Updates to Medical Policies and Clinical UM Guidelines

Effective January 2, 2015

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 January 2, 2015

- **DRUG.00064 Levodopa/Carbidopa Intestinal Infusion**: This document addresses a novel formulation of the levodopa/carbidopa intestinal (intraduodenal) gel infusion for the treatment of late-stage Parkinson's disease.
  - Levodopa/carbidopa intestinal gel infusion is considered investigational and not medically necessary for all indications.

- **DRUG.00065 Recombinant Coagulation Factor IX, Fc Fusion Protein (rFIXFc)**: This document addresses recombinant coagulation Factor IX protein, fusion protein (rFIXFc) (Alprolix™) that temporarily replaces the missing coagulation Factor IX needed for effective hemostasis in individuals with hemophilia B.
  - Outlines the medically necessary, and investigational and not medically necessary criteria for the use of recombinant coagulation Factor IX, Fc Fusion [rFIXFc].

- **GENE.00039 Genetic Testing for Frontotemporal Dementia (FTD)**: This document addresses genetic testing for the screening, diagnosis and management of frontotemporal dementia (FTD). This document does not address genetic testing for Alzheimer’s disease.
  - Genetic testing for FTD is considered investigational and not medically necessary for all indications, including but not limited to the following:
    - As a diagnostic or prognostic technique in individuals with symptoms suggestive of FTD; or
    - As a screening technique in asymptomatic individuals with or without a family history of FTD; or
    - Prenatal or preimplantation genetic testing to establish a diagnosis of FTD in the offspring of Individuals with a genetic mutation known to cause FTD
  - Tier 2 genetic testing code 81406 will pend for specific diagnoses, also listed 81479 NOC; considered Inv&NMN.

- **GENE.00042 Genetic Testing for Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy (CADASIL) Syndrome**: This document addresses genetic testing for CADASIL syndrome, a rare, autosomal dominant, cerebrovascular disease that is considered to be the most common cause of hereditary stroke and hereditary vascular dementia in adults.
Genetic testing for inherited CADASIL syndrome is considered investigational and not medically necessary for all indications, including but not limited to:
- To confirm a diagnosis of a suspected inherited CADASIL syndrome; or
- For preconceptional planning for potentially at-risk individuals; or
- For preimplantation embryonic testing in potentially at-risk individuals

Tier 2 genetic testing code 81406 will pend for specific diagnoses, considered Inv&NMN.

**OR-PR.00005 Upper Extremity Myoelectric Orthoses**: This document addresses the use of upper extremity myoelectric orthoses, which are intended to augment the function of individuals with upper arm weakness or partial paralysis due to neurological conditions, trauma, or other problems. Such devices use neurologic sensors, microprocessor units, and electric motors to provide self-initiated movement of the affected limb.

The use of myoelectric upper extremity orthotic devices is considered investigational and not medically necessary for all indications, including but not limited to use by individuals with stroke, trauma, or neurological disorders.

**Revised Medical Policies and Adopted Clinical UM Guidelines Effective January 2, 2015**

**DME.00011 Electrical Stimulation as a Treatment for Pain and Related Conditions: Surface and Percutaneous Devices**: This document specifically addresses auricular electrostimulation, H-wave stimulation, interferential stimulation therapy, microcurrent electrical nerve stimulation, pulsed electrical stimulation, percutaneous neuromodulation therapy and sympathetic therapies.

- Added auricular electrostimulation as investigational and not medically necessary for all indications including, but not limited to, treatment of acute and chronic pain
- Updated Description, Rationale, Background, Coding, Reference and Index sections
- Added 64999 NOC code for percutaneous neuromodulation, S8130, S8131 for interferential stimulators and S8930 for auricular electrostimulation

**DME.00037 Cooling Devices and Combined Cooling/Heating Devices**: This document addresses the devices utilized for the treatment of pain and swelling after trauma and surgery, and for musculoskeletal and other conditions. Included are both passive cold therapy devices, active cold therapy devices, as well as devices that combine compression or heat therapy in the same device.

- No change to position statement
- Updated Description, Rationale, Coding and Reference sections
- The medical policy coding section was updated to include existing HCPCS codes E0676 and E1399 which may be used for cooling devices

**DRUG.00015 Prevention of Respiratory Syncytial Virus Infections**: This document addresses prevention of respiratory syncytial virus infection (RSV) with palivizumab (Synagis®), a monoclonal antibody produced by DNA recombinant technology to an RSV protein.

- Reformatted/re-ordered medically necessary position statements
- Revised position statements to correspond with updated 2014 American Academy of Pediatrics (AAP) recommendations
- Updated Description, Rationale, Background, Definition and Reference sections

**DRUG.00043 Tocilizumab (Actemra®)**: This document addresses the use of tocilizumab (Actemra) in adults with moderately to severely active rheumatoid arthritis (RA), children 2 years of age and older with active polyarticular juvenile arthritis (PJIA) or active systemic juvenile idiopathic arthritis (SJIA), and for other conditions.

