

Distribution Date: December 1, 2018

The following medical protocol updates include 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. Three new protocols have been added and two have been archived.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 January 1, 2019:

Genetic Testing for Breast Cancer Gene Expression Prognosis Assay

Changes:

- One medically necessary policy statement was clarified to address the use of gene expression assays for deciding the *value of adjuvant therapy* in individuals with *stage I* breast cancer; one criterion from this statement was changed; and MammaPrint® assay was added as a test which may be medically necessary when criteria are met;
- One medically necessary policy statement with criteria was added to address the use of MammaPrint to inform decisions on adjuvant systemic chemotherapy for individuals who have stage II breast cancer;
- One investigational policy statement was added to address the use of MammaPrint in individuals who have a low clinical risk for recurrence.

Medicare Advantage changes:

- One medically necessary policy statement with criteria was added to address Oncotype DX® DCIS assay for women diagnosed with DCIS who are planning on having breast conserving surgery and considering adjuvant radiation therapy;
- One medically necessary policy statement was added to address the EndoPredict® breast cancer gene expression test for the management of post-menopausal women when criteria are met.

Genetic Testing for Developmental Delay and Autism Spectrum Disorder

Changes:

- One investigational policy statement was added addressing broad gene panel testing using next-generation sequencing in all cases of suspected genetic abnormality in children with developmental delay, intellectual disability and autism spectrum disorder;
- All content related to whole exome and whole genome sequencing was removed from this protocol and can be found in the Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders Protocol which was posted in 2017.

Genetic Testing for FAP and Lynch Syndrome

Change:

- The title was changed to Genetic Testing for Lynch Syndrome and Other Inherited Colon Cancer Syndromes.

Medicare Advantage changes:

- One medically necessary policy statement with criteria was added addressing microsatellite instability analysis (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency;
- One not medically necessary policy statement was added addressing testing for variants in the APC gene.

Genetic Testing for Leukemia and Lymphoma

Change:

- Multiple changes to both medically necessary and investigational policy statements over the wide range of disease states addressed in this protocol.

Medicare Advantage change:

- Multiple changes to medically necessary and not medically necessary policy statements.

Genetic Testing for Noninvasive Prenatal Testing

Changes:

- A medically necessary policy statement addressing nucleic acid sequencing-based testing of maternal plasma for sex chromosomal aneuploidy has been deleted;
- An investigational policy statement addressing testing for twin zygosity was added.

Medicare Advantage change:

- The Medicare Advantage section was removed from this protocol.

Genetic Testing for the Diagnosis of Inherited Peripheral Neuropathies

Medicare Advantage changes:

- A medically necessary policy statement has been added addressing genetic testing for hereditary peripheral neuropathies using a genomic sequence analysis panel;
- A not medically necessary policy statement has been added addressing other genetic testing for hereditary peripheral neuropathies not performed as listed.

Magnetic Resonance-Guided Focused Ultrasound

Change:

- A medically necessary policy statement was added addressing magnetic resonance-guided high-intensity ultrasound ablation for the treatment of medicine-refractory essential tremors.

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

Medicare Advantage changes:

- A medically necessary policy statement with criteria was added addressing BRAF gene analysis;
- A medically necessary policy statement was added addressing epidermal growth factor receptor (EGFR) testing, common variants, as a technique to predict treatment response for individuals with non-small-cell-lung cancer undergoing treatment with EGFR tyrosine kinase inhibitor (TKI) therapy.

Myoelectric Prosthetic Components for the Upper Limb

Changes:

- The protocol title was changed to Myoelectric Prosthetic and Orthotic Components for the Upper Limb;
- One investigational policy statement was added addressing upper-limb prosthetic components with both sensor and myoelectric control;
- One investigational policy statement was added addressing myoelectric controlled upper-limb orthoses.

Radiofrequency Ablation of Primary or Metastatic Liver Tumors

Changes:

- Policy statements were reworked to distinguish between inoperable and operable tumors, to include the Milan criteria, and to distinguish between primary and metastatic disease;
- One investigational policy statement was added addressing radiofrequency ablation of primary, operable hepatocellular carcinoma.

