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# Protocol

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## Medical Services Protocol Updates

The following clinical protocol update includes information on protocols that have had an annual review recently resulting in a revision to the guidelines or no changes at all. Four (4) new Protocols have been added and two (2) existing protocols have been deleted.

Please note that some of this protocol update may not pertain to the members you provide care to, as it may relate to contracts that are not available in your geographic area.

### Protocol Revision Summary

The effective date of these changes is July 1, 2010:

#### Bariatric Surgery

Added to the policy statement:

- Revision surgery may be **medically necessary** in specific situations
- Endoluminal/endoscopic bariatric procedures are **investigational** as both primary and revision procedures

#### Biopsy of the Prostate

Effective May 1, 2010 as communicated in a previous Stat Bulletin

Added:

- “Refer to” notes for Saturation Biopsy for Diagnosis and Staging of Prostate Cancer and Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer; usual number of biopsy cores indicated in description, with a refer to note a second time to the separate Saturation Biopsy protocol if 20 or more cores are taken
- **Not medically necessary** for transperineal biopsy (as per above however, if 20 or more cores taken, the policy statement on that is in the Saturation Biopsy Protocol)
- **Medically necessary** criteria for repeat biopsies
- Definitions and normal/abnormal values for PSA, PSA velocity, percent free PSA and PSA density
- Definition on how many PSA and over what time frame they are measured for determining PSA velocity

#### Charged-Particle (Proton or Helium Ion) Radiation Therapy

- Policy statement will also now apply to Medicare Advantage members
- No change made to the policy statement

#### Computer-assisted Musculoskeletal Surgical Navigational Orthopedic Procedure

- No change made to the current **investigational** statement; no separate payment made as communicated in a previous Stat Bulletin
- Separate section added for Medicare Advantage

### **Continuous Passive Motion (CPM) in the Home Setting**

Policy guideline section added which indicates maximum use times: total knee arthroplasty—17 days, and post intra-articular cartilage repair procedures of the knee—six weeks

### **Cryosurgical Ablation of Miscellaneous Solid Tumors other Than Liver, Prostate, or Dermatologic Tumors**

- Policy statement will also now apply to Medicare Advantage members
- No change made to the policy statement

### **Cryosurgical Ablation of Primary or Metastatic Liver Tumors**

- Policy statement will also now apply to Medicare Advantage members
- No change made to the policy statement

### **Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome**

- Portable monitoring (with any device) is considered **investigational** in children, i.e., those younger than 18 years of age, and indications specific to pediatric patients have been included
- Two full-night sleep studies (second night to initiate CPAP) are **not medically necessary** in those patients whom diagnosis could have been made in the first part of the first night study

### **Dynamic Posturography**

- Policy statement remains **not medically necessary**
- Removal of Identification of early Multiple Sclerosis in patients with balance impairment when MRI is normal as an indication in the Medicare Advantage criteria

### **Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus**

- Cryoablation is added to the title
- Added to the policy statement:
  - Radiofrequency ablation is **medically necessary** for Barrett's esophagus with high-grade dysplasia
  - Radiofrequency ablation is **investigational** for Barrett's esophagus with low-grade dysplasia or in the absence of dysplasia
  - Cryoablation is **investigational**

### **Endovascular Grafts for Abdominal Aortic Aneurysms**

Added to the policy statement that endovascular graft is **medically necessary** for ruptured abdominal aortic aneurysms

### **Hematopoietic Stem-Cell Transplantation for Acute Lymphoblastic Leukemia (ALL)**

Added to the policy statement that allogeneic hematopoietic stem-cell transplantation may be **medically necessary** to treat adult ALL in first remission for *any* risk level

### **Hematopoietic Stem-Cell Transplantation for Breast Cancer**

Policy statement revised:

- Single or tandem autologous stem-cell transplantation is considered **not medically necessary** to treat any stage of breast cancer
- Allogeneic stem-cell transplantation changed to *allogeneic* hematopoietic stem-cell transplantation (which is investigational to treat any stage breast cancer)

### **Implantable Bone-Conduction and Bone-Anchored Hearing Aids**

- **Medically necessary** policy statement now specifies "five years of age and older"

- Statement added to policy guideline section: “When the bone-anchored hearing aid is to be used in those with single-sided sensorineural deafness, a trial should generally first be arranged with a BAHA device on a headband placed on the mastoid of the deaf ear to determine the likely benefit of the BAHA”

### **Laboratory Testing for HIV Tropism**

Added treatment-naïve patients to the policy statement as one of the **medically necessary** indications for testing

