Updates to Medical Policies and Clinical UM Guidelines

Effective November 15, 2014

The major new policies and changes are summarized below. Please refer to the specific policy for coding, language, and rationale updates and changes that are not summarized below.

New Medical Policies Effective November 15, 2014

**DRUG.00062 Obinutuzumab (Gazyva®):** This document addresses the use of obinutuzumab, a humanized monoclonal antibody of the IgG1 subclass that targets the CD20 antigen expressed on the cell surface of pre-B- and mature B-lymphocytes. Once obinutuzumab binds to the targeted cell, various pathways are triggered, resulting in the lysis of the B-cells.

- Obinutuzumab is considered medically necessary as first line treatment of chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) when used in combination with chlorambucil.
- Obinutuzumab is considered investigational and not medically necessary when the medically necessary criteria are not met, and for all other indications.

**DRUG.00063 Ofatumumab (Arzerra™):** This document addresses the use of ofatumumab, a humanized, cytolytic monoclonal antibody directed against the surface antigen CD20, which is expressed on more than 90% of B-cell lymphocytes from pre-B-cell stage to maturity.

- Ofatumumab is considered medically necessary for first line therapy for chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) in combination with chlorambucil.
- Ofatumumab is considered medically necessary for the treatment of relapsed or refractory CLL/SLL used as a single agent and only in one line of therapy.
- Ofatumumab is considered investigational and not medically necessary when the criteria above are not met, and for all other indications.

**GENE.00036 Genetic Testing for Hereditary Pancreatitis:** This document addresses the use of genetic testing for hereditary pancreatitis.

- Genetic testing for hereditary pancreatitis is considered investigational and not medically necessary.

**GENE.00037 Genetic Testing for Macular Degeneration:** This document addresses genetic testing for age related macular degeneration (AMD), which is aimed at identifying individuals at risk of developing advanced AMD.

- Genetic testing for macular degeneration is considered investigational and not medically necessary.
• **GENE.00038 Genetic Testing for Statin-Induced Myopathy**: This document addresses genetic testing for predicting the risk of myopathy in individuals being treated, or considered for treatment, with statin therapy.
  
  - Genetic testing for the presence of variants in the SLCO1B1 gene to identify individuals at increased risk of statin-induced myopathy is considered investigational and not medically necessary.

• **GENE.00040 Genetic Testing for CHARGE Syndrome**: This document addresses genetic testing for CHARGE syndrome, which is a rare genetic condition associated with multiple congenital anomalies.
  
  - Preimplantation, preconceptual, or in utero genetic testing for CHARGE syndrome is considered medically necessary to rule out a disease causing mutation when the individual being tested has a family history of a first-degree relative with CHARGE syndrome.
  
  - Genetic testing for CHARGE syndrome is considered medically necessary to confirm suspected diagnosis of CHARGE syndrome in infants and children suspected of having CHARGE syndrome and with some but not all clinical features of CHARGE syndrome present.
  
  - Genetic testing for CHARGE syndrome is considered investigational and not medically necessary in all other situations.

• **GENE.00041 Short Tandem Repeat Analysis for Specimen Provenance Testing**: This document addresses the clinical validity and clinical utility of short tandem repeat (STR) analysis using the know error® DNA Specimen Provenance Assay (DSPA) to confirm the identity of a biopsy specimen.
  
  - Genetic testing to confirm the identity of a biopsy specimen using short tandem repeat based methodology [know error DNA Specimen Provenance Assay (DSPA)] is considered not medically necessary.

• **SURG.00139 Intraoperative Assessment of Surgical Margins during Breast-Conserving Surgery with Radiofrequency Spectroscopy or Optical Coherence Tomography**: This document addresses the use of radiofrequency spectroscopy (RFS) and optical coherence tomography (OCT), which are technologies that have been proposed to detect the presence of malignant tissue on the excised tissue samples in the operating room during breast-conserving surgery.
  
  - The use of radiofrequency spectroscopy or optical coherence tomography for intraoperative assessment of surgical margins during breast-conserving surgery is considered investigational and not medically necessary.

