NOTICE OF MATERIAL CHANGE TO CONTRACT

Anthem BlueCross BlueShield

January 1, 2019

RE: Medical Policy and Clinical UM Guideline changes notification letter

Dear Provider:

Anthem Blue Cross and Blue Shield and our subsidiary company, HMO Colorado (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 April 1, 2019:

- **MED.00126 Fractional Exhaled Nitric Oxide and Exhaled Breath Condensate Measurements for Respiratory Disorders:** This document addresses the measurement of exhaled nitric oxide and exhaled breath condensate for the diagnosis and monitoring of asthma and other respiratory disorders.
    - The measurement of exhaled nitric oxide is considered Investigational and Not Medically Necessary in the diagnosis and monitoring of asthma and other respiratory disorders.
    - The measurement of exhaled breath condensate is considered Investigational and Not Medically Necessary in the diagnosis and monitoring of asthma and other respiratory disorders

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

- **CG-BEH-01 Screening and Assessment for Autism Spectrum Disorders and Rett Syndrome:** This document addresses various tools used in the screening and testing of individuals with suspected Autism Spectrum Disorders (ASDs) and Rett syndrome.
    - Added tests for metabolic markers in the blood, urine, tissue, or other biologic materials (also known as metabolomics), including but not limited to Amino Acid Dysregulation Metabotype (ADDM) testing as Not Medically Necessary.

- **CG-SURG-27 Sex Reassignment Surgery:** This document addresses sex reassignment surgery (also known as gender reassignment surgery and gender confirmation surgery), which is one treatment option for extreme cases of gender dysphoria, a condition in which a person feels a strong and persistent identification with the opposite gender accompanied with a severe sense of discomfort in their own gender.
    - Added criteria requiring referral letters to mastectomy Medically Necessary statement.

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 **Providers**, then **Providers Overview**. Select **Find Resources for Your State**, and pick **Colorado**. 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**. Click on the link titled "**Medical Policies and Clinical UM Guidelines (for Local Plan Members)**". Click **Continue**, then select the either the **Medical Policies** or the **UM Guidelines** tab.

To view the list of specific clinical UM guidelines adopted by Colorado, navigate to the Disclaimer page by following the instructions above; scroll to the bottom of the page. Above the "Continue" button, click on the link titled "**Specific Clinical UM Guidelines adopted by Anthem Blue Cross and Blue Shield of Colorado**."

Sincerely,

Elizabeth Kraft, 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
ADMIN.00001	Medical Policy Formation	• Updated Description/Scope section concerning MPTAC membership to include behavioral health (BH) specialists. • Updated text regarding subspecialty committees, including removal of BH subcommittee. • Clarified that third party criteria (TPC) subcommittees may include BH specialists. • Removed the Blue Cross Blue Shield Association (BCBSA) from acceptable independent technology evaluation programs and materials that may be used in evaluating the medical necessity or investigational status of new or existing services and/or procedures.
MED.00100	Diaphragmatic/Phrenic Nerve Stimulation and Diaphragm Pacing Systems	• Medical policy archived 01/03/2019. Converted to CG-MED-79.
RAD.00002	Positron Emission Tomography (PET) and PET/CT Fusion	• Medical policy archived 01/03/2019. Converted to CG-MED-80.
DRUG.00046	Ipilimumab (Yervoy®)	• Added Medically Necessary criteria for ipilimumab as primary treatment when used in combination with nivolumab for unresectable metachronous colorectal cancer metastases when criteria are met. • Clarified Medically Necessary criteria for ipilimumab when used in combination with nivolumab as subsequent therapy for unresectable advanced or metastatic colorectal cancer.
DRUG.00062	Obinutuzumab (Gazyva®)	• Reformatted Medically Necessary criteria. • Added obinutuzumab as Medically Necessary for the treatment of CLL/SLL in the first-line of therapy in combination with bendamustine and as a single agent when criteria are met.
DRUG.00071	Pembrolizumab (Keytruda®)	• Added the use of pembrolizumab for the first-line treatment of metastatic squamous NSCLC as Medically Necessary when criteria are met. • Added the use of pembrolizumab for the treatment of small cell lung cancer (SCLC) as subsequent therapy as Medically Necessary when criteria are met. • Removed "Presence of human immunodeficiency virus (HIV) infection, hepatitis B infection and hepatitis C infection" from Investigational and Not Medically Necessary statement. • Added "Treatment used as first-line therapy, except as described in Medically Necessary criteria" to Investigational and Not Medically Necessary statement.
DRUG.00075	Nivolumab (Opdivo®)	• Revised Medically Necessary criteria for nivolumab as primary treatment to include in combination with ipilimumab for unresectable metachronous colorectal cancer metastases when criteria are met. • Clarified Medically Necessary criteria for nivolumab when used in combination with ipilimumab as subsequent therapy for unresectable advanced or metastatic colorectal cancer. • Removed "Presence of human immunodeficiency virus (HIV) infection, hepatitis B infection and hepatitis C infection" from Investigational and Not Medically Necessary statement.
DRUG.00090	Bezlotoxumab (ZINPLAVA™)	• Clarified Medically Necessary criteria for individuals at high risk of Clostridium difficile infection recurrence.

