Updates to Medical Policies and Clinical UM Guidelines

Effective May 1, 2016

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 May 1, 2016

- **DRUG.00079 Bendamustine Hydrochloride (TREANDA®):** This document addresses the indications for the use of bendamustine hydrochloride (HCL), a cytotoxic, bifunctional mechlorethamine derivative with alkylator and antimetabolite activities used in the treatment of oncologic conditions.
  - Outlines the medically necessary, and investigational and not medically necessary, criteria for bendamustine HCL

- **DRUG.00080 Mepolizumab (Nucala®):** This document addresses the use of mepolizumab (Nucala), a humanized monoclonal antibody against interleukin-5 used for the treatment of individuals with severe eosinophilic asthma not well controlled with inhaled corticosteroids and long-acting beta-agonists.
  - Outlines the medically necessary, and investigational and not medically necessary, criteria for mepolizumab

- **THER-RAD.00011 Image-guided Radiation Therapy (IGRT) with External Beam Radiation Therapy (EBRT):** This document addresses image-guided radiation therapy (IGRT) when used in combination with conformal external beam radiation therapy (EBRT).
  - Outlines the medically necessary, and investigational and not medically necessary, criteria for IGRT used in conjunction with EBRT

Revised Medical Policies and Adopted Clinical UM Guidelines Effective May 1, 2016

- **LAB.00031 Advanced Lipoprotein Testing:** This document addresses the use of advanced testing of lipoproteins for cardiovascular disease (CVD) risk assessment and management and all other indications.
  - Title revised (old title was from Advanced Lipoprotein Testing in Cardiac Disease Risk Assessment and Management)
  - Expanded scope of policy
  - Revised position statement to state that advanced lipoprotein testing is investigational and not medically necessary for CVD risk assessment and management and for all other indications
  - Updated Description, Rationale, Coding and Reference sections
• MED.00103 Automated Evacuation of Meibomian Gland: This document addresses the use of devices which will automate the process of applying heat and intermittent pressure for the treatment of meibomian gland dysfunction, and associated imaging.
  o Revised scope of document to include imaging associated with the automated evacuation devices
  o Added tear film imaging as investigational and not medically necessary
  o Updated Description, Background, Coding and Reference sections

• MED.00113 Therapeutic Apheresis: This document addresses therapeutic apheresis, a procedure by which blood is removed from the body, separated into components, manipulated and returned to the individual.
  o Revised medically necessary indication for thrombotic microangiopathy clarifying that plasmapheresis (plasma exchange) is medically necessary for the treatment of thrombotic microangiopathy secondary to ticlopidine or malignancy
  o Added HLA incompatibility with haplo-type hematopoietic stem cell transplant as a medically necessary indication for plasmapheresis or plasma exchange
  o Made a minor formatting change in medically necessary criteria for erythrocytapheresis or phlebotomy
  o Clarified that the treatment of thrombotic microangiopathy secondary to drugs other than ticlopidine (for example, clopidogrel, cyclosporine, gemcitabine, quinine, or tacrolimus) is investigational and not medically necessary
  o Removed hematopoietic stem cell transplant – ABO incompatible as investigational and not medically necessary indication for cytapheresis
  o Made minor wording changes throughout position statement
  o Updated Description, Rationale, Definitions, Coding and References sections

• SURG.00024 Bariatric Surgery and Other Treatments for Clinically Severe Obesity: This document addresses surgical and other treatments for clinically severe obesity.
  o Title revised (old title was Surgery for Clinically Severe Obesity)
  o Expanded scope of document to include non-surgical treatments
  o Added an investigational and not medically necessary statement for surgical procedures when criteria are not met
  o Revised investigational and not medically necessary statement addressing other procedures and treatment modalities
  o Added balloon systems (such as the ReShape® Integrated Dual Balloon System) and vagus (or vagal) nerve blocking devices (such as the MAESTRO® Rechargeable System) as investigational and not medically necessary
  o Updated Description, Rationale, Background, Definitions, Coding, Reference and Index sections

• THER-RAD.00008 Neutron Beam Radiotherapy: This document addresses neutron beam radiation therapy.
  o Re-categorized (previous category and number was RAD.00047)
  o Revised position statement to now consider neutron beam radiotherapy investigational and not medically necessary for all indications
  o Updated Rationale, Coding and Reference sections

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

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 UniCare’s medical policies. Review procedures have been refined to facilitate claim investigation.

You can access the complete list of Medical Policies and Clinical UM Guidelines from unicarestateplan.com. On the Providers page, select the button for Medical Policies; then select Review all medical policies and clinical UM guidelines.
The revised medical policies listed below will become effective for *services rendered on or after May 1, 2016.*

