

Distribution Date: March 3, 2014

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. Three new protocols have been added and two have been archived.

Please note that portions of this protocol update may not pertain to the members for whom you provide care.

Protocol Revision Summary

The effective date of these changes is April 1, 2014 unless otherwise indicated:

Ambulance (Emergency)

Revision under Benefit Application section: "For general business, New York State mandated coverage for pre-hospital emergency services and land transportation provided by ambulance services and prudent layperson language regarding emergency conditions may impact medical necessity determinations."

Ambulatory Event Monitors and Mobile Outpatient Cardiac Telemetry (formerly Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry)

The medical necessity criteria for implantable loop monitors was revised from "a prior trial of *Holter monitor* and other external ambulatory event monitors has been unsuccessful" to "a prior trial of other external ambulatory event monitors has been unsuccessful."

Aqueous Shunts and Stents for Glaucoma

Added:

- The implantation of a single FDA-approved micro-stent in conjunction with cataract surgery may be considered medically necessary in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.
- Micro-stents are investigational in all other situations.

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

Added that MammaPrint® (Agendia) may be a medically necessary test for Medicare Advantage if criteria already stated in the Protocol are met.

Balloon Ostial Dilation for Treatment of Chronic Sinusitis (formerly Balloon Sinuplasty for Treatment of Chronic Sinusitis)

Title changed as indicated.

Bariatric Surgery

Changes:

- For General Business, clarification was added that revision surgery includes complications of laparoscopic adjustable gastric banding.

- For Medicare Advantage, facility certification requirement was removed, and the medical necessity statement which included open and laparoscopic biliopancreatic diversion was expanded to include gastric reduction duodenal switch.

Bone Morphogenetic Protein

This is **no longer medically necessary** when harvesting an iliac crest bone graft is feasible; the Policy Guidelines include situations where autograft might not be feasible.

Charge-Particle (Proton or helium Ion) Radiation Therapy

Changes effective March 1, 2014:

- Treatment of pediatric central nervous system tumors was added as medically necessary, with additional clarification in the Policy Guidelines.
- Administrative changes included to clarify that the Protocol does not address metastatic central nervous system (brain/spine) and bone cancer, as per the STAT Bulletin *Radiation Oncology Preauthorization Update*, January 15, 2014, Volume: 20 Issue 1.

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

The description was updated to include the FDA-approved artificial pancreas type system. (No change to the effective date.)

Diagnosis and Treatment of Sacroiliac Joint Pain

Added that if the medical necessity criteria are not met this is considered investigational.

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Changes:

- Stress fractures added to investigational statement.
- Compliance with non-weight bearing clarified.
- Added "Noninvasive electrical bone growth stimulation for treatment of fracture nonunions or congenital pseudoarthroses in the appendicular skeleton is considered investigational if all of the above criteria are not met."

Electrostimulation and Electromagnetic Therapy for Treating Wounds

Sentence restructured: "Electrical stimulation *for the treatment of wounds, including but not limited to* low-intensity direct current (LIDC), high-voltage pulsed current (HVPC), alternating current (AC), and transcutaneous electrical nerve stimulation (TENS), is considered investigational."

Endovascular Grafts for Abdominal Aortic Aneurysms

The investigational statement for fenestrated grafts was removed.

Genetic Testing for Hereditary Breast and/or Ovarian Cancer

For General Business:

- Added to the investigational policy statement: "including those with a family history of pancreatic cancer."
- Policy guidelines were updated, including adding history of pancreatic cancer and aggressive prostate cancer for family members in the criteria for "consideration of high risk for individuals with breast cancer."

For Medicare Advantage:

- A separate medical necessity policy statement has been added; note Medicare Advantage can only cover if the member is affected with cancer, and the results will impact treatment plan.

Genetic Testing for Lynch Syndrome and Other Inherited Colon Cancer (formerly Genetic Testing for Lynch Syndrome and Other Inherited Intestinal Polyposis Syndromes)

Title changed as indicated.

For General Business added:

- BRAF V600E or MLH1 promoter methylation may be considered medically necessary when MLH1 protein is not expressed in the tumor on IHC analysis
- If medical necessity criteria not met then the service is investigational.

