Protocol

Medical Services Protocol Updates

Distribution Date: **March 1, 2013**

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. Three 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 April 1, 2013 unless otherwise indicated:

Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

For General Business:

- The medically necessary indication for patients with atrial fibrillation treated with catheter ablation was revised for clarity. Added that use of continuous monitors that record for longer than 72 hours and use in cryptogenic stroke is investigational.

For Medicare Advantage:

- Added that external electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage may be considered medically necessary for the same indications as dynamic electrocardiography (e.g., Holter™ monitoring).

Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis in Patients with Breast Cancer

Changes:

- Additions made to the investigational statement: Bilateral disease and DCIS are investigational indications for Oncotype DX.
- Additional newer assays (among them NexCourse Breast IHC4) identified as investigational.
- The separate Medicare Advantage policy statement has been removed.

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

The words “may be” have been removed from the Medicare Advantage not medically necessary statement.

Cosmetic vs. Reconstructive Surgery or Services

Changes:

- All information regarding breast reconstruction following mastectomy has been removed, and will only be discussed in the Reconstructive Breast Surgery/Management of Breast Implants Protocol.
- Added to the description: “The concept of reconstructive may overlap with the concept of medically necessity. For example, services intended to correct a functional impairment may also be considered medically necessary and thus makes them eligible for coverage.”

Dynamic Posturography

Removed the Medicare Advantage medically necessary criteria; this service is investigational for all business.

Electrical Bone Growth Stimulation of the Appendicular Skeleton
Arthrodesis/failed arthrodesis has been added to the list of investigational uses, and a policy guideline section was added further defining fresh fracture, delayed union, and non-union.

Electromagnetic Navigation Bronchoscopy
Removed the Medicare Advantage medically necessary statement and the general business statement will be applicable for Medicare Advantage.

Gastric Electrical Stimulation
The investigational statement which included idiopathic etiology has been changed to "idiopathic *or* post-surgical etiology."

Genetic Testing for Hereditary Breast and/or Ovarian Cancer
Policy Statement Additions:

- Medically necessary statement for testing for women with breast cancer and two or more close relatives with pancreatic cancer.
- Testing for rearrangements (BART) changed to remove the additional criteria that had been required.

Additional Change for Medicare Advantage:

- The medically necessary indications are only applicable if the member is personally affected by cancer.
- Added definition that limited family history is fewer than two first- or second-degree female relatives or female relatives surviving beyond 45 years in either lineage.

Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes
Changes:

- Title changed from Genetic Testing for Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability Testing.
- A medically necessary indication was added for patients with endometrial cancer and one first-degree relative diagnosed with a Lynch-associated cancer.
- The medically necessary statement that referred to "colorectal cancer patients with classical FAP" was changed to "colorectal cancer patients with a clinical picture suggestive but not definitive for FAP."
- Added to Policy Guidelines that testing is available from a number of laboratories.

Implantable Bone-Conduction and Bone-Anchored Hearing Aids
Our Benefit Application Section was updated to clarify that while the main policy statement is applicable to the BAHA® Softband™ (transcutaneously worn BAHA), the requirement to be five years of age and older does not apply. Also, tests used to determine hearing loss may vary dependent on the age of the child."

Implantable Cardioverter Defibrillator (ICD)
A policy statement was added that use of subcutaneous ICD is investigational for all indications.

Liver Transplant*

- Non-alcoholic steatohepatitis cirrhosis was added to the medically necessary policy statement.
- Liver retransplantation has been added as medically necessary if meeting certain defined indications.
- Cholangiocarcinoma added as a medically necessary indication, and further guidelines included in the Policy Guidelines section.

Lysis of Epidural Adhesions
Removed the Medicare Advantage medically necessary policy statement; this will be considered investigational for all business.

Microarray-Based Gene Expression Testing for Cancers of Unknown Primary
The policy statement has been generalized to "gene expression testing" because of the addition to the policy of other commercially available tests besides Pathwork; added to the Medicare Advantage medically necessary statement, that it should only be ordered by the treating physician.

Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers
Added:

- Two investigational statements regarding: (1) use of lymphedema pumps to treat trunk or chest in patients with lymphedema limited to upper and/or lower limbs, and (2) use to treat venous ulcers.
- To the first three policy statements added "applied to the limb."
- Statement "not medically necessary" regarding use to the trunk or chest for Medicare Advantage.

Proteomics-based Testing for the Evaluation of Ovarian (Adnexal) Masses
This will now be considered investigational for all indications; applies to both ROMA test as well as OVA1.

Reconstructive Breast Surgery/Management of Breast Implants
Relocated "refer to the Cosmetic vs. Reconstructive Services Protocol" to the end of the guideline and clarified that the Cosmetic vs. Reconstructive Protocol would not be applicable to reconstruction due to a medically necessary mastectomy.

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids
Removed from the title: "for Moderate to Severe Sensorineural Hearing Loss."

Sensory Integration Therapy
Updated the Medicare Advantage policy statement reference to "cognitive defect" to "sensory problems" in the medically necessary policy statement.

Total Artificial Hearts and Implantable Ventricular Assist Devices
Changes:

- The medically necessary policy statement on TAH now reads: "…Total artificial hearts with FDA-approved devices may be considered medically necessary as a bridge to heart transplantation for patients with biventricular failure who have no other reasonable medical or surgical treatment options, who are ineligible for other univentricular or biventricular support devices, and are currently listed as heart transplantation candidates or are undergoing evaluation to determine candidacy for heart transplantation, and not expected to survive until a donor heart can be obtained…"
- Preauthorization is required through Utilization Management; however, all patients will continue to be followed by Case Management.

