UnitedHealthcare®

December 2018

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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Take Note

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UPDATED

In This Issue

Medical Benefit Drug Policy Updates

Coverage Determination Guideline (CDG) Updates

Utilization Review Guideline (URG) Updates

Take Note

ANNUAL CPT® AND HCPCS CODE UPDATES

Beginning Jan. 1, 2019, all applicable Medical Policies, Medical Benefit Drug Policies, and Coverage Determination Guidelines will be modified to reflect the 2019 Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) code additions, revisions, and deletions. Refer to the following sources for information on the 2019 code updates:

- American Medical Association. Current Procedural Terminology: CPT®
- Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System: HCPCS

Complete details on impacted policies and corresponding code edits will be provided in the January 2019 edition of the Medical Policy Update Bulletin.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Athletic Pubalgia Surgery	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Bronchial Thermoplasty	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Chemosensitivity and Chemoresistance Assays in Cancer	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)

Computed Tomographic Colonography	Dec. 1, 2018	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)

Computerized Dynamic Posturography	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)

Core Decompression for Avascular Necrosis	Dec. 1, 2018	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)

Corneal Hysteresis and Intraocular Pressure Measurement	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Cytological Examination of Breast Fluids for Cancer Screening	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Discogenic Pain Treatment	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Electrical Bioimpedance for Cardiac Output Measurement	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)

Epiduroscopy, Epidural Lysis of Adhesions and Functional Anesthetic Discography	Dec. 1, 2018	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)

Femoroacetabular Impingement Syndrome	Jan. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated coverage rationale:
		  ○ Modified language to clarify surgical treatment for femoroacetabular impingement (FAI) syndrome is *proven and* medically necessary when the [listed] criteria are met
		  ○ Replaced criterion requiring:
		  ▪ "Moderate-to-severe persistent hip or groin pain that limits activity and is worsened by *flexion activities (e.g.,* squatting or prolonged sitting)" with "moderate-to-severe *symptoms typical of FAI* (persistent hip or groin pain that limits activity and is worsened by *bending of the joint such as* squatting or prolonged sitting)"
		  ▪ "*Radiographic* confirmation of FAI" with "*imaging studies (X-rays, MRI or CT scans)* confirming FAI"
		• Added *Definitions* section; relocated definitions previously outlined in the *Coverage Rationale* section
		• Updated supporting information to reflect the most current description of services, clinical evidence, and references

Gastrointestinal Motility Disorders, Diagnosis and Treatment	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)

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Policy Title	Effective Date	Summary of Changes
UPDATED		
High Frequency Chest Wall Compression Devices	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Home Traction Therapy	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Intrauterine Fetal Surgery	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Laser Interstitial Thermal Therapy	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Light and Laser Therapy for Cutaneous Lesions and Pilonidal Disease	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)

Lithotripsy for Salivary Stones	Dec. 1, 2018	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)

Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD)	Dec. 1, 2018	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)

Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Jan. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated coverage rationale; modified language to clarify the listed services are:
		  ○ Proven ***and*** medically necessary (as described)
		  ○ Unproven ***and*** not medically necessary (as described)
		• Updated list of applicable CPT codes; added 81425, 81426, 81427, 81443*, and 81479 *(*annual code edit)*

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Motorized Spinal Traction	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)

Nerve Graft to Restore Erectile Function During Radical Prostatectomy	Dec. 1, 2018	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)

Occipital Neuralgia and Headache Treatment	Jan. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)
		• Added definition of:
		  ○ Neurectomy
		  ○ Rhizotomy
		• Updated list of applicable CPT codes; removed 95972
		• Updated supporting information to reflect the most current references

Plagiocephaly and Craniosynostosis Treatment	Dec. 1, 2018	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)
		• Added *Definitions* section; relocated definitions previously outlined in the *Coverage Rationale* and *Description of Services* sections

Platelet Derived Growth Factors for Treatment of Wounds	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Preterm Labor Management	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Prolotherapy for Musculoskeletal Indications	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)

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UPDATED		

Sensory Integration Therapy and Auditory Integration Training	Dec. 1, 2018	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)

Thermography	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)

Virtual Upper Gastrointestinal Endoscopy	Dec. 1, 2018	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)

Visual Information Processing Evaluation and Orthoptic and Vision Therapy	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)
Warming Therapy and Ultrasound Therapy for Wounds	Dec. 1, 2018	• Simplified coverage rationale (no change to guidelines)

Whole Exome and Whole Genome Sequencing	Jan. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated coverage rationale; modified language to clarify the listed services are:
		  ○ Proven ***and*** medically necessary (as described)
		  ○ Unproven ***and*** not medically necessary (as described)
		• Updated list of applicable CPT codes; added 81425, 81426, and 81427

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Abnormal Uterine Bleeding and Uterine Fibroids	Jan. 1, 2019	• Revised coverage rationale:
		  ○ Modified language to clarify:
		  ▪ The listed services are:
			Levonorgestrel-Releasing Intrauterine Device
			Levonorgestrel-releasing intrauterine devices (LNG-IUD) (e.g., Mirena®, Skyla®, Liletta® or Kyleena™) are proven and medically

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Abnormal Uterine Bleeding and Uterine Fibroids *(continued)*	Jan. 1, 2019	– Proven ***and*** medically necessary (as described) – Unproven ***and*** not medically necessary (as described) ▪ The listed MCG™ Care Guidelines should be referenced for medical necessity *clinical coverage criteria* ○ Replaced language indicating "uterine artery embolization (UAE) is proven *and/or* medically necessary for treating symptomatic uterine fibroids *for women who do not wish to preserve their childbearing potential which has been documented and confirmed in the medical record*" with "uterine artery embolization (UAE) is proven *and* medically necessary for treating symptomatic uterine fibroids" ○ Simplified content addressing unproven and not medically necessary indications ○ Removed language indicating transcervical ultrasound-guided radiofrequency ablation is investigational due to lack of FDA approval ○ Replaced reference to "*laparoscopic* ultrasound-guided radiofrequency	**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, 22nd edition, 2018, 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®)

