Protocol

Medical Services Protocol Updates

Distribution Date: **December 1, 2017**

The following Medical Protocol update includes information on protocols that have undergone a review over the last several months as part of an annual review, or an additional review in order to make changes. The review may have resulted in a revision to the guidelines or no changes at all. One new protocol has been added and none have been archived.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 January 1, 2018:

Cochlear Implant

Change:

- A medically necessary policy statement with criteria and a not medically necessary policy statement have been added, each addressing replacement of internal and/or external components.

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

Changes:

- Criteria was added to the medically necessary policy statement addressing continuous (i.e., long-term) monitoring of glucose levels in interstitial fluid to include patients with type 1 diabetes who have demonstrated an understanding of the technology, are motivated to use the device correctly and consistently, are expected to adhere to a comprehensive diabetes treatment plan supervised by a qualified provider, and are capable of using the device to recognize alerts and alarms;
- The criteria in one bullet of the medically necessary policy statement addressing continuous (i.e., long-term) monitoring of glucose levels in interstitial fluid has been adjusted to include *impaired awareness of hypoglycemia* as well as patients with type I diabetes mellitus who have recurrent, unexplained, severe, (generally blood glucose levels less than 50 mg/dl) hypoglycemia.

Medicare Advantage changes:

- The not medically necessary policy statement has been removed and replaced by a medically necessary policy statement with criteria addressing therapeutic continuous glucose monitors (CGMs) and related supplies;
- A corresponding not medically necessary policy statement has been added for situations when the coverage criteria are not met.

Diagnosis and Treatment of Sacroiliac Joint Pain

Change:

- One investigational policy statement was added addressing arthrography of the sacroiliac joint.

DNA-Based Testing for Adolescent Idiopathic Scoliosis

Medicare Advantage change:

- One not medically necessary policy statement was added addressing DNA-based prognostic testing for adolescent idiopathic scoliosis.

Gene Expression Testing to Predict Coronary Artery Disease
Changes:

- The title was changed to Gene Expression Testing in the Evaluation of Patients with Stable Ischemic Heart Disease;
- The investigational policy statement was rephrased to address gene expression testing for the evaluation of patients with stable ischemic heart disease instead of to predict coronary artery disease.

Medicare Advantage changes:

- A listing of criteria to meet Corus CAD™ test indications has been deleted;
- A Medicare Advantage Policy Guideline Section has been added to provide test indications published by the developer.

Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer
Changes:

- The title was changed to Protein and Genetic Testing for Prostate Cancer;
- One medically necessary policy statement with criteria was added addressing multigene expression (Prolaris™; Oncotype Dx) assay on prostate cancer tissue to determine prognosis;
- One medically necessary policy statement with criteria was added addressing ConfirmMDx epigenetic molecular assay;
- One investigational policy statement was added addressing ConfirmMDx and other prostate tissue gene methylation testing in all other situations;
- An existing investigational policy statement was expanded to include additional genetic and protein biomarkers for the diagnosis of prostate cancer;
- An investigational policy statement was added to address gene expression assays to determine prognosis.

Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing
Medicare Advantage Change:

- A not medically necessary policy statement was added addressing genetic cancer susceptibility panels using next generation sequencing.

Genetic Testing for Alpha$_1$-Antitrypsin Deficiency
Medicare Advantage change:

- A medically necessary policy statement was added for genetic testing for alpha$_1$-antitrypsin deficiency to guide therapeutic decision-making for patients who have antitrypsin deficiency.

Genetic Testing for Breast Cancer Gene Expression Prognosis Assay
Changes:

- The medically necessary policy statement with criteria addressing the use of gene expression assays for deciding the risk of distant recurrence in individuals with intermediate risk early stage breast cancer was rephrased for clarification;
- Endopredict was added as an assay, which is medically necessary when criteria are met;
- An investigational policy statement was added addressing all other gene expression assays (except the 21 gene Oncotype DX) to predict the value of adjuvant chemotherapy in early stage breast cancer;
- *To consider length of treatment with tamoxifen* was added as an indication in the investigational policy statement addressing indications for multigene breast cancer panel assays.

Medicare Advantage changes:

- The medically necessary policy statement addressing the Oncotype DX DCIS assay has been removed;

- One of the two medically necessary policy statements addressing the Prosigna breast cancer gene signature assay has been removed.

Genetic Testing for Cystic Fibrosis
Medicare Advantage change:

- The not medically necessary policy statement has been replaced with a medically necessary policy statement addressing cystic fibrosis transmembrane conductance regulator (CFTR) (e.g., cystic fibrosis) gene analysis, common variants, (e.g., ACMG/ACOG guidelines) for an individual who has or may have cystic fibrosis to guide therapeutic decision-making.

