitative sensory testing (QST), testing and interpretation per extremity; using vibration stimuli to assess large diameter fiber sensation	EIU	2/21/2023
0108T	Quantitative sensory testing (QST), testing and interpretation per extremity; using cooling stimuli to assess small nerve fiber sensation and hyperalgesia	EIU	2/21/2023
0109T	Quantitative sensory testing (QST), testing and interpretation per extremity; using heat-pain stimuli to assess small nerve fiber sensation and hyperalgesia	EIU	2/21/2023
0110T	Quantitative sensory testing (QST), testing and interpretation per extremity; using other stimuli to assess sensation	EIU	2/21/2023
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)	EIU	2/21/2023
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List	EIU	2/21/2023

	separately in addition to code for primary procedure)		
0174T	Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation	EIU	2/21/2023
0175T	Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation	EIU	2/21/2023
0198T	Measurement of ocular blood flow by repetitive intraocular pressure sampling, with interpretation and report	EIU	2/21/2023
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed	EIU	2/21/2023
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed	EIU	2/21/2023
0202T	Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, with or without injection of bone cement, including fluoroscopy, single level, lumbar spine	EIU	2/21/2023
0207T	Evacuation of Meibomian glands, automated, using heat and intermittent pressure, unilateral	EIU	2/21/2023
0208T	Pure tone audiometry (threshold), automated (includes use of computer-assisted device); air only	EIU	2/21/2023
0209T	Pure tone audiometry (threshold), automated (includes use of computer-assisted device); air and bone	EIU	2/21/2023

0210T	Speech audiometry threshold, automated (includes use of computer-assisted device);	EIU	2/21/2023
0211T	Speech audiometry threshold, automated (includes use of computer-assisted device); with speech recognition	EIU	2/21/2023
0212T	Comprehensive audiometry threshold evaluation and speech recognition (0209T, 0211T combined), automated (includes use of computer-assisted device)	EIU	2/21/2023
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	EIU	2/21/2023
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest	EIU	2/21/2023
0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest	EIU	2/21/2023
0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autolog	EIU	2/21/2023
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intraoperative interrogation, programming, and repositioning, when performed)	EIU	2/21/2023
0267T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	EIU	2/21/2023
0268T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, pulse generator	EIU	2/21/2023

	only (includes intraoperative interrogation, programming, and repositioning, when performed)		
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	EIU	2/21/2023
0270T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	EIU	2/21/2023
0271T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	EIU	2/21/2023
0272T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day);	EIU	2/21/2023
0273T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming	EIU	2/21/2023
0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or	EIU	2/21/2023

	foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar		
0278T	Transcutaneous electrical modulation pain reprocessing (e.g., scrambler therapy), each treatment session (includes placement of electrodes)	EIU	2/21/2023
0330T	Tear film imaging, unilateral or bilateral, with interpretation and report	EIU	2/21/2023
0331T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment;	EIU	2/21/2023
0332T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment, with tomographic SPECT	EIU	2/21/2023
0335T	Insertion of sinus tarsi implant	EIU	2/21/2023
0338T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral	EIU	2/21/2023
0339T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral	EIU	2/21/2023
0342T	Therapeutic apheresis with selective HDL delipidation and plasma reinfusion	EIU	2/21/2023
0351T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real time intraoperative	EIU	2/21/2023
0352T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; interpretation and report, real time or referred	EIU	2/21/2023

0353T	Optical coherence tomography of breast, surgical cavity; real time intraoperative	EIU	2/21/2023
0354T	Optical coherence tomography of breast, surgical cavity; interpretation and report, real time or referred	EIU	2/21/2023
0358T	Bioelectrical impedance analysis whole body composition assessment, supine position, with interpretation and report	EIU	2/21/2023
0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed	EIU	2/21/2023
0395T	High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed	EIU	2/21/2023
0397T	Endoscopic retrograde cholangiopancreatography (ERCP), with optical endomicroscopy (List separately in addition to code for primary procedure)	EIU	2/21/2023
0398T	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed	EIU	2/21/2023
0408T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes	EIU	2/21/2023
0409T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only	EIU	2/21/2023
0410T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; atrial electrode only	EIU	2/21/2023
0411T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and	EIU	2/21/2023

	programming of sensing and therapeutic parameters; ventricular electrode only		
0412T	Removal of permanent cardiac contractility modulation system; pulse generator only	EIU	2/21/2023
0413T	Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular)	EIU	2/21/2023
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only	EIU	2/21/2023
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode, (atrial or ventricular lead)	EIU	2/21/2023
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator	EIU	2/21/2023
0417T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable cardiac contractility modulation system	EIU	2/21/2023
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable cardiac contractility modulation system	EIU	2/21/2023
0424T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)	EIU	2/21/2023
0425T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; sensing lead only	EIU	2/21/2023
0426T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; stimulation lead only	EIU	2/21/2023
0427T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; pulse generator only	EIU	2/21/2023
0428T	Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only	EIU	2/21/2023

