Updates to Medical Policies and Clinical UM Guidelines

Effective July 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 July 15, 2014

GENE.00034 SensiGene® Fetal RhD Genotyping Test: This document addresses the use of the SensiGene® Fetal RhD Genotyping blood test as a noninvasive diagnostic assessment tool to determine the fetal RhD genotype in an RhD-negative mother.

- Genetic testing to determine fetal RhD genotype using the SensiGene Fetal RhD Genotyping test is considered investigational and not medically necessary.

GENE.00035 Genetic Testing for TP53 Mutations (Li-Fraumeni Syndrome): This document addresses genetic testing for mutations in the TP53 gene which may be performed for the purpose of diagnosis, risk assessment, and/or disease management for individuals with Li-Fraumeni syndrome (LFS).

- Outlines the medically necessary, and investigational and not medically necessary criteria for TP53 gene mutation testing for Li-Fraumeni syndrome (LFS).

SURG.00138 Laser Treatment of Onychomycosis: This document addresses the safety and efficacy of laser treatments for onychomycosis.

- Laser treatment of onychomycosis is considered investigational and not medically necessary.

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

DRUG.00013 Administration of Immunoglobulin as a Treatment of Recurrent Spontaneous Abortion: This document addresses the administration of immunoglobulin as a treatment of recurrent spontaneous abortion.

- Title revised. Previously titled: Intravenous Immunoglobulin as a Treatment of Recurrent Spontaneous Abortion
- Revised position statement to include intramuscular and subcutaneous administration
- Existing CPT codes 90281, 90284, and HCPCS codes J1460, J1559, J1560, S9338 were added to the policy coding section for IM and SC injections
- Updated Description, Rationale, Background, Coding and Reference sections
GENE.00007 Cardiac Ion Channel Genetic Testing: This document addresses genetic testing of cardiac ion channel mutations in persons with suspected channelopathies, such as long QT syndrome (LQTS), in order to determine the risk for sudden cardiac death (SCD).

- Added genetic testing for all other cardiac ion channel mutations, including, but not limited to Brugada Syndrome (BrS), Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT) and Short QT Syndrome (SQTS) as investigational and not medically necessary
- HCPCS code S3861 and CPT Tier 2 for genes for short QT, Brugada and CPVT were added to the policy coding section
- Updated Description, Rationale, Definition, Coding and Reference sections

GENE.00012 Preconceptional or Prenatal Genetic Testing of a Parent or Prospective Parent: This document addresses preconceptional or prenatal genetic testing on a parent or prospective parent to determine carrier status of an autosomal recessive disorder, an x-linked disorder, or a disorder with variable penetrance. The testing is typically done prior to pregnancy to guide reproductive decisions.

- Clarified investigational and not medically necessary statement
- Added preconceptional or prenatal genetic testing using panels of genes (with or without next generation sequencing), including but not limited to, whole genome and whole exome sequencing, is considered investigational and not medically necessary unless all components of the panel have been determined to be medically necessary based on the medically necessary criteria. However, individual components of a panel may be considered medically necessary when criteria above are met
- Added 81479 (NOC) to the policy coding section for sequencing panels, whole genome and whole exome as Investigational and not medically necessary
- Updated Rationale, Background, Definition, Coding and Reference sections

GENE.00013 Diagnostic Genetic Testing of a Potentially Affected Individual (Adult or Child): This document addresses diagnostic genetic testing of a potentially affected individual (adult or child).

- Added the use of gene expression profiling as medically necessary when criteria are met
- Added diagnostic genetic testing using panels of genes (with or without next generation sequencing), including but not limited to, whole genome and whole exome sequencing, as considered investigational and not medically necessary unless all components of the panel have been determined to be medically necessary based on the medically necessary criteria. However, individual components of a panel may be considered medically necessary when criteria are met.
- Added 81599 (NOC) to the policy coding section for gene expression profiling
- Added 81479 (NOC) to the policy coding section for sequencing panels, whole genome and whole exome
- Updated Rationale, Background, Definition, Coding, Reference and Index sections

LAB.00027 Selected Blood, Serum and Cellular Allergy and Toxicity Tests: This document addresses select unproven blood, serum, and cellular allergy and toxicity tests.

- Title revised, previously titled: Antigen Leukocyte Cellular Antibody Test (ALCAT) for Chemical and Food Allergies
- Expanded the scope of document to address selected unproven blood, serum and cellular allergy and toxicity tests
- Revised the position statement to indicate that the following tests are considered investigational and not medically necessary:
  - Antigen leukocyte cellular antibody test (ALCAT); or
  - Cytotoxic test; or
  - HEMOCODE Food Tolerance System; or
  - IgG food sensitivity test; or
  - Immuno Blood Print test; or
  - Leukocyte histamine release test (LHRT)
LAB.00029 Rupture of Membranes (ROM) Testing in Pregnancy: This document addresses testing for suspected rupture of membranes (ROM) with test kits, such as the AmniSure® ROM test, which detects PAMG-1 (placental alpha-1 microglobulin), a protein marker of amniotic fluid in vaginal secretions; the ROM Plus® Fetal Membrane Rupture test, which tests both placental protein 12 (PP12) and alpha-fetoprotein (AFP); and the Actim® PROM test, which tests for insulin-like growth factor binding protein 1 (IGFBP-1).

