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| MEDICAL POLICY | Investigational and Non-Covered Medical Technologies (All Lines of Business Except Medicare) |
| Effective Date: 10/1/2021 | Medical Policy Number: 23 |
|  10/1/2021 | Medical Policy Committee Approved Date: 7/17; 12/17; 6/18; 8/18; 10/18; 12/18; 1/19; 3/19; 9/19; 11/19; 12/19; 4/2020; 6/2020; 7/2020; 8/2020; 9/2020; 10/2020; 12/2020; 2/2021; 03/2021; 6/2021; 9/2021 |
| Medical Officer | Date |

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding each of the medical technologies listed below in the CPT/HCPCS CODE section below. The evidence was determined to be insufficient to support the clinical utility, diagnostic efficacy, and/or safety of these technologies. Additional high-quality studies are needed to establish the long-term efficacy, durability, and safety of these technologies for any condition; therefore, all of the following medical services listed in the CPT/HCPCS CODE section below are considered **investigational and are not covered**.

Link to [Policy Summary](#)

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CPT/HCPCS CODES

| All Lines of Business Except Medicare | | |
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| Not Covered | | |
| CPT Temporary (T) Codes | | |
| Code | Description | Manufacturer & Device Name (if applicable) |
| 0100T | Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy | - |
| 0190T | Placement of intraocular radiation source applicator (List separately in addition to primary procedure) | NeoVista Epi-Rad90™ Ophthalmic System |
| 0205T | TERMED 12/31/19 Intravascular catheter-based coronary vessel or graft spectroscopy (eg, infrared) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation, and report, each vessel (List separately in addition to code for primary procedure) | |
| 0213T | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level | - |
| 0214T | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level (List separately in addition to code for primary procedure) | |
| 0215T | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure) | |
| 0216T | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level | |
| 0217T | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; second level (List separately in addition to code for primary procedure) | |
| 0218T | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with | |
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| | ultrasound guidance, lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure) | |
| 0219T | Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical | TruFUSE® by miniSURG™ Corp. |
| 0220T | Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic | |
| 0221T | Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar | |
| 0222T | Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure) | |
| 0274T | Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic | - |
| 0275T | Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar | - |
| 0278T | Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes) | - |
| 0329T | Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report | SENSIMED Triggerfish® by Sensimed AG |
| 0335T | Extra-osseous subtalar joint implant for talotarsal stabilization | - |
| 0337T | Endothelial function assessment, using peripheral vascular response to reactive hyperemia, non-invasive (eg, brachial artery ultrasound, peripheral artery tonometry), unilateral or bilateral | EndoPAT™ 2000 by Itamar Medical Ltd. |
| 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 | Symplicity™ Renal Denervation (RDN) System by Medtronic |

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| | aortogram and diagnostic renal angiography when performed; unilateral | EnligHTN™ multi-electrode renal denervation system by St. Jude Medical™ |
| 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 | One-Shot™ Renal Denervation System by Covidien Vessix™ Renal Denervation System by Boston Scientific™ CARTO® Thermocool Smarttouch® Catheter by Biosense Webster® |
| 0341T | TERMED 12/31/19 Quantitative pupillometry with interpretation and report, unilateral or bilateral | NPi® 200 Pupillometer System by NeurOptics® VIP® 300 Pupillometer by NeurOptics® |
| 0342T | Therapeutic apheresis with selective HDL delipidation and plasma reinfusion | - |
| 0351T | Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real-time intraoperative | RS-3000 Advance by NIDEK© |
| 0352T | Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; interpretation and report, real-time or referred | |
| 0353T | Optical coherence tomography of breast, surgical cavity; real-time intraoperative | |
| 0354T | Optical coherence tomography of breast, surgical cavity; interpretation and report, real-time or referred | |
| 0356T | Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each | OTX-TP (travoprost insert) by Ocular Therapeutix™, Inc. |
| 0377T | TERMED 12/31/19 | Solesta® by Salix® Pharmaceuticals |

