Updates to Medical Policies and Clinical UM Guidelines

*Effective October 15, 2013*

The updated policies listed below are effective for service dates on and after October 15, 2013. 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 October 15, 2013**

- **DRUG.00056 Ado-trastuzumab emtansine (Kadcyla™):** This policy addresses ado-trastuzumab emtansine (Kadcyla™) which is an antibody-drug conjugate (ADC) that targets the human epidermal growth factor receptor 2 protein (HER2).
  - Outlines the medically necessary and investigational and not medically necessary criteria for ado-trastuzumab emtansine

- **LAB.00029 AmniSure® ROM (Rupture of Membranes) Test:** This policy addresses the AmniSure® test which detects PAMG-1 (placental alpha-1 microglobulin) protein marker of amniotic fluid in vaginal secretions and is intended for use by health care professionals as a point-of-care service to aid in the detection of rupture of membranes (ROM) in pregnant women with signs, symptoms or complaints suggestive of ROM.
  - The use of the AmniSure ROM (Rupture of Membranes) test is considered investigational and not medically necessary for all indications, including detection of preterm ROM

- **MED.00112 Autonomic Testing:** This policy addresses the use of autonomic testing.
  - The use of autonomic nervous system function testing for sudomotor function using quantitative sudomotor axon reflex test (QSART), the thermoregulatory sweat test (TST), silastic sweat imprint, sympathetic skin response (SSR), or quantitative direct and indirect reflex test of sudomotor function (QDIRT) is considered investigational and not medically necessary for all indications
  - The use of autonomic nervous system function testing for cardiovagal innervations is considered investigational and not medically necessary for all indications
  - The use of autonomic nervous system function testing for vasomotor adrenergic innervations is considered investigational and not medically necessary for all indications

- **SURG.00137 Focused Microwave Thermotherapy for Breast Cancer:** This policy addresses focused microwave thermotherapy as a treatment for breast cancer.
  - Focused microwave thermotherapy is considered investigational and not medically necessary as a treatment for breast cancer
Revised Medical Policies and Adopted Clinical UM Guidelines Effective October 15, 2013

- **DRUG.00003 Chelation Therapy**: This policy addresses the medical necessity of chelation therapy.
  - Removed emergency treatment of hypercalcemia as medically necessary indication
  - Updated Reference, Coding and Index sections

- **DRUG.00006 Botulinum Toxin**: This policy addresses the use of both type A and type B botulinum toxin products (e.g., Botox® [OnabotulinumtoxinA], Myobloc™ [RimabotulinumtoxinB], Dysport® [AbobotulinumtoxinA] and Xeomin® [IncobotulinumtoxinA]), for the treatment of all health conditions, with the exception of hyperhidrosis.
  - Added the use of botulinum toxin, whether with the same or a different product, following failure of an initial trial for the treatment of a medically necessary condition as investigational and not medically necessary. Note: when the initial product was stopped due to a product specific intolerance or allergic reaction (rather than clinical failure), this investigational and not medically necessary statement does not apply.
  - Updated Rationale and Reference sections

- **DRUG.00009 Growth Hormone**: This policy addresses the use of human growth hormone for the treatment of children, adolescents and adults with a variety of medical conditions.
  - Revised position statement to consider growth hormone therapy not medically necessary to increase height in children with idiopathic short stature
  - Updated Rationale, Background, Definition, Coding and Reference sections

- **DRUG.00024 Omalizumab (Xolair®)**: This policy addresses omalizumab (Xolair®) which is a monoclonal antibody that interferes with allergic response by binding to immuno-globulin E (IgE). The drug received FDA approval in 2003 and is indicated for individuals 12 years of age and above with moderate to severe persistent asthma, who have shown reactivity to an allergen and whose symptoms are inadequately controlled with inhaled corticosteroids.
  - Revised medically necessary criteria for the initiation of treatment to require that symptoms are inadequately controlled for a minimum of 3 months of prior combination controller therapy
  - Updated Rationale and Reference sections

- **DRUG.00050 Eculizumab (Soliris®)**: This policy addresses the use of eculizumab in the treatment of individuals with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), and other conditions.
  - Revised medically necessary criteria for PNH by removing transfusion requirement and removing requirement to be on therapeutic anticoagulation therapy when experiencing a major adverse vascular event (MAVE)
  - Revised medically necessary criteria for PNH by adding criteria requiring that LDH be greater than 1,000 U/L.
  - Revised medically necessary criteria for the treatment of aHUS to address an initial 6-week trial
  - Revised medically necessary criteria for aHUS by adding criteria requiring that thrombotic thrombocytopenic purpura (TTP) has been ruled out (for example, normal ADAMTS 13 activity and no evidence of an ADAMTS 13 inhibitor), or if TTP cannot be ruled out by laboratory and clinical evaluation, a trial of plasma exchange did not result in clinical improvement
  - Added criteria addressing the continuation of therapy for aHUS
  - Clarified investigational and not medically necessary statement
  - Updated Rationale, Background, Definition and Reference sections
• **GENE.00001 Genetic Testing for Cancer Susceptibility**: This policy addresses genetic testing for individuals who are at higher than average risk for the development of cancer.
  o Revised BRCA1 and BRCA2 medically necessary criteria for individuals with a personal history of cancer
  o Revised BRCA1 and BRCA2 medically necessary criteria for individuals with a family history of cancer
  o Revised medically necessary criteria for HNPCC/Lynch Syndrome
  o Clarified medically necessary criteria for MYH (Human MutY homolog)-associated Polyposis (MAP)
  o Updated Rationale and Reference sections

