Protocol

Medical Services Protocol Updates

Distribution Date: **December 1, 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. Two new protocols have been added and two have been archived.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 January 1, 2015 unless otherwise indicated:

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

Changes:

- New medical necessity statement added for monitoring of patients with cryptogenic stroke.
- Investigational statement changed on continuous ambulatory monitors from "longer than 72 hours" to "longer than 48 hours."

For Medicare Advantage:

- No change to policy statements.

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

Changes:

For General Business:

- Investigational policy statement was updated to include newer assays BreastPRS, EndoPredict™, BluePrint®, and TargetPrint®.
- PAM20 was changed to Prosigna™.
- Policy statement was added that the use of gene expression assays in men with breast cancer is considered investigational.

For Medicare Advantage:

- No change.

Chelation Therapy for Off-Label Uses (formerly Chelation Therapy)

Changes:

- Title changed to include off-label uses.
- Medical necessity policy statement for on-label uses was deleted from policy statement section and moved to a new policy guidelines section.
- Information about toxic and normal heavy metal levels was added to the policy guidelines; the investigational policy statement is unchanged.

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Editorial/administrative changes:

- Order reversed for criteria with home sleep study discussed first, then lab polysomnography.
- Removed preauthorization requirement for home sleep studies for Medicare Advantage.
- Removed reference to Medicaid Managed Care in the preauthorization statement.

This protocol version is already posted on website, effective October 1, 2014.

Endovascular Grafts for Abdominal Aortic Aneurysms

Changes:

- Policy statement updated to clarify that situations not meeting the criteria in the first medical necessity policy statement would be considered investigational.
- Separate Medicare policy (coverage criteria) no longer exists; therefore, separate Medicare Advantage section removed from our protocol.

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Changes:

For General Business:

- The policy statement was updated to include a statement that intracranial flow diverting stents may be medically necessary for aneurysms meeting criteria.
- "Policy Guidelines" section was added stating that this policy addresses only intracranial endovascular interventions and includes anatomic criteria that intracranial aneurysms need to meet in order for endovascular treatment to be considered medically necessary.

For Medicare Advantage:

- No change.

Extracorporeal Photopheresis

Changes:

- New medical necessity policy statement added for extracorporeal photopheresis in refractory acute graft-versus-host disease.
- For autoimmune diseases, investigational policy statement updated to include severe atopic dermatitis and Crohn's disease.
- Policy guidelines clarified regarding organ rejection after solid organ transplant vs. graft-versus-host-disease.

Separate Medicare Advantage criteria remains unchanged.

General Approach to Evaluating the Utility of Genetic Panels

Changes:

- Revisions made to "Criteria to be used in evaluating genetic panels."
- Medicare Advantage, general policy statement, that services are eligible for only members personally afflicted with a condition for which this information may be used to determine their treatment plan.

General Approach to Genetic Testing

Changes:

- Policy Guidelines section was revised. Two diseases from the medical necessity list were removed because there are separate policies addressing them:
  - testing for hereditary pancreatitis is investigational
  - testing thalassemias is not medically necessary
- Medicare Advantage there is a general policy statement about services being eligible for only members personally afflicted with a condition, for which this information may be used to determine their treatment plan.

Genetic Testing for FMR1 Mutations (Including Fragile X Syndrome)
Changes:

- Terminology was updated to reflect current DSM-V diagnostic categories, i.e., "intellectual disability" replaces "mental retardation."
- Policy statement on testing relatives of affected individuals reworded for clarity.

Genetic Testing for Hereditary Hearing Loss (Formerly Genetic Testing for Nonsyndromic Hearing Loss)
Changes:

- The policy title and policy statements were changed to refer to "hereditary hearing loss" (from "nonsyndromic hearing loss").

Genetic Testing for Hereditary Hemochromatosis
Changes were made in the Policy Guidelines:

- In second bullet, inflammatory states were defined.
- Iron studies were clarified to mean serum ferritin and transferrin saturation.

Genetic Testing for Mental Health Conditions
Change in preauthorization process, will no longer be done through behavioral health vendor.

Isolated Small Bowel Transplant
Change for General Business:

- Pediatric patients were added to the investigational (all other situations for living donors) policy statement on patients with intestinal failure who are able to tolerate TPN.

Kidney Transplant
Changes:

- Change made to the medical necessity policy statements to include that re-transplant after a failed transplant may be medically necessary "in patients who meet criteria for a kidney transplantation."
- A policy statement was added that kidney transplant is considered investigational in all other situations.
- Covered conditions associated with end-stage renal disease were moved to the Policy Guidelines section.

Lung Volume Reduction Surgery for Severe Emphysema
Changes:

- Editorial changes were made such as FEV-1 changed to FEV1, or "greater than or equal to 15%" changed to "15% or more," etc.
- No change to the Medicare Advantage medically necessary, not medically necessary, and investigational policy statements.

Noninvasive Prenatal Testing for Trisomy 21 Using Cell-Free Fetal DNA (Formerly Sequencing-Based Tests to Determine Trisomy 21 from Maternal Plasma DNA)
Title changed from Sequencing-Based Tests to Determine Trisomy 21 from Maternal Plasma DNA.

Occlusion of Uterine Arteries Using Transcatheter Embolization
Change:

- Uterine arteriovenous malformation added to investigational policy statement.

Open and Thoracoscopic Approaches to Treat Atrial Fibrillation (Maze and Related Procedures)
Change to the second investigational policy statement: "drug resistant" removed.

Pharmacogenomic and Metabolite Markers for Patients Treated With Thiopurines
Change:

- A statement was added that genotypic and/or phenotypic analysis of the enzyme TPMT is considered investigational in all other situations.