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| | Anoscopy with directed submucosal injection of bulking agent for fecal incontinence | |
| 0378T | Visual field assessment, with concurrent real time data analysis and accessible data storage with patient initiated data transmitted to a remote surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional | ForeseeHome® age-related macular degeneration (AMD) Monitoring Program by Notal Vision™, Ltd. |
| 0379T | Visual field assessment, with concurrent real time data analysis and accessible data storage with patient initiated data transmitted to a remote surveillance center for up to 30 days; technical support and patient instructions, surveillance, analysis, and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional | |
| 0381T | TERMED 12/31/2020 External heart rate and 3-axis accelerometer data recording up to 14 days to assess changes in heart rate and to monitor motion analysis for the purposes of diagnosing nocturnal epilepsy seizure events; includes report, scanning analysis with report, review and interpretation by a physician or other qualified health care professional | ProGuardianREST by Cyberonics® |
| 0382T | TERMED 12/31/2020 External heart rate and 3-axis accelerometer data recording up to 14 days to assess changes in heart rate and to monitor motion analysis for the purposes of diagnosing nocturnal epilepsy seizure events; review and interpretation only | |
| 0383T | TERMED 12/31/2020 External heart rate and 3-axis accelerometer data recording from 15 to 30 days to assess changes in heart rate and to monitor motion analysis for the purposes of diagnosing nocturnal epilepsy seizure events; includes report, scanning analysis with report, review and interpretation by a physician or other qualified health care professional | |
| 0384T | TERMED 12/31/2020 External heart rate and 3-axis accelerometer data recording from 15 to 30 days to assess changes in heart rate and to monitor motion analysis for the purposes of diagnosing nocturnal epilepsy seizure events; review and interpretation only | |
| 0385T | TERMED 12/31/2020 External heart rate and 3-axis accelerometer data recording more than 30 days to assess changes in heart rate and to monitor motion analysis for the purposes of diagnosing nocturnal epilepsy seizure events; includes report, scanning analysis with report, | |

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| | review and interpretation by a physician or other qualified health care professional | |
| 0386T | TERMED 12/31/2020 External heart rate and 3-axis accelerometer data recording more than 30 days to assess changes in heart rate and to monitor motion analysis for the purposes of diagnosing nocturnal epilepsy seizure events; review and interpretation only | |
| 0394T | High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed | |
| 0395T | High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed | – |
| 0396T | TERMED 12/31/2020 Intra-operative use of kinetic balance sensor for implant stability during knee replacement arthroplasty (List separately in addition to code for primary procedure) | – |
| 0397T | Endoscopic retrograde cholangiopancreatography (ERCP), with optical endomicroscopy (List separately in addition to code for primary procedure) | MagniView EC-3890Zi Video Colonoscope BY Pentax Medical |
| 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 | – |
| 0400T | TERMED 12/31/2020 Multi-spectral digital skin lesion analysis of clinically atypical cutaneous pigmented lesions for detection of melanomas and high risk melanocytic atypia; one to five lesions | |
| 0401T | TERMED 12/31/2020 Multi-spectral digital skin lesion analysis of clinically atypical cutaneous pigmented lesions for detection of melanomas and high risk melanocytic atypia; six or more lesions | |
| 0404T | Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency | – |
| 0405T | TERMED 12/31/2020 Oversight of the care of an extracorporeal liver assist system patient requiring review of status, review of laboratories and other studies, and revision of orders and liver assist care plan (as appropriate), within a calendar month, 30 minutes or more of non-face to face time | – |
| 0406T | Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant | |

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| 0407T | Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with biopsy, polypectomy or debridement | PROPEL® Sinus Implant (Intersect® ENT) |
| 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 | Cardiac Contractility Modulation (CCM) System by Impulse Dynamics |
| 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 | |
| 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 | |
| 0411T | Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only | |
| 0412T | Removal of permanent cardiac contractility modulation system; pulse generator only | |
| 0413T | Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular) | |
| 0414T | Removal and replacement of permanent cardiac contractility modulation system pulse generator only | |
| 0415T | Repositioning of previously implanted cardiac contractility modulation transvenous electrode (atrial or ventricular lead) | |
| 0416T | Relocation of skin pocket for implanted cardiac contractility modulation pulse generator | |
| 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 | |
| 0418T | Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system | |
| 0421T | Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration | AquaBeam® by Procept BioRobotics |

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| | and/or dilation, and internal urethrotomy are included when performed) | |
| 0422T | Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral | Breastview Visual Mapping System by Medical Tactile, Inc. iBreast Exam™ (iBE) by UE LifeSciences Inc. |
| 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) | Remedē® System by Respicardia® |
| 0425T | Insertion or replacement of neurostimulator system for treatment of central sleep apnea; sensing lead only | |
| 0426T | Insertion or replacement of neurostimulator system for treatment of central sleep apnea; stimulation lead only | |
| 0427T | Insertion or replacement of neurostimulator system for treatment of central sleep apnea; pulse generator only | |
| 0428T | Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only | |
| 0429T | Removal of neurostimulator system for treatment of central sleep apnea; sensing lead only | |
| 0430T | Removal of neurostimulator system for treatment of central sleep apnea; stimulation lead only | |
| 0431T | Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only | |
| 0432T | Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only | |
| 0433T | Repositioning of neurostimulator system for treatment of central sleep apnea; sensing lead only | |
| 0434T | Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea | |
| 0435T | Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session | |
| 0436T | Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; during sleep study | |
| 0443T | Real time spectral analysis of prostate tissue by fluorescence spectroscopy | |

