UnitedHealthcare®

March 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.

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UPDATED		
Breast Imaging for Screening and Diagnosing Cancer	Mar. 1, 2019	• Updated list of applicable CPT codes; added language to clarify: ○ Computer-aided detection (CAD) is included with the MRI breast CPT code 77048 and 77049 procedures; if CAD is performed with these codes, there is no additional reimbursement
Chelation Therapy for Non-Overload Conditions	Mar. 1, 2019	• Updated and reformatted coverage rationale: ○ Simplified content ○ Modified list of unproven and not medically necessary indications; replaced "chronic, progressive diseases *(not involving heavy metal toxicity or overload conditions) and other disorders*" with "chronic, progressive diseases *associated with non-overload conditions*" • Updated supporting information to reflect the most current clinical evidence and references
Cytological Examination of Breast Fluids for Cancer Screening	Apr. 1, 2019	• Updated supporting information; replaced reference to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"
Extracorporeal Shock Wave Therapy (ESWT)	Apr. 1, 2019	• Simplified coverage rationale (no change to guidelines) • Updated supporting information; replaced reference to "MCG™ Care Guidelines" with "MCG™ Care Guidelines, *23rd edition*"
Platelet Derived Growth Factors for Treatment of Wounds	Mar. 1, 2019	• Updated list of related policies; added reference link to the policy titled *Prolotherapy for Musculoskeletal Indications* • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references; no change to coverage rationale or lists of applicable codes

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Abnormal Uterine Bleeding and Uterine Fibroids	Apr. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Revised coverage rationale; replaced reference to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"	**Levonorgestrel-Releasing Intrauterine Device** **Levonorgestrel-releasing intrauterine devices (LNG-IUD) (e.g., Mirena®, Skyla®, Liletta® or Kyleena™) are proven and medically necessary for treating menorrhagia**. Refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for additional information. **Uterine Fibroids** **Uterine artery embolization (UAE) is proven and medically necessary for treating symptomatic uterine fibroids**. For medical necessity clinical coverage criteria, see MCG™ Care Guidelines,

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REVISED			
Abnormal Uterine Bleeding and Uterine Fibroids *(continued)*	Apr. 1, 2019		23rd edition, 2019, Uterine Artery Embolization, ACG: A-0287 (AC). **UAE is unproven and not medically necessary for the purpose of preserving childbearing potential for women with symptomatic uterine fibroids due to insufficient evidence of efficacy**. **The following procedures are unproven and not medically necessary for treating uterine fibroids due to insufficient evidence of efficacy**: • Magnetic resonance-guided focused ultrasound ablation (MRgFUS) • Ultrasound-guided radiofrequency ablation (e.g., Acessa™, Sonata®)
Attended Polysomnography for Evaluation of Sleep Disorders	Apr. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* section • Revised coverage rationale: ○ Simplified content ○ Replaced references to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*" • Updated list of applicable CPT codes; revised description for 95808 and 95810	**Home Sleep Apnea Testing** **Home Sleep Apnea Testing (HSAT), using a portable monitor, is medically necessary for evaluating adults with suspected OSA**. Where HSAT is indicated, an autotitrating Positive Airway Pressure (APAP) device is an option to determine a fixed PAP pressure. **Attended Full-Channel Nocturnal Polysomnography, Performed in a Healthcare Facility or Laboratory Setting** **Attended full-channel nocturnal polysomnography is medically necessary for evaluating individuals with suspected OSA when**: • Results of previous HSAT are negative, indeterminate or technically inadequate to make a diagnosis of OSA; **or** • Individual is a child or adolescent (i.e., less than 18 years of age); **or** • Individual is known to have one or more of the following comorbid medical conditions that prohibits the use of a HSAT: ○ Significant Chronic Pulmonary Disease as defined by a forced expiratory volume (FEV_1) % predicted of <60 (Pellegrino et al., 2005) ○ Progressive neuromuscular disease/neurodegenerative disorder (examples include, but are not limited to, Parkinson's disease, myotonic dystrophy, amyotrophic lateral sclerosis, multiple sclerosis with associated pulmonary disease, history of stroke with persistent neurological sequelae) ○ Moderate to severe heart failure (New York Heart Association class III or IV) ○ Body mass index (BMI) >50 (DeMaria et al., 2007; Blackstone and Cortés, 2010) ○ Obesity Hypoventilation Syndrome

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Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Apr. 1, 2019		○ Documented ongoing epileptic seizures in the presence of symptoms of sleep disorder Also, see the Repeat Testing section below. **Attended full-channel nocturnal polysomnography is medically necessary for evaluating sleep disorders other than OSA when following an appropriate clinical assessment:** • OSA has been excluded; **or** • OSA has been adequately treated; **or** • A secondary condition in addition to OSA is suspected; **and** • One or more of the following conditions is suspected: ○ Periodic Limb Movement Disorder (PLMD) (not leg movements associated with another disorder such as sleep disordered breathing) ○ Restless Legs Syndrome (RLS)/Willis-Ekbom Disease that has not responded to treatment ○ Parasomnia with documented disruptive, violent or potentially injurious sleep behavior suspicious of rapid eye movement sleep behavior disorder (RBD) ○ Narcolepsy, once other causes of excessive sleepiness have been ruled out by appropriate clinical assessment (also see the MSLT section below) ○ Central Sleep Apnea **The following studies are not medically necessary due to insufficient evidence of efficacy**: • Attended full-channel nocturnal polysomnography for evaluating **any** of the following conditions: ○ Circadian Rhythm Disorders ○ Depression ○ Insomnia • Actigraphy for any sleep disorders **Daytime Sleep Studies** **Multiple Sleep Latency Testing (MSLT) is medically necessary when it is indicated by all of the following**: • Suspected narcolepsy; **and** • Other causes of Excessive Sleepiness have been excluded by appropriate

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Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Apr. 1, 2019		clinical assessment For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC). **Maintenance of Wakefulness Testing (MWT) is medically necessary for evaluating the following**: • An individual who is unable to stay awake, resulting in a safety issue; **or** • Assessing response to treatment in individuals with Narcolepsy or idiopathic Hypersomnia For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC). **The following studies are not medically necessary due to insufficient evidence of efficacy**: • Multiple Sleep Latency Testing (MSLT) for evaluating OSA, Insomnia or circadian rhythm disorders • Maintenance of Wakefulness Testing (MWT) for evaluating OSA, Insomnia or circadian rhythm disorders • PAP-Nap **Attended PAP Titration** **When an individual meets the above criteria for an attended full-channel nocturnal polysomnography sleep study, the following are medically necessary**: • A split-night sleep study, performed in a healthcare facility or laboratory setting, for diagnosis and PAP titration • A full night study for PAP titration, when a split-night sleep study is inadequate or not feasible and the individual has a confirmed diagnosis of OSA Also, see the Repeat Testing section below. **Attended Repeat Testing** **Repeat attended full-channel nocturnal polysomnography, performed in a health care facility or laboratory setting, as well as repeat PAP**

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Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Apr. 1, 2019		**titration, is medically necessary for certain individuals who have persistent or new symptoms, despite documented appropriate current treatment or PAP therapy (e.g., equipment failure, improper mask fit, pressure leaks, inadequate pressure and medical problems including nasal congestion have been addressed and appropriately managed)**. Repeat testing and repositioning/adjustments for oral sleep appliances can be done in the home unless the individual meets criteria for an attended sleep study.
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Apr. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Revised and reformatted coverage rationale: ○ Simplified content ○ Replaced reference to "MCG™ Care Guidelines, *22nd* edition, *2018*" with "MCG™ Care Guidelines, *23rd* edition, *2019*" • Modified notation pertaining to the list of applicable ICD-10 diagnosis codes to clarify *procedure codes for continuous glucose monitoring (CGM) are* unproven and not medically necessary *when reported with the [listed] diagnosis codes* for type 2 diabetes or gestational diabetes • Updated supporting information to reflect the most current FDA information	**Insulin Delivery** **External insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for managing individuals with type 1 or insulin-requiring type 2 diabetes**. For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Insulin Infusion Pump ACG:A-0339 (AC). **Note**: Programmable disposable external insulin pumps (e.g., Omnipod) are considered clinically equivalent to standard insulin pumps. **Due to insufficient evidence of efficacy, the following devices are unproven and not medically necessary for managing individuals with diabetes**: • Implantable insulin pumps • Insulin infuser ports • Nonprogrammable transdermal insulin delivery systems (e.g., V-Go) **Continuous Glucose Monitoring (CGM)** **CGM is proven and medically necessary for managing individuals with diabetes in the following circumstances**: • Short-term use (3-7 days) by a healthcare provider for diagnostic purposes • Long-term use for personal use at home for managing individuals with type 1 diabetes who meet **all** of the following criteria: ○ Have demonstrated adherence to a physician ordered diabetic treatment plan; **and** ○ Are on an intensive insulin regimen (3 or more insulin injections per

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Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes *(continued)*	Apr. 1, 2019		day or insulin pump therapy) **Due to insufficient evidence of efficacy, the following services and/or devices are unproven and not medically necessary for managing individuals with diabetes**: • Long-term CGM for managing individuals with type 2 or gestational diabetes • CGM using an implantable glucose sensor (e.g., Eversense) • CGM using a noninvasive device
Elbow Replacement Surgery (Arthroplasty)	Apr. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* section • Revised coverage rationale: ○ Replaced reference to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"; refer to 23rd edition for complete details on applicable updates to the MCG™ Care Guidelines	**Elbow replacement surgery is proven and medically necessary in certain circumstances**. For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Elbow Arthroplasty, S-420 (ISC).
Electrical and Ultrasound Bone Growth Stimulators	Apr. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* section • Revised coverage rationale: ○ Replaced reference to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"; refer to 23rd edition for complete details on applicable updates to the MCG™ Care Guidelines	**Electrical and electromagnetic bone growth stimulators are proven and medically necessary in certain circumstances**. For medical necessity clinical coverage criteria, see the following MCG™ Care Guidelines, 23rd edition, 2019: • Bone Growth Stimulators, Electrical and Electromagnetic ACG: A-0565 (AC) • Bone Growth Stimulators, Ultrasonic ACG: A-0414 (AC)