Radiofrequency Ablation of Primary or Metastatic Liver Tumors
Change:

- In the policy guidelines, the second statement was clarified from "…should also not be candidates for liver transplantation" to "…should also not be candidates for liver transplantation unless RFA is used as a bridge to transplant."

Sacral Nerve Neuromodulation/Stimulation
Changes:

- First medically necessary statement on fecal incontinence, clarified length of time after surgery trial stimulation can take place.
- Overactive bladder was added to the medically necessary diagnoses.
- Policy Guidelines section added with a definition of overactive bladder syndrome.

Saturation Biopsy for Diagnosis and Staging of Prostate Cancer
Changes:

- "Taking more than 20 core tissue samples at one time" was removed from the policy statement.
- A policy guidelines section was added containing a saturation biopsy definition.

Temporomandibular Joint Dysfunction
Change:

- Due to medical management of hyaluronic acid now, use of hyaluronic acid for TMJ has been included in the protocol as investigational.

No change to the separate Medicare Advantage non-covered and medically necessary policy statements.

Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders
Changes:

- Addition of a Medicare Advantage medical necessity policy statement with medically necessary indications for confirmed diagnosis of major depressive disorder (MDD), single or recurrent episode, delivered by a device that is FDA-approved or – cleared for the treatment of MDD and meets specified criteria such as refractory to pharmacologic management, etc.
- Effective date retroactive to Medicare effective date of August 15, 2014; this date is being applied for all lines of business.
- Preauthorization is required (through the behavioral health services vendor).

Transmyocardial Revascularization
Change:

- Policy statement added indicating open transmyocardial revascularization is considered investigational for all other indications not meeting the medical necessity criteria

No change to the separate Medicare Advantage statement.

Use of Common Genetic Variants (single nucleotide polymorphisms) to Predict Risk of Nonfamilial Breast Cancer (formerly Use of Common Genetic Variants to Predict Risk of Nonfamilial Breast Cancer and Non-BRCA Breast Cancer Risk Assessment [e.g., OncoVue])
Change:

- Investigational policy statement added: OncoVue® and BREVAGen™ are investigational for all indications.

Vagus Nerve Stimulation
Changes:

For General Business:

- The policy statement was updated to include the addition of tinnitus and traumatic brain injury to the list of investigational conditions.
- A policy statement was added that non implantable vagus nerve stimulation devices are considered investigational for all indications.

For Medicare Advantage:

- No change.

Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon
Changes to policy statement:

- Portal hypertensive enteropathy and unexplained chronic abdominal pain added to the investigational policy statement.
- Statement added indicating wireless capsule endoscopy may be medically necessary in patients with established diagnosis of Crohn's disease for unexpected change(s) in the course of disease or response to treatment suggesting the initial diagnosis may be incorrect and re-examination may be indicated.

New Protocols

The effective date of these new protocols is January 1, 2015.

Chromosomal Microarray Testing for the Evaluation of Early Pregnancy Loss
This is considered investigational;

- Protocol description explains that current practice in recurrent pregnancy (early) is karyotyping of metaphase cells after cells from the products of conception are cultured in tissue, although this approach has limitations, so CMA is being evaluated; however there are no studies that identify how patient management is changed by using CMA, nor have studies shown that patient outcomes are improved.
- Services are reviewed upon claim submission.

Dopamine Transporter Imaging with Single-Photon Emission Computed Tomography (DAT-SPECT)

- DAT-SPECT is investigational for all indications, including but not limited to, aiding in the diagnosis of patients with clinically uncertain Parkinsonian syndromes, essential tremor, or dementia with Lewy bodies, and for the monitoring of disease progression.

Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Ambulance (Emergency)
- Biofeedback as a Treatment of Urinary Incontinence in Adults

- Blepharoplasty
- Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure
- Continuous Passive Motion in the Home Setting
- Cosmetic vs. Reconstructive Surgery or Services
- Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors
- Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)
- Diagnosis and Management of Idiopathic Environmental Intolerance (i.e., Multiple Chemical Sensitivities)
- Diagnosis and Treatment of Chronic Cerebrospinal Venous Insufficiency in Multiple Sclerosis
- Diagnosis and Treatment of Sacroiliac Joint Pain
- DNA-Based Testing for Adolescent Idiopathic Scoliosis
- Endometrial Ablation
- Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus
- Facet Arthroplasty
- Genetic Cancer Susceptibility Panels Using Next Generation Sequencing
- Genetic Testing for Alpha-1 Antitrypsin Deficiency
- Genetic Testing for Inherited Thombophilia
- Genetic Testing for Rett Syndrome
- Genetic Testing for Statin-Induced Myopathy
- Genetic Testing for the Diagnosis of Inherited Peripheral Neuropathies
- Hematopoietic Stem-Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome
- Home Prothrombin Time Monitoring
- In Vitro Chemoresistance and Chemosensitivity Assays
- Intradialytic Parenteral Nutrition
- Meniscal Allografts and Other Meniscal Implants (Formerly Meniscal Allografts and Other Meniscus Implants)
- Neurofeedback
- Orthognathic Surgery
- Percutaneous Intradiscal Electrothermal Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty
- Photodynamic Therapy for Choroidal Neovascularization
- Preimplantation Genetic Testing
- Prolotherapy
- Reconstructive Breast Surgery/Management of Breast Implants
- Semi-Implantable and Fully Implantable Middle Ear Hearing Aids
- Treatment of Hyperhidrosis
- Treatment of Tinnitus
- Urinary Tumor Markers for Bladder Cancer
- Wireless Pressure Sensors in Endovascular Aneurysm Repair

Deleted Protocols

Effective immediately, the following protocol is archived:

- Total Ankle Replacement

Effective January 1, 2015, the following protocol is archived:

- Non-BRCA Breast Cancer Risk Assessment (e.g., OncoVue)

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.