Protocol

Medical Services Protocol Updates

Distribution Date: **September 1, 2015**

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. Five new protocols have been added and no protocols have been archived.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, 2015, unless otherwise indicated:

Artificial Intervertebral Disc: Cervical Spine

Changes:

- Medically necessary criteria have been added to this protocol;
- The investigational statement has been expanded to include a sample listing of indications which are investigational.

Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

Change:

- One medically necessary policy statement regarding osteochondral allografting to repair full-thickness chondral defects of the knee caused by acute or repetitive trauma was clarified by adding, "*when other cartilage repair techniques (e.g., microfracture, osteochondral autografting, or autologous chondrocyte implantation) would be inadequate due to the size, location, or depth of the lesion.*"

Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions

Changes:

- Title changed to *Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Non-Orthopedic Conditions*;
- The single investigational statement for autologous blood-derived preparations was adjusted and now addresses wound care only;
- Orthopedic applications are now addressed in the *Orthopedic Applications of Platelet Rich Plasma Protocol* (see New Protocols section).

Bio-Engineered Skin and Soft Tissue Substitutes

Medicare Advantage change:

- The medically necessary uses of EpiFix® were expanded to include venous stasis ulcers (previously diabetic ulcers only).

Catheter Ablation as Treatment for Atrial Fibrillation

Changes:

- The existing medically necessary and investigational policy statements were adjusted so that cryoablation is included as a medically necessary treatment for atrial fibrillation;

- One additional medically necessary statement was added for transcatheter radiofrequency ablation or cryoablation to use atrial fibrillation as an initial treatment for patients with symptomatic paroxysmal atrial fibrillation when a rhythm-control strategy is desired.

Cryoablation of Prostate Cancer
Changes:

- Title changed to *Whole Gland Cryoablation of Prostate Cancer*;
- Language was clarified to refer to "whole gland" cryoablation as distinct from subtotal or focal cryoablation, including a change in the medically necessary policy statement.

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome
Change:

- Policy guidelines were clarified to indicate a physician must order sleep studies and refer as needed to a dentist for treatment with an oral appliance.

Genetic Testing of Mitochondrial Disorders
Changes:

- Title changed to *Genetic Testing for Mitochondrial Disorders*;
- Medically necessary and not medically necessary policy statements were reworded to be consistent with standard genetic language;
- Criteria added to ensure testing is restricted to the specific mutations that are documented to be pathogenic to the mitochondrial disorder being considered.

Keratoprosthesis
Change:

- The one policy statement addressing Boston keratoprosthesis was expanded with additional conditions for which this procedure is considered medically necessary.

Noninvasive Prenatal Testing for Fetal Aneuploidies Using Cell-Free Fetal DNA
Changes:

- Title change to *Noninvasive Prenatal Screening for Fetal Aneuploidies Using Cell-Free Fetal DNA*;
- The policy statement regarding nucleic acid sequencing-based testing of maternal plasma for trisomy 21 was changed by removing the requirement that the pregnancy be high risk to qualify as medically necessary;
- The not medically necessary policy statement applying to average risk singleton pregnancies was removed.

Orthopedic Applications of Stem-Cell Therapy
Changes:

- Title change to *Orthopedic Applications of Stem Cell Therapy (Including Allograft and Bone Substitute Products Used With Autologous Bone Marrow)*;
- Addition of one investigational policy statement, for all orthopedic applications, addressing the use of allograft or synthetic bone graft substitutes that must be combined with autologous blood or bone marrow.

Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation
Change:

- All medically necessary and investigational policy statements were changed to include Kiva® as a medically necessary treatment when consistent with the stated criteria.

Medicare Advantage change:

- Definition of "recent" compression fracture added to clarify medically necessary policy statement.

Posterior Tibial Nerve Stimulation for Voiding Dysfunction
Changes:

- Title change to *Percutaneous Tibial Nerve Stimulation*;
- The single policy statement was reworded and a second investigational indication of fecal incontinence has been added.

