

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
Effective Date: 11/1/2021	Medical Policy Number: 220
 11/1/2021	Medical Policy Committee Approved Date: 7/17; 12/17; 3/18; 6/18; 8/18; 12/18; 1/19; 3/19; 5/19; 9/19; 11/19; 12/19; 4/2020; 6/2020; 07/2020; 8/2020; 9/2020; 10/2020; 12/2020; 2/2021; 3/2021; 5/2021; 6/2021; 8/2021; 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:

Medicare Only

POLICY CRITERIA	
<p>The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.</p>	
Service	Medicare Guidelines
<i>MolDX: Molecular Diagnostic Tests (MDT)</i>	<ul style="list-style-type: none"> Local Coverage Determination (LCD): MolDX: Molecular Diagnostic Tests (MDT) (L36256) Local Coverage Article (LCA): MolDX: Molecular Diagnostic Tests (MDT) (A57527)
<i>MolDX: PreDx</i>	<ul style="list-style-type: none"> Local Coverage Article (LCA): MolDX: PreDx (A55599)
<i>MolDX: BRCA1 and BRCA2 Genetic Testing</i>	<ul style="list-style-type: none"> Local Coverage Determination (LCD): MolDX: BRCA1 and BRCA2 Genetic Testing (L36163) Local Coverage Article (LCA): Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing (A57355)
<i>Infrared Therapy Devices</i>	<ul style="list-style-type: none"> National Coverage Determination (NCD) for Infrared Therapy Devices (270.6) Local Coverage Article (LCA): Billing and Coding: Wound Care (A55909)
<i>Corneal Hysteresis</i>	<ul style="list-style-type: none"> Local Coverage Determination (LCD): Corneal Hysteresis (L38211)

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

	<ul style="list-style-type: none"> Local Coverage Article (LCA): Billing and Coding: Corneal Hysteresis (A56910)
<i>Non-contact wound therapy</i>	<ul style="list-style-type: none"> National Coverage Determination (NCD) for Noncontact Normothermic Wound Therapy (270.2) Local Coverage Determination (LCD) for Low Frequency, Non-contact, Non-thermal Ultrasound (MIST Therapy) (L37228) Local Coverage Article (LCA) for Billing and Coding Wound Care (A55909)
<i>Surfacer® Inside-Out® Access Catheter System (C9780)</i>	<p>The Surfacer® Inside-Out® Access Catheter system is currently undergoing trials and evaluation and there is an associated Medicare-approved investigational device exemption (IDE) study for this product (<i>Evaluation of the Surfacer System Approach to Central Venous Access; NCT03209050</i>); however, it is classified as a Category A device. According to the <i>Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies</i>, “MAOs are responsible for payment of claims related to enrollees’ participation in both Category A and B IDE studies that are covered by the MAC with jurisdiction over the MA plan’s service area. The MAO is responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies. The MAO is also responsible for CMS-approved Category B devices. CMS will not approve Category A devices because they are statutorily excluded from coverage.” Therefore, while routine care and services are eligible for coverage, including unrelated care, Category A devices are not.</p>

BILLING GUIDELINES

Claims for these services will always be reviewed when they are billed with an unlisted procedure code.

CPT/HCPCS CODES

Medicare Only	
The following CPT/HCPCS codes will be denied as not medically necessary and not covered.	
A6000	Non-contact wound warming wound cover for use with the non-contact wound warming device and warming card
C1824	Generator, cardiac contractility modulation (implantable)
C9752	Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e. g. , fluoroscopy), lumbar/sacrum

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

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)
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance
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
J2010	Injection, lincomycin hcl, up to 300 mg
28446	Open osteochondral autograft, talus (includes obtaining graft[s])
46707	Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS])
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
64910	Nerve repair; with synthetic conduit or vein allograft (eg, nerve tube), each nerve
84431	Thromboxane metabolite(s), including thromboxane if performed, urine
86305	Human epididymis protein 4 (HE4)
91132	Electrogastrography, diagnostic, transcutaneous
91133	Electrogastrography, diagnostic, transcutaneous; with provocative testing
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report
97026	Application of a modality to 1 or more areas; infrared
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes
0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (List separately in addition to code for primary procedure)
0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue
0072T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle
0198T	Measurement of ocular blood flow by repetitive intraocular pressure sampling, with interpretation and report

