Protocol

Medical Services Protocol Updates

Distribution Date: **September 1, 2018**

The following Medical Protocol updates 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 One new protocol has been added and two have been archived.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, 2018, unless otherwise indicated:

Aqueous Shunts and Stents for Glaucoma

Changes:

- One investigational policy statement was added to address insertion of ab interno aqueous stents approved by the Food and Drug Administration (FDA) as a method to reduce intraocular pressure in patients with glaucoma where medical therapy has failed to adequately control intraocular pressure;
- Existing medically necessary and investigational policy statements were modified to clarify indications for ab externo aqueous shunts and ab interno aqueous stents.

Medicare Advantage changes:

- One medically necessary policy statement was redundant to the general business policy statements and was removed;
- One new medically necessary policy statement was added to address the XEN® 45 device for the management of refractory glaucoma (as defined in the protocol).

Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

Changes:

- Two new indications have been added to the medically necessary policy statements which address fresh osteochondral allografting and osteochondral autografting as repair techniques;
- Particulated cartilage was added as an investigational treatment for focal articular cartilage lesions.

Automated Percutaneous and Percutaneous Endoscopic Discectomy

Medicare Advantage change:

- A statement was added to recognize additional potential for coverage through a prospective, longitudinal study of Percutaneous Image-guided Lumbar Decompression (PILD) procedures using an FDA-approved/cleared device that completed an approved Centers for Medicare and Medicaid Services (CMS) randomized control trial that met CMS criteria.

Closure Devices for Patent Foramen Ovale and Atrial Septal Defects

Changes:

- The investigational policy statement addressing closure of patent foramen ovale (PFO) using a transcatheter approach has been removed;

- A medically necessary policy statement with criteria has been added addressing the percutaneous transcatheter closure of a patent foramen ovale using the AMPLATZER™ PFO Occluder to reduce the risk of recurrent ischemic stroke.

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome
Change:

- One new investigational policy statement was added addressing palate and mandible expansion devices for the treatment of obstructive sleep apnea (OSA).

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)
Change:

- One criterion in the medically necessary policy statement addressing the use of endovascular mechanical embolectomy using a device with FDA approval for the treatment of acute ischemic stroke was adjusted to include receiving endovascular mechanical embolectomy within 12 hours of symptom onset *OR within 24 hours of symptom onset if there is evidence of a mismatch between specific clinical and imaging criteria*.

Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies
Medicare Advantage change:

- A medically necessary policy statement with criteria has been added addressing Next Generation Sequencing (NGS) as a diagnostic laboratory test.

Genetic Testing for Hereditary Breast and Ovarian Cancer Syndrome
Changes:

- Changes were effective 08/01/18;
- Additional criteria were added under genetic testing for BRCA 1 and BRCA 2 variants;
- Additional criteria were added under genetic testing for PALB2 variants;
- Medically necessary criteria was added addressing genetic testing for PALB2, PTEN, STK11, and CDH1 variants.

Genetic Testing for Li-Fraumeni Syndrome
Change:

- One criterion in the medically necessary policy statement addressing genetic testing for TP53 mutations to confirm a diagnosis of Li-Fraumeni Syndrome has been updated to conform to National Comprehensive Cancer Network (NCCN) guidelines.

Hematopoietic Stem Cell Transplantation for Solid Tumors of Childhood
Changes:

- Title has been changed to Hematopoietic Cell Transplantation for Solid Tumors of Childhood;
- Metastatic retinoblastoma was added as an indication for which autologous hematopoietic cell transplantation may be considered medically necessary;
- In concert with the above change, an existing policy statement was amended so that autologous hematopoietic cell transplantation is considered investigational as initial treatment of retinoblastoma without metastasis.

Image-Guided Minimally Invasive Decompression for Spinal Stenosis
Medicare Advantage Change:

- Information has been added to address potential for coverage through a prospective, longitudinal study of PILD procedures using an FDA-approved/cleared device, that completed a CMS-approved randomized control trial (RCT), that met the criteria listed for an approved clinical study.

Miscellaneous Genetic and Molecular Diagnostic Tests
Change:

- The genetic testing categories in the policy statement were revised; there is no change to the policy position of investigational for tests addressed in this protocol.

Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation
Changes:

- The title has been changed to Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation;
- An investigational policy statement addressing radiofrequency kyphoplasty has been added;
- Existing policy statements have been reworded for clarification.

Percutaneous Tibial Nerve Stimulation
Changes:

- A medically necessary policy statement has been added addressing percutaneous tibial nerve stimulation for an initial 12-week course for individuals with non-neurogenic urinary dysfunction, including overactive bladder, who meet criteria;
- The investigational policy statement has been adjusted to accommodate the new medically necessary indications.

