

Distribution Date: March 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. Four new Protocols have been added and two existing Protocols have been deleted.

Note: Some of the Protocol updates may not pertain to the members to whom you provide care.

Protocol Revision Summary

The effective date of these changes is April 1, 2012 unless otherwise indicated:

Allogeneic Hematopoietic Stem-Cell Transplantation for Genetic Diseases and Acquired Anemias*

Medicare Advantage medically necessary policy statement added

Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

A medically necessary indication was added to the policy statement for use of auto-trigger devices in patients treated for atrial fibrillation to evaluate for asymptomatic episodes.

Aqueous Shunts for Glaucoma

The canaloplasty policy statement has been removed and it is now in a separate new Protocol (see New Protocols below for Protocol "Viscocalostomy and Canaloplasty").

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

Added to the Policy Guideline section a definition for HER2 positivity

Added to the to the Benefit Application section

- Labs are **required** to have HER2 proficiency
- Statement: "Documentation on file with the treating physician should indicate that results of the Oncotype DX test are expected to play a significant role in management of the patient. For example, a patient with a large, high grade carcinoma who, in agreement with the oncologist and patient, has decided to have adjuvant chemotherapy regardless of the results of the test would not be an appropriate candidate for this test."

Autologous Hematopoietic Stem-Cell Transplantation for Malignant Astrocytomas and Gliomas

Removed the Medicare Advantage policy statement (Medicare Advantage will follow the policy of general business)

Automated Percutaneous and Endoscopic Discectomy

Endoscopic discectomy is added to the policy statement, and it is investigational.

Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy

A Benefit Application section was added indicating that there is no separate payment because payment is part of the evaluation.

Cosmetic vs. Reconstructive Surgery or Services

Gender reassignment services are added to the Protocol and would never be considered to meet the definition of reconstructive services.

Cytoreductive Surgery and Perioperative Intraperitoneal Chemotherapy for the Treatment of Pseudomyxoma Peritonei, Peritoneal Carcinomatosis of Gastrointestinal Origin, and Peritoneal Mesothelioma

- Use of term “hyperthermic” changed to “perioperative intraperitoneal chemotherapy” “cytoreductive” changed to “cytoreductive surgery” throughout Protocol
- Added a policy statement that cytoreductive surgery and perioperative intraperitoneal chemotherapy for the treatment of peritoneal mesothelioma may be considered medically necessary

Diagnosis and Treatment of Sacroiliac Joint Pain

- Title changed from Sacroiliac Joint Arthrography and Injection
- Statement that radiofrequency ablation of the sacroiliac joint is investigational added
- Medical necessity criteria added for sacroiliac joint dysfunction and pain at that joint which is referred from lumbosacral spine disease or hip problems
- Policy Guideline section added explaining some of the provocation testing that is used to help determine appropriate candidates
- **Preauthorization will be required for all lines of business**

Digital Breast Tomosynthesis

Included a Benefit Application section which indicates this will be not be paid separately in addition to the mammography codes effective January 15, 2012 and communicated previously in a STAT Bulletin.

Dynamic Posturography

An additional medically necessary indication for identification of early multiple sclerosis has been added for Medicare Advantage.

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Immediate post-surgical treatment after appendicular skeletal surgery has been added to the investigational policy statement.

Electromagnetic Navigation Bronchoscopy

- For general business added criteria for medical necessity:
 - in patients with solitary pulmonary nodules who meet specified criteria
 - for patients with an identified lung lesion(s) and a coexisting cancer who meet specified criteria
 - to aid in placement of fiducial markers in patients who are to undergo radiotherapeutic treatment of malignant solitary pulmonary nodules who meet specified criteria
 - for placement of fiducial markers to help localize a nodule by fluoroscopy during thorascopic excision that would otherwise not be palpable without a thoracotomy
- For Medicare Advantage, updated the criteria for fiducial marker indication to be specific to anticipated use of stereotactic radiosurgery for specified malignancy or high suspicion of malignancy as per brushing, washing, aspirate or biopsy
- **Preauthorization will be required for all business**

Enhanced External Counterpulsation (ECCP) for Chronic Stable Angina or Congestive Heart Failure

- Policy Guideline section is being removed because it contradicts the last statement in the policy statement section

- Added that EECF for erectile dysfunction and ischemic stroke is investigational

Genetic Testing for Familial Cutaneous Malignant Melanoma

The word “familial” added to the policy title, and throughout the policy in place of “hereditary”; this wording improvement was made to the Protocol as of January 1, 2012.

