



October 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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UPDATED		
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Oct. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language to clarify the listed services are: <ul style="list-style-type: none"> Proven and medically necessary (as described); see the referenced MCG™ Care Guidelines for <i>medical necessity</i> clinical coverage criteria Unproven and not medically necessary (as described) Investigational, unproven and not medically necessary (as described)
Elbow Replacement Surgery (Arthroplasty)	Oct. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language to clarify: <ul style="list-style-type: none"> The listed service is proven and medically necessary in certain circumstances See the referenced MCG™ Care Guidelines for <i>medical necessity</i> clinical coverage criteria
Electrical and Ultrasound Bone Growth Stimulators	Oct. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language to clarify: <ul style="list-style-type: none"> The listed devices are proven and medically necessary in certain circumstances See the referenced MCG™ Care Guidelines for <i>medical necessity</i> clinical coverage criteria
Epiduroscopy, Epidural Lysis of Adhesions and Functional Anesthetic Discography	Oct. 1, 2018	<ul style="list-style-type: none"> Replaced references to “patient(s)” with “individual(s)” Updated coverage rationale: <ul style="list-style-type: none"> Modified language pertaining to clinical evidence/study findings; replaced language indicating “there is insufficient evidence to conclude that epiduroscopy can improve <i>patient</i> management or <i>disease</i> outcomes” with “there is insufficient evidence to conclude that epiduroscopy can improve management or outcomes of <i>[the listed] conditions</i>” Updated supporting information to reflect the most current clinical evidence, CMS information, and references
Hysterectomy for Benign Conditions	Oct. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language to clarify: <ul style="list-style-type: none"> The listed service is proven and medically necessary in certain circumstances See the referenced MCG™ Care Guidelines for <i>medical necessity</i> clinical coverage criteria
Obstructive Sleep Apnea Treatment	Oct. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language to clarify the listed services are: <ul style="list-style-type: none"> Proven and medically necessary (as described); see the referenced MCG™ Care Guidelines for <i>medical necessity clinical coverage</i> criteria Unproven and not medically necessary (as described)
Pneumatic Compression Devices	Oct. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language to clarify: <ul style="list-style-type: none"> The listed devices are proven and medically necessary in certain circumstances See the referenced MCG™ Care Guidelines for <i>medical necessity</i> clinical coverage criteria
Shoulder Replacement Surgery (Arthroplasty)	Oct. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language to clarify: <ul style="list-style-type: none"> The listed service is proven and medically necessary in certain circumstances See the referenced MCG™ Care Guidelines for <i>medical necessity</i> clinical coverage criteria

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Policy Title	Effective Date	Summary of Changes	
UPDATED			
Surgical Treatment for Spine Pain	Oct. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language to clarify the listed services are: <ul style="list-style-type: none"> Proven and medically necessary (as described); see the referenced MCG™ Care Guidelines for <i>medical necessity</i> clinical coverage criteria Unproven and not medically necessary (as described) 	
Total Knee Replacement Surgery (Arthroplasty)	Oct. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language to clarify: <ul style="list-style-type: none"> The listed service is proven and medically necessary in certain circumstances See the referenced MCG™ Care Guidelines for <i>medical necessity</i> clinical coverage criteria 	
Unicondylar Spacer Devices for Treatment of Pain or Disability	Oct. 1, 2018	<ul style="list-style-type: none"> Added definition of: <ul style="list-style-type: none"> Unicompartmental Unicondylar Interpositional Spacer Updated supporting information to reflect the most current description of services, clinical evidence, and CMS information 	