Transcatheter Aortic-Valve Implantation for Aortic Stenosis
For General Business added:

- Medically necessary indications for patients who are at high risk for open surgery using the transfemoral approach, and patients who are at high risk for open surgery using the transapical approach.
- Investigational statement for treatment of degenerated bio-prosthetic valve or failed TAVI (Valve-in-Valve approach), and for vascular approaches other than transfemoral or transapical.

For Medicare Advantage:

- The facilities/providers must meet the Medicare "registry" requirements.
- Off label uses might be eligible through valid clinical trials (billed to original Medicare).
- Investigational for members in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
NDO Plicator™, and Esophyx® procedures were added as more example of investigational procedure names.

Treatment of Hyperhidrosis
Microwave treatment was added as investigational for primary focal hyperhidrosis.

Ultrasound Accelerated Fracture Healing Device
Arthrodesis/failed arthrodesis was added to the list of investigational uses, and the definition of delayed unions was revised to three months.

Vagus Nerve Stimulation
Heart failure and fibromyalgia were added to the list of uses considered investigational; for Medicare Advantage, clarified that the medically necessary indication for "partial-onset" seizures must also be the type of seizures that surgery is not recommended for, or that surgery failed.

Wearable Cardioverter-Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator Placement
Clarification was made to the policy statement: The wording "have all of the following" was removed from the medically necessary statement.

New Protocols

The effective date of these new Protocols is April 1, 2013:

- Implantable Sinus Spacers and Stents for Postoperative Use Following Endoscopic Sinus Surgery: *Investigational.*
- Interspinous Fixation (Fusion) Devices: *Investigational.*
- Intra-articular Hyaluronan Injections for Osteoarthritis: *Medically necessary* indications for osteoarthritis of the knee and *investigational* for all else; for Medicare Advantage osteoarthritis of the shoulder will also be a *medically necessary* indication.

Clinical Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Allogeneic Hematopoietic Stem-Cell Transplantation for Genetic Diseases and Acquired Anemias*
- Ambulance (Emergency)
- Analysis of Human DNA in Stool Samples as a Technique for Colorectal Cancer Screening
- Artificial Intervertebral Disc: Lumbar Spine
- Autologous Hematopoietic Stem-Cell Transplantation for Malignant Astrocytomas and Gliomas*
- Automated Percutaneous and Endoscopic Discectomy
- Axial Lumbosacral Interbody Fusion
- Balloon Sinuplasty for Treatment of Chronic Sinusitis

- Cryosurgical Ablation of Primary or Metastatic Liver Tumors
- Cytoreductive Surgery and Perioperative Intraperitoneal Chemotherapy for the Treatment of Pseudomyxoma Peritonei, Peritoneal Carcinomatosis of Gastrointestinal Origin, and Peritoneal Mesothelioma
- Diagnosis and Treatment of Sacroiliac Joint Pain
- Digital Breast Tomosynthesis
- Electrical Stimulation for the Treatment of Arthritis
- Electrostimulation and Electromagnetic Therapy for Treating Wounds
- Enhanced External Counterpulsation (EECP) for Chronic Stable Angina or Congestive Heart Failure
- Functional Neuromuscular Electrical Stimulation
- Genetic Testing for Familial Cutaneous Malignant Melanoma
- Genetic Testing for Warfarin Dose
- Heart/Lung Transplant*
- Heart Transplant*
- Hematopoietic Stem-Cell Transplantation for Autoimmune Diseases*
- Hematopoietic Stem-Cell Transplantation for CNS Embryonal Tumors and Ependymoma*
- Hematopoietic Stem-Cell Transplantation for Epithelial Ovarian Cancer*
- Hematopoietic Stem-Cell Transplantation for Hodgkin Lymphoma*
- Hematopoietic Stem-Cell Transplantation for Miscellaneous Solid Tumors in Adults*
- Home Prothrombin Time Monitoring
- Home Uterine Activity Monitoring
- Immune Cell Function Assay
- Implantation of Intrastromal Corneal Ring Segments
- In Vitro Chemoresistance and Chemosensitivity Assays
- Intradialytic Parenteral Nutrition
- Isolated Small Bowel Transplant*
- Keratoprosthesis
- Magnetoencephalography/Magnetic Source Imaging
- NOTCH3 Genotyping for Diagnosis of CADASIL
- Orthoptic/Vision Therapy
- Quantitative Sensory Testing
- Reduction Mammoplasty
- Saturation Biopsy for Diagnosis and Staging of Prostate Cancer
- Skin Contact Monochromatic Infrared Energy as a Technique to Treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions
- Subtalar Arthroereisis
- Threshold Electrical Stimulation as a Treatment of Motor Disorders
- Viscocanalostomy and Canaloplasty

*For Medicare Advantage, these Protocols, as well as all other Solid Organ and Hematopoietic Stem-Cell Transplantation Protocols are in the process of being revised:

- Adding the statement that we will arrange to have members evaluated by the Transplant Facility for the Facility Transplant Team to determine if the member is a candidate for a transplant.
- Removing medically necessary/not medically necessary/investigational policy statements, where they currently exist.

Please remember to contact our Case Management Team at 1-877-878-8785 when you have a Medicare Advantage member who may need a transplant.

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.