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| 0444T | Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral | Dextenza™ by Ocular Therapeutix™, Inc. |
| 0445T | Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral | |
| 0449T | Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device | AqueSys XEN® Gel Stent by Allergan |
| 0450T | Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure) | |
| 0469T | Retinal polarization scan, ocular screening with on-site automated results, bilateral | - |
| 0470T | Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; first lesion | - |
| 0471T | Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; each additional lesion (List separately in addition to code for primary procedure) | |
| 0472T | Device evaluation, interrogation, and initial programming of intra-ocular 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 | - |
| 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 | |
| 0481T | Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed | - |
| 0485T | Optical coherence tomography (OCT) of middle ear, with interpretation and report; unilateral | - |
| 0486T | Optical coherence tomography (OCT) of middle ear, with interpretation and report; bilateral | |
| 0487T | Biomechanical mapping, transvaginal, with report | - |
| 0489T | Autologous adipose-derived regenerative cell therapy for scleroderma in the hands; adipose tissue harvesting, isolation and | - |

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| | preparation of harvested cells including incubation with cell dissociation enzymes, removal of non-viable cells and debris, determination of concentration and dilution of regenerative cells | |
| 0490T | Autologous adipose-derived regenerative cell therapy for scleroderma in the hands; multiple injections in one or both hands | |
| 0491T | Ablative laser treatment, non-contact, full field and fractional ablation, open wound, per day, total treatment surface area; first 20 sq cm or less | – |
| 0492T | Ablative laser treatment, non-contact, full field and fractional ablation, open wound, per day, total treatment surface area; each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure) | – |
| 0493T | Contact near-infrared spectroscopy studies of lower extremity wounds (eg, for oxyhemoglobin measurement) | – |
| 0506T | Macular pigment optical density measurement by heterochromatic flicker photometry, unilateral or bilateral, with interpretation and report | MacuScope™ by Medelsis |
| 0507T | Near-infrared dual imaging (ie, simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report | LipiScan™ Dynamic Meibomian Imager™ (DMI) by TearScience® |
| 0508T | Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia | Bindex® by Bone Index Finland Ltd. |
| 0510T | Removal of sinus tarsi implant | – |
| 0511T | Removal and reinsertion of sinus tarsi implant | – |
| 0512T | Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound | – |
| 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]) | |
| 0516T | Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only | – |
| 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 | |
| 0518T | Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing | |

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| 0519T | Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter) | | |
| 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 | | |
| 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 | | |
| 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 | | |
| 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) | AngelMed® Guardian System by Angel Medical Systems | |
| 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 | | |
| 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 | | |
| 0528T | Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report | | |
| 0529T | Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report | | |
| 0530T | Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; complete system (electrode and implantable monitor) | | |
| 0531T | Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; electrode only | | |
| 0532T | Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; implantable monitor only | | |
| 0533T | Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; includes set-up, patient training, configuration of monitor, data | | - |

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| | upload, analysis and initial report configuration, download review, interpretation and report | |
| 0534T | Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; set-up, patient training, configuration of monitor | |
| 0535T | Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; data upload, analysis and initial report configuration | |
| 0536T | Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; download review, interpretation and report | |
| 0544T | Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transeptal puncture | — |
| 0545T | Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach | — |
| 0546T | Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial mastectomy, with report | — |
| 0547T | Bone-material quality testing by microindentation(s) of the tibia(s), with results reported as a score | — |
| 0553T | Percutaneous transcatheter placement of iliac arteriovenous anastomosis implant, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention | — |
| 0554T | Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone mineral density, interpretation and report | — |
| 0555T | Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data | — |
| 0556T | Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density | — |
| 0557T | Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; interpretation and report | — |

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| 0559T | Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure | — |
| 0560T | Anatomic model 3D-printed from image data set(s); each additional individually prepared and 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 | — |
| 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) | — |
| 0564T | Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on percent of cytotoxicity observed, a minimum of 14 drugs or drug combinations | — |
| 0567T | Permanent fallopian tube occlusion with degradable biopolymer implant, transcervical approach, including transvaginal ultrasound | — |
| 0568T | Introduction of mixture of saline and air for sonosalpingography to confirm occlusion of fallopian tubes, transcervical approach, including transvaginal ultrasound and pelvic ultrasound | — |
| 0569T | Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis | Abbot TriClip Transcatheter Tricuspid Valve Repair System |
| 0570T | Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to code for primary procedure) | |
| 0571T | Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed | — |
| 0572T | Insertion of substernal implantable defibrillator electrode | — |
| 0573T | Removal of substernal implantable defibrillator electrode | — |
| 0574T | Repositioning of previously implanted substernal implantable defibrillator-pacing electrode | — |
| 0575T | Programming device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values | — |

