Protocol

Medical Services Protocol Updates

Distribution Date: **September 1, 2012**

The following Medical Protocol update includes information on Protocols that have recently undergone an annual review. The review may have resulted in a revision to the guidelines or no changes at all. Five new Protocols have 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 October 1, 2012 unless otherwise indicated:

Allogeneic Pancreas Transplant

Changes:

- Absolute and relative contraindications were combined and placed in the Policy Guidelines Section
- How these contraindications are applied are subject to the judgment of the transplant center
- A note on the proportion of pancreas transplant recipients with type 2 diabetes was added to Policy Guidelines.

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

A reference to a Drug Therapy Guideline has been removed.

Automated Ambulatory Blood Pressure Monitoring for the Diagnosis of Hypertension in Patients with Elevated Office Blood Pressure

Our policy statement has been re-written resulting in minimal changes:

"Automated ambulatory blood pressure monitoring over a 24-hour period may be considered **medically necessary** for patients with elevated office BP, when performed one time to differentiate between 'white coat hypertension' and true hypertension, and when the following conditions are met:

- Office blood pressure elevation is in the mild to moderate range (< 180/110), not requiring immediate treatment with medications;
- There is an absence of hypertensive end-organ damage on physical examination and laboratory testing.

All other uses of ambulatory blood pressure monitoring for patients with elevated office BP, including but not limited to repeat testing in patients with persistently elevated office BP, is considered **investigational**."

The existent criteria statement which followed Medicare, even though it was very similar, has been relocated in the Protocol as a Medicare Advantage policy statement.

Biofeedback as a Treatment of Fecal Incontinence or Constipation

For Medicare Advantage, a change was made from allowing two to three sessions to five to six sessions of biofeedback.

Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure

Cardiac Resynchronization Therapy added to the title.

Deep Brain Stimulation
Added a separate Medicare Advantage policy statement, similar in content to the existing general business policy statement, but also including wording about the potential for category B Investigational Device Exemption (IDE) DBS clinical trials related to deep brain stimulation.

Digital Breast Tomosynthesis
Preauthorization is required by the ordering physician, if despite our position that this service is investigational, the service is felt necessary; the supporting medical documentation must be sent to Use Management. Our Protocol Technology Assessment explains all the criteria that must be met for a service not to be considered investigational.

Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus
Policy statement updated to include radiofrequency ablation for treatment of Barrett's esophagus with low-grade dysplasia is medically necessary when the initial diagnosis of low-grade dysplasia is confirmed by *two* pathologists expert in GI pathology.

Endovascular Procedures (Angioplasty and/or Stenting) for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)
Added IDE trial information to the Medicare Advantage criteria section.

Extracranial Carotid Angioplasty/Stenting (Formerly Carotid Percutaneous Transluminal Angioplasty [PTA] with Stenting)
Changes:

- Policy statement has been re-worded but generally the medically necessary criteria are not changed.
- Carotid dissection is indicated as investigational.
- Added a separate Medicare Advantage section with medically necessary criteria, including IDE trial information.

Facet Joint Denervation
Changes:

- Statement on radiofrequency denervation clarified
- Laser denervation, cryodenervation, and therapeutic blocks added as investigational
- "Radiofrequency" removed from title.

Genotyping for 9p21 Single Nucleotide Polymorphisms to Predict Risk of Cardiovascular Disease or Aneurysm
Change made to the title to include aneurysm as well as to include in the investigational policy statement these indications: Identification of patients at risk for aneurysmal disease and additional cardiovascular disease examples (peripheral vascular disease, coronary artery calcification; polypoidal choroidal vasculopathy).

Hematopoietic Stem-Cell Transplantation for Primary Amyloidosis
Added "age 64 and older" to the Medicare Advantage not medically necessary policy statement regarding primary AL amyloidosis.

Hematopoietic Stem-Cell Transplantation for Solid Tumors of Childhood
Policy statement modified to state specifically that tandem autologous HSCT for high-risk neuroblastoma is considered medically necessary, but tandem autologous HSCT remains investigational for all other indications; effective June 1, 2012.

Homocysteine Testing in the Screening, Diagnosis, and Management of Cardiovascular Disease
The Medicare Advantage medically necessary policy statement was removed; Medicare Advantage will follow general business policy statement which says this service is investigational.

Ingestible pH and Pressure Capsule
The investigational policy statement was amended to include measurement of whole gut transit time and evaluation of gut motility disorders other than gastroparesis.

In Vitro Chemoresistance and Chemosensitivity Assays
Added a medically necessary policy statement in the Medicare Advantage criteria for the ChemoFX® test; all other assays will continue to be considered investigational.