For Medicare Advantage clarified:

- This test is medically necessary (per the criteria already indicated) for individuals who are affected with cancer, provided it will be used in the management of their cancer, such as if the member tests negative, they could be spared from prophylactic surgery such as total versus partial colectomy, or that frequency of surveillance may be altered dependent on the carrier status determined by the test.

Genetic Testing of CADASIL Syndrome (formerly NOTCH3 Genotyping for Diagnosis of CADASIL)

Changes:

- Title changed as indicated.
- A medical necessity indication was added for patients with a high likelihood of CADASIL syndrome but in whom the diagnosis cannot be made by other methods.
- A Policy Guidelines section was added to further explain the criteria.
- If the criteria are not met the test is investigational.

Heart Transplant

Medical necessity statement for retransplantation was added as well as a statement that when the medical necessity criteria are not met, the transplant is considered investigational.

Heart/Lung Transplant

Medical necessity statement for retransplantation was added as well as a statement that when the medical necessity criteria are not met, the transplant is considered investigational.

Hematopoietic Stem-Cell Transplantation for Autoimmune Diseases

Chronic inflammatory demyelinating polyneuropathy was added as an investigational indication.

Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery (formerly Implantable Sinus Spacers and Stents for Postoperative Use Following Endoscopic Sinus Surgery)

Title changed as indicated.

Intra-articular Hyaluronan Injections for Osteoarthritis

Policy statement change, effective July 1, 2014:

- Use in all joints will be considered **not medically necessary**.

Background:

- The current position as medically necessary for osteoarthritis of the knee was based on older trials that showed some positive effects on pain and function scores. However, the evidence from those trials had some uncertainty due to variable trial quality, potential publication bias, and unclear clinical significance of the changes reported.

- More recent analysis of trials by specialty organizations, such as the American Academy of Orthopedic Surgeons (AAOS), concluded there was not significant clinical improvement. This caused them to strongly recommend against its use, as noted in our Q4 2013 *Vital Signs* newsletter.
- The National Institute for Health and Clinical Excellence (NICE) also does not recommend its use.
- Members should be directed to alternate treatments for osteoarthritis of the knee and cannot be billed for this service.

Isolated Small Bowel Transplant

Small bowel retransplant after a failed primary small bowel transplant was added as medically necessary.

Microarray-Based Gene Expression Testing for Cancers of Unknown Primary

Separate Medicare Advantage medically necessary statement has been removed and this service is now **investigational** for Medicare Advantage members.

Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Changes:

- The last policy statement “lymphedema pumps” was replaced with “pneumatic compression pumps.”
- The policy statements for lymphedema treatment are all for lymphedema pumps.
- Added to the Benefit Application section that the existence of Legislative Mandates may impact whether a service could be considered not medically necessary or investigational.

Proteomics-based Testing Related to Ovarian Cancer (formerly Proteomics-based Testing for the Evaluation of Ovarian (Adnexal) Masses)

Title changed as indicated.

Reconstructive Breast Surgery/Management of Breast Implants

Changes:

- Clarified that functional impairment is required in order for a service to be determined reconstructive for *other* than post mastectomy indications, and that lumpectomy is included under partial mastectomy.
- Added a Benefit Application section stating that the existence of Legislative Mandates may impact whether a service could be considered not medically necessary or investigational.

Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

Changes, effective March 1, 2014:

- Added uveal melanoma to the “including, but not limited to” investigational statement.
- Administrative changes included to clarify that the Protocol does not address metastatic central nervous system (brain/spine) and bone cancer, as per the STAT Bulletin *Radiation Oncology Preauthorization Update*, January 15, 2014, Volume: 20 Issue 1.

Transcatheter Aortic Valve Implantation for Aortic Stenosis

TAVI by the transapical approach for patients who are not suitable candidates for open surgery was added as medically necessary.

Treatment of Hyperhidrosis

Radiofrequency ablation was added as investigational.

Ultrasound Accelerated Fracture Healing Device

Clarification was added in the medically necessary statement regarding nonunion of previously surgically-treated fractures, and in the investigational statement regarding fresh surgically-treated closed fractures.