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| | with analysis, review and report by a physician or other qualified health care professional | |
| 0576T | Interrogation device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter | — |
| 0577T | Electrophysiological evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters) | — |
| 0578T | Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional | — |
| 0579T | Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results | — |
| 0580T | Removal of substernal implantable defibrillator pulse generator only | — |
| 0581T | Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral | — |
| 0582T | Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance | Rezum® |
| 0583T | Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia | — |
| 0594T | Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device | FITBONE® System PRECICE UNYTE® Nail |
| 0598T | Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity) | MolecuLight i:X™ |
| 0599T | Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (eg, upper extremity) (List separately in addition to code for primary procedure) | MolecuLight i:X™ |

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| MEDICAL POLICY | Investigational and Non-Covered Medical Technologies (All Lines of Business Except Medicare) |
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| 0602T | Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent | MediBeacon's Transdermal GFR Measurement System (TGFR) and patented pharmaceutical Lumitrace™ |
| 0603T | Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours | MediBeacon's Transdermal GFR Measurement System (TGFR) and patented pharmaceutical Lumitrace™ |
| 0604T | Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment | Home OCT (Notal Vision) |
| 0605T | Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days | Home OCT (Notal Vision) |
| 0606T | Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days | Home OCT (Notal Vision) |
| 0607T | Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment | |
| 0608T | Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional | |

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| MEDICAL POLICY | Investigational and Non-Covered Medical Technologies (All Lines of Business Except Medicare) |
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| 0609T | Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, on biomarkers (ie, lactic acid, carbohydrate, alanine, laal, propionic acid, proteoglycan, and collagen) in at least 3 discs | NOCISCAN™ Suite (Nocimed) |
| 0610T | Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmission of biomarker data for software analysis | NOCISCAN™ Suite (Nocimed) |
| 0611T | Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); postprocessing for algorithmic analysis of biomarker data for determination of relative chemical differences between discs | NOCISCAN™ Suite (Nocimed) |
| 0612T | Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report | NOCISCAN™ Suite (Nocimed) |
| 0613T | Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed | InterAtrial Shunt Device (IASD), Corvia Medical |
| 0614T | Removal and replacement of substernal implantable defibrillator pulse generator | Extravascular Implantable Cardioverter Defibrillator (EV ICD) system, Medtronic |
| 0615T | Eye-movement analysis without spatial calibration, with interpretation and report | EyeBOX exam, Oculogica |
| 0616T | Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens | CustomFlex Artificial Iris, Human Optics |
| 0617T | Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens | CustomFlex Artificial Iris, Human Optics |
| 0618T | Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange | CustomFlex Artificial Iris, Human Optics |
| 0621T | Trabeculostomy ab interno by laser | |
| 0622T | Trabeculostomy ab interno by laser; with use of ophthalmic endoscope | |
| 0623T | Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with | |

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| | review of computerized analysis output to reconcile discordant data, interpretation and report | |
| 0624T | Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission | |
| 0625T | Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography | |
| 0626T | Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report | |
| 0631T | Transcutaneous visible light hyperspectral imaging measurement of oxyhemoglobin, deoxyhemoglobin, and tissue oxygenation, with interpretation and report, per extremity | |
| 0632T | Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance | |
| 0639T | Wireless skin sensor thermal anisotropy measurement(s) and assessment of flow in cerebrospinal fluid shunt, including ultrasound guidance, when performed | |
| 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 | |
| 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 | |
| 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 | |
| 0643T | Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach | Revivent TC System - BioVentrix |

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| 0644T | Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed | AngioVac System |
| 0645T | Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed | Neovasc Reducer |
| 0646T | Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed | Intrepid Transcatheter Mitral Valve Replacement System (Medtronic) |
| 0647T | Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report | Puma-G System (Ultrasound Gastronomy) |
| 0648T | Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session | EchoMRI Body Composition Analysis |
| 0649T | Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure) | EchoMRI Body Composition Analysis |
| 0655T | Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging | Visualase Laser Ablation, Medtronic |
| 0656T | Vertebral body tethering, anterior; up to 7 vertebral segments | |
| 0657T | Vertebral body tethering, anterior; 8 or more vertebral segments | |
| 0658T | Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score | Nevisense, SciBase |
| 0659T | Transcatheter intracoronary infusion of supersaturated oxygen in conjunction with percutaneous coronary revascularization during acute myocardial infarction, including catheter placement, imaging guidance (eg, fluoroscopy), angiography, and radiologic supervision and interpretation | TherOx Downstream® System, TherOx Inc |
| 0660T | Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach | |

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| 0661T | Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant | |
| 0662T | Scalp cooling, mechanical; initial measurement and calibration of cap | |
| 0663T | Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure) | |