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REVISED			
Abnormal Uterine Bleeding and Uterine Fibroids *(continued)*	Jan. 1, 2019	ablation" and "*transcervical* ultrasound-guided radiofrequency ablation" with "ultrasound-guided radiofrequency ablation" • Updated supporting information to reflect the most current clinical evidence, FDA information, and references	
Attended Polysomnography for Evaluation of Sleep Disorders	Jan. 1, 2019	• Replaced references to "patient(s)" with "individual(s)" • Reformatted and revised coverage rationale: ○ Simplified content addressing: ▪ Home sleep apnea testing ▪ Attended full-channel nocturnal polysomnography performed in a healthcare facility or laboratory setting ○ Added language to indicate attended full-channel nocturnal polysomnography is medically necessary for evaluating sleep disorders other than OSA when, following an appropriate clinical assessment, *a secondary condition in addition to OSA is suspected* • Updated definition of: ○ Obstructive Sleep Apnea (OSA) ○ PAP-Nap • Updated supporting information	**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 ○ Documented ongoing epileptic seizures in the presence of symptoms

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REVISED			
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Jan. 1, 2019	to reflect the most current clinical evidence and references	of sleep disorder Also, see 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 MSLT section below) ○ Central Sleep Apnea **Attended full-channel nocturnal polysomnography is not medically necessary for diagnosing ANY of the following conditions:** • Circadian Rhythm Disorders • Depression • Insomnia There is insufficient published clinical evidence that evaluation of the above disorders with polysomnography (PSG) in the absence of symptoms of sleep disorder leads to better health outcomes. **Actigraphy is not medically necessary for diagnosing sleep disorders**. A review of the evidence does not establish the effectiveness of Actigraphy as a stand-alone tool for the diagnosis of sleep disorders. In addition, definitive patient selection criteria for the use of Actigraphy devices for the diagnosis of sleep disorders have not been established.

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REVISED			
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Jan. 1, 2019		**Daytime Sleep Studies** **Multiple Sleep Latency Testing (MSLT) is medically necessary for evaluating individuals with suspected Narcolepsy when other causes of Excessive Sleepiness have been excluded by appropriate clinical assessment**. For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 22nd edition, 2018, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC). **Maintenance of Wakefulness Testing (MWT) is medically necessary for evaluating individuals whose inability to remain awake constitutes a safety issue, or for assessing response to treatment in individuals with Narcolepsy or idiopathic Hypersomnia**. For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 22nd edition, 2018, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC). **Multiple Sleep Latency Testing (MSLT) and the Maintenance of Wakefulness Test (MWT) are not medically necessary for evaluating OSA, Insomnia or circadian rhythm disorders**. Available published evidence is insufficient to demonstrate improved management of these conditions through the use of MSLT. Published evidence is limited to poorly controlled studies. **An abbreviated daytime sleep study (PAP-Nap), to acclimate individuals to PAP and its delivery, is not medically necessary**. Further results from large, prospective studies are needed to assess the clinical value of this test. **Attended PAP Titration** **A split-night sleep study, performed in a healthcare facility or laboratory setting, is medically necessary for diagnosis and PAP titration when an individual meets the above criteria for an attended sleep study**. **When a split-night sleep study is inadequate or not feasible, a full-night study, performed in a healthcare facility or laboratory setting, is medically necessary for PAP titration when an individual meets the above criteria for an attended full-channel nocturnal**

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REVISED			
Attended Polysomnography for Evaluation of Sleep Disorders *(continued)*	Jan. 1, 2019		**polysomnography and has a confirmed diagnosis of OSA**. Also, see 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 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.
Balloon Sinus Ostial Dilation	Jan. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* section • Revised coverage rationale: ○ Modified language to clarify the listed services are: ▪ Proven ***and*** medically necessary (as described) ▪ Unproven ***and*** not medically necessary (as described) ○ Added language to indicate: ▪ Balloon sinus ostial dilation is proven and medically necessary [for treating] Recurrent Acute Rhinosinusitis (defined as four episodes per year of Acute Rhinosinusitis with	**Balloon sinus ostial dilation is proven and medically necessary when either of the following conditions is present:** • Chronic Rhinosinusitis (defined as rhinosinusitis lasting longer than 12 weeks) when ALL of the following are met: ○ Chronic Rhinosinusitis of the sinus to be dilated is confirmed on CT scan. CT scan findings of Chronic Rhinosinusitis include one or more of the following: ▪ Mucosal thickening, ▪ Bony remodeling, ▪ Bony thickening, or ▪ Obstruction of the ostiomeatal complex ○ Balloon sinus ostial dilation is limited to the frontal, maxillary or sphenoid sinuses ○ Balloon sinus ostial dilation is performed either as a stand-alone procedure or as part of Functional Endoscopic Sinus Surgery (FESS) ○ Balloon sinus ostial dilation is performed in individuals whose symptoms persist despite medical therapy with one or more of the following: ▪ Nasal lavage ▪ Antibiotic therapy, if bacterial infection is suspected ▪ Intranasal corticosteroids • Recurrent Acute Rhinosinusitis (defined as four episodes per year of

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REVISED			
Balloon Sinus Ostial Dilation *(continued)*	Jan. 1, 2019	distinct symptom-free intervals between episodes) with all of the following: - Sinonasal symptoms and - Computed tomography (CT) evidence of ostial occlusion and/or mucosal thickening in the sinus to be dilated ▪ Balloon sinus ostial dilation is unproven and not medically necessary for treating all other conditions that do not meet the criteria [listed in the policy] due to insufficient evidence of efficacy ○ Replaced reference to "persons" with "individuals" ○ Simplified content addressing unproven and not medically necessary indications • Added definition of: ○ Acute Rhinosinusitis (ARS) ○ Recurrent Acute Rhinosinusitis (RARS) • Updated supporting information to reflect the most current description of services, clinical evidence, and references	Acute Rhinosinusitis with distinct symptom free intervals between episodes) with ALL of the following: ○ Sinonasal symptoms and ○ Computed tomography (CT) evidence of ostial occlusion and/or mucosal thickening in the sinus to be dilated **Balloon sinus ostial dilation is unproven and not medically necessary for treating the following due to insufficient evidence of efficacy:** • Nasal polyps or tumors • All other conditions that do not meet the above criteria

