NOTICE OF MATERIAL CHANGE TO CONTRACT

Anthem BlueCross BlueShield

September 1, 2018

RE: Medical Policy, Clinical UM Guidelines 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 December 1, 2018

- **DRUG.00096 Ibalizumab-uiyk (Trogarzo™):** This document outlines the Medically Necessary and Investigational & Not Medically Necessary criteria for the use of ibalizumab-uiyk, a humanized monoclonal antibody (mAb) that belongs to the class of human immune deficiency virus (HIV) drugs known as entry and fusion inhibitors which prevent HIV from attaching to and entering human cells.

- **GENE.00049 Circulating Tumor DNA Testing for Cancer (Liquid Biopsy):** This document addresses the use of a circulating tumor DNA (ctDNA) test for the diagnosis or treatment of cancer.
    - Use of a circulating tumor DNA (ctDNA) test for the diagnosis or treatment of cancer is considered Investigational & Not Medically Necessary for all indications.

Revised Medical Policies and Adopted Clinical UM Guidelines effective December 1, 2018:

- **ANC.00007 Cosmetic and Reconstructive Services: Skin Related:** This document addresses the cosmetic, reconstructive, and medically necessary uses of a selection of techniques used in the treatment of skin lesions and related conditions.
    - Added microneedling (also known as percutaneous collagen induction therapy or skin needling) as Cosmetic & Not Medically Necessary for all indications.

- **DRUG.00003 Chelation Therapy:** This document addresses the uses of chelation therapy. Chelation therapy uses naturally occurring or chemically designed molecules to reduce potentially dangerous levels of heavy metals within the body. Chelation therapy is routinely performed for cases of iron overload, lead poisoning, copper toxicity, and other heavy metal conditions. This document is not applicable to agents used for the treatment of drug overdose or toxicities.
    - Clarified that the use of chelation for treatment of heavy metals is only appropriate in the setting of a confirmed diagnosis by laboratory testing.

- **DRUG.00031 Subcutaneous Hormone Replacement Implants:** This document addresses indications for the use of subcutaneous hormone implants for the treatment of hormone deficit conditions. This document does not address the use of hormone implants for treatment of other indications for example contraception or treatment of cancer.
    - Clarified Medically Necessary statement for subcutaneous testosterone implants used for continuation of hormone replacement therapy when criteria are met.

- **SURG.00145 Mechanical Circulatory Assist Devices (Ventricular Assist Devices, Percutaneous Ventricular Assist Devices and Artificial Hearts):** This document addresses mechanical circulatory assist devices which include Ventricular assist devices (VADs), Percutaneous ventricular assist devices (pVADs), and Total artificial heart.
    - Added Impella CP® Heart Pump to list of examples of pVADs considered Investigational &Not Medically Necessary.

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.00007	Immunizations	• Removed Not Medically Necessary statement addressing FluMist for the 2016-2017 flu season. • ACIP now recommends any licensed age-appropriate influenza vaccine for the 2018-2019 season, including FluMist.
DME.00027	Ultrasound Bone Growth Stimulation	• Medical policy archived 09/20/2018. Converted to CG-DME-45.
DRUG.00006	Botulinum Toxin	• Medical policy archived 09/20/2018. Converted to CG-DRUG-103. • Added Xeomin for "chronic sialorrhea in adults" to CECEA table.
DRUG.00024	Omalizumab (Xolair®)	• Medical policy archived 09/20/2018. Converted to CG-DRUG-104.
DRUG.00040	Abatacept (Orencia®)	• Medical policy archived 09/20/2018. Converted to CG-DRUG-105.
DRUG.00046	Ipilimumab (Yervoy®)	• Added ipilimumab in combination with nivolumab as subsequent therapy for metastatic colorectal cancer as Medically Necessary when criteria are met. • Added ipilimumab in combination with nivolumab as first-line treatment of stage IV or recurrent NSCLC as Medically Necessary when criteria are met. • Clarified Medically Necessary statement for RCC. • Removed NSCLC from Investigational & Not Medically Necessary statement.
DRUG.00047	Brentuximab Vedotin (Adcetris®)	• Medical policy archived 09/20/2018. Converted to CG-DRUG-106.
DRUG.00050	Eculizumab (Soliris®)	• Revised Medically Necessary statement for resumption of eculizumab when relapse occurs in an individual who has discontinued therapy, adding "…or greater than 25% from baseline" to criteria addressing atypical hemolytic uremic syndrome. • Added Guillain-Barre syndrome to Investigational & Not Medically Necessary statement.
DRUG.00058	Pharmacotherapy for Hereditary Angioedema	• Medical policy archived 09/20/2018. Converted to CG-DRUG-107.
DRUG.00064	Enteral Carbidopa and Levodopa Intestinal Gel Suspension	• Medical policy archived 09/20/2018. Converted to CG-DRUG-108. • Consolidated 'not medically necessary' indications into a single 'not medically necessary' statement in Clinical Indications section.
DRUG.00067	Ramucirumab (Cyramza®)	• Added Medically Necessary statement for use of ramucirumab in locally advanced, unresectable or metastatic urothelial carcinoma when criteria are met. • Removed genitourinary cancer from the Investigational & Not Medically Necessary statement.
DRUG.00071	Pembrolizumab (Keytruda®)	• Added the treatment of recurrent or metastatic cervical cancer as Medically Necessary when criteria are met. • Added adjuvant therapy for the treatment of resected high-