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Epidural Steroid and Facet Injections for Spinal Pain	May 1, 2019	• Revised and reformatted coverage rationale: ○ Simplified content ○ Modified notation to clarify this policy: ▪ Addresses Epidural Steroid Injections (ESI) of the lumbar spine only ▪ Does not address Epidural Steroid Injections of the cervical or thoracic spine, nor does it address injections for obstetrical or surgical anesthetic ▪ Addresses Facet Joint Injections of multiple sites and is not limited to Facet Joint Injections of the lumbar spine ○ Replaced language indicating "ESI are proven and medically necessary for treating *acute and sub-acute sciatica or radicular pain of the low back* caused by spinal stenosis, disc herniation or degenerative changes in the vertebrae" with "ESI are proven and medically necessary for treating *lumbar radicular pain* caused by spinal stenosis, disc herniation or degenerative changes in the vertebrae" ○ Added language pertaining to ESI limitations to indicate: ▪ A maximum of three (3)	**Note**: This policy addresses Epidural Steroid Injections (ESI) of the lumbar spine only. The policy does not address Epidural Steroid Injections of the cervical or thoracic spine, nor does it address injections for obstetrical or surgical anesthetic. The policy addresses Facet Joint Injections of multiple sites and is not limited to Facet Joint Injections of the lumbar spine. **The following are proven and medically necessary**: • Epidural Steroid Injections (ESI) for treating lumbar radicular pain caused by spinal stenosis, disc herniation or degenerative changes in the vertebrae • ESI for the short-term management of low back pain when the following criteria are met: ○ The pain is associated with symptoms of nerve root irritation and/or low back pain due to disc extrusions and/or contained herniations; and ○ The pain is unresponsive to Conservative Treatment, including but not limited to pharmacotherapy, exercise or physical therapy • Diagnostic Facet Joint Injection (FJI) and/or facet nerve block (e.g., medial branch block) to localize the source of pain to the facet joint in persons with spinal pain **The following are unproven and not medically necessary due to insufficient evidence of efficacy**: • The use of ultrasound guidance for ESIs and FJIs • ESI for **all** other indications of the lumbar spine not included above • Therapeutic FJI for treating chronic spinal pain **Epidural Steroid Injection Limitations** • A maximum of three (3) ESI (regardless of level, location, or side) in a year will be considered medically necessary when criteria (indications for coverage) are met for each injection • A session is defined as one date of service in which ESI injection(s) are performed • A year is defined as the 12-month period starting from the date of service of the first approved injection

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Epidural Steroid and Facet Injections for Spinal Pain *(continued)*	May 1, 2019	ESI (regardless of level, location, or side) in a year will be considered medically necessary when criteria (indications for coverage) are met for each injection ▪ A session is defined as one date of service in which ESI injection(s) are performed ▪ A year is defined as the 12-month period starting from the date of service of the first approved injection • Added definition of: ○ Conservative Therapy ○ Epidural Steroid Injections (ESI) ○ Facet Joint Injections (FJIs) ○ Non-Radicular Back Pain ○ Radicular Back Pain ○ Radiculopathy • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	
Glaucoma Surgical Treatments	Apr. 1, 2019	• Revised and reformatted coverage rationale: ○ Simplified content ○ Replaced language indicating: ▪ "The iStent® Trabecular Micro-Bypass Stent System is proven and medically necessary when used in	**The following are proven and medically necessary**: • Glaucoma drainage devices for treating refractory glaucoma when medical or surgical treatments have failed or are inappropriate • iStent® Trabecular Micro-Bypass Stent System for treating mild to moderate open-angle glaucoma when used in combination with cataract surgery • Canaloplasty for treating primary open-angle glaucoma **The following are unproven and not medically necessary for treating any type of glaucoma due to insufficient evidence of efficacy and/or**

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Glaucoma Surgical Treatments *(continued)*	Apr. 1, 2019	combination with cataract surgery for treating mild to moderate open-angle glaucoma *and a cataract in adults currently being treated with ocular hypotensive medication*" with "the iStent® Trabecular Micro-Bypass Stent System is proven and medically necessary for treating mild to moderate open-angle glaucoma when used in combination with cataract surgery" ▪ "The CyPass® Micro-Stent System is unproven and not medically necessary *when used in combination with cataract surgery* for treating *mild-to-moderate primary open-angle* glaucoma *(POAG)*" with "the CyPass® Micro-Stent System is unproven and not medically necessary for treating *any type of* glaucoma" ▪ "The Xen® Glaucoma Treatment System is unproven and is not medically necessary for treating *refractory* glaucoma *when*	**safety**: • CyPass® Micro-Stent System • Xen® Glaucoma Treatment System • Hydrus® Microstent • Glaucoma drainage devices that are not FDA approved • Viscocanalostomy

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Glaucoma Surgical Treatments *(continued)*	Apr. 1, 2019	*conventional medical or surgical treatments have failed, or in patients with primary open-angle glaucoma, pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy*" with "the Xen® Glaucoma Treatment System is unproven and is not medically necessary for treating *any type of* glaucoma" ○ Added language to indicate the Hydrus® Microstent is unproven and not medically necessary for treating any type of glaucoma due to insufficient evidence of efficacy and/or safety • Updated list of applicable CPT codes; added 66170 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	
Hip Resurfacing and Replacement Surgery (Arthroplasty)	Apr. 1, 2019	• Revised coverage rationale: ○ Replaced references to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"; refer to 23rd edition for complete details	**Hip Replacement Surgery (Arthroplasty)** **Hip replacement surgery (arthroplasty) is proven and medically necessary in certain circumstances**. For medical necessity clinical coverage criteria, see the following MCG™ Care Guidelines, 23rd edition, 2019: • Hip Arthroplasty, S-560 (ISC) • Hip: Displaced Fracture of Femoral Neck, Hemiarthroplasty, S-600 (ISC)

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Hip Resurfacing and Replacement Surgery (Arthroplasty) *(continued)*	Apr. 1, 2019	on applicable updates to the MCG™ Care Guidelines • Updated list of applicable CPT codes; removed 27299 • Updated supporting information to reflect the most current FDA and CMS information	**Hip Resurfacing Arthroplasty** **Hip resurfacing is proven and medically necessary in certain circumstances**. For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Hip Resurfacing, S-565 (ISC).
Hysterectomy for Benign Conditions	Apr. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* section • Revised coverage rationale: ○ Replaced reference to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"; refer to 23rd edition for complete details on applicable updates to the MCG™ Care Guidelines	**Hysterectomy is proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, see the following MCG™ Care Guidelines, 23rd edition, 2019: • Hysterectomy, Abdominal, ORG: S-650 (ISC) • Hysterectomy, Vaginal, ORG: S-660 (ISC) • Hysterectomy, Laparoscopic, ORG: S-665 (ISC)
Implanted Electrical Stimulator for Spinal Cord	Apr. 1, 2019	• Revised coverage rationale: ○ Replaced reference to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"; refer to 23rd edition for complete details on applicable updates to the MCG™ Care Guidelines • Updated list of applicable HCPCS codes; added C1823	**Implanted electrical stimulators for spinal cord, including high-frequency dorsal column stimulators (also known as BurstDR spinal cord stimulators), are proven and medically necessary**. For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Implanted Electrical Stimulator, Spinal Cord ACG: A-0243 (AC). **Note**: • Coverage of a replacement battery/generator for a previously implanted electrical stimulator is appropriate when the individual's existing battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty. • For Dorsal Root Ganglion (DRG) stimulation, please refer to the Medical Policy titled Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation.

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Knee Replacement Surgery (Arthroplasty), Total and Partial	Apr. 1, 2019	• Changed policy title; previously titled *Total Knee Replacement Surgery (Arthroplasty)* • Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* section • Revised coverage rationale: ○ Replaced reference to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"; refer to 23rd edition for complete details on applicable updates to the MCG™ Care Guidelines • Updated supporting information to reflect the most current CMS information	**Knee replacement surgery (arthroplasty) is proven and medically necessary in certain circumstances**. For medical necessity clinical coverage criteria, see the following MCG™ Care Guidelines, 23rd edition, 2019: • For Total Knee Arthroplasty: Knee Arthroplasty, Total, S-700 (ISC) • For Unicompartmental Knee Arthroplasty: Musculoskeletal Surgery or Procedure GRG: SG-MS (ISC GRG)
Obstructive Sleep Apnea Treatment	Apr. 1, 2019	• Revised and reformatted coverage rationale: ○ Simplified content ○ Replaced references to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"	**Nonsurgical Treatment** **Removable oral appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) as documented by a sleep study (e.g., polysomnography or Home Sleep Apnea Testing)**. Refer to the Medical Policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information. For many individuals, oral appliance therapy (OAT) may be an effective alternative to failed continuous positive airway pressure (CPAP) therapy. Documentation of the following is required: • A patient presenting with symptoms of OSA be seen in a face-to-face evaluation with a qualified physician (MD or DO) trained in sleep medicine prior to beginning treatment for OAT (AASM and AADSM, December 2012) • A treating physician (MD or DO) must diagnose OSA and recommend course of treatment • If the patient refuses CPAP therapy, documentation of the refusal from the patient's treating physician (MD or DO) must be supplied

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Obstructive Sleep Apnea Treatment *(continued)*	Apr. 1, 2019		For information on snoring and oral appliances, see the Coverage Determination Guideline titled Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements. For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Oral Appliances (Mandibular Advancement Devices), A-0341 (ACG). **The following are unproven and not medically necessary due to insufficient evidence of efficacy**: • Removable oral appliances for treating central sleep Apnea • Nasal dilator devices for treating Obstructive Sleep Apnea (OSA) **Surgical Treatment** **The following surgical procedures are proven and medically necessary for treating Obstructive Sleep Apnea as documented by polysomnography**. For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019. • Uvulopalatopharyngoplasty (UPPP): Uvulopalatopharyngoplasty (UPPP), A-0245 (ACG) • Maxillomandibular Advancement Surgery (MMA): Maxillomandibular Osteotomy and Advancement, A-0248 (ACG); Also, see the Coverage Determination Guideline titled Orthognathic (Jaw) Surgery • Multilevel Procedures Whether Done in a Single Surgery or Phased Multiple Surgeries: Mandibular Osteotomy, A-0247 (ACG) **The following surgical procedures are unproven and not medically necessary for treating Obstructive Sleep Apnea due to insufficient evidence of efficacy**: • Laser-assisted uvulopalatoplasty (LAUP) • Palatal implants • Lingual suspension - Also referred to as tongue stabilization, tongue stitch or tongue fixation • Transoral robotic surgery (TORS) • Implantable hypoglossal nerve stimulation • Radiofrequency ablation of the soft palate and/or tongue base