- Clarified Added Janus kinase inhibitors (for example, tofacitinib citrate [Xeljanz®]) for use in combination with tocilizumab as not medically necessary
- Clarified that the use of tocilizumab 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
- Updated Description, Rationale, Background, Definition and Reference sections
• **DRUG.00057 Canakinumab (Ilaris®):** The document addresses the indications for use of canakinumab (Ilaris), a humanized monoclonal antibody, interleukin-1 beta (IL-1ß) inhibitor drug.
  o Added Janus kinase inhibitors (for example, tofacitinib citrate [Xeljanz®]) for use in combination with canakinumab as not medically necessary
  o Clarified that the use of canakinumab 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
  o Added Behçet's disease as an investigational and not medically necessary indication
  o Renamed chronic infantile neurological cutaneous articular syndrome (CINCA) to neonatal-onset multisystem inflammatory disease (NOMID) in investigational and not medically necessary criteria
  o Updated Description, Rationale, Background, Definition and References sections

• **GENE.00010 Genotype Testing for Genetic Polymorphisms to Determine Drug-Metabolizer Status:** This document addresses genotype testing for genetic polymorphisms which can identify variants of specific genes associated with abnormal and normal drug metabolism.
  o Added genotype testing in hepatitis C virus (HCV) genotype 1a for the presence of the NS3 Q80K polymorphism as medically necessary before beginning treatment with Olysio™ (simeprevir) plus peginterferon and ribavirin
  o Added the use of testing panels for genetic polymorphisms to determine drug-metabolizer status as investigational and not medically necessary unless all components of the panel have been determined to be medically necessary based on the criteria in this document
  o Updated Description, Rationale, Coding, Reference and Index sections
  o Added existing code 87902 for HCV testing; also added gene CYP3A4 to Tier 2 code 81401 and diagnosis codes for mental disorders

• **MED.00112 Autonomic Testing:** This document addresses the use of autonomic testing.
  o Added the use of Sudoscan testing as investigational and not medically necessary
  o Updated Description, Rationale, Background, Coding, References
  o No specific code for Sudoscan; added 95999 NOC

• **SURG.00007 Vagus Nerve Stimulation:** This document addresses the indications for use of implantable vagus nerve stimulation (VNS) device, the electronic analysis of the implanted neurostimulator pulse generator system, and non-implantable (transcutaneous) VNS devices for the treatment of medically and surgically refractory seizures associated with intractable epilepsy and as a treatment of other conditions.
  o Expanded scope to include non-implantable (transcutaneous) VNS devices
  o Added non-implantable vagus nerve stimulation devices as investigational and not medically necessary for all indications
  o Clarified investigational and not medically necessary statement for implantable VNS
  o Updated Description, Rationale, Background, Coding, Reference and Index sections
  o No specific code for transcutaneous (non-implantable) VNS; listed E1399 NOC

• **SURG.00020 Bone-Anchored and Bone Conduction Hearing Aids:** This document addresses the use of implantable bone-anchored hearing aids; transcutaneously worn, non-surgical application of a bone-anchored hearing aid using headband or Softband; partially implantable magnetic bone conduction hearing aids; and an intraoral bone conduction hearing aid as an alternative to an air conduction hearing aid in the treatment of moderate-to-severe hearing loss (HL), or to improve speech recognition in individuals with unilateral sensorineural hearing loss (also referred to as single sided deafness).
  o Title revised, Old title: Bone-Anchored Hearing Aids
  o Expanded scope of policy to include bone conduction hearing aids
  o Clarified both medically necessary position statements for implantable bone-anchored hearing aids
  o Clarified medically necessary criteria for transcutaneously worn, non-surgical application of an implantable bone-anchored hearing aid

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• **SURG.00055 Cervical Artificial Intervertebral Discs:** This document addresses the use of U.S. Food & Drug Administration (FDA) approved (Pre-Market Approval [PMA]) cervical artificial intervertebral discs as treatments for symptomatic cervical disc disease when conservative treatment options have been unsuccessful.
  - Clarified definition of osteoporosis in medically necessary criteria
  - Added cervical spine malignancy as a contraindication to disc implantation
  - Updated Description, Rationale and Reference sections

• **CG-DRUG-05 Recombinant Erythropoietin Products:** This document addresses recombinant, or man-made, erythropoietin products.
  - Added medically necessary, and not medically necessary clinical indications for methoxy polyethylene glycol-epoetin beta (Mircera)
  - Reformatted clinical indications section
  - Updated Description, Coding, Discussion, Reference and Index sections
  - Added HCPCS codes Q9972, Q9973 for Mircera

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.](unicarestateplan.com)
The revised medical policies listed below will become effective for services rendered on or after January 2, 2015.

<table>
<thead>
<tr>
<th>Medical Policy Number</th>
<th>Medical Policy Title</th>
<th>Medical Policy / Clinical Guideline Changes</th>
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<tbody>
<tr>
<td>LAB.00011</td>
<td>Analysis of Proteomic Patterns</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>• 83520 Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified</td>
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