Warming Therapy and Ultrasound Therapy for Wounds	Nov. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language pertaining to clinical evidence/study findings to indicate: <ul style="list-style-type: none"> The safety and efficacy of warming therapy or noncontact normothermic wound therapy for the treatment of chronic wounds has not been established in the published medical literature; limitations of the existing studies include small samples, a lack of controls and/or randomization, and short follow-up times Evidence for the use of low frequency ultrasound to treat wounds consists of studies that lack adequate sample sizes and proper control groups; further controlled trials with larger sample sizes are necessary to demonstrate that low frequency ultrasound is beneficial for health outcomes in patients with wounds Updated list of applicable HCPCS codes; removed A4639 and E0221 Updated supporting information to reflect the most current clinical evidence, CMS information, and references 	
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Electric Tumor Treatment Field Therapy	Nov. 1, 2018	<ul style="list-style-type: none"> Revised coverage rationale: <ul style="list-style-type: none"> Newly diagnosed histologically-confirmed Supratentorial glioblastoma [known also as glioblastoma multiforme (GBM)] <ul style="list-style-type: none"> Added language to clarify guidelines apply to <i>newly diagnosed</i> Supratentorial glioblastoma 	<p>The use of U.S. Food and Drug Administration (FDA) approved devices to generate electric tumor treatment fields (TTF) to treat newly diagnosed histologically-confirmed Supratentorial glioblastoma (known also as glioblastoma multiforme [GBM] or World Health Organization [WHO] grade IV astrocytoma) is proven and medically necessary when used according to FDA labeled indications, contraindications, warnings and precautions, and when ALL of the following criteria are met:</p> <ul style="list-style-type: none"> Initial treatment with radiation therapy has been completed; and Individual is receiving Temozolomide; and

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Electric Tumor Treatment Field Therapy (continued)	Nov. 1, 2018	<ul style="list-style-type: none"> ○ Removed language indicating this service is proven/medically necessary “as adjunctive therapy” [when criteria is met] ○ Modified coverage criteria: <ul style="list-style-type: none"> ▪ Replaced criterion requiring “initial treatment <i>with debulking surgery or biopsy followed by chemoradiation with concomitant Temozolomide and radiotherapy</i> has been completed” with “initial treatment <i>with radiation therapy</i> has been completed” ▪ Added criterion requiring the individual is receiving Temozolomide <p>Recurrent GBM</p> <ul style="list-style-type: none"> ○ Added language to indicate: <ul style="list-style-type: none"> ▪ The use of FDA approved devices to generate electric tumor treatment fields (TTF) is proven and medically necessary following radiologically-confirmed recurrence of GBM in the supratentorial region of the brain after initial chemotherapy and when all of the following criteria are met: <ul style="list-style-type: none"> - The device is used as a monotherapy; and 	<ul style="list-style-type: none"> • Individual has a Karnofsky Performance Status (KPS) score of ≥ 60; and • Individual or caregiver has been trained and is willing and able to apply the device daily; and • Individual is willing to wear the device at least 18 hours daily. <p>Recurrent GBM</p> <p>The use of FDA approved devices to generate electric TTF is proven and medically necessary following radiologically-confirmed recurrence of GBM in the supratentorial region of the brain after initial chemotherapy and when ALL of the following criteria are met:</p> <ul style="list-style-type: none"> • The device is used as a monotherapy • Individual has a KPS score of ≥ 60; and • Individual or caregiver has been trained and is willing and able to apply the device daily; and • Individual is willing to wear the device at least 18 hours daily. <p>When all of the above criteria are met for either newly diagnosed or recurrent GBM, an initial 3 months of electric TTF therapy will be approved.