Protocol

Medical Services Protocol Updates

Distribution Date: **May 31, 2013**

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. Eleven new Protocols have been added.

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 July 1, 2013, unless otherwise indicated:

Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions
A statement was added for Medicare Advantage about the potential for benefits if the member is receiving this treatment in a valid clinical trial (billed to original fee-for-service Medicare, not Medicare Advantage).

Bio-Engineered Skin and Soft Tissue Substitutes
Added:

- Four additional product names to the investigational list;
- Medical necessity criteria for EpiFix® and Primatrix™ Dermal Repair Scaffold for the Medicare Advantage policy statement;

Removed:

- Dermagraft® from being considered medically necessary for dystrophic epidermolysis bullosa (due to withdrawal of HDE status); and

Changed:

- For Medicare Advantage, the Apligraf® usual number of applications from four to five, and the first criteria statement regarding adequate blood supply.

Biofeedback as a Treatment of Fecal Incontinence or Constipation
Changes made:

- Biofeedback for constipation in adults may be considered medically necessary for patients with dyssynergia-type constipation who meet criteria specified in the protocol, and if not met it is considered investigational;
- A Policy Guideline section defines ROME III and pelvic floor dyssynergia criteria;
- The separate Medicare Advantage policy statement was removed (general business policy statement will apply to Medicare Advantage).

Biofeedback for Miscellaneous Indications
Pain management during labor was added to the list of investigational indications.

Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure
Added that triple-site (triventricular) cardiac resynchronization therapy (CRT) is investigational.

Cardiac Rehabilitation in the Outpatient Setting
Minor changes were made:

- The "and" in the list of conditions considered medically necessary for cardiac rehabilitation was changed to "or";
- Policy Guidelines were changed to indicate that it is "preferable" to start within 90 days of the cardiac event (as opposed to "must" start within 90 days).

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid
Added:

- A policy statement was added to indicate that artificial pancreases are considered investigational;
- Clarification that the Protocol does not address medical necessity for regular insulin pumps;

Removed:

- The word "symptomatic" from the third policy statement.

Cytochrome p450 Genotyping
The wording for the medical necessity statement for clopidogrel was clarified, and investigational statements were added for selective norepinephrine reuptake inhibitors as well as tricyclic antidepressants.

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome
Changes:

- Criteria for oral appliances were clarified;
- Nasal expiratory positive airway pressure (EPAP) was added as investigational;

Changes for Medicare Advantage:

- For oral appliances, one of the three criteria under "B" are required (previously it was the first or second, plus the third);
- Tongue retaining devices were changed from investigational to not covered (dental);
- Updates made to the requirements regarding the kind of facility oversight that must exist for those providing polysomnography.

Diagnosis and Treatment of Sacroiliac Joint Pain
Added fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint as considered investigational, including but not limited to percutaneous and minimally invasive techniques.

Endovascular Grafts for Abdominal Aortic Aneurysms
Medical necessity criteria have been added separately for Medicare Advantage:
Endovascular repair using FDA approved prosthesis will be considered medically necessary for treatment of patients with abdominal aortic or aortoiliac aneurysm having morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with required introduction systems;
- Nonaneurysmal infrarenal aortic segment (neck) proximal to the aneurysms with:
  - Length > 4 mm and unsuitable for a non-fenestrated graft
  - Diameter < 31 mm and > 19 mm
  - Angle < 45 degrees relative to long axis of aneurysm
  - Angle < 45 degrees relative to axis of suprarenal aorta
- Ipsilateral iliac artery fixation site > 30 mm in length and between 9-21 mm in diameter;
- Contralateral iliac artery distal fixation site > 30 mm in length and between 7-21 mm in diameter.

Extracorporeal Photopheresis

- The title was changed from "Solid-Organ Transplant and for Graft-versus-Host Diseases, Autoimmune Disease, and Cutaneous T-cell Lymphoma" and a policy statement was added that extracorporeal photopheresis is investigational for all other indications.
- For Medicare Advantage a statement was added about the potential coverage for the treatment of bronchiolitis obliterans syndrome (BOS) following lung allograft transplantation if extracorporeal photopheresis is provided in a valid clinical trial (which would be billed to original fee-for-service Medicare not Medicare Advantage).

