August 1, 2019

RE: Medical Policy and Clinical UM Guidelines 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 Colorado/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 effective for service dates on and after November 1, 2019:

- **GENE.00051 Bronchial Gene Expression Classification for the Diagnostic Evaluation of Lung Cancer:** This document addresses gene expression classification for the diagnostic evaluation of lung cancer in individuals with suspected lung cancer following identification of pulmonary lesions on computed tomography (CT) scans.
    - The use of bronchial gene expression classification for the diagnostic evaluation of lung cancer in individuals with pulmonary lesions is considered Investigational and Not Medically Necessary.

- **MED.00129 Gene Therapy for Spinal Muscular Atrophy:** This document addresses gene therapy for spinal muscular atrophy (SMA), a rare, and often fatal genetic disease affecting muscle strength and movement.
    - A one-time infusion of onasemnogene abeparvovec-xioi (Zolgensma®) is considered Medically Necessary in individuals with spinal muscular atrophy (SMA) type 1 when all of the criteria are met.
    - Onasemnogene abeparvovec-xioi is considered Investigational and Not Medically Necessary when criteria are not met, including for repeat infusions, and for all other indications.

- **SURG.00153 Cardiac Contractility Modulation Therapy:** This document addresses the use of cardiac contractility modulation therapy designed to treat chronic moderate-to-severe heart failure.
    - The use of cardiac contractility modulation therapy is considered Investigational and Not Medically Necessary for all indications, including but not limited to heart failure.

Revised Medical Policies and Adopted Clinical UM Guidelines effective November 1, 2019:

- **DME.00037 Cooling Devices and Combined Cooling/Heating Devices:** This document addresses the devices utilized for the treatment of pain and swelling after trauma and surgery and for musculoskeletal and other conditions.
    - Added devices that combine cooling and vibration to the Investigational and Not Medically Necessary statement.

- **LAB.00027 Selected Blood, Serum and Cellular Allergy and Toxicity Tests:** This document addresses selected unproven blood, serum and cellular allergy and toxicity tests.
    - Added Mediator Release Test to Investigational and Not Medically Necessary statement.

- **LAB.00033 Protein Biomarkers for the Screening, Detection and Management of Prostate Cancer:** This document addresses the use of protein biomarkers for the screening, detection and management of prostate cancer.
    - Clarified Investigational and Not Medically Necessary statement to include 4Kscore and AR-V7.

- **OR-PR.00003 Microprocessor Controlled Lower Limb Prosthesis:** This document addresses the use of microprocessor controlled lower limb prostheses including, but not limited to, knee prostheses (such as the Otto-Bock C-Leg® device, the Genium™ Bionic Prosthetic System, the Genium™ X2® and X_3® devices, the Ossur Rheo Knee®, and the Endolite Intelligent Prosthesis®) and foot-ankle prostheses (such as the Proprio Foot®, the PowerFoot BiOM, and the Endolite élan foot).
    - Clarified Medically Necessary position statement criteria 2 through 4.
    - Added statement that use of prosthetic devices that combine both a microprocessor controlled knee and foot-ankle prosthesis is considered Investigational and Not Medically Necessary for all indications.

- **SURG.00011 Allogeneic, Xenographic, Synthetic, and Composite Products for Wound Healing and Soft Tissue Grafting:** This document addresses the use of soft tissue (e.g., skin, ligament, cartilage, etc.) substitutes in wound healing and surgical procedures.
    - Added new Medically Necessary and Investigational and Not Medically Necessary statements addressing amniotic membrane-derived products for conjunctival and corneal indications, including KeraSys and Prokera.
    - Added new products to Investigational and Not Medically Necessary statement.

- **SURG.00045 Extracorporeal Shock Wave Therapy:** This document addresses the use of extracorporeal shock wave therapy (ESWT), including Extracorporeal Pulse Activation Therapy (EPAT®), for the treatment of musculoskeletal conditions, soft tissue injuries, and erectile dysfunction.
    - Added erectile dysfunction, Peyronie's disease and wound repair to the Investigational and Not Medically Necessary statement.
    - Revised title. Previous Title: Extracorporeal Shock Wave Therapy for Orthopedic Conditions.