</p> <p>Subsequent approval(s) for continuation of electric TTF is based on:</p> <ul style="list-style-type: none"> • MRI scan has been performed $\leq 2-4$ months prior to request and documents no evidence of disease progression. ; and • KPS score of ≥ 60; and • Documentation that the individual has been wearing the device at least 18 hours daily. <p>The use of devices to generate electric tumor treatment fields (TTF) is considered investigational, unproven, and not medically necessary when the criteria above are not met and for all other indications.</p> <p>The FDA has not approved the use of electric TTF devices for indications other than GBM. Further studies are needed to determine the safety and long-term efficacy of electric TTF therapy for other types of cancer.</p> <p>Computer software used for therapeutic radiology clinical treatment planning in conjunction with electric tumor treatment field (TTF) therapy is unproven and not medically necessary.</p> <p>There is insufficient evidence to establish the efficacy of these products in the long-term outcomes of patients receiving electric TTF therapy.</p>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Electric Tumor Treatment Field Therapy (continued)	Nov. 1, 2018	<ul style="list-style-type: none"> - Individual has a KPS score of >60; and - Individual or caregiver has been trained and is willing and able to apply the device daily; and - Individual is willing to wear the device at least 18 hours daily <ul style="list-style-type: none"> ▪ When all of the criteria [listed in the policy] are met for recurrent GBM, an initial 3 months of electric TTF therapy will be approved ○ Modified coverage criteria for continuation of electric TTF therapy to indicate subsequent approval is based on: <ul style="list-style-type: none"> ▪ MRI scan has been performed <2-4 months prior to request and documents no evidence of disease progression; and ▪ KPS score of >60; and ▪ Documentation that the individual has been wearing the device at least 18 hours daily • Updated supporting information to reflect the most current clinical evidence, FDA information, and references 	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD)	Nov. 1, 2018	<ul style="list-style-type: none"> • Revised coverage rationale: <ul style="list-style-type: none"> ○ Updated list of unproven/not medically necessary endoscopic plication or suturing devices: <ul style="list-style-type: none"> ▪ Added "MUSE™ System (anterior partial fundoplication)" ▪ Replaced "EsophyX™ System with SerosaFuse™ Fastener" with "EsophyX™ System Fastener" ○ Added language to indicate endoluminal therapy with GERDx™ is investigational, unproven and not medically necessary for treating gastroesophageal reflux disease (GERD) as it has not received U.S. Food and Drug Administration (FDA) approval <ul style="list-style-type: none"> ▪ There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of endoscopic plication with this device ▪ Well-designed clinical trials with long-term follow up are required to establish that this therapy benefits health outcomes in individuals with GERD by eliminating symptoms, preventing recurrence of symptoms or progression 	<p>Endoscopic therapies are unproven and not medically necessary for treating gastroesophageal reflux disease (GERD).</p> <p>Endoscopic therapies include:</p> <ul style="list-style-type: none"> • Radiofrequency energy: <ul style="list-style-type: none"> ○ Stretta® System • Endoscopic plication or suturing: <ul style="list-style-type: none"> ○ Bard® EndoCinch™ Endoscopic Suturing System ○ Endoscopic Suturing Device (ESD) ○ Surgical Endoscopic Plication System (EPS) ○ EsophyX™ System Fastener (transoral incisionless fundoplication [TIF] procedure) ○ MUSE™ System (anterior partial fundoplication) • Injection or implantation techniques: <ul style="list-style-type: none"> ○ Plexiglas® (polymethylmethacrylate [PMMA]) procedure ○ Durasphere® <p>The safety and long-term efficacy of endoscopic therapies for the treatment of GERD have not been established in the published medical literature. Well-designed clinical trials with long-term follow up are required to establish that endoscopic therapies benefit health outcomes in individuals with GERD by eliminating symptoms, preventing recurrence of symptoms or progression of disease, healing esophagitis, and reducing or eliminating the need for pharmacologic therapy.</p> <p>Endoluminal therapy with GERDx™ is investigational, unproven and not medically necessary for treating GERD as it has not received U.S. Food and Drug Administration (FDA) approval.</p> <p>There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of endoscopic plication with this device. Well-designed clinical trials with long-term follow up are required to establish that this therapy benefits health outcomes in individuals with GERD by eliminating symptoms, preventing recurrence of symptoms or progression of disease, healing esophagitis, and reducing or eliminating the need for pharmacologic therapy.</p> <p>The LINX™ Reflux Management System is unproven and not medically necessary for treating GERD.</p> <p>The safety and long-term efficacy of this system has not been established in the peer-reviewed medical literature.</p>