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		risk stage III melanoma as Medically Necessary when criteria are met. • Added the treatment of primary mediastinal large B-cell lymphoma as Medically Necessary when criteria are met. • Added continuation maintenance therapy of recurrent or metastatic NSCLC (squamous cell and nonsquamous) as Medically Necessary when criteria are met. • Clarified Medically Necessary criteria addressing urothelial carcinoma.
DRUG.00075	Nivolumab (Opdivo®)	• Added nivolumab in combination with ipilimumab as subsequent therapy for metastatic colorectal cancer as Medically Necessary when criteria are met. • Added nivolumab in combination with ipilimumab as first-line treatment of stage IV or recurrent NSCLC as Medically Necessary when criteria are met.
DRUG.00087	Asfotase Alfa (Strensiq™)	• Medical policy archived 09/20/2018. Converted to CG-DRUG-109.
DRUG.00088	Atezolizumab (Tecentriq®)	• Clarified Medically Necessary criteria addressing urothelial carcinoma. • Added Medically Necessary statements for first-line and continuation maintenance therapy for nonsquamous NSCLC.
DRUG.00091	Naltrexone Implantable Pellets	• Medical policy archived 09/20/2018. Converted to CG-DRUG-110.
DRUG.00093	Sebelipase alfa (KANUMA™)	• Medical policy archived 09/20/2018. Converted to CG-DRUG-111.
DRUG.00098	Lutetium Lu 177 dotatate (Lutathera®)	• Added Medically Necessary statement for use of lutetium Lu 177 dotatate in locally advanced bronchopulmonary or thymus NETs when criteria are met. • Added Medically Necessary statement for use of lutetium Lu 177 dotatate as primary treatment for locally unresectable or metastatic pheochromocytoma or paraganglioma when criteria are met.
DRUG.00103	Abaloparatide (Tymlos™) Injection	• Medical policy archived 09/20/2018. Converted to CG-DRUG-112.
GENE.00006	Epidermal Growth Factor Receptor (EGFR) Testing	• Added osimertinib (Tagrisso™) to Medically Necessary statement. • Added new Medically Necessary and Investigational & Not Medically Necessary statements addressing the use of circulating tumor DNA testing.
GENE.00008	Analysis of Fecal DNA for Colorectal Cancer Screening	• Medical policy archived 09/01/2018.
GENE.00011	Gene Expression Profiling for Managing Breast Cancer Treatment	• Removed Medically Necessary criterion requiring "Histology is not tubular or colloid (also referred to as mucinous)". • Simplified HER2 Medically Necessary criteria.
GENE.00025	Molecular Profiling and Proteogenomic Testing for the Evaluation of Malignant Tumors	• Expanded Medically Necessary criteria for NSCLC to assess tumor mutation burden and identify candidates for checkpoint inhibition immunotherapy.
GENE.00028	Genetic Testing for Colorectal Cancer Susceptibility	• Corrected typographical error in the Medically Necessary criteria for Lynch syndrome by changing “MSH1” to “MLH1”.