CPT Codes

| Code | Description | Manufacturer & Device Name (if applicable) |
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| 30468 | Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s) | LATERA® absorbable nasal implant (Stryker) |
| 57465 | Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect (List separately in addition to code for primary procedure) | DYSIS Medical digital colposcope |
| 62263 | Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days | |
| 62264 | Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day | |
| 64454 | Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed | — |
| 64910 | Nerve repair; with synthetic conduit or vein allograft (eg, nerve tube), each nerve | — |
| 77422 | High energy neutron radiation treatment delivery; single treatment area using a single port or parallel-opposed ports with no blocks or simple blocking | — |
| 77423 | High energy neutron radiation treatment delivery; 1 or more isocenter(s) with coplanar or non-coplanar geometry with blocking and/or wedge, and/or compensator(s) | — |
| 81506 | Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbA1c, insulin, hs-CRP, adiponectin, ferritin, interleukin 2-receptor alpha), utilizing serum or plasma, algorithm reporting a risk score | Boston Heart Prediabetes Assessment® |

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| | | PreDx® Diabetes Risk Score (DRS) by Tethys Bioscience, Inc |
| 83951 | Oncoprotein; des-gamma-carboxy-prothrombin (DCP) | — |
| 96103 | TERMED 12/31/18 Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI), administered by a computer, with qualified health care professional interpretation and report | — |
| 96931 | Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion | VivaScope® 1500 by Caliber Imaging & Diagnostics, Inc. |
| 96932 | Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, first lesion | |
| 96933 | Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, first lesion | |
| 96934 | Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, each additional lesion (List separately in addition to code for primary procedure) | |
| 96935 | Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, each additional lesion (List separately in addition to code for primary procedure) | |
| 96936 | Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion (List separately in addition to code for primary procedure) | |
| 97610 | Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day | |

| HCPCS Codes | | |
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| Code | Description | Manufacturer & Device Name (if applicable) |
| A6000 | Non-contact wound warming wound cover for use with the non-contact wound warming device and warming card | |
| C1761 | Catheter, transluminal intravascular lithotripsy, coronary | Shockwave Coronary Rx Lithoplasty System |
| C1824 | Generator, cardiac contractility modulation (implantable) | Cardiac Contractility Modulation for |

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| | | Chronic Heart Failure (i.e., Optimizer by Impulse Dynamics) |
| C2596 | Probe, image-guided, robotic, waterjet ablatio | AquaBeam aquablation by PROCEPT BioRobotics Corporation |
| C9048 | Dexamethasone, lacrimal ophthalmic insert, 0.1 mg | Dextenza by Ocular Therapeutix, Inc. |
| C9122 | Mometasone furoate sinus implant, 10 micrograms (sinuva) | Sinuva® |
| C9352 | Microporous collagen implantable tube (neuragen nerve guide), per centimeter length | — |
| C9353 | Microporous collagen implantable slit tube (neurawrap nerve protector), per centimeter length | — |
| C9355 | Collagen nerve cuff (neuromatrix), per 0.5 centimeter length | — |
| C9361 | Collagen matrix nerve wrap (neuromend collagen nerve wrap), per 0.5 centimeter length | — |
| C9745 | Nasal endoscopy, surgical; balloon dilation of eustachian tube | Aera® Eustachian Tube Balloon Dilation (ETBD) System by Acclarent |
| C9752 | Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum | — |
| C9753 | Destruction of intraosseous basivertebral nerve, each additional vertebral body, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum (list separately in addition to code for primary procedure) | |
| C9759 | Transcatheter intraoperative blood vessel microinfusion(s) (e.g., intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed | Bullfrog Micro-infusion device by Mercator Medsystems |
| C9764 | Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed | Shockwave Medical Peripheral IVL System by Shockwave Medical Inc |
| C9765 | Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed | Shockwave Medical Peripheral IVL System by |

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| | | Shockwave Medical Inc |
| C9766 | Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed | Shockwave Medical Peripheral IVL System by Shockwave Medical Inc |
| C9767 | Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed | Shockwave Medical Peripheral IVL System by Shockwave Medical Inc |
| C9768 | Endoscopic ultrasound-guided direct measurement of hepatic portosystemic pressure gradient by any method (list separately in addition to code for primary procedure) | Echotip by Cook Medical |
| C9771 | Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral | Clarifix by Arrinex Inc |
| C9772 | Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed | Shockwave Medical Peripheral IVL System by Shockwave Medical Inc |
| C9773 | Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed | Shockwave Medical Peripheral IVL System by Shockwave Medical Inc |
| C9774 | Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed | Shockwave Medical Peripheral IVL System by Shockwave Medical Inc |
| C9775 | Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed | Shockwave Medical Peripheral IVL System by Shockwave Medical Inc |
| C9780 | Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance | Surfacer® Inside-Out® Access Catheter System (Surfacer System) |