<table>
<thead>
<tr>
<th>Medical Policy Number</th>
<th>Medical Policy Title</th>
<th>Medical Policy / Clinical Guideline Changes</th>
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| DRUG.00047            | Brentuximab Vedotin (Adcetris®) | • Clarified medically necessary criteria addressing Hodgkin lymphoma  
• Added the treatment of individuals with CD30+ positive T-cell lymphoma that is relapsed or refractory to first-line therapy as medically necessary  
• Updated Rationale, Background, Coding and Reference sections |
| DRUG.00051            | Ziv-aflibercept (Zaltrap®) | • Added anal adenocarcinoma, appendiceal adenocarcinoma and small bowel adenocarcinoma as medically necessary when criteria are met  
• Updated Rationale, Background, Definition, Coding and Reference sections |
| DRUG.00053            | Carfilzomib (Kyprolis®) | • Title revised - replaced trademark in brand name with registered mark  
• Clarified and reformatted medically necessary criteria addressing the treatment of multiple myeloma  
• Added carfilzomib in combination with lenalidomide and dexamethasone as medically necessary when the individual has received one to three prior lines of therapy  
• Added the treatment of Waldenström’s macroglobulinemia as medically necessary when criteria are met  
• Updated Description, Rationale, Background, Coding, Reference and Index sections |
| DRUG.00066            | Antihemophilic Factors and Clotting Factors | • Clarified medically necessary criteria addressing recombinant Factor VIIa (NovoSeven RT) by adding "for the treatment of bleeding episodes and peri-operative management" in individuals with Glanzmann’s thrombasthenia and a documented refractoriness to platelet transfusions with or without antibodies to platelets  
• Added the drug Nuwiq as medically necessary when the recombinant antihemophilic factor (Factor VIII) criteria are met  
• Added human plasma-derived coagulation Factor X, (Coagadex) as medically necessary when criteria are met |
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<tr>
<th>DRUG.00066</th>
<th>Antihemophilic Factors and Clotting Factors</th>
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| **(continued)** | • Added Coagadex as investigational and not medically necessary when the criteria are not met and for all other indications including, but not limited to perioperative management of bleeding in major surgery in individuals with moderate and severe hereditary Factor X deficiency  
• Clarified medically necessary criteria addressing human plasma-derived concentrate Factor XIII (Corifact)  
• Updated Description, Rationale, Background, Coding, Reference and Appendix sections |

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<tr>
<th>DRUG.00071</th>
<th>Pembrolizumab (Keytruda®)</th>
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| **(continued)** | • Revised ECOG performance status criterion to be 0-2 (previously 0-1) in medically necessary criteria addressing individuals with melanoma  
• Added the treatment of metastatic non-small cell lung cancer (NSCLC) as medically necessary when criteria are met  
• Clarified investigational and not medically necessary section  
• Updated Description, Rationale, Background, Definition, Coding, Reference and Index sections |

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<thead>
<tr>
<th>DRUG.00075</th>
<th>Nivolumab (Opdivo®)</th>
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| **(continued)** | • Revised medically necessary criteria addressing nivolumab used as second-line or subsequent therapy for individuals with melanoma with documented disease progression while receiving or since completing most recent therapy, to include in combination with ipilimumab, if PD-1 agent not previously used  
• Revised ECOG performance status criterion to be 0-2 (previously 0-1) in medically necessary criteria addressing individuals with melanoma and NSCLC  
• Expanded the use of nivolumab for the treatment of metastatic NSCLC to include all types (removed the word squamous)  
• Added the treatment of advanced or metastatic (clear cell) renal cell carcinoma (RCC) as medically necessary when criteria are met  
• Updated investigational and not medically necessary statement  
• Updated Description, Rationale, Background, Coding, Reference and Index sections |

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<tr>
<th>GENE.00002</th>
<th>Preimplantation Genetic Diagnosis Testing</th>
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| **(continued)** | • Added a history of trisomy in a previous pregnancy as a medically necessary indication for preimplantation genetic testing  
• Made minor wording changes in medically necessary section  
• Updated Description and Reference sections  
• Removed ICD-9 codes from Coding section |
<table>
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<tr>
<th>Code</th>
<th>Title</th>
<th>Changes</th>
<th>Details</th>
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| GENE.00011      | Gene Expression Profiling for Managing Breast Cancer Treatment | • Revised medically necessary criteria addressing tumor size to state: tumor greater than 1.0 cm and less than or equal to 5.0 cm (previously the upper limit was 4.0 cm)  
• Made minor wording changes in position statement  
• Updated Rationale, Reference and Index sections  
• Removed ICD-9 codes from Coding section |                                                                 |
| GENE.00014      | Analysis of KRAS Status                    | • Removed the registered and trademark symbols from the position statement  
• Updated Description, Rationale, Background, Definition, Coding, Reference and Index sections |                                                                 |
| GENE.00019      | BRAF Mutation Analysis                     | • Added BRAF V600E mutation analysis as medically necessary for individuals with non-small cell lung cancer (NSCLC) to select those who would benefit from treatment with vemurafenib (Zelboraf®)  
• Added BRAF V600E mutation analysis as medically necessary for individuals with relapsed hairy-cell leukemia to select those who would benefit from treatment with vemurafenib (Zelboraf®)  
• Updated Description, Rationale, Background, Definitions, Coding and Reference sections |                                                                 |
| SURG.00011      | Allogeneic, Xenographic, Synthetic and Composite Products for Wound Healing and Soft Tissue Grafting | • Added Perlane and Restlyane to list of products considered investigational and not medically necessary  
• Updated Description, Rationale, Coding and Reference sections |                                                                 |
| SURG.00024      | Bariatric Surgery and Other Treatments for Clinically Severe Obesity | • Title revised (was Surgery for Clinically Severe Obesity)  
• Expanded scope of document to include non-surgical treatments  
• Added an investigational and not medically necessary statement for surgical procedures when criteria are not met  
• Revised investigational and not medically necessary statement addressing other procedures and treatment modalities  
• Added balloon systems (such as the ReShape® Integrated Dual Balloon System) and vagus (or vagal) nerve blocking devices (such as the MAESTRO® Rechargeable System) as investigational and not medically necessary  
• Updated Description, Rationale, Background, Definitions, Coding, Reference and Index sections |                                                                 |
| SURG.00121      | Transcatheter Heart Valve Procedures       | • Added the SAPIEN 3 transcatheter heart valve to medically necessary criteria addressing transcatheter aortic valve replacement (TAVR)  
• Made minor wording changes in position statement  
• Updated Rationale, Description, Background and Reference sections  
• Removed ICD-9 codes from Coding section |                                                                 |