Protocol

Medical Services Protocol Updates

Distribution Date: **June 1, 2017**

The following update includes information on protocols that have undergone a review over the last several months, or an additional review in order to make changes. An 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 Three new protocols have been added and two have been archived.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 to whom you provide care.

Protocol Revision Summary

The effective date of these changes is July 1, 2017:

Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

Changes:

- The medically necessary policy statement, addressing the use of continuous ambulatory monitors that record and store information for periods longer than 48 hours as a diagnostic alternative to Holter monitoring or patient-activated or auto-activated external ambulatory event monitors, has been eliminated. A second medically necessary policy statement has been adjusted to include this information;
- One of the criteria in the medically necessary policy statement addressing the use of implantable ambulatory event monitors, either patient activated or auto-activated, has been clarified. It now states, "In patients who require long-term monitoring for atrial fibrillation or possible atrial fibrillation" in place of "in patients with cryptogenic stroke who have had a negative standard work-up for atrial fibrillation including a 24-hour Holter monitor."

Bioengineered Skin and Soft Tissue Substitutes

Changes:

- This protocol has been revised so that content addressing amniotic membrane products has been removed to a separate new protocol, *Amniotic Membrane and Amniotic Fluid;*
- The medically necessary policy statement addressing treatment of chronic, noninfected, full-thickness diabetic lower extremity ulcers was edited to add AlloPatch®;
- The investigational policy statement has been edited with multiple additions and deletions of pertinent products.

Charged-Particle (Proton or Helium Ion) Radiotherapy

Change:

- Title change to *Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions*.

Medicare Advantage changes:

- A new Medicare Advantage section was added with one medically necessary policy statement for the use of proton beam therapy in instances where sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiotherapy and is of added clinical benefit to the patient;
- A Medicare Advantage Policy Guidelines section provides additional guidance regarding disease sites that support the use of proton beam therapy.

Cytochrome P450 Genotyping
Medicare Advantage change:

- One medically necessary policy statement with criteria was added addressing once-per-lifetime CYP2C619 genotyping.

Genetic Testing for Breast Cancer Gene Expression Prognosis Assay
Medicare Advantage changes:

- Three new medically necessary statements with criteria have been added addressing PROSIGNA®, Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, and the Oncotype DX DCIS assay;
- An investigational policy statement addressing BCI use in newly diagnosed breast cancer patients has been removed;
- Oncotype DX® Breast and the MammaPrint™ tests have been added to a medically necessary policy statement.

Genetic Testing for Developmental Delay and Autism Spectrum Disorder
Change:

- The following patient populations have been added under the policy statement addressing genetic testing for FMR1 mutations that may be considered medically necessary: women with primary ovarian failure under the age of 40 in whom fragile X-associated ovarian failure is suspected and individuals with neurologic symptoms consistent with fragile X-associated tremor/ataxia syndrome.

Genetic Testing for Hereditary Breast and Ovarian Cancer Syndrome
Change:

- One investigational policy statement was expanded to include testing for ataxia telangiectasia mutated (ATM) gene abnormalities.

Intensity-Modulated Radiotherapy: Central Nervous System Tumors
Change:

- The position of the not medically necessary policy statement, addressing intensity-modulated radiotherapy for the treatment of tumors of the central nervous system for all indications not meeting the criteria, was changed to investigational.

KRAS, NRAS, and BRAF Mutation Analysis in Metastatic Colorectal Cancer
Medicare Advantage changes:

- One criterion from the medically necessary policy statement, addressing Kirsten rat sarcoma (KRAS) viral oncogene homolog (e.g., carcinoma) gene analysis; additional variant(s) (e.g., codon 61, codon 146), was deleted;
- A new medically necessary policy statement was added addressing BRAF gene analysis in patients with metastatic colorectal cancer when needed to determine if a Medicare approved therapy is a reasonable option given the individual's specific clinical presentation.

Stereotactic Radiosurgery and Stereotactic Body Radiotherapy
Medicare Advantage changes:

- One medically necessary policy statement with criteria, addressing stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT) for treatment of cranial lesions, was added;
- One medically necessary policy statement with criteria, addressing SRS and SBRT for treatment of tumors of other sites, was added;

- Two not medically necessary policy statements provide further guidance on limitations for SBRT and SRS/SBRT for cranial lesions.

New Protocols

The effective date of these new protocols is July 1, 2017:

Amniotic Membrane and Amniotic Fluid

- There is one medically necessary policy statement addressing treatment of nonhealing diabetic lower-extremity ulcers using human amniotic membrane products (AmnioBand® Membrane, Biovance®, Epifix®, Grafix™);
- There are three investigational policy statements which address injection of micronized or particulated human amniotic membrane, injection of human amniotic fluid, and all other human amniotic membrane products and indications not listed;
- Preauthorization is required.

