**Updates to Medical Policies and Clinical UM Guidelines**

*Effective October 15, 2011*

UniCare is pleased to provide you with our updated and new Medical Policies and Clinical UM Guidelines. The major new policies and changes are summarized below. Additional changes are included in Attachment A at the end of this document. Please refer to the specific policy for coding, language, and rationale updates and changes that are not summarized in this notice.

**IMPORTANT NOTE REGARDING DRUG.00044 Belimumab (Benlysta®):** The medical policy for belimumab was included in our first quarter notice, dated April 12, 2011. At that time, the use of belimumab was considered investigational and not medically necessary for all indications. However, shortly after and before this medical policy became effective, belimumab was approved by the FDA. A new medical policy has now been developed that addresses medical necessity criteria for the use of belimumab in the treatment of individuals age 18 or older with active antibody-positive systemic lupus erthematosus (SLE) and for other indications. Our revised medical policy is available to view online at [www.unicarestateplan.com](http://www.unicarestateplan.com) > Providers > WellPoint Medical Policies.

**New Medical Policies Effective October 15, 2011**

- **GENE.00020  Microarray-Based Gene Expression Profile Testing for Multiple Myeloma:** This policy addresses the proposed use of the My Prognostic Risk Signature™ (MyPRS™) microarray-based test to analyze an individual’s genomic information to determine the gene expression profile (GEP) associated with multiple myeloma.
  - Microarray-based gene expression profile testing using the MyPRS™ test is considered investigational and not medically necessary for all indications, including but not limited to:
    - use as a risk stratification tool to predict outcomes in individuals with newly diagnosed multiple myeloma; or
    - assist in determining the prognosis for survival in individuals with relapsed multiple myeloma

- **GENE.00021  Comparative Genomic Hybridization (CGH) Microarray Testing for Developmental Delay, Autism Spectrum Disorder and Mental Retardation:** This policy address aCGH testing for developmental delay, autism spectrum disorder and mental retardation, however, it does not address other testing like karyotyping, FISH, or other genetic molecular testing.
  - CGH microarray testing is considered investigational and not medically necessary for the evaluation of developmental delay, autism spectrum disorder and mental retardation
• **SURG.00124 Carotid Sinus Baroreceptor Stimulation for the Treatment of Drug Resistant Hypertension:** This policy addresses the insertion and use of a carotid sinus baroreflex activation device for the treatment of drug resistant hypertension.
  o The use of a carotid sinus baroreflex activation device is considered investigational and not medically necessary for all indications

• **TRANS.00036 Stem Cell Therapy for Peripheral Vascular Disease:** This policy addresses the use of stem cell therapy for the treatment of peripheral vascular disease (PVD).
  o The use of stem cell therapy for the treatment of peripheral vascular disease (PVD) is considered investigational and not medically necessary

**Revised Medical Policies and Adopted Clinical UM Guidelines effective October 15, 2011:**

• **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).
  o Added criterion for electrically powered vacuum assisted wound therapy that requires individual to be 13 years of age or older

• **DRUG.00038 Bevacizumab (Avastin®) for Oncologic Indications:** This policy addresses the indications and criteria for the use of bevacizumab in the treatment of oncologic conditions.
  o Revised criteria for NSCLC by adding that bevacizumab is medically necessary when used as first-line therapy for individuals with performance status 0 - 1 and no history of hemoptysis when used in combination with both:
    • platinum-based therapy and
    • taxane or pemetrexed
  o Revised criteria for breast cancer by removing docetaxel and capecitabine from medically necessary criteria

• **LAB.00020 Skin Nerve Fiber Density Testing:** This policy addresses the pathological analysis, from skin biopsy specimens, of intraepidermal nerve fiber (IENF) density and the pathological analysis for sweat gland nerve fiber density for the diagnosis of small-fiber neuropathy (SFN).
  o Title revised
  o Expanded scope of policy
  o Added pathological analysis of sweat gland nerve fiber density testing for the diagnosis of small-fiber neuropathy as investigational and not medically necessary for all indications

• **LAB.00024 Immune Cell Function Assay:** This policy addresses an immune cell function assay, the ImmuKnow™, which was developed for use in the detection of cell mediated immunity (CMI) in individuals undergoing immunosuppressive therapy post solid organ transplant. The assay has also been investigated as a method of identifying individuals at risk for early acute kidney transplant rejection prior to the transplant and for the evaluation of a variety of non solid organ transplant related conditions such as
autologous and allogeneic hematopoietic stem-cell transplant recipients, immunodeficiency diseases and multiple sclerosis.

