February 1, 2017

RE: Medical Policy, Clinical UM Guidelines, and Specialty Pharmacy changes notification letter

Dear Provider:

Anthem Blue Cross and Blue Shield and our subsidiary company, HMO Nevada (Anthem) are pleased to provide you with our updated and new medical policies. Anthem will also be implementing changes to our Clinical Utilization Management (UM) Guidelines that are adopted for Nevada. The Clinical UM guidelines published on our website represent the clinical UM guidelines currently available to all Plans for adoption throughout our organization. Because local practice patterns, claims systems and benefit designs vary, a local Plan may choose whether or not to implement a particular clinical UM guideline. The link below can be used to confirm whether or not the local Plan has adopted the clinical UM guideline(s) in question. Adoption lists are created and maintained solely by each local Plan.

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 and Adopted Clinical UM Guidelines effective for service dates on and after May 1, 2017:

- **DME.00040 Automated Insulin Delivery Devices**: This document addresses the use of automated insulin delivery devices. Such devices integrate a continuous interstitial glucose monitor (CIGM) with an insulin infusion pump to enable automated control of pump action based on real-time glucose monitor readings. Such devices may also be referred to as “artificial pancreas devices.”
  - Outlines the Medically Necessary and Investigational and Not Medically Necessary criteria for automated insulin delivery devices.

- **DRUG.00090 Bezlotoxumab (ZINPLAVA™)**: This document addresses the use of bezlotoxumab (ZINPLAVA), a fully human monoclonal (mAb) IgG1/kappa antibody that binds to Clostridium difficile (C. difficile) toxin B, used to reduce recurrence of Clostridium difficile infection (CDI).
  - Outlines the Medically Necessary and Investigational and Not Medically Necessary criteria for bezlotoxumab (ZINPLAVA).

- **DRUG.00097 Olaratumab (Lartruvo™)**: This document addresses olaratumab (Lartruvo), a recombinant human immunoglobulin G subclass 1 (IgG1) monoclonal antibody used for the treatment of adults with late stage soft tissue sarcoma under certain conditions.
  - Outlines the Medically Necessary and Investigational and Not Medically Necessary criteria for olaratumab (Lartruvo).

- **DRUG.00102 Cabazitaxel (Jevtana®)**: This document addresses cabazitaxel (Jevtana), a tubulin-binding taxane used in combination with prednisone for the treatment of hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen. It acts to inhibit cell division and growth of cancer and can promote cell death.
  - Outlines the Medically Necessary and Investigational and Not Medically Necessary criteria for cabazitaxel (Jevtana).
LAB.00033 Protein Biomarkers for the Screening, Detection and Management of Prostate Cancer: This document addresses the use of protein biomarkers, specifically the 4Kscore® test, for the screening, detection and management of prostate cancer. The 4Kscore is a combination test that involves measures of fPSA (free prostate specific antigen), tPSA (total PSA), iPSA (intact PSA) and human kallikrein 2 (hK2) proteins.

- The use of protein biomarker tests (that is, 4Kscore) for the screening, detection, and management of prostate cancer are considered Investigational and Not Medically Necessary.

New Medical Policies and Adopted Clinical UM Guidelines effective for service dates on and after November 17, 2016 (informational only):

- CG-DRUG-64 - FDA-Approved Biosimilar Products: [Note: FDA-approved biosimilar products were moved from DRUG.00002 Tumor Necrosis Factor Antagonists.]

Revised Medical Policies and Adopted Clinical UM Guidelines effective May 1, 2017:

- DRUG.00051 Ziv-aflibercept (Zaltrap®): This document addresses the use of ziv-aflibercept (Zaltrap) and does not address the use of aflibercept (Eylea®) intravitreal injection for age-related macular degeneration.

- GENE.00002 Preimplantation Genetic Diagnosis Testing: This document addresses the use of preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS) which is performed as part of an assisted reproductive procedure.

- GENE.00025 Molecular Profiling and Proteogenomic Testing for the Evaluation of Malignant Tumors: This document addresses molecular profiling and proteogenomic testing for the evaluation of malignant tumors. Previous title: Molecular Profiling for the Evaluation of Malignant Tumors.