Prostatic Urethral Lift

- Under general business there is one investigational policy statement for all indications;
- Under Medicare Advantage there are two medically necessary policy statements with criteria addressing prostatic urethral lift procedures;
- This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders

- There is one medically necessary policy statement with criteria addressing whole exome sequencing (WES) for the evaluation of unexplained congenital or neurodevelopmental disorders in children;
- There are three investigational policy statements addressing WES for the diagnosis of genetic disorders in all other situations, whole genome sequencing (WGS) for the diagnosis of genetic disorders and WES and WGS for screening for genetic disorders;
- This protocol considers this test or procedure to have investigational applications. If the physician feels this service is medically necessary for these applications, preauthorization is recommended.

Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms (Formerly Allogeneic Hematopoietic Stem Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms)
- Allogeneic Pancreas Transplant
- Antigen Leukocyte Antibody Test
- Artificial Pancreas Device Systems
- Automated Ambulatory Blood Pressure Monitoring for the Diagnosis of Hypertension in Patients With Elevated Office Blood Pressure
- Biofeedback as a Treatment of Chronic Pain
- Biofeedback as a Treatment of Fecal Incontinence or Constipation
- Blepharoplasty
- Cardiac Rehabilitation in the Outpatient Setting

- Catheter Ablation for Cardiac Arrhythmias
- Computed Tomography Perfusion Imaging of the Brain
- Confocal Laser Endomicroscopy
- Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid
- Cosmetic vs. Reconstructive Surgery or Services
- Cytoreductive Surgery and Perioperative Intraperitoneal Chemotherapy for Select Intra-Abdominal and Pelvic Malignancies
- Deep Brain Stimulation
- Dermatologic Applications of Photodynamic Therapy
- Dynamic Spinal Visualization
- Electrostimulation and Electromagnetic Therapy for Treating Wounds
- Endovascular Therapies for Extracranial Vertebral Artery Disease
- Functional Neuromuscular Electrical Stimulation
- Gender Reassignment Surgery
- Genetic Testing for Alzheimer Disease
- Genetic Testing for Hereditary Hemochromatosis
- Genetic Testing for Marfan Syndrome, Thoracic Aortic Aneurysms and Dissections, and Related Disorders
- Genetic Testing for Predisposition to Inherited Hypertrophic Cardiomyopathy
- Hematopoietic Cell Transplantation for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
- Hematopoietic Cell Transplantation for Chronic Myelogenous Leukemia (Formerly Hematopoietic Stem Cell Transplantation for Chronic Myelogenous Leukemia)
- Hematopoietic Stem Cell Transplantation for Acute Myeloid Leukemia
- Hematopoietic Stem Cell Transplantation for Non-Hodgkin Lymphomas
- Hyperbaric Oxygen Therapy
- Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
- Intensity-Modulated Radiotherapy: Abdomen and Pelvis
- Intensity-Modulated Radiotherapy: Cancer of the Head and Neck or Thyroid
- Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas (Formerly Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas or Metastasis to the Brain)
- Islet Transplantation
- Isolated Small Bowel Transplant
- Kidney Transplant
- Light Therapy for Psoriasis
- Liver Transplant
- Lung and Lobar Lung Transplant
- Manipulation Under Anesthesia
- Measurement of Exhaled Nitric Oxide and Exhaled Breath Condensate in the Diagnosis and Management of Respiratory Disorders (Formerly Measurement of Exhaled Nitric Oxide and Exhaled Breath Condensate in the Diagnosis and Management of Asthma and Other Respiratory Disorders)
- Measurement of Serum Antibodies to Infliximab and Adalimumab
- Negative Pressure Wound Therapy in the Outpatient Setting
- Nerve Graft With Radical Prostatectomy (Formerly Nerve Graft in Association With Radical Prostatectomy)
- Neurofeedback
- Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease
- Optical Coherence Tomography of the Anterior Eye Segment

- Orthognathic Surgery
- Outpatient Pulmonary Rehabilitation
- Panniculectomy and Abdominoplasty
- Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
- Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy
- Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation
- Pharmacogenetic Testing for Pain Management
- Placental and Umbilical Cord Blood as a Source of Stem Cells
- Plugs for Anal Fistula Repair
- Small Bowel/Liver and Multivisceral Transplant
- Technology Assessment
- Total Artificial Hearts and Implantable Ventricular Assist Devices
- Transanal Radiofrequency Treatment of Fecal Incontinence
- Transcatheter Arterial Chemoembolization to Treat Primary or Metastatic Liver Malignancies
- Treatment of Varicose Veins/Venous Insufficiency
- Vertebral Axial Decompression
- Wearable Cardioverter Defibrillators

Deleted Protocols

Effective immediately, the following protocols are archived (unless otherwise noted):

- Diagnosis and Treatment of Chronic Cerebrospinal Venous Insufficiency in Multiple Sclerosis
- Quantitative Assay for Measurement of HER2 Total Protein Expression and HER2 Dimers (archived effective July 1, 2017)

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