UnitedHealthcare®

May 2019

medical policy update bulletin

Medical Policy, Medical Benefit Drug Policy & Coverage Determination Guideline Updates

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Medical Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline, Utilization Review Guideline, and Quality of Care Guideline updates.*

*Where information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

Overview

This bulletin provides complete details on UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline (CDG), Utilization Review Guideline (URG), and/or Quality of Care Guideline (QOCG) updates. The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare has recently adopted a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the health service. In the event of an inconsistency or conflict between the information provided in this bulletin and the posted policy, the provisions of the posted policy will prevail. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

The complete library of UnitedHealthcare Medical Policies, Medical Benefit Drug Policies, CDGs, URGs, and QOCGs is available at **UHCprovider.com** > *Policies and Protocols > Commercial Policies > Medical & Drug Policies and Coverage Determination Guidelines.*

Tips for using the Medical Policy Update Bulletin:

- From the table of contents, click the policy title to be directed to the corresponding policy update summary.
- From the policy updates table, click the policy title to view a complete copy of a new, updated, or revised policy.

Policy Update Classifications

New

New clinical coverage criteria and/or documentation review requirements have been adopted for a health service (e.g., test, drug, device or procedure)

Updated

An existing policy has been reviewed and changes have not been made to the clinical coverage criteria or documentation review requirements; however, items such as the clinical evidence, FDA information, and/or list(s) of applicable codes may have been updated

Revised

An existing policy has been reviewed and revisions have been made to the clinical coverage criteria and/or documentation review requirements

Replaced

An existing policy has been replaced with a new or different policy

Retired

The health service(s) addressed in the policy are no longer being managed or are considered to be proven/medically necessary and are therefore not excluded as unproven/not medically necessary services, unless coverage guidelines or criteria are otherwise documented in another policy

Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a health service must be determined in accordance with the member's benefit plan and any applicable federal or state regulatory requirements. Additionally, UnitedHealthcare reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

In This Issue

Medical Policy Updates

Page

UPDATED

REVISED

Medical Benefit Drug Policy Updates

NEW

UPDATED

REVISED

Coverage Determination Guideline (CDG) Updates

UPDATED

REVISED

In This Issue

Utilization Review Guideline (URG) Updates

UPDATED

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		

Negative Pressure Wound Therapy	Jun. 1, 2019	• Simplified coverage rationale (no change to guidelines)
		• Relocated the following terms/descriptions from the *Coverage Rationale* section to the *Definitions* section:
		  ○ Gustilo Grade III Fracture
		  ○ National Pressure Ulcer Advisory Panel (NPUAP) Staging System
		• Updated list of applicable HCPCS codes; removed A7000

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Omnibus Codes	May 1, 2019	• Removed coverage guidelines for percutaneous cryoablative therapy of pulmonary tumors, including the pleura or chest wall when involved by tumor extension (CPT code 32994) (no longer requires clinical review)	Refer to the policy for complete details on the coverage guidelines for Omnibus Codes.

Therapeutic Radio-pharmaceuticals	Jul. 1, 2019	• Revised coverage rationale:
		  ○ Simplified content
		  ○ Added language to indicate Azedra® (iobenguane I 131) injection for intravenous use is:
		  ▪ Proven and medically necessary when all the following criteria are met:
		  - Individual with positive iobenguane scan; and
		  - Individual has unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy
		  ▪ Unproven and not
			Azedra® (iobenguane I 131) injection for intravenous use is proven and medically necessary when ALL the following criteria are met:
			• Individual with positive iobenguane scan; and
			• Individual has unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy
			
			Azedra® (iobenguane I 131) injection for intravenous use is unproven and not medically necessary for ALL other indications due to insufficient evidence of efficacy.
			
			Lutathera® (lutetium Lu 177 dotatate) injection for intravenous use is proven and medically necessary for the treatment of somatostatin receptor-positive metastatic or unresectable locally advanced gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults, who have progressed on a high dose somatostatin analog (e.g., long acting octreotide, lanreotide).
			
			Lutathera® (lutetium Lu 177 dotatate) injection for intravenous use is unproven and not medically necessary for ALL other indications due to insufficient evidence of efficacy.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Therapeutic Radio-pharmaceuticals *(continued)*	Jul. 1, 2019	medically necessary for all other indications due to insufficient evidence of efficacy • Added definition of: ○ Azedra® (iobenguane I 131) ○ Pheochromocytoma • Updated list of applicable codes; added notation to clarify HCPCS codes A4641 and A9508 are intended to be reported for diagnostic use and are not appropriate for reporting therapeutic use of the radiopharmaceuticals addressed in this policy • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references	**Radium-223 (Xofigo®) is proven and medically necessary when ALL of the following criteria are met**: • Individual has metastatic, castration-resistant prostate cancer (mCRCP); and • Individual has bone metastases documented on imaging; and • Individual is not/will not be receiving concurrent chemotherapy, biologic therapy, or immunotherapy (concurrent use of hormonal therapy is permitted); and • Individual has no current visceral metastatic disease **Radium-223 (Xofigo®) is unproven and not medically necessary for ALL other indications due to insufficient evidence of efficacy**.
Transpupillary Thermotherapy	Jun. 1, 2019	• Revised coverage rationale; replaced language indicating "transpupillary thermotherapy is unproven and not medically necessary for treating choroidal neovascularization and macular degeneration due to insufficient evidence of efficacy" with "transpupillary thermotherapy is unproven and not medically necessary for treating *all other indications* [not listed as proven and medically necessary] due to insufficient evidence of efficacy; *these include but are not limited to* choroidal neovascularization and macular degeneration"	**Transpupillary thermotherapy is proven and medically necessary for treating the following**: • Retinoblastoma • Choroidal melanomas **Transpupillary thermotherapy is unproven and not medically necessary for treating all other indications due to insufficient evidence of efficacy**. These include but are not limited to: • Choroidal neovascularization • Macular degeneration

