PriorityHealth

MEDICAL POLICY
No. 91117-R11

EXPERIMENTAL/INVESTIGATIONAL/UNPROVEN CARE/ BENEFIT EXCEPTIONS

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Date of Origin: June 30, 1988	**Status: Current**

Summary of Changes

Clarifications:

- Pg. 11, Section VII. CODING: Clarification was provided to “Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control” to indicate that this procedure is covered ONLY for Medicare ONLY when performed in an approved coverage with evidence development (CED) clinical trial.
- Appendix B, pp. 27-28: Clarification was provided to indicate that leadless pacemaker procedures are covered ONLY for Medicare ONLY when performed in an approved coverage with evidence development (CED) clinical trial

I. POLICY/CRITERIA

A. Any drug, device, treatment or procedure that is experimental, investigational or unproven is not a covered benefit. A drug, device, treatment or procedure is experimental, investigational or unproven if *any* of the following apply:

1. The drug or device cannot be lawfully marketed in the United States without the approval of the Food and Drug Administration (FDA) and such approval has not been granted; or

2. The drug, device, treatment or procedure is provided pursuant to oversight by an institutional review board or other body that approves or reviews research concerning safety, toxicity or efficacy; or

3. The patient informed consent documents describe the drug, device, treatment or procedure as experimental or investigational or in other terms that indicate the service is being evaluated for its safety, toxicity or efficacy; or

4. Reliable Evidence shows that the drug, device, treatment or procedure is the subject of on-going Phase I or Phase II clinical trials; is the research, experimental, study or investigational arm of on-going Phase III clinical trials; or is otherwise under study to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis; or

5. Reliable Evidence shows that the prevailing opinion among experts regarding the drug, device, treatment or procedure is that further studies or clinical trials are necessary to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis.

B. The exclusion of coverage for experimental, investigational, or unproven treatment may be **reviewed for exception** if the condition is:
   1) a terminal illness, or
   2) a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

   Individual case review may allow coverage for care or treatment that is investigational, yet promising for the conditions described. Requests for individual consideration require prior Plan approval.

   Coverage for care and services received in a clinical trial is defined in the *Clinical Trials Medical Policy #91606*. Refer to the "Clinical Trials" policy for benefits and limitations.

   Note: A Clinical Trials Coverage Reference Sheet (Appendix C) can be found at the end of this policy.

   Member must have an advance care planning assessment (see Appendix A at the end of this medical policy) completed by a qualified provider. The assessment should accompany the request for a benefit exception.

   All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist.

   1. Limits/Indications
      a. All accepted standard treatments and technologies must be considered or used prior to review for exception under this policy.
      b. Any treatment or evaluation (including additional opinions) authorized under this policy must be received at a participating facility or a facility within the reinsurance network.
      c. Any treatment authorized must be under the auspices of a nationally recognized sponsor such as the National Institutes of Health (NIH) and adhere to the US regulation standards of being approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits.
      d. When care is available both within a clinical trial and outside a clinical trial, coverage preference will be given to the clinical trial. When care is available within multiple trials, coverage will be given to the more definitive trial (e.g. Phase III over Phase II).
      e. Informed consent must be documented.

f. An independent expert physician review panel may be consulted to determine the appropriateness of the recommended treatment. The panel members will each provide their opinion on whether the treatment is promising and likely to be effective for that individual patient.
g. Care outside the United States is not covered.

2. Costs associated with experimental care

   Funding for experimental care, which covers the cost of protocol development and data collection traditionally comes from a variety of sources including pharmaceutical companies, research institutions and government agencies (referred to as "sponsors"). The following is intended to clarify what the plan will cover and what the sponsoring facility is expected to cover.

   a. The administrative costs are borne by the facility or sponsor, including:
      1. Data gathering
      2. Statistical study
      3. Regulatory requirements
      4. Contractual agreements
      5. Meetings and travel
   b. The routine patient care costs (conventional care) are covered by Priority Health.
      1. Routine patient care costs are items or services that are typically covered benefits when provided outside a clinical trial or experimental care.
      2. "Routine" services include services that would be approved for coverage under this policy, even when delivered within the context of a clinical trial or experimental care.
   c. Coverage for devices classified under the FDA Investigational Device Exemption (IDE) or Humanitarian Use Device (HUD)/Humanitarian Device Exemption (HDE). See definitions pp. 5-6 & Appendix C for product specific coverage
      1. IDEs
         a. Category A IDEs and associated care and services are not covered benefits
         b. Category B IDEs when used in a clinical trial and prior authorized by Priority Health:
            1. Routine patient care costs in a clinical trial are covered as defined above in 2b.
            2. The device is not a covered benefit
      2. HUD/HDEs. Devices that have FDA approval for humanitarian use or as HDEs are considered experimental and investigational

and excluded from coverage unless they are listed as covered in Appendix D.

d. The costs associated in the delivery of the investigational agent are covered by Priority Health.
   1. Services required solely for the provision of the investigational item shall be provided in accordance with the benefits of the patient's health plan. Coverage would include procedures, drugs or devices approved for coverage for any medical indication.
   2. The clinically appropriate monitoring of the effects of the item or service should be considered routine patient care costs.
   3. The prevention of complications of the item or service should be considered routine patient care costs.
   4. This coverage shall include payment for reasonable and medically necessary services to administer the drug or use the device under evaluation in the clinical trial.
e. Costs incurred for patient care generated specifically by the clinical trial or experimental care shall be borne by the facility or sponsor.
   1. The cost of the investigational drug, device, or service itself.
   2. Costs incurred for patient care generated specifically by the clinical trial. Examples of these are costs for additional medication, laboratory studies, or diagnostic imaging.
   3. The health plan's coverage of "routine costs" would *not* include non-FDA approved drugs or devices or unapproved medical procedures.
   4. Coverage would *not* include diagnostic tests that are performed for investigational purposes but not necessary for the patient's medical management.
   5. It would also *not* include services beyond the scope of the subscriber's contract.
f. Costs of treating adverse side effects experienced during treatment are covered by Priority Health. Priority Health will cover medical care needed to treat any complications arising from the experimental and investigational service, when the medical services provided are otherwise covered under the subscriber contract.
   1. It is recognized that while quality trials are designed with the utmost attention to patient safety, complications can occur when patients are participating in a clinical trial.
   2. It is reasonable to expect that in the event of an adverse reaction, the payers' commitment to offer their member's treatment for any medically necessary treatment would apply.