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine
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)
0206T	TERMED 12/31/19 Computerized database analysis of multiple cycles of digitized cardiac electrical data from two or more ECG leads, including transmission to a remote center, application of multiple nonlinear mathematical transformations, with coronary artery obstruction severity assessment
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
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)
0234T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; renal artery
0235T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; visceral artery (except renal), each vessel
0236T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; abdominal aorta
0237T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; brachiocephalic trunk and branches, each vessel
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
----------------	--

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 (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day)
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 (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming
0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)
0290T	Corneal incisions in the recipient cornea created using a laser, in preparation for penetrating or lamellar keratoplasty (List separately in addition to code for primary procedure)
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed
0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report
0330T	Tear film imaging, unilateral or bilateral, with interpretation and report
0331T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment
0332T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment; with tomographic SPECT
0333T	Visual evoked potential, screening of visual acuity, automated, with report
0335T	Insertion of sinus tarsi implant
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
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
0341T	TERMED 12/31/19 Quantitative pupillometry with interpretation and report, unilateral or bilateral
0342T	Therapeutic apheresis with selective HDL delipidation and plasma reinfusion

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
----------------	--

0347T	Placement of interstitial device(s) in bone for radiostereometric analysis (RSA)
0348T	Radiologic examination, radiostereometric analysis (RSA); spine, (includes cervical, thoracic and lumbosacral, when performed)
0349T	Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow, and wrist, when performed)
0350T	Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies), (includes hip, proximal femur, knee, and ankle, when performed)
0351T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real-time intraoperative
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
0357T	TERMED 12/31/19 Cryopreservation; immature oocyte(s)
0358T	Bioelectrical impedance analysis whole body composition assessment, with interpretation and report
0373T	Adaptive behavior treatment with protocol modification, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.
0376T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; each additional device insertion (List separately in addition to code for primary procedure)
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
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

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
----------------	--

	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, 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
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)
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
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

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system
0419T	Destruction of neurofibroma, extensive (cutaneous, dermal extending into subcutaneous); face, head and neck, greater than 50 neurofibromas
0420T	Destruction of neurofibroma, extensive (cutaneous, dermal extending into subcutaneous); trunk and extremities, extensive, greater than 100 neurofibromas
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)
0422T	Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral
0423T	Secretory type II phospholipase A2 (sPLA2-IIA)
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)
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
0439T	Myocardial contrast perfusion echocardiography, at rest or with stress, for assessment of myocardial ischemia or viability (List separately in addition to code for primary procedure)
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
----------------	--

0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)
0443T	Real-time spectral analysis of prostate tissue by fluorescence spectroscopy, including imaging guidance (List separately in addition to code for primary procedure)
0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral
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
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)
0464T	Visual evoked potential, testing for glaucoma, with interpretation and report
0465T	Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)
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
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)

The following CPT codes are components of another service, and are never separately billable to the contractor or the patient.

93050	Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive
0126T	TERMED 12/31/2020 Common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment
0159T	TERMED 12/31/18 Computer-aided detection, including computer algorithm analysis of MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation, breast MRI (List 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 (List separately in addition to code for primary procedure)
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

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
----------------	--

0208T	Pure tone audiometry (threshold), automated; air only
0209T	Pure tone audiometry (threshold), automated; air and bone
0210T	Speech audiometry threshold, automated
0211T	Speech audiometry threshold, automated; with speech recognition
0212T	Comprehensive audiometry threshold evaluation and speech recognition (0209T, 0211T combined), automated
0399T	TERMED 12/31/19 Myocardial strain imaging (quantitative assessment of myocardial mechanics using image-based analysis of local myocardial dynamics) (List separately in addition to code for primary procedure)
0437T	Implantation of non-biologic or synthetic implant (eg, polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to code for primary procedure)
The following CPT codes will be denied as investigational and not covered.	
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)
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)
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
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
97545	Work hardening/conditioning; initial 2 hours
97546	Work hardening/conditioning; each additional hour (List separately in addition to code for primary procedure)
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
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
0380T	TERMED 12/31/19 Computer-aided animation and analysis of time series retinal images for the monitoring of disease progression, unilateral or bilateral, with interpretation and report
0400T	TERMED 12/31/2020