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| E0231 | Non-contact wound warming device (temperature control unit, ac adapter and power cord) for use with warming card and wound cover. | |
| E0232 | Warming card for use with the non contact wound warming device and non contact wound warming wound cover | |
| G0069 | Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes | — |
| J1096 | Dexamethasone, lacrimal ophthalmic insert, 0.1 mg | Dextenza® by Ocular Therapeutix, Inc. |
| J7401 | Mometasone furoate sinus implant, 10 micrograms | — |
| J7402 | Mometasone furoate sinus implant, (sinuva), 10 micrograms | SINUVA |
| K1002 | Cranial electrotherapy stimulation (ces) system, includes all supplies and accessories, any type | — |
| K1004 | Low frequency ultrasonic diathermy treatment device for home use, includes all components and accessories | — |
| K1007 | Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors | ReWalk™ Exoskeleton by ReWalk Robotics |
| K1009 | Speech volume modulation system, any type, including all components and accessories | SpeechVive by SpeechVive Inc. |

CPT U Codes (Proprietary Laboratory Analyses codes)

| Code | Description | Proprietary Name and Clinical Laboratory and/or Manufacturer |
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| 0002U | Oncology (colorectal), quantitative assessment of three urine metabolites (ascorbic acid, succinic acid and carnitine) by liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring acquisition, algorithm reported as likelihood of adenomatous polyps | PolypDX™ by Atlantic Diagnostic Laboratories, LLC, and Metabolomic Technologies Inc. |
| 0004U | TERMED 12/31/17 Infectious disease (bacterial), DNA, 27 resistance genes, PCR amplification and probe hybridization in microarray format (molecular detection and identification of AmpC, carbapenemase and ESBL coding genes), bacterial culture colonies, report of genes detected or not detected, per isolate | Gram-Negative Bacterial Resistance Gene-PCR Panel by Mayo Medical Laboratories |
| 0025U | Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine, quantitative | UrSure by UrSure, Inc. |

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| 0054U | Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service | AssuranceRX Micro Serum Test by Firstox™ |
| 0058U | Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative | Merkel SmT Oncoprotein Antibody Titer, University of Washington Department of Laboratory Medicine |
| 0059U | Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative | |
| 0061U | Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis | Spatial Frequency Domain Imaging (SFDI) by Modulated Imaging, Inc. |
| 0080U | Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy | BDX-XL2 by Biodesix® |
| 0083U | Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations | Onco4D™ by Animated Dynamics, Inc. |
| 0085U | TERMED 12/31/19 Cytotoxic distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA) | IBSchek™ test by Commonwealth Diagnostics International, Inc. |
| 0086U | Infectious disease (bacterial and fungal), organism identification, blood culture, using rRNA FISH, 6 or more organism targets, reported as positive or negative with phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility | Accelerate PhenoTest™ BC kit by Accelerate Diagnostics, Inc. |
| 0087U | Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score | Molecular Microscope® MMDx—Heart test by Kashi Clinical Laboratories. |
| 0088U | Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection | Molecular Microscope® MMDx—Kidney test |

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| | | by Kashi Clinical Laboratories |
| 0089U | Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es) | Pigmented Lesion Assay (PLA) by DermTech |
| 0090U | Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical result (ie, benign, indeterminate, malignant) | myPath® Melanoma by Myriad |
| 0092U | Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy | REVEAL Lung Nodule Characterization by MagArray, Inc. |
| 0095U | Inflammation (eosinophilic esophagitis), ELISA analysis of eotaxin-3 (CCL26 [C-C motif chemokine ligand 26]) and major basic protein (PRG2 [proteoglycan 2, pro eosinophil major basic protein]), specimen obtained by swallowed nylon string, algorithm reported as predictive probability index for active eosinophilic esophagitis | Esophageal String Test™ (EST) by Cambridge Biomedical, Inc. |
| 0096U | Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine | HPV, High-Risk, Male Urine by Molecular Testing Labs |
| 0105U | Nephrology (chronic kidney disease), multiplex electrochemiluminescent immunoassay (ECLIA) of tumor necrosis factor receptor 1A, receptor superfamily 2 (TNFR1, TNFR2), and kidney injury molecule-1 (KIM-1) combined with longitudinal clinical data, including APOL1 genotype if available, and plasma (isolated fresh or frozen), algorithm reported as probability score for rapid kidney function decline (RKFD) | KidneyIntelXTM, RenalytixAI |
| 0107U | Clostridium difficile toxin(s) antigen detection by immunoassay technique, stool, qualitative, multiple-step method | Singulex Clarity C.diff toxins A/B assay by Singulex |
| 0108U | Gastroenterology (Barrett’s esophagus), whole slide–digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer | TissueCypher® Barrett’s Esophagus Assay by Cernostics |
| 0109U | Infectious disease (Aspergillus species), real-time PCR for detection of DNA from 4 species (A. fumigatus, A. terreus, A. niger, and A. flavus), blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species | MYCODART Dual Amplification Real Time PCR Panel for 4 Aspergillus species, RealTime Laboratories, |