Definitions:

Reliable Evidence means published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device, treatment or procedure.

Terminal Illness — A disease that can be expected to result in death within 1 year in the absence of effective treatment.

Promising — Preliminary scientific data supports reasonable likelihood of success of the treatment for the diagnosis.

Clinical Trials (*from the National Cancer Institute*)

Clinical trials in cancer therapy are conducted to decrease morbidity and mortality from cancer. New drug development is one part of this effort, but other parts include the integration of multiple treatment modalities, the testing of new combinations of existing drugs, the testing of new dose schedules and routes of administration, the application of new diagnostic tests in choosing treatment regimens, and the evaluation of supportive care methods.

Phase I — The initial clinical test of a new treatment modality. Most Phase I patients have cancer for which no other effective therapeutic options are known, and patients with any type of cancer are admitted to most Phase I trials.

Phase II — The initial efficacy trial of a new cancer agent. The trial is done on groups of patients with one type of cancer.

Phase III — Designed to compare one or more treatments. A new drug or drug combination ("research arm") may be tested against a drug combination of proven efficacy. The patients are randomly allocated to the treatment options.

Clinical Trials for Investigational New Drugs (*from the Food & Drug Administration*)

Phase I — Testing concerned primarily with the safety of the drug and normally done on a small number (20-100) of healthy volunteers.

Phase II — This phase of drug testing involves a few hundred patients and is designed to show whether the drug is effective in treating the disease or condition for which it is intended. Most Phase II studies are randomized controlled trials.

Phase III — The population size is expanded to several hundred to several thousand to clarify the drug's benefit-risk relationship and discover side effects and adverse reactions.

These three phases are necessary for FDA marketing approval of a new drug. Post marketing surveillance (*Phase IV*) is done to detect adverse reactions that might not have been detected in earlier trials.

Investigational Device Studies (IDEs)

Category A (Experimental) device refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B (Non-experimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

II. LIMITS/INDICATIONS

Coverage determinations will be made by a Priority Health medical director or clinical pharmacist. If coverage is denied as experimental, investigational or unproven, the medical director/clinical pharmacist will determine, on a case-by-case basis, when coverage resumes.

III. MEDICAL NECESSITY REVIEW

☒ Required ☐ Not Required ☐ Not Applicable

IV. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN/MICHILD:** ***For Medicaid/Healthy Michigan Plan/MIChild members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this***

policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

V. DESCRIPTION

Experimental and investigational (with respect to medical research), refers to a procedure, device or pharmaceutical agent that is still undergoing pre-clinical or clinical evaluation, and/or has not yet received regulatory approval**.** When basic **s**afety and efficacy have been demonstrated by the experimental scientific process the investigational phase begins.

Medical research is conducted to aid the body of knowledge in the field of medicine. This can be divided into two general categories: New treatments that are tested in clinical trials, and all other research contributing to the development of new treatments. A new treatment refers to any form of previously untested treatment for a particular pathology. This can take the form of a new surgical procedure, a new drug, or a new treatment regimen. These are extensively tested in clinical trials prior to wide-spread use. Formal clinical trials have, among other aspects, extensive written research protocols that adhere to established research principles and study design.

At the early stages, study protocols usually focus on the safety of the new drug, device, or procedure using a single group of research subjects. Such “single arm” trials generally are followed by more extensive studies that measure the experimental intervention against alternative therapies and/or involve a rudimentary comparison between experimental and control subject groups. As the research further matures, the new intervention will be tested in double-blind randomized studies, the so-called “gold-standard” of research. Depending on study results, the intervention may become a generally recognized standard of care.

VI. REFERENCES

Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies, CMS MLN Matters, MM8921, effective January 1, 2015.

VII. CODING

See Policies:

91448 Clinical Trials for Cancer Care
91606 Clinical Trials

GENERAL NOT COVERED services based on Experimental, Investigational, Unproven Care and plan document language. *This List is not inclusive. These codes are not included in any specific medical policy.*

CPT/HCPCS codes:

28446 Open osteochondral autograft, talus (includes obtaining graft[s])

31627 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s]) *(Not separately payable)*

32994 Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation

33255 Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); without cardiopulmonary bypass

33258 Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure)

33274 Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed (*Covered for Medicare)*

33275 Transcatheter removal of permanent leadless pacemaker, right ventricular *(Covered for Medicare)*

33418 Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis

33419 Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis (es) during same session (List separately in addition to code for primary procedure)

34839 Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time

34841 Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)

34842 Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprosthesis (superior mesenteric, celiac and/or renal artery[s])

34843 Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by

	deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprosthesis (superior mesenteric, celiac and/or renal artery[s])
34844	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprosthesis (superior mesenteric, celiac and/or renal artery[s])
34845	Endovascular repair of visceral aorta and intrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprosthesis (superior mesenteric, celiac and/or renal artery[s])
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprosthesis (superior mesenteric, celiac and/or renal artery[s])
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprosthesis (superior mesenteric, celiac and/or renal artery[s]) (Procedures 34839 - 34848 covered for Priority Medicare)
43206	Esophagoscopy, rigid or flexible; with optical endomicroscopy
43252	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with optical endomicroscopy
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy
55400	Vasovasostomy, vasovasorrhaphy
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed *(Not separately payable)*

