Protocol

Medical Services Protocol Updates

Distribution Date: **March 2, 2015**

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. Nine new protocols have been added and four have been archived.

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

Protocol Revision Summary

The effective date of these changes is April 1, 2015, unless otherwise indicated:

Analysis of Human DNA in Stool Samples as a Technique for Colorectal Cancer Screening

Change:

- For Medicare Advantage: A new Medicare national coverage determination (NCD) was effective as of November 3, 2014; a statement was added to the protocol that Medicare Advantage will cover the Cologuard test when specific criteria are met. No local coverage determination (LCD).

Aqueous Shunts and Stents for Glaucoma

Change:

- Medicare Advantage section removed from protocol, as separate Medicare coverage criteria no longer exists.

Balloon Ostial Dilation for Treatment of Chronic Sinusitis

Change:

- Trademark name removed from investigational policy statement.

Bariatric Surgery

Changes:

- Policy statement changed to read that bariatric surgery in patients with a body mass index (BMI) of less than 35 kg/m^2 is considered not medically necessary (previously investigational);
- The previously existing investigational policy statement was expanded with examples of endoscopic procedures considered investigational as a primary or revision procedure, as well as the addition of laparoscopic gastric plication to the list of bariatric surgery procedures considered investigational for the treatment of morbid obesity in adults who have failed weight loss by conservative measures;
- Additional medically necessary and investigational policy statements were added to provide criteria regarding concomitant hiatal hernia repair with bariatric surgery.

BCR-ABL1 Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia

Administrative change:

- Language added to Policy Guidelines to clarify the timing of testing in patients who are responding to treatment or who have a complete cytogenetic response.
- The effective date of this protocol is unchanged.

Gene Expression-Based Assays for Cancers of Unknown Primary
Changes:

- Title change from Microarray-Based Gene Expression Testing for Cancers of Unknown Primary;
- For Medicare Advantage: Medicare LCD is effective in states where the testing is exclusively performed, therefore the following tests are medically necessary for Medicare Advantage members: Cancer TYPE ID developed by bioTheranostics©, and Tissue of Origin developed by Pathwork®.

Genetic Testing for Mental Health Conditions
Change:

- For Medicare Advantage: Medicare LCD criteria became available October 24, 2014. The Medicare Advantage medically necessary statement will provide coverage when specific criteria are met. A Medicare LCD is effective in the state where the testing is exclusively performed, therefore the following test is medically necessary for Medicare Advantage members: GeneSight® Psychotropic (Assurex Health, Inc., Mason, OH).

Genetic Testing of CADASIL Syndrome
Change:

- The word "and" was added between the two bullets in the policy statement to clarify that both conditions should be met for the testing to be medically necessary.

Genetic Testing, Including Chromosomal Microarray Analysis and Next-Generation Sequencing Panels for the Evaluation of Developmental Delay/Intellectual Disability, Autism Spectrum Disorder, and/or Congenital Anomalies
Changes:

- Title change from Genetic Testing, Including Chromosomal Microarray Analysis and Next-Generation Sequencing Panels, for the Evaluation of Children with Developmental Delay/Intellectual Disability or Autism Spectrum Disorder. Prenatal testing has been removed from the title;
- The investigational policy statement regarding prenatal testing has been removed from this protocol.

Intra-Articular Hyaluronan Injections for Osteoarthritis
Change:

- One existing policy statement was split to create two policy statements: one not medically necessary statement for intra-articular hyaluronan injections to the knee and one new investigational policy statement for injections to all other sites.

Molecular Analysis for Targeted Therapy of Non-Small-Cell Lung Cancer
Changes:

- The following two policies were merged to create this policy: Epidermal Growth Factor Receptor (EGFR) Mutation Analysis for Patients with Non-Small-Cell Lung Cancer (NSCLC) and KRAS Mutation Analysis in Non-Small-Cell Lung Cancer (archived);
- One new investigational policy statement appears in this merged policy specifying testing in the genes ROS, RET, MET, BRAF and HER2 for targeted therapy in patients with NSCLC as investigational;
- Addition of policy statements to include analysis for EML4-ALK and ROS1 mutations as medically necessary to predict treatment response to Crizotinib.

Reduction Mammoplasty
Change:

- Criteria in the medically necessary policy statement include change of cup size to "DD" from "D," BMI of

35 or less (previously 30) to eliminate obesity as a contributing factor causing symptoms, and symptoms are specifically reiterated in this statement as "back, neck and /or shoulder pain and/or paresthesia of hands and/or arms."

Sensory Integration Therapy and Auditory Integration Therapy
Changes:

- Title of policy changed from Sensory Integration Therapy;
- Investigational policy statement expanded to include auditory integration therapy;
- Additional information in description related to auditory integration therapy.

Transcatheter Aortic Valve Implantation for Aortic Stenosis
Changes:

- Medically necessary policy statement was broadened to include both FDA-approved transcatheter aortic valve repair systems and wording was added to state that the devices should be used according to their FDA-approved indication;
- The investigational policy statement had the phrase "procedures performed via the transaxillary, transiliac, transaortic, or other approaches are investigational" removed based on the approval of the CoreValve device with these approaches.

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
Administrative change:

- One investigational policy statement was reworded, replacing the phrase transesophageal endoscopic gastroplasty with transoral incisionless fundoplication (TIF) (i.e., Esophyx®), and the examples of the EndoCinch™ and NDO Plicator™ were removed from the statement. The intent of the statement is unchanged.
- The effective date of this protocol is unchanged.