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REVISED			
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) <i>(continued)</i>	Nov. 1, 2018	<p>of disease, healing esophagitis, and reducing or eliminating the need for pharmacologic therapy</p> <ul style="list-style-type: none"> ○ Modified language pertaining to clinical evidence/study findings for: <ul style="list-style-type: none"> Endoscopic Therapies for Treating GERD <ul style="list-style-type: none"> ▪ Replaced reference to “patients” with “individuals” ▪ Added language to clarify the safety and <i>long-term</i> efficacy of endoscopic therapies for the treatment of GERD have not been established in the published medical literature ▪ Removed language indicating current studies are generally of small to moderate size, lack adequate control or comparison groups, and provide only short-term follow-up The LINX™ Reflux Management System for Treating GERD <ul style="list-style-type: none"> ▪ Revised language to indicate the safety and long-term efficacy of this system has not been established in the peer-reviewed medical 	See the Medical Policy titled <i>Bariatric Surgery</i> for information regarding endoscopic therapies for the treatment of obesity.

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REVISED			
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) <i>(continued)</i>	Nov. 1, 2018	<p>literature; see the policy titled <i>Bariatric Surgery</i> for information regarding endoscopic therapies for the treatment of obesity</p> <ul style="list-style-type: none"> Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references 	
Transcatheter Heart Valve Procedures	Dec. 1, 2018	<ul style="list-style-type: none"> Revised coverage rationale: <ul style="list-style-type: none"> Replaced references to "patient(s)" with "individual(s)" Removed reference links to the <i>Benefit Considerations</i> section of the policy Removed language indicating percutaneous transcatheter mitral valve annuloplasty via the coronary sinus is investigational due to lack of FDA approval Added language to indicate transcatheter tricuspid valve repair or replacement is unproven and not medically necessary <ul style="list-style-type: none"> There is insufficient evidence in the clinical literature demonstrating the long-term safety and efficacy of transcatheter procedures for treating tricuspid valve disease Further results from prospective, randomized 	<p><u>Aortic Valve</u></p> <p>Transcatheter aortic heart valve replacement is proven and medically necessary for treating intermediate or higher risk* individuals, when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions and ALL of the following criteria are met:</p> <ul style="list-style-type: none"> Severe calcific native aortic valve stenosis as indicated by ONE of the following: <ul style="list-style-type: none"> Mean aortic valve gradient >40 mmHg; or Peak aortic jet velocity >4.0 m/s; or Aortic valve area of ≤ 0.8 cm² Individual is symptomatic (New York Heart Association [NYHA] class II or greater) and symptoms are due to aortic valve stenosis Individual requires valve replacement surgery but is at intermediate or higher risk* for serious surgical complications or death from open valve replacement surgery as determined by an interventional cardiologist and an experienced cardiothoracic surgeon. <p>*Society of Thoracic Surgeons (STS) risk categories are as follows (Nishimura et al., 2014):</p> <ul style="list-style-type: none"> Intermediate - predicted risk of mortality (PROM) score of 4-8% High - PROM score of >8% <p>For a complete list of indications, contraindications, warnings and precautions by device, see the <i>FDA</i> section of the policy.</p> <p><u>Pulmonary Valve</u></p> <p>Transcatheter pulmonary heart valve replacement is proven and</p>

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REVISED			