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Transpupillary Thermotherapy *(continued)*	Jun. 1, 2019	• Updated supporting information to reflect the most current clinical evidence, CMS information, and references	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Evenity™ (Romosozumab-Aqqg)	May 1, 2019	Evenity (romosozumab-aqqg) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the policy titled Review at Launch for New to Market Medications for additional details. **Evenity is proven for the treatment of osteoporosis in postmenopausal patients at high risk for fracture.** **Evenity is medically necessary when ALL of the following criteria are met**: I. Diagnosis of osteoporosis; **and** II. **One** of the following: A. BMD T-score ≤-2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); **or** B. History of one of the following resulting from minimal trauma: 1. Vertebral compression fracture 2. Fracture of the hip 3. Fracture of the distal radius 4. Fracture of the pelvis 5. Fracture of the proximal humerus **or** C. **Both** of the following: 1. BMD T-score between -1 and -2.5 (BMD T-score greater than-2.5 and less than or equal to -1) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) 2. **One** of the following: a. FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more b. FRAX 10-year fracture probabilities: hip fracture at 3% or more **and** III. History of failure, contraindication, or intolerance to oral or intravenous bisphosphonate therapy; **and** IV. Patient is not receiving Evenity in combination with **any** of the following: A. Parathyroid hormone analogs (e.g., Forteo, Tymlos) B. RANK ligand inhibitors (e.g., Prolia, Xgeva) **and** V. Evenity dosing is in accordance with the United States Food and Drug Administration approved labeling: 210mg once monthly; **and** VI. Authorization is for no more than 12 months. **Reauthorization/Continuation of Care Criteria** The clinical benefit of Evenity has not been demonstrated beyond 12 months in phase 3 clinical trials. The continued use of Evenity beyond 12 months is unproven and not medically necessary.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Mifeprex® (Mifepristone)	May 1, 2019	• Updated coverage rationale; added language to clarify Mifeprex (mifepristone), in combination with misoprostol, is proven and medically necessary for *the medical* termination of *intrauterine* pregnancy through 70 days gestation when administered under the supervision of a qualified physician • Updated supporting information to reflect the most current clinical evidence, CMS information, and references

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Botulinum Toxins A and B	May 1, 2019	• Revised coverage rationale; added criterion for chronic migraine headache requiring botox is not used in combination with CGRP antagonists [i.e., Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab)]	This policy refers to the following drug products: **Botulinum toxin types A and B:** • Dysport® (abobotulinumtoxinA) • Xeomin® (incobotulinumtoxinA) • Botox® (onabotulinumtoxinA) • Myobloc® (rimabotulinumtoxinB) Refer to the policy for complete details on the coverage guidelines for Botulinum Toxins A and B.
Complement Inhibitors (Soliris® & Ultomiris™)	May 1, 2019	• Revised coverage rationale; updated coverage criteria for **paroxysmal nocturnal hemoglobinuria (PNH)**: **Initial Therapy** ○ Added criteria requiring: ▪ Documentation supporting the diagnosis of PNH that includes both of the following: - Flow cytometry analysis confirming presence of PNH clones - Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle	Ultomiris (ravulizumab-cwvz) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the policy titled Review at Launch for New to Market Medications for additional details. This policy refers to the following complement inhibitor drug products: • Soliris (eculizumab) • Ultomiris (ravulizumab-cwvz) I. **Soliris is proven for the treatment of atypical Hemolytic Uremic Syndrome (aHUS).** **Soliris is medically necessary when all of the following criteria are met**: A. **Initial Therapy:** 1. Documentation supporting the diagnosis of aHUS by ruling out **both** of the following: a. Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS); b. Thrombotic thrombocytopenia purpura (TTP) (e.g., rule out ADAMTS13 deficiency); **and** 2. Soliris is initiated and titrated according to the US FDA labeled dosing for aHUS, up to a maximum of 1200 mg every 2 weeks;

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Complement Inhibitors (Soliris® & Ultomiris™) *(continued)*	May 1, 2019	dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.) ▪ Patient is treatment naïve with both Soliris and Ultomiris ○ Removed criteria requiring: ▪ Documentation supporting the diagnosis of PNH that includes one of the following: - At least 10% PNH type III red cells - Greater than 50 % of glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient poly-morphonuclear cells (PMNs) ▪ One of the following: - Patient is transfusion dependent as defined as hemoglobin ≤ 7 g/dL or both of the following: • Hemoglobin ≤ 9 g/dL • Patient is experiencing symptoms of anemia - Patient has a documented history	**and** 3. Prescribed by or in consultation with a hematologist; **and** 4. Initial authorization will be for no more than 6 months. B. **Continuation Therapy**: 1. Patient has previously been treated with Soliris; **and** 2. Documentation demonstrating a positive clinical response from baseline (e.g., reduction of plasma exchanges, reduction of dialysis, increased platelet count, reduction of hemolysis); **and** 3. Soliris is dosed according to the US FDA labeled dosing for aHUS: 1200 mg every 2 weeks; **and** 4. Prescribed by or in consultation with a hematologist; **and** 5. Reauthorization will be for no more than 12 months. II. **Soliris is unproven and not medically necessary for treatment of Shiga Toxin E. Coli-related Hemolytic Uremic Syndrome (STEC-HUS).** III. **Soliris and Ultomiris are proven for the treatment of paroxysmal Nocturnal Hemoglobinuria (PNH).** **Soliris and Ultomiris are medically necessary when all of the following criteria are met**: A. **Initial Therapy:** 1. Documentation supporting the diagnosis of PNH that includes **both** of the following: a. Flow cytometry analysis confirming presence of PNH clones. b. Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.) **and** 2. Patient is treatment naïve with both Soliris and Ultomiris; **and** 3. Soliris or Ultomiris are dosed according to the US FDA labeled dosing for PNH; **and** 4. Prescribed by or in consultation with a hematologist or oncologist; **and** 5. Initial authorization will be for no more than 6 months. B. **Continuation Therapy**: 1. Patient has previously been treated with Soliris or Ultomiris; **and** 2. Documentation demonstrating a positive clinical response from