Treatment of Hyperhidrosis

Medicare Advantage change:

- One medically necessary policy statement was added addressing Onabotulinumtoxin A as treatment of severe primary axillary hyperhidrosis (primary focal hyperhidrosis) that is inadequately managed with topical therapy.

Urinary Tumor Markers for Bladder Cancer

Changes:

- The protocol title was changed to Urinary Biomarkers for Cancer Screening, Diagnosis, and Surveillance;
- The scope of the investigational policy statement was broadened to include the use of urinary tumor markers in screening for precancerous colonic polyps.

New Protocols

The effective date of these new protocols is January 1, 2019:

Balloon Dilation of the Eustachian Tube

- There is one investigational policy statement addressing balloon dilation of the Eustachian tube for treatment of patients with chronic Eustachian tube dilatory dysfunction.
- This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

Buprenorphine Implant for Treatment of Opioid Dependence

- There is one medically necessary policy statement with criteria addressing buprenorphine subdermal implants.
- There is one investigational policy statement addressing buprenorphine subdermal implants.
- There is one investigational policy statement addressing retreatment with buprenorphine implant after a prior 12-month treatment period.
- Preauthorization is required.

Cranial Electrotherapy Stimulation and Auricular Electrostimulation

- There are two investigational policy statements, one each addressing cranial electrotherapy stimulation and electrical stimulation of auricular acupuncture points in all situations.
- This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

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)
- Cochlear Implant
- Computer-Assisted Navigation for 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
- DNA-Based Testing for Adolescent Idiopathic Scoliosis
- Dopamine Transporter Imaging With Single-Photon Emission Computed Tomography
- Endometrial Ablation
- Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus
- Endovascular Stent Grafts for Abdominal Aortic Aneurysms
- Enhanced External Counterpulsation
- Extracorporeal Photophoresis
- Facet Arthroplasty
- Gene Expression Testing in the Evaluation of Patients with Stable Ischemic Heart Disease
- General Approach to Evaluating the Utility of Genetic Panels
- General Approach to Genetic Testing
- Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing
- Genetic Testing for Alpha₁-Antitrypsin Deficiency
- Genetic Testing for Cystic Fibrosis
- Genetic Testing for Epilepsy
- Genetic Testing for Hereditary Hearing Loss
- Genetic Testing for Statin-Induced Myopathy
- Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome
- Hematopoietic Cell Transplantation for Waldenström Macroglobulinemia
- Implantable Bone-Conduction and Bone-Anchored Hearing Aids
- In Vitro Chemoresistance and Chemosensitivity Assays
- Intradialytic Parenteral Nutrition
- KIF6 Genotyping for Predicting Cardiovascular Risk and/or Effectiveness of Statin Therapy
- Lung Volume Reduction Surgery for Severe Emphysema
- Magnetic Resonance Imaging–Targeted Biopsy of the Prostate
- Meniscal Allografts and Other Meniscal Implants
- Multibiomarker Disease Activity Blood Test for Rheumatoid Arthritis (Formerly Vectra[®] DA Blood Test for Rheumatoid Arthritis)
- Occlusion of Uterine Arteries Using Transcatheter Embolization
- Open and Thoracoscopic Approaches to Treat Atrial Fibrillation and Atrial Flutter (Maze and Related Procedures)
- Orthopedic Applications of Platelet-Rich Plasma
- Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions
- Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

- Pharmacogenomic and Metabolite Markers for Patients Treated With Thiopurines
- Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis
- Preimplantation Genetic Testing
- Prolotherapy
- 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
- Ultrasound Accelerated Fracture Healing Device
- Use of Common Genetic Variants (Single Nucleotide Variants) to Predict Risk of Nonfamilial Breast Cancer
- Wireless Capsule Endoscopy to Diagnose Disorders of the Small Bowel, Esophagus, and Colon

Deleted Protocols

Effective immediately, the following protocols are archived:

- Catheter Ablation for Cardiac Arrhythmias
- Plasma Exchange

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 our Provider Service Department.