

**Distribution Date: March 1, 2018**

The following medical protocol update includes information on protocols that have undergone an annual review over the last several months, or an additional review in order to make changes. The annual review may have resulted in a revision to the guidelines or no changes at all. One new protocol has been added.

Please note that portions of this protocol update may not pertain to the members to whom you provide care.

### **Protocol Revision Summary**

The effective date of these changes is April 1, 2018:

#### **Artificial Pancreas Device Systems**

Changes:

- The investigational policy statement now includes the use of a hybrid closed-loop insulin delivery system as an artificial pancreas device system;
- The criteria in one bullet of the medically necessary policy statement has been changed so that the phrase *OR recurrent, unexplained, severe, (generally blood glucose levels less than 50 mg/dl) hypoglycemia for whom hypoglycemia puts the patient or others at risk* has been removed.

#### **Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions**

Changes:

- One bullet in the medically necessary policy statement addressing autologous chondrocyte implantation for the treatment of disabling full-thickness articular cartilage defects of the knee caused by acute or repetitive trauma was clarified;
- The investigational policy statement addressing matrix-induced autologous chondrocyte implantation was removed.

#### **Bariatric Surgery**

Change:

- A new investigational policy statement was added to address bariatric surgery for the treatment of morbid obesity in preadolescent children.

#### **Carrier Testing for Genetic Diseases**

Changes:

- The title was changed to Carrier Screening for Genetic Diseases;
- A not medically necessary policy statement addressing all targeted screening not meeting any of the above criteria was added;
- The position of the not medically necessary policy statement addressing expanded carrier screening panels was changed to investigational.

**Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors**

Changes:

- A new medically necessary policy statement with criteria was added to address cryosurgical ablation to treat lung cancer;
- The investigational policy statement was adjusted to accommodate this change;
- The site of *bone* was added to the investigational policy statement.

**Gene Expression-Based Assays for Cancers of Unknown Primary**

Medicare Advantage changes:

- A medically necessary policy statement addressing molecular testing, using the Rosetta Cancer Origin™ test (prognostic) has been added;
- An investigational policy statement addressing other applications of this technology has been added.

**Genetic Testing for Cardiac Ion Channelopathies**

Medicare Advantage changes:

- A not medically necessary policy statement addressing genetic testing procedures for Cardiac Ion Channelopathies (e.g., Brugada Syndrome, Long QT Syndrome, Short QT Syndrome, Catecholaminergic Polymorphic Ventricular Tachycardia) submitted under specified panels;
- A not medically necessary policy statement addressing individual specified genetic tests.

**Genetic Testing for Warfarin Dose**

Medicare Advantage changes:

- The Medicare Advantage statement has been clarified to identify potential for coverage with evidence development (CED);
- A not medically necessary policy statement has been added for pharmacogenomic testing of CYP2C9 or VKORC1 alleles to predict warfarin responsiveness outside the context of CED.

**Genetic Testing of CADASIL Syndrome**

Changes:

- The medically necessary policy statement now includes *skin biopsy* as one test that could inform pre-test probability of CADASIL;
- A new medically necessary policy statement with criteria was added addressing testing for individuals who are asymptomatic with a family member with a diagnosis of CADASIL syndrome.

**Hematopoietic Stem Cell Transplantation for Hodgkin Lymphoma**

Changes:

- The title has changed to Hematopoietic Cell Transplantation for Hodgkin Lymphoma;
- Reference to myeloablative allogeneic hematopoietic cell transplantation has been removed from an existing medically necessary policy statement;
- The medically necessary policy statement addressing reduced-intensity allogeneic hematopoietic cell transplantation has been removed;
- A medically necessary policy statement addressing allogeneic hematopoietic cell transplantation, using either myeloablative or reduced-intensity conditioning regimens in patients with primary refractory or relapsed Hodgkin lymphoma has been added.

**Implantable Cardioverter Defibrillators**

Change:

- An investigational policy statement addressing the use of the implantable cardioverter defibrillator for secondary prevention for patients who do not meet the criteria for secondary prevention has been added.