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Complement Inhibitors (Soliris® & Ultomiris™) *(continued)*	May 1, 2019	of major adverse vascular events from thromboembolism ○ Replaced criterion requiring "[drug is] prescribed by or in consultation with a hematologist" with "[drug is] prescribed by or in consultation with a hematologist *or oncologist*" **Continuation Therapy** ○ Modified list of examples of documentation demonstrating a positive clinical response from baseline; added: ▪ Decrease in LDH ▪ Improvement in hemolysis ▪ Increased reticulocyte count ○ Replaced criterion requiring "[drug is] prescribed by or in consultation with a hematologist" with "[drug is] prescribed by or in consultation with a hematologist *or oncologist*" • Updated supporting information to reflect the most current references	baseline (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc.); **and** 3. Soliris or Ultomiris are dosed according to the US FDA labeled dosing for PNH; **and** 4. Prescribed by or in consultation with a hematologist or oncologist; **and** 5. Reauthorization will be for no more than 12 months. IV. **Soliris is proven for the treatment of generalized Myasthenia Gravis.** **Soliris is medically necessary when all of the following criteria are met:** A. **Initial therapy:** 1. Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG) by a neurologist or in consultation with a neurologist confirming **all** of the following: a. Patient has not failed a previous course of Soliris therapy; **and** b. Positive serologic test for anti-AChR antibodies; **and** c. **One** of the following: i. History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation ii. History of positive anticholinesterase test, e.g., edrophonium chloride test iii. Patient has demonstrated improvement in MG signs on oral cholinesterase inhibitors, as assessed by the treating neurologist **and** d. Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; **and** e. Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 6 at initiation of therapy; **and** 2. **Both** of the following: a. History of failure of at least **two** immunosuppressive agent

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Complement Inhibitors (Soliris® & Ultomiris™) *(continued)*	May 1, 2019		over the course of at least 12 months [e.g., azathioprine, methotrexate, cyclosporine, mycophenylate, etc.]; **and** b. Patient has required 2 or more courses of plasmapheresis/ plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control **and** 3. Patient is currently on a stable dose (at least 2 months) of immunosuppressive therapy; **and** 4. Soliris is initiated and titrated according to the US FDA labeled dosing for gMG, up to a maximum of 1200 mg every 2 weeks; **and** 5. Prescribed by or in consultation with a Neurologist; **and** 6. Initial authorization will be for no more than 6 months. B. **Continuation therapy:** 1. Patient has previously been treated with Soliris; **and** 2. Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by at least **all** of the following: a. Improvement and/or maintenance of at least a 3 point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline. b. Reduction in signs and symptoms of myasthenia gravis c. Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Soliris.* ***Note:** Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Soliris therapy will be considered as treatment failure. **and** 3. Soliris is dosed according to the US FDA labeled dosing for gMG: up to a maximum of 1200 mg every 2 weeks; **and** 4. Prescribed by or in consultation with a Neurologist; **and** 5. Reauthorization will be for no more than 12 months.
Enzyme Replacement Therapy	May 1, 2019	• Revised coverage rationale: ○ Updated list of applicable enzyme replacement therapy products; removed Adagen® (pegademase bovine)	This policy refers to the following enzyme replacement therapy products: • Aldurazyme® (laronidase) • Elaprase® (idursulfase) • Fabrazyme® (agalsidase beta) • Kanuma™ (sebelipase alfa)

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Enzyme Replacement Therapy *(continued)*	May 1, 2019	○ Removed coverage criteria for Adagen® (pegademase bovine) *(removed from market)* ○ Updated coverage criteria for Revcovi: ▪ Removed specific dosage quantities ▪ Replaced references to "*pegademase* therapy" with "*elapegademase* therapy" • Updated list of applicable HCPCS codes; removed J2504 • Updated supporting information to reflect the most current background information, clinical evidence, FDA and CMS information, and references	• Lumizyme® (alglucosidase alfa) • Mepsevii™ (vestronidase alfa-vjbk) • Naglazyme® (galsulfase) • Revcovi™ (elapegademase-lvlr) • Vimizim® (elosulfase alfa) Refer to the policy for complete details on the coverage guidelines for Enzyme Replacement Therapy.
Ketamine	May 1, 2019	• Revised coverage rationale: ○ Added language to indicate: ▪ This policy refers to the following ketamine products: - Ketalar (ketamine) - Spravato (esketamine) ▪ Spravato (esketamine) nasal spray is proven and/or medically necessary for the treatment of treatment-resistant depression (TRD) when **all** of the following criteria are met: **Initial Therapy** - Diagnosis for major	This policy refers to the following ketamine products: • Ketalar (ketamine) • Spravato (esketamine) **Spravato (esketamine) Nasal Spray** **Spravato is proven and/or medically necessary for the treatment of treatment-resistant depression (TRD) when ALL of the following criteria are met:** ***Initial Therapy*** I. Diagnosis for major depressive disorder (MDD) according to the current DSM (i.e., DSM-5), by a mental health professional; **and** II. Patient has not experienced a clinically meaningful improvement after treatment with at least **two** different antidepressants of adequate dose, duration (at least 6 weeks), and adherence in the current depressive episode **(Must document medications, doses, and durations)**; **and** III. Patient is to receive Spravato therapy in conjunction with another oral antidepressant; **and** IV. Provider and/or the provider's healthcare setting is certified in the Spravato REMS program; **and**

