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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 Two new protocols have been added and two have been archived.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 July 1, 2014 unless otherwise indicated:

Allogeneic Hematopoietic Stem-Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms (formerly Allogeneic Stem-Cell Transplantation for Myelodysplastic Syndromes and Myeloproliferative Neoplasms)

Added:

- “Hematopoietic” to the title.
- A statement indicating transplant is **investigational** when the criteria in the protocol are not met.

Allogeneic Pancreas Transplant

Changes:

- Modified the **medical necessity** statement on re-transplantation to state that it applies to patients who meet criteria for pancreas transplant.
- Added a statement that all other indications are considered **investigational**.

Automated Ambulatory Blood Pressure Monitoring for the Diagnosis of Hypertension in Patients with Elevated Office Blood Pressure

Added:

- Monitoring of treatment effectiveness as an additional **investigational** use.
- To the policy guidelines, special considerations for children.

BCR-ABL1 Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia (formerly BCR-ABL1 Testing for Diagnosis, Monitoring, and Drug Resistance Mutation Detection in Chronic Myelogenous Leukemia [CML])

Changes:

- Policy statements added for acute lymphoblastic leukemia (ALL): The testing is considered **medically necessary** prior to initiation of treatment, for disease monitoring and to evaluate for TKI resistance.
- Title changed from BCR-ABL1 Testing for Diagnosis, Monitoring, and Drug Resistance Detection in Chronic Myelogenous Leukemia.

Bio-Engineered Skin and Soft Tissue Substitutes

Changes:

- The first **medical necessity** policy statement was expanded to include other acellular dermal matrix products.
- Additional product names were added to the **investigational** list and several were removed.
- A Benefit Application Section notes that legislative language may impact whether a service is considered **investigational**.

Cochlear Implant

Reference to the protocol on Clinical Trials has been removed. (That protocol was previously archived.)

Cognitive Rehabilitation

The **investigational** policy statement was expanded to include epilepsy/seizure disorders and autism spectrum disorders.

Cytochrome p450 Genotyping

Dosing of anti-tuberculosis medications was added as an **investigational** use.

Deep Brain Stimulation

Added anorexia nervosa, alcohol addiction, and chronic pain to the “including, but not limited to” **investigational** policy statement.

Dermatologic Applications of Photodynamic Therapy

Superficial basal cell cancer (when surgery and radiation are contraindicated) and actinic keratosis of the face and scalp were changed from being considered not medically necessary to **medically necessary**.

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Changes:

- Oral pressure therapy added as **investigational**.
- Clarification that diagnostic home sleep study would be a one night study.
- Oral appliances clarified to pertain to adults.
- PAP-NAP studies added as **investigational**.
- Telemonitored home sleep studies added as **not medically necessary**.

Changes specifically for Medicare Advantage:

- Added **medically necessary** and **non-covered** statements regarding replacement of oral appliances.

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms) (formerly Endovascular Procedures [Angioplasty and/or Stenting] for Intracranial Arterial Disease [Atherosclerosis and Aneurysms])

Changes:

- Title changed from Endovascular Procedures (Angioplasty and/or Stenting) for Intracranial Arterial Disease (Atherosclerosis and Aneurysms).
- Added an **investigational** statement for endovascular interventions (mechanical embolectomy, which was previously in a separate protocol [now archived], as well as angioplasty and stenting) for acute stroke.

Epidermal Growth Factor Receptor (EGFR) Mutation Analysis for Patients with Non-Small Cell Lung Cancer (NSCLC)

Added afatinib to the existent **medical necessity** policy statement.

Facet Joint Denervation

Types of chemodenervation were added to the existent **investigational** statement.

Genetic Testing for Cardiac Ion Channelopathies (formerly Genetic Testing for Congenital Long QT Syndrome)

Changes:

- Title changed from Genetic Testing for Congenital Long QT Syndrome.
- Added that it may be **medically necessary** for CPVT (catecholaminergic polymorphic ventricular tachycardia) when the specified criteria are met.
- **Investigational** statements added for Brugada syndrome and short QT syndrome.