- Title revised, previously titled: AmniSure® ROM (Rupture of Membranes) Test
- Expanded scope of document
- Revised position statement to state – Evaluation of cervicovaginal fluid for specific amniotic fluid protein(s), (for example, placental alpha microglobulin-1 [PAMG-1], placental protein 12 [PP12], alpha-fetoprotein), is considered investigational and not medically necessary for all indications, including detection of preterm ROM
- Updated Description, Rationale, Reference and Index sections

LAB.00030 Measurement of Serum Concentrations of Tumor Necrosis Factor Antagonist Drugs and Antibodies to Anti-Tumor Necrosis Factor Antagonist Drugs: This document addresses the measurement of serum concentrations of tumor necrosis factor (TNF) antagonist drugs and antibodies to TNF antagonist drugs in individuals with various conditions.

- Title revised, previously titled: Measurement of Serum Concentrations of Infliximab (IFX) or Antibodies-to- Infliximab (ATI)
- Expanded scope of document
- Revised position statement to state – The measurement of serum concentrations of tumor necrosis factor antagonist drugs or antibodies to tumor necrosis factor antagonist drugs is considered investigational and not medically necessary under all circumstances
- Updated Description, Rationale, Reference and Index sections

MED.00110 Growth Factors, Silver-based Products and Autologous Tissues for Wound Treatment and Soft Tissue Grafting: This document addresses the use of recombinant human platelet-derived growth factor (i.e., becaplermin [Regranex®]), antimicrobial silver wound dressings, (e.g., Acticoat, Actisorb™, and Silversorb®), autologous blood-derived wound products, (e.g., Autologel™, SafeBlood™, Vitagel®), platelet rich plasma (PRP), and bone marrow aspirate concentrate.

- Added the use of bone marrow aspirate concentrate (BMAC) as investigational and not medically necessary for all indications, including for the treatment of critical limb ischemia
- Added 20999 (NOC) to the policy coding section for administration
- Updated Description, Rationale, Background, Definition, Coding, Reference and Index sections

SURG.00001 Carotid, Vertebral and Intracranial Artery Stent Placement with or without Angioplasty: This document addresses extracranial carotid, vertebral and intracranial artery stent placement with or without angioplasty.

- Title revised, previously titled: Carotid, Vertebral and Intracranial Artery Angioplasty with or without Stent Placement
- Expanded position statement to include open approach procedures
- CPT code 37217 was added to the policy coding section to review for medical necessity
- Updated Description, Coding and Reference sections
SURG.00028 Surgical and Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH) and Other Genitourinary Conditions: This document addresses various surgical and minimally invasive procedures used in the treatment of BPH, and the use of these procedures for other genitourinary conditions.

- Reformatted investigational and not medically necessary criteria
- Added prostatic arterial embolization and prostatic urethral lift for the treatment of BPH as investigational and not medically necessary
- Reformatted other sections of position statement with no change to criteria
- CPT code 37243, and HCPCS code C9734 were added to the policy coding section as investigation and not medically necessary for BPH diagnosis
- Updated Rationale, Background, Coding, Reference and Index sections

SURG.00108 Endothelial Keratoplasty: This document addresses the use of a variety of endothelial keratoplasty (EK) techniques, which are used to treat conditions affecting the cornea. The available EK procedures include Descemet’s membrane endothelial keratoplasty (DMEK), Descemet’s stripping endothelial keratoplasty (DSEK), Descemet’s stripping automated endothelial keratoplasty (DSAEK) and Descemet’s membrane automated endothelial keratoplasty (DMAEK). Other similar procedures addressed in this document include Femto second Laser-Assisted Corneal Endothelial Keratoplasty (FLEK or FLAK) or Femtosecond and Excimer Lasers-Assisted Endothelial Keratoplasty (FELEK).

- Restructured position statements
- Added Descemet’s membrane endothelial keratoplasty (DMEK) and Descemet’s membrane automated endothelial keratoplasty (DMAEK) as medically necessary for the treatment of disorders of the corneal endothelium including but not limited to the following:
  - Fuchs’ endothelial dystrophy; or
  - Aphakic and pseudophakic bullous keratopathy (corneal edema following cataract extraction); or
  - Failure or rejection of a previous corneal transplant
- Added DMEK and DMAEK as investigational and not medically necessary to treat disease or injury of the corneal stroma (for example, keratoconus, corneal ulcers caused by infection and traumatic corneal injuries)
- CPT code 37217 was added to the policy coding section to review for medical necessity
- Added femtosecond laser-assisted corneal endothelial keratoplasty (FLEK) or femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK) as investigational and not medically necessary for all indications
- Updated Description, Rationale, Background, Coding, Reference and Index sections

SURG.00109 Surgical Treatment of Femoroacetabular Impingement Syndrome: This document addresses the surgical treatment of femoroacetabular impingement syndrome including the capsular plication procedure.

- Added the use of capsular plication for the treatment of femoroacetabular impingement syndrome (FAIS) as investigational and not medically necessary under all circumstances
- Updated Description, Rationale, Definition, Coding and Reference sections