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ketamine *(continued)*	May 1, 2019	depressive disorder (MDD) according to the current DSM (i.e., DSM-5), by a mental health professional; and - Patient has not experienced a clinically meaningful improvement after treatment with at least two different antidepressants of adequate dose, duration (at least 6 weeks), and adherence in the current depressive episode (must document medications, doses, and durations); and - Patient is to receive Spravato therapy in conjunction with another oral antidepressant; and - Provider and/or the provider's healthcare setting is certified in the Spravato REMS program; and - Spravato dosing is in accordance with the United States Food and Drug Administration approved labeling; and	V. Spravato dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** VI. Initial authorization will be for no longer than 12 weeks. ***Continuation Therapy*** I. Patient has previously been treated with Spravato; **and** II. Documentation demonstrating a positive clinical response from baseline (e.g., improved Montgomery-Asberg Depression Rating Scale [MADRS], clinical remission, response, etc.), as defined by the provider; **and** III. Patient is to receive Spravato therapy in conjunction with another oral antidepressant; **and** IV. Provider and/or the provider's healthcare setting is certified in the Spravato REMS program; **and** V. Spravato dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** VI. Authorization will be for no longer than 6 months. **Spravato is unproven and not medically necessary for the following:** • Anesthetic agent • Chronic pain (including but not limited to nonmalignant pain, Fibromyalgia, neuropathic pain, Complex Regional Pain Syndrome, Reflex Sympathetic Dystrophy) • Migraine headaches **Ketalar (ketamine) Injection** **Ketamine injection is considered medically necessary and may be covered for the following:** • Anesthesia for diagnostic and surgical procedures that do not require skeletal muscle relaxation, OR • The induction of anesthesia prior to administration of other anesthesia agents, OR • As supplemental anesthesia for low-potency agents, such as nitrous oxide **Ketamine injection is investigational, and therefore not proven or medically necessary for the following:** • Psychiatric disorders (including, but not limited to depression, bipolar disorder, & posttraumatic stress disorder) • Chronic pain (including but not limited to nonmalignant pain, Fibromyalgia, neuropathic pain, Complex Regional Pain Syndrome, Reflex Sympathetic Dystrophy)

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ketamine *(continued)*	May 1, 2019	- Initial authorization will be for no longer than 12 weeks **Continuation Therapy** - Patient has previously been treated with Spravato; and - Documentation demonstrating a positive clinical response from baseline (e.g., improved Montgomery-Asberg Depression Rating Scale [MADRS], clinical remission, response, etc.), as defined by the provider; and - Patient is to receive Spravato therapy in conjunction with another oral antidepressant; and - Provider and/or the provider's healthcare setting is certified in the Spravato REMS program; and - Spravato dosing is in accordance with the United States Food and Drug Administration approved labeling; and - Authorization will be	• Migraine headaches

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ketamine *(continued)*	May 1, 2019	for no longer than 6 months ▪ Spravato is unproven and not medically necessary for the following: - Anesthetic agent - Chronic pain (including but not limited to nonmalignant pain, Fibromyalgia, neuropathic pain, Complex Regional Pain Syndrome, Reflex Sympathetic Dystrophy) - Migraine headaches ○ Replaced references to "ketamine" with "ketamine *injection*" • Added list of applicable ICD-10 diagnosis codes: F33.0, F33.1, F33.2, F33.3, F33.40, F33.41, F33.42, F33.8, and F33.9 • Updated supporting information to reflect the most current background information, clinical evidence, FDA information, and references	
Lemtrada (Alemtuzumab)	May 1, 2019	• Revised coverage rationale: ○ Updated coverage criteria for patients who are: **Treatment-Naïve to Alemtuzumab** ▪ Modified list of products to which the patient must have a history of	**Lemtrada (alemtuzumab) is proven and medically necessary for treatment of relapsing forms of multiple sclerosis when ALL of the following criteria are met**: I. Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses); **and** II. **One** of the following: A. **Treatment-naïve to alemtuzumab:** 1. Patient has history of failure following a trial for at least 4 weeks

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Lemtrada (Alemtuzumab) *(continued)*	May 1, 2019	failure following a trial for at least 4 weeks or history of intolerance; removed "daclizumab (Zinbryta™)" **Treatment-Experienced with Alemtuzumab** ▪ Added criterion requiring documentation of positive clinical response to alemtuzumab therapy ○ Modified list of examples of disease modifying agents for multiple sclerosis the patient must not receive in combination with alemtuzumab; added "ocrelizumab" ○ Added language to indicate authorization is for no more than 12 months ○ Removed language indicating coverage for Lemtrada is limited to up to two treatment courses (5 day initial and 3 day end course); requests for additional doses/courses beyond two courses will not be approved • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	**or** history of intolerance to at least **two** of the following: a. interferon β-1a (Avonex® or Rebif®) b. interferon β-1b (Betaseron® or Extavia®) c. glatiramer acetate (Copaxone® or Glatopa®) d. dimethyl fumarate (Tecfidera®) e. teriflunomide (Aubagio®) f. fingolimod (Gilenya®) g. peginterferon beta-1a (Plegridy™) h. natalizumab (Tysabri®) i. ocrelizumab (Ocrevus®) **and** 2. Patient has **not** been previously treated with alemtuzumab; **and** 3. Patient is **not** receiving alemtuzumab in combination with another disease modifying agent for multiple sclerosis (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, teriflunomide, ocrelizumab, etc.); **and** 4. Initial dosing is administered: 12 mg intravenously daily for 5 consecutive days; **and** 5. Regimen is administered only once within 12 months; **and** 6. Initial authorization is for no more than 12 months **or** B. **Treatment-experienced with alemtuzumab:** 1. Patient has previously received treatment with alemtuzumab; **and** 2. Documentation of positive clinical response to alemtuzumab therapy; **and** 3. Patient is **not** receiving alemtuzumab in combination with another disease modifying agent for multiple sclerosis (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, teriflunomide, ocrelizumab etc.); **and** 4. Retreatment dosing is administered: 12 mg intravenously daily for 3 consecutive days; **and** 5. Regimen is administered only once within 12 months; **and** 6. Authorization is for no more than 12 months **Alemtuzumab is unproven and not medically necessary for the treatment of:** • Rheumatoid arthritis • Autoimmune neutropenia • Autoimmune hemolytic anemia