Genetic Testing for Duchenne and Becker Muscular Dystrophy

Added if criteria not met the service would be considered **not medically necessary**.

Genetic Testing for Familial Alzheimer's Disease

TREM2 (Triggering Receptor Expressed on Myeloid Cells 2) added to the **investigational** policy statement.

Genetic Testing for Hereditary Breast and/or Ovarian Cancer

Policy statement and policy guidelines sections reorganized:

- Added the USPSTF (United States Preventive Services Task Force) 2013 recommendation for determining who should be considered high risk and referred to genetic professional (for that specialist to determine if testing is **medically necessary**) to the policy guidelines.
- The criteria to use for determining those high-risk individuals that should have testing are now in the policy statement section.

Genetic Testing for PTEN Hamartoma Tumor Syndrome

Changes:

- Prenatal testing removed from the **investigational** statement.
- Clarification of testing strategy made in Policy Guidelines.

Genetic Testing, Including Chromosomal Microarray Analysis and Next-Generation Sequencing Panels, for Prenatal Evaluation and the Evaluation of Children with Developmental Delay/Intellectual Disability or Autism Spectrum Disorder (formerly Chromosomal Microarray [CMA] Analysis for the Genetic Evaluation of Patients with Developmental Delay/Intellectual Disability or Autism Spectrum Disorder)

Changes:

- Policy statement added that NGS (next-generation sequencing) panel testing is considered **investigational** in all cases of suspected genetic abnormality in children with developmental delay/intellectual disability or autism spectrum disorder.
- Title changed from Chromosomal Microarray (CMA) Analysis for the Genetic Evaluation of Patients with Developmental Delay/Intellectual Disability or Autism Spectrum Disorder.

Hematopoietic Stem-Cell Transplantation for Acute Lymphoblastic Leukemia

For children, changed allogeneic HSCT for treatment of relapsing ALL after a prior *autologous* HSCT from investigational to **medically necessary**.

Hematopoietic Stem-Cell Transplantation for Acute Myeloid Leukemia

In the third medical necessity policy statement "allogeneic" has been changed to "autologous".

Hyperbaric Oxygen Pressurization (HBO)

Added conditions to the **investigational** policy statement: bisphosphonate-related osteonecrosis of the jaw, refractory mycoses (mucormycosis, actinomycosis, conidiobolus coronato), motor dysfunction associated with stroke, herpes zoster, and vascular dementia.

Implantable Cardioverter Defibrillator (ICD)

Added “after reversible causes (e.g., acute ischemia) have been excluded” to the existent **medical necessity** statement on secondary prevention in adults.

Intensity-Modulated Radiation Therapy (IMRT): Abdomen and Pelvis

Administrative language removed from the preauthorization statement (no change to the process, IMRT for colorectal cancer is still managed by a preauthorization review by the radiation oncology services vendor).

Intra-Articular Hyaluronan Injections for Osteoarthritis

As communicated in the first quarter newsletter, the policy statement has changed, effective July 1, 2014:

- Use in all joints will be considered **not medically necessary**.

Background:

- The current position as medically necessary for osteoarthritis of the knee was based on older trials that showed some positive effects on pain and function scores. However, the evidence from those trials had some uncertainty due to variable trial quality, potential publication bias, and unclear clinical significance of the changes reported.
- More recent analysis of trials by speciality organizations, such as the American Academy of Orthopedic Surgeons (AAOS), concluded there was not significant clinical improvement. This caused them to strongly recommend against its use, as noted in our Q4 2013 *Vital Signs* newsletter.
- The National Institute for Health and Clinical Excellence (NICE) also does not recommend its use.
- Members should be directed to alternate treatments for osteoarthritis of the knee as it will not be covered by the Plan and members cannot be billed for it if it is provided.

Intraoperative Neurophysiologic Monitoring (sensory-evoked potentials, motor-evoked potentials, EEG monitoring)

Added to the benefit application section a statement that the physician who is supervising the monitoring must be dedicating his time to only our member for the time it is being provided and billed.