Medical Policy Number	Medical Policy Title	Medical Policy / Clinical Guideline Changes
GENE.00006	Epidermal Growth Factor Receptor (EGFR) Testing	• Simplified Medically Necessary and Investigational and Not Medically Necessary statements.
LAB.00029	Rupture of Membranes Testing in Pregnancy	• Revised title. Previous title: Rupture of Membranes (ROM) Testing in Pregnancy. • Removed acronym from position statement.
MED.00109	Corneal Collagen Cross-Linking	• Added Medically Necessary statements with clinical criteria. • Investigational and Not Medically Necessary statement changed to all "other" indications.
SURG.00098	Mechanical Embolectomy for Treatment of Acute Stroke	• Made minor wording clarification to Medically Necessary statement.
SURG.00103	Intraocular Anterior Segment Aqueous Drainage Devices (without extraocular reservoir)	• Added the implantation of Hydrus Microstent as Medically Necessary when criteria are met. • Added Hydrus Microstent to Investigational and Not Medically Necessary statement for all other indications not listed as Medically Necessary. • Added Hydrus Microstent to Investigational and Not Medically Necessary statement for anterior segment aqueous drainage devices inserted internally or externally without an extraocular reservoir.
SURG.00120	Internal Rib Fixation Systems	• Add the use of an internal rib fixation system as Medically Necessary for the treatment of flail chest resulting in the inability to discontinue mechanical ventilation in the absence of other causes of ventilator dependency such as severe brain injury.
SURG.00121	Transcatheter Heart Valve Procedures	• Revised Medically Necessary statements for TAVR, removing "end stage renal disease requiring chronic dialysis or creatinine clearance" from list of comorbid conditions or contraindications that would preclude the expected benefit from aortic stenosis correction.
TRANS.00024	Hematopoietic Stem Cell Transplantation for Select Leukemias and Myelodysplastic Syndrome	• Added minimal residual disease (MRD) positivity following induction as a "high risk" factor to acute lymphoblastic leukemia (ALL) Medically Necessary criteria. • Revised Medically Necessary statement addressing allogeneic stem cell transplantation for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) to state: "Allogeneic (ablative or non-myeloablative stem cell transplantation is considered Medically Necessary for individuals with CLL or SLL who are refractory to small molecule inhibitor therapy" (removed all other current criteria).
CG-DME-40	Noninvasive Electrical Bone Growth Stimulation of the Appendicular Skeleton	• Revised title. Previous title: Electrical Bone Growth Stimulation. • Revised scope of document to only address noninvasive electrical bone growth stimulation of the appendicular skeleton. • Removed information related to invasive and semi-invasive electrical bone growth stimulation for all conditions and noninvasive bone growth stimulation for spinal conditions.
CG-DRUG-45	Octreotide acetate (Sandostatin®; Sandostatin® LAR Depot)	• Removed abbreviations from Clinical Indication statements.
CG-DRUG-62	Fulvestrant (FASLODEX®)	• Replaced specific brand name drugs (palbociclib and abemaciclib) with the general term of "CDK4/6 inhibitor" in Medically Necessary criteria.