Facet Joint Denervation

Chemodenervation was added to the investigational policy statement and sacroiliac joint was removed from the investigational policy statement (there is a separate Protocol for SI joint criteria).

Functional Neuromuscular Electrical Stimulation (NMES)

Cerebral palsy was added to the investigational policy statement for general business.

Genetic Testing for Inherited Disorders

An administrative change was made to the "Related Protocols" section and conditions covered by the guidelines, due to new Protocols having been added that deal with specific conditions which had been previously discussed in this general Protocol.

Hematopoietic Stem-Cell Transplantation for Acute Myeloid Leukemia

Minor change was made to the Policy Guidelines: added "or non-myeloablative conditioning" as the other terminology referred to for reduced-intensity conditioning (RIC) (had been already explained in the Protocol description, the reason this is a minor change).

Hyperbaric Oxygen Pressurization (HBO)

Changes made to the policy statements for general business:

- Bell's palsy added as investigational;
- "Chronic wounds, other than those in patients with diabetes who meet the criteria specified in the medically necessary statement are investigational";
- Crush injuries, reperfusion injury, compartment syndrome added as examples in bullet point on acute traumatic ischemia(a medical necessity indication);
- Correction that acute ischemic stroke is investigational;

For Medicare Advantage, a separate section was added which indicates in addition to the general business criteria, there are four additional medical necessity indications for Medicare Advantage.

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence (formerly Periurethral Bulking Agents for the Treatment of Urinary Incontinence)

The scope of the Protocol was expanded as perianal bulking agents to treat fecal incontinence were added as investigational.

Intensity-Modulated Radiation Therapy (IMRT): Abdomen and Pelvis

Changes made:

- IMRT may be considered medically necessary for all anal cancers;
- IMRT may be considered medically necessary for the treatment of tumors of the abdomen and pelvis when dosimetric planning predicts the volume of small intestine receiving doses > 45 Gy with standard 3-D conformal radiation would result in unacceptable risk of small intestine injury;

- IMRT is investigational for all other uses (see Protocol for complete indications for coverage);
- A paragraph was added to the policy guidelines regarding toxic radiation dose to tissues and definition of a clinically significant decrease in radiation dose;
- The separate policy statement has been removed for Medicare Advantage. (General business policy statement will apply to Medicare Advantage.)

Kidney Transplant
Retransplant after a failed primary transplant may be considered medically necessary.

Lung and Lobar Lung Transplant
A change was made in the lobar lung medical necessity statement: "children and adolescents" changed to "carefully selected patients."

Microprocessor-Controlled Prostheses for the Lower Limb
For Medicare Advantage, medical necessity criteria for the powered and programmable flexion/extension assist control device were added.

MRI-Guided Focused Ultrasound (MRgFUS) (Formerly MRI-Guided Focused Ultrasound [MRgFUS] for the Treatment of Uterine Fibroids and Other Tumors)
The investigational policy statements were reformatted to just one investigational statement.

Negative Pressure Wound Therapy in the Outpatient Setting
For Medicare Advantage: A typographical correction was made by the removal of the reference to "A or B". Also added indications that NPWT might be used for inpatient because, if still needed on discharge, this could also be medically necessary: complications of surgically created wound or traumatic wound where a more accelerated formation of granulation tissue is necessary.

Quantitative Assay for Measurement of HER2 Total Protein Expression and HER2 Dimers
A separate medical necessity policy statement was added for Medicare Advantage.

Total Artificial Hearts and Implantable Ventricular Assist Devices
The medical necessity policy statement for children was amended to change the age range from 5-16 to 0-16 (due to the November 2011 FDA HDE status of the EXCOR pediatric VAD for bridge to transplant).

Transcatheter Arterial Chemoembolization (TACE) to Treat Primary or Metastatic Liver Malignancies
A small change was made to the INR value in the Pugh Scale for two points vs. three points.

Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders
For Medicare Advantage a separate policy statement was added to indicate this is not medically necessary.

Treatment of Varicose Veins/Venous Insufficiency
Changes made:

- Mechanochemical ablation was added as a technique of treatment which is investigational;
- Policy statement on accessory saphenous veins was modified to include isolated incompetence of the accessory saphenous vein as medically necessary;
- Expanded the Medicare Advantage medically necessary criteria.

New Protocols

The effective date of these new Protocols is July 1, 2013, unless otherwise indicated:

BCR-ALB1 Testing for Diagnosis, Monitoring, and Drug Resistance Mutation Detection in Chronic Myelogenous Leukemia (CML)

- This includes medically necessary indications for BCR/ALB 1 for diagnosis (with a policy guideline to explain) and monitoring of treatment response at the specific schedule (per the policy guidelines).
- ABL kinase evaluation is medically necessary when there is disease progression, and investigational in absence of disease progression.
- Preauthorization is required.

Confocal Laser Endomicroscopy

This is investigational and preauthorization is not be required.

Cooling Devices Used in the Outpatient Setting

- Active and passive cooling devices are considered not medically necessary**.**
- Combination active cooling and compression (cryopneumatic) devices are considered investigational.
- Preauthorization is not required.

Genetic Testing for Duchenne and Becker Muscular Dystrophy

- This is medically necessary to establish a diagnosis in a male with clinical signs and symptoms suggestive of a dystrophinopathy and as testing for at-risk female relatives with at-risk females defined in a policy guideline section.
- Preauthorization is required.
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Genetic Testing for PTEN Hamartoma Tumor Syndrome

- This is medically necessary to confirm a diagnosis in a patient with signs of PHTS and in first degree relatives of a proband with a known PTEN mutation.
- It is investigational for all other indications, including, but not limited to, prenatal testing.
- Preauthorization is required.

Intraoperative Neurophysiologic Monitoring (sensory-evoked potentials, motor-evoked potentials, EEG monitoring), effective October 1, 2013**:**

- Visual-evoked potential and motor-evoked using transcranial magnetic stimulation are investigational;
- Intraoperative EMG and nerve conduction velocity monitoring on peripheral nerves are not medically necessary;
- Intraoperative monitoring including somatosensory-evoked potentials, motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, EMG of cranial nerves, EEG and electrocorticography may be medically necessary during spinal, intracranial, or vascular procedures;
- Preauthorization is not required.

Laboratory Tests for Heart Transplant Rejection

- The Heartsbreath test and evaluation of genetic expression in peripheral blood are investigational.
- Preauthorization is not required.

Microwave Tumor Ablation

- This is investigational for primary and metastatic tumors.
- Preauthorization is not required.

Monitored Anesthesia Care (MAC)
This Protocol documents a policy we have been following for several years, and was in the past communicated in two STAT Bulletins. It also includes several changes now to the medical necessity risk factors:

- Severe sleep apnea was changed to "documented sleep apnea;"
- Extreme age is now considered as "patients younger than 18 years or 70 years or older;"
- Preauthorization continues to be required by the physician performing the therapeutic or diagnostic procedure.

Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis

- This is medically necessary post op for major orthopedic or other major surgeries based on the member risk for DVT and whether they have a contraindication for drugs that might be needed to prevent DVT.
- It is investigational after other surgeries and not medically necessary after 30 days.
- Preauthorization is not required.

Sequencing-based Tests to Determine Trisomy 21 from Maternal Plasma DNA

- This is medically necessary for women with high-risk singleton pregnancies as defined in a policy guidelines section and combined with karyotyping (in positive results), not medically necessary for average risk singleton pregnancies, and investigational in twin and multiple pregnancies.
- Preauthorization is required.