**Invasive Prenatal (Fetal) Diagnostic Testing**

Medicare Advantage change:

- A not medically necessary policy statement identifying genetic testing procedures that are unlikely to impact therapeutic decision-making in the clinical management of the patient was added.

**Lipid Apheresis**

Changes:

- The phrase *a six-month trial* was removed, and no longer describes diet therapy in the medically necessary policy statement addressing LDL apheresis;
- An existing policy statement was expanded to include nonfamilial hypercholesterolemia, sudden sensorineural hearing loss, severe diabetic foot ulcerations, peripheral artery disease, and non-arteritic acute anterior ischemic optic neuropathy as uses for which this treatment is considered investigational.

**Molecular Analysis for Targeted Therapy of Non-Small-Cell Lung Cancer**

Changes:

- A medically necessary policy statement addressing the analysis of the BRAF V600E variant to predict treatment response to BRAF or MEK inhibitor therapy (e.g., dabrafenib [Tafinlar®] and trametinib [Mekinist®]) in patients with advanced lung adenocarcinoma or in whom an adenocarcinoma component cannot be excluded has been added;
- The corresponding policy statement has been amended so that analysis for genetic alterations in the BRAF gene for targeted therapy in patients with NSCLC *in all other situations* is investigational.

**Molecular Markers in Fine Needle Aspirates of the Thyroid**

Changes:

- The medically necessary policy statement has been reworked and simplified;
- An investigational policy statement addressing the use of any other gene expression classifier in fine-needle aspirates of the thyroid has been removed;
- An investigational policy statement addressing mutation analysis in fine-needle aspirates of the thyroid has been removed.

**Multimarker Serum Testing Related to Ovarian Cancer**

Change:

- Overa™ (all uses) was added to the investigational policy statement.

**Noninvasive Techniques for the Evaluation and Monitoring of Patients With Chronic Liver Disease**

Medicare Advantage change:

- The medically necessary policy statement has been removed.

**Prostatic Urethral Lift**

Changes:

- A medically necessary policy statement with criteria addressing the use of prostatic urethral lift in individuals with moderate to severe lower urinary tract obstruction due to benign prostatic hyperplasia has been added;
- The investigational policy statement has been reworded to address the use of prostatic urethral lift *in other situations*.

**Spinal Cord Stimulation**

Changes:

- The title has changed to Spinal Cord and Dorsal Root Ganglion Stimulation;
- The descriptor *wireless injectable* no longer applies to the phrase dorsal root ganglion neurostimulation in the investigational policy statement.

**Surgical Ventricular Restoration**

Change:

- The investigational policy statement was changed so that post-infarction left ventricular aneurysm is no longer included as a condition.

**Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease**

Medicare Advantage change:

- A policy statement addressing the conditions under which transoral incisionless fundoplication will not be considered medically necessary has been added.

**Viscocalostomy and Canaloplasty**

Change:

- The policy position on viscocalostomy has been changed from investigational to not medically necessary.

**New Protocol**

The effective date of this new protocol is April 1, 2018:

**Circulating Tumor DNA for Management of Non-Small-Cell Lung Cancer (Liquid Biopsy)**

- There is one medically necessary policy statement with criteria addressing analysis of two types of somatic sensitizing variants within the epidermal growth factor receptor (EGFR) gene—small deletions in exon 19 and a point mutation variant in exon 21 (L858R)—using the cobas<sup>®</sup> EGFR Mutation Test v2 with plasma specimens to detect circulating tumor DNA (ctDNA);
- There is one investigational policy statement addressing analysis of other EGFR sensitizing variants within exons 18 to 24 using ctDNA for applications related to NSCLC;
- There is one investigational policy statement addressing analysis of EGFR T790M resistance variant for targeted therapy with osimertinib using ctDNA or for other applications related to NSCLC;
- There is one investigational policy statement addressing analysis of two types of somatic mutations variants within the EGFR gene—small deletions in exon 19 and a point mutation variant in exon 21 (L858R)—using ctDNA for patients with advanced NSCLC of squamous cell type;
- Preauthorization is not required.

## Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Actigraphy
- Allogeneic Hematopoietic Cell Transplantation for Genetic Diseases and Acquired Anemias (Formerly Allogeneic Hematopoietic Stem Cell Transplantation for Genetic Diseases and Acquired Anemias)
- Aqueous Shunts and Stents for Glaucoma
- Artificial Intervertebral Disc: Cervical Spine
- Artificial Intervertebral Disc: Lumbar Spine
- Autonomic Nervous System Testing
- Axial Lumbosacral Interbody Fusion
- Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis (Formerly Balloon Ostial Dilation for Treatment of Chronic Sinusitis)
- Biofeedback for Miscellaneous Indications
- Cardiovascular Risk Panels
- Chromosomal Microarray Testing for the Evaluation of Pregnancy Loss (Formerly Chromosomal Microarray Analysis for the Evaluation of Pregnancy Loss)
- Closure Devices for Patent Foramen Ovale and Atrial Septal Defects
- Cryosurgical Ablation of Primary or Metastatic Liver Tumors
- Dynamic Posturography
- Electrical Bone Growth Stimulation of the Appendicular Skeleton
- Electrical Stimulation for the Treatment of Arthritis
- Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures
- Electromagnetic Navigation Bronchoscopy
- Endobronchial Ultrasound for Diagnosis and Staging of Lung Cancer
- Endothelial Keratoplasty
- Facet Joint Denervation
- Gastric Electrical Stimulation
- Genetic Testing for Familial Cutaneous Malignant Melanoma
- Genetic Testing for Human Leukocyte Genes (HLA)
- Genetic Testing for Mental Health Conditions
- Heart Transplant
- Heart/Lung Transplant
- Hematopoietic Cell Transplantation for Autoimmune Diseases (Formerly Hematopoietic Stem Cell Transplantation for Autoimmune Diseases)
- Hematopoietic Cell Transplantation for Central Nervous System Embryonal Tumors and Ependymoma (Formerly Hematopoietic Stem Cell Transplantation for Central Nervous System Embryonal Tumors and Ependymoma)
- Hematopoietic Cell Transplantation for Epithelial Ovarian Cancer (Formerly Hematopoietic Stem Cell Transplantation for Epithelial Ovarian Cancer)
- Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults (Formerly Hematopoietic Stem Cell Transplantation for Miscellaneous Solid Tumors in Adults)
- Hip Resurfacing
- Immune Cell Function Assay
- Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease
- Implantation of Intrastromal Corneal Ring Segments

- Interspinous Fixation (Fusion) Devices
- Intra-Articular Hyaluronan Injections for Osteoarthritis
- Low-Level Laser Therapy
- Lysis of Epidural Adhesions
- Magnetoencephalography/Magnetic Source Imaging
- Microwave Tumor Ablation
- Multitarget Polymerase Chain Reaction Testing for Diagnosis of Bacterial Vaginosis
- Occipital Nerve Stimulation
- Orthoptic/Vision Therapy
- Periureteral Bulking Agents as a Treatment of Vesicoureteral Reflux
- Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers
- Quantitative Sensory Testing
- Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors
- Radioimmunoscinigraphy (Monoclonal Antibody Imaging) With Indium 111 Capromab Pendetide for Prostate Cancer
- Reduction Mammoplasty for Breast-Related Symptoms
- Scintimammography and Gamma Imaging of the Breast and Axilla
- Sensory Integration Therapy and Auditory Integration Therapy
- Subtalar Arthroereisis
- Surgical Treatment of Bilateral Gynecomastia
- Transcatheter Aortic Valve Implantation for Aortic Stenosis
- Transcatheter Mitral Valve Repair
- Transcatheter Pulmonary Valve Implantation

**The above are brief summaries.** Please refer to the protocols posted on our provider website, for the details of the updated and new protocols that affect your practice. If you need help finding a specific protocol update, please contact Provider Service.