KRAS and BRAF Mutation Analysis in Metastatic Colorectal Cancer

The **medical necessity** statement on KRAS testing was slightly re-worded.

Laboratory Testing for HIV Tropism

Changes:

- HIV V3 genotyping by deep sequencing was removed from the first policy statement.
- That statement was also revised to reflect that tropism testing should be used only when there is an immediate plan to use an HIV co-receptor antagonist.
- Information about V3 genotyping testing methods was added to the policy guidelines

Laboratory Tests for Heart Transplant Rejection

The second **investigational** statement was slightly re-worded.

Liver Transplant

Changes:

- **Medical necessity** statement on polycystic disease of the liver moved to a separate statement.
- Pediatric non-metastatic hepatoblastoma added as **medically necessary**.
- **Investigational** statement added for all other indications not meeting the medical necessity criteria.

Lung and Lobar Lung Transplant

Policy statements added indicating lung or lobar lung retransplantation is **medically necessary** and that transplantation is **investigational** in all other situations not meeting the medical necessity criteria.

Magnetic Resonance Imaging-Guided Focused Ultrasound (formerly MRI-Guided Focused Ultrasound [MRgFUS])

The title was changed from MRI-Guided Focused Ultrasound (MRgFUS).

Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease (formerly Novel Lipid Risk Factors in Risk Assessment and Management of Cardiovascular Disease)

Changes:

- Added B-type natriuretic protein, cystatin C, fibrinogen and leptin as **investigational**.
- Policy statement about panel testing deleted.
- Title changed from Novel Lipid Risk Factors in Risk Assessment and Management of Cardiovascular Disease.

Optical Coherence Tomography of the Anterior Eye Segment

A separate Medicare Advantage policy statement has been added with **medical necessity** criteria.

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

Changes:

- To the policy statements where Flutter or Flutter and Acapella were mentioned: Those product names have been replaced with the generic terminology, “oscillatory positive expiratory pressure device”.
- In the medical necessity paragraph for high-frequency chest wall compression devices and IPV devices, “standard chest therapy” in the last sentence has been changed to “standard therapy”.

Outpatient Pulmonary Rehabilitation

Added that pulmonary rehabilitation programs are **investigational** in all other situations (those not meeting the medical necessity criteria indicated in the policy statement).

Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence (formerly Pelvic Floor Stimulation as a Treatment of Urinary Incontinence)

Fecal incontinence has been added to the content now and is **investigational**.

Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis (formerly Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis)

Changes:

- “Pneumatic” removed from policy statements and policy title; “Postsurgical” added to policy title.
- Major non-orthopedic surgery changed to “major non-orthopedic surgery or non-major orthopedic surgery” in the third and fourth policy statements.
- Added a Benefit Application section for general business that is a reminder that legislative mandates may impact whether the service could be considered **not medically necessary** or **investigational**.

Small Bowel/Liver and Multivisceral Transplant

Added an **investigational** statement for situations when the medical necessity criteria are not met.

Spinal Cord Stimulation

The **investigational** statement was modified to state “all other situations”, and cancer-related pain was added as an example.

Wearable Cardioverter-Defibrillators (formerly Wearable Cardioverter-Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator Placement)

Changes:

- The title was changed.
- Indications were added and/or clarified as **investigational**: “High-risk patients awaiting heart transplant,” patients with newly diagnosed non-ischemic cardiomyopathy, women with peripartum cardiomyopathy, and all other uses not described as medically necessary are considered investigational.

New Protocols

The effective date of these new protocols is July 1, 2014.

Antigen Leukocyte Antibody Test (ALCAT)

- This test is considered **not medically necessary**.
- Preauthorization is not required.

JAK2 and MPL Mutation Analysis in Myeloproliferative Neoplasms

- The policy statement indicates potential medically necessary situations (diagnosis of patients suspected of having myeloproliferative neoplasms) and investigational in all other circumstances.
- Preauthorization is required.