New Protocols

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

Autonomic Nervous System Testing

- Autonomic nervous system testing, may be considered medically necessary when the specific criteria are met, and is considered investigational in all other situations when criteria are not met, or when using portable automated devices;
- *Preauthorization is not required*.

Cardiovascular Risk Panels

- Assessment of cardiac risk using cardiovascular risk panels is considered investigational;
- *Preauthorization is not required but is recommended if, despite this protocol position, the physician feels this service is medically necessary.*

Computed Tomography Perfusion Imaging of the Brain

- Computed Tomography Perfusion Imaging of the Brain is considered investigational.
- *Preauthorization is not required but is recommended if, despite the position of the protocol, the physician feels the service is medically necessary.*

Endobronchial Ultrasound for Diagnosis and Staging of Lung Cancer

- Endobronchial ultrasound guidance with transbronchial needle biopsy may be considered medically necessary for the evaluation of peripheral pulmonary lesions in patients with suspected lung cancer when specific criteria are met and for mediastinal staging in patients with diagnosed lung cancer when specific criteria are met;
- Endobronchial ultrasound is considered not medically necessary for diagnosis and staging of lung cancer when the criteria are not met and is considered investigational for all other indications;
- *Preauthorization is not required.*

Invasive Prenatal (Fetal) Diagnostic Testing

- Chromosome microarray (CMA) testing may be considered medically necessary, as an alternative to karyotyping in patients who are undergoing invasive diagnostic prenatal (fetal) testing;
- Invasive diagnostic prenatal (fetal) testing for molecular analysis for single-gene disorders may be considered medically necessary when criteria are met and a pregnancy has been identified as being high-risk;
- Invasive diagnostic prenatal (fetal) testing is considered investigational when criteria are not met. The use of next-generation sequencing in the setting of invasive prenatal testing is considered investigational;
- *Preauthorization is required.*

Measurement of Serum Antibodies to Infliximab and Adalimumab

- Measurement of Serum Antibodies to Infliximab and Adalimumab is considered investigational;
- *Preauthorization is not required but is recommended if, despite the position of the protocol, the physician feels the service is medically necessary.*

Multitarget Polymerase Chain Reaction Testing for Diagnosis of Bacterial Vaginosis

- Multitarget polymerase chain reaction (PCR) testing for diagnosis of bacterial vaginosis is considered investigational;
- *Preauthorization is not required.*

Radioimmunoscintigraphy Imaging (Monoclonal Antibody Imaging) With Indium-111 Capromab Pendetide (ProstaScint®) for Prostate Cancer

- Radioimmunoscintigraphy Imaging with Indium-111 Capromab Pendetide for Prostate Cancer is considered investigational;
- *Preauthorization is not required but is recommended if, despite the position of the protocol, the physician feels the service is medically necessary.*

Surgical Treatment of Bilateral Gynecomastia

- Surgical Treatment of Bilateral Gynecomastia is considered not medically necessary;
- *Preauthorization is required.*

Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Allogeneic Hematopoietic Stem-Cell Transplantation for Genetic Diseases and Acquired Anemias
- Artificial Intervertebral Disc: Lumbar Spine
- Axial Lumbosacral Interbody Fusion

- Biofeedback for Miscellaneous Indications
- Bone Morphogenetic Protein
- Carrier Testing for Genetic Diseases
- Closure Devices for Patent Foramen Ovale and Atrial Septal Defects
- 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
- Electrostimulation and Electromagnetic Therapy for Treating Wounds
- Electrical Bone Growth Stimulation of the Appendicular Skeleton
- Electrical Stimulation for the Treatment of Arthritis
- Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures
- Electromagnetic Navigation Bronchoscopy
- Endothelial Keratoplasty
- Facet Joint Denervation
- Gastric Electrical Stimulation
- Genetic Testing for Familial Cutaneous Malignant Melanoma
- Genetic Testing for Lynch Syndrome and Other Inherited Colon Cancer Syndromes
- Genetic Testing for Warfarin Dose
- Heart Transplant
- Heart/Lung Transplant
- Hematopoietic Stem-Cell Transplantation for Autoimmune Diseases
- Hematopoietic Stem-Cell Transplantation for Central Nervous System 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
- Immune Cell Function Assay
- Implantable Bone-Conduction and Bone-Anchored Hearing Aids
- Implantable Cardioverter Defibrillator
- Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery
- Implantation of Intrastromal Corneal Ring Segments
- Interspinous Fixation (Fusion) Devices
- Lysis of Epidural Adhesions
- Magnetoencephalography/Magnetic Source Imaging
- Microwave Tumor Ablation
- Orthoptic/Vision Therapy
- Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers
- Proteomics-Based Testing Related to Ovarian Cancer
- Quantitative Sensory Testing
- Subtalar Arthroereisis
- Surgical Ventricular Restoration
- Ultrasound Accelerated Fracture Healing Device
- Viscocanalostomy and Canaloplasty

Deleted Protocols

Effective immediately, the following protocols are archived:

- Home Uterine Activity Monitoring
- Skin Contact Monochromatic Infrared Energy as a Technique to Treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions
- Threshold Electrical Stimulation as a Treatment of Motor Disorders

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

- KRAS Mutation Analysis in Non-Small-Cell Lung Cancer

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.