Photodynamic Therapy for Choroidal Neovascularization
Medicare Advantage Changes:

- The medically necessary policy statement for the use of verteporfin for age-related macular degeneration (AMD), histoplasmosis (ocular, presumed) and myopia (pathologic) was removed;
- The medically necessary policy statement for the use of verteporfin for central serous chorioretinopathy was removed;
- Two conditions were added to an existing policy statement as investigational indications for ocular photodynamic therapy with verteporfin: a diagnosis of AMD with occult and no classic choroidal neovascularization (CNV) lesions, and minimally classic CNV lesions.

Stem Cell Therapy for Peripheral Arterial Disease
Change:

- The investigational policy statement has been expanded to include additional possible sources of stem cells.

Treatment of Tinnitus
Changes:

- The medically necessary policy statement was expanded to include examples of psychological coping therapy including cognitive-behavioral therapy, self-help cognitive-behavioral therapy, tinnitus coping therapy, acceptance and commitment therapy, and psychophysiological treatment;
- Biofeedback was added as a type of therapy which is considered investigational.

Tumor Treatment Fields Therapy for Glioblastoma

Changes:

- The title was changed to Tumor Treating Fields Therapy;
- A medically necessary policy statement with criteria was added addressing tumor treating fields therapy to treat glioblastoma multiforme as an adjunct to standard maintenance therapy with temozolomide in patients with newly diagnosed glioblastoma multiforme following initial treatment with surgery, radiotherapy, and/or chemotherapy;
- An existing policy statement was expanded by adding conditions for which tumor treating fields therapy is considered investigational.

New Protocol

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

Gene Expression Profiling for Cutaneous Melanoma

- Three investigational policy statements address gene expression testing in the evaluation of patients with suspicious pigmented lesions, in patients with melanocytic lesions with indeterminate histopathologic features and in patients with cutaneous melanoma;
- This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions
- Biofeedback as a Treatment of Headache
- Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure
- Bronchial Thermoplasty
- Cognitive Rehabilitation
- Computer-Aided Evaluation of Malignancy With Magnetic Resonance Imaging of the Breast
- Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid
- Cooling Devices Used in the Outpatient Setting
- Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy
- Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions
- Extracranial Carotid Artery Stenting
- Fecal Analysis in the Diagnosis of Intestinal Dysbiosis
- Fecal Microbiota Transplantation
- Genetic Testing for Duchenne and Becker Muscular Dystrophy
- Genetic Testing for Lactase Insufficiency
- Genetic Testing for Lipoprotein(a) Variant(s) as a Decision Aid for Aspirin Treatment
- Genetic Testing for Mitochondrial Disorders
- Genetic Testing for PTEN Hamartoma Tumor Syndrome
- Genotype-Guided Tamoxifen Treatment (Formerly Genetic Testing for Tamoxifen Treatment)
- Hematopoietic Cell Transplantation for Acute Lymphoblastic Leukemia
- Hematopoietic Cell Transplantation for Primary Amyloidosis
- Hematopoietic Cell Transplantation in the Treatment of Germ Cell Tumors
- Hippotherapy

- Homocysteine Testing in the Screening, Diagnosis, and Management of Cardiovascular Disease and Venous Thromboembolic Disease
- Ingestible pH and Pressure Capsule
- Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
- Intraoperative Neurophysiologic Monitoring
- Keratoprosthesis
- Laboratory Testing for HIV Tropism
- Laboratory Tests for Heart Transplant Rejection
- Magnetic Resonance-Guided Focused Ultrasound
- Microprocessor-Controlled Prostheses for the Lower Limb
- Molecular Testing for the Management of Pancreatic Cysts or Barrett Esophagus (Formerly PathFinderTG® Molecular Testing)
- Multigene Expression Assay for Predicting Recurrence in Colon Cancer
- Oncologic Applications of Photodynamic Therapy, Including Barrett Esophagus
- Orthognathic Surgery
- Orthopedic Applications of Stem Cell Therapy (Including Allografts and Bone Substitutes Used With Autologous Bone Marrow)
- Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome
- Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
- Percutaneous Vertebroplasty and Sacroplasty
- Progenitor Cell Therapy for the Treatment of Damaged Myocardium due to Ischemia
- Protein and Genetic Testing for Prostate Cancer
- Radioembolization for Primary and Metastatic Tumors of the Liver
- Surgical Treatment of Femoroacetabular Impingement
- Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome
- Temporomandibular Joint Dysfunction
- Thermography
- Vestibular Function Testing
- Whole Gland Cryoablation of Prostate Cancer

Deleted Protocols

Effective immediately, the following protocols are archived:

- Drug Testing in Pain Management and Substance Abuse Treatment
- Prophylactic Mastectomy

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 our Provider Service department.