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Pneumatic Compression Devices	Apr. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* section • Revised coverage rationale; replaced reference to "MCG™ Care Guidelines, *22nd* edition, *2018*" with "MCG™ Care Guidelines, *23rd* edition, *2019*"	**Pneumatic compression devices are proven and medically necessary in certain circumstances**. For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Intermittent Pneumatic Compression with Extremity Pump ACG: ACG: A-0340 (AC). Refer to the *Applicable Codes* section of the policy for more information regarding the review of HCPCS code E0652 (pneumatic compressor, segmental home model with calibrated gradient pressure).
Shoulder Replacement Surgery (Arthroplasty)	Apr. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* section • Revised coverage rationale: ○ Replaced reference to "MCG™ Care Guidelines, *22nd* edition, *2018*" with "MCG™ Care Guidelines, *23rd* edition, *2019*"; refer to 23rd edition for complete details on applicable updates to the MCG™ Care Guidelines	**Shoulder replacement surgery is proven and medically necessary in certain circumstances**. For medical necessity clinical coverage criteria, see the following MCG™ Care Guidelines, 23rd edition, 2019: • Shoulder Arthroplasty, S-634 (ISC) • Shoulder Hemiarthroplasty, S-633 (ISC)
Surgical Treatment for Spine Pain	Apr. 1, 2019	• Revised coverage rationale and supporting information: ○ Replaced references to "MCG™ Care Guidelines, *22nd* edition, *2018*" with "MCG™ Care Guidelines, *23rd* edition, *2019*"; refer to 23rd edition for complete details on applicable updates to the MCG™ Care Guidelines	**The following spinal procedures are proven and medically necessary**: • Spinal fusion using extreme lateral interbody fusion (XLIF®) • Direct lateral interbody fusion (DLIF) For the following spinal procedures, refer to MCG™ Care Guidelines, 23rd edition: • Cervical Diskectomy or Microdiskectomy, Foraminotomy, Laminotomy, S-310 (ISC) • Lumbar Diskectomy, Foraminotomy, or Laminotomy S-810 (ISC) • Cervical Laminectomy S-340 (ISC) • Lumbar Laminectomy S-830 (ISC) • Cervical Fusion, Anterior S-320 (ISC) • Cervical Fusion, Posterior S-330 (ISC) Lumbar Fusion S-820 (ISC)

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Surgical Treatment for Spine Pain *(continued)*	Apr. 1, 2019		**The following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy (this includes procedures that utilize interbody cages, screws, and pedicle screw fixation devices*)**:
			• Laparoscopic anterior lumbar interbody fusion (LALIF)*
			• Transforaminal lumbar interbody fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization)*
			• Axial lumbar interbody fusion (AxiaLIF®)*
			• Interlaminar lumbar instrumented fusion (ILIF) (e.g., Coflex-F®)*
			• Spinal decompression and interspinous process decompression systems for the treatment of lumbar spinal stenosis (e.g., Interspinous process decompression (IPD), Minimally invasive lumbar decompression (MILD))
			• Spinal stabilization systems
			  ○ Stabilization systems for the treatment of degenerative spondylolisthesis
			  ○ Total facet joint arthroplasty, including facetectomy, laminectomy, foraminotomy, vertebral column fixation
			  ○ Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement for the treatment of back pain
			• Stand-alone facet fusion without an accompanying decompressive procedure:
			  ○ This includes procedures performed with or without bone grafting and/or the use of posterior intrafacet implants such as fixation systems, facet screw systems or anti-migration dowels

Temporo-mandibular Joint Disorders	Apr. 1, 2019	• Revised coverage rationale; replaced reference to "MCG™ Care Guidelines, *22nd* edition" with "MCG™ Care Guidelines, *23rd* edition"	**The following services are proven and medically necessary for treating disorders of the temporomandibular joint (TMJ)**: • Arthrocentesis • Injections of corticosteroids for rheumatoid arthritis related disorders • Trigger point injections • Physical therapy • Occlusal splints (stabilization and repositioning splints) • Sodium Hyaluronate for disc displacement and osteoarthritis • Partial or total joint replacement when other treatments have failed For medical necessity clinical coverage criteria for the following services, refer to MCG™ Care Guidelines, 23rd edition, 2019: • Arthroplasty-Temporomandibular Joint Arthroplasty, ACG: A-0523 (AC)

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Temporo-mandibular Joint Disorders *(continued)*	Apr. 1, 2019		• Arthroscopy-Temporomandibular Joint Arthroscopy, ACG: A-0492 (AC) • Arthrotomy- Temporomandibular Joint Arthrotomy, ACG: A-0522 (AC);Temporomandibular Joint Modified Condylotomy, ACG: A-0521 (AC) **The following services are unproven and not medically necessary for treating disorders of the temporomandibular joint (TMJ) due to insufficient evidence of efficacy**: • Biofeedback • Craniosacral manipulation • Passive rehabilitation therapy • Low-load prolonged-duration stretch (LLPS) devices
Vagus Nerve Stimulation	May 1, 2019	• Revised coverage rationale: ○ Updated list of unproven and not medically necessary indications; replaced "transcutaneous (non-implantable) vagus nerve stimulation for treating all indications" with "transcutaneous (non-implantable) vagus nerve stimulation *(e.g., gammaCore® for headaches)* for *preventing or* treating all indications" • Updated supporting information to reflect the most current FDA information and references	**Implantable vagus nerve stimulators are proven and medically necessary for treating epilepsy in individuals with ALL of the following** (see below for implants that allow detection and stimulation of increased heart rate): • Medically refractory epileptic seizures with failure of two or more trials of single or combination antiepileptic drug therapy or intolerable side effects of antiepileptic drug therapy; and • The individual is not a surgical candidate or has failed a surgical intervention; and • No history of left or bilateral cervical vagotomy. The U.S. Food and Drug Administration (FDA) identifies a history of left or bilateral cervical vagotomy as a contraindication to vagus nerve stimulation **Implantable vagus nerve stimulators are unproven and not medically necessary for treating ALL other conditions due to insufficient evidence of efficacy**. These conditions include but are not limited to: • Alzheimer's disease • Anxiety disorder • Autism spectrum disorder • Back and neck pain • Bipolar disorder • Bulimia • Cerebral palsy • Chronic pain syndrome • Cluster headaches • Depression

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Vagus Nerve Stimulation *(continued)*	May 1, 2019		• Fibromyalgia • Heart failure • Migraines • Morbid obesity • Narcolepsy • Obsessive-compulsive disorder • Paralysis agitans • Sleep disorders • Tourette's syndrome **The following are unproven and not medically necessary due to insufficient evidence of efficacy**: • Vagus nerve stimulation implants that allow detection and stimulation of increased heart rate (e.g., AspireSR™ Model 106) for treating epilepsy • Transcutaneous (nonimplantable) vagus nerve stimulation (e.g., gammaCore® for headaches) for preventing or treating all indications **Note**: For vagus nerve blocking for the treatment of obesity, refer to the Medical Policy titled Bariatric Surgery.

Medical Benefit Drug Policy Updates

TAKE NOTE

Medical Benefit Drug Policy Template Update

Effective Mar. 1, 2019, the UnitedHealthcare Commercial Medical Benefit Drug Policies were transferred to a more streamlined template; changes include:

- Simplification and relocation of the *Instructions for Use*
- Removal or simplification and relocation of the *Benefits Considerations* section

Policy guidelines have not been modified in any way as a result of this template update.

Policy Title	Effective Date	Summary of Changes
UPDATED		
Buprenorphine (Probuphine® & Sublocade™)	Mar. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Updated coverage rationale: ○ Clarified medical necessity criteria for continuation of therapy with buprenorphine extended-release injection (e.g., Sublocade) for the treatment of moderate to severe opioid use disorder; replaced criterion requiring "physician documentation that the patient has experienced a positive clinical response to buprenorphine extended-release therapy" with "physician documentation that the patient has experienced a positive clinical response to buprenorphine extended-release therapy, *as defined by the provider*"
Exondys 51® (Eteplirsen)	Mar. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or lists of applicable codes

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Complement Inhibitors (Soliris® & Ultomiris™)	Mar. 1, 2019	• Changed policy title; previously titled *Soliris® (Eculizumab)* • Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Updated list of related policies; added reference link to the policy titled *Review at Launch for New to Market Medications* • Revised coverage rationale: ○ Updated list of applicable complement inhibitor drug products; added Ultomiris (ravulizumab-cwvz) ○ Added language to indicate:	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:

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Complement Inhibitors (Soliris® & Ultomiris™) *(continued)*	Mar. 1, 2019	▪ Ultomiris (ravulizumab-cwvz) has been added to the Review at Launch program and 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 ▪ Ultomiris is proven for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) and medically necessary when all of the [listed] criteria are met ○ Updated medical necessity criteria for therapy with Soliris and Ultomiris for treatment of PNH; replaced criterion requiring "[the complement inhibitor drug product] is *initiated and titrated* according to the US Food and Drug Administration (FDA) labeled dosing for PNH, *up to a maximum of 900 mg every 2 weeks*" with "[the complement inhibitor drug product] is *dosed* according to the US FDA labeled dosing for PNH" • Updated list of applicable HCPCS codes; added J3590 • Updated supporting information	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; **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 with at least **one** of the following criteria: a. At least 10% PNH type III red cells; b. Greater than 50 % of glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient poly-morphonuclear cells (PMNs); **and** 2. **One** of the following: a. Patient is transfusion dependent as defined as **one** of the following: i. Hemoglobin ≤ 7 g/dL;

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Complement Inhibitors (Soliris® & Ultomiris™) *(continued)*	Mar. 1, 2019	to reflect the most current background information, clinical evidence, FDA and CMS information, and references	i. **Both** of the following: 1) Hemoglobin ≤ 9 g/dL 2) Patient is experiencing symptoms of anemia **or** b. Patient has a documented history of major adverse vascular events from thromboembolism; **and** 3. Soliris or Ultomiris aredosed according to the US FDA labeled dosing for PNH,; **and** 4. Prescribed by or in consultation with a hematologist; **and** 5. 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., increased or stabilization of hemoglobin levels, reduction in transfusions, 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; **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

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Complement Inhibitors (Soliris® & Ultomiris™) *(continued)*	Mar. 1, 2019		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 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