58750	Tubotubal anastomosis
69090	Ear piercing
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar
82075	Alcohol (ethanol), breath
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)
83876	Myeloperoxidase (MPO)
83951	Oncoprotein; des-gamma-carboxy-prothrombin (DCP)
84145	Procalcitonin (PCT)
84431	Thromboxane metabolite(s), including thromboxane if performed, urine
86305	Human epididymis protein 4 (HE4)
86352	Cellular function assay involving stimulation (e.g., mitogen or antigen) and detection of biomarker (e.g., ATP)
88130	Sex chromatin identification; Barr bodies
91117	Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, e.g., meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report
93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)
93740	Temperature gradient studies
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral
96020	Neurofunctional testing selection and administration during noninvasive imaging functional brain mapping, with test administered entirely by a physician or other qualified health care professional (i.e., psychologist), with review of test results and report
96931	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion
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
99026	Hospital mandated on call service; in-hospital, each hour
99027	Hospital mandated on call service; out-of-hospital, each hour
99070	Supplies and materials (except spectacles), provided by the physician or other qualified health care professional over and above those usually included with the office visit or other services rendered (list drugs, trays, supplies, or materials provided)
99071	Educational supplies, such as books, tapes, and pamphlets, for the patient's education at cost to physician or other qualified health care professional
99075	Medical testimony
99080	Special reports such as insurance forms, more than the information conveyed in the usual medical communications or standard reporting form
99082	Unusual travel (e.g., transportation and escort of patient)
A4563	Rectal control system for vaginal insertion, for long term use, includes pump and all supplies and accessories, any type each
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed
C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)
G0219	PET imaging whole body; melanoma for noncovered indications
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)
G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control (Exception: Covered ONLY for Medicare ONLY when performed in an approved coverage with evidence development (CED) clinical trial)
G0429	Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) (e.g., as a result of highly active antiretroviral therapy)
G0513	Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service) (*payable for Medicare only)*
G0514	Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code g0513 for additional 30 minutes of preventive service) (*payable for Medicare only)*
G0516	Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant)

G0517 Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)
G0518 Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)

J0470 Injection, dimercaprol, per 100 mg
J0570 Buprenorphine implant, 74.2 mg
J7318 – J7329 Hyaluronic acid derivatives (*Covered for Priority Medicare only)*
J8670 Rolapitant, oral, 1 mg
J3490 Unclassified Drugs (*Explanatory notes must accompany claims billed with unlisted codes) Not* **covered when submitted for Ketamine or other not covered drugs. All associated services are also excluded.**

Q2026 Injection, Radiesse, 0.1 ml
Q2028 Injection, sculptra, 0.5 mg

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
0006U Prescription drug monitoring, 120 or more drugs and substances, definitive tandem mass spectrometry with chromatography, urine, qualitative report of presence (including quantitative levels, when detected) or absence of each drug or substance with description and severity of potential interactions, with identified substances, per date of service
0007U Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service
0011U Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites
0021U Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'- UTR-BMI1, CEP 164, 3'-UTRRopporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score
0024U Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative
0025U Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine, quantitative
0035U Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking induced conformational conversion, qualitative
0038U Vitamin D, 25 hydroxy D2 and D3, by LCMS/MS, serum microsample, quantitative
0039U Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity
0041U Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM
0042U Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG

0043U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM
0044U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG
0051U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service
0052U	Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation
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
0062U	Autoimmune (systemic lupus erythematosus) IgG and Igm analysis of 80 biomarkers, utilizing serum, and algorithm reported with a risk score
0063U	Neurology (autism), 32 amines by LCMS/MS, using plasma, and algorithm reported as metabolic signature associate with autism spectrum disorder
0064U	Antibody, Treponema pallidum, total and rapid plasma regain (RPR), immunoassay, qualitative
0065U	Syphilis test, non-treponemal antibody, immunoassay, qualitative (RPR)
0066U	Placental alpha-micro globulin-1 (PAMG1), immunoassay with direct optical observation, cervico-vaginal fluid, each specimen
0077U	Immunoglobulin paraprotein (M-protein), qualitative, immunoprecipitation and mass spectrometry, blood or urine, including isotype
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
0082U	Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service
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

AMA CPT Copyright Statement:
All Current Procedure Terminology (CPT) codes, descriptions, and other data are copyrighted by the American Medical Association.

This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion.

Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

The name "Priority Health" and the term "plan" mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.

APPENDIX A
ADVANCE CARE PLANNING ASSESSMENT

1. **Medical history and reason for referral:**

2. **Patient's understanding of current disease status and overall prognosis:**

   Medical care options discussed with patient:

3. **Has patient completed an Advance Care Planning conversation, including designation of patient advocate as part of the advance directive, with a certified ACP facilitator*? Yes ☐ No ☐ If no, answer questions 4-9. If yes, this form is complete.**

4. **What are patient's wishes/goals for remainder of life (quality of life vs. length of life; importance of physical comfort; how patient wishes to spend time, etc.)?**

5. **How does patient describe their current physical/mental symptoms? What is quality of life rating using QOL, HR QOL scale, SF 36 (short-form health questionnaire)?**

6. **Spiritual or cultural beliefs related to illness and death that would affect enrollment? Yes ☐ No ☐**

7. **Is advance directive complete? Yes ☐ No ☐ (i.e. Making Choices Michigan)**

8. **Patient has designated a durable power of attorney for healthcare? Yes ☐ No ☐**

9. **Does family/patient advocate support patient's preference for medical care as outlined in advance directive? Yes ☐ No ☐**

***Certified ACP facilitators are trained through the Respecting Choices® curriculum. Trained facilitators are available at health systems, Making Choices Michigan, and community organizations.**

APPENDIX B

Category III Codes

Category III codes were introduced by the American Medical Association (AMA) in 2001 as a temporary code set to represent emerging technology, services and procedures for the purpose of data collection relative to usage, enhance practice management, and to replace local codes. Services represented by these codes may represent experimental and/or unproven care. These codes are evaluated with each code release and coverage status is determined. This listing applies to all lines of business unless otherwise stated and is subject to change without notice. This listing is not an all-inclusive list of unproven or investigational care. Coverage status of procedures *may* also be referenced in the medical policy listed.