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REVISED			

Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation	Jan. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Revised coverage rationale:
		  ○ Simplified content
		  ○ Modified language to clarify the listed services are:
		  ▪ Proven ***and*** medically necessary (as described)
		  ▪ Unproven ***and*** not medically necessary (as described)
		  ○ Added language to indicate scrambler therapy (ST) is unproven and not medically necessary
		• Updated list of applicable CPT codes; added 0278T and 64999
		• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references
			Functional electrical stimulation (FES) is proven and medically necessary as a component of a comprehensive rehabilitation program in members with lower limb paralysis due to spinal cord injury (SCI) when all of the following criteria are met:
			• Demonstration of intact lower motor units (L1 and below) (both muscle and peripheral nerves);
			• Muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;
			• Demonstration of brisk muscle contraction;
			• Demonstration of sensory perception sufficient for muscle contraction;
			• Demonstration of a high level of motivation, commitment and cognitive ability for device use;
			• Ability to transfer independently;
			• Demonstration of independent standing tolerance for at least 3 minutes;
			• Demonstration of hand and finger function to manipulate controls;
			• Post-recovery from SCI and restorative surgery of at least 6 months;
			• Absence of hip and knee degenerative disease;
			• Absence of history of long bone fracture secondary to osteoporosis
			
			Neuromuscular electrical stimulation (NMES) is proven and medically necessary when nerve supply to the muscle is intact and origin of the condition is non-neurological for the following indications:
			• Disuse muscle atrophy
			• Wrist and finger function for partial paralysis following stroke
			• Prevention or correction of shoulder subluxation for partial paralysis following stroke
			
			The following are unproven and not medically necessary due to insufficient evidence of efficacy:
			• FES for treating ANY other indication not listed above
			• NMES for treating ANY other indication not listed above
			• Interferential therapy (IFT) for treating musculoskeletal disorders/injuries, or to facilitate healing of nonsurgical soft tissue injuries or bone fractures
			• Pulsed electrical stimulation (PES)
			• Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS)
			• Microcurrent electrical nerve stimulation (MENS)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation *(continued)*	Jan. 1, 2019		• Percutaneous electrical nerve stimulation (PENS) or percutaneous neuromodulation therapy (PNT) • Dorsal root ganglion (DRG) stimulation • Scrambler Therapy (ST)
Neurophysiologic Testing and Monitoring	Jan. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* section • Revised coverage rationale; replaced language indicating: ○ "Physiologic recording of tremor using accelerometers is unproven and not medically necessary" with "physiologic recording of *movement disorder symptoms, including bradykinesia, dyskinesia, and* tremor using *wearable devices with* accelerometers *or gyroscopes* is unproven and not medically necessary" ○ "There is insufficient evidence and too few studies to conclude that these devices improve therapeutic responses for the purpose of decreasing tremor in individuals with *tremor*" with "there is insufficient evidence and too few studies to conclude that these devices improve therapeutic responses for the purpose of decreasing *bradykinesia,*	**Electromyography (EMG)** **Surface electromyography (SEMG) is unproven and not medically necessary.** There is limited and insufficient evidence to support the use of SEMG. Studies varied considerably in SEMG instrumentation, SEMG protocol, and diagnostic algorithm. Depending on the study's SEMG approach, diagnostic performance ranged from poor to fair. Further research is needed to standardize SEMG approaches and diagnostic algorithms, increase diagnostic performance, and to assess the role of SEMG in clinical practice. **Surface electromyography (SEMG) based seizure monitoring systems are unproven and not medically necessary.** There is insufficient evidence to conclude that SEMG based seizure monitoring systems improve care and health outcomes in patients with seizures. Well-designed controlled studies are needed to determine the efficacy of these devices. **Macroelectromyography (macro-EMG) testing is unproven and not medically necessary.** There is limited and insufficient evidence to support the use of macro-EMG. Additional studies are needed to establish how this test improves diagnostic capabilities and physician decision-making. **Nerve Conduction Studies** ***Nerve Conduction Studies Performed in Conjunction with Needle Electromyography*** **Nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) and neuromuscular junction testing are proven and medically necessary when performed in conjunction with needle electromyography for any of the following known or suspected disorders:** • Peripheral nerve entrapment syndromes

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REVISED			
Neurophysiologic Testing and Monitoring *(continued)*	Jan. 1, 2019	*dyskinesia, and* tremor in individuals with *movement disorder symptoms*" • Updated list of applicable CPT codes to reflect annual code edits; added 0533T, 0534T, 0535T, and 0536T • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	• Generalized neuropathies • Hereditary, metabolic, or degenerative polyneuropathy • Plexopathy (acquired disorder in tissue along nerves that causes motor and sensory dysfunction) • Neuromuscular junction disorders • Myopathies • Motor neuron disease • Spine disorder with nerve root impingement symptoms • Cervical, thoracic, and/or lumbosacral radiculopathy • Guidance for botulinum toxin injection for spasmodic dysphonia or segmental dystonia when it is difficult to isolate affected muscles • Traumatic nerve lesions ***Nerve Conduction Studies Performed without Needle Electromyography*** **Nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) are proven and medically necessary when performed without needle electromyography for individuals who have any of the above known or suspected disorders with any of the following clinical indications:** • Individuals treated with anticoagulants; or • Individuals with lymphedema; or • Individuals being evaluated for carpal tunnel syndrome The American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) states that it is in the best interest of individuals, in the majority of situations, for the needle EMG and the NCS examination to be conducted and interpreted on-site in real time. According to the AANEM, the use of the term "real time" with regard to nerve conduction studies indicates that information from the history and physical examinations are integrated, the specific and tailored electrodiagnostic (EDX) study is performed, and the analysis of the waveforms are all done at the same time and while the individual is present in the EDX laboratory (AANEM, Proper Performance and Interpretation of Electrodiagnostic Studies, 2014; AANEM, What does 'On Site' and 'Real Time' Mean?, 2014). **Nerve conduction studies are unproven and not medically necessary for all conditions other than those listed above as proven.** There is limited and insufficient evidence to conclude that nerve conduction