Transcatheter Heart Valve Procedures <i>(continued)</i>	Dec. 1, 2018	<p>controlled trials are needed to determine safety, efficacy, durability and the ideal candidates for the procedure</p> <ul style="list-style-type: none"> Updated list of applicable CPT codes; added 33999 Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references 	<p>medically necessary, when used according to FDA labeled indications, contraindications, warnings and precautions, in individuals with right ventricular outflow tract (RVOT) dysfunction with one of the following clinical indications for intervention:</p> <ul style="list-style-type: none"> Moderate or greater pulmonary regurgitation; and/or Pulmonary stenosis with a mean RVOT gradient \geq 35 mmHg. <p><u>Mitral Valve</u></p> <p>Transcatheter mitral valve replacement is unproven and not medically necessary. There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of catheter-delivered mitral valve prostheses for treating mitral disease. Further results from prospective, randomized controlled trials are needed to determine device durability and the ideal candidates for the procedure.</p> <p>Percutaneous transcatheter mitral valve leaflet repair is unproven and not medically necessary. There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of catheter-delivered mitral valve leaflet repair devices for treating mitral regurgitation. Further results from prospective, randomized controlled trials are needed to determine device durability and the ideal candidates for the procedure.</p> <p>Percutaneous transcatheter mitral valve annuloplasty via the coronary sinus is unproven and not medically necessary. There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of coronary sinus annuloplasty devices for treating mitral regurgitation. Further results from prospective, randomized controlled trials are needed to determine safety, efficacy, durability and the ideal candidates for the procedure.</p> <p><u>Tricuspid Valve</u></p> <p>Transcatheter tricuspid valve repair or replacement is unproven and not medically necessary. There is insufficient evidence in the clinical literature demonstrating the long-term safety and efficacy of transcatheter procedures for treating tricuspid valve disease. Further results from prospective, randomized controlled trials are needed to determine safety, efficacy, durability and the ideal candidates</p>

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Transcatheter Heart Valve Procedures <i>(continued)</i>	Dec. 1, 2018		<p>for the procedure.</p> <p>Valve-in-Valve (ViV) Procedures Transcatheter heart valve replacement within a failed bioprosthesis (valve-in-valve procedure) is unproven and not medically necessary. There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of ViV procedures. Further results from prospective studies are needed to determine the ideal candidates for this procedure.</p> <p>Cerebral Protection Transcatheter cerebral protection devices (e.g., Sentinel™) are unproven and not medically necessary. There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of transcatheter cerebral protection devices in improving neurological and cognitive function following transcatheter aortic valve replacement.</p>
Visual Information Processing Evaluation and Orthoptic and Vision Therapy	Nov. 1, 2018	<ul style="list-style-type: none"> • Reformatted and revised coverage rationale: <ul style="list-style-type: none"> ○ Removed and relocated definitions to the <i>Definitions</i> section of the policy ○ Replaced language indicating “Orthoptic or Vision Therapy is unproven and not medically necessary for treating [the listed indications]” with “Orthoptic Therapy or Vision Therapy is unproven and not medically necessary for treating <i>all other indications</i> [not listed as proven/medically necessary] <i>including but not limited to</i> [the listed indications]” ○ Removed list of specific Orthoptic Therapy or Vision Therapy devices that are unproven and not medically 	<p>Occlusion Therapy is proven and medically necessary for treating Amblyopia.</p> <p>Prism Adaptation Therapy is proven and medically necessary for treating Esotropia.</p> <p>Orthoptic Therapy or Vision Therapy is proven and medically necessary for treating Convergence Insufficiency.