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Lemtrada (Alemtuzumab) *(continued)*	May 1, 2019		• Pure red cell aplasia • Immune thrombocytopenic purpura • Evans syndrome • Autoimmune pancytopenia
Maximum Dosage	May 1, 2019	• Updated list of related policies; added reference link to the policy titled: ○ *Denosumab (Prolia® & Xgeva®)* ○ *Oncology Medication Clinical Coverage* • Revised coverage rationale: ○ Updated list of applicable drug products; added: ▪ Denosumab (Prolia® & Xgeva®) ▪ Nivolumab (Opdivo®) ▪ Pegfilgrastim-cbqv (Udenyca™) ○ Added HCPCS code based maximum dosage information for: **Opdivo (nivolumab)** ▪ Maximum Dosage per Administration: 480 mg ▪ HCPCS Code: J9299 ▪ Maximum Allowed: 480 HCPCS units (1 mg per unit) **Prolia (denosumab)** ▪ Diagnosis: Osteoporosis ▪ Maximum Dosage per Administration: 60 mg ▪ HCPCS Code: J0897 ▪ Maximum Allowed: 60 HCPCS units (1 mg per unit) **Udenyca (pegfilgrastim-**	This policy provides information about the maximum dosage per administration for certain medications administered by a medical professional. **Drug Products:** • bevacizumab (Avastin®) • denosumab (Prolia® & Xgeva®) • eculizumab (Soliris®) • infliximab (Remicade®) • infliximab-dyyb (Inflectra™) • infliximab-abda (Renflexis™) • nivolumab (Opdivo®) • omalizumab (Xolair®) • pegfilgrastim (Neulasta®) • pegfilgrastim-cbqv (Udenyca™) • pegfilgrastim-jmdb (Fulphila™) • rituximab (Rituxan®) • trastuzumab (Herceptin®) • ustekinumab (Stelara®) • vedolizumab (Entyvio®) • zoledronic acid (zoledronic acid, Reclast® and Zometa®) **Most medications have a maximum dosage based upon body surface area or patient weight or a set maximal dosage independent of patient body size, and are proven when used according to labeled indications or when otherwise supported by published clinical evidence.** **The medications included in this policy when given beyond maximum dosages based upon body surface area or patient weight or a set maximal dosage independent of patient body size are not supported by package labeling or published clinical evidence and are unproven.** This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (128 kg) and body surface area (2.59

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Maximum Dosage *(continued)*	May 1, 2019	**cbqv)** ▪ Maximum Dosage per Administration: 6 mg total dose ▪ HCPCS Code: Q5111 ▪ Maximum Allowed: 12 HCPCS units (0.5mg per unit) **Xgeva (denosumab)** ▪ Diagnosis: Oncology ▪ Maximum Dosage per Administration: 120 mg ▪ HCPCS Code: J0897 ▪ Maximum Allowed: 120 HCPCS units (1 mg per unit) ○ Added maximum allowed quantities for National Drug Code (NDC) billing for: **Opdivo (nivolumab)** ▪ NDC: 00003-3734-13 - How Supplied: 240 mg/24 mL solution in vials - Maximum Allowed: 48 mL ▪ NDC: 00003-3772-11 - How Supplied: 40 mg/4 mL solution in vials - Maximum Allowed: 8 mL ▪ NDC: 00003-3774-12 - How Supplied: 100 mg/10 mL solution in vials - Maximum Allowed: 40 mL **Prolia (denosumab)**	meters^2) in the U.S. (adult male, 30 to 39 years, Fryar, 2016). In some cases, the maximum allowed units and/or vials may exceed the upper level limit as defined within this policy due to an individual patient body weight > 128 kg or body surface area > 2.59 meters^2. Refer to the policy for complete details on the coverage guidelines for Maximum Dosage.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Maximum Dosage *(continued)*	May 1, 2019	▪ Diagnosis: Osteoporosis ▪ NDC: 55513-0710-01 ▪ How Supplied: 60 mg/1 mL prefilled syringe ▪ Maximum Allowed: 1 mL **Udenyca (pegfilgrastim-cbqv)** ▪ NDC: 70114-0101-01 ▪ How Supplied: 6 mg/0.6mL prefilled syringe ▪ Maximum Allowed: 0.6mL **Xgeva (denosumab)** ▪ Diagnosis: Oncology ▪ NDC: 55513-0730-01 ▪ How Supplied: 120 mg/1.7 mL solution in vials ▪ Maximum Allowed: 1.7 mL • Updated list of applicable HCPCS codes; added J0897, J9173, and Q5111 • Updated list of applicable NDCs; added 00003-3734-13, 00003-3772-11, 00003-3774-12, 55513-0710-01, 55513-0730-01, and 70114-0101-01 • Updated supporting information to reflect the most current CMS information and references	
Spinraza™ (Nusinersen)	May 1, 2019	• Revised coverage rationale: ○ Added coverage criteria for **spinal muscular atrophy (SMA)** requiring: **Initial Therapy** ▪ Patient has not	**Spinraza™ (nusinersen) is proven and medically necessary for:** I. The treatment of **Spinal Muscular Atrophy (SMA)** in patients who meet **all** of the following criteria: A. For **initial therapy**, **all** of the following: 1. Diagnosis of spinal muscular atrophy type I, II, or III by, or in consultation with, a neurologist with expertise in the diagnosis of

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Spinraza™ (Nusinersen) *(continued)*	May 1, 2019	previously received gene replacement therapy for the treatment of SMA; or ▪ One of the following: - Both of the following: • Patient recently received gene replacement therapy within the previous 6 months; and • Patient has experienced a declination in clinical status since receipt of gene replacement therapy **or** - Both of the following: • Patient has previously received gene replacement therapy; and • Patient has experienced a declination in clinical status that represents a potential abatement of gene therapy efficacy **Continuation Therapy** ▪ One of the following:	SMA; **and** 2. Submission of medical records (e.g., chart notes, laboratory values) confirming **both** of the following: a. The mutation or deletion of genes in chromosome 5q resulting in **one** of the following: i. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13); **or** ii. Compound heterozygous mutation (e.g., deletion of SMN1 exon 7[allele 1] and mutation of SMN1 [allele 2]) **and** b. Patient has at least 2 copies of SMN2 **and** 3. Patient is **not** dependent on **either** of the following: a. Invasive ventilation or tracheostomy b. Use of non-invasive ventilation beyond use for naps and nighttime sleep **and** 4. Submission of medical records (e.g., chart notes, laboratory values) of the baseline exam of at least **one** of the following exams (based on patient age and motor ability) to establish baseline motor ability: a. Hammersmith Infant Neurological Exam Part 2 (**HINE-2**) (infant to early childhood) b. Hammersmith Functional Motor Scale Expanded (**HFMSE**) c. Upper Limb Module (**ULM**) Test (Non ambulatory) d. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (**CHOP INTEND**) **and** 5. Spinraza is prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA; **and** 6. **One** of the following: a. Patient has not previously received gene replacement therapy for the treatment of SMA; **or** b. **One** of the following: i. **Both** of the following: 1) Patient recently received gene replacement therapy within the previous 6 months; **and** 2) Patient has experienced a declination in clinical status since receipt of gene replacement therapy