Medical Policy Number	Medical Policy Title	Medical Policy / Clinical Guideline Changes
CG-DRUG-63	Levoleucovorin Products	• Revised title. Previously titled: Levoleucovorin Calcium (Fusilev®). • Revised scope to include all available FDA-approved levoleucovorin agents (Fusilev & Khapzory). • Added NCCN 2A indications to the Medically Necessary clinical indications statements.
CG-DRUG-65	Tumor Necrosis Factor Antagonists	• Revised Medically Necessary statement for use of adalimumab (Humira) for individuals with hidradenitis suppurativa lowering the age from 18 to 12 years of age or older.
CG-DRUG-77	Radium Ra 223 Dichloride (Xofigo®)	• Added the use of Radium Ra 223 in combination with abiraterone acetate plus prednisone/prednisolone as Not Medically Necessary.
CG-DRUG-78	Antihemophilic Factors and Clotting Factors	• Added Medically Necessary and Not Medically Necessary criteria for antihemophilic factor (factor VIII) damoctocog alfa pegol (Jivi). • Expanded Medically Necessary criteria for emicizumab (Hemlibra). • Expanded Medically Necessary criteria for coagulation Factor X, Human plasma-derived (Coagadex).
CG-DRUG-88	Dupilumab (Dupixent®)	• Added the treatment of moderate to severe asthma as Medically Necessary when criteria are met. • Added Medically Necessary criteria for continuation of therapy.
CG-DRUG-107	Pharmacotherapy for Hereditary Angioedema	• Added Takhzyro as Medically Necessary when criteria are met. • Updated Not Medically Necessary criteria to include Takhzyro.
CG-GENE-01	Janus Kinase 2 (JAK2)V617F and JAK2 exon 12 Gene Mutation Assays	• Revised title. Previous title: Janus Kinase 2 (JAK2) V617F Gene Mutation Assay. • Added Medically Necessary and Not Medically Necessary criteria for Janus Kinase 2 exon 12 gene mutation testing. • Removed select abbreviations from the Clinical Indications section.
CG-GENE-03	BRAF Mutation Analysis	• Changed “vemurafenib (Zelboraf®)” to “an FDA-approved BRAF inhibitor” in the Medically Necessary statement addressing individuals with NSCLC. • Added new indication which reads: “BRAF V600E mutation analysis is considered Medically Necessary in individuals with Erdheim-Chester Disease to identify those who would benefit from treatment with vemurafenib (Zelboraf®)”.
CG-MED-26	Neonatal Levels of Care	• Clarified Medically Necessary criteria for: 1) General Nursery or Well-Baby Nursery; 2) Level I Surveillance Special Care Nursery; 3) Level II Neonatal Intensive Care; and 4) Level III Neonatal Intensive Care.
CG-MED-65	Manipulation Under Anesthesia	• Revised title. Previous title: Manipulation Under Anesthesia of the Spine and Joints other than the Knee. • Removed manipulation of shoulder from scope of document. • Updated Clinical Indications.
CG-REHAB-07	Skilled Nursing and Skilled Rehabilitation Services (Outpatient)	• Clarified description of provider of outpatient skilled rehabilitation services in Clinical Indications section.
CG-SURG-60	Cervical Total Disc Arthroplasty	• Revised clinical indications to note that Secure-C cervical artificial disc is considered Medically Necessary at a single level when criteria are met.
CG-THER-RAD-03	Radioimmunotherapy and Somatostatin Receptor Targeted Radiotherapy	• Moved content of DRUG.00098 Lutetium Lu 177 dotatate (Lutathera®) to this Clinical UM Guideline. • Added Medically Necessary and Not Medically Necessary criteria for iobenguane I 131 (Azedra), a newly FDA approved radiolabeled norepinephrine analog targeted therapy.