Coverage notes apply to all products unless specified. **Updated:** August 2018

TBD = Coverage to be determined

Code	Description	Coverage Notes
0042T	Cerebral perfusion analysis using computed tomography with contrast administration, including post-processing of parametric maps with determination of cerebral blood flow, cerebral blood volume, and mean transit time	Not Covered for Medicaid
0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (List separately in addition to code for primary procedure)	Covered for Medicaid
0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images (List separately in addition to code for primary procedure)	Covered for Medicaid
0058T	Cryopreservation; reproductive tissue, ovarian	Not Covered (Policy #91163)
0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue	Not Covered (Policy #91573)
0072T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue	Not Covered (Policy #91573)
0075T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; initial vessel	Not Covered for Medicaid (Policy #91495)
0076T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; each additional vessel (List separately in addition to code for primary procedure)	Not Covered for Medicaid (Policy #91495)
0085T	Breath test for heart transplant rejection	Not Covered
0095T	Removal of total disc arthroplasty, anterior approach cervical; each additional interspace (List separately in addition to code for primary procedure)	Not Covered for Medicaid or Medicare; Requires prior auth (Policy #91581)

Code	Description	Coverage Notes
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach; each additional interspace, cervical (List separately in addition to code for primary procedure)	Not Covered for Medicaid or Medicare; (Policy #91581)
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy	Covered for Medicare
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy	Not Covered (Policy #91527)
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle	Not Covered (Policy #91527)
0106T	Quantitative sensory testing (QST), testing and interpretation per extremity; using touch pressure stimuli to assess large diameter sensation	Not Covered
0107T	Quantitative sensory testing (QST), testing and interpretation per extremity; using vibration stimuli to assess large diameter fiber sensation	Not Covered
0108T	Quantitative sensory testing (QST), testing and interpretation per extremity; using cooling stimuli to assess small nerve fiber sensation and hyperalgesia	Not Covered
0109T	Quantitative sensory testing (QST), testing and interpretation per extremity; using heat-pain stimuli to assess small nerve fiber sensation and hyperalgesia	Not Covered
0110T	Quantitative sensory testing (QST), testing and interpretation per extremity; using other stimuli to assess sensation	Not Covered
0111T	Long-chain (C20-22) omega-3 fatty acids in red blood cell (RBC) membranes	Not Covered (Policy #91559)
0126T	Common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment	Not Covered (Policy #91559)
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace	Not Covered (Policy #91581)
0164T	Removal of total disc arthroplasty, anterior approach, lumbar, each additional interspace	Not Covered (Policy #91581)
0165T	Revision of total disc arthroplasty, anterior approach, lumbar, each additional interspace	Not Covered (Policy #91581)
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)	Not Covered for Medicaid

Code	Description	Coverage Notes
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	Not Covered for Medicaid
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (i.e., TEMS) including muscularis propria (i.e., full thickness)	Not Covered for Medicaid
0191T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach into the trabecular meshwork; initial insertion	Covered
0198T	Measurement of ocular blood flow by repetitive intraocular pressure sampling, with interpretation and report	Covered for Medicaid only (Policy #91538)
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device (if utilized), 1 or more needles, includes imaging guidance and bone biopsy, when performed	Not Covered (Policies #91581 & #91590)
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device (if utilized), 2 or more needles, includes imaging guidance and bone biopsy, when performed	Not Covered (Policies #91581 & #91590)
0202T	Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, with or without injection of bone cement, including fluoroscopy, single level, lumbar spine	Not Covered (Policies #91581 & #91590)
0205T	Intravascular catheter-based coronary vessel or graft spectroscopy (e.g., 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)	Not Covered (Policy # 91559)
0206T	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	Covered
0207T	Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral	Covered
0208T	Pure tone audiometry (threshold), automated (includes use of computer-assisted device); air only	Covered (Policy #91544)
0209T	Pure tone audiometry (threshold), automated (includes use of computer-assisted device);air and bone	Covered (Policy #91544)
0210T	Speech audiometry threshold, automated (includes use of computer-assisted device);	Covered (Policy #91544)
0211T	Speech audiometry threshold, automated (includes use of computer-assisted device);with speech recognition	Covered (Policy #91544)

Code	Description	Coverage Notes
0212T	Comprehensive audiometry threshold evaluation and speech recognition (0209T, 0211T combined), automated	Covered (Policy #91544)
0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level	Covered
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)	Covered
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)	Covered
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level	Covered
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)	Covered
0218T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)	Covered
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	Not Covered (Policies #91590 & #91581)
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	Not Covered (Policies #91590 & #91581)
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	Not Covered (Policies #91590 & #91581)
0222T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), each additional vertebral segment (List separately in addition to code for primary procedure)	Not Covered (Policies #91590 & #91581)
0228T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level	Not Covered
0229T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; each additional level (List separately in addition to code for primary procedure)	Not Covered