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Complement Inhibitors (Soliris® & Ultomiris™) *(continued)*	Mar. 1, 2019		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.
Gonadotropin Releasing Hormone Analogs	Mar. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Revised coverage rationale; **Gender Dysphoria in Adolescents** ○ Updated coverage criteria for initial therapy; replaced criterion requiring "medication is prescribed by or in consultation with a *pediatric* endocrinologist or *by a physician working in a multidisciplinary clinic for transgender youth*" with "medication is prescribed by or in consultation with an *endocrinologist* or *a medical provider experienced in gender dysphoria hormone therapy*" ○ Updated coverage criteria for continuation of therapy; replaced criterion requiring "documentation of LH suppression *using a GnRH stimulation test*" with "documentation *(within the last 6 months)* of LH suppression *assessing for*	Refer to the policy titled *Oncology Medication Clinical Coverage* for updated information based on the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications. This policy refers to the following gonadotropin releasing hormone analog (GnRH analog) drug products: • Firmagon (degarelix) • Lupaneta Pack (leuprolide acetate injection & norethindrone acetate tablets) • Lupron Depot (leuprolide acetate) • Lupron Depot-Ped (leuprolide acetate) • Supprelin LA (histrelin acetate) • Trelstar (triptorelin pamoate) • Triptodur (triptorelin) • Vantas (histrelin acetate) • Zoladex (goserelin acetate) Refer to the policy for complete details on the coverage guidelines for Gonadotropin Releasing Hormone Analogs.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Gonadotropin Releasing Hormone Analogs *(continued)*	Mar. 1, 2019	*appropriate suppression or a change in dosing"* **Adjunct for Gender-Affirming Hormonal Therapy for Transgender Adults** ○ Updated coverage criteria for initial therapy: ▪ Replaced criterion requiring "medication is prescribed by or in consultation with an endocrinologist or a medical provider *knowledgeable* in transgender hormone therapy" with "medication is prescribed by or in consultation with an endocrinologist or a medical provider *experienced* in transgender hormone therapy" ▪ Added criterion requiring "inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, LH, or gonadotropins (e.g., menses, testosterone)" ▪ Removed criterion requiring one of the following: - Hormonal and/or anti-hormone (e.g., anti-androgen) therapy is not sufficient to suppress and/or overcome	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Gonadotropin Releasing Hormone Analogs *(continued)*	Mar. 1, 2019	natal secondary sex characteristics or gonadotropins (e.g., menses, testosterone); or - History of failure, contraindication, or intolerance to hormonal and/or antihormonal therapy at the required strengths for suppression due to increased risk of comorbid disease (e.g., thromboembolism, liver dysfunction, cardiovascular disease, type 2 diabetes, etc.) ○ Updated coverage criteria for continuation of therapy; added criterion requiring "documentation (within the last 6 months) of LH suppression assessing for appropriate suppression or a change in dosing"	
Ilumya™ (Tildrakizumab-Asmn)	Mar. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Revised coverage rationale: ○ Modified list of preferred biologic products to which the patient must demonstrate treatment	Ilumya, for subcutaneous injection, is obtained under the pharmacy benefit when self-administered, and is indicated in the treatment of plaque psoriasis. **Initial Therapy** **Ilumya (tildrakizumab) is proven for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met:** **I.** Diagnosis of moderate to severe plaque psoriasis; **and** **II.** Physician attestation that the patient is unable to self-administer or there

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ilumya™ (Tildrakizumab-Asmn) *(continued)*	Mar. 1, 2019	failure, contraindication, or intolerance; added Cimzia (certolizumab)	is no competent caregiver to administer the drug. Physician must submit explanation; **and** **III.** Patient is not receiving Ilumya in combination with **any** of the following: A. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] B. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] C. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] **and** **IV.** Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** **V.** Initial authorization will be for no longer than 12 months. **Ilumya (tildrakizumab) is medically necessary for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met:** **I. Submission of medical records** (e.g., chart notes, laboratory values) documenting **all** of the following: A. Diagnosis of chronic moderate to severe plaque psoriasis; **and** B. Greater than or equal to 5 % body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; **and** C. **Both** of the following: 1. History of failure, contraindication, or intolerance to **one** of the following topical therapies: a. Corticosteroids (e.g., betamethasone, clobetasol, desonide) b. Vitamin D analogs (e.g., calcitriol, calcipotriene) c. Tazarotene d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) e. Anthralin f. Coal tar **and** 2. History of contraindication, intolerance, or failure of a 3 month trial of methotrexate; **and** D. History of failure, contraindication, or intolerance to **two** of the following preferred biologic products: 1. Humira (adalimumab) 2. Stelara (ustekinumab) 3. Tremfya (guselkumab) 4. Cimzia (certolizumab)

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ilumya™ (Tildrakizumab-Asmn) *(continued)*	Mar. 1, 2019		**and** E. **One** of the following: 1. History of a 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity **or** 2. **Both** of the following: a. History of intolerance or adverse event to Cosentyx b. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Ilumya **and** F. Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug. Physician must submit explanation; **and** G. Patient is not receiving Ilumya in combination with **any** of the following: 1. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)] 2. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] 3. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] **and** H. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** I. Initial authorization will be for no longer than 12 months. **Continuation Therapy** **Ilumya (tildrakizumab) will be reauthorized for provider administration based on all of the following criteria:** **I.** Documentation of positive clinical response to Ilumya therapy; **and** **II.** Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug. Physician must submit explanation; **and** **III.** Patient is not receiving Ilumya in combination with **any** of the following: A. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] B. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] C. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] **and**

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ilumya™ (Tildrakizumab-Asmn) *(continued)*	Mar. 1, 2019		**IV.** Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** **V.** Reauthorization will be for no longer than 12 months.
Immune Globulin (IVIG and SCIG)	Mar. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Revised coverage rationale: ○ Removed language indicating immune globulin is unproven and not medically necessary for: ▪ Autoimmune hemolytic anemia ▪ Neonatal sepsis, treatment ▪ Systemic lupus erythematosus **Chronic Inflammatory Demyelinating Polyneuropathy** ○ Updated medical necessity criteria for initial therapy; modified criterion requiring electrodiagnostic findings (consistent with EFNS/PNS guidelines for definite CIDP) to indicate at least **one** of the following must be present: ▪ Motor distal latency prolongation in 2 nerves ▪ Reduction of motor conduction velocity in 2 nerves ▪ Prolongation of F-wave latency in 2 nerves	This policy refers to the following intravenous (IV) and subcutaneous (SC) immune globulin (IG) products (List not all inclusive): • Bivigam™ (IV) • Carimune® NF (IV) • Cuvitru™ (SC) • Flebogamma® DIF (IV) • Gammagard® Liquid (IV, SC) • Gammagard® S/D (IV) • Gammaked™ (IV, SC) • Gammaplex® (IV) • Gamunex®-C (IV, SC) • Hizentra® (SC) • HyQvia® (SC) • Octagam® (IV) • Panzyga® (IV) • Privigen® (IV) In absence of a product listed, and in addition to applicable criteria outlined within the drug policy, prescribing and dosing information from the package insert is the clinical information used to determine benefit coverage. **Diagnoses Addressed in this Policy** • Asthma (severe, persistent, high-dose steroid-dependent) • Autoimmune bullous diseases • Autoimmune uveitis • Bone marrow transplantation (BMT) • Chronic inflammatory demyelinating polyneuropathy • Chronic lymphocytic leukemia (CLL), prevention of infection in B-cell CLL • Cytomegalovirus (CMV) induced pneumonitis in solid organ transplants • Dermatomyositis or polymyositis • Diabetes mellitus • Enteroviral meningoencephalitis • Feto-neonatal alloimmune thrombocytopenia • Graves' ophthalmopathy

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Immune Globulin (IVIG and SCIG) *(continued)*	Mar. 1, 2019	▪ Absence of F-waves in at least 1 nerve ▪ Partial motor conduction block of at least 1 motor nerve ▪ Abnormal temporal dispersion in at least 2 nerves ▪ Distal CMAP duration increase in at least 1 nerve **Multiple Sclerosis, Relapsing Forms** ○ Replaced reference to "relapsing *remitting* forms of multiple sclerosis" with "relapsing forms of multiple sclerosis" **Myasthenia Gravis** ○ Replaced notation indicating "evidence does not support the use of immune globulin maintenance therapy for *generalized myasthenia gravis or* for ocular myasthenia" with "evidence does not support the use of immune globulin maintenance therapy for ocular myasthenia" ○ Added language to indicate immune globulin is proven for refractory myasthenia gravis; immune globulin is medically necessary for the treatment of refractory myasthenia gravis when **all** of the following criteria are met:	• Guillain-Barré syndrome (GBS) • HIV-infection, prevention of bacterial infection in pediatric HIV • Immune thrombocytopenia • IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy • Kawasaki disease • Lambert-Eaton myasthenic syndrome (LEMS) • Lennox Gastaut syndrome • Lymphoproliferative disease, treatment of bacterial infections • Monoclonal gammopathy • Multifocal motor neuropathy (MMN) • Multiple sclerosis, relapsing forms • Myasthenia gravis • Neuromyeltis optica • Paraproteinemic neuropathy • Posttransfusion purpura • Post B-cell targeted therapies • Primary immunodeficiency syndromes • Rasmussen syndrome • Renal transplantation, prevention of acute humoral rejection • Rheumatoid arthritis, severe • Rotaviral enterocolitis • Staphylococcal toxic shock • Stiff-person syndrome • Thrombocytopenia, secondary to HCV, HIV, or pregnancy • Toxic epidermal necrolysis or Stevens-Johnson syndrome • Urticaria, delayed pressure • Unproven indications Refer to the policy for complete details on the coverage guidelines for Immune Globulin (IVIG and SCIG).