• **SURG.00011 Allogeneic, Xenographic, Synthetic and Composite Products for Wound Healing and Soft Tissue Grafting**: This policy addresses the use of soft tissue (e.g., skin, ligament, cartilage, etc.) substitutes in wound healing and surgical procedures.
  o Added new products to investigational and not medically necessary list
  o Updated Description, Rationale, Background, Coding and Reference sections

• **SURG.00047 Transendoscopic Therapy for Gastroesophageal Reflux Disease and Dysphagia**: This document addresses selected transendoscopic therapies for the treatment of gastroesophageal reflux disease (GERD) and dysphagia.
  o Title revised, previously titled: Transendoscopic Therapy for Gastroesophageal Reflux Disease
  o Expanded scope of policy to also address dysphagia
  o Added per-oral endoscopic myotomy (POEM) to investigational and not medically necessary position statement
  o Updated Description, Rationale, Background, Coding and Reference sections

• **SURG.00122 Venous Angioplasty with or without Stent Placement**: This policy addresses the use of venous angioplasty as a treatment modality.
  o Title revised, previously titled: Venous Angioplasty with or without Stent Placement for the Treatment of Multiple Sclerosis
  o Added the following conditions as medically necessary:
    o Arterio-venous dialysis access grafts which are stenotic or thrombosed
    o Thrombotic obstruction of major hepatic veins (Budd-Chiari syndrome)
    o Superior Vena Cava Syndrome
    o Congenital heart disease including, but not limited not:
      - stenosis or hypoplasia of a pulmonary artery in a child
      - symptomatic stenosis/occlusion of superior or inferior vena cave
      - venous narrowing due to repair of sinus venous atrial septal defect (ASD)
      - venous obstruction of an atrial baffle following Mustard or Senning repair of transposition of The great arteries
  o Revised investigational and not medically necessary criteria
  o Updated Description, Rationale, Background, Definition, Coding and Reference sections

• **TRANS.00024 Hematopoietic Stem Cell Transplantation for Select Leukemia’s and Myelodysplastic Syndrome**: This policy addresses hematopoietic stem cell transplantation (SCT) in the treatment of the select leukemias and myelodysplastic disorders.
  o Clarified medically necessary criteria addressing allogeneic SCT for AML
  o Removed medically necessary criteria addressing autologous SCT for AML and ALL
  o Revised investigational and not medically necessary criteria for autologous SCT for AML and ALL
  o Revised medically necessary criteria addressing allogeneic SCT for CML
  o Updated Rationale, Background, Coding and Reference 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.

Attachment A

The revised medical policies listed below will become effective for services rendered on or after October 15, 2013.

<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.00007</td>
<td>Cardiac Ion Channel Genetic Testing</td>
<td>The following code has been added to this policy and is considered not medically necessary if criteria not met:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• <strong>81404</strong> Molecular pathology procedure, Level 5 (e.g., analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• <strong>81406</strong> Molecular pathology procedure, Level 7 (e.g., analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia)</td>
</tr>
</tbody>
</table>

(cont’d on next page)
<table>
<thead>
<tr>
<th>Medical Policy Number</th>
<th>Medical Policy Title</th>
<th>Medical Policy / Clinical Guideline Changes</th>
</tr>
</thead>
</table>
| GENE.00012            | Preconceptional or Prenatal Genetic Testing of a Parent or Prospective Parent         | Updated the coding section and system edits to pend the following codes for medical necessity review for additional diagnosis:  
•  **81404** Molecular pathology procedure, Level 5 (e.g., analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)  
•  **81405** Molecular pathology procedure, Level 6 (e.g., analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons)  
The following code has been added to this policy and is considered not medically necessary if criteria not met:  
•  **81406** Molecular pathology procedure, Level 7 (e.g., analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia) |
| GENE.00013            | Diagnostic Genetic Testing of a Potentially Affected Individual (Adult or Child)     | The following code has been added to this policy and is considered not medically necessary if criteria not met:  
•  **81405** Molecular pathology procedure, Level 6 (e.g., analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons)  
•  **81406** Molecular pathology procedure, Level 7 (e.g., analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia)  
Updated the coding section and system edits to pend the following codes for medical necessity review for additional diagnosis  
•  **81404** Molecular pathology procedure, Level 5 (e.g., analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis) |
| GENE.00017            | Genetic Testing for Diagnosis and Management of Hereditary Cardiomyopathies (including ARVD/C) | The following code has been added to this policy and is considered not medically necessary if criteria not met:  
•  **81403** Molecular pathology procedure, Level 4 (e.g., analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)  
•  **81408** Molecular pathology procedure, Level 9 (e.g., analysis of >50 exons in a single gene by DNA sequence analysis) |