Clinical Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Allogeneic Pancreas Transplant
- Allogeneic Stem-Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms
- Arthroscopic Debridement and Lavage as Treatment for Osteoarthritis of the Knee
- Artificial Intervertebral Disc: Cervical Spine
- Automated Ambulatory Blood Pressure Monitoring for the Diagnosis of Hypertension in Patients with Elevated Office Blood Pressure
- Bariatric Surgery
- Biofeedback as a Treatment of Chronic Pain
- Biofeedback as a Treatment of Headache
- Bone Morphogenetic Protein
- Catheter Ablation for Cardiac Arrhythmias
- Catheter Ablation of the Pulmonary Veins as Treatment for Atrial Fibrillation
- Charged-Particle (Proton or Helium Ion) Radiation Therapy
- Chelation Therapy
- Chromosomal Microarray (CMA) Analysis for the Genetic Evaluation of Patients with Developmental Delay/Intellectual Disability or Autism Spectrum Disorder
- Closure Devices for Patent Foramen Ovale and Atrial Septal Defects
- Cochlear Implant
- Cognitive Rehabilitation
- Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure
- Deep Brain Stimulation
- Dermatologic Applications of Photodynamic Therapy
- Diagnosis and Treatment of Chronic Cerebrospinal Venous Insufficiency in Multiple Sclerosis

- Dynamic Spinal Visualization
- Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures
- End-Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema
- Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus
- Epidermal Growth Factor Receptor (EGFR) Mutation Analysis for Patients with Non-Small Cell Lung Cancer (NSCLC)
- Extracranial Carotid Angioplasty/Stenting
- Fetal Surgery for Prenatally Diagnosed Malformations
- Gait Analysis
- Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer
- Genetic Testing for Congenital Long QT Syndrome
- Genetic Testing for Familial Alzheimer's Disease
- Genetic Testing for Predisposition to Inherited Hypertrophic Cardiomyopathy
- Hematopoietic Stem-Cell Transplantation for Acute Lymphoblastic Leukemia
- Hematopoietic Stem-Cell Transplantation for Breast Cancer
- Hematopoietic Stem-Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma
- Hematopoietic Stem-Cell Transplantation for Chronic Myelogenous Leukemia
- Hematopoietic Stem-Cell Transplantation for Multiple Myeloma
- Hematopoietic Stem-Cell Transplantation for Non-Hodgkin Lymphomas
- Hematopoietic Stem-Cell Transplantation for Solid Tumors of Childhood
- Hematopoietic Stem-Cell Transplantation in the Treatment of Germ-Cell Tumors
- Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas or Metastasis to the Brain
- Islet Transplantation
- KRAS and BRAF Mutation Analysis in Metastatic Colorectal Cancer
- KRAS Mutation Analysis in Non-Small Cell Lung Cancer (NSCLC)
- Laboratory Testing for HIV Tropism
- Low-Density Lipid Apheresis
- Manipulation under Anesthesia
- Measurement of Exhaled Nitric Oxide and Exhaled Breath Condensate in the Diagnosis and Management of Asthma and Other Respiratory Disorders
- Mechanical Embolectomy for Treatment of Acute Stroke
- Nerve Graft in Association with Radical Prostatectomy
- Oncologic Applications of Photodynamic Therapy, Including Barrett's Esophagus
- Open and Thoracoscopic Approaches to Treat Atrial Fibrillation (Maze and Related Procedures)
- Optical Coherence Tomography for Imaging of Coronary Arteries
- Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders
- Outpatient Pulmonary Rehabilitation
- Pelvic Floor Stimulation as a Treatment of Urinary Incontinence
- Percutaneous Electrical Nerve Stimulation (PENS) or Percutaneous Neuromodulation Therapy (PNT)
- Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines
- Plasma Exchange
- Real-Time Intra-Fraction Target Tracking During Radiation Therapy
- Routine Services for Qualifying Clinical Trials
- Scintimammography/Breast-Specific Gamma Imaging/Molecular Breast Imaging

- Small Bowel/Liver and Multivisceral Transplant
- Spinal Cord Stimulation
- Surgical Interruption of Pelvic Nerve Pathways for Primary and Secondary Dysmenorrhea
- Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome
- Surgical Ventricular Restoration
- Technology Assessment
- Thermography
- Transanal Radiofrequency Treatment of Fecal Incontinence
- Vertebral Axial Decompression
- Vertebral Fracture Assessment with Densitometry

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.