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Immune Globulin (IVIG and SCIG) *(continued)*	Mar. 1, 2019	▪ Diagnosis of refractory generalized myasthenia gravis by or in consultation with a physician or center with expertise in management of myasthenia gravis; and ▪ Documentation that the disease status is unchanged or worsening (persistent or worsening symptoms that limit functioning) despite failure, contraindication, or intolerance to **both** of the following (used in adequate doses and duration): - Corticosteroids; and - **Two** immunomodulator therapies (e.g., azathioprine, mycophenolate mofetil, cyclosporine, methotrexate, tacrolimus) and ▪ Currently receiving immunomodulator therapy (e.g., corticosteroids, azathioprine, mycophenolate mofetil, cyclosporine, methotrexate, tacrolimus), used in adequate doses, for	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Immune Globulin (IVIG and SCIG) *(continued)*	Mar. 1, 2019	long-term management of myasthenia gravis; and ▪ IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 days; dosing interval may need to be adjusted in patients with severe comorbidities **Primary Immunodeficiency Syndromes** ○ Updated medical necessity criteria; replaced criterion requiring "initial IVIG dose is *300 to 600* mg/kg every 3 to 4 weeks and titrated based upon patient response" with "initial IVIG dose is *200 to 800* mg/kg every 3 to 4 weeks, *based on product prescribing information*, and titrated based upon patient response" **Stiff-Person Syndrome** ○ Updated medical necessity criteria; removed criterion requiring history of failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) • Updated list of applicable ICD-10 diagnosis codes; added G70.00 • Updated supporting information to reflect the most current clinical evidence and references	

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		

Breast Reduction Surgery	Apr. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section
		• Updated and reformatted coverage rationale:
		  ○ Simplified content
		  ○ Added language to clarify most UnitedHealthcare plans have a specific exclusion for breast reduction surgery except as required by the Women's Health and Cancer Rights Act of 1998; refer to the *Coverage Limitations and Exclusions* section of the policy
		• Updated definitions:
		  ○ Added definition of "Women's Health and Cancer Rights Act of 1998, §713(a)"
		  ○ Removed definition of "Congenital Anomaly (California only)"
		  ○ Modified definition of:
		  ▪ Cosmetic Procedures
		  ▪ Cosmetic Procedures (California only)
		  ▪ Reconstructive Procedures (California only)
		• Updated supporting information to reflect the most current references

Emergency Health Care Services and Urgent Care Center Services	Apr. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated list of related policies; added reference link to the Reimbursement Policy titled *Urgent Care Policy, Professional*
		• Updated coverage rationale; replaced references to "patient(s)" with "member(s)"
		• Updated list of applicable HCPCS codes for urgent care; added language to indicate [the listed] codes many not be payable due to the Reimbursement Policy titled *Urgent Care Policy, Professional*

Panniculectomy and Body Contouring Procedures	Apr. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated coverage rationale; replaced reference to "patients" with "members"
		• Updated definitions:
		  ○ Removed definition of "Congenital Anomaly (California only)"
		  ○ Modified definition of:
		  ▪ Cosmetic Procedures (California only)
		  ▪ Reconstructive Procedures (California only)
		• Updated list of applicable CPT codes; added language to clarify:
		  ○ 15830, 15847, and 15877 may be cosmetic; review is required to determine if [the service is] considered cosmetic or reconstructive
		  ○ 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, 15876, 15878, and 15879 are considered cosmetic; the codes do not improve a functional, physical or physiological impairment
		• Updated supporting information; replaced reference to "MCG™ Care Guidelines, *22nd* edition, *2018*" with "MCG™ Care Guidelines, *23rd* edition, *2019*"

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		

Rhinoplasty and Other Nasal Surgeries	Apr. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated definitions:
		  ○ Removed definition of "Congenital Anomaly (California only)"
		  ○ Modified definition of:
		  ▪ Cosmetic Procedures (California only)
		  ▪ Reconstructive Procedures (California only)
		• Updated list of applicable CPT codes; added notation to clarify the listed codes may be cosmetic and review is required to determine if [the services] are considered cosmetic or reconstructive
		• Updated supporting information; replaced reference to "MCG™ Care Guidelines, *22nd* edition, *2018*" with "MCG™ Care Guidelines, *23rd* edition, *2019*"

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair	Apr. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Revised coverage rationale:
		  ○ Replaced references to:
		  ▪ "Patient(s)" with "member(s)"
		  ▪ "Visual Field testing" with "*Reliable* Visual Field testing"
		  ○ Replaced criterion for upper eyelid blepharoplasty, upper eyelid blepharoptosis, and brow ptosis requiring "automated peripheral or superior Visual Field testing [with appropriate taping] showing improvement of 30% or more" with "automated peripheral or superior *Reliable* Visual Field
			Indications for Coverage
			Some states require benefit coverage for services that UnitedHealthcare considers Cosmetic Procedures, such as repair of external Congenital Anomalies in the absence of a Functional Impairment. Please refer to the member specific benefit plan document.
			
			Criteria for a Coverage Determination that Surgery is Reconstructive and Medically Necessary
			The following must be available when requested by UnitedHealthcare:
			• Best corrected visual acuity in both eyes, all members (except pediatrics)
			• Eye exam (chief complaint, HPI)
			• Clear, high-quality, clinical photographs (eye level, frontal with the member looking straight ahead, light reflex visible and centered)
			• Peripheral or superior Visual Fields automated, reliable (refer to the *Definitions* section of the policy), un-taped/taped are preferable. Note the following:
			  ○ In situations where computerized Reliable Visual Field testing is not available, we will accept manual Reliable Visual Field testing.
			  ○ In situations where Reliable Visual Field testing is not possible, see section below: "When the Member is Not Capable of Reliable Visual Field Testing."
			
			Note: The Visual Fields and high-quality, clinical photographs must be

Coverage Determination Guideline (CDG) Updates

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Apr. 1, 2019	testing [with appropriate taping] showing improvement of 30% *(or 12 degrees)* or more" ○ Added language to indicate brow ptosis repair (CPT 67900) as an adjunct to upper eyelid blepharoplasty (CPT 15822 and 15823) is considered reconstructive and medically necessary when: ▪ The criteria for each separate service are met, and ▪ Automated peripheral and superior Reliable Visual Field testing demonstrates differential taping showing: - 30% (or 12 degrees) or more improvement in total number of points seen with the eyelid taped up, and - An additional 30% (or 12 degrees) or more improvement in total number of points seen with the eyelid + eyebrow taped up, confirming the contribution of brow ptosis to visual field obstruction ○ Removed language identifying symptoms as "patient complaints"	consistent. If multiple procedures are requested, the following criteria must be met: • All criteria for each individual procedure must be met; and • Reliable Visual Field testing shows visual impairment which can't be addressed by one procedure alone; and • High-quality, clinical photograph findings are consistent with Visual Field findings. **Upper eyelid blepharoplasty (CPT 15822 and 15823) is considered reconstructive and medically necessary when the following criteria are present**: • Ptosis has been ruled out as the primary cause of Visual Field obstruction; and • Clear, high-quality, clinical photographs must show that the extra skin is the primary cause of Visual Field obstruction; and • The member must have a Functional or Physical Impairment complaint directly related to an abnormality of the eyelid(s); and • Excess skin (dermatochalasis/blepharochalasis) touches the lashes; and • Automated peripheral or superior Reliable Visual Field testing, with the eyelid skin taped and un-taped, showing improvement of 30% (or 12 degrees) or more. ○ In situations where computerized Reliable Visual Field testing is not available, we will accept manual Reliable Visual Field testing. ○ In situations where Reliable Visual Field testing is not possible, see section below: "When the Member is Not Capable of Reliable Visual Field Testing." **Note**: Extended blepharoplasty may be indicated for blepharospasm (eyelids are forced shut) when the following two criteria are met: • Debilitating symptoms (e.g., pain); and • Conservative treatment has been tried and failed, or is contraindicated (e.g., Botox®). **Upper eyelid blepharoptosis repair (CPT 67901–67909) is considered reconstructive and medically necessary when the following criteria are present**: • The member must have a Functional or Physical Impairment complaint directly related to the position of the eyelid(s); and • Other treatable causes of ptosis are ruled out (e.g., recent Botox®

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Apr. 1, 2019	• Updated definitions:
		  ○ Removed definition of "Congenital Anomaly (California only)"
		  ○ Modified definition of:
		  ▪ Cosmetic Procedures (California only)
		  ▪ Functional or Physical or Physiological Impairment
		  ▪ Reconstructive Procedures (California only)
		  ▪ Reliable (Visual Fields)
		• Updated list of applicable procedure codes; added language to indicate the [listed] codes may be cosmetic and review is required to determine if considered cosmetic or reconstructive
		• Updated supporting information; replaced reference to "MCG™ Care Guidelines, *22nd* edition, *2018*" with "MCG™ Care Guidelines, *23rd* edition, *2019*"
			injections, myasthenia gravis when applicable); and
			• Eyelid droop (upper eyelid ptosis) and a Marginal Reflex Distance -1 (MRD-1) of 2.0 mm or less; and
			• The MRD is documented in clear, high-quality, clinical photographs with the member looking straight ahead and light reflex centered on the pupil; and
			• Automated peripheral or superior Reliable Visual Field testing, with the eyelids taped and un-taped, showing improvement of 30% (or 12 degrees) or more improvement in the number of points seen.
			  ○ In situations where computerized Reliable Visual Field testing is not available, we will accept manual Reliable Visual Field testing.
			  ○ In situations where Reliable Visual Field testing is not possible, see section below: "When the Member is Not Capable of Reliable Visual Field Testing."
			
			Note: For children under age 10 years, ptosis repair is covered to prevent amblyopia. Reliable Visual Field testing is not required, but high-quality, clinical photographs are required.
			
			Brow ptosis (CPT 67900) is considered reconstructive and medically necessary when the following criteria are present:
			• Other causes have been eliminated as the primary cause for the Visual Field obstruction (e.g., Botox® treatments within the past six (6) months); and
			• The member must have a functional complaint related to brow ptosis. Brow ptosis must be documented in two high-quality, clinical photographs. One showing the eyebrow below the bony superior orbital rim, and a second photograph with the brow elevated that eliminates the Visual Field defect; and
			  ○ Automated peripheral and superior Reliable Visual Field testing, with differential taping (eyebrow and eyebrow + eyelid) showing 30% (or 12 degrees) or more improvement in total number of points seen with the eyebrow taped up. In situations where computerized Reliable Visual Field testing is not available, we will accept manual Reliable Visual Field testing.
			  ○ In situations where Reliable Visual Field testing is not possible, see section below: "When the Member is Not Capable of Reliable Visual Field Testing."
			• Documentation indicating the specific brow lift procedure (e.g., supra-

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Apr. 1, 2019		ciliary, mid forehead or coronal, pretrichial, direct brow lift vs browpexy, internal brow lift).
			
			Brow ptosis repair (CPT 67900) as an adjunct to upper eyelid blepharoplasty (CPT 15822 and 15823) is considered reconstructive and medically necessary when the criteria for each separate service are met (as per above) AND:
			• Automated peripheral and superior Reliable Visual Field testing demonstrates the following:
			  ○ Differential taping showing 30% (or 12 degrees) or more improvement in total number of points seen with the eyelid taped up and an additional 30% (or 12 degrees) or more improvement in total number of points seen with the eyelid + eyebrow taped up, confirming the contribution of brow ptosis to visual field obstruction.
			