- LAB.00011 Analysis of Proteomic Patterns: This document addresses the use of proteomics, which is the study of the structure and function of proteins, including antibodies and other biomarkers.

- MED.00057 MRI Guided High Intensity Focused Ultrasound Ablation for Non-Oncologic Indications: This document addresses magnetic resonance imaging (MRI) guided high intensity focused ultrasound (HIFU) ablation, also known as magnetic resonance guided ultrasound (MRgFUS), which used to treat any non-
oncologic indications, including but not limited to uterine fibroids or benign prostatic hyperplasia (BPH). Previous title: MRI Guided High Intensity Focused Ultrasound Ablation of Uterine Fibroids.

- Revised title.
- Expanded scope of document to include all non-oncologic indications.
- Revised position statement to say: "MRI guided high intensity focused ultrasound ablation is considered Investigational and Not Medically Necessary for all non-oncologic indications, including but not limited to benign prostatic hyperplasia and uterine fibroids."
- Moved language addressing high-intensity focused ultrasound (HIFU) ablation for BPH from policy SURG.00028.

- **SURG.00129 Oral, Pharyngeal and Maxillofacial Surgical Treatment for Obstructive Sleep Apnea or Snoring:** This document addresses surgical treatments for obstructive sleep apnea (OSA), such as uvulopalatopharyngoplasty (UPPP), hyoid myotomy and jaw realignment surgery, laser surgery, radiofrequency ablation, palatal implants, and other procedures. Previous title: Oral, Pharyngeal and Maxillofacial Surgical Treatment for Obstructive Sleep Apnea.

  - Revised title.
  - Clarified criteria addressing failed surgical interventions in jaw realignment surgery.
  - Made format changes throughout position statement.
  - Added uvulopalatopharyngoplasty, soft tissue reconstruction, or jaw realignment surgery as Not Medically Necessary when criteria are not met.

- **SURG.00144 Occipital Nerve Block Therapy for the Treatment of Headache and Occipital Neuralgia:** This document addresses occipital nerve block (or blockade), as a therapy for treatment of headache syndromes.

  - Added existing CPT code 64450 for lesser occipital nerve block per CPT coding instructions.

New Pre-certification Requirements for Specialty Pharmacy Drugs effective for dates of service on or after May 1, 2017:

Anthem will also be implementing changes to our Pre-Certification Quick Reference Guide. Listed below are specialty pharmacy codes from new or current Clinical UM Guidelines that will be added to our existing pre-service review process.

Pre-service clinical review of these specialty pharmacy drugs will be managed by AIM Specialty Health® (AIM), a separate company administering the program on behalf of Anthem.

<table>
<thead>
<tr>
<th>Medical Policy or Clinical UM Guideline number</th>
<th>Drug code</th>
<th>Drug Names</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CG-DRUG-09</td>
<td>J3490</td>
<td>Cuvitru</td>
<td>New drug to existing Clinical UM Guideline</td>
</tr>
<tr>
<td>CG-DRUG-54</td>
<td>J0180</td>
<td>Agalsidase beta (Fabrazyme)</td>
<td>New Clinical UM Guideline</td>
</tr>
<tr>
<td>CG-DRUG-55</td>
<td>J1322</td>
<td>Elosulfase alfa (Vimizim)</td>
<td>New Clinical UM Guideline</td>
</tr>
<tr>
<td>CG-DRUG-56</td>
<td>J1458</td>
<td>Galsulfase (Naglazyme)</td>
<td>New Clinical UM Guideline</td>
</tr>
<tr>
<td>CG-DRUG-57</td>
<td>J1743</td>
<td>Idursulfase (Elaprase)</td>
<td>New Clinical UM Guideline</td>
</tr>
<tr>
<td>CG-DRUG-58</td>
<td>J1931</td>
<td>Laronidase (Aldurazyme)</td>
<td>New Clinical UM Guideline</td>
</tr>
<tr>
<td>CG-DRUG-62</td>
<td>J9395</td>
<td>Fulvestrant (Faslodex)</td>
<td>New Clinical UM Guideline</td>
</tr>
<tr>
<td>CG-DRUG-63</td>
<td>J0641</td>
<td>Levoleucovorin Calcium (Fusilev)</td>
<td>New Clinical UM Guideline</td>
</tr>
<tr>
<td>DRUG.00002</td>
<td>J3590</td>
<td>Adalimumab-atto (Amjevita)</td>
<td>New Drug to existing Medical Policy</td>
</tr>
</tbody>
</table>
Anthem will be expanding the Specialty Pharmacy Level of Care Medication list:

Listed below are specialty pharmacy codes from new or current Medical Policies and Clinical UM Guidelines that will be added to our existing Level of Care review process using CG-DRUG-47, effective May 1, 2017.

Level of care pre-service clinical review of these specialty pharmacy drugs will be managed by AIM.

Level of Care drug list

FAQ link
http://www.aimprovider.com/specialtyrx/FAQ.html

<table>
<thead>
<tr>
<th>Medical Policy or Clinical UM Guideline number</th>
<th>Drug code</th>
<th>Drug Names</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRUG.00090</td>
<td>J3490, J3590</td>
<td>Bezlotoxumab (Zinplava)</td>
<td>New Medical Policy</td>
</tr>
<tr>
<td>DRUG.00097</td>
<td>J9999</td>
<td>Olaratumab (Lartruvo)</td>
<td>New Medical Policy</td>
</tr>
<tr>
<td>DRUG.00102</td>
<td>J9043</td>
<td>Cabazitaxel (Jevtana)</td>
<td>New Medical Policy</td>
</tr>
<tr>
<td>DRUG.00066</td>
<td>J7192</td>
<td>Afstyla</td>
<td>New Drug to existing Medical Policy</td>
</tr>
</tbody>
</table>

Anthem will expand the Specialty Pharmacy program to include level of care review for hemophilia drug indications:

Listed below are details about upcoming changes to the current coverage guideline, Specialty Pharmaceuticals CG-DRUG-47 beginning May 1, 2017.

<table>
<thead>
<tr>
<th>Clinical Guideline Number</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>CG-DRUG-55</td>
<td>This coverage guideline will apply to hemophilia drug indications beginning with dates of service on and after May 1, 2017.</td>
</tr>
<tr>
<td>CG-DRUG-57</td>
<td></td>
</tr>
</tbody>
</table>

The level of care pre-service clinical review of these specialty pharmacy drugs will be managed by AIM.

Specialty pharmacy program expands to include Utilization Review of Drug Dosage and Frequency:

Beginning with dates of service on and after May 1, 2017, Anthem will implement a new clinical guideline, Drug Dosage, Frequency, and Route of Administration CG-DRUG-53. This will apply to the review process for Specialty Pharmacy. The expanded program will continue to be administered by AIM. Based on the information you provide, AIM will review the drug for clinical appropriateness, and drug dosage and frequency against health plan clinical criteria.

As part of pre cert process the following will be required:

1. Weight, Height, Age, Gender
2. Dose per treatment and Directions per treatment (frequency), and duration (length of therapy)
To ensure accurate and timely payment, it is important that you provide the above requested information effective May 1, 2017.

Note: Drug wastage should be reported with modifier “JW”. Providers may be reimbursed for single dose vial drug wastage beyond the approved dosage that is authorized per the Utilization Review process outlined above. The Provider is expected to utilize the most economical combination of vial sizes for the drug administered and must report the drug wastage as a separate line item on the claim form with modifier “JW” appended. Anthem reimbursement limits will apply and will take into consideration applicable wastage based on the most economical combination of vial sizes.

Clinically equivalent requirement:

Below are Clinical Guidelines and Medical Policies that have been updated to include the requirement of a clinically equivalent treatment effective May 1, 2017.