- Title revised
  - Clarified that the immune cell function assay is investigational and not medically necessary for all indications including, but not limited to:
    - For management of organ transplant rejection in an individual undergoing immunosuppressive therapy following solid organ transplant
    - For identification of an individual at risk for rejection prior to kidney or any other solid organ transplant
    - For management of an individual undergoing autologous or allogeneic hematopoietic stem cell transplant
    - For management of an individual with an immunodeficiency disease (e.g. severe combined immunodeficiency disease [SCID])
    - For management of an individual with multiple sclerosis

- **RAD.00002 Positron Emission Tomography (PET) and PET/CT Fusion:** This document addresses the use of PET scans and PET/CT fusion.
  - Clarified cardiac criteria addressing left ventricular dysfunction
  - Added assessment of suspected cardiac sarcoidosis when MRI is contraindicated as medically necessary indication
  - Added interim PET scanning during a course of treatment to evaluate response to treatment as investigational and not medically necessary (Note: Interim PET scanning is not considered restaging)
  - Added PET Mammography (PEM) for the detection of breast cancer or subsequent monitoring of breast cancer as investigational and not medically necessary

- **SURG.00011 Autologous, Allogeneic, Xenographic, Synthetic and Composite Products for Wound Healing and Soft Tissue Grafting:** This policy addresses the use of skin substitutes and growth factors in wound healing and surgical procedures.
  - Added synthetic soft-tissue grafting materials (e.g., SportMesh™) as investigational and not medically necessary for all applications
  - Added xenographic-related or derived products (e.g., MediHoney®) as investigational and not medically necessary for all applications

- **SURG.00045 Extracorporeal Shock Wave Therapy for Orthopedic Conditions:** This policy addresses the use of extracorporeal shock wave treatment (ESWT) for musculoskeletal conditions, including chronic plantar fasciitis, lateral epicondylitis (tennis elbow) and tendinitis of the supraspinatus muscle or rotator cuff.
  - Added Extracorporeal Pulse Activation Therapy (EPAT®) as investigational and not medically necessary

- **SURG.00054 Endovascular/Endoluminal Repair of Aortic Aneurysms:** This policy addresses the use of stent grafts placed endovascularly for the treatment of aortic and aortoiliac aneurysms.
  - Added the use of fenestrated and branched endovascular/endoluminal stent graft devices as investigational and not medically necessary

- **TRANS.00024 Hematopoietic Stem Cell Transplantation for Select Leukemias and Myelodysplastic Syndrome:** This policy addresses hematopoietic stem cell transplantation in the treatment of select leukemias and myelodysplastic disorders.
  - Clarified and reformatted AML criteria
  - Reformatted and clarified criteria in all other sections of position statement
  - Removed redundant medically necessary statements in ALL and CLL/SLL sections
• Changed wording of "myelodysplastic disorder (MPD)" to "myelodysplastic neoplasms (MPN)"

• **TRANS.00027  Hematopoietic Stem Cell Transplantation for Pediatric Solid Tumors:** This document addresses hematopoietic stem cell transplantation for pediatric solid tumors.
  - Removed allogeneic transplant (ablative or non myeloablative) as medically necessary for neuroblastoma
  - Clarified that allogeneic (ablative or non myeloablative) transplant for neuroblastoma is investigational and not medically necessary
  - Added language in Rationale addressing stage IV retinoblastoma and the possibility of randomized clinical trials

WellPoint Medical Policies and Clinical UM Guidelines are developed by our national 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 [www.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, 2011.

<table>
<thead>
<tr>
<th>Medical Policy Number</th>
<th>Medical Policy Title</th>
<th>Medical Policy / Clinical Guideline Changes</th>
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</thead>
</table>
| ANC.00008             | Cosmetic and Reconstructive Services of the Head and Neck | Updated system edits to match policy position statement and coding section for the following codes:  
  • 21256 Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (eg, micro-opthalmia) |

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<th>Medical Policy Number</th>
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<th>Medical Policy / Clinical Guideline Changes</th>
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<tbody>
<tr>
<td>SURG.00064</td>
<td>Cardiac Resynchronization Therapy (CRT) with or without an Implantable Cardioverter Defibrillator (CRT/ICD) for the Treatment of Heart Failure</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>
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<td>• 33224 Insert of Pacing Electrode, Cardiac Venous System, to Previous Placed Pacemaker or Pacing Cardioverter-Defibrillator Pulse</td>
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<tr>
<td></td>
<td></td>
<td>• 33225 Insert of Pacing Electrode, Cardiac Venous System, Left Ventricular Pacing, at time of insert of pacing Cardioverter-Defibrillator Pulse</td>
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<tr>
<td></td>
<td></td>
<td>• 33226 Repositioning of Previously Implanted Cardiac Venous System Electrode</td>
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<td>• 00530 Anesthesia for permanent transvenous pacemaker insertion</td>
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<td>• 33207 Insertion or replacement of permanent pacemaker with transvenous electrode(s); ventricular</td>
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<td>• 33208 Insertion or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular</td>
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<td>• 33211 Insertion or replacement of temporary transvenous dual chamber pacing electrodes (separate procedure)</td>
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<td>• 33213 Insertion or replacement of pacemaker pulse generator only; dual chamber</td>
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<td>• 33214 Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)</td>
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<td>• 93640 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement;</td>
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<tr>
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<td>• 93641 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation</td>
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<td>• 93642 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator</td>
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<tr>
<td>SURG.00065</td>
<td>Local Ablative Techniques for Treating Primary and Metastatic Liver Malignancies</td>
<td>Updated the coding section and system edits to pend the following codes for medical necessity review for additional diagnosis:</td>
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<tr>
<td></td>
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<td>• 47120 Hepatectomy, resection of liver; partial lobectomy</td>
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<td>• 47122 Hepatectomy, resection of liver; trisegmentectomy</td>
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<td>• 47125 Hepatectomy, resection of liver; total left lobectomy</td>
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<tr>
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<td>• 47130 Hepatectomy, resection of liver; total right lobectomy</td>
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