			Note: For Browpexy/internal brow lift, see Coverage Limitations and Exclusions.
			
			Eyelid surgery with an anophthalmic socket (has no eyeball) is considered reconstructive and medically necessary when both of the following criteria are present:
			• The member has an anophthalmic condition; and
			• The member is experiencing difficulties fitting or wearing an ocular prosthesis.
			
			Lower eyelid blepharoplasty (CPT 15820 and 15821) is usually cosmetic, however, is considered reconstructive and medically necessary only when all of the following criteria are present:
			• There is documented facial nerve damage; and
			• Clear, high-quality, clinical photographs document the pathology; and
			• The member is unable to close the eye due to the lower lid dysfunction; and
			• Functional Impairment including both of the following:
			  ○ Documented uncontrolled tearing or irritation; and
			  ○ Conservative treatments tried and failed.
			
			Ectropion (eyelid turned outward) (CPT 67914 through 67917) or punctal eversion is considered reconstructive and medically necessary when all of the following criteria are present:

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Apr. 1, 2019		• Clear, high-quality, clinical photographs document the pathology; and
			• Corneal or conjunctival injury with both of the following criteria:
			  ○ Subjective symptoms include either:
			  ▪ Pain or discomfort; or
			  ▪ Excess tearing; and
			  ○ Any one of the following:
			  ▪ Exposure keratitis; and/or
			  ▪ Keratoconjunctivitis; and/or
			  ▪ Corneal ulcer.
			
			Entropion (eyelid turned inward) (CPT 67921–67924) is considered reconstructive and medically necessary when all of the following criteria are present:
			• Clear, high-quality, clinical photographs must document the following:
			  ○ Lid turned inward; and
			  ○ At least one of the following:
			  ▪ Trichiasis; or
			  ▪ Irritation of cornea or conjunctiva; and
			  ○ Subjective symptoms including either of the following:
			  ▪ Excessive tearing; or
			  ▪ Pain or discomfort.
			
			Lid retraction surgery (CPT 67911) is considered reconstructive and medically necessary when all of the following criteria are present:
			• Other causes have been eliminated as the reason for the lid retraction such as use of dilating eye drops, glaucoma medications; and
			• Clear, high-quality, clinical photographs document the pathology; and
			• There is Functional Impairment (such as 'dry eyes', pain/discomfort, tearing, blurred vision); and
			• Tried and failed conservative treatments; and
			• In cases of thyroid eye disease two or more Hertel measurements at least 6 months apart with the same base measurements are unchanged.
			
			Canthoplasty/canthopexy (CPT 21280, 21282, 67950, 67961, 67966) is considered reconstructive and medically necessary when all of the following criteria are present:
			• Functional Impairment; and
			• Clear, high-quality, clinical photographs document the pathology; and
			• Repair of ectropion or entropion will not correct condition; and

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Apr. 1, 2019		• At least one of the following is present:
			  ○ Epiphora (excess tearing) not resolved by conservative measures; or
			  ○ Corneal dryness unresponsive to lubricants; or
			  ○ Corneal ulcer.
			
			Repair of Floppy Eyelid Syndrome (FES) (CPT 67961 and 67966) is considered reconstructive and medically necessary when all of the following are present when documented and confirmed by history and examination:
			• Subjective symptoms must include eyelids spontaneously "flipping over" when the member sleeps due to rubbing on the pillow, **and** one of the following:
			  ○ Eye pain or discomfort; or
			  ○ Excess tearing; or
			  ○ Eye irritation, ocular redness and discharge.
			• Physical Examination that documents the following:
			  ○ Eyelash Ptosis; and
			  ○ Significant upper eyelid laxity; and
			  ○ Presence of Giant Papillary Conjunctivitis;
			  or
			  ○ Corneal findings such as:
			  ▪ Superficial Punctate Erosions (SPK); or
			  ▪ Corneal abrasion (documentation of a history of corneal abrasion or recurrent erosion syndrome is considered sufficient); or
			  ▪ Microbial Keratitis.
			• Clear, high-quality, clinical photographs that clearly document Floppy Eyelid Syndrome and demonstrate both of the following:
			  ○ Lids must be everted in the photographs; and
			  ○ Conjunctival surface (underbelly) of the lids must clearly demonstrate Giant Papillary Conjunctivitis.
			• Documentation that conservative treatment has been tried and failed, examples may include:
			  ○ Ocular lubricants both drops (daytime) and ointments (bedtime); or
			  ○ Short trial of antihistamines; or
			  ○ Topical steroid drops; or
			  ○ Eye Shield and/or Taping the lids at bedtime.
			• Other causes of the eye findings have been ruled out, examples may include:
			  ○ Allergic conjunctivitis

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Blepharoplasty, Blepharoptosis and Brow Ptosis Repair *(continued)*	Apr. 1, 2019		○ Atopic keratoconjunctivitis ○ Blepharitis ○ Contact lens (CL) complication ○ Dermatochalasis ○ Ectropion ○ Giant Papillary Conjunctivitis (GPC) that is not related to FES ○ Ptosis of the lid(s) ○ Superior limbic keratoconjunctivitis (SLK) ***When the Member is Not Capable of Reliable Visual Field Testing*** Reliable Visual Field testing is not required when the member is not capable of performing a Visual Field test. The following are some examples: • If the member is a child 12 years old or under. • If the member has intellectual disabilities (previously known as mental retardation) or some other severe neurologic disease. **Coverage Limitations and Exclusions** Some states require benefit coverage for services that UnitedHealthcare considers Cosmetic Procedures, such as repair of external Congenital Anomalies in the absence of a Functional Impairment. Please refer to the member specific benefit plan document. Cosmetic Procedures are excluded from coverage: • Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a Reconstructive Procedure. • Any procedure that does not meet the reconstructive criteria above in the Indications for Coverage section above. • Browpexy/internal brow lift is not designed to improve function. It is considered a Cosmetic Procedure and is not a covered service.
Orthognathic (Jaw) Surgery	Apr. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit*	**Indications for Coverage** Orthognathic (jaw) surgery is a standard exclusion from coverage in most fully-insured plans. The following list represents the covered exceptions to the orthognathic (jaw) surgery exclusion.

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Orthognathic (Jaw) Surgery *(continued)*	Apr. 1, 2019	*Considerations* section
		• Revised coverage rationale:
		  ○ Replaced references to "MCG™ Care Guidelines, *22nd* edition, *2018*" with "MCG™ Care Guidelines, *23rd* edition, *2019*"
		  ○ Removed California mandate language pertaining to Reconstructive Procedures
		• Updated definitions:
		  ○ Removed definition of "Congenital Anomaly (California only)"
		  ○ Modified definition of:
		  ▪ Cosmetic Procedures (California only)
		  ▪ Reconstructive Procedures (California only)
			The following are eligible for coverage as reconstructive and medically necessary:
			• Acute traumatic injury and Post-Surgical Sequela (see Post-Surgical Sequela in *Definitions* section of the policy)
			• Cancerous or non-cancerous tumors and cysts, Cancer and Post-Surgical Sequela (see Cancer Sequela and Post-Surgical Sequela in *Definitions* section of the policy)
			
			The following are eligible for coverage when the criteria are met (refer to *Criteria* section below):
			• Obstructive sleep apnea (also see Medical Policy titled Obstructive Sleep Apnea Treatment)
			• Cleft lip/palate (for cleft lip/palate related Jaw Surgery)
			• Congenital anomalies that meet the criteria for reconstructive. Depending on a member-specific clinical review, examples include: Pierre Robin Syndrome, Hemifacial Microsomia, and Treacher Collins Syndrome.
			
			Criteria
			All orthognathic (jaw) surgeries are subject to some level of review. For the above covered exceptions that require review, the following criteria should be applied.
			
			Orthognathic (jaw) surgery is a reconstructive procedure and medically necessary and is considered covered when both the skeletal deformity AND the Functional Impairment criteria below are met:
			• The presence of **any** 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
			  ○ **Vertical Discrepancies**:
			Presence of a vertical facial skeletal deformity which is two or more standard deviations from published norms for accepted skeletal landmarks:

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Orthognathic (Jaw) Surgery *(continued)*	Apr. 1, 2019		▪ 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 • In addition to meeting the skeletal deformity requirement above, 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, as measured by polysomnography (AASM Obstructive Sleep Apnea; and Practice Parameters for the Surgical Modifications of the Upper Airway for Obstructive Sleep Apnea in Adults), is defined as: ▪ Moderate for AHI or RDI ≥ 15 and ≤ 30 ▪ Severe for AHI or RDI > 30/hr **And** oropharyngeal narrowing secondary to maxillomandibular deficiency is the primary cause of moderate to severe obstructive sleep apnea. [See MCG™ Care Guidelines, 23rd edition, 2019, Maxillomandibular Osteotomy and Advancement A-0248 (ACG).] **Obstructive Sleep Apnea** For medical necessity clinical coverage criteria, in addition to the criteria above, please also refer to the following:

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Orthognathic (Jaw) Surgery *(continued)*	Apr. 1, 2019		• **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 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** Except where state mandated, the following are not covered: • Cosmetic and non-reconstructive Jaw Surgery and jaw alignment procedures (Orthognathic Surgery) that do not meet the criteria in the Indications for Coverage section above are excluded from coverage. • Surgery for torus mandibularis and torus palatinus for fabrication of dentures is not covered. • Pre and post-surgical orthodontic treatment. ***Additional Information*** 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. Please refer to the member specific benefit plan document.
Preventive Care Services	Apr. 1, 2019	• Revised list of applicable procedure and diagnosis codes for: **Preventive Care Services** *Syphilis Screening* ○ Updated service description: ▪ Added language to clarify the June 2016 USPSTF 'A' rating applies to non-pregnant adults and adolescents at increased risk	Refer to the policy for complete details on the coverage guidelines for Preventive Care Services.