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Neurophysiologic Testing and Monitoring *(continued)*	Jan. 1, 2019		studies are beneficial for health outcomes in individuals with disorders other than those listed above as proven. **Non-invasive automatic, portable, or automated point of care nerve conduction monitoring systems (e.g., the NC-stat® System, the Brevio® NCS-Monitor, and the Advance™ System) that test only distal motor latencies and conduction velocities are unproven and not medically necessary for the purpose of electrodiagnostic testing.** Studies of these devices are primarily small case series or uncontrolled or poorly controlled comparison studies. Large, robust randomized, controlled studies are needed to prove the safety and efficacy of this technology. **Physiologic Recording of Movement Disorder Symptoms** **Physiologic recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor using wearable devices with accelerometers or gyroscopes is unproven and not medically necessary.** There is insufficient evidence and too few studies to conclude that these devices improve therapeutic responses for the purpose of decreasing bradykinesia, dyskinesia, and tremor in individuals with movement disorder symptoms. Well-designed controlled studies are needed to determine the usefulness of these devices. **Quantitative Sensory Testing** **Quantitative sensory testing, including monofilament testing, pressure-specified sensory testing, computer assisted sensory examinations, and current perception threshold (CPT) testing is unproven and not medically necessary.** Definitive conclusions for quantitative sensory testing including monofilament testing, pressure-specified sensory testing, computer assisted sensory examinations, and CPT testing cannot be determined due to limited evidence that this testing impacts patient management. Further research is needed to validate the clinical utility of quantitative sensory testing. **Visual Evoked Potentials for Glaucoma** **Visual evoked potential testing is unproven and not medically necessary for diagnosing and evaluating glaucoma.** Visual evoked potentials (VEPs) show some promise as a tool for diagnosing glaucoma, but definitive conclusions cannot be drawn due to evidence that is

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Neurophysiologic Testing and Monitoring *(continued)*	Jan. 1, 2019		limited and inconsistent. Evidence regarding the use of VEP testing for monitoring progression in individuals at risk for glaucoma is too limited to allow evaluation of sensitivity or positive predictive value. VEP has not been shown to be as good or better than standard visual testing in managing individuals with glaucoma. This policy does not address intraoperative neurophysiologic testing.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Botulinum Toxins A and B	Dec. 1, 2018	• 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			
Enzyme Replacement Therapy	Dec. 1, 2018	• Revised coverage rationale: ○ Updated list of applicable enzyme replacement therapy products; added Revcovi™ (elapegademase-lvlr) ○ Added language to indicate: ▪ Revcovi (elapegademase-lvlr) is proven for the treatment of severe combined immunodeficiency disease (SCID) associated with a deficiency of adenosine deaminase (ADA) ▪ Revcovi is medically necessary when the additional criteria [listed in the policy] are met • Added lists of applicable codes for Revcovi: ○ HCPCS code J3590 ○ ICD-10 diagnosis code D81.3 • Updated supporting information to reflect the most current background information, clinical evidence, FDA information, and references	This policy refers to the following enzyme replacement therapy products: • Adagen® (pegademase bovine) • Aldurazyme® (laronidase) • Elaprase® (idursulfase) • Fabrazyme® (agalsidase beta) • Kanuma™ (sebelipase alfa) • Lumizyme® (alglucosidase alfa) • Mepsevii™ (vestronidase alfa-vjbk) • Naglazyme® (galsulfase) • Revcovi™ (elapegademase-lvlr) • Vimizim® (elosulfase alfa) **I. Adagen (pegademase bovine) and Revcovi (elapegademase-lvlr) are proven for the treatment of severe combined immunodeficiency disease (SCID) associated with a deficiency of adenosine deaminase (ADA).** **Adagen and Revcovi are medically necessary when the following additional criteria are met:** A. For initial therapy, all of the following: 1. Diagnosis of SCID; **and** 2. Deficiency of adenosine deaminase is confirmed by any of the following: a. Deficiency or absence of ADA in plasma, lysed erythrocytes, fibroblasts (cultured from amniotic fluid), or chorionic villi b. Increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates compared to laboratory standard c. Decrease in ATP concentration in erythrocytes d. Molecular genetic confirmation of mutations in both alleles of the *ADA1* gene e. Positive screening by T cell receptor excision circles (TRECs); **and** 3. One of the following: a. Patient is not a suitable candidate for hematopoietic cell