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| | | Inc/MycoDART, Inc |
| 0110U | Prescription drug monitoring, one or more oral oncology drug(s) and substances, definitive tandem mass spectrometry with chromatography, serum or plasma from capillary blood or venous blood, quantitative report with steady-state range for the prescribed drug(s) when detected | Oral OncolyticAssuranceR X, Firstox Laboratories, LLC |
| 0112U | Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene | MicroGenDX qPCR & NGS for Infection, MicroGenDX |
| 0114U | Gastroenterology (Barrett’s esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett’s esophagus | EsoGuard™ by Lucid Diagnostics |
| 0115U | Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected | ePlex Respiratory Pathogen (RP) Panel, GenMark Diagnostics, Inc |
| 0116U | Prescription drug monitoring, enzyme immunoassay of 35 or more drugs confirmed with LC-MS/MS, oral fluid, algorithm results reported as a patient-compliance measurement with risk of drug to drug interactions for prescribed medications | Snapshot Oral Fluid Compliance, Ethos Laboratories |
| 0117U | Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid, homocysteine, pyroglutamic acid, vanilmandelate, 5-hydroxyindoleacetic acid, hydroxymethylglutarate, ethylmalonate, 3-hydroxypropyl mercapturic acid (3-HPMA), quinolinic acid, kynurenic acid), LC-MS/MS, urine, algorithm reported as a pain-index score with likelihood of atypical biochemical function associated with pain | Foundation PI SM by Ethos Laboratories |
| 0118U | Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA | Viracor TRACTM dd-cfDNA, Viracor Eurofins |
| 0121U | Fetal congenital abnormalities, biochemical assays of 3 analytes (free beta-hCG, PAPP-A, AFP), time-resolved fluorescence immunoassay, maternal dried-blood spot, algorithm reported as risk scores for fetal trisomies 13/18 and 21 | Flow Adhesion of Whole Blood on VCAM-1 (FAB-V) by Functional Fluidics |
| 0122U | Sickle cell disease, microfluidic flow adhesion (P-Selectin), whole blood | Flow Adhesion of Whole Blood to P-SELECTIN (WB-PSEL), by Functional Fluidics |
| 0123U | Mechanical fragility, RBC, shear stress and spectral analysis profiling | Mechanical Fragility, RBC by shear stress |

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| | | profiling and spectral analysis by Functional Fluidics |
| 0125U | Fetal congenital abnormalities and perinatal complications, biochemical assays of 5 analytes (free beta-hCG, PAPP-A, AFP, placental growth factor, and inhibin-A), time-resolved fluorescence immunoassay, maternal serum, algorithm reported as risk scores for fetal trisomies 13/18, 21, and preeclampsia | Maternal Fetal Screen T1SM, Eurofins NTD, LLC, |
| 0126U | Fetal congenital abnormalities and perinatal complications, biochemical assays of 5 analytes (free beta-hCG, PAPP-A, AFP, placental growth factor, and inhibin-A), time-resolved fluorescence immunoassay, includes qualitative assessment of Y chromosome in cell-free fetal DNA, maternal serum and plasma, predictive algorithm reported as a risk scores for fetal trisomies 13/18, 21, and preeclampsia | Maternal Fetal Screen T1 + Y Chromosome SM, Eurofins NTD, LLC |
| 0127U | Obstetrics (preeclampsia), biochemical assays of 3 analytes (PAPP-A, AFP, and placental growth factor), time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia | Preeclampsia Screen T1SM, Eurofins NTD, LLC |
| 0128U | Obstetrics (preeclampsia), biochemical assays of 3 analytes (PAPP-A, AFP, and placental growth factor), time-resolved fluorescence immunoassay, includes qualitative assessment of Y chromosome in cell-free fetal DNA, maternal serum and plasma, predictive algorithm reported as a risk score for preeclampsia | Preeclampsia Screen T1 + Y ChromosomeSM, Eurofins NTD, LLC |
| 0136U | ATM (ataxia telangiectasia mutated) (eg, ataxia telangiectasia) mRNA sequence analysis (List separately in addition to code for primary procedure) | +RTMinsight™ for ATM by Ambry Genetics |
| 0139U | Neurology (autism spectrum disorder [ASD]), quantitative measurements of 6 central carbon metabolites (ie, α-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, and succinate), LC-MS/MS, plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD) | NeuroPointDX NPDX ASD by NeuroPoint Dx |
| 0140U | Infectious disease (fungi), fungal pathogen identification, DNA (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected | — |
| 0141U | Infectious disease (bacteria and fungi), gram-positive organism identification and drug resistance element detection, DNA (20 gram-positive bacterial targets, 4 resistance genes, 1 pan gram-negative bacterial target, 1 pan Candida target), blood culture, amplified probe technique, each target reported as detected or not detected | |