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Spinraza™ (Nusinersen) *(continued)*	May 1, 2019	- Patient has not previously received gene replacement therapy for the treatment of SMA; or - Both of the following: • Patient has previously received gene replacement therapy; and • Patient has experienced a declination in clinical status that represented a potential failure or abatement of gene therapy efficacy ▪ Submission of medical records (e.g., chart notes, laboratory values) with the most recent results (< 1 month prior to request) documenting a positive clinical response from pretreatment baseline status to Spinraza therapy as demonstrated by both of the following: - Patient was prescribed Spinraza due to clinical declination after receipt of gene	**or** ii. **Both** of the following: 1) Patient has previously received gene replacement therapy; **and** 2) Patient has experienced a declination in clinical status that represents a potential abatement of gene therapy efficacy **and** 7. Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures; **and** 8. Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg for each loading dose; **and** 9. Initial authorization will be for no more than 4 loading doses. B. For **continuation therapy**, **all** of the following: 1. Diagnosis of spinal muscular atrophy type I, II, or III by, or in consultation with, a neurologist with expertise in the diagnosis of SMA; **and** 2. Submission of medical records (e.g., chart notes, laboratory values) confirming **both** of the following: a. The mutation or deletion of genes in chromosome 5q resulting in **one** of the following: i. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13); **or** ii. Compound heterozygous mutation (e.g., deletion of SMN1 exon 7[allele 1] and mutation of SMN1 [allele 2]) **and** b. Patient has at least 2 copies of SMN2 **and** 3. Patient is **not** dependent on **either** of the following: a. Invasive ventilation or tracheostomy b. Use of non-invasive ventilation beyond use for naps and nighttime sleep **and** 4. **One** of the following: a. Patient has not previously received gene replacement therapy for the treatment of SMA; **or** b. **Both** of the following:

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Spinraza™ (Nusinersen) *(continued)*	May 1, 2019	therapy; and - Patients clinical status has stabilized after receipt of Spinraza therapy ○ Added language to indicate Spinraza is not proven or medically necessary for: ▪ Spinal muscular atrophy without chromosome 5q mutations or deletions ▪ Routine concomitant treatment of SMA in patients who have previously received gene replacement therapy • Updated supporting information to reflect the most current background information, clinical evidence, CMS information, and references	i. Patient has previously received gene replacement therapy; and ii. Patient has experienced a declination in clinical status that represented a potential failure or abatement of gene therapy efficacy **and** 5. Submission of medical records (e.g., chart notes, laboratory values) with the most recent results (< 1 month prior to request) documenting a positive clinical response **from pretreatment baseline status** to Spinraza therapy as demonstrated by at least **one** of the following exams: a. **HINE-2** milestones: i. **One** of the following: 1) Improvement or maintenance of previous improvement of at least 2 point (or maximal score) increase in ability to kick 2) Improvement or maintenance of previous improvement of at least 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp **and** ii. **One** of the following: 1) The patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement) 2) Achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) **or** b. **HFMSE: One** of the following: i. Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so **or** c. **ULM: One** of the following:

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Spinraza™ (Nusinersen) *(continued)*	May 1, 2019		i. Improvement or maintenance of previous improvement of at least a 2 point increase in score from pretreatment baseline ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so **or** d. **CHOP INTEND: One** of the following: i. Improvement or maintenance of previous improvement of at least a 4 point increase in score from pretreatment baseline ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so **or** e. **Both** of the following: i. Patient was prescribed Spinraza due to clinical declination after receipt of gene therapy; **and** ii. Patients clinical status has stabilized after receipt of Spinraza therapy **and** 6. Spinraza is prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA; **and** 7. Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures; **and** 8. Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg every 4 months, starting 4 months after the last loading dose; **and** 9. Reauthorization will be for no more than 3 maintenance doses (12 months). **Spinraza is not proven or medically necessary for spinal muscular atrophy without chromosome 5q mutations or deletions. Spinraza is not proven or medically necessary for routine concomitant treatment of SMA in patients who have previously received gene replacement therapy**.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Vaccines	May 1, 2019	• Revised coverage rationale: ○ Removed language indicating: ▪ The standard UnitedHealthcare Certificate of Coverage covers preventive health services, including immunizations, administered in a physician office; some immunizations are excluded, e.g., immunizations that are required for travel, employment, education, insurance, marriage, adoption, military service, or other administrative reasons ▪ Implementation of covered vaccines will typically occur within 60 days after publication in the MMWR ○ Updated conditions of coverage to clarify the *following conditions apply to all covered vaccines; a vaccine* is considered covered after both of the following conditions are satisfied: ▪ US Food and Drug Administration (FDA) approval; and ▪ *Explicit* ACIP *recommendations* (e.g., should, shall, is) rather	**Conditions:** The following conditions apply to all covered vaccines. A vaccine is considered covered after **both** of the following conditions are satisfied: 1. US Food and Drug Administration (FDA) approval; **and** 2. Explicit ACIP recommendations (e.g., should, shall, is) rather than a permissive ("may") recommendation, published in the Morbidity & Mortality Weekly Report (MMWR) of the Centers for Disease Control and Prevention (CDC). **Coverage Clarifications:** • **Preventive**: For a list of vaccines that are covered under the preventive care benefit, see the Coverage Determination Guideline titled Preventive Care Services. • **Therapeutic**: Certain vaccines are used as a medical treatment. For example, therapeutic treatment of an animal bite using the rabies vaccine. These vaccines are under the plan's treatment benefits, not under preventive care benefits. • **Excluded**: Vaccines that that fall under one of the exclusions in the member-specific benefit plan document. For example, most plans exclude travel-specific vaccines.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Vaccines *(continued)*	May 1, 2019	than a permissive ("may") recommendation, published in the Morbidity & Mortality Weekly Report (MMWR) of the Centers for Disease Control and Prevention (CDC) ○ Updated coverage clarification notations: ▪ Modified instruction to clarify the Coverage Determination Guideline titled *Preventive Care Services* should be referenced for *a list of vaccines that are covered under the preventive care benefit* ▪ Added language to indicate: - Certain vaccines are used as a medical treatment • For example, therapeutic treatment of an animal bite using the rabies vaccine • These vaccines are under the plan's treatment benefits, not under preventive care benefits - Vaccines that that fall under one of the	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Vaccines *(continued)*	May 1, 2019	exclusions in the member-specific benefit plan document are excluded; for example, most plans exclude travel-specific vaccines • Updated supporting information to reflect the most current and references; removed CMS information	