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Enzyme Replacement Therapy *(continued)*	Dec. 1, 2018		transplantation (HCT) b. Patient has failed HCT; **and** 4. Dosing is in accordance with the United States Food and Drug Administration approved labeling: dosing is started at 10 U/kg for the first dose, and titrated up to a maximum dose of 30 U/kg per week; **and** 5. Initial authorization will be for no more than 12 months. B. For continuation therapy, all of the following: 1. Patient has previously received treatment with pegademase therapy; **and** 2. Patient has experienced a positive clinical response to pegademase therapy (e.g., normalization of plasma ADA activity, erythrocyte dATP levels, improvement of disease symptoms, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling: appropriate maintenance dosing, up to a maximum dose of 30 U/kg per week; **and** 4. Reauthorization will be for no more than 12 months. **II. Aldurazyme (laronidase) is proven for the treatment of mucopolysaccharidosis I (MPS I).** **Aldurazyme is medically necessary when the following additional criteria are met:** A. For initial therapy, all of the following: 1. Diagnosis of any of the MPS I syndromes confirmed by one the following: a. Hurler variant (severe mucopolysaccharidosis I; also MPS IH) b. Hurler-Scheie variant (attenuated mucopolysaccharidosis I; also MPS IHS) c. Scheie variant (attenuated mucopolysaccharidosis I; also MPS IS); **and** 2. Diagnosis of MPS I is confirmed by either of the following: a. Deficiency or absence of fibroblast or leukocyte enzyme activity of alpha-L-iduronidase enzyme activity b. Molecular genetic confirmation of mutations in the alpha-L-iduronidase gene; **and**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Enzyme Replacement Therapy *(continued)*	Dec. 1, 2018		3. Presence of clinical signs and symptoms of the disease (e.g., asymptomatic with affected older sibling, cardiac abnormalities, corneal clouding, dysostosis multiplex, hepatomegaly, restrictive lung disease, etc.); **and** 4. Dosing is in accordance with the United States Food and Drug Administration approved labeling: Administered dose does not exceed 0.58 mg/kg intravenously once every week; **and** 5. Initial authorization will be for no more than 12 months. B. For continuation therapy, all of the following: 1. Patient has previously received treatment with laronidase therapy; **and** 2. Patient has experienced a positive clinical response to laronidase therapy (e.g., improved endurance, improved functional capacity, reduced urine dermatan sulfate/heparan sulfate excretion, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling: administered dose does not exceed 0.58 mg/kg intravenously once every week; **and** 4. Reauthorization will be for no more than 12 months. **III. Elaprase (idursulfase) is proven for the treatment of mucopolysaccharidosis II (MPS II, Hunter Syndrome). Elaprase is medically necessary when the following additional criteria are met:** A. For initial therapy, all of the following: 1. Diagnosis of MPS II confirmed by one the following: a. Deficiency in iduronate 2-sulfatase enzyme activity as measured in fibroblasts or leukocytes combined with normal enzyme activity level of another sulfatase b. Molecular genetic testing for deletion or mutations in the iduronate 2-sulfatase gene; **and** 2. Presence of clinical signs and symptoms of the disease (e.g., hepatosplenomegaly, skeletal deformities, dysostosis, neurocognitive decline, cardiovascular disorders, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling: administered dose does not exceed 0.5 mg/kg intravenously once every week; **and** 4. Initial authorization will be for no more than 12 months.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Enzyme Replacement Therapy *(continued)*	Dec. 1, 2018		B. For continuation therapy, all of the following: 1. Patient has previously received treatment with idursulfase therapy; **and** 2. Patient has experienced a positive clinical response to idursulfase therapy (e.g., improved endurance, improved functional capacity, reduced spleen volume, reduced urine glycosaminoglycan excretion, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling: administered dose does not exceed 0.5 mg/kg intravenously once every week; **and** 4. Reauthorization will be for no more than 12 months. **IV. Fabrazyme (agalsidase beta) is proven for the treatment of Fabry disease.** **Fabrazyme is medically necessary when the following additional criteria are met:** A. For initial therapy, all of the following: 1. Diagnosis of Fabry disease as confirmed by one the following: a. Absence or deficiency (< 5% of mean) of normal alpha-galactosidase A (α-Gal A) enzyme activity in leukocytes, dried blood spots, or serum analysis b. Molecular genetic testing for deletion or mutations in the galactosidase alpha gene; **and** 2. Presence of clinical signs and symptoms of the disease (e.g., Acroparesthesias, angiokeratomas, whorls, anhidrosis/hypohidrosis, renal disease, exercise/heat/cold intolerance, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling: administered dose does not exceed 1 mg/kg intravenously every two weeks; **and** 4. Initial authorization will be for no more than 12 months. B. For continuation therapy, all of the following: 1. Patient has previously received treatment with agalsidase therapy; **and** 2. Patient has experienced a positive clinical response to agalsidase therapy (e.g., improved renal function, reduction in mean plasma GL-3 levels, decreased GL-3 inclusions, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Enzyme Replacement Therapy *(continued)*	Dec. 1, 2018		Administration approved labeling: administered dose does not exceed 1 mg/kg intravenously every two weeks; **and** 4. Reauthorization will be for no more than 12 months. **V. Kanuma (sebelipase alfa) is proven for the treatment of lysosomal acid lipase deficiency [LAL-D, Wolman disease (WD), cholesteryl ester disease (CESD)].** **Kanuma is medically necessary when the following additional criteria are met:** A. For initial therapy, all of the following: 1. Diagnosis of lysosomal acid lipase deficiency [LAL-D, Wolman disease (WD), cholesteryl ester disease (CESD)] as confirmed by one the following: a. Absence or deficiency lysosomal acid lipase activity by dried blood spot test b. Molecular genetic testing for deletion or mutations in the lipase A, lysosomal acid type (*LIPA*) gene; **and** 2. Presence of clinical signs and symptoms of the disease (e.g., abdominal distention, hepatosplenomegaly, liver fibrosis, ascities, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling by one of the following: a. For rapidly progressive disease presenting within the first 6 months of life: administered initial starting dose is 1 mg/kg intravenously once weekly, up to a maximum of 3 mg/kg once weekly b. Pediatric and adult patients with stabilized disease: administered dose does not exceed 1 mg/kg intravenously every other week; **and** 4. Initial authorization will be for no more than 12 months. B. For continuation therapy, all of the following: 1. Patient has previously received treatment with sebelipase therapy; **and** 2. Patient has experienced a positive clinical response to sebelipase therapy [e.g., improved disease symptoms, improvement of laboratory values (LFTs, cholesterol, triglycerides), etc.]; **and** 3. Dosing is in accordance with the United States Food and Drug

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Enzyme Replacement Therapy *(continued)*	Dec. 1, 2018		Administration approved labeling by one of the following: a. For rapidly progressive disease presenting within the first 6 months of life: administered dose is 1 mg/kg intravenously once weekly, up to a maximum of 3 mg/kg once weekly b. Pediatric and adult patients with stabilized disease: administered dose does not exceed 1 mg/kg intravenously every other week; **and** 4. Reauthorization will be for no more than 12 months. **VI. Lumizyme (alglucosidase alfa) is proven for the treatment of Pompe disease.** **Lumizyme is medically necessary when the following additional criteria are met:** A. For initial therapy, one (1. or 2.) of the following: 1. All of the following for infantile-onset Pompe disease: a. Diagnosis of infantile-onset Pompe disease as confirmed by one the following: i. Absence or deficiency (<1% of the lab specific normal mean) acid alpha-glucosidase deficiency (GAA) activity in skin fibroblasts ii. Molecular genetic testing for deletion or mutations in the *GAA* gene; **and** b. Presence of clinical signs and symptoms of the disease (e.g., cardiac hypertrophy, respiratory distress, skeletal muscle weakness, etc.); **and** c. Dosing is in accordance with the United States Food and Drug Administration approved labeling: administered dose does not exceed 20 mg/kg intravenously every two weeks; **and** d. Initial authorization will be for no more than 12 months; **or** 2. All of the following for late-onset (non-infantile) Pompe disease: a. Diagnosis of late-onset Pompe disease as confirmed by one the following: i. Absence or deficiency (<40% of the lab specific normal mean) acid alpha-glucosidase deficiency (GAA) activity in lymphocytes, fibroblasts or muscle