<table>
<thead>
<tr>
<th>Medical Policy</th>
<th>Impacted Products</th>
<th>Clinically Equivalent / Cost Effective Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA-Approved Biosimilar Products; CG-DRUG-64</td>
<td>Inflectra®</td>
<td>Remicade®</td>
</tr>
<tr>
<td>CG-DRUG-29</td>
<td>Euflexxa®, Gel-One®, GelSyn®, Genvisc 850®, Hyalgan®, Hymovis®, Supartz®</td>
<td>Monovisc®, Orthovisc®, Synvisc®, Synvisc One®</td>
</tr>
</tbody>
</table>

All changes referenced in this letter only apply to Local Plan members. They do not apply to BlueCard out-of-area, selected National Accounts, Medicare, Medicare Advantage (MA), or Federal Employee Plan (FEP) members.

Note: If the service is not prior authorized/pre-certified, records will be requested for post service review based on the same criteria listed in the medical policy or clinical guideline.

Ordering and servicing physicians should submit a precertification request for these additional requirements for services starting May 1, 2017 to AIM through the AIM Provider Portal at [http://www.aimspecialtyhealth.com/goweb](http://www.aimspecialtyhealth.com/goweb) (available 24/7 to process orders in real-time), through the Availity Web Portal at [www.availity.com](http://www.availity.com), or by calling the AIM call center at 877-291-0366.

Note: Retrospective requests received more than 2 business days after the date of service will not be accepted by AIM for precertification review. Any post-service clinical review would be handled by Anthem according to the terms of the applicable health benefit plan and/or provider agreement.

Anthem Medical Policies and Clinical UM Guidelines are developed by our national Medical Policy and Technology Assessment Committee. The Committee, which includes Anthem medical directors and representatives from practicing physician groups, meets quarterly to review current scientific data and clinical developments.

All coverage written or administered by Anthem 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 Anthem’s medical policies. Review procedures have been refined to facilitate claim investigation.
Anthem’s Medical Policies and Clinical UM Guidelines are available online:

The complete list of our Medical Policies and Clinical UM Guidelines may be accessed on Anthem’s Web site at anthem.com. Select Menu, and under the Support heading select theProviderslink. Choose Nevada from the drop down list, and press Enter. On the Provider Home page, from the Medical Policy, Clinical UM Guidelines, Pre-Cert Requirements tout (2nd blue box on the left side of page), select enter. Choose on the link Medical Policies and Clinical UM Guidelines (for Local Plan Members). Select Continue, and then either the Medical Policies or the UM Guidelines tab.

To view the list of specific clinical UM guidelines adopted by Nevada, navigate to the Disclaimer page by following the instructions above; scroll to the bottom of the page. Above the “Continue” button, select the link Specific Clinical UM Guidelines adopted by Anthem Blue Cross and Blue Shield of Nevada.

Anthem’s Pre-certification Quick Reference Guide is available online:

Anthem’s Pre-certification Quick Reference Guide will be updated with this information and posted online by February 15, 2017. The Pre-Certification Quick Reference Guide is also available online at anthem.com. Follow the directions above, but select the link titled Pre-Certification/Pre-Authorization Requirements (for Local Plan members).