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

	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
0403T	Preventive behavior change, intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to individuals in a group setting, minimum 60 minutes, per day
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
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 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)

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

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
0507T	Near-infrared dual imaging (ie, simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia
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
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)
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

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

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 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 transseptal 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
0559T	Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

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
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 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

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

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
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
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)
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)
0602T	Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent
0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours
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
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
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
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
0609T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, on biomarkers (ie,

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

	lactic acid, carbohydrate, alanine, laal, propionic acid, proteoglycan, and collagen) in at least 3 discs
0610T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmission of biomarker data for software analysis
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
0612T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report
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
0614T	Removal and replacement of substernal implantable defibrillator pulse generator
0615T	Eye-movement analysis without spatial calibration, with interpretation and report
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
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
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
0621T	Trabeculectomy ab interno by laser
0622T	Trabeculectomy 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 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

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

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
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
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
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
0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report
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
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)
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
----------------	---

0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score
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
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach
0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant
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
0025U	Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine, quantitative
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
0058U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative
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
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
0085U	TERMED 12/31/19 Cytotoxic distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)
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
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
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

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

0089U	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)
0092U	Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy
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
0096U	Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine
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)
0107U	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
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 paraffinembedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer
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
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
0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene
0114U	Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus
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
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),

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

	quinolinic acid, kynurenic acid), LCMS/MS, urine, algorithm reported as a pain-index score with likelihood of atypical biochemical function associated with pain
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
0121U	Sickle cell disease, microfluidic flow adhesion (VCAM-1), whole blood
0122U	Sickle cell disease, microfluidic flow adhesion (P-Selectin), whole blood
0123U	Mechanical fragility, RBC, shear stress and spectral analysis profiling
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
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
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
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
0139U	CODE TERMED 09/31/2021 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)
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
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

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

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
0156U	Copy number (eg, intellectual disability, dysmorphology), sequence analysis
0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results
0166U	Liver disease, 10 biochemical assays (α 2-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
0167U	Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood
0170U	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis
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
0176U	Cytotoxic distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)
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
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)
0210U	Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR)
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
0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score
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
0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia
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, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth
0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma
C1761	Catheter, transluminal intravascular lithotripsy, coronary

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
----------------	--

C2596	Probe, image-guided, robotic, waterjet ablation
C9122	Mometasone furoate sinus implant, 10 micrograms (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
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
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
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
C9766	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
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
C9768	Endoscopic ultrasound-guided direct measurement of hepatic portosystemic pressure gradient by any method (list separately in addition to code for primary procedure)
C9771	Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed
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
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed
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
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
J7401	Mometasone furoate sinus implant, 10 micrograms
J7402	Mometasone furoate sinus implant, (sinuva), 10 micrograms
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

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

K1009	Speech volume modulation system, any type, including all components and accessories
-------	---

DESCRIPTION

Medicare does not cover items and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Section 1862 (a) (1) of the Social Security Act is the basis for denying payment for types of care, or specific items, services, or procedures that are not excluded by any other statutory clause and meet all technical requirements for coverage but are determined to be any of the following:

- Not generally accepted in the medical community as safe and effective in the setting and for the condition for which it is used.
- Not proven to be safe and effective based on peer review or scientific literature.
- Experimental.
- Not medically necessary in the particular case.
- Furnished at a level, duration or frequency that is not medically appropriate.
- Not furnished in accordance with accepted standards of medical practice.

OR

- Not furnished in a setting (such as inpatient care at a hospital or SNF, outpatient care through a hospital or physician's office or home care) appropriate to the patients' medical needs and condition.