Code	Description	Coverage Notes
0230T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level	Not Covered
0231T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; each additional level (List separately in addition to code for primary procedure)	Not Covered
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed	Not Covered (Policy #91553)
0234T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; renal artery	Covered (Policy #91561)
0235T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; visceral artery (except renal), each vessel	Covered
0236T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; abdominal aorta	Covered
0237T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; brachiocephalic trunk and branches, each vessel	Covered
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel	Covered
0249T	Ligation, hemorrhoidal vascular bundle(s), including ultrasound guidance	Covered for Medicare only
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the suprachoroidal space	Covered
0254T	Endovascular repair of iliac artery bifurcation (e.g., aneurysm, pseudoaneurysm, arteriovenous malformation, trauma) using bifurcated endoprosthesis from the common iliac artery into both the external and internal iliac artery, including all selective and/or nonselective catheterization(s) required for device placement and all associated radiological supervision and interpretation, unilateral;	Covered
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest	Not Covered (Policy # 91066)
0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, 1 leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest	Not Covered (Policy #91006)
0265T	Unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy	Not Covered (Policy #91006)

Code	Description	Coverage Notes
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)	Not Covered (Policy #91468)
0267T	lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	Not Covered (Policy #91468)
0268T	pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	Not Covered (Policy #91468)
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	Not Covered (Policy #91468)
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	Not Covered (Policy #91468)
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	Not Covered (Policy #91468)
0272T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day);	Not Covered (Policy #91468)
0273T	. . . . with programming	Not Covered (Policy #91468)
0274T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic	Not Covered
0275T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar	Covered for Medicare only Policy # 91591
0278T	Transcutaneous electrical modulation pain reprocessing (e.g., scrambler therapy), each treatment session (includes placement of electrodes)	Not Covered (Policy #91468)
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)	Not separately payable (Policies #91529 & #91572)

Code	Description	Coverage Notes
0295T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	Not Covered for Medicaid
0296T	. . .recording (includes connection and initial recording)	Not Covered for Medicaid
0297T	. . . scanning analysis with report	Not Covered for Medicaid
0298T	. . . review and interpretation	Not Covered for Medicaid
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens	Not Covered for Medicaid (Policy #91538)
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	Not Covered (Policy # 91468 & #91595)
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator	Not Covered (Policy #91468 & #91595)
0314T	Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator	Not Covered (Policy #91468 & #91595)
0315T	Vagus nerve blocking therapy (morbid obesity); removal of pulse generator	Not Covered (Policy #91468 & #91595)
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator	Not Covered (Policy #91468, & #91595)
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed	Not Covered (Policy #91468 & #91595)
0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report	Not Covered (Policy # 91538)
0330T	Tear film imaging, unilateral or bilateral, with interpretation and report	Not Covered (Policy # 91538)
0331T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment;	Not Covered
0332T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment; with tomographic SPECT	Not Covered
0333T	Visual evoked potential, screening of visual acuity, automated, with report	Not Covered (Policy #91538)
0335T	Insertion of sinus tarsi implant	Not Covered (Policy #91121)
0338T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural road mapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral	Not Covered

Code	Description	Coverage Notes
0339T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural road mapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral	Not Covered
0341T	Quantitative pupillometry with interpretation and report, unilateral or bilateral	Not Covered
0342T	Therapeutic apheresis with selective HDL delipidation and plasma reinfusion	Not Covered
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus	Not Covered (Policy #91597)
0347T	Placement of interstitial device(s) in bone for radiostereometric analysis (RSA)	Not Covered
0348T	Radiologic examination, radiostereometric analysis (RSA); spine, (includes, cervical, thoracic and lumbosacral, when performed)	Not Covered
0349T	Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow and wrist, when performed)	Not Covered
0350T	Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies), (includes hip, proximal femur, knee and ankle, when performed)	Not Covered
0351T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real time intraoperative	Not separately payable
0352T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; interpretation and report, real time or referred	Not separately payable
0353T	Optical coherence tomography of breast, surgical cavity; real time intraoperative	Not separately payable
0354T	Optical coherence tomography of breast, surgical cavity; interpretation and report, real time or referred	Not separately payable
0355T	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report	Not Covered
0356T	Insertion of drug-eluting implant (including punctual dilation and implant removal when performed) into lacrimal canaliculus, each	Not Covered
0357T	Cryopreservation; immature oocyte(s)	Not Covered (Policy #91163)
0358T	Bioelectrical impedance analysis whole body composition assessment, supine position, with interpretation and report	Not Covered

Code	Description	Coverage Notes
0362T	Behavior identification supporting assessment, 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.	Not Covered (Policy #91615)
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	Not Covered (Policy #91615)
0375T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels	Not Covered (Policy #91581)
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)	Not Covered for Medicaid (Policy #91538)
0377T	Anoscopy with directed submucosal injection of bulking agent for fecal incontinence	Not Covered
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	Not Covered (Policy #91538)
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	Not Covered (Policy #91538)
0380T	Computer-aided animation and analysis of time series retinal images for the monitoring of disease progression, unilateral or bilateral, with interpretation and report	Not Covered (Policy #91538)
0381T	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	Not Covered