Genetic Testing for Hereditary Breast and/or Ovarian Cancer

The policy statement has been amended based on new guidelines and evidence that refines risk stratification for BRCA mutations. The high-risk definitions in the Policy Guidelines were expanded to include both the U.S. Preventive Services Task Force (USPSTF) definition and adaptation of the National Comprehensive Cancer Network (NCCN) 2011 definition.

Genetic Testing for Inherited Disorders

- This comment applies to conditions identified: “These conditions, as well as a vast number of other inherited disorders may be medically necessary to have genetic testing for. However, determination of those that are medically necessary will be through review of the medical information submitted with the preauthorization request by a Medical Director.” While preauthorization is required for all genetic testing, be sure to submit all the appropriate documentation for these to eliminate service delays.
- Additional investigational uses were added to the Protocol.

Genetic Testing for Inherited Susceptibility to Colon Cancer, Including Microsatellite Instability Testing

Additional medically necessary indications added for testing for EPCAM (gene for the epithelial cell adhesion molecule) mutations in patients with colorectal cancer and negative MMR (mismatch repair) mutations.

Heart/Lung Transplant*

Changes:

- Added severe heart failure added to second bullet point of medically necessary statement
- Contraindications moved to Policy Guidelines
- Absolute and relative contraindications combined
- Removed Medicare Advantage policy section (Medicare Advantage will follow general business policy)

Heart Transplant*

Changes:

- Contraindications moved to Policy Guidelines
- Absolute and relative contraindications combined
- Removed Medicare Advantage policy section (Medicare Advantage will follow general business policy)

Hematopoietic Stem-Cell Transplantation for Autoimmune Diseases

Removed Medicare Advantage policy section (Medicare Advantage will follow general business policy that this is investigational)

Hematopoietic Stem-Cell Transplantation for CNS Embryonal Tumors and Ependymoma*

Removed Medicare Advantage policy section (Medicare Advantage will follow general business policy)

Hematopoietic Stem-Cell Transplantation for Epithelial Ovarian Cancer

Removed Medicare Advantage policy section (Medicare Advantage will follow general business policy that this is investigational)

Hematopoietic Stem-Cell Transplantation for Hodgkin Lymphoma*

Separate Medicare Advantage criteria section to indicate medically necessary only for:

- Autologous HSCT that is for advanced Hodgkin's when conventional therapy has failed and there is no HLA-matched donor
- Allogeneic HSCT for primary refractory Hodgkin's

Hematopoietic Stem-Cell Transplantation for Miscellaneous Solid Tumors in Adults

Removed Medicare Advantage policy section (Medicare Advantage will follow general business policy that this is investigational)

Immune Cell Function Assay

Solid organs removed from title and therefore a policy statement about HSCT and all other indications being investigational has been added.

Isolated Small Bowel Transplant*

Separate Medicare Advantage medical necessity policy statements were added

Liver Transplant*

Changes:

- Neuroendocrine tumor metastases were added to the investigational statement
- Hepatocellular carcinoma that has extended beyond the liver and ongoing alcohol and/or drug abuse was changed from investigational to not medically necessary
- "Patients with an active infection" was removed from the investigational policy statement

Lysis of Epidural Adhesions

A Medicare Advantage policy statement has been added to indicate this is medically necessary "in the treatment of chronic refractory cervical, lumbar, and thoracic pain that has failed to respond to more conservative treatment measures.... It is not expected that services will exceed one every six months to the same anatomical region."

Magnetoencephalography/Magnetic Source Imaging

Policy statement changed to indicate this is medically necessary to localize seizure focus when specified criteria are met.

Meniscal Allografts and Collagen Meniscus Implants

Changes:

- Statement about adolescents removed as it now pertains to only adults and those under age 55
- A specific time frame for conservative treatment removed
- Added that it may be medically necessary combined with other procedures for focal articular cartilage lesions (ACI or osteochondral allografts or autografts)

Microarray-Based Gene Expression Testing for Cancers of Unknown Primary

A separate Medicare Advantage medical necessity policy statement has been added.