### **Measurement of Exhaled Nitric Oxide and Exhaled Breath Condensate in the Diagnosis and Management of Asthma and Other Respiratory Disorders**

- Policy statement divided into two policy statements to separate exhaled nitric oxide and exhaled breath condensate
- Language added to clarify the meaning of “other respiratory disorders”

### **Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders**

Policy statement revised to indicate *intrapulmonary percussive devices* in addition to high-frequency chest wall compression devices are **medically necessary** in cystic fibrosis and chronic bronchiectasis when specific criteria met

### **Open and Thoroscopic Approaches to Treat Atrial Fibrillation (Maze and Related Procedures)**

- Policy title updated to reflect evolving procedures
- Policy guideline statement added indicating that (given other less-invasive alternatives) the need to perform the maze procedure without concomitant cardiac surgery would be very limited
- Term “symptomatic” added to the first policy statement to clarify that this procedure is **medically necessary** for treatment of symptomatic drug-resistant atrial fibrillation or flutter
- Second policy statement revised to read, “Minimally invasive, off-pump maze procedures, including those done via mini-thoracotomy are considered **investigational** for treatment of drug-resistant atrial fibrillation or flutter”

### **Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines**

- Policy title updated from Azathioprine (6-MP) to Thiopurines
- Phenotypic analysis of thiopurine methyltransferase (TPMT) added to policy statement as **medically necessary**
- Policy statement revised to be specific to a single use of the genotypic or phenotypic analysis of TPMT testing
- Policy statement revised to include all of the testing indications from the FDA labeling

### **Radiofrequency Catheter Ablation of the Pulmonary Veins as Treatment for Atrial Fibrillation**

- Policy statement added to indicate that repeat treatment may be **medically necessary** under certain circumstances
- Information added to Policy Guidelines about repeat (follow-up) procedures

### **New Protocols**

The effective date of the following new Protocols is July 1, 2010, unless otherwise indicated:

- Aqueous Shunts and Devices for Glaucoma

- Hematopoietic Stem-Cell Transplantation for Chronic Myelogenous Leukemia (effective June 1, 2009, formerly part of Blood or Marrow Transplantation; prior approval required and must be obtained through Case Management)
- Implantation of Intrastromal Corneal Ring Segments
- Saturation Biopsy for Diagnosis and Staging of Prostate Cancer (effective May 1, 2010, formerly part of Biopsy of the Prostate as communicated in a previous Stat Bulletin)

## **Clinical Protocols Reviewed Without Change**

Previous effective dates indicated remain accurate:

- Biomarker Genes for Detection of Lymph Node Metastases in Breast Cancer
- Cochlear Implant
- Breast Brachytherapy after Breast-Conserving Surgery, as Boost with Whole Breast Irradiation, or alone as Accelerated Partial Breast Irradiation (APBI)
- Diagnosis and Management of Idiopathic Environmental Intolerance (i.e., Clinical Ecology)
- Electrical Stimulation for the Treatment of Arthritis
- Electrostimulation and Electromagnetic Therapy for the Treatment of Chronic Wounds
- End Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema
- Extracorporeal Photopheresis as a Treatment of Graft-Versus-Host Disease, Autoimmune Disease, and Cutaneous T-cell Lymphoma
- Fetal Surgery for Prenatally Diagnosed Malformations
- Genetic Testing for Familial Alzheimer's Disease
- Hematopoietic Stem-Cell Transplantation for Epithelial Ovarian Cancer
- KRAS Mutation Analysis in Non-Small Cell Lung Cancer
- Microarray-Based Gene Expression Testing for Cancers of Unknown Primary
- Nerve Graft in Association with Radical Prostatectomy
- Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids
- Outpatient Pulmonary Rehabilitation
- Percutaneous Electrical Nerve Stimulation (PENS) or Percutaneous Neuromodulation Therapy (PNT)
- Serum Antibodies for the Diagnosis of Inflammatory Bowel Disease
- Spinal Cord Stimulation
- Subtalar Arthroereisis
- Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/ Neurologic Disorders
- Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
- Wearable Cardioverter-Defibrillators

## **Deleted Protocols**

Effective immediately, the following Protocol is archived; refer to the Technology Assessment Protocol for criteria that must be met to support medical necessity:

- Videofluoroscopic Evaluation of Velopharyngeal Dysfunction

Effective immediately, this protocol is archived and not replaced due to a national criteria set that is followed with possible reissue of a corporate medical protocol in the future.

- Serial Endpoint Testing for the Diagnosis and Treatment of Allergic Disorders

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.