Prophylactic Mastectomy
Changes:

- A bullet was added to the policy guidelines with examples of additional specific gene mutations that are recognized as conferring increased risk;
- Policy guidelines were clarified with information that contralateral prophylactic mastectomy is discouraged but may be considered when all pertinent variables are assessed;
- Contralateral prophylactic mastectomy in women with breast cancer who do not meet high risk criteria was removed from the investigational policy statement.

Radioembolization for Primary and Metastatic Tumors of the Liver
Changes:

- One medically necessary statement which previously referenced only the treatment of unresectable hepatic metastases, now includes metastasis from melanoma (ocular or cutaneous), or breast cancer that are refractory to systemic therapies;
- The investigational statement addressing treatment of primary intrahepatic cholangiocarcinoma was removed in favor of a medically necessary policy statement in the case of unresectable tumors.

New Protocols

The effective date of these new protocols is October 1, 2015, unless otherwise indicated.

Molecular Markers in Fine Needle Aspirates of the Thyroid

- Policy statements indicate mutation analysis in fine-needle aspirates of the thyroid is considered to be investigational;
- The use of a gene expression classifier in fine-needle aspirates of the thyroid that are cytologically considered to be indeterminate, atypical, or suspicious for malignancy are considered to be investigational;
- *Preauthorization is not required but is recommended if, despite this protocol position, the physician feels this service is medically necessary.*

Molecular Panel Testing of Cancers to Identify Targeted Therapies

- The use of expanded cancer mutation panels for selecting targeting cancer treatment is considered investigational;
- *Preauthorization is not required but is recommended if, despite this protocol position, the physician feels this service is medically necessary.*

Orthopedic Applications of Platelet-Rich Plasma

- The use of platelet rich plasma is investigational for all orthopedic applications;
- *Preauthorization is not required but is recommended if, despite this protocol position, the physician feels this service is medically necessary.*

Real-Time Intra-Fraction Motion Management During Radiation Therapy

- **The current effective date of October 1, 2014 is unchanged;**
- Title change to *Real-Time Intrafraction Motion Management During Radiotherapy*;
- Real-time intrafraction target tracking during radiotherapy to adjust radiation doses or monitor target movement during individual radiotherapy treatment sessions is considered investigational;
- Respiratory gating techniques for the delivery of radiotherapy are considered investigational.

Urine Drug Testing in Pain Management and Substance Abuse Treatment

- This protocol has medically necessary policy statements regarding point of care qualitative urine drug testing for both outpatient pain management and outpatient substance abuse treatment;
- There is one medically necessary statement for quantitative drug testing;
- There is one not medically necessary statement for situations which do not meet stated criteria;
- *Preauthorization is not required.*

Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions
- Automated Percutaneous and Endoscopic Discectomy
- 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
- Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions
- Fecal Analysis in the Diagnosis of Intestinal Dysbiosis
- Fecal Microbiota Transplantation
- Gene Expression Testing to Predict Coronary Artery Disease
- 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 Tamoxifen Treatment
- Genotyping for 9p21 Single Nucleotide Polymorphisms to Predict Risk of Cardiovascular Disease or Aneurysm
- Hematopoietic Stem Cell Transplantation for Acute Lymphoblastic Leukemia
- Hematopoietic Stem Cell Transplantation for Primary Amyloidosis
- Hematopoietic Stem Cell Transplantation for Waldenström Macroglobulinemia
- Hip Resurfacing
- 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
- Low-Level Laser Therapy
- Multigene Expression Assay for Predicting Recurrence in Colon Cancer
- Myoelectric Prosthetic Components for the Upper Limb
- Occipital Nerve Stimulation
- Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome
- PathFinderTG® Molecular Testing
- Percutaneous Vertebroplasty and Sacroplasty
- Periureteral Bulking Agents as a Treatment of Vesicoureteral Reflux
- Placental and Umbilical Cord Blood as a Source of Stem Cells
- Plugs for Fistula Repair
- Progenitor Cell Therapy for the Treatment of Damaged Myocardium due to Ischemia
- Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors
- Serum Biomarker Tests for Multiple Sclerosis
- Stem Cell Therapy for Peripheral Arterial Disease
- Surgical Treatment of Femoroacetabular Impingement
- Systems Pathology in Prostate Cancer
- 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.