Protocol

Medical Services Protocol Updates

Distribution Date: **June 1, 2018**

The following medical protocol update includes information on protocols that have undergone an annual review over the last several months, 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. Two new protocols have been added and none have been archived.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, 2018:

Amniotic Membrane and Amniotic Fluid

Changes:

- A medically necessary policy statement was added addressing sutured human amniotic membrane grafts for the treatment of specifically named ophthalmic indications;
- An investigational policy statement was added addressing sutured human amniotic membrane grafts for the treatment of all other ophthalmic conditions;
- An investigational policy statement was added addressing human amniotic membrane without suture, e.g., Prokera®, AmbioDisk™, for ophthalmic indications;
- Two existing policy statements were changed to include examples of conditions for which some products are considered investigational.

Artificial Pancreas Device Systems

Changes:

- The criteria were updated in the medically necessary policy statement addressing use of a U.S. Food and Drug Administration-approved artificial pancreas device system with a low glucose suspend feature in patients with type 1 diabetes;
- The investigational policy statement addressing the use of hybrid closed-loop insulin delivery system as an artificial pancreas device system was clarified;
- Pertinent information addressing considerations for the appropriate use of these devices was added to the policy guidelines.

Bioengineered Skin and Soft Tissue Substitutes

Changes:

- DermACELL® and FlexHD® Pliable™ were added as allogeneic acellular dermal matrix products that are considered medically necessary for use in breast reconstructive surgery when criteria are met;
- Integra® Flowable Wound Matrix was added as a tissue-engineered skin substitute that is considered medically necessary for treatment of chronic, noninfected, full-thickness diabetic lower-extremity ulcers;
- Three products have been removed from the list of skin and soft tissue substitutes that are investigational.

Cardiac Rehabilitation in the Outpatient Setting
Change:

- One investigational policy statement was added addressing Intensive cardiac rehabilitation with the Ornish program for reversing heart disease or Pritikin program.

Deep Brain Stimulation
Change:

- The criteria have been expanded in the medically necessary policy statement addressing unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus.

Diagnosis and Treatment of Sacroiliac Joint Pain
Changes:

- A medically necessary policy statement with criteria addressing minimally invasive fusion/stabilization of the sacroiliac joint using a triangular titanium implant was added;
- The investigational policy statement was adjusted for this change**.**

Gender Reassignment Surgery
Changes:

- Twelve months of continuous hormonal therapy is recommended prior to specific listed genital surgeries;
- The time frame (two years) for an existing diagnosis of gender dysphoria has been removed in favor of a *persistent and well documented diagnosis*;
- One (not two) letter of recommendation is required for breast/chest surgery;
- Twelve months of successful continuous full-time living in the social role congruent with the desired gender is required only prior to specific listed genital surgeries;
- One procedure has been added as medically necessary for female-to-male sex reassignment surgical procedures.

Genetic Testing for Marfan Syndrome, Thoracic Aortic Aneurysms and Dissections, and Related Disorders
Medicare Advantage Change:

- A not medically necessary policy statement was added addressing the aortic dysfunction or dilation genomic sequence analysis panel and the duplication/deletion analysis panel.

Hyperbaric Oxygen Therapy
Medicare Advantage change**:**

- One criterion under the medically necessary policy statement was amended so that osteoradionecrosis should be an adjunct to conventional treatment, but is no longer limited to osteonecrosis of the jaw with evidence of overt bony fracture or bony reabsorption.

KRAS, NRAS, and BRAF Mutation Analysis in Metastatic Colorectal Cancer
Changes:

- The title has been changed to KRAS, NRAS, and BRAF Variant Analysis in Metastatic Colorectal Cancer;
- The policy position for BRAF variant analysis has been changed to medically necessary for patients with metastatic colorectal cancer who are found to be wild-type on KRAS and NRAS variant analysis to guide management decisions.

Liver Transplant
Changes:

- The title was changed to Liver Transplant and Combined Liver-Kidney Transplant;
- A medically necessary policy statement was added addressing combined liver-kidney transplantation in patients who qualify for liver transplantation and have advanced irreversible kidney disease.

Molecular Markers in Fine Needle Aspirates of the Thyroid
Changes:

- ThyroSeq v2 was added to the medically necessary policy statement with criteria for use in fine-needle aspirates of thyroid nodules with indeterminate cytologic findings;
- A medically necessary policy statement was added listing four molecular marker tests or gene expression classifiers for use with fine-needle aspirates of thyroid nodules with indeterminate or suspicious findings to rule in malignancy and guide surgical planning;
- An investigational policy statement addressing mutation analysis in fine-needle aspirates of the thyroid was added.