**Revised Medical Policies and Adopted Clinical UM Guidelines Effective November 15, 2014**

• **DME.00009 Vacuum Assisted Wound Therapy in the Outpatient Setting**: This document addresses the use of vacuum assisted wound therapy (also known as negative pressure wound therapy or NPWT) in the outpatient setting for a variety of wounds (i.e., ulcers related to pressure sores, venous or arterial insufficiency or neuropathy).
  
  - Added portable, battery-powered, single use (disposable) vacuum assisted wound therapy devices as investigational and not medically necessary for all conditions.
  
  - HCPCS code A9272 for disposable devices will be denied as investigational and not medically necessary for all indications.
  
  - Updated Description, Rationale, Background, Definition, Coding, Reference and Index sections.
• **DRUG.00002 Tumor Necrosis Factor Antagonists:** This document addresses the indications for a class of biologic disease-modifying antirheumatic drugs (DMARDs) known as tumor necrosis factor (TNF) antagonists (inhibitors), that target specific pathways of the immune system and either enhance or inhibit immune response.
  - Added the use of infliximab or adalimumab as medically necessary for non-infectious uveitis when criteria are met.
  - Updated medically necessary criteria with FDA labeled clinical indications and usage language for each TNF antagonist.
  - Added the use of tofacitinib citrate (Xeljanz®) in combination with each TNF antagonist as not medically necessary.
  - Clarified that the use of any TNF antagonist is not medically necessary if an individual has not had a TST or a CDC-recommended equivalent to evaluate for latent TB prior to initiating therapy.
  - Removed Behcet’s syndrome from list of indications considered investigational and not medically necessary for the use of infliximab [underlying cause of uveitis].
  - HCPCS codes J1745 (infliximab) and J0135 (adalimumab) will pend for additional diagnosis codes for non-infectious uveitis and underlying conditions.
  - Updated Rationale, Background and Reference sections.

• **DRUG.00006 Botulinum Toxin:** This document addresses the use of both botulinum toxin type A (BTA) and botulinum toxin type B (BTB), including Botox® (OnabotulinumtoxinA), Myobloc™ (RimabotulinumtoxinB), Dysport® (AbobotulinumtoxinA) and Xeomin® (IncobotulinumtoxinA), for the treatment of all health conditions, with the exception of hyperhidrosis.
  - Clarified medically necessary criteria addressing neurogenic overactive bladder.
  - Added the use of botulinum toxin as a treatment of idiopathic overactive bladder in adults who are unresponsive to or intolerant of a trial of anticholinergic therapy as medically necessary.
  - Added “for individuals who met criteria for an initial trial” to medically necessary statement addressing continuation of treatment.
  - Added Behcet's syndrome, Hirschsprung's disease, post-mastectomy reconstruction syndrome and Reynaud’s syndrome to list of conditions considered investigational and not medically necessary.
  - Drug and administration codes will now pend for criteria for urinary diagnoses.
  - Updated Description, Rationale, Definition, Coding and Reference sections.

• **DRUG.00036 Cetuximab (Erbitux®):** This document addresses the use of cetuximab in the treatment of oncologic conditions.
  - Removed medically necessary criteria for non-small cell lung cancer (NSCLC).
  - Revised investigational and not medically necessary statement to include NSCLC.
  - HCPCS code J9055 will no longer pend for lung cancer diagnoses; will be considered investigational and not medically necessary.
  - Updated Rationale, Background, Coding and Reference sections.

• **RAD.00030 Wireless Capsule Endoscopy for Gastrointestinal Imaging and the Patency Capsule:** This document addresses the use of wireless capsule endoscopy (WCE) for imaging the esophagus, small bowel and colon, and use of the patency capsule to ensure that there are no strictures in the digestive tract to impede passage of the wireless endoscopy capsule.
  - Title revised, previously titled: Wireless Capsule Endoscopy for Esophageal and Small Bowel Imaging and the Patency Capsule.
  - Expanded scope of policy to include imaging of the colon.
  - Clarified that the medically necessary criteria addresses wireless capsule endoscopy of the small bowel.
  - Clarified that enteroclysis includes CT enteroclysis in medically necessary criteria.
  - Clarified the medically necessary criteria addressing use of capsule endoscopy to investigate anemia with concomitant iron deficiency.
  - Added wireless capsule endoscopy as a means to perform colorectal cancer screening or identify colon disease as investigational and not medically necessary.
• Added new CPT Category III code 0355T effective 07/01/14 for colon wireless endoscopy as investigational and not medically necessary.
• Updated Description, Rationale, Background, Coding, Reference and Index sections.