Orthoptic/Vision Therapy

Combined Orthoptic Training for the Treatment of Vision or Learning Disorders into this Protocol.

Pneumatic Compression Pumps

Changes:

- Added medical necessity criteria for venous insufficiency/stasis ulcers
- Updated Benefit Application section that these are only initially allowed as rental, and after three months if they still meet clinical criteria, then additional documentation of compliance and effectiveness is required before further rental or purchase approval is given

Quantitative Sensory Testing

Added two testing examples to the investigational policy statement: vibration perception threshold testing and thermal threshold testing

Reconstructive Breast Surgery/Management of Breast Implants

Added statements:

- Both implant-based and autologous approaches to breast reconstruction are medically necessary
- Use of autologous fat grafting and adipose-derived stem cells for augmentation or reconstruction of the breast is considered investigational

Reduction Mammoplasty

- Removed the Schnur Scale and added five criteria including that a minimum amount of tissue (500 grams per breast) must be removed and that all members must have a BMI of 30 or less
- Added that the use of liposuction to accomplish reduction mammoplasty is investigational
- All areas of the Protocol that have referred to mastectomy are consistent and indicate that malignancy would not be the only reason for a mastectomy

Saturation Biopsy for Diagnosis and Staging of Prostate Cancer

Policy statement was revised to state that saturation biopsy is taking *more* than 20 core tissue samples at one time

Semi-Implantable and Fully Implantable Middle Ear Hearing Aid for Moderate to Severe Sensorineural Hearing Loss

Fully implantable hearing aids are also included in the investigational policy statement.

Threshold Electrical Stimulation as a Treatment of Motor Disorders

Changed from investigational to not medically necessary

Total Artificial Hearts and Implantable Ventricular Assist Devices

- Percutaneous ventricular assist devices (pVAD) were added to the policy as investigational
- For Medicare Advantage, revised the medical necessity criteria for VAD as destination therapy and included a link to the eligible facilities

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

The 3rd and 4th investigational policy statements were combined and zirconium oxide spheres were added as investigational.

Treatment of Hyperhidrosis

The “not medically necessary” statement was moved to end of policy.

Ultrasound Accelerated Fracture Healing Device

Added:

- Treatment of delayed unions as medically necessary
- Definition of fresh fractures

New Protocols

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

- Axial Lumbosacral Interbody Fusion
- DNA-Based Testing for Adolescent Idiopathic Scoliosis
- NOTCH3 Genotyping for Diagnosis of CADASIL
- Viscocanalostomy and Canaloplasty

*Includes a Benefit Application section to remind the reader that individual transplant facilities may have *additional* criteria or protocol that must be met for a patient to be considered eligible for a transplant.

Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Analysis of Human DNA in Stool Samples as a Technique for Colorectal Cancer Screening
- Ambulance (Emergency)
- Artificial Intervertebral Disc: Lumbar Spine
- Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid
- Cryoablation of Prostate Cancer
- Cryosurgical Ablation of Primary or Metastatic Liver Tumors
- Diagnosis and Management of Idiopathic Environmental Intolerance (i.e., Clinical Ecology)
- Electrical Stimulation for the Treatment of Arthritis
- Electrostimulation and Electromagnetic Therapy for Treating Wounds
- Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions
- Functional Neuromuscular Electrical Stimulation
- Gastric Electrical Stimulation
- Genetic Testing for Warfarin Dose
- Home Prothrombin Time Monitoring
- Home Uterine Activity Monitoring
- Implantation of Intrastromal Corneal Ring Segments
- In Vitro Chemoresistance and Chemosensitivity Assays
- Intradialytic Parenteral Nutrition
- Keratoprosthesis
- Proteomics-based Testing for the Evaluation of Ovarian (Adnexal) Masses
- Sensory Integration Therapy
- Skin Contact Monochromatic Infrared Energy as a Technique to Treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions
- Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy
- Subtalar Arthroereisis
- T-Wave Alternans

- Vagus Nerve Stimulation
- Wearable Cardioverter-Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator Placement

Deleted Protocols

Effective immediately, the following Protocol is archived:

- Minimally Invasive Lumbar Interbody Fusion

Effective April 1, 2012, the following Protocol is archived:

- Orthoptic Training for the Treatment of Vision or Learning Disorders (combined into Protocol Orthoptic/Vision Therapy as per above)

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.