</p> <p>Orthoptic Therapy or Vision Therapy is unproven and not medically necessary for treating all other indications including but not limited to:</p> <ul style="list-style-type: none"> • Dyslexia or other learning and reading disabilities • Exotropia (eye deviates outward) without convergence insufficiency • Nystagmus (involuntary movement of the eyeballs) • Convergence excess (esotropia is greater for near vision than for far vision) • Divergence insufficiency • Divergence excess • Stroke or traumatic brain injury with visuospatial deficit, hemispatial neglect, or visual loss <p>Additional well-designed studies with larger sample sizes and longer follow-</p>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Visual Information Processing Evaluation and Orthoptic and Vision Therapy (continued)	Nov. 1, 2018	<p>necessary for treating dyslexia and other learning and reading disabilities</p> <ul style="list-style-type: none"> ○ Modified language pertaining to clinical evidence/study findings to indicate: <ul style="list-style-type: none"> ▪ Additional well-designed studies with larger sample sizes and longer follow-up periods are needed to establish the clinical utility of Orthoptic or Vision Therapy for [the listed unproven and not medically necessary] indications ▪ The available data supporting the use of visual perceptual therapy to treat learning or developmental disabilities is inadequate to support its use; additional well-designed studies with larger sample sizes and long-term follow-up are needed to establish the diagnostic utility of this therapy ▪ There is inadequate evidence of efficacy for [Vision Restoration Therapy (VRT)]; additional randomized controlled trials with larger sample sizes and longer follow-up periods 	<p>up periods are needed to establish the clinical utility of Orthoptic or Vision Therapy for these indications.</p> <p>The use of visual information processing evaluations to diagnose reading or learning disabilities is unproven and not medically necessary. There is inadequate clinical evidence to support the use of visual information processing evaluations for diagnosing reading or learning-related disabilities. Additional well-designed studies with larger sample sizes are needed to establish the diagnostic utility of this procedure.</p> <p>Visual perceptual therapy is unproven and not medically necessary for treating any type of learning disability or language disorder, including developmental delay. The available data supporting the use of visual perceptual therapy to treat learning or developmental disabilities is inadequate to support its use. Additional well-designed studies with larger sample sizes and long-term follow-up are needed to establish the diagnostic utility of this therapy.</p> <p>Vision Restoration Therapy (VRT) is unproven and not medically necessary for treating visual field deficits following stroke or neurotrauma. There is inadequate evidence of efficacy for this treatment. Additional randomized controlled trials with larger sample sizes and longer follow-up periods are needed to determine the clinical utility of VRT.</p>

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REVISED			
Visual Information Processing Evaluation and Orthoptic and Vision Therapy <i>(continued)</i>	Nov. 1, 2018	<p>are needed to determine the clinical utility of VRT</p> <ul style="list-style-type: none"> • Added definition of: <ul style="list-style-type: none"> ○ Amblyopia ○ Convergence Insufficiency ○ Estropia ○ Exotropia ○ Occlusion Therapy ○ Orthoptic Therapy ○ Prism Adaptation Therapy ○ Strabismus ○ Vision Restoration Therapy (VRT) ○ Vision Therapy • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references 	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	
UPDATED			
White Blood Cell Colony Stimulating Factors	Oct. 1, 2018	<ul style="list-style-type: none"> Updated list of applicable HCPCS codes to reflect quarterly code edits; added Q5110 	
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Hereditary Angioedema (HAE), Treatment and Prophylaxis	Oct. 1, 2018	<ul style="list-style-type: none"> Updated list of related policies; added reference link to the policy titled <i>Self-Administered Medications</i> Added language to indicate Takhzyro (lanadelumab) is a self-administered injection and obtained under the members' pharmacy benefit Revised coverage rationale: Berinert, Ruconest, and Kalbitor <ul style="list-style-type: none"> Reformatted coverage statements; separated content addressing "proven" and "medically necessary" guidelines/criteria Added medical necessity criteria requiring: <ul style="list-style-type: none"> Diagnosis of hereditary angioedema (HAE) as confirmed by one of the following: <ul