Negative Pressure Wound Therapy in the Outpatient Setting
Medicare Advantage Change:

- Two indications were added to the not medically necessary policy statement addressing a negative pressure wound therapy pump and supplies: stage I or II pressure ulcers and active bleeding.

Transcatheter Arterial Chemoembolization to Treat Primary or Metastatic Liver Malignancies
Changes:

- The medically necessary policy statement addressing transcatheter hepatic arterial chemoembolization of the liver has been clarified for treatment of hepatocellular cancer that is unresectable but confined to the liver and not associated with portal vein thrombosis so that *liver function is not characterized as Child-Pugh class C;*
- The medically necessary policy statement addressing transcatheter hepatic arterial chemoembolization of the liver has been clarified for treatment of liver metastasis in symptomatic patients with metastatic neuroendocrine tumors whose symptoms persist despite *systemic therapy and who are not candidates for surgical resection.*

Treatment of Varicose Veins/Venous Insufficiency
Medicare Advantage Changes:

- A medically necessary policy statement addresses acceptable treatments for eliminating saphenous reflux. Sclerotherapy and ligation with or without stripping are no longer included;
- A second medically necessary policy statement addresses treatments for symptomatic varicose tributaries;
- The medically necessary policy statement addressing endovenous ablation therapy has been revised, changing the maximum vein diameter from 20mm to 12mm;
- There are two additions to the not medically necessary policy statement.

New Protocols

The effective date of these new protocols is July 1, 2018:

Bioimpedance Devices for Detection and Management of Lymphedema

- There is one investigational policy statement addressing devices using bioimpedance (bioelectrical impedance spectroscopy) for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema;
- *This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.*

Light Therapy for Vitiligo

- There is one medically necessary policy statement addressing psoralen plus ultraviolet A for the treatment of vitiligo that is not responsive to other forms of conservative therapy, e.g., topical corticosteroids, coal/tar preparations, ultraviolet light;
- There is one medically necessary policy statement addressing narrow-band ultraviolet B (UVB) for the treatment of vitiligo that is not responsive to other forms of conservative therapy, e.g., topical corticosteroids, coal/tar preparations;
- There is one investigational policy statement addressing targeted phototherapy using methods other than UVB for the treatment of vitiligo;
- *Preauthorization is required.*

Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms
- Allogeneic Pancreas Transplant
- Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry
- Antigen Leukocyte Antibody Test
- Automated Ambulatory Blood Pressure Monitoring for 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
- Catheter Ablation for Cardiac Arrhythmias
- Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions
- Computed Tomography Perfusion Imaging of the Brain
- Confocal Laser Endomicroscopy
- Cosmetic vs. Reconstructive Surgery or Services
- Cytochrome P450 Genotyping
- Cytoreductive Surgery and Perioperative Intraperitoneal Chemotherapy for Select Intra-Abdominal and Pelvic Malignancies
- 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

- Genetic Testing for Alzheimer Disease
- Genetic Testing for Hereditary Hemochromatosis
- Genetic Testing for Predisposition to Inherited Hypertrophic Cardiomyopathy
- Hematopoietic Cell Transplantation for Acute Myeloid Leukemia (Formerly Hematopoietic Stem Cell Transplantation for Acute Myeloid Leukemia)
- Hematopoietic Cell Transplantation for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
- Hematopoietic Cell Transplantation for Chronic Myeloid Leukemia
- Hematopoietic Cell Transplantation for Non-Hodgkin Lymphomas (Formerly Hematopoietic Stem Cell Transplantation for Non-Hodgkin Lymphomas)
- 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
- Intensity-Modulated Radiotherapy: Central Nervous System Tumors
- Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas
- Islet Transplantation
- Isolated Small Bowel Transplant
- Kidney Transplant
- Light Therapy for Psoriasis
- 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
- Measurement of Serum Antibodies to Infliximab and Adalimumab
- Nerve Graft With Radical Prostatectomy
- Neurofeedback
- Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease
- Optical Coherence Tomography of the Anterior Eye Segment
- Outpatient Pulmonary Rehabilitation
- Panniculectomy and Abdominoplasty
- 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
- Stereotactic Radiosurgery and Stereotactic Body Radiotherapy
- Technology Assessment
- Total Artificial Hearts and Implantable Ventricular Assist Devices
- Transanal Radiofrequency Treatment of Fecal Incontinence
- Vertebral Axial Decompression
- Wearable Cardioverter Defibrillators
- Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders

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.