Lung and Lobar Lung Transplant
The absolute and relative contraindications were combined and placed in the Policy Guidelines Section; added that application of these contraindications are subject to the judgment of the transplant center.

Optical Coherence Tomography (OCT) of the Anterior Eye Segment
The title was changed from Anterior Eye Segment Optical Imaging.

PathFinderTG® Molecular Testing
The Medicare Advantage policy statement was updated to specifically indicate the test as only medically necessary for pancreatic cyst/mass where fluid chemistries and/or cytology evaluations were inconclusive.

Plasma Exchange
Changes:

- One of the investigational examples, lupus, was revised to clarify that it includes SLE nephritis Myeloma with acute renal failure and catastrophic antiphospholipid syndrome were changed from investigational to medically necessary
- Dense deposit disease with Factor H deficiency and/or elevated C3 nephritis factor and focal segmental glomerulosclerosis after renal transplant were added as medically necessary
- The investigational statement on focal segmental glomerulosclerosis was modified to indicate that it applies to situations other than after renal transplant
- Hyperviscosity syndromes with renal failure (other than associated with multiple myeloma or Waldenström's macroglobulinemia) were added as investigational
- Serum creatinine threshold was removed from the policy statement on ANCA-associated vasculitis
- *Preauthorization will now be required.*

Posterior Tibial Nerve Stimulation for Voiding Dysfunction
Neurogenic bladder was added to the list of investigational indications.

Prophylactic Mastectomy
The term "p53" was updated to the more current "TP53" terminology in the Policy Guidelines.

Radioembolization for Primary and Metastatic Tumors of the Liver
The separate Medicare Advantage policy statement has been removed, and the general business medically necessary and investigational policy statements will be applicable to Medicare Advantage.

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors
Effective January 1, 2012 (this change was made retro active to the first of the year due to the positive nature of the change), added primary and metastatic pulmonary tumors as medically necessary indications for this treatment.

Transcatheter Arterial Chemoembolization (TACE) to Treat Primary or Metastatic Liver Malignancies
A policy statement added: TACE for unresectable cholangiocarcinoma is considered investigational.

Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence
The separate Medicare Advantage policy statement has been removed, and the general business investigational policy statement will apply for Medicare Advantage for both transvaginal and transurethral radiofrequency tissue remodeling.

New Protocols

The effective date of these new Protocols is October 1, 2012:

- Genetic Testing for Tamoxifen Treatment: *Preauthorization is recommended if the physician feels this is medically necessary despite that our policy statement indicates it is investigational*.
- Hip Resurfacing
- Intensity Modulated Radiation Therapy (IMRT): *Central Nervous System Tumors: Preauthorization is not required but is recommended if the indication it would be used for does not meet our medical necessity criteria.*
- Transcatheter Closure of Patent Ductus Arteriosus
- Transcatheter Pulmonary Valve Implantation

Clinical Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Allogeneic Stem-Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms
- Arthroscopic Debridement and Lavage as Treatment for Osteoarthritis of the Knee
- Auditory Brainstem Implant
- Biofeedback as a Treatment of Chronic Pain
- Biofeedback as a Treatment of Headache
- Chelation Therapy
- Cognitive Rehabilitation
- Cytochrome p450 Genotyping
- Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer
- Genetic Testing for Lipoprotein(a) Variant(s) as a Decision Aid for Aspirin Treatment
- Hematopoietic Stem-Cell Transplantation for Multiple Myeloma
- Hematopoietic Stem-Cell Transplantation in the Treatment of Germ-Cell Tumors
- Hippotherapy
- Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis
- Interspinous Distraction Devices (Spacers)
- Low-Level Laser Therapy
- Multigene Expression Assay for Predicting Recurrence in Colon Cancer

- Occipital Nerve Stimulation
- Oncologic Applications of Photodynamic Therapy, Including Barrett's Esophagus
- Orthopedic Applications of Stem-Cell Therapy
- Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome
- Pelvic Floor Stimulation as a Treatment of Urinary Incontinence
- Percutaneous Vertebroplasty, Sacroplasty and Kyphoplasty
- Placental/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
- Scintimammography/Breast-Specific Gamma Imaging/Molecular Breast Imaging
- Stem-cell Therapy for Peripheral Arterial Disease
- Surgical Treatment of Femoroacetabular Impingement
- Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome
- Systems Pathology for Predicting Risk of Recurrence in Prostate Cancer
- Treatment of Varicose Veins/Venous Insufficiency

The above are brief summaries. Please refer to the Protocols, posted on the provider web site, for the details of the updated Protocols and the new Protocols that affect your practice. If you need assistance obtaining specific Protocol updates, please contact Provider Service.