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Preventive Care Services *(continued)*	Apr. 1, 2019	▪ Removed May 2009 USPSTF 'A' rating ▪ Added September 2018 USPSTF 'A' rating to indicate the USPSTF recommends early screening for syphilis infection in all pregnant women *Screening and Behavioral Counseling Interventions in Primary Care to Reduce Unhealthy Alcohol Use in Adults* (previously titled *Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse*) ○ Updated service description: ▪ Removed May 2013 USPSTF 'B' rating ▪ Added November 2018 USPSTF 'B' rating to indicate the USPSTF recommends screening for unhealthy alcohol use in primary care settings in adults 18 years or older, including pregnant women, and providing persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce unhealthy alcohol use *Screening for Intimate Partner Violence* ○ Updated service description: ▪ Removed January 2013	

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Preventive Care Services *(continued)*	Apr. 1, 2019	▪ USPSTF 'B' rating ▪ Added October 2018 USPSTF 'B' rating to indicate the USPSTF recommends that clinicians screen for intimate partner violence in women of reproductive age and provide or refer women who screen positive to ongoing support services ▪ Added reference link to the *Screening and Counseling for Interpersonal and Domestic Violence* section of the policy **Expanded Women's Health Preventive Health** *Screening and Counseling for Interpersonal and Domestic Violence* ○ Added reference link to the *Screening for Intimate Partner Violence* section of the policy	
Speech Language Pathology Services	Apr. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* section • Revised coverage rationale; replaced reference to "MCG™ Care Guidelines, *22nd* edition, *2018*" with "MCG™ Care Guidelines, *23rd* edition, *2019*" • Removed definition of	**Indications for Coverage** ***Benefit Interpretation*** **Speech therapy (speech–language pathology services) for the treatment of disorders of speech, language, voice, communication and auditory processing are covered when the disorder results from**: • Autism spectrum disorders • Cancer • Congenital Anomaly (including but not limited to the following) ○ Downs syndrome ○ Cleft palate ○ Tongue tie

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Speech Language Pathology Services *(continued)*	Apr. 1, 2019	"Congenital Anomaly (California only)"	• Injury (including but not limited to the following)
			  ○ Otitis media resulting in hearing loss documented by testing (such as audiogram or notes of such testing).
			  ○ Vocal cord injuries (e.g., edema, nodules, polyps)
			  ○ Stroke/CVA
			  ○ Trauma
			  ○ Cerebral palsy
			  ○ Static encephalopathy
			• Stroke
			
			Services of a speech-language pathologist or other licensed healthcare professional (within the scope of his/her licensure) to treat the above disorders may be covered when:
			• There is a need for the supervision of a licensed therapist for speech–language therapy, swallowing or feeding rehabilitative or Restorative Therapy Services.
			• The services are part of a treatment plan with documented goals for functional improvement of the individual's condition, e.g., speech, articulation, swallowing or communication with or without alternative methods.
			• The teaching of an individual and or caregiver is required to strengthen muscles, improve feeding techniques or improve speech–language skills to progress toward the documented treatment plan goals. Once the individual and/or caregiver are trained the services are no longer skilled, therefore custodial, and not a covered health service. Refer to the Coverage Determination Guideline titled Skilled Care and Custodial Care Services.
			• Mandated benefits (federal and state) for speech therapy. Examples may include Developmental Delay, autism, cleft palate and/or lip, aphasia.
			
			Rehabilitation Services for feeding and or swallowing rehabilitative or Restorative Therapy Services:
			• Swallowing Disorders (dysphagia)
			• Feeding disorders including problems with gathering food and sucking, chewing, or swallowing food. For example, a child who cannot pick up food and get it to his/her mouth or cannot completely close his/her lips to keep food from falling out of his/her mouth may have a feeding disorder
			• Auditory (Aural) rehabilitation which includes speech–language therapy,

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Speech Language Pathology Services *(continued)*	Apr. 1, 2019		e.g., when a auditory implant or cochlear implant is a covered healthcare service **Outpatient rehabilitation can occur in the following settings**: • Physician's office • Therapist's office • Member's place of residence • Separate part of a clinic or hospital where speech therapy is performed **Discharge criteria includes the following**: • Treatment goals and objectives have been met • Speech, language, communication, or feeding and swallowing disorder are within normal limits or is consistent with the individual's baseline • Communication abilities have become comparable to those of others of the same chronological age, gender, ethnicity, or cultural and linguistic background • The desired level of enhanced communication skills has been reached • The speech, language, communication, and/or feeding and swallowing skills no longer affect the individual's health status • The individual is unwilling to participate in treatment, requests discharge, or exhibits behavior that interferes with improvement or participation in treatment (e.g., noncompliance, non attendance) • The level of services do not require a Speech-Language Pathologist or other licensed healthcare professional (within the scope of his/her licensure) • The individual is unable to tolerate treatment because of a serious medical, psychological, or other condition. • The individual will get services from a different provider **Note**: State mandates always take precedence over plan language. ***Additional Information*** • Eligible speech therapy received in the home from a Home Health Agency is covered under Home Health Care. The Home Health Care section only applies to services that are rendered by a Home Health Agency. • Eligible speech therapy received in the home from an independent speech therapist (a speech therapist that is not affiliated with a Home Health Agency) is covered under Rehabilitation Services-Outpatient Therapy.

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Speech Language Pathology Services *(continued)*	Apr. 1, 2019		• Swallowing and feeding rehabilitation therapy may be done with speech Rehabilitation Services; when performed together both should be billed and only the speech therapy will count toward the speech therapy benefit limit, if applicable. • Swallowing therapy (92526) when billed alone will count toward the speech therapy benefit limit, if applicable. • Cochlear implant monitoring (remapping and reprogramming of implant) and rehabilitation following the cochlear implant surgery is usually billed as aural rehabilitation. This is not covered as a speech therapy benefit. The member specific benefit plan document must be referenced for any applicable limits that may apply to aural rehabilitation. ***For Medical Necessity Clinical Coverage Criteria*** Refer to MCG™ Care Guidelines, 23rd edition, 2019. **Coverage Limitations and Exclusions** • Benefits for cognitive rehabilitation therapy are covered only when Medically Necessary following a post-traumatic brain Injury or cerebral vascular accident • Devices and computers to assist in communication and speech (refer to the Coverage Determination Guideline titled Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements) • Speech therapy if the provider is school based (check benefit language and state mandates) • Idiopathic Developmental Delay (no Illness to explain the cause of Developmental Delay in speech–language) • Sign language (does not require the services of a licensed or certified healthcare professional) • Speech therapy beyond the benefit maximum (visits limits) • Benefits are not available for maintenance/preventive treatment. Please refer to the member specific benefit plan document • A child being bilingual is not considered a developmental speech or Developmental Delay and speech therapy is usually not a covered health service, except when other criteria for speech therapy are met (see the *Definitions* section of the policy for Speech Delay – Bilingualism) • Home Speech Therapy for the convenience of a provider or member

Utilization Review Guideline (URG) Updates

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UPDATED		

Inpatient Pediatric Feeding Programs	Mar. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed Benefit Considerations section

Propranolol Treatment for Infantile Hemangiomas: Inpatient Protocol	Mar. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale

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Chemotherapy Observation or Inpatient Hospitalization	Apr. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		  ○ Replaced content heading titled:
		  ▪ "Utilization Management Guiding Principles" with "Coverage Rationale"
		  ▪ "Definitions" with "Description of Services"
		• Revised and reformatted coverage rationale:
		  ○ Simplified content
		  ○ Replaced reference to "patient" with "individual"
		  ○ Removed specific parameters for drugs and conditions requiring an observation unit or inpatient hospital stay
		  ○ Updated list of clinical conditions or complications of cancer chemotherapy which, when present, may
			Introduction
			Most cancer chemotherapies can be administered safely and effectively in a physician office or through home healthcare services. However, because of the risk of certain toxicities or individual comorbidities, some cancer chemotherapy may be administered either in a facility observation unit or an inpatient unit.
			
			The following drugs may require an observation unit or inpatient hospital stay:
			• Campath® (alemtuzumab)
			• Cisplatin (high-dose) > 75 mg/m2
			• Interleukin 2 infusion
			• Ifosphamide infusion > 1g/m2/day (usually given consecutive days)
			• Methotrexate > 500 mg/m2
			• Other complex multiple-drug or multiple-day regimens such as Hyper-CVAD, ESHAP or EPOCH, Einhorn regimen
			
			The following are clinical conditions or complications of cancer chemotherapy which, when present, may require an observation stay:
			• Known hypersensitivity reactions from previous infusion
			• Congestive heart failure or chronic renal failure requiring high volume fluid infusions
			• Transcatheter arterial chemoembolization (TACE) or intra-arterial chemotherapy infusion
			• Comorbidities that require an observation or overnight stay