0429T	Removal of neurostimulator system for treatment of central sleep apnea; sensing lead only	EIU	2/21/2023
0430T	Removal of neurostimulator system for treatment of central sleep apnea; stimulation lead only	EIU	2/21/2023
0431T	Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only	EIU	2/21/2023
0432T	Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only	EIU	2/21/2023
0433T	Repositioning of neurostimulator system for treatment of central sleep apnea; sensing lead only	EIU	2/21/2023
0434T	Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea	EIU	2/21/2023
0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session	EIU	2/21/2023
0436T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; during sleep study	EIU	2/21/2023
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve	EIU	2/21/2023
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve	EIU	2/21/2023
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)	EIU	2/21/2023
0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral	EIU	2/21/2023
0445T	Subsequent placement of a drugeluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral	EIU	2/21/2023
0464T	Visual evoked potential, testing for glaucoma, with interpretation and report	EIU	2/21/2023

0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral	EIU	2/21/2023
0472T	Device evaluation, interrogation, and initial programming of intraocular retinal electrode array (eg, retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional	EIU	2/21/2023
0473T	Device evaluation and interrogation of intra-ocular retinal electrode array (eg, retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional	EIU	2/21/2023
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space (CyPass MicroStent)	EIU	2/21/2023
0485T	Optical coherence tomography (OCT) of middle ear, with interpretation and report; unilateral	EIU	2/21/2023
0486T	Optical coherence tomography (OCT) of middle ear, with interpretation and report; bilateral	EIU	2/21/2023
0506T	Macular pigment optical density measurement by heterochromatic flicker photometry, unilateral or bilateral, with interpretation and report	EIU	2/21/2023
0507T	Near-infrared dual imaging (ie, simultaneous reflective and transilluminated light) of meibomian glands, unilateral or bilateral, with interpretation and report	EIU	2/21/2023
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia	EIU	2/21/2023
0510T	Removal of sinus tarsi implant	EIU	2/21/2023
0511T	Removal and reinsertion of sinus tarsi implant	EIU	2/21/2023
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])	EIU	2/21/2023

0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	EIU	2/21/2023
0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; pulse generator component(s) (battery and/or transmitter) only	EIU	2/21/2023
0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing	EIU	2/21/2023
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)	EIU	2/21/2023
0520T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter), including placement of a new electrode	EIU	2/21/2023
0521T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording, and disconnection per patient encounter, wireless cardiac stimulator for left ventricular pacing	EIU	2/21/2023
0522T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, wireless cardiac stimulator for left ventricular pacing	EIU	2/21/2023
0524T	Endovenous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring	EIU	2/21/2023
0525T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)	EIU	2/21/2023

0526T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; electrode only	EIU	2/21/2023
0527T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; implantable monitor only	EIU	2/21/2023
0528T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report	EIU	2/21/2023
0529T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report	EIU	2/21/2023
0530T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation, complete system (electrode and implantable monitor)	EIU	2/21/2023
0531T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation, electrode only	EIU	2/21/2023
0532T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation, implantable monitor only	EIU	2/21/2023
0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture	EIU	2/21/2023
0546T	Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial mastectomy, with report	EIU	2/21/2023
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional	EIU	2/21/2023
0559T	Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure	EIU	2/21/2023
0560T	Anatomic model 3D-printed from image data set(s); each additional individually prepared and	EIU	2/21/2023

	processed component of an anatomic structure (List separately in addition to code for primary procedure)		
0561T	Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide	EIU	2/21/2023
0562T	Anatomic guide 3D-printed and designed from image data set(s); each additional anatomic guide (List separately in addition to code for primary procedure)	EIU	2/21/2023
0563T	Evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral	EIU	2/21/2023
0583T	Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia	EIU	2/21/2023
0627T	Percutaneous injection of allogeneic cellular and/or tissuebased product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level	EIU	2/21/2023
0628T	Percutaneous injection of allogeneic cellular and/or tissuebased product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)	EIU	2/21/2023
0629T	Percutaneous injection of allogeneic cellular and/or tissuebased product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level	EIU	2/21/2023
0630T	Percutaneous injection of allogeneic cellular and/or tissuebased product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)	EIU	2/21/2023
0631T	Transcutaneous visible light hyperspectral imaging measurement of oxyhemoglobin, deoxyhemoglobin, and tissue oxygenation, with interpretation and report, per extremity	EIU	2/21/2023
0640T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition, interpretation and report, each flap or wound	EIU	2/21/2023