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GENE.00029	Genetic Testing for Breast and/or Ovarian Cancer Syndrome	• Added genetic testing to detect BRCA and BART as Medically Necessary for individuals who require confirmatory testing for a BRCA1/BRCA2 mutation(s) detected by a Food and Drug Administration (FDA)-authorized direct-to-consumer (DTC) test report.
MED.00005	Hyperbaric Oxygen Therapy (Systemic/Topical)	• Medical policy archived 09/20/2018. Converted to CG-MED-73.
MED.00051	Implantable Ambulatory Event Monitors and Mobile Cardiac Telemetry	• Medical policy archived 09/20/2018. Converted to CG-MED-74.
MED.00107	Medical and Other Non-Behavioral Health Related Treatments for Autism Spectrum Disorders and Rett Syndrome	• Medical policy archived 09/20/2018. Converted to CG-MED-75.
MED.00123	Axicabtagene ciloleucel (Yescarta®)	• Revised Title. Previous title: Axicabtagene ciloleucel (Yescarta™). • Reformatted and clarified Medically Necessary criteria. • Updated Investigational & Not Medically Necessary statement.
MED.00124	Tisagenlecleucel (Kymriah®)	• Revised Title. Previous title: Tisagenlecleucel (Kymriah™). • Added large B-cell lymphoma as Medically Necessary indication when criteria are met. • Updated Investigational & Not Medically Necessary statement.
RAD.00019	Magnetic Source Imaging and Magnetoencephalography	• Medical policy archived 09/20/2018. Converted to CG-MED-76.
RAD.00022	Magnetic Resonance Spectroscopy (MRS)	• Medical policy archived 09/20/2018.
RAD.00029	CT Colonography (Virtual Colonoscopy) for Colorectal Cancer	• Medical policy archived 09/20/2018.
RAD.00042	SPECT/CT Fusion Imaging	• Medical policy archived 09/20/2018. Converted to CG-MED-77.
RAD.00043	Computed Tomography Scans for Lung Cancer Screening	• Medical policy archived 09/20/2018.
RAD.00045	Cerebral Perfusion Imaging Using Computed Tomography	• Medical policy archived 09/20/2018.
RAD.00046	Cerebral Perfusion Studies using Diffusion and Perfusion Magnetic Resonance Imaging	• Medical policy archived 09/20/2018.
RAD.00049	Low-Field and Conventional Magnetic Resonance Imaging (MRI) for Screening, Diagnosing and Monitoring	• Medical policy archived 09/20/2018.
RAD.00051	Functional Magnetic Resonance Imaging	• Medical policy archived 09/20/2018.
RAD.00055	Magnetic Resonance Angiography of the Spinal Canal	• Medical policy archived 09/20/2018.
MED.00081	Cognitive Rehabilitation	• Medical policy archived 09/20/2018. Converted to CG-REHAB-11. • Removed "Note" in Clinical Indications referring to CG-REHAB-09 Acute Inpatient Rehabilitation.