Sincerely,

Elizabeth Kraft, M.D.
Medical Director
Anthem Blue Cross and Blue Shield

Enclosure: Attachment A
<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>DME.00036</td>
<td>Ultraviolet Light Therapy Delivery Devices for Home Use</td>
<td>• Added cutaneous T-cell lymphoma, including mycosis fungoides and Sézary syndrome, as Medically Necessary indications for in-home UVB light therapy when criteria are met.</td>
</tr>
</tbody>
</table>
| DRUG.00038            | Bevacizumab (Avastin®) for Non-Ophthalmologic Indications | • Clarified wording in Medically Necessary position statements without changes to existing criteria.  
• Added the use of bevacizumab for malignant mesothelioma as Medically Necessary when criteria are met.  
• Removed malignant mesothelioma from Investigational and Not Medically Necessary statement.  
• Updated formatting in position statements. |
| DRUG.00039            | Trastuzumab (Herceptin®) | • Medical Policy archived. |
| DRUG.00041            | Rituximab (Rituxan®) for Non-Oncologic Indications | • Revised title.  
• Revised scope of document to only address non-oncologic indications.  
• Removed Medically Necessary statements and all other language throughout policy addressing the use of rituximab for oncologic indications.  
• Clarified Medically Necessary criteria for the treatment of rheumatoid arthritis.  
• Clarified Medically Necessary statement for the treatment of thrombotic thrombocytopenia purpura by adding diagnostic criteria.  
• Combined Investigational and Not Medically Necessary statements and clarified that the language only addresses non-oncologic indications. |
| DRUG.00042            | Ustekinumab (Stelara®) | • Added the treatment of Crohn’s disease as Medically Necessary when criteria are met.  
• Removed Crohn’s disease from the Investigational and Not Medically Necessary statement. |
| DRUG.00057            | Canakinumab (Ilaris®) | • Added familial Mediterranean fever (FMF), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD), and tumor necrosis factor receptor associated periodic syndrome (TRAPS) as Medically Necessary indications when criteria are met.  
• Removed FMF, MKD and TRAPS from the Investigational and Not Medically Necessary statement. |
| DRUG.00066            | Antihemophilic Factors and Clotting Factors | • Added antihemophilic factor VIII recombinant, Afstyla, as Medically Necessary when criteria are met.  
• Added Afstyla as Investigational and Not Medically Necessary when Medically Necessary criteria are not met and for all other indications. |
| DRUG.00071            | Pembrolizumab (Keytruda®) | • Added the first-line treatment of advanced (metastatic) NSCLC as Medically Necessary when criteria are met.  
• Added the treatment of recurrent, unresectable or metastatic head and neck squamous cell carcinoma as Medically Necessary when criteria are met.  
• Added the treatment of Merkel-cell carcinoma (MCC) as Medically Necessary when criteria are met.  
• Clarified the Medically Necessary criteria for the treatment of metastatic NSCLC as a second or subsequent line of therapy.  
• Updated Investigational and Not Medically Necessary statement. |
| **DRUG.00075** | Nivolumab (Opdivo®) | • Added the treatment of recurrent, unresectable or metastatic squamous cell carcinoma of the head and neck (SCCHN) as Medically Necessary when criteria are met.  
• Updated investigational and Not Medically Necessary statement. |
| **DRUG.00088** | Atezolizumab (Tecentriq™) | • Added the treatment of metastatic non-small cell lung cancer (NSCLC) as Medically Necessary when criteria are met.  
• Removed “solid tumors” from the Investigational and Not Medically Necessary list. |
| **GENE.00019** | BRAF Mutation Analysis | • Added BRAF V600E mutation analysis as Medically Necessary for individuals with metastatic colorectal cancer to identify those who would benefit from epidermal growth factor receptor (EGFR)-directed therapy.  
• Replaced the word “select” with the word “identify” in Medically Necessary position statements. |
| **MED.00083** | Melanoma Vaccines | • Added talimogene laherparepvec as an intralesional treatment of unresectable melanoma as Medically Necessary when criteria are met.  
• Updated Investigational and Not Medically Necessary statements. |
| **SURG.00028** | Surgical and Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH) and Other Genitourinary Conditions | • Made formatting change in Not Medically Necessary statement.  
• Moved position statement and all other language addressing high-intensity focused ultrasound (HIFU) ablation to policy MED.00057. |
| **THER-RAD.00010** | Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiotherapy (SBRT) | • Changed Gleason score verbiage in Medically Necessary criteria addressing prostate cancer from “less than or equal to 6” to “equal to 6”. |
| **CG-DRUG-15** | Gonadotropin Releasing Hormone Analogs | • Document archived. |
| **CG-DRUG-38** | Pemetrexed Disodium (Alimta®) | • Revised the Medically Necessary clinical indications addressing malignant mesothelioma.  
• Added second-line therapy and beyond as a single agent for thymic cancer and thymomas as Medically Necessary.  
• Removed thymic cancer and thymomas from Not Medically Necessary indications. |