Code	Description	Coverage Notes
0382T	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	Not Covered
0383T	External heart rate and 3-axis accelerometer data recording from 15 to 30 days to assess changes in heart rate 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	Not Covered
0384T	External heart rate and 3-axis accelerometer data recording from 15 to 30 days to assess changes in heart rate to monitor motion analysis for the purposes of diagnosing nocturnal epilepsy seizure events; review and interpretation only	Not Covered
0385T	External heart rate and 3-axis accelerometer data recording more than 30 days to assess changes in heart rate 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	Not Covered
0386T	External heart rate and 3-axis accelerometer data recording more than 30 days to assess changes in heart rate to monitor motion analysis for the purposes of diagnosing nocturnal epilepsy seizure events; review and interpretation only	Not Covered
0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed	Covered for Medicare only
0395T	High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed	Covered for Medicare only
0396T	Intra-operative use of kinetic balance sensor for implant stability during knee replacement arthroplasty (List separately in addition to code for primary procedure)	Not Separately Payable
0397T	Endoscopic retrograde cholangiopancreatography (ERCP), with optical endomicroscopy (List separately in addition to code for primary procedure)	Not Separately Payable
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	Not Covered
0399T	Myocardial strain imaging (quantitative assessment of myocardial mechanics using image-based analysis of local myocardial dynamics)	Not separately payable for Facilities; Not covered for Medicaid
0400T	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	Not Covered (Policy #91456)

Code	Description	Coverage Notes
0401T	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	Not Covered (Policy #91456)
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)	Not Covered for Medicaid (Policies #91538 & #91529)
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	Not Covered for Medicaid
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency	Not Covered (Policy #91573)
0405T	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	Not Covered
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	Not Covered
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	Not Covered
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	Not Covered
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	Not Covered
0412T	Removal of permanent cardiac contractility modulation system; pulse generator only	Not Covered
0413T	Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular)	Not Covered
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only	Not Covered
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode, (atrial or ventricular lead)	Not Covered
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator	Not Covered

Code	Description	Coverage Notes
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	Not Covered
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable cardiac contractility modulation system	Not Covered
0419T	Destruction neurofibromata, extensive, (cutaneous, dermal extending into subcutaneous); face, head and neck, greater than 50 neurofibromata	Not Covered for Medicaid
0420T	Destruction neurofibromata, extensive, (cutaneous, dermal extending into subcutaneous); trunk and extremities, extensive, greater than 100 neurofibromata	Not Covered for Medicaid
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)	Not Covered
0422T	Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral	Not Covered (Policy #91545)
0423T	Secretory type II phospholipase A2 (sPLA2-IIA)	Not Covered (Policy #91559)
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)	Not Covered (Policies #91468 & 91333)
0425T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; sensing lead only	Not Covered (Policies #91468 & 91333)
0426T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; stimulation lead only	Not Covered (Policies #91468 & 91333)
0427T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; pulse generator only	Not Covered (Policies #91468 & 91333)
0428T	Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only	Not Covered (Policies #91468 & 91333)
0429T	Removal of neurostimulator system for treatment of central sleep apnea; sensing lead only	Not Covered (Policies #91468 & 91333)
0430T	Removal of neurostimulator system for treatment of central sleep apnea; stimulation lead only	Not Covered (Policies #91468 & 91333)
0431T	Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only	Not Covered (Policies #91468 & 91333)
0432T	Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only	Not Covered (Policies #91468 & 91333)
0433T	Repositioning of neurostimulator system for treatment of central sleep apnea; sensing lead only	Not Covered (Policies #91468 & 91333)

Code	Description	Coverage Notes
0434T	Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea	Not Covered (Policies #91468 & 91333)
0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session	Not Covered (Policies #91468 & 91333)
0436T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; during sleep study	Not Covered (Policies #91468 & 91333)
0437T	Implantation of non-biologic or synthetic implant (e.g., polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to code for primary procedure)	Not Covered for Medicare and Medicaid
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)	Not Covered
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve	Not Covered
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve	Not Covered
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (e.g., brachial plexus, pudendal nerve)	Not Covered
0443T	Real time spectral analysis of prostate tissue by fluorescence spectroscopy	Not Covered
0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral	Not Covered (Policy #91538)
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	Not Covered
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	Not Covered (Policy #91466)
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision	Not Covered -(Policy #91466)
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	Not Covered (Policy #91466)
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device	Not Covered for Medicaid (Policy #91538)
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)	Not Covered for Medicaid (Policy #91538)

Code	Description	Coverage Notes
0451T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; complete system (counterpulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes)	Not Covered (Policy #91509)
0452T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; aortic counterpulsation device and vascular hemostatic seal	Not Covered (Policy #91509)
0453T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; mechano-electrical skin interface	Not Covered (Policy #91509)
0454T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; subcutaneous electrode	Not Covered (Policy #91509)
0455T	Removal of permanently implantable aortic counterpulsation ventricular assist system; complete system (aortic counterpulsation device, vascular hemostatic seal, mechano-electrical skin interface and electrodes)	Not Covered (Policy #91509)
0456T	Removal of permanently implantable aortic counterpulsation ventricular assist system; aortic counterpulsation device and vascular hemostatic seal	Not Covered (Policy #91509)
0457T	Removal of permanently implantable aortic counterpulsation ventricular assist system; mechano-electrical skin interface	Not Covered (Policy #91509)
0458T	Removal of permanently implantable aortic counterpulsation ventricular assist system; subcutaneous electrode	Not Covered (Policy #91509)
0459T	Relocation of skin pocket with replacement of implanted aortic counterpulsation ventricular assist device, mechano-electrical skin interface and electrodes	Not Covered (Policy #91509)
0460T	Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode	Not Covered (Policy #91509)
0461T	Repositioning of previously implanted aortic counterpulsation ventricular assist device; aortic counterpulsation device	Not Covered (Policy #91509)
0462T	Programming device evaluation (in person) with iterative adjustment of the implantable mechano-electrical skin interface and/or external driver to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable aortic counterpulsation ventricular assist system, per day	Not Covered (Policy #91509)
0463T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable aortic counterpulsation ventricular assist system, per day	Not Covered (Policy #91509)