Genetic Testing for Developmental Delay and Autism Spectrum Disorder
Changes:

- One medically necessary statement with criteria was reworked; addressing genetic testing for Rett syndrome-associated genes, e.g., MECP2, FOXG1, or CDKL5, to establish a genetic diagnosis of Rett syndrome in a child with developmental delay and signs/symptoms of Rett syndrome, when a definitive diagnosis cannot be made without genetic testing;
- A second medically necessary policy statement was added addressing targeted genetic testing for a known familial Rett syndrome-associated variant to determine carrier status of a mother or a sister of an individual with Rett syndrome;
- The investigational policy statement addressing all other indications for genetic testing in Rett Syndrome was further defined for clarification;
- The investigational policy statement addressing whole exome sequencing (WES) was removed and a medically necessary policy statement with criteria was added addressing WES for the evaluation of unexplained congenital or neurodevelopmental disorder in children;
- Two investigational policy statements were added addressing WES in all situations not meeting criteria and whole genome sequencing.

Medicare Advantage change:

- A not medically necessary policy statement was added addressing genetic testing (excluding WES) for FMR1 and Rett Syndrome not meeting the criteria in the protocol.

Genetic Testing for Hereditary Breast and Ovarian Cancer Syndrome
Change:

- The investigational policy statement on PALB2 testing has been replaced by a medically necessary policy statement with criteria for PALB2 testing.

Genetic Testing for Hereditary Hearing Loss
Medicare Advantage change:

- A not medically necessary policy statement addressing genetic testing for hearing loss genes has been added.

Genetic Testing for Leukemia and Lymphoma
Changes:

- The medically necessary policy statement addressing Acute Myeloid Leukemia (AML) in patients with normal karyotype has been changed to include CEBPA variant testing;
- A new medically necessary policy statement was added addressing KIT gene testing in patients with CBF AML;
- The investigational policy statement was adjusted to accommodate the above changes;

- A new medically necessary policy statement was added to address genetic testing in Acute Myelomonocytic Leukemia for (AML/ETO t(8;21) translocation);
- A bullet was added to the medically necessary policy statement addressing genetic testing in patients with suspected myelofibrosis, or essential thrombocythemia; the criteria now includes MPL Gene Mutations in exon 10 and CALR testing in the diagnosis of patients presenting with clinical, laboratory, or pathologic findings suggesting essential thrombocythemia or primary myelofibrosis.

Medicare Advantage changes:

- Multiple additions were made to criteria in the medically necessary policy statement addressing testing for genes associated with this protocol;
- A new medically necessary policy statement with criteria was added addressing targeted genomic sequential analysis panel, hematolymphoid neoplasm, DNA analysis, 5-50 genes in the evaluation of blood or bone marrow samples. A Medicare Advantage Policy Guidelines section was added to further define this policy statement.

Genetic Testing for Noninvasive Prenatal Testing

Medicare Advantage change:

- A not medically necessary policy statement has been added to address fetal chromosomal microdeletions genomic sequence analysis.

Genetic Testing for the Diagnosis of Inherited Peripheral Neuropathies

Changes:

- A medically necessary policy statement was added addressing the situation when the diagnosis of an inherited motor or sensory neuropathy is suspected due to signs and/or symptoms but a definitive diagnosis cannot be made without genetic testing;
- The investigational policy statement was amended to include sensory neuropathy.

In Vitro Chemoresistance and Chemosensitivity Assays

Medicare Advantage change:

- A not medically necessary policy statement addressing the chemosensitivity assay ChemoFX® has been added.

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

Changes:

- All policy statements have been reworked including medically necessary criteria now addressing KRAS and MET genes;
- Three new medically necessary policy statements have been added addressing EGFR T790M testing for individuals with first order family members who have Hereditary Lung Cancer Syndrome with EGFR T790M germline mutations; PD-L1 testing in advanced or recurrent disease when therapy with nivolumab or pembrolizumab is being considered and analysis for other EGFR mutations within exons 18-24;
- One investigational policy statement has been added addressing BAP1 gene testing.

Oncologic Applications of Photodynamic Therapy, Including Barrett Esophagus

Change:

- One indication addressing palliative treatment of unresectable cholangiocarcinoma when used with stenting was added to the medically necessary policy statement related to one or more courses of photodynamic therapy.

Open and Thoracoscopic Approaches to Treat Atrial Fibrillation and Atrial Flutter (Maze and Related Procedures)

Changes:

- The qualifier *drug-resistant* was removed from the medically necessary policy statement addressing the maze or modified maze procedure, performed on a non-beating heart during cardiopulmonary bypass with concomitant cardiac surgery for treatment of symptomatic atrial fibrillation or flutter;
- The qualifiers *symptomatic* and *drug resistant* were removed from the not medically necessary policy statement addressing the use of an open maze or modified maze procedure performed on a non-beating heart during cardiopulmonary bypass without concomitant cardiac surgery for treatment of atrial fibrillation or flutter.

Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions

Change:

- One not medically necessary policy statement was eliminated and the subject matter (the use of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices in patients with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above) was incorporated in the investigational policy statement.

Ultrasound Accelerated Fracture Healing Device

Changes:

- The policy position has been reversed so that medically necessary and investigational policy statements have been struck;
- Three new not medically necessary policy statements have been added addressing low-intensity pulsed ultrasound as a treatment of fresh fractures surgically managed or nonsurgically managed; as a treatment of fracture nonunion and delayed union fractures, and as a treatment of stress fractures, osteotomy, and distraction osteogenesis.

Use of Common Genetic Variants (Single Nucleotide Polymorphisms) to Predict Risk of Nonfamilial Breast Cancer

Change:

- The title was changed to Use of Common Genetic Variants (Single Nucleotide Variants) to Predict Risk of Nonfamilial Breast Cancer;

Medicare Advantage change:

- One not medically necessary policy statement was added for testing for one or more single nucleotide polymorphisms (SNPs) for chromosomal abnormalities.

Wearable Cardioverter Defibrillators

Changes:

- Medically necessary indications have been added and the investigational policy statement has been adjusted to accommodate this change;
- Policy guideline information has been added to address appropriate reassessment after 90 days.

New Protocol

The effective date of this new protocol is January 1, 2018:

Magnetic Resonance Imaging–Targeted Biopsy of the Prostate

- There is one medically necessary policy statement addressing magnetic resonance imaging–targeted biopsy of the prostate for diagnosis and active surveillance of prostate cancer;
- Preauthorization is not required.

Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Ambulance (Emergency)
- Biofeedback as a Treatment of Urinary Incontinence in Adults
- Catheter Ablation as Treatment for Atrial Fibrillation
- Chelation Therapy for Off-Label Uses
- Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management (Liquid Biopsy)
- Computer-Assisted Navigation for Orthopedic Procedure (Formerly Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure)
- Continuous Passive Motion in the Home Setting
- 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 and Intracellular Micronutrient Analysis
- Dopamine Transporter Imaging With Single-Photon Emission Computed Tomography (Formerly Dopamine Transporter Single-Photon Emission Computed Tomography)
- Endometrial Ablation
- Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus
- Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)
- Endovascular Stent Grafts for Abdominal Aortic Aneurysms
- Enhanced External Counterpulsation
- Extracorporeal Photopheresis
- Facet Arthroplasty
- General Approach to Evaluating the Utility of Genetic Panels
- General Approach to Genetic Testing
- Genetic Testing for Epilepsy
- Genetic Testing for FAP and Lynch Syndrome
- Genetic Testing for Statin-Induced Myopathy
- Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome (Formerly Hematopoietic Stem Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome)
- Hematopoietic Cell Transplantation for Waldenström Macroglobulinemia (Formerly Hematopoietic Stem Cell Transplantation for Waldenström Macroglobulinemia)
- Implantable Bone-Conduction and Bone-Anchored Hearing Aids
- Intradialytic Parenteral Nutrition
- KIF6 Genotyping for Predicting Cardiovascular Risk and/or Effectiveness of Statin Therapy
- Lung Volume Reduction Surgery for Severe Emphysema

- Meniscal Allografts and Other Meniscal Implants
- Myoelectric Prosthetic Components for the Upper Limb
- Occlusion of Uterine Arteries Using Transcatheter Embolization
- Orthopedic Applications of Platelet-Rich Plasma
- Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty (Formerly Percutaneous Intradiscal Electrothermal Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty)
- Pharmacogenomic and Metabolite Markers for Patients Treated With Thiopurines
- Plasma Exchange
- Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis
- Preimplantation Genetic Testing
- Prolotherapy
- Radiofrequency Ablation of Primary or Metastatic Liver Tumors
- Reconstructive Breast Surgery/Management of Breast Implants
- Sacral Nerve Neuromodulation/Stimulation
- Saturation Biopsy for Diagnosis, Staging, and Management of Prostate Cancer
- Semi-Implantable and Fully Implantable Middle Ear Hearing Aids
- Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders
- Transcutaneous Electrical Nerve Stimulation
- Transmyocardial Revascularization
- Treatment of Hyperhidrosis
- Tumor Treatment Fields Therapy for Glioblastoma
- Urinary Tumor Markers for Bladder Cancer
- Vagus Nerve Stimulation
- Vectra® DA Blood Test for Rheumatoid Arthritis
- Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon (Formerly Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon)

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.