0641T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition only, each flap or wound	EIU	2/21/2023
0642T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); interpretation and report only, each flap or wound	EIU	2/21/2023
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	EIU	2/21/2023
0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score	EIU	2/21/2023
0664T	Donor hysterectomy (including cold preservation); open, from cadaver donor	EIU	2/21/2023
0665T	Donor hysterectomy (including cold preservation); open, from living donor	EIU	2/21/2023
0666T	Donor hysterectomy (including cold preservation); laparoscopic or robotic, from living donor	EIU	2/21/2023
0667T	Donor hysterectomy (including cold preservation); recipient uterus allograft transplantation from cadaver or living donor	EIU	2/21/2023
0668T	Backbench standard preparation of cadaver or living donor uterine allograft prior to transplantation, including dissection and removal of surrounding soft tissues and preparation of uterine vein(s) and uterine artery(ies), as necessary	EIU	2/21/2023
0669T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; venous anastomosis, each	EIU	2/21/2023
0670T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; arterial anastomosis, each	EIU	2/21/2023
0672T	Endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissues surrounding the female bladder neck and proximal urethra for urinary incontinence	EIU	2/21/2023

0691T	Automated analysis of an existing computed tomography study for vertebral fracture(s), including assessment of bone density when performed, data preparation, interpretation, and report (Unnamed Zebra Medical/Nanox product)	EIU	2/21/2023
0692T	Therapeutic ultrafiltration	EIU	2/21/2023
0694T	3-dimensional volumetric imaging and reconstruction of breast or axillary lymph node tissue, each excised specimen, 3-dimensional automatic specimen reorientation, interpretation and report, realtime intraoperative	EIU	2/21/2023
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance	EIU	2/21/2023
0735T	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)	EIU	2/21/2023

Experimental & Investigational Services
Medical Necessity Guideline

REGULATORY NOTES:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the servicearea who are medical experts in the appropriate field, review of FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions. If at any time a CMS Local or National Coverage Determination (LCD or NCD) is published that conflicts with the criteria set forth herein, the NCD or LCD criteria shall supersede these criteria.

Disclaimer:

This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

1. Centers for Medicare & Medicaid Services. (2014). *Guidance for the public, industry, and CMS staff: Coverage with evidence development.* Retrieved from https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27
2. Centers for Medicare & Medicaid Services. (2014). *Medicare benefit policy manual: Chapter 14 medical devices.* Retrieved from https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c14.pdf
3. Centers for Medicare & Medicaid Services. (2015). *Local coverage article: Clinical trials – Medical policy article (A52840*). Retrieved from https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52840&ver=2&DocID=A52840&bc=gAAAABAAAAAA&
4. Centers for Medicare & Medicaid Services. (n.d.). *Medicare & clinical research studies.* Retrieved from https://www.medicare.gov/Pubs/pdf/02226-medicare-and-clinical-research-studies.pdf

ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

Experimental & Investigational Services
Medical Necessity Guideline

1/1/24	HCPCS code K1006 replaced by HCPCS code E2001
12/31/23	Approved by Utilization Management Committee
11/9/23	Removed CPT code 76981
10/12/23	Added CPT code 22505
4/13/2023	Removed codes G0283, 37243, 56620, 64585, 64910, and 90868. Added additional codes to the list.
1/11/2023	Added a column "Last Review Date" to the Code Chart in the Authorization Section.
1/4/2023	Added iovera as an Experimental and Investigational Service. CPT codes 64640 and 64624 were added.
6/2/2022	Removed CPT and HCPCS codes 33289, 93264, C2624 as MassHealth. Templated updated.
8/4/2021	Overview: Added greater detail to the definition of EIS. Definitions added: Authoritative or reliable evidence, clinical trial, experimental/investigation/unproven services, generally accepted standards of medical practice, medical necessary, net health outcome, not medically necessary, routine costs (in the context of clinical trials). Decision guidelines added: criteria when EIS is not covered and covered, coverage of routine costs for EIS in clinical trials.
5/18/2021	Added in the overview: the review of information from appropriate government regulatory bodies: CMS, Commonwealth of Massachusetts, and FDA.
5/13/2021	Removed CPT codes 0194T and 64566 as there are LCD coverage. Added CardioMEMs as an Experimental and Investigational Service. CPT codes 33289 and 93264, and HCPCS code C2624 added. Added HCPCS code (K1006) for the PureWick Systems.
8/26/2020	Updated approval signature

APPROVALS:

David Mello, DO
CCA Senior Clinical Lead [Print]

Senior Medical Director
Title [Print]

David Mello
Signature

12/22/23
Date

Click here to enter text.
CCA Senior Operational Lead [Print]

Title [Print]

Signature

Date

Nazlim Hagmann, MD
CCA CMO or Designee [Print]

Chief Medical Officer
Title [Print]

Nazlim Hagmann
Signature

12/22/23
Date

Experimental & Investigational Services
Medical Necessity Guideline