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		

Habilitative Services and Outpatient Rehabilitation Therapy	May 1, 2019	• Updated coverage rationale:
		  ○ Simplified content
		  ○ Modified list of coverage limitations and exclusions for both habilitative services and rehabilitation therapy to clarify coverage is excluded for *services that continue* once the treatment plan goals are met

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Ambulance Services	Jun. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Revised coverage rationale:
		  ○ Simplified content
		  ○ Removed language pertaining to:
		  ▪ Cost-effective alternatives [UHIC 2007 Certificate of Coverage (COC) and 2009 COC Amendment]
		  ▪ Negotiated rates for out-of-network coverage
		  ○ Updated list of examples of non-ambulance transportation services that are not eligible for coverage; added "rideshare services such as Lyft and Uber"
		• Removed definition of "Medically Necessary (2011 Generic COC)"
			Indications for Coverage
			Air Ambulance
			As a general guideline, when it would take a ground ambulance 30-60 minutes or more to transport a member whose medical condition at the time of pick-up required immediate and rapid transport due to the nature and/or severity of the member's illness/injury, air transportation may be appropriate.
			
			Air ambulance transportation should meet the following criteria:
			• The member's destination is an acute care hospital; and
			• The member's condition is such that the ground ambulance (basic or advanced life support) would endanger the member's life or health; or
			• Inaccessibility to ground ambulance transport or extended length of time required to transport the member via ground ambulance transportation could endanger the member; or
			• Weather or traffic conditions make ground ambulance transportation impractical, impossible, or overly time consuming
			
			Emergency Ambulance (Ground, Water, or Air)
			Coverage includes Emergency ambulance transportation (including wait time and treatment at the scene) by a licensed ambulance service from the location of the sudden illness or injury, to the nearest hospital where Emergency health services can be performed.
			
			The following Emergency ambulance services are covered:
			• Ground ambulance or air ambulance transportation requiring basic life support or advanced life support
			• Supplies that are needed for advanced life support or basic life support to stabilize a member's medical condition
			• Treatment at the scene (paramedic services) without ambulance

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ambulance Services *(continued)*	Jun. 1, 2019		transportation • Wait time associated with covered ambulance transportation • Transportation to a hospital that provides a required higher level of care that was not available at the original hospital ***Non-Emergency Ambulance (Ground or Air) Between Facilities*** Coverage includes non-Emergency ambulance transportation by a licensed ambulance service (either ground or air ambulance, as we determine appropriate) between facilities only when the transport meets one of the following: • From an out-of-Network Hospital to the closest Network Hospital when Covered Health Care Services are required • To the closest Network Hospital or facility that provides the required Covered Health Care Services that were not available at the original Hospital or facility • From a Short-Term Acute Care Facility to the closest Network Long-Term Acute Care Facility (LTAC), Network Inpatient Rehabilitation Facility, or other Network Sub-Acute Facility where the required Covered Health Care Services can be delivered • When the member's condition requires treatment at another facility and another mode of transportation would endanger the member's medical condition The applicable benefit level for eligible non-Emergency ambulance transportation depends on the member pick-up location (origin) as follows: • If the member is inpatient and is transported from a hospital to another hospital or inpatient facility, coverage levels for these ambulance services may vary. • If the member is in a sub-acute setting and is transported to an outpatient facility and back (outpatient hospital, outpatient facility, or physician's office), these ambulance services are covered under the benefits that apply to that sub-acute setting. For example, if the member is at a Skilled Nursing Facility, the ambulance transport to an outpatient facility (dialysis facility or radiation whether or not it is attached to a hospital) and back is covered under the Skilled Nursing Facility/Inpatient Rehabilitation Facility Services section of the COC. **Pre-Service Notification Requirements for Non-Emergency Ambulance**

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ambulance Services *(continued)*	Jun. 1, 2019		• If UnitedHealthcare initiates the non-Emergency ambulance transportation, member notification is not required. • If UnitedHealthcare does not initiate the non-Emergency ambulance transportation, certain plans may require the member or the provider to call in for notification. • Provider notification requirements are not addressed by this document. ***Out-of-Network Ambulance (Emergency)*** If the ambulance transportation is covered, the benefit level for out-of-Network Emergency ambulance (ground, water, or air) is covered at the Network level of deductible and coinsurance. **Coverage Limitations and Exclusions** The following services are not eligible for coverage: • Ambulance services from providers that are not properly licensed to be performing the ambulance services rendered. • Air ambulance transportation that does not meet the covered indications in the Air Ambulance criteria listed above. • Non-ambulance transportation. Non-ambulance transportation is not covered even if rendered in an Emergency situation. Examples include but are not limited to: o Commercial or private airline or helicopter o A police car ride to a hospital o Medi-van or wheel-chair van transportation o Taxi ride, bus ride, rideshare services such as Lyft and Uber, etc. • Ambulance transportation when other mode of transportation is appropriate. Except as indicated under the Indications for Coverage section above, ambulance services when transportation by other means would not endanger the member's health are not covered. • Ambulance transportation to a home, residential, domiciliary or custodial facility is not covered. • Ambulance transportation that violates the notification criteria listed in the Indications for Coverage section above. • Ambulance transportation for member convenience or other miscellaneous reasons for member and/or family. Examples include but are not limited to: o Member wants to be at a certain hospital or facility for personal/preference reasons o Member is in foreign country, or out of state, and wants to come