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Enzyme Replacement Therapy *(continued)*	Dec. 1, 2018		ii. Molecular genetic testing for deletion or mutations in the *GAA* gene; **and** b. Presence of clinical signs and symptoms of the disease (e.g., cardiac hypertrophy, respiratory distress, skeletal muscle weakness, etc.); **and** c. Dosing is in accordance with the United States Food and Drug Administration approved labeling: administered dose does not exceed 20 mg/kg intravenously every two weeks; **and** d. Initial authorization will be for no more than 12 months. B. For continuation therapy, all of the following: 1. Patient has previously received treatment with alglucosidase therapy; **and** 2. Patient has experienced a positive clinical response to alglucosidase therapy (e.g., improved respiratory/cardiac function, improved endurance, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling: administered dose does not exceed 20 mg/kg intravenously every two weeks; **and** 4. Reauthorization will be for no more than 12 months. **VII. Mepsevii (vestronidase alfa-vjbk) is proven for the treatment of mucopolysaccharidosis VII (Sly syndrome).** **Mepsevii is medically necessary when the following additional criteria are met:** A. For initial therapy, all of the following: 1. Diagnosis of mucopolysaccharidosis VII confirmed by **either** of the following: a. Absence or deficiency of fibroblast or leukocyte enzyme activity of beta glucuronidase b. Molecular genetic confirmation of mutations in the *GUSB* gene; **and** 2. Presence of clinical signs and symptoms of the disease (e.g., enlarged liver and spleen, joint limitations, airway obstruction or pulmonary problems, limitation of mobility while still ambulatory, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug

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REVISED			
Enzyme Replacement Therapy *(continued)*	Dec. 1, 2018		Administration approved labeling: Administered dose does not exceed 4 mg/kg intravenously once every two weeks; **and** 4. Initial authorization will be for no more than 12 months. B. For continuation therapy, all of the following: 1. Patient has previously received treatment with vestronidase therapy; **and** 2. Patient has experienced a positive clinical response to vestronidase therapy (e.g., improved endurance, improved functional capacity, improved pulmonary function, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling: Administered dose does not exceed 4 mg/kg intravenously once every two weeks; **and** 4. Reauthorization will be for no more than 12 months. **VIII. Naglazyme (galsulfase) is proven for the treatment of mucopolysaccharidosis VI (Maroteaux-Lamy syndrome). Naglazyme is medically necessary when all of the following additional criteria are met:** A. For initial therapy, all of the following: 1. Diagnosis of mucopolysaccharidosis VI confirmed by either of the following: a. Absence or deficiency of fibroblast or leukocyte enzyme activity of N-acetylgalactosamine 4-sulfatase (arylsulfatase) b. Molecular genetic confirmation of mutations in the ASB gene (5q13-q14); **and** 2. Presence of clinical signs and symptoms of the disease (e.g., kyphoscoliosis, genu valgum, pectus carinatum, gait disturbance, growth deficiency, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling: administered dose does not exceed 1 mg/kg intravenously once every week; **and** 4. Initial authorization will be for no more than 12 months. B. For continuation therapy, all of the following: 1. Patient has previously received treatment with galsulfase therapy; **and** 2. Patient has experienced a positive clinical response to galsulfase therapy (e.g., improved endurance, improved functional capacity, reduced urine dermatan sulfate excretion, etc.); **and**

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Enzyme Replacement Therapy *(continued)*	Dec. 1, 2018		3. Dosing is in accordance with the United States Food and Drug Administration approved labeling: administered dose does not exceed 1 mg/kg intravenously once every week; **and** 4. Reauthorization will be for no more than 12 months. **IX. Vimizim (elosulfase alfa) is proven for the treatment of mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome). Vimizim is medically necessary when all of the following additional criteria are met:** A. For initial therapy, all of the following: 1. Diagnosis of Morquio A syndrome confirmed by either of the following: a. Absence or deficiency of fibroblast or leukocyte GALNS enzyme activity b. Molecular genetic testing for mutations in the *GALNS* gene (16q24.3); **and** 2. Presence of clinical signs and symptoms of the disease (e.g., kyphoscoliosis, genu valgum, pectus carinatum, gait disturbance, growth deficiency, etc.); **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling: administered dose does not exceed 2 mg/kg IV once every week; **and** 4. Initial authorization will be for no more than 12 months. B. For continuation therapy, all of the following: 1. Patient has previously received treatment with elosulfase alfa therapy; **and** 2. Patient has experienced a positive clinical response to elosulfase alfa therapy (e.g., improved endurance, improved functional capacity, reduced urine keratan sulfate excretion); **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling: administered dose does not exceed 2 mg/kg IV once every week; **and** 4. Reauthorization will be for no more than 12 months.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Onpattro™ (Patisiran)	Dec. 1, 2018	• Revised coverage rationale; updated medical necessity criteria for: **Initial Therapy** ○ Added criteria requiring: ▪ [Onpattro is] prescribed by or in consultation with a neurologist ▪ Patient has not had a liver transplant ○ Modified list of examples of signs and symptoms of the disease [polyneuropathy of hATTR amyloidosis] to include peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc. ○ Replaced criterion requiring "patient is not receiving *patisiran* in combination with oligonucleotide agents (e.g., inotersen) or tafamidis meglumine" with "patient is not receiving *Onpattro* in combination with oligonucleotide agents [e.g., *Tegsedi* (inotersen)] or tafamidis meglumine" **Continuation Therapy** ○ Replaced references to "patisiran" with "Onpattro" ○ Added criterion requiring [Onpattro is] prescribed by or in consultation with a neurologist ○ Modified list of examples of a positive clinical response to	**Onpattro (patisiran) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Please reference the policy titled Review at Launch for New to Market Medications for additional details.** **Onpattro (patisiran) is proven for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis.** **Onpattro (patisiran) is medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in patients who meet ALL of the following criteria:** I. For **initial therapy**, **all** of the following: A. **Both** of the following: 1. Diagnosis of hATTR amyloidosis with polyneuropathy 2. Documentation that the patient has a pathogenic TTR mutation (e.g., V30M); **and** B. Prescribed by or in consultation with a neurologist; **and** C. Documentation of **one** of the following: 1. Patient has a baseline polyneuropathy disability (PND) score ≤IIIb 2. Patient has a baseline FAP Stage 1 or 2; **and** D. Patient has not had a liver transplant; **and** E. Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.); **and** F. Patient is not receiving Onpattro in combination with either of the following: 1. Oligonucleotide agents [e.g., Tegsedi (inotersen)] 2. Tafamidis meglumine; **and** G. Patisiran dosing is in accordance with the US Food and Drug Administration prescribing information (0.3 mg/kg up to a maximum of 30mg, every 3 weeks); **and** H. Initial authorization is for no more than 12 months. II. For **continuation therapy**, **all** of the following:

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Onpattro™ (Patisiran) *(continued)*	Dec. 1, 2018	Onpattro to include improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc. ○ Replaced criterion requiring "patient is not receiving *patisiran* in combination with oligonucleotide agents (e.g., inotersen) or tafamidis meglumine" with "patient is not receiving *Onpattro* in combination with oligonucleotide agents [e.g., *Tegsedi* (inotersen)] or tafamidis meglumine"	A. Patient has previously received treatment with Onpattro; **and** B. Prescribed by or in consultation with a neurologist; **and** C. Documentation of **one** of the following: 1. Patient continues to have a polyneuropathy disability (PND) score ≤IIIb 2. Patient continues to have a FAP Stage 1 or 2; **and** D. Documentation that the patient has experienced a positive clinical response to Onpattro (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.); **and** E. Patient is not receiving Onpattro in combination with either of the following: 3. Oligonucleotide agents [e.g., Tegsedi (inotersen)] 4. Tafamidis meglumine; **and** F. Patisiran dosing is in accordance with the US Food and Drug Administration prescribing information (0.3 mg/kg up to a maximum of 30mg, every 3 weeks); **and** G. Authorization is for no more than 12 months. **Onpattro (patisiran) is unproven and not medically necessary for the treatment of:** • Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis • Primary or leptomeningeal amyloidosis
Self-Administered Medications	Dec. 1, 2018	• Updated list of related policies; added reference link to the policy titled *Hereditary Angioedema (HAE), Treatment and Prophylaxis* • Revised coverage rationale: ○ Added language to indicate: ▪ Self-administered medications are excluded from standard medical benefit plans ▪ We will determine if a medication is self-administered based on	Self-administered medications are excluded from standard medical benefit plans. We will determine if a medication is self-administered based on the following: I. Medication is **not** typically administered or directly supervised by a qualified provider or licensed/certified health professional in an outpatient setting; **and** II. Medication does **not** require continuous or periodic monitoring immediately before, during, or after administration by a qualified provider or licensed/certified health professional in an outpatient setting; **and** III. Route of administration (e.g., oral, topical, rectal, subcutaneous or some intramuscular injections); **and** IV. Dosage form (e.g., prefilled syringe, auto-injector, tablet, capsule, suppository); **and**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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Self-Administered Medications *(continued)*	Dec. 1, 2018	the [listed criteria] ○ Removed language indicating: ▪ This Medical Benefit Drug Policy is to support benefit plan language to exclude from medical coverage those medications that are determined as 'self-administered' by the patient for whom the drug is prescribed ▪ A medication may be determined "self-administered" and will not be covered under the medical benefit when the [listed] evidence is taken into consideration • Updated and reformatted list of applicable self-administered medications and corresponding HCPCS codes: ○ Transferred content to linked file format ○ Added: ▪ Ajovy (fremanezumab-vfrm) (HCPCS codes C9399 and J3590) ▪ Takhzyro (lanadelumab-flyo) (HCPCS codes C9029 and J3590)	V. Acuity of condition (e.g., chronic disease); **and** VI. Frequency of administration; **and** VII. The medication is **not** specifically allowed under the medical benefit; **and** VIII. Standards of medical practice allowing for self-administration (e.g., self-infused hemophilia factor); **and** IX. Evaluation of any established medical literature or compendia including but not limited to: A. FDA approved prescribing information B. Manufacturer provided medical literature C. Peer reviewed medical literature D. Evidence-based practice guidelines E. Self-administration utilization statistics F. Compendia (e.g., IBM Micromedex® DRUGDEX®, Clinical Pharmacology)

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Clinical Trials	Dec. 1, 2018	• Updated coverage rationale; replaced references to "Covered Health Service(s)" with "Covered Health *Care* Service(s)" • Updated definition of "Covered Health Care Service(s)"
Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements	Jan. 1, 2019	• Updated coverage rationale: **Indications for Coverage** ○ Replaced language indicating: ▪ "Breast pumps may be covered *as DME*" with "breast pumps may be covered *under the preventive care services benefit*" ▪ "Mobility Devices (manual wheelchair, electric wheelchairs, transfer chair or scooters) are a Covered Health Care Service" with "Mobility Devices (manual wheelchair, electric wheelchairs, transfer chair or scooters*/power-operated vehicles*) are a Covered Health Care Service *when Medically Necessary*" ○ Added language to clarify cranial *molding* helmets (cranial remolding orthosis, billed with S1040) used to facilitate a successful post-surgical outcome are covered as DME and are not subject to the orthotic device exclusion **Coverage Limitations and Exclusions** ○ Replaced language indicating "cranial helmets *used for other indications other than those in the Indications for Coverage [of the policy]* are excluded from coverage *under the orthotics exclusion*" with "cranial *molding* helmets *and cranial banding* are excluded from coverage *except when used to avoid the need for surgery and/or to facilitate a successful surgical outcome*" ○ Added language to clarify powered *and non-powered* exoskeleton devices are excluded from coverage • Updated definition of: ○ Covered Health Care Service(s) ○ Medically Necessary

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Preventive Care Services	Jan. 1, 2019	• Revised list of applicable procedure and diagnosis codes for: **Preventive Care Services** *Genetic Counseling and Evaluation for BRCA Testing; and BRCA Lab Screening* ○ Updated list of applicable CPT codes for BRCA lab screening to reflect annual code edits:	Refer to the policy for complete details on the coverage guidelines for Preventive Care Services.