- **SURG.00121 Transcatheter Heart Valve Procedures:** This document addresses the transcatheter (percutaneous or catheter-based) approach for aortic or pulmonary heart valve replacement, transcatheter mitral valve repair using leaflet repair or percutaneous annuloplasty, and transcatheter tricuspid valve repair or replacement.
    - Added Investigational and Not Medically Necessary statement to address use of transcatheter tricuspid valve repair or replacement for all indications.

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**, and select **Providers.** Under the *Provider Resources* heading, select **Policies and Guidelines**. Select **Nevada** as Your State. Select **View Medical Policies & UM Guidelines**. Select the link titled "**Medical Policies and Clinical UM Guidelines (for Local Plan Members)**". Choose **Continue**, then select the 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, choose the link titled "**Specific Clinical UM Guidelines adopted by Anthem Blue Cross and Blue Shield of Nevada**."

Sincerely,

Allen Marino, M.D.
Medical Director
Anthem Blue Cross and Blue Shield

Attachment A – Revised Medical Policies and Clinical Guidelines

Medical Policy Number	Medical Policy Title	Medical Policy / Clinical Guideline Changes
DME.00038	Static Progressive Stretch (SPS) and Patient-Actuated Serial Stretch (PASS) Devices	• Added information related to the Elite Seat device to the Description/Scope, Rationale and Index sections (moved from CG-DME-39 Dynamic Low-Load Prolonged-Duration Stretch Devices).
DRUG.00046	Ipilimumab (Yervoy®)	• Added Medically Necessary criteria for ipilimumab in combination with nivolumab for the treatment of individuals with malignant pleural mesothelioma as a subsequent therapy when criteria are met.
DRUG.00053	Carfilzomib (Kyprolis®)	• Added Medically Necessary criteria for carfilzomib to be used for relapsed or refractory multiple myeloma when used in combination with pomalidomide and dexamethasone when the individual has received at least two prior therapies, including a proteasome inhibitor and an immunomodulatory agent (for example, lenalidomide or thalidomide).
DRUG.00062	Obinutuzumab (Gazyva®)	• Added Medically Necessary criteria for combination therapy to treat CLL in the first-line setting.
DRUG.00067	Ramucirumab (Cyramza®)	• Added Medically Necessary statement for use of ramucirumab for hepatocellular cancer when criteria are met. • Removed hepatocellular cancer from Investigational and Not Medically Necessary statement.
DRUG.00071	Pembrolizumab (Keytruda®)	• Revised Medically Necessary statement for first-line use of pembrolizumab to include cytologically confirmed stage III NSCLC, and PD-L1 gene expression 1% or greater of tumor cells. • Added Medically Necessary statement for pembrolizumab in combination with axitinib as first-line treatment of advanced RCC when criteria are met.
DRUG.00075	Nivolumab (Opdivo®)	• Added Medically Necessary criteria for nivolumab in combination with ipilimumab for treatment of individuals with malignant pleural mesothelioma as subsequent therapy when criteria are met.
DRUG.00107	Avelumab (Bavencio®)	• Added Medically Necessary criteria for advanced renal cell carcinoma.
GENE.00010	Genotype Panel Testing for Genetic Polymorphisms to Determine Drug-Metabolizer Status	• Removed genotype testing for single polymorphisms of metabolizing enzymes for specific drugs and moved into a separate clinical utilization management guideline (CG-GENE-11). • Revised title. Previous title: Genotype Testing for Genetic Polymorphisms to Determine Drug-Metabolizer Status.
GENE.00011	Gene Expression Profiling for Managing Breast Cancer Treatment	• Made administrative update to Position Statement.
GENE.00021	Chromosomal Microarray Analysis (CMA) for Developmental Delay, Autism Spectrum Disorder, Intellectual Disability (Intellectual	• Medical policy archived 09/04/2019. Converted to CG-GENE-10.