Wearable Cardioverter-Defibrillators (formerly Wearable Cardioverter-Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator Placement)

Title changed as indicated.

The following Protocols underwent annual review, which resulted in only administrative changes to clarify that the Protocols do not address metastatic central nervous system (brain/spine) and bone cancer, as per the STAT Bulletin *Radiation Oncology Preauthorization Update*, January 15, 2014, Volume: 20 Issue 1. The effective date of these Protocol changes is March 1, 2014:

- Intensity Modulated Radiation Therapy (IMRT): Central Nervous System Tumors
- Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas to the Brain (formerly Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas or Metastasis to the Brain)
- Real-Time Intra-Fraction Target Tracking During Radiation Therapy

New Protocols

The effective date of these new protocols is April 1, 2014.

Carrier Testing for Genetic Disease

- Protocol provides general guidance about **medical necessity** for carrier screening, including example populations: Ashkenazi Jewish for several genetic diseases, African, Southeast Asian, Mediterranean descent for hemoglobinopathies, and all women that might consider pregnancy for cystic fibrosis.
- All other situations are **investigational**.
- Carrier screening panels are **not medically necessary**.
- This testing would be considered **not medically necessary** for Medicare Advantage members.
- Preauthorization is required.

Endothelial Keratoplasty

- This may be **medically necessary** for treatment of endothelial dysfunction by endothelial keratoplasty (Descemet's stripping endothelial keratoplasty [DSEK], Descemet's stripping automated endothelial keratoplasty [DSAEK], Descemet's membrane endothelial keratoplasty [DMEK], or Descemet's membrane automated endothelial keratoplasty [DMAEK]).
- It is **investigational** for the following techniques: Femtosecond laser-assisted corneal endothelial keratoplasty (FLEK) or femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK).
- Endothelial keratoplasty is not **medically necessary** when endothelial dysfunction is not the primary cause of decreased corneal clarity.
- Preauthorization is not required.

Genetic Testing for Nonsyndromic Hearing Loss

- Includes **medical necessity** indications for the diagnosis confirmation in hereditary nonsyndromic hearing loss and preconception in specified situations.
- All other uses are **investigational**.
- Preauthorization is required.

Medical Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Allogeneic Hematopoietic Stem-Cell Transplantation for Genetic Diseases and Acquired Anemias
- Analysis of Human DNA in Stool Samples as a Technique for Colorectal Cancer Screening
- Artificial Intervertebral Disc: Lumbar Spine
- Axial Lumbosacral Interbody Fusion
- Cosmetic vs. Reconstructive Surgery or Services
- 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
- Dynamic Posturography
- Electrical Stimulation for the Treatment of Arthritis
- Electromagnetic Navigation Bronchoscopy
- Gastric Electrical Stimulation
- Genetic Testing for Familial Cutaneous Malignant Melanoma
- Genetic Testing for Warfarin Dose
- 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
- Implantable Bone-Conduction and Bone-Anchored Hearing Aids
- Implantable Cardioverter Defibrillator (ICD)
- Implantation of Intrastromal Corneal Ring Segments
- In Vitro Chemoresistance and Chemosensitivity Assays
- Interspinous Fixation (Fusion) Devices
- Liver Transplant
- Lysis of Epidural Adhesions
- Magnetoencephalography/Magnetic Source Imaging
- Orthoptic/Vision Therapy
- Quantitative Sensory Testing
- Saturation Biopsy for Diagnosis and Staging of Prostate Cancer
- Semi-Implantable and Fully Implantable Middle Ear Hearing Aids
- Sensory Integration Therapy
- 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
- Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
- Vagus Nerve Stimulation
- Viscocanalostomy and Canaloplasty

Deleted Protocols

Effective immediately, the following protocols are archived:

- Autologous Hematopoietic Stem-Cell Transplantation for Malignant Astrocytomas and Gliomas
- Digital Breast Tomosynthesis (effective February 1, 2014, as per STAT Bulletin *Digital Breast Tomosynthesis Coverage Update*, January 24, 2014, Volume: 20 Issue 2)

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