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ambulance Services *(continued)*	Jun. 1, 2019		home for a surgical procedure or treatment (this includes those recently discharged from inpatient care) ○ Member is going for a routine service and is medically able to use another mode of transportation ○ Member is deceased and family wants transportation to the coroner's office or mortuary • Ambulance transportation deemed not appropriate. Examples include but are not limited to: ○ Hospital to home ○ Home to physician's office ○ Home (e.g., residence, nursing home, domiciliary or custodial facility) to a hospital for a scheduled service • If the member is at a Skilled Nursing Facility/Inpatient Rehabilitation Facility and has met the annual day/visit limit on Skilled Nursing Facility/Inpatient Rehabilitation Facility Services, ambulance transports (during the non-covered days) are not eligible.
Orthognathic (Jaw) Surgery	Jul. 1, 2019	• Revised coverage rationale: ○ Simplified content ○ Replaced language indicating "[the listed services] *are* eligible for coverage as reconstructive and medically necessary" with "[the listed services] *may be* eligible for coverage as reconstructive and medically necessary" ○ Modified list of services that may be eligible for coverage as reconstructive and medically necessary; removed: ▪ Post-Surgical Sequela ▪ Cleft lip/palate (for cleft lip/palate related Jaw Surgery) ○ Modified list of coverage limitations and exclusions; removed:	Orthognathic (jaw) surgery is a standard exclusion from coverage in most fully-insured plans. The following represents exceptions to the orthognathic (jaw) surgery exclusion and may be eligible for coverage as reconstructive and medically necessary: • Acute traumatic injury • Cancerous or non-cancerous tumors and cysts • Obstructive sleep apnea • Congenital anomalies **Criteria** **Orthognathic (jaw) surgery may be eligible for coverage as reconstructive and medically necessary for the conditions cited above when the following criteria below are met**: • The presence of one or more of the following facial skeletal deformities associated with masticatory malocclusion: ○ Anteroposterior Discrepancies (established norm=2mm): ▪ Maxillary/Mandibular Incisor Relationship: Overjet of 5mm or more or a 0 to a negative value ▪ Maxillary/Mandibular Anteroposterior Molar Relationship: Discrepancy of 4mm or more ▪ These values represent two or more standard deviation from published norm

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Orthognathic (Jaw) Surgery *(continued)*	Jul. 1, 2019	▪ Surgery for torus mandibularis and torus palatinus for fabrication of dentures ○ Removed language indicating some states may require orthognathic (jaw) surgery for cleft lip and cleft palate, or for services that UnitedHealthcare considers Cosmetic Procedures, such as repair of external congenital anomalies in the absence of a Functional Impairment • Updated definitions: ○ Added definition of "Obstructive Sleep Apnea" ○ Removed definition of: ▪ Cancer Sequela ▪ Post-Surgical Sequela • Updated supporting information to reflect the most current references	○ Vertical Discrepancies: Presence of a vertical facial skeletal deformity which is two or more standard deviations from published norms for accepted skeletal landmarks ▪ Open bite: - No vertical overlap of anterior teeth - Unilateral or bilateral posterior open bite greater than 2mm ▪ Deep overbite with impingement or irritation of buccal or lingual soft tissues of the opposing arch ▪ Supraeruption of a dentoalveolar segment due to lack of occlusion ○ Transverse Discrepancies: ▪ Presence of a transverse skeletal discrepancy which is two or more standard deviations from published norms ▪ Total bilateral maxillary palatal cusp to mandibular fossa discrepancy of 4mm or greater, or a unilateral discrepancy of 3mm or greater, given normal axial inclination of the posterior teeth ○ Asymmetries: Anteroposterior, transverse or lateral asymmetries greater than 3mm with concomitant occlusal asymmetry **AND** • The individual must also have one or more of the following Functional Impairments: ○ Masticatory (chewing) and swallowing dysfunction due to skeletal malocclusion (e.g., inability to incise/and or chew solid foods, choking on incompletely masticated solid foods, damage to soft tissue during mastication, malnutrition) ○ Documentation of speech deficits to support existence of speech impairment due to skeletal malocclusion ○ Moderate to Severe Obstructive Sleep Apnea (OSA) with Oropharyngeal narrowing secondary to maxillomandibular deficiency ▪ For medical necessity clinical coverage criteria for OSA, also refer to the following: - **Maxillomandibular Advancement Surgery (MMA)**: For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Maxillomandibular Osteotomy and Advancement, A-0248 (ACG). - **Multilevel Procedures Whether Done in a Single Surgery or Phased Multiple Surgeries**: There are a variety of procedure combinations, including mandibular

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Orthognathic (Jaw) Surgery *(continued)*	Jul. 1, 2019		osteotomy and genioglossal advancement with hyoid myotomy (GAHM). For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Mandibular Osteotomy, A-0247 (ACG). **Coverage Limitations and Exclusions** Orthognathic surgery for the following is not covered: • Cosmetic and non-reconstructive Jaw Surgery and jaw alignment procedures • Pre and post-surgical orthodontic treatment

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Immune Globulin – Site of Care	May 1, 2019	• Changed policy title; previously titled *Immune Globulin Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Infusion* • Simplified coverage rationale (no change to guidelines)