Protocol

Medical Services Protocol Updates

Distribution Date: **September 1, 2019**

The following medical protocol updates include 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. Two new protocols have been added and one has been archived.

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 October 1, 2019, unless otherwise indicated:

Artificial Pancreas Device Systems

Changes:

- This was a local protocol but has now been changed to a tracked protocol following Blue Cross and Blue Shield Association (BCBSA) policy statements.
- One medically necessary policy statement added the use of FDA-approved automated insulin delivery system with additional criteria listed including age, glycated hemoglobin levels, and documented nocturnal hypoglycemic events.

Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management (Liquid Biopsy)

Change:

- Investigational policy statement slightly expanded to now read: The use of circulating tumor DNA and/or circulating tumor cells is considered investigational for all indications reviewed herein.

Closure Devices for Patent Foramen Ovale and Atrial Septal Defects

Changes:

- One medically necessary policy statement clarified, adding when transcatheter closure of secundum atrial septal defects may be medically necessary.
- One investigational policy statement added that transcatheter closure of secundum atrial septal defects is considered investigational.

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Changes:

- Two not medically necessary policy statements were changed to investigational. Policy statements revised to include new terminology of home sleep apnea test and clarify that devices include a minimum of three sensors. Addition of a Dentist Certified in Sleep Medicine to the list of treating physicians.
- Preauthorization is required.
- The effective date for this protocol is September 1, 2019.

Gene Expression Profiling for Cutaneous Melanoma
Medicare Advantage changes:

- A new medically necessary policy statement was added stating that there is medically necessary criteria for DecisionDx-melanoma testing if certain criteria are met.
- The effective date for this protocol is June 1, 2019.

Gene Expression Testing in the Evaluation of Patients with Stable Ischemic Heart Disease
Medicare Advantage change:

- Previously referenced local coverage determination (LCD) has been revised to rescind coverage. Since initial coverage, the manufacturer has failed to demonstrate that testing resulted in improved patient outcomes or that testing changed physician management to result in improved patient outcomes. Medicare Advantage section removed altogether.

Genetic Testing for Hereditary Breast, Ovarian Cancer Syndrome and Other High-Risk Cancers (Formally: Genetic Testing for Hereditary Breast and Ovarian Cancer Syndrome)
Change:

- Medically necessary policy statements and investigational policy statement reformatted to classify criteria by an individual's history; patients with cancer or with a personal history of cancer, patients without cancer or without history of cancer.

Laboratory Tests for Heart and Kidney Transplant Rejection
Medicare Advantage change:

- One medically necessary policy statement added that addresses the AlloSure assay test.

Molecular Testing for the Management of Pancreatic Cysts, Barrett Esophagus and Solid Pancreaticobiliary Lesions (Formerly: Molecular Testing for the Management of Pancreatic Cysts or Barrett Esophagus)
Change:

- The investigational policy statement now includes solid pancreaticobiliary lesions.

Spinal Cord and Dorsal Root Ganglion Stimulation
Change:

- The previous investigational policy statement regarding Dorsal root ganglion neurostimulation was changed to medically necessary.

Steroid-Eluting Sinus Stents (Formerly: Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease)
Change:

- A new investigational policy statement added stating that the use of drug-eluting sinus stents is considered investigational on all other conditions.

Treatment of Varicose Veins/Venous Insufficiency
Changes:

- One medically necessary policy statement was added for concurrent treatment of the accessory saphenous veins along with the great or small saphenous veins.
- The product cyanoacrylate adhesive was added to the medically necessary and the not medically necessary policy statements.

New Protocols

The effective date of these new protocols is October 1, 2019, unless otherwise indicated:

Fecal Calprotectin Testing

- The policy position is medically necessary and investigational.
- One medically necessary policy statement that states that fecal calprotectin may be considered medically necessary for the evaluation of patients when the differential dx IBS or non-inflammatory bowel disease (including IBS) for whom endoscopy with biopsy is being considered. One investigational policy statement that states that fecal calprotectin testing is considered investigational in the management of IBS, including the management of active IBS and surveillance for relapse of disease in remission.
- Preauthorization is not required.

Polysomnography for Non-respiratory Sleep Disorders

- The policy position is medically necessary and investigational.
- Three medically necessary policy statements that address criteria for when a PSG would be medically necessary for certain disorders. One not medically necessary policy statement states: PSG for the diagnosis of periodic limb movement disorder is considered not medically necessary when there is concurrent untreated obstructive sleep apnea, restless legs syndrome, narcolepsy, or rapid eye movement sleep behavior disorder. One investigational policy statement states: PSG is considered investigational for the diagnosis of non-respiratory sleep disorders not meeting the criteria above, including but not limited to nightmare disorder, depression, sleep-related bruxism, or non-injurious disorders of arousal.
- Preauthorization is required.
- The effective date for this protocol is September 1, 2019

Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions
- Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions
- Automated Percutaneous and Percutaneous Endoscopic Discectomy
- Bronchial Thermoplasty
- Catheter Ablation as Treatment for Atrial Fibrillation
- Cochlear Implant
- Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy
- Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)
- Enhanced External Counterpulsation
- Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions
- Fecal Analysis in the Diagnosis of Intestinal Dysbiosis
- Fecal Microbiota Transplantation
- Genetic Testing for Lactase Insufficiency
- Genetic Testing for Li-Fraumeni Syndrome
- Genetic Testing for Lipoprotein(a) Variant(s) as a Decision Aid for Aspirin Treatment
- Genetic Testing for Mitochondrial Disorders
- Genotype-Guided Tamoxifen Treatment
- Hematopoietic Cell Transplantation for Acute Lymphoblastic Leukemia

- Hematopoietic Cell Transplantation for Primary Amyloidosis
- Hematopoietic Cell Transplantation for Waldenström Macroglobulinemia
- Hippotherapy
- Homocysteine Testing in the Screening, Diagnosis, and Management of Cardiovascular Disease and Venous Thromboembolic Disease
- Image-Guided Minimally Invasive Decompression for Spinal Stenosis
- Ingestible pH and Pressure Capsule
- Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
- Keratoprosthesis
- KIF6 Genotyping for Predicting Cardiovascular Risk and/or Effectiveness of Statin Therapy
- Miscellaneous Genetic and Molecular Diagnostic Tests
- Multigene Expression Assay for Predicting Recurrence in Colon Cancer
- Myoelectric Prosthetic and Orthotic Components for the Upper Limb
- Orthopedic Applications of Platelet-Rich Plasma
- Orthopedic Applications of Stem Cell Therapy (Including Allografts and Bone Substitutes Used With Autologous Bone Marrow)
- Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions
- Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome
- Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation
- Percutaneous Tibial Nerve Stimulation
- Percutaneous Vertebroplasty and Sacroplasty
- Progenitor Cell Therapy for the Treatment of Damaged Myocardium due to Ischemia
- Radioembolization for Primary and Metastatic Tumors of the Liver
- Stem Cell Therapy for Peripheral Arterial Disease
- Surgical Treatment of Femoroacetabular Impingement
- Tumor Treating Fields Therapy
- Whole Gland Cryoablation of Prostate Cancer

Deleted Protocols

Effective immediately, the following protocols are archived:

- Computer-Aided Evaluation of Malignancy With Magnetic Resonance Imaging of the Breast
- Radioimmunoscintigraphy (Monoclonal Antibody Imaging) With Indium 111 Capromab Pendetide for Prostate Cancer

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.