BlueCross BlueShield of Western New York

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Protocol

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Medical Services Protocol Updates

The following clinical protocol update includes information on protocols that have recently undergone an annual review. The review may have resulted in a revision to the guidelines or no changes at all. Six new protocols have been added and two existing protocols have been deleted.

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 October 1, 2011:

Aqueous Shunts and Devices for Glaucoma

Added:

- Canaloplasty will be indicated medically necessary under specified conditions.
- A Policy Guidelines section that states there are limitations for stents and tensioning devices when very low intraocular pressure (IOP) is needed to reduce glaucoma damage.

Bariatric Surgery

- Added that sleeve gastrectomy will be indicated medically necessary for general business.
- Removed the parenthetical statement under LAP-BAND® which discussed the ages of the patients in the FDA clinical trials.

Biofeedback as a Treatment for Headaches

Policy Guidelines section was added, which provides information about the number (10-20) and length (30-60 minutes) for biofeedback sessions.

Biventricular Pacemakers for the Treatment of Heart Failure

Removed “congestive” from the title and added medically necessary indications for New York State Association class II.

Cardiac Rehabilitation in the Outpatient Setting

Added:

- “In the outpatient setting” to the title and the medical necessity policy statement.
- Heart/lung transplantation and coronary stenting as medically necessary indications.
- Repeat programs are investigational.
- The three National Coverage Decisions regarding intensive cardiac rehabilitation (ICR) were added to the Medicare Advantage criteria, as well as the names of the two Medicare-approved ICR programs.

Cosmetic vs. Reconstructive Surgery or Services

Added:

- "or services" in the body of the protocol, as it is in the title (this supports the intention of the policy title which is to define not only surgical but also medical services as cosmetic or reconstructive; some of our members have plans that provide coverage for cosmetic surgery through a rider to their contract).
- Additional functional deficit language, including examples.

Cytochrome p450 Genotyping

Typographical change made to the first medically necessary policy statement: changed "phenotype" to "genotype."

Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Typographical change made to the first two policy statements: added word "lumbar." (**Note:** this did not change policy statement intent; all cervical are investigational. The change was made in May to expedite this clarification.)

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

Added that it is medically necessary for two types of mutations in patients with advanced NSCLC (non-squamous cell type); however, for those with squamous cell history, it is investigational.

Gait Analysis

Added more examples to the existent investigational examples:

- Surgical planning for conditions other than gait disorders associated with cerebral palsy.
- Post-operative evaluation of surgical outcomes.
- Rehabilitation planning and/or evaluation of all conditions.

Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer*

Changed the policy statement for prostate cancer antigen (PCA3) to include use for determining prognosis is also investigational.

Hematopoietic Stem-Cell Transplantation for Acute Myeloid Leukemia**

Added:

- Minimal changes to the description and the policy guideline table (Risk Status of AML Based on Cytogenetic and Molecular Factors).
- Medicare Advantage criteria per CMS National Coverage Determination.

Hematopoietic Stem-Cell Transplantation for Multiple Myeloma**

Added:

- "In the tandem sequence" to the medically necessary tandem autologous-autologous statement.
- Medicare Advantage criteria per CMS National Coverage Determination.

Hematopoietic Stem-Cell Transplantation for Non-Hodgkin Lymphomas**

Added:

- Medically necessary indications for allogeneic as salvage therapy for mantle cell lymphoma, as well as investigational statements for autologous as salvage therapy and allogeneic to consolidate a first remission.

- For peripheral T-cell lymphoma, medically necessary statements for autologous to consolidate first remission in specific situations and autologous and allogeneic as salvage therapy.
- Investigational statement for allogeneic hematopoietic stem-cell transplantation to consolidate a first complete remission.
- Medicare Advantage criteria per CMS National Coverage Determination.

Hematopoietic Stem-Cell Transplantation in the Treatment of Germ-Cell Tumors**

- Deleted statement "Except as noted above for treatment of certain testicular tumors, tandem or sequential autologous hematopoietic stem-cell transplantation is considered investigational to treat germ-cell tumors of any stage."
- Medicare Advantage criteria per CMS National Coverage Determination.

Hyperbaric Oxygen Pressurization (HBO)

Updated treatment length recommendations based on the most current (2008) Undersea and Hyperbaric Medical Society HBO Committee report on utilization.

Islet Transplantation**

Medicare Advantage criteria added per CMS National Coverage Determination.

Kidney Transplant**

Medicare Advantage criteria section removed because the separate section is not necessary.

Low-Level Laser Therapy

Removed the statement that previously indicated the policy excluded neck pain; therefore, use for neck pain is also investigational.

Manipulation under Anesthesia

- Removed "for Treatment of Chronic Spinal or Pelvic Pain" from the title.
- Added that manipulation under anesthesia over multiple sessions or multiple joints is investigational.

Microprocessor-Controlled Prostheses for the Lower Limb

Added to Policy Guideline section:

- Evaluation should be performed by an independent, qualified professional.
- A trial period to evaluate tolerability and efficacy of the prosthesis in a real-life setting may be appropriate.

Added a separate Medicare Advantage policy statement to indicate prosthesis being eligible if functional level is three or above and clinical documentation supports the need for the feature.

Minimally Invasive Lumbar Interbody Fusion

Protocol title changed.

Policy statements for other minimally invasive approached added:

- Minimally invasive ALIF, PLIF, TLIF considered medically necessary.
- Laparoscopic ALIF, AxiaLIF and lateral interbody fusion (e.g., XLIF, DLIF) are investigational.
- Preauthorization is required.

Negative Pressure Wound Therapy in the Outpatient Setting

Added:

- The word "powered" to the existing policy statements.
- New policy statement that non-powered NPWT systems are investigational.