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| 0142U | Infectious disease (bacteria and fungi), gram-negative bacterial identification and drug resistance element detection, DNA (21 gram-negative bacterial targets, 6 resistance genes, 1 pan gram-positive bacterial target, 1 pan Candida target), amplified probe technique, each target reported as detected or not detected | |
| 0151U | Infectious disease (bacterial or viral respiratory tract infection), pathogen specific nucleic acid (DNA or RNA), 33 targets, real-time semi-quantitative PCR, bronchoalveolar lavage, sputum, or endotracheal aspirate, detection of 33 organismal and antibiotic resistance genes with limited semi-quantitative results | BioFire® FilmArray® Pneumonia Panel by Biomérieux |
| 0152U | Infectious disease (bacteria, fungi, parasites, and DNA viruses), DNA, PCR and next-generation sequencing, plasma, detection of >1,000 potential microbial organisms for significant positive pathogens | Karius® Test by Karius |
| 0156U | Copy number (eg, intellectual disability, dysmorphology), sequence analysis | SMASH™ Genomic Assay by Marvel Genomics® |
| 0164U | Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results | IBSChek®, Commonwealth Diagnostics International, Inc |
| 0166U | Liver disease, 10 biochemical assays (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation | LiverFASt™, Fibronostics |
| 0167U | Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood | ADEXUSDx hCG Test, NOWDiagnostics |
| 0170U | Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis | Clarifi™, Quadrant Biosciences, Inc |
| 0174U | Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents | LC-MS/MS Targeted Proteomic Assay, OncoOmicDx Laboratory, LDT |
| 0176U | Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA) | IBSChek®, Commonwealth Diagnostics International, Inc |

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| 0202U | Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected | BioFire Respiratory 2.1 (RP2.1) Panel with SARS-CoV-2 |
| 0203U | Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected | QIAstat-Dx Respiratory SARS-CoV-2 Panel |
| 0206U | Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amylospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease | DISCERN, NeuroDiagnostics, |
| 0207U | Disease quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure) | DISCERN, NeuroDiagnostics, |
| 0210U | Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR) | BioPlex 2200 RPR Assay - Quantitative, Bio-Rad Laboratories |
| 0219U | Infectious agent (human immunodeficiency virus), targeted viral next-generation sequence analysis (ie, protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm reported as prediction of antiviral drug susceptibility | Sentosa® SQ HIV-1 Genotyping Assay, Vela Diagnostics USA, |
| 0220U | Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score | PreciseDx™ Breast Cancer Test, PreciseDx, PreciseDx |
| 0228U | Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer | PanGIA Prostate, Genetics Institute of America, Entopsis, LLC |
| 0243U | Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia | PIGF Preeclampsia Screen, PerkinElmer |
| 0247U | Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone-binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, | PreTRM®, Sera Prognostics, Sera Prognostics, Inc® |

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| | combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth | |
| 0251U | Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma | Intrinsic Hepcidin IDx™ Test, IntrinsicDx, Intrinsic LifeSciences™ |
| 0255U | Andrology (infertility), sperm-capacitation assessment of ganglioside GM1 distribution patterns, fluorescence microscopy, fresh or frozen specimen, reported as percentage of capacitated sperm and probability of generating a pregnancy score | Cap-Score™ Test, Androvia LifeSciences Lab |
| 0259U | Nephrology (chronic kidney disease), nuclear magnetic resonance spectroscopy measurement of myo-inositol, valine, and creatinine, algorithmically combined with cystatin C (by immunoassay) and demographic data to determine estimated glomerular filtration rate (GFR), serum, quantitative | GFR by NMR, Labtech™ Diagnostics |
| 0261U | Oncology (colorectal cancer), image analysis with artificial intelligence assessment of 4 histologic and immunohistochemical features (CD3 and CD8 within tumor-stroma border and tumor core), tissue, reported as immune response and recurrence-risk score | Immunoscore®, HaliDx, HaliDx |
| 0262U | Oncology (solid tumor), gene expression profiling by real-time RT-PCR of 7 gene pathways (ER, AR, PI3K, MAPK, HH, TGFB, Notch), formalin-fixed paraffinembedded (FFPE), algorithm reported as gene pathway activity score | OncoSignal 7 Pathway Signal, Protean BioDiagnostics, Philips Electronics Nederland BV |
| 0263U | Neurology (autism spectrum disorder [ASD]), quantitative measurements of 16 central carbon metabolites (ie, ?ketoglutarate, alanine, lactate, phenylalanine, pyruvate, succinate, carnitine, citrate, fumarate, hypoxanthine, inosine, malate, S-sulfocysteine, taurine, urate, and xanthine), liquid chromatography tandem mass spectrometry (LC-MS/MS), plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD) | NPDX ASD and Central Carbon Energy Metabolism, Stemina Biomarker Discovery, Inc. |

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding each of the medical technologies listed below in the CPT/HCPCS CODE section below. The evidence was insufficient to support the clinical utility, diagnostic efficacy, and/or safety of these technologies. Evidence reviews and summaries for each technology addressed in this policy may be made available upon request.

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INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.