Code	Description	Coverage Notes
0464T	Visual evoked potential, testing for glaucoma, with interpretation and report	Not Covered (Policy #91538
0465T	Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)	Not Covered (Policy #91538
0466T	Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)	Not Covered (Policy #91333, Policy #91468)
0467T	Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator	Not Covered (Policy #91333, Policy #91468)
0468T	Removal of chest wall respiratory sensor electrode or electrode array	Not Covered (Policy #91333, Policy #91468)
0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral ► (Do not report 0469T in conjunction with 92002-92014) ◄ ► (For ocular photo screening, see 99174, 99177) ◄	Not Covered (Policy #91538)
0470T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; first lesion	Not Covered
0471T	each additional lesion (List separately in addition to code for primary procedure) ► (Use 0471T in conjunction with 0470T) ◄ ► (For optical coherence tomography for coronary vessel or graft, see 92978, 92979)◄ ►(For reflectance confocal microscopy [RCM] of the skin, see 96931, 96932, 96933, 96934, 96935, 96936) ◄	Not Covered
0472T	Device evaluation, interrogation, and initial programming of intraocular retinal electrode array (e.g., 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	Covered for Medicare only (Policy #91538)
0473T	Device evaluation and interrogation of intra-ocular retinal electrode array (e.g., retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional ► (For implantation of intra-ocular electrode array, use 0100T) ◄ ► (For reprogramming of implantable intra-ocular retinal electrode array device, use 0473T)◄	Covered for Medicare only (Policy #91538)
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space	Not covered for Medicaid (Policy #91538)
0475T	Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording and storage, data scanning with signal extraction, technical analysis and result, as well as supervision, review, and interpretation of report by a physician or other qualified health care professional	Not Covered

Code	Description	Coverage Notes
0476T	patient recording, data scanning, with raw electronic signal transfer of data and storage January 0477T	Not Covered
0477T	Recording of fetal magnetic cardiac signal using at least 3 channels; signal extraction, technical analysis, and result	Not Covered
0478T	review, interpretation, report by physician or other qualified health care professional	Not Covered
0479T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; first 100 cm2 or part thereof, or 1% of body surface area of infants and children	Not Covered
0480T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; each additional 100 cm2, or each additional 1% of body surface area of infants and children, or part thereof (List separately in addition to code for primary procedure)	Not Covered
0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed	Not Covered (Policy #91553)
0482T	Absolute quantitation of myocardial blood flow, positron emission tomography (PET), rest and stress (List separately in addition to code for primary procedure)	Not Covered
0483T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed	Not Covered (Policy # 91597)
0484T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (e.g., thoracotomy, transapical)	Not Covered (Policy #91597)
0485T	Optical coherence tomography (OCT) of middle ear, with interpretation and report; unilateral	Not Covered
0486T	Optical coherence tomography (OCT) of middle ear, with interpretation and report; bilateral	Not Covered
0487T	Biomechanical mapping, transvaginal, with report	Not Covered
0488T	Preventive behavior change, online/electronic structured intensive program for prevention of diabetes using a standardized diabetes prevention program curriculum, provided to an individual, per 30 days	Not covered for Medicare or Medicaid
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	Not Covered
0490T	Autologous adipose-derived regenerative cell therapy for scleroderma in the hands; multiple injections in one or both hands	Not Covered
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	Not Covered

Code	Description	Coverage Notes
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)	Not Covered
0493T	Near-infrared spectroscopy studies of lower extremity wounds (e.g., for oxyhemoglobin measurement)	Not Covered
0494T	Surgical preparation and cannulation of marginal (extended) cadaver donor lung(s) to ex vivo organ perfusion system, including decannulation, separation from the perfusion system, and cold preservation of the allograft prior to implantation, when performed	Not Covered (Policy #91272)
0495T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (e.g., pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; first two hours in sterile field	Not Covered (Policy #91272)
0496T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (e.g., pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; each additional hour (List separately in addition to code for primary procedure)	Not Covered (Policy #91272)
0497T	External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recorder without 24 hour attended monitoring; in-office connection	Not Covered
0498T	External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recording without 24 hour attended monitoring; review and interpretation by a physician or other qualified health care professional per 30 days with at least one patient-generated triggered event	Not Covered
0499T	Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed	Not Covered
0500T	Infectious agent detection by nucleic acid (DNA or RNA), human papillomavirus (HPV) for five or more separately reported high-risk HPV types (e.g., 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) (i.e., genotyping)	Not Covered

Code	Description	Coverage Notes
0501T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report	Not Covered for Medicaid (Policy #91614)
0502T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission	Not Covered for Medicaid (Policy #91614)
0503T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model	Not Covered for Medicaid (Policy #91614)
0504T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report	Not Covered for Medicaid (Policy #91614)
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural road mapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	Not Covered for Medicaid
0506T	Macular pigment optical density measurement by heterochromatic flicker photometry, unilateral or bilateral, with interpretation and report	Not Covered (Policy #91538)
0507T	Near-infrared dual imaging (i.e., simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report	Not Covered (Policy #91538)
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia	Not Covered (Policy #91494)
0509T	Electroretinography (ERG) with interpretation and report, pattern (PERG)	Not Covered (Policy #91538)

Code	Description	Coverage Notes
0510T	Removal of sinus tarsi implant	Covered (Policy #91117)
0511T	Removal and reinsertion of sinus tarsi implant	Not Covered (Policy #91117)
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	Not Covered (Policy #91527)
0513T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure)	Not Covered (Policy # 91527)
0514T	Intraoperative visual axis identification using patient fixation. (List separately in addition to code for primary procedure)	Not Covered (Policy #91538)
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])	Not Covered (Policy # 91419)
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	Not Covered (Policy # 91419)
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) (batter and/or transmitter) only	Not Covered (Policy #91419)
0518T	Removal of only pulse generator component(s) (batter and/or transmitter) of wireless cardiac stimulator for left ventricular pacing	Not Covered (Policy #91419)
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)	Not Covered (Policy #91419)
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	Not Covered (Policy #91419)
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	Not Covered (Policy #91419)