To be considered medically necessary, items and services must have been established as safe and effective. That is, the items and services must be:

- Consistent with the symptoms or diagnosis of the illness or injury under treatment.
- Necessary and consistent with generally accepted professional medical standards (e. g. , not experimental or investigational).
- Not furnished primarily for the convenience of the patient, the attending physician or other physician or supplier.
- Furnished at the most appropriate level that can be provided safely and effectively to the patient.

Medicare is a defined benefit program; contractors sometimes have to decide whether a service fits one of the defined benefits categories. Services that this contractor considers non-covered because the service does not fit into a benefit category are also included on this list.

A service or procedure on the national non-coverage list may be non-covered for a variety of reasons. It may be non-covered based on a specific exclusion contained in the Medicare law (for example, acupuncture) it may be viewed as not yet proven safe and effective and, therefore, not medically reasonable and necessary; or it may be a procedure that is always considered cosmetic in nature and is denied on that basis. The precise basis for a national decision to non-cover a procedure may be found in

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

the references cited in this policy. These national non-covered services are listed in this LCD for informational purposes only.

A service or procedure on the local list is always denied on the basis that Noridian does not believe it is ever medically reasonable and necessary. The Noridian list of LCD exclusions contains procedures that, for example, are:

- Experimental.
- Not proven safe and effective.

OR

- Not approved by the FDA.

Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures and services performed using devices that have not been approved for marketing by the FDA or for those not included in an FDA-approved investigational (IDE) trial.

If a test, treatment or procedure is neither specifically covered nor excluded in Medicare law or guidelines, carriers must make a coverage determination that is based upon the general acceptance of the test, treatment or procedure by the professional medical community as an effective and proven treatment for the condition for which it is being used. Medicare will make payment only when a service is accepted as effective and proven. Some tests or services are obsolete and have been replaced by more advanced procedures. The tests or procedures may be paid only if the physician who performs them satisfactorily justifies the medical need for the procedure(s).

“When processing a claim, carriers continue to determine if a service is reasonable and necessary to treat illness or injury. If a service is not reasonable and necessary to treat illness or injury for any reason (including lack of safety and efficacy because it is an experimental procedure, etc.), carriers consider the service noncovered notwithstanding the presence of a payment amount for the service in the Medicare fee schedule. The presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare. The nature of the status indicator in the database does not control coverage except where the status is N for noncovered. ” [Medicare Claims Processing Manual (CMS Pub. 100-04, Chapter 23, Section 30 A)]

It is important to note that the fact that a new service or procedure has been issued a CPT code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. Noridian evaluates new services, procedures, drugs or technology and considers national and local policies before these new services may be considered Medicare covered services.

This LCD contains listings of numerous non-covered services which have no specific CPT code. Adding difficulty to correct coding for such services is the fact that there are many where two or more specific

MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
-----------------------	---

unlisted codes could arguably be used to designate the service. Initial preparation of the LCD to cover every possible code use – and more importantly, maintenance of the LCD as code changes occur – is difficult if not impossible.

Therefore, providers must bear in mind that any service that is described in any Noridian LCD as “non-covered” will remain non-covered no matter which CPT code is selected for billing. Since many of the unlisted codes, however, are also correctly used for billing of covered services, it is likely that prepay denial edits cannot be implemented into the claims processing computer system. Because of this, clearly non-covered services can in some instances be paid. Providers are reminded that these paid services will be subject to recoupment by Noridian, as well as other review contractors, including the Recovery Audit Contractors (RACs).

Services that this contractor considers a component of another service and never separately billable or payable are also included here unless those services are already included in the mutually exclusive Correct Coding edits. For some services one or more of the Medicare payment systems (for example, the Physician Fee Schedule or the Outpatient Prospective Payment System) may indicate that the service is bundled or packaged or not paid for some other reason, in which case those indicators take precedence over the placement in this policy.

This is not an all-inclusive list of services not covered or not paid separately by Medicare.

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.

MEDICAL POLICY

**Investigational and Non-Covered
Medical Technologies
(Medicare Only)**