Protocol

Medical Services Protocol Updates

Distribution Date: **September 1, 2016**

The following Medical Protocol update includes information on protocols that have undergone a review over the last several months for annual review, 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 One new protocol has been added and four have been archived.

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

Protocol Revision Summary

The effective date of these changes is October 1, 2016:

Automated Percutaneous and Endoscopic Discectomy

Medicare Advantage change:

- Percutaneous image-guided lumbar decompression (PILD) may have potential for coverage when provided through Coverage with Evidence Development (CED) for members with lumbar spinal stenosis who meet the criteria of, and are enrolled in, an approved clinical study.

Bio-Engineered Skin and Soft Tissue Substitutes

Changes:

- Integra® Dermal Regeneration Template and Amniotic Membrane Graft (including each of the following: Biovance®, Epifix®, Grafix™) were added to the medically necessary treatments for chronic, noninfected, full-thickness diabetic lower extremity ulcers;
- TransCyte™ was deleted as a medically necessary treatment of second- and third-degree burns;
- The list of skin and soft tissue substitutes considered investigational was edited with five deletions and one addition.

Medicare Advantage changes:

- Three additional products (Grafix®, Integra®Omnigraft Dermal Regeneration Matrix and *HYALOMATRIX®)* with associated criteria were added;
- Not medically necessary indications were added for Theraskin®;
- An edit was made to the criteria for Integra®Dermal Regeneration Template.

Catheter Ablation as Treatment for Atrial Fibrillation

Changes:

- The medically necessary policy statement addressing transcatheter radiofrequency ablation or cryoablation to treat atrial fibrillation was clarified by adding the descriptor *recurrent (more than one episode, with four or fewer episodes in the previous six months)*;
- Cryoablation was added as a treatment in the investigational policy statement.

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Changes:

- The list of conditions, associated with the medically necessary policy statement addressing a single unattended home study when adult patients have no evidence by history or physical examination of a

health condition that might alter ventilation or require alternative treatment, was changed;
- The content addressing periodic limb movements in sleep and restless limb syndrome has been removed throughout the protocol.

Gene Expression Testing to Predict Coronary Artery Disease (CAD)
Medicare Advantage change:
- The lists of typical symptoms, atypical symptoms, and common CAD risk factors used to determine medical necessity were edited with additions and deletions.

Keratoprosthesis
Change:
- The medically necessary policy statement has been clarified.

KRAS, NRAS, and BRAF Mutation Analysis in Metastatic Colorectal Cancer
Change:
- The policy positon for NRAS mutation analysis was changed from investigational to medically necessary.

Medicare Advantage change:
- A Medicare Advantage section was added — including a policy statement with medically necessary criteria.

Molecular Analysis for Targeted Therapy of Non-Small-Cell Lung Cancer
Medicare Advantage change:
- A Medicare Advantage section was added — including a policy statement with medically necessary criteria.

Molecular Markers in Fine Needle Aspirates of the Thyroid
Medicare Advantage change:
- A medically necessary policy statement was added addressing the Affirma® test.

Multigene Expression Assay for Predicting Recurrence in Colon Cancer
Change:
- The investigational policy statement subject was changed from stage II colon cancer to stage 2 or stage 3 colon cancer.

Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders
Changes:
- The title changed to *Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions;*
- *Respiratory conditions associated with neuromuscular disorders* was added as a lung disease for which high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices are considered investigational.

PathFinderTG® Molecular Testing
Medicare Advantage change:
- The Medicare Advantage section was changed to include a policy statement with medically necessary criteria. Information regarding clinical trials was eliminated.

Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation
Medicare Advantage change:

- The medically necessary policy statement was broadened by adding osteopenic compression fractures as an indication and by removing the descriptor 'debilitating' from the indication of persisting or progressive pain.

Percutaneous Vertebroplasty and Sacroplasty
Medicare Advantage change:

- The medically necessary policy statement was broadened by adding osteopenic compression fractures as an indication.

Prophylactic Mastectomy
Change:

- The medically necessary policy statement addressing lobular carcinoma in situ was removed because information added to the policy guideline section made this statement redundant.

Urine Drug Testing in Pain Management and Substance Abuse Treatment
Changes:

- The title changed to *Drug Testing in Pain Management and Substance Abuse Treatment;*
- A policy statement was added to address hair drug testing and oral fluid drug testing as investigational.

Medicare Advantage change:

- A new Medicare Advantage section replaced previous guidance, including medically necessary and not medically necessary policy statements.

New Protocol

The effective date of this new protocol is October 1, 2016:

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

- There is one investigational policy statement addressing the use of circulating tumor DNA and circulating tumor cells for all indications;
- There is no Medicare Advantage section;
- 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:

- Artificial Intervertebral Disc: Cervical Spine
- Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions
- Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions (Formerly Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Non-Orthopedic Conditions)
- Bronchial Thermoplasty
- Cochlear Implant
- Computer-Aided Evaluation of Malignancy With Magnetic Resonance Imaging of the Breast
- Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy
- Enhanced External Counterpulsation

- Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies (Formerly Molecular Panel Testing of Cancers to Identify Targeted Therapies)
- 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
- Genetic Testing for Tamoxifen Treatment
- Hematopoietic Cell Transplantation for Acute Lymphoblastic Leukemia (Formerly Hematopoietic Stem Cell Transplantation for Acute Lymphoblastic Leukemia)
- Hematopoietic Stem Cell Transplantation for Primary Amyloidosis
- Hematopoietic Stem Cell Transplantation for Waldenström Macroglobulinemia
- Hippotherapy
- Homocysteine Testing in the Screening, Diagnosis, and Management of Cardiovascular Disease
- Human Leukocyte Antigen Testing for Celiac Disease
- Image-Guided Minimally Invasive Lumbar Decompression for Spinal Stenosis
- Ingestible pH and Pressure Capsule
- Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
- KIF6 Genotyping for Predicting Cardiovascular Risk and/or Effectiveness of Statin Therapy
- Myoelectric Prosthetic 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) (Formerly Orthopedic Applications of Stem Cell Therapy [Including Allograft and Bone Substitute Products Used With Autologous Bone Marrow])
- Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome
- Percutaneous Tibial Nerve Stimulation
- 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
- Whole Gland Cryoablation of Prostate Cancer

Deleted Protocols

Effective immediately (unless otherwise noted) the following protocols are archived:

- Detection of Circulating Tumor Cells in the Management of Patients With Cancer (effective October 1, 2016)
- Genotyping for 9p21 Single Nucleotide Polymorphisms to Predict Risk of Cardiovascular Disease or Aneurysm
- Real-Time Intrafraction Motion Management During Radiotherapy
- Serum Biomarker Tests for Multiple Sclerosis

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.