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SURG.00010	Treatments for Urinary Incontinence	• Administrative changes made to Investigational & Not Medically Necessary statement.
SURG.00014	Cochlear Implants and Auditory Brainstem Implants	• Medical policy archived 09/20/2018. Converted to CG-SURG-81.
SURG.00020	Bone-Anchored and Bone Conduction Hearing Aids	• Medical policy archived 09/20/2018. Converted to CG-SURG-82.
SURG.00023	Breast Procedures; including Reconstructive Surgery, Implants and Other Breast Procedures	• Added confirmed cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as Medically Necessary indication for implant removal.
SURG.00024	Bariatric Surgery and Other Treatments for Clinically Severe Obesity	• Medical policy archived 10/31/2018. Converted to CG-SURG-83.
SURG.00032	Transcatheter Closure of Patent Foramen Ovale and Left Atrial Appendage for Stroke Prevention	• Expanded Medically Necessary statement for transcatheter closure of PFO using FDA approved device as preventive therapy for individuals with a history of cryptogenic stroke who are under age 60 without trial of anticoagulation when criteria are met.
SURG.00049	Mandibular/Maxillary (Orthognathic) Surgery	• Medical policy archived 09/20/2018. Converted to CG-SURG-84.
SURG.00051	Hip Resurfacing	• Medical policy archived 10/31/2018. Converted to CG-SURG-85.
SURG.00054	Endovascular/Endoluminal Repair of Aortic Aneurysms, Aortoiliac Disease, Aortic Dissection and Aortic Transection	• Medical policy archived 10/31/2018. Converted to CG-SURG-86.
SURG.00074	Nasal Surgery for the Treatment of Obstructive Sleep Apnea (OSA) and Snoring	• Medical policy archived 09/20/2018. Converted to CG-SURG-87. • Revised title to Nasal Surgery for the Treatment of Obstructive Sleep Apnea and Snoring
SURG.00085	Mastectomy for Gynecomastia	• Medical policy archived 09/20/2018. Converted to CG-SURG-88.
SURG.00090	Radiofrequency Neurolysis and Pulsed Radiofrequency Therapy for Trigeminal Neuralgia	• Medical policy archived 09/20/2018. Converted to CG-SURG-89.
TRANS.00018	Donor Lymphocyte Infusion for Hematologic Malignancies after Allogeneic Hematopoietic Progenitor Cell Transplantation	• Medical policy archived 09/20/2018. Converted to CG-TRANS-03.
CG-ADMIN-02	Clinically Equivalent Cost Effective Services – Targeted Immune Modulators	• Added certolizumab pegol (Cimzia®) for use in adult plaque psoriasis to CECEA-TIM table (FDA expanded approval of certolizumab pegol [Cimzia]).
CG-DME-07	Augmentative and Alternative Communication (AAC) Devices/Speech Generating Devices (SGD)	• Clarified that a high technology device is electronic and a low technology device is non-electronic in Medically Necessary criteria.
CG-DRUG-09	Immune Globulin (Ig) Therapy	• Added secondary hypogammaglobulinemia or agammaglobulinemia following chimeric antigen receptor (CAR) T cell treatment to Medically Necessary indications.
CG-DRUG-65	Tumor Necrosis Factor Antagonists	• Added the use of infliximab for immune checkpoint inhibitor

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		therapy-related toxicities (grade 3 or grade 4 adverse events) as Medically Necessary when criteria are met. • Added the use of certolizumab pegol for plaque psoriasis as Medically Necessary when criteria are met. • Added vedolizumab to Not Medically Necessary statement for use in combination with each TNF antagonist.
CG-DRUG-68	Bevacizumab (Avastin®) for Non-Ophthalmologic Indications	• Added Medically Necessary statement for use of bevacizumab in advanced or recurrent endometrial carcinoma when criteria are met. • Expanded Medically Necessary statement for use of bevacizumab as first-line treatment of non-squamous NSCLC in combination chemotherapy with platinum-based therapy, a taxane, and atezolizumab when criteria are met. • Expanded Medically Necessary statement for use of bevacizumab as maintenance therapy in non-squamous cell NSCLC as a single agent or in combination with atezolizumab when criteria are met. • Expanded Medically Necessary statements for use of bevacizumab in advanced or metastatic ovarian cancer following initial surgical resection (both initial and maintenance therapy) when criteria are met. • Clarified Medically Necessary statement for maintenance therapy with bevacizumab for malignant mesothelioma, adding “unresectable”.
CG-DRUG-73	Denosumab (Prolia®, Xgeva®)	• Added Medically Necessary indication for Prolia in the treatment of adults with glucocorticoid-induced osteoporosis when criteria met.
CG-DRUG-81	Tocilizumab (Actemra®)	• Added Medically Necessary statement for use of tocilizumab in chronic antibody-mediated renal transplant rejection when criteria are met.
CG-GENE-03	BRAF Mutation Analysis	• Added BRAF V600E mutation analysis as Medically Necessary in individuals with locally advanced, unresectable or metastatic anaplastic thyroid cancer to identify those who would benefit from treatment with dabrafenib (Tafinlar®) in combination with trametinib (Mekinist®).
CG-SURG-24	Functional Endoscopic Sinus Surgery (FESS)	• Removed time requirement of "at least 4 consecutive weeks" for antibiotic therapy from Medically Necessary criteria.
CG-SURG-73	Balloon Sinus Ostial Dilation	• Removed time requirement of "at least 4 consecutive weeks" for antibiotic therapy from Medically Necessary criteria.
CG-THER-RAD-03	Radioimmunotherapy and Somatostatin Receptor Targeted Radiotherapy	• Updated criteria to clarify non-FDA approved somatostatin analogs (including octreotide, lanreotide and vapreotide) are Not Medically Necessary for use as therapeutic receptor targeted radionuclide therapy.