Medical Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Arthroscopic Debridement and Lavage as Treatment for Osteoarthritis of the Knee
- Artificial Intervertebral Disc: Cervical Spine
- Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions
- Biofeedback as a Treatment of Chronic Pain
- Biofeedback as a Treatment of Headache
- Biofeedback as a Treatment of Fecal Incontinence or Constipation
- Biofeedback for Miscellaneous Indications
- Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure
- Cardiac Rehabilitation in the Outpatient Setting
- Catheter Ablation for Cardiac Arrhythmias
- Catheter Ablation of the Pulmonary Veins as Treatment for Atrial Fibrillation
- Chelation Therapy
- Closure Devices for Patent Foramen Ovale and Atrial Septal Defects
- Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure
- Confocal Laser Endomicroscopy
- Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

- Cooling Devices Used in the Outpatient Setting
- Diagnosis and Treatment of Chronic Cerebrospinal Venous Insufficiency in Multiple Sclerosis
- Dynamic Spinal Visualization
- Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures
- End-Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema
- Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus
- Extracorporeal Photophoresis
- Extracranial Carotid Angioplasty/Stenting
- Fetal Surgery for Prenatally Diagnosed Malformations
- Functional Neuromuscular Electrical Stimulation
- Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer
- Genetic Testing for Predisposition to Inherited Hypertrophic Cardiomyopathy
- Hematopoietic Stem-Cell Transplantation for Breast Cancer
- Hematopoietic Stem-Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma
- Hematopoietic Stem-Cell Transplantation for Chronic Myelogenous Leukemia
- Hematopoietic Stem-Cell Transplantation for Non-Hodgkin Lymphomas
- Hematopoietic Stem-Cell Transplantation for Solid Tumors of Childhood
- Hematopoietic Stem-Cell Transplantation in the Treatment of Germ-Cell Tumors
- Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
- Intensity-Modulated Radiation Therapy (IMRT): Cancer of the Head and Neck or Thyroid
- Islet Transplantation
- Kidney Transplant
- KRAS Mutation Analysis in Non-Small Cell Lung Cancer (NSCLC)
- Low-Density Lipid Apheresis
- Manipulation Under Anesthesia
- Measurement of Exhaled Nitric Oxide and Exhaled Breath Condensate in the Diagnosis and Management of Asthma and Other Respiratory Disorders
- Microprocessor-Controlled Prostheses for the Lower Limb
- Microwave Tumor Ablation
- Monitored Anesthesia Care (MAC)
- Negative Pressure Wound Therapy in the Outpatient Setting
- Nerve Graft in Association with Radical Prostatectomy
- Oncologic Applications of Photodynamic Therapy, Including Barrett's Esophagus
- Optical Coherence Tomography for Imaging of Coronary Arteries
- Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)
- Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines
- Plasma Exchange
- Quantitative Assay for Measurement of HER2 Total Protein Expression and HER2 Dimers
- Scintimammography/Breast-Specific Gamma Imaging/Molecular Breast Imaging
- Sequencing-Based Tests to Determine Trisomy 21 from Maternal Plasma DNA
- Surgical Interruption of Pelvic Nerve Pathways for Primary and Secondary Dysmenorrhea Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome
- Surgical Ventricular Restoration
- Technology Assessment

- Thermography
- Total Artificial Hearts and Implantable Ventricular Assist Devices
- Transanal Radiofrequency Treatment of Fecal Incontinence
- Transcatheter Arterial Chemoembolization (TACE) to Treat Primary or Metastatic Liver Malignancies
- Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders
- Treatment of Varicose Veins/Venous Insufficiency
- Vertebral Axial Decompression
- Vertebral Fracture Assessment With Densitometry

Deleted Protocols

Effective immediately, the following protocols are archived:

- Gait Analysis
- Mechanical Embolectomy for Treatment of Acute Stroke

The above are brief summaries. Please refer to the protocols, posted on the provider website, for the details of the updated and new protocols that affect your practice. If you need assistance obtaining specific protocol updates, please contact Provider Service.