Medical Policy Number	Medical Policy Title	Medical Policy / Clinical Guideline Changes
	Development Disorder) and Congenital Anomalies	
GENE.00029	Genetic Testing for Breast and/or Ovarian Cancer Syndrome	• Expanded Medically Necessary indications for BRCA1/2 and BART testing: - Added Medically Necessary criteria for individuals with a personal or family history of breast cancer diagnosed between the ages of 46 and 50 years. - Revised criteria for individuals with a personal history of breast cancer and relatives on the same side of the family with pancreatic cancer so that the phrase “at least 2 or more first-, second- or third-degree relatives” was changed to “at least 1 or more first-, second- or third-degree relatives. - Expanded Medically Necessary criteria addressing an individual with a history of pancreatic cancer. - Revised criterion for individuals with a family (no personal) history of cancer to include “when they have a relative who would meet any one of the criteria for individuals with a personal history of cancer, but that relative is not available for testing.”
GENE.00044	Analysis of PIK3CA Status in Tumor Cells	• Added Medically Necessary indication for PIK3CA mutation testing using tumor tissue when treatment with a phosphatidylinositol-3-kinase (PI3K) inhibitor (for example, alpelisib) is indicated. • Modified the Investigational and Not Medically Necessary statement: changed “for all indications” to “for all other indications not listed above.”
MED.00109	Corneal Collagen Cross-Linking	• Modified Medically Necessary statement on progressive keratoconus. • Modified Medically Necessary criteria on corneal ectasia.
SURG.00005	Partial Left Ventriculectomy	• Removed the acronym for partial left ventriculectomy (PLV) from the Position Statement.
SURG.00023	Breast Procedures; including Reconstructive Surgery, Implants and Other Breast Procedures	• Added reduction mammaplasty done in advance of mastectomy or lumpectomy for breast cancer to the covered Reconstructive procedures.
SURG.00028	Surgical and Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH) and Other Genitourinary Conditions	• Added Prostatic urethral lift to Medically Necessary statement with criteria for treatment of benign prostatic hyperplasia. • Changed to "Prostatic urethral lift when criteria are not met" in Investigational and Not Medically Necessary statement. • Prostatic urethral lift to Investigational and Not Medically Necessary statement for treatment of genitourinary conditions other than benign prostatic hyperplasia.
SURG.00106	Ablative Techniques as a Treatment for Barrett's Esophagus	• Medical policy archived 09/04/2019. Converted to CG-SURG-101.
SURG.00120	Internal Rib Fixation Systems	• Clarified Medically Necessary statement regarding open approach and dependency of mechanical ventilation.
SURG.00133	Alcohol Septal Ablation for Treatment of Hypertrophic Cardiomyopathy	• Medical policy archived 09/04/2019. Converted to CG-SURG-102.

Medical Policy Number	Medical Policy Title	Medical Policy / Clinical Guideline Changes
CG-ANC-06	Ambulance Services: Ground; Non-Emergent	• Clarified Medically Necessary statement with examples of bed-confined. • Clarified Not Medically Necessary statement.
CG-DME-07	Augmentative and Alternative Communication (AAC) Devices with Digitized or Synthesized Speech Output	• Revised Clinical Indications to specify scope of the document as limited to digitized and synthesized speech generating devices. • Revised title. Previous title: Augmentative and Alternative Communication (AAC) Devices/Speech Generating Devices (SGD).
CG-DME-42	Non-implantable Insulin Infusion and Blood Glucose Monitoring Devices	• Added notes to Description section addressing device types. • Clarified and updated formatting in the Clinical Indications section.
CG-DME-45	Ultrasound Bone Growth Stimulation	• In the Medically Necessary statement, clarified what is meant by "location and poor vascular supply in Bullet 3a.
CG-DRUG-62	Fulvestrant (FASLODEX®)	• Added Medically Necessary indication for use of fulvestrant in combination with alpelisib for the treatment of advanced or metastatic breast cancer when criteria are met.
CG-DRUG-106	Brentuximab Vedotin (Adcetris)	• Expanded Medically Necessary indications to include combination therapy with cyclophosphamide, doxorubicin, and prednisone for previously untreated adult T-cell leukemia/lymphoma and hepatosplenic gamma-delta T-Cell lymphoma.
CG-MED-59	Upper Gastrointestinal Endoscopy in Adults	• In Sequential or Periodic Diagnostic EGD in Adults section of Clinical Indications, changed "and" to "or" in criterion A.1.
CG-SURG-81	Cochlear Implants and Auditory Brainstem Implants	• Removed text related to FDA approval status from the Medically Necessary statements.
CG-SURG-85	Hip Resurfacing	• Removed text related to FDA approval status from the Medically Necessary statements.