Coverage Determination Guideline (CDG) Updates

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Preventive Care Services *(continued)*	Jan. 1, 2019	▪ Added 81163, 81164, 81165, 81166, and 81167 ▪ Removed 81211, 81213, and 81214 *Cervical Cancer Screening* (previously titled *Cervical Cancer Screening, Pap Smear*) ○ Updated service description: ▪ Removed March 2012 USPSTF 'A' rating ▪ Added August 2018 USPSTF 'A' rating to indicate: - The USPSTF recommends screening for cervical cancer every 3 years with cervical cytology alone in women aged 21 to 29 years - For women aged 30 to 65 years, the USPSTF recommends screening: • Every 3 years with cervical cytology alone, • Every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or • Every 5 years with hrHPV testing in combination with	

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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Preventive Care Services *(continued)*	Jan. 1, 2019	cytology (cotesting) ○ Reformatted lists of applicable codes and preventive benefit instructions for cervical cytology (pap test) ○ Added lists of applicable codes for human papillomavirus DNA testing (HPV): ▪ CPT/HCPCS codes: 0500T, 87624, 87625, and G0476 ▪ Diagnosis codes: Z00.00, Z00.01, Z01.411, Z01.419, Z11.51, and Z12.4 ○ Added preventive benefit instructions for human papillomavirus DNA testing (HPV) to indicate: ▪ Benefit age limit of 30 years and older ▪ Requires one of the diagnosis codes listed in [the policy for Human Papillomavirus DNA Testing (HPV)] *Cholesterol Screening (Lipid Disorders Screening)* ○ Updated list of applicable CPT codes for cholesterol screening to reflect annual code edits; added 83722 *Breast Cancer: Medications for Risk Reduction* [previously titled *Chemoprevention of Breast Cancer (Counseling)*]	

Coverage Determination Guideline (CDG) Updates

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Preventive Care Services *(continued)*	Jan. 1, 2019	○ Updated service description: ▪ Removed July 2002 USPSTF 'B' rating ▪ Added September 2013 USPSTF 'B' rating to indicate the USPSTF recommends: - Clinicians engage in shared, informed decision making with women who are at increased risk for breast cancer about medications to reduce their risk - For women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene *Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions* (previously titled *Screening for Obesity in Adults*) ○ Updated service description: ▪ Removed June 2012 USPSTF 'B' rating ▪ Added September 2018 USPSTF 'B' rating to indicate the USPSTF recommends that clinicians offer or refer	

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Preventive Care Services *(continued)*	Jan. 1, 2019	adults with a body mass index (BMI) of 30 or higher (calculated as weight in kilograms divided by height in meters squared) to intensive multicomponent behavioral interventions ○ Removed reference link to *Wellness Examinations* section of the policy for additional information on applicable codes *Dyslipidemia Screening (Bright Futures)* ○ Updated list of applicable CPT codes for dyslipidemia screening lab work to reflect annual code edits; added 83722 **Preventive Immunizations** *Seasonal Influenza ('flu')* ○ Updated list of applicable CPT codes to reflect annual code edits; added 90689 *Rotavirus (RV1, RV5)* ○ Changed applicable age group for CPT codes 90680 and 90681 from "adult and pediatric" to "pediatric" **Expanded Women's Preventive Health** *Screening for Cervical Cancer* ○ Replaced list of applicable codes and preventive benefit instructions for *Human Papillomavirus DNA Testing*	

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Preventive Care Services *(continued)*	Jan. 1, 2019	*(HPV)* with instruction to refer to the *Cervical Cancer Screening* row in the *Preventive Care Services* section of the policy for details **Diagnosis Codes** *Pregnancy Diagnosis Code List* ○ Added O60.00,O60.02, O60.03, O88.011, O88.012, O88.013, O88.019, O88.111, O88.112, O88.113, O88.119, O88.211, O88.212, O88.213, O88.219, O88.311, O88.312, O88.313, O88.319, O88.811, O88.812, O88.813, O88.819 ○ Removed O86.00, O86.01, O86.02, O86.03, O86.04, O86.09	

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Specialty Medication Administration – Site of Care Review Guidelines	Jan. 1, 2019	• Updated list of related policies; added reference link to the policy titled: ○ *Ilumya™ (Tildrakizumab-Asmn)* ○ *Onpattro™ (Patisiran)* • Revised coverage rationale: ○ Replaced reference(s) to: ▪ "Patient" with "individual" ▪ "Persons" with "individuals" ○ Updated list of applicable specialty medications that require healthcare provider administration; added Ilumya™ (Tildrakizumab-asmn) and Onpattro™ (Patisiran) ○ Modified language to clarify the listed MCG™ Care Guidelines should be referenced for medical necessity *clinical coverage* criteria • Updated supporting information to reflect the most current references	This guideline addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes: • 19 Off Campus-Outpatient Hospital; and • 22 On Campus-Outpatient Hospital. Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion 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 intravenous medication infusion is medically necessary for individuals who meet any of the following criteria (submission of medical records is required, detailing at least ONE of the following):** • Medically unstable based upon submitted clinical history; or • Initial medication infusion of or re-initiation after more than 6 months following discontinuation of therapy; or • Previous experience of a severe adverse event following infusion. Examples include but are not limited to anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; or • Continuing experience of adverse events that cannot be mitigated by pre-medications or infusion rate adjustments; or • Physically and/or cognitively impaired **and** no home caregiver available; or • Difficulty establishing and maintaining patent vascular access; or • Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy. This policy applies to these specialty medications that require healthcare provider administration: • Actemra® (Tocilizumab) • Adagen® (Pegademase bovine) • Aldurazyme® (Laronidase) • Aralast NP™ (A1-PI) • Benlysta® (Belimumab)

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Specialty Medication Administration – Site of Care Review Guidelines *(continued)*	Jan. 1, 2019		• Cerezyme® (Imiglucerase) • Crysvita® (Burosumab) • Elaprase® (Idursulfase) • Elelyso® (Taliglucerase) • Entyvio® (Vedolizumab) • Exondys 51™ (Eteplirsen) • Fabrazyme® (Agalsidase beta) • Glassia™ (A1-PI) • Ilaris® (Canakinumab) • Ilumya™ (Tildrakizumab-asmn) • Inflectra™ (Infliximab-dyyb) • Kanuma® (Sebelipase alfa) • Lumizyme® (Alglucosidase alfa) • Mepsevii™ (Vestronidase alfa-vjbk) • Naglazyme® (Galsulfase) • Ocrevus™ (Ocrelizumab) • Onpattro™ (Patisiran) • Orencia® (Abatacept) • Prolastin®-C™ (A1-PI) • Radicava™ (edaravone) • Remicade® (Infliximab) • Renflexis™ (Infliximab-abda) • Simponi Aria® (Golimumab) • Soliris® (Eculizumab) • Trogarzo™ (Ibalizumab) • Vimizim® (Elosulfase alfa) • VPRIV® (Velaglucerase) • Zemaira® (A1-PI) For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 22nd edition, 2018, Home Infusion Therapy, CMT: CMT-0009(SR).