Code	Description	Coverage Notes
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	Not Covered (Policy #91419)
0523T	Intraprocedural coronary fractional flow reserve (FFR) with 3D functional mapping of color-coded FFR values for the coronary tree, derived from coronary angiogram data, for real-time review and interpretation of possible atherosclerotic stenosis(es) intervention (List separately in addition to code for primary procedure)	Not Covered (Policy #91419)
0524T	Endovenous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring	Not Covered (Policy #91326)
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)	Not Covered (Policy #91117)
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	Not Covered (Policy #91117)
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	Not Covered (Policy #91117)
0528T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report	Not Covered (Policy #91117)
0529T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report	Not Covered (Policy #91117)
0530T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; complete system (electrode and implantable monitor)	Not Covered (Policy #91117)
0531T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; electrode only	Not Covered (Policy #91117)

Code	Description	Coverage Notes
0532T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; implantable monitor only	Not Covered (Policy #91117)
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	Not Covered (Policy #91117)
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	Not Covered (Policy #91117)
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	Not Covered (Policy #91117)
0536T	Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; download review, interpretation and report	Not Covered (Policy #91117)
0537T	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day	Not Covered
0538T	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)	Not Covered
0539T	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration	Not Covered
0540T	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous	Not Covered
0541T	Myocardial imaging by magnetocardiography (MCG) for detection of cardiac ischemia, by signal acquisition using minimum 36 channel grid, generation of magnetic-field time-series images, quantitative analysis of magnetic dipoles, machine learning-derived clinical scoring, and automated report generation, single study;	Not Covered

Code	Description	Coverage Notes
0542T	Myocardial imaging by magnetocardiography (MCG) for detection of cardiac ischemia, by signal acquisition using minimum 36 channel grid, generation of magnetic-field time-series images, quantitative analysis of magnetic dipoles, machine learning-derived clinical scoring, and automated report generation, single study; interpretation and report	Not Covered

APPENDIX C

CLINICAL TRIALS COVERAGE REFERENCE SHEET***

	Commercial Fully-funded	**Commercial Self-funded**	**Medicare**	
Clinical Trials	Routine services* only, use *Clinical Trials Policy #91606*	Non-grandfathered groups: routine services only, use *Clinical Trials Policy #91606* Grandfathered groups opting out of PPACA: use *Clinical Trials for Cancer Policy #91448*	Original Medicare covers routine services for those trials that are Medicare approved If trial is not Medicare approved, there is no coverage under Original Medicare or Priority Health Medicare.	
IDE (Investigational Device Exemption)Trial: Category A Device	Never covered. Device and all services, including routine services, are not covered. Use *Experimental & Investigational Policy #91117*	Never covered. Device and all services, including routine services, are not covered. Use *Experimental & Investigational Policy #91117*	Device is never covered. Routine care items and services in CMS-approved Category A IDE studies are covered by Priority Health Medicare	
IDE Trial: Category B Device	Routine services only; device not covered.** Use *Experimental & Investigational Policy #91117*	Device and all services, including routine services, are not covered.** Use *Experimental & Investigational Policy #91117*	All services, including the device, are covered by Priority Health Medicare	
Clinical Studies Approved Under Evidence Development (CED)	Use *Experimental & Investigational Policy #91117* to determine coverage	Use *Experimental & Investigational Policy #91117* and individual plan documents to determine coverage	All care and services are covered by Priority Health Medicare	

*Routine patient care costs are items or services that are typically covered benefits when provided outside a clinical trial. The clinical trial protocol may be needed to determine the specific services that are covered and excluded.

**Priority Health may, at its discretion, choose to cover the experimental device if the cost of that device is less than the non-experimental arm of the trial.

*****For Medicaid/Healthy Michigan refer to section III "Application to Products"**

APPENDIX D

HUMANITARIAN USE DEVICE (HUD)/ HUMANITARIAN DEVICE EXEMPTION (HDE) REFERENCE SHEET

The following HUDs/HDEs may be covered when used in accordance with their FDA approval

HUD/HDE Covered Devices	Medical Policy Supporting Coverage
1. Impella circulatory assistance	Ventricular Assist Devices medical policy #91509
2. NeuRX diaphragmatic stimulator for spinal cord injury	Stimulation Therapy and Devices medical policy #91468
3. Epicel cultured epidermal autografts	Skin Substitutes and Soft Tissue Grafts medical policy #91560
4. Abiocor replacement heart-may be covered for destination therapy as part of a clinical trial	Ventricular Assist Devices and Artificial Hearts medical policy #91509
5. Vertical expandable prosthetic titanium rib (VEPTR)	Titanium Rib medical policy #91505
6. INTACS for keratoconus	Vision Care medical policy #91538
7. Dystonia stimulation therapy	Stimulation Therapy and Devices medical policy #91468
8. Enterra Therapy System	Gastroparesis Testing and Treatment medical policy #91572
9. TheraSphere: covered for FDA HDE indication. TheraSphere is indicated for radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma (HCC) who can have placement of appropriately positioned hepatic arterial catheters. The device is also indicated for HCC patients with partial or branch portal vein thrombosis/occlusion, when clinical evaluation warrants the treatment.	No medical policy

Note: Devices that have FDA approval for humanitarian use or as HDEs are considered experimental and investigational and excluded from coverage unless they are listed above.

The FDA list of HDEs can be found @ http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm(Accessed October 23, 2017)