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Chemotherapy Observation or Inpatient Hospitalization *(continued)*	Apr. 1, 2019	require an observation stay; replaced "intra-arterial *hepatic* infusion" with "*transcatheter arterial chemoembolization (TACE) or* intra-arterial *chemotherapy* infusion" ○ Updated list of clinical conditions which require an inpatient hospital stay; replaced "prophylaxis of tumor lysis syndrome" with "prophylaxis of tumor lysis syndrome *in cases of high grade lymphoma with large masses*" ○ Replaced reference to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"; refer to 23rd edition for complete details on applicable updates to the MCG™ Care Guidelines • Updated supporting information to reflect the most current description of services	• Cancer chemotherapy administered during a hospitalization for an unrelated problem **The following are clinical conditions which require an inpatient hospital stay**: • Acute leukemia induction therapy or consolidation therapy • Intra-arterial infusion of chemotherapy • Prophylaxis of tumor lysis syndrome in cases of high grade lymphoma with large masses • Comorbidities that require an inpatient stay Conditions requiring observation unit or inpatient hospital treatment other than those noted above will be reviewed on a case-by-case basis. **For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, for the following**: • Observation care criteria for chemotherapy: Chemotherapy: Observation Care OCG: OC-008 (ISC) • Inpatient admission criteria for administration of chemotherapy: Chemotherapy: ORG: M-87 (ISC) and Neutropenia after Chemotherapy ORG: P-300 (ISC) • Admission to home health services for all the above drugs or therapeutic agents: Chemotherapy: ORG: M-2087 (HC) and Neutropenia after Chemotherapy ORG: P-2300 (HC) • Use of infusion pump for delivery of chemotherapy and therapeutic agents: Infusion Pump: ACG: A-0618(AC) **Additional Review Points** A written protocol will be expected to be followed by the provider administering the chemotherapy drug. Any requests for an extension of the inpatient stay beyond the recommended day(s) must be clinically reviewed.
Immune Globulin Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Infusion	Apr. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Revised coverage rationale: ○ Modified language to clarify: ▪ The listed place of	This guideline addresses the criteria for consideration of allowing hospital outpatient facility infusion services for intravenous Immune Globulin (IVIG) and subcutaneous Immune Globulin (SCIG) therapy. This includes hospital based services with the following CMS/AMA Place of Service (POS) codes: • 19 (Off Campus-Outpatient Hospital); and • 22 (On Campus-Outpatient Hospital)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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Immune Globulin Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Infusion *(continued)*	Apr. 1, 2019	service codes are in accordance with the Centers for Medicare and Medicaid Services (CMS) and *American Medical Association (AMA)* ▪ Clinical use of Immune Globulin is proven ***and*** medically necessary [as noted] ○ Added language to indicate: ▪ Alternative Sites of Care, such as non-hospital outpatient infusion, physician office, ambulatory infusion suites, or home infusion services are well accepted places of service for medication infusion therapy; if an individual does not meet criteria for outpatient hospital facility infusion, alternative Sites of Care may be used ▪ Outpatient hospital facility-based infusion may be granted to initiate, re-initiate, or change Immune Globulin products for a short duration (e.g., 4 weeks) ▪ Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the	Alternative Sites of Care, such as non-hospital outpatient infusion, physician office, ambulatory infusion suites, or home infusion services are well accepted places of service for medication infusion therapy. If an individual does not meet criteria for outpatient hospital facility infusion, alternative Sites of Care may be used. **Clinical use of Immune Globulin is proven and medically necessary, in accordance with the UnitedHealthcare Medical Benefit Drug Policy titled Immune Globulin (IVIG and SCIG).** **Outpatient hospital facility-based Immune Globulin infusion is medically necessary for individuals who meet at least ONE of the following criteria (submission of medical records is required)**: 1. Documentation that the individual is medically unstable for administration of Immune Globulin at the alternative Sites of Care as determined by any of the following: a. The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; **or** b. The individual's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative Site of Care; **or** c. Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; **or** d. Difficulty establishing and maintaining patent vascular access; **or** 2. Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting; **or** 3. Initial infusion, change of Immune Globulin product, or re-initiation of therapy after more than 6 months; **or** 4. Individual has immunoglobulin A (IgA) deficiency with anti-IgA antibodies;

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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Immune Globulin Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Infusion *(continued)*	Apr. 1, 2019	individual's ability to receive therapy at an alternative Site of Care ○ Updated guidelines to indicate outpatient hospital facility-based Immune Globulin infusion is medically necessary for individuals who meet at least one of the following criteria (submission of medical records is required): ▪ Documentation that the individual is medically unstable for administration of Immune Globulin at the alternative Sites of Care as determined by any of the following: - The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; or - The individual's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative Site	**or** 5. Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy (if the prescriber cannot infuse in the office setting). Outpatient hospital facility-based infusion may be granted to initiate, re-initiate, or change Immune Globulin products for a short duration (e.g., 4 weeks). Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative Site of Care. **Note**: If more than one of the above criteria are met, then the greatest of the applicable approval time periods will be allowed.

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Immune Globulin Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Infusion *(continued)*	Apr. 1, 2019	of Care; or - Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; or - Difficulty establishing and maintaining patent vascular access or ▪ Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting; or ▪ Initial infusion, change of Immune Globulin product, or re-initiation of therapy after more than 6 months; or	

Utilization Review Guideline (URG) Updates

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Immune Globulin Site of Care Review Guidelines for Medical Necessity of Hospital Outpatient Facility Infusion *(continued)*	Apr. 1, 2019	▪ Patient has immunoglobulin A (IgA) deficiency with anti-IgA antibodies; or ▪ Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy (if the prescriber cannot infuse in the office setting) • Removed list of applicable place of service (POS) codes • Updated supporting information to reflect the most current references	
Office Based Program	Apr. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* and *Description of Services* sections • Updated list of related policies; removed reference link to the policy titled *Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins* • Revised and reformatted coverage rationale: ○ Added content previously located in the *Description of Services* section ○ Replaced references to "patient(s)" with "individual(s)"	Before using this guideline, please check the member specific benefit plan document. The purpose of this guideline is the following: • To aim to encourage more cost-effective sites of service for certain outpatient surgical procedures, when medically appropriate to minimize out-of-pocket costs for UnitedHealthCare members and to improve cost efficiencies for the overall health care system. • To apply to UnitedHealthcare commercial plans that require services to be medically necessary. Refer to the member specific benefit plan document to determine if medical necessity applies. With the exception of the following qualifying conditions, certain elective procedures should be performed in an office setting. Some individuals may require more complex care due to certain medical factors or functional limitations and it may be appropriate to have the procedure in an outpatient hospital setting or ambulatory surgery center (not an all-inclusive list): • Individual unable to cooperate with procedure due to mental status, severe anxiety, or extreme pain sensitivity • Failed office based procedure attempt due to body habitus, abnormal

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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Office Based Program *(continued)*	Apr. 1, 2019	○ Added language to indicate specific procedure codes for services can be found on the *Prior Authorization List* (refer to the *References* section [of the policy]) • Revised list of applicable codes for which prior authorization is required if not performed in an office setting; removed 10120, 10140, 11400, 11401, 11404, 11420, 11421, 11423, 11424, 36473, 36475, 36478, 45300, 45330, 46922, 55250, 62320, 62322, and 64520 • Updated supporting information to reflect the most current references	anatomy, or technical difficulties • Bleeding disorder that would cause a significant risk of morbidity • Allergy to local anesthetic The following will be taken into account to determine whether the elective procedure is being performed in a cost-effective setting: • Member specific benefit plan document • Geographic availability of an in-network provider • Office capability (i.e., appropriate equipment) • Significant member comorbidities **Potential Documentation Requirements** • Physician office notes **Elective Procedures List** Prior authorization is required for the following procedures if not performed in an office setting (see list of *Applicable Codes*). Specific procedure codes for services can be found on the *Prior Authorization List* (refer to the *References* section of the policy).

Quality of Care Guideline (QOCG) Updates

Policy Title	Effective Date	Summary of Changes	Guiding Principles
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Hospital Readmissions	Apr. 1, 2019	• Revised guiding principles and supporting information; replaced references to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"	**Readmission Review Overview** ***UnitedHealthcare Commercial (Employer & Individual Plan Readmissions)*** Admissions to an acute, general, short-term hospital occurring within 30 days of the date of discharge from the same acute, general, short-term hospital or hospital system for the same, similar, or related diagnosis may be subject to readmission review. UnitedHealthcare and its affiliates may conduct readmission reviews to determine if there was an admission that was considered clinically related with a reasonable expectation that it could have been prevented by one of more of the following: • Optimal provision of quality care during the initial hospitalization • Optimal discharge planning • Optimal post-discharge follow-up • Improved coordination between inpatient and outpatient health care teams Excluded from readmission review are: • Transfers from out of network to in-network facilities • Transfers of patients to receive care not available at the first facility • Readmissions that are planned for repetitive treatments such as cancer chemotherapy, transfusions for chronic anemia, other similar repetitive treatments or for scheduled elective surgery • Skilled Nursing and Rehabilitation facilities (SNF and Rehab) • Admits associated with malignancies, burns, and cystic fibrosis • Admissions with a discharge status of left against medical advice • Obstetrical readmissions • Readmissions > = 30 days from the initial admission ***Documentation for Determination*** Upon request from the Health Plan, the facility and/or facilities agree to forward all medical records and supporting documentation of the first and subsequent admissions to UnitedHealthcare or one of its affiliates. This can occur either concurrently during the inpatient stay, prepayment or post-payment review of the claim. ***Review Process***

Quality of Care Guideline (QOCG) Updates

Policy Title	Effective Date	Summary of Changes	Guiding Principles
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Hospital Readmissions *(continued)*	Apr. 1, 2019		• Review of the facility contract to determine if readmission review is applicable. • At the request of UHC, the hospital must submit medical records pertaining to the readmission as well as the index/anchor admission to first identify whether the case is a potentially preventable readmission. Initial review should determine whether the readmission was **clinically related** to the index/anchor admission. A readmission is considered to be clinically related to the initial admission if it belongs to one of five different categories: ○ A medical readmission for a continuation or recurrence of the reason for the initial admission or closely related condition (e.g., readmission for diabetes following an initial admission for diabetes) ○ A medical readmission for an acute decompensation of a chronic problem that was not related to the initial admission but was plausibly related to care either during or immediately after the initial admission (e.g., a readmission for previously diagnosed diabetes in a patient whose initial admission was for an acute myocardial infarction) ○ A medical readmission for an acute medical complication plausibly related to care during the initial admission (e.g., a patient with a hernia repair discharged with a urinary catheter readmitted for treatment of a urinary tract infection) ○ An unplanned readmission for surgical procedure to address a continuation or a recurrence of the problem causing the initial admission (e.g., a patient readmitted for an appendectomy following an initial admit for abdominal pain and fever) ○ An unplanned readmission for a surgical procedure to address a complication resulting from care during the initial admission (e.g., a readmission for drainage of a post-operative wound abscess following an initial admission for a bowel resection) Once the initial review has determined to be **clinically related**, further evaluation would determine whether the readmission was **potentially preventable**. The review shall focus on the following: • Whether the patient meets inpatient or alternative setting criteria using the appropriate MCG™ Care Guidelines, 23rd edition, 2019. • Whether discharge plans were followed according to generally accepted medical standards (*Generally Accepted Standards of Medical Practice, Certificate of Coverage).* These are standards that are based on credible

Quality of Care Guideline (QOCG) Updates

Policy Title	Effective Date	Summary of Changes	Guiding Principles
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Hospital Readmissions *(continued)*	Apr. 1, 2019		scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials, or, if not available, observational studies from more than one institution that suggest a causal relationship between the service or treatment and health outcomes. If no credible scientific evidence is available, then standards that are based on physician specialty society recommendations or professional standards of care may be considered. • Documentation in the hospital record that an appointment was made within the first week or within an appropriate time frame after discharge from the initial admission. • Whether appropriate telephone numbers have been given to the patient for calls to the hospital or primary care provider for related discharge questions. • Whether a health care advocate/provider did an in-home safety assessment and appropriate follow up as needed. • Whether written discharge instructions were provided and explained to the patient/caregiver prior to discharge (Project Boost). • Documentation that all required prescriptions were given to the patient and the patient was educated in the appropriate use of the medication. • Whether documentation supports that durable medical equipment has been arranged for the patient and the patient has been appropriately educated on its use. • Whether documentation supports that all salient financial and social needs of the patient have been addressed.