Clarified: Two-week trial is a minimum of two weeks.

A change to the description of the wound stages was made for Medicare Advantage.

Orthoptic Training for the Treatment of Learning Disabilities

- Added a medically necessary statement for convergence insufficiency.
- Policy statement for learning disabilities changed from investigational to not medically necessary.
- Policy Guideline section added to define convergence insufficiency and stereoacuity.
- Preauthorization is required.

Percutaneous Vertebroplasty Sacroplasty and Kyphoplasty

A policy statement has been included noting that sacroplasty is investigational.

Posterior Tibial Nerve Stimulation for Voiding Dysfunction

Added “overactive bladder syndrome” as another example of an investigational use.

Radioembolization for Primary and Metastatic Tumors of the Liver

For general business, this may also be considered medically necessary in unresectable hepatic metastasis from colorectal carcinoma in liver-dominant disease that is refractory to chemotherapy.

Radiofrequency Facet Joint Denervation

Changed the trial of diagnostic blocks required from three to two blocks.

Routine Services for Qualifying Clinical Trials

Added “Routine Services for Qualifying” to the title because that is what the protocol discusses.

Scintimammography/Breast-Specific Gamma Imaging/Molecular Breast Imaging

“Molecular breast imaging” added to the protocol title and the policy statement; it is also investigational.

Small Bowel/Liver and Multivisceral Transplant**

Medicare Advantage criteria per CMS National Coverage Determination.

Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

Added a separate policy statement for Medicare Advantage that this may be medically necessary (using the Novasys Transurethral RF System) per the FDA approval criteria as included in the statement.

Ultrasound Accelerated Fracture Healing Device

For Medicare Advantage, the investigational statement has been changed to “not medically necessary” and added to that same statement to include uses for fractures of the skull, vertebrae or related to a tumor as not medically necessary.

Vertebral Fracture Assessment with Densitometry

Added a Benefit Application section that supports what has been in place for several years in regards to processing claims submitted for this service, which states: “If vertebral fracture assessment with densitometry is billed in addition to other services, because it is investigational and does not add any additional value, it will be considered incidental to the other service(s).”

New Protocols

The effective date of these new protocols is October 1, 2011:

Hematopoietic Stem-Cell Transplantation for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma**

Preauthorization is required through case management.

Anterior Eye Segment Optical Imaging

This is investigational. If it is billed in addition to an eye evaluation or evaluation and management services, because it is investigational and is not proven to add additional value, it will be considered incidental to the other service(s).

Genetic Testing for Lipoprotein(a) Variant(s) as a Decision Aid for Aspirin Treatment*

Genotyping for 9p21 Single Nucleotide Polymorphisms to Predict Risk of Cardiovascular Disease or Aneurysm*

Placental/Umbilical Cord Blood as a Source of Stem Cells**

Preauthorization is required through case management.

Stem-cell Therapy for Peripheral Arterial Disease*

*Preauthorization is not required, but is recommended if, despite the protocol position, you feel the service is medically necessary. As a reminder, for laboratory services, many of our members have contracts that do not permit a lab specimen to be sent to a laboratory other than a contractually designated laboratory unless advance approval is given by us.

**Includes a Benefit Application section to remind the reader that individual transplant facilities may have *additional* criteria or protocol that must be met for a patient to be considered eligible for a transplant.

Clinical Protocols Reviewed Without Change

Previous effective dates indicated remain accurate for the following:

- Ambulatory Blood Pressure Monitoring
- Arthroscopic Debridement and Lavage as Treatment for Osteoarthritis of the Knee
- Auditory Brainstem Implant
- Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions
- Biofeedback as a Treatment of Chronic Pain
- Chelation Therapy
- Closure Devices for Patent Foramen Ovale and Atrial Septal Defects
- Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy
- Genetic Testing for Hereditary Breast and/or Ovarian Cancer
- High-Sensitivity C-Reactive Protein
- Hippotherapy
- Homocysteine Testing in the Screening, Diagnosis, and Management of Cardiovascular Disease
- Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis
- Ingestible pH and Pressure Capsule
- Interspinous Distraction Devices (Spacers)

- Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas or Metastasis to the Brain
- Low-Density Lipid Apheresis
- Lysis of Epidural Adhesions
- MRI-Guided Focused Ultrasound (MRgFUS) for the Treatment of Uterine Fibroids and Other Tumors
- Multigene Expression Assay for Predicting Recurrence in Colon Cancer
- Myoelectric Prosthesis for the Upper Limb
- Occipital Nerve Stimulation
- Oncologic Applications of Photodynamic Therapy, Including Barrett's Esophagus
- Orthopedic Applications of Stem-Cell Therapy
- Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome
- PathFinderTG® Molecular Testing
- Pelvic Floor Stimulation as a Treatment of Urinary Incontinence
- Phototherapeutic Keratectomy
- Plasma Exchange
- Plugs for Fistula Repair
- Progenitor Cell Therapy for the Treatment of Damaged Myocardium Due to Ischemia
- Prophylactic Mastectomy
- Sacroiliac Joint Arthrography and Injection
- Surgical Interruption of Pelvic Nerve Pathways for Primary and Secondary Dysmenorrhea
- Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome
- Surgical Treatment of Femoroacetabular Impingement
- Surgical Ventricular Restoration
- Systems Pathology for Predicting Risk of Recurrence in Prostate Cancer
- Technology Assessment
- Thermography
- Transanal Radiofrequency Treatment of Fecal Incontinence
- Treatment of Varicose Veins/Venous Insufficiency

Deleted Protocols

Effective immediately, the following protocols are archived:

- External Infusion Pumps
- Phototherapy Light for the Treatment of Seasonal Affective and Other Depressive Disorders (preauthorization is no longer required)

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