• SURG.00014 Cochlear Implants and Auditory Brainstem Implants: This document addresses cochlear implants, auditory brainstem implants, and replacement or upgrade of speech processor and controller components.
  • Clarified medically necessary criteria for unilateral or bilateral implantation of an FDA-approved single or multi-channel cochlear implant.
  • Added hybrid cochlear implants as investigational and not medically necessary for all indications.
  • No specific code for hybrid implants; added 69949 NOC code.
  • Updated Description, Rationale, Background, Definition, Coding and Reference sections.

• CG-DME-01 External (Portable) Continuous Insulin Infusion Pump: This document addresses the medically necessary uses of external insulin infusion pumps.
  • Added the use of a disposable external insulin pump with no wireless communication capability (for example, V-Go®) as not medically necessary under all circumstances.
  • Added new HCPCS codes S1034, S1035, S1036, S1037 effective 07/01/2014 for MiniMed 530G artificial pancreas with criteria.
  • Updated Description, Coding, Discussion and Reference sections.

• CG-DRUG-15 Gonadotropin Releasing Hormone (GnRH) Analogs: This document addresses gonadotropin releasing hormone (GnRH) analogs, which are synthetic analogs of naturally occurring GnRH.
  • Updated medically necessary clinical indication addressing the use of goserelin acetate or leuprolide acetate in breast cancer to include breast cancer in men.
  • Added medically necessary, and not medically necessary, clinical indications addressing leuprolide acetate for depot suspension and norethindrone acetate tablets (Lupaneta pack) for gynecology uses.
  • Added limits for duration of treatment of endometriosis, both initial and re-treatment for all GnRH analogs.
  • Added separate medically necessary statement for nafarelin acetate in the treatment of endometriosis.
  • Updated Description, Discussion, Reference and Index sections

WellPoint Medical Policies and Clinical UM Guidelines are developed by our Medical Policy and Technology Assessment Committee. The Committee, which includes WellPoint medical directors and representatives from practicing physician groups, meets quarterly to review current scientific data and clinical developments.

All coverage written or administered by UniCare excludes from coverage services or supplies that are investigational and/or not medically necessary. A member’s claim may not be eligible for payment if it was determined not to meet medical necessity criteria set in WellPoint’s medical policies. Review procedures have been refined to facilitate claim investigation.

You can access the complete list of WellPoint Medical Policies and Clinical UM Guidelines from unicarestateplan.com > Providers > WellPoint Medical Policies > adopted clinical UM guidelines.
The revised medical policies listed below will become effective for services rendered on or after November 15, 2014.

<table>
<thead>
<tr>
<th>Medical Policy Number</th>
<th>Medical Policy Title</th>
<th>Medical Policy / Clinical Guideline Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENE.00005</td>
<td>BCR-ABL Mutation Analysis (Qualitative)</td>
<td>Updated the coding section and system edits to pend the following codes for medical necessity review for additional diagnosis:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>81403 Molecular pathology procedure, Level 4 (e.g., analysis of single exon by DNA sequence analysis, analysis of &gt;10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)</td>
</tr>
<tr>
<td>MED.00113</td>
<td>Therapeutic Apheresis</td>
<td>The following code has been added to this policy and is considered Investigational and Not Medically Necessary when criteria not met:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>99195 Phlebotomy, therapeutic (separate procedure)</td>
</tr>
<tr>
<td>SURG.00026</td>
<td>Deep Brain, Cortical, and Cerebellar Stimulation</td>
<td>Updated system edits to match policy position statement and coding section for the following codes:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>61850 Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>61860 Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical</td>
</tr>
<tr>
<td>SURG.00072</td>
<td>Lysis of Epidural Adhesions</td>
<td>Updated system edits to match policy position statement and coding section for the following codes:</td>
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<tr>
<td></td>
<td></td>
<td>62281 Injection/infusion of neurolytic substance (e.g., alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, cervical or thoracic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>62282 Injection/infusion of neurolytic substance (e.g., alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, lumbar, sacral (caudal)</td>
</tr>
</tbody>
</table>