style="list-style-type: none"> Confirmed monoallelic mutation known to cause HAE in either the SERPING1 or F12 gene A C4 level below the lower limit of normal and one of the 	<p>This policy refers only to the following drug products:</p> <ul style="list-style-type: none"> C1 Esterase Inhibitor [human] <ul style="list-style-type: none"> Berinert® (for intravenous injection) Cinryze® (for intravenous injection) C1 Esterase Inhibitor [recombinant] <ul style="list-style-type: none"> Ruconest® (for intravenous injection) Plasma Kallikrein Inhibitor [human] <ul style="list-style-type: none"> Kalbitor® (ecallantide, for subcutaneous injection) <p>Firazyr (icatibant), Haegarda (C1 esterase inhibitor [human]), and Takhzyro (lanadelumab) are self-administered injections and obtained under the members' pharmacy benefit.</p> <p>Hereditary Angioedema</p> <p>I. Berinert, Ruconest, and Kalbitor are proven for the treatment of hereditary angioedema (HAE) when both of the following are met:</p> <ol style="list-style-type: none"> Used for treatment of an acute HAE attack; and Not used in combination with other approved treatments for acute HAE attacks (e.g. Berinert, Cinryze, Firazyr, Kalbitor or Ruconest). <p>Berinert, Ruconest, and Kalbitor are medically necessary for the treatment of hereditary angioedema (HAE) when all of the following criteria are met:</p> <ol style="list-style-type: none"> Diagnosis of hereditary angioedema (HAE) as confirmed by one of the following: <ol style="list-style-type: none"> Confirmed monoallelic mutation known to cause HAE in either the SERPING1 or F12 gene A C4 level below the lower limit of normal and one of the following (per laboratory standard): <ol style="list-style-type: none"> C1 inhibitor (C1-INH) antigenic level below the lower limit of normal

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Hereditary Angioedema (HAE), Treatment and Prophylaxis (continued)	Oct. 1, 2018	<p>following (per laboratory standard):</p> <ul style="list-style-type: none"> • C1 inhibitor (C1-INH) antigenic level below the lower limit of normal • C1-INH functional level below the lower limit of normal <ul style="list-style-type: none"> ▪ Prescribed by one of the following specialists: <ul style="list-style-type: none"> - Immunologist - Allergist - Rheumatologist ▪ For Berinert and Ruconest only: Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug <p>Cinryze</p> <ul style="list-style-type: none"> ○ Replaced reference to “C1 esterase inhibitors for prophylaxis” with “products indicated for prophylaxis” ○ Updated list of drugs that cannot be used in combination with other products indicated for the prophylaxis against HAE attacks; added “Takhzyro” ○ Added criteria requiring: <ul style="list-style-type: none"> ▪ Diagnosis of hereditary angioedema (HAE) as confirmed by one of the 	<ul style="list-style-type: none"> b. C1-INH functional level below the lower limit of normal <p>and</p> <ul style="list-style-type: none"> B. Used for treatment of an acute HAE attack; and C. Not used in combination with other approved treatments for acute HAE attacks (e.g. Berinert, Cinryze, Firazyr, Kalbitor or Ruconest); and D. Prescribed by one of the following specialists: <ol style="list-style-type: none"> 1. Immunologist 2. Allergist 3. Rheumatologist <p>and</p> <ul style="list-style-type: none"> E. For Berinert and Ruconest requests only; physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug. <p>II. Cinryze is proven for the treatment of hereditary angioedema (HAE) when one of the following are met:</p> <ul style="list-style-type: none"> A. Both of the following: <ol style="list-style-type: none"> 1. Used for prophylaxis against HAE attacks; and 2. Not used in combination with other products indicated for the prophylaxis against HAE attacks (e.g. Haegarda, Takhzyro) <p>or</p> <ul style="list-style-type: none"> B. Both of the following: <ol style="list-style-type: none"> 1. Used for treatment of an acute HAE attack; and 2. Not used in combination with other approved treatments for acute HAE attacks (e.g. Berinert, Cinryze, Firazyr, Kalbitor or Ruconest). <p>Cinryze is medically necessary for the treatment of hereditary angioedema (HAE) when all of the following criteria are met:</p> <ul style="list-style-type: none"> A. Diagnosis of hereditary angioedema (HAE) as confirmed by one of the following: <ol style="list-style-type: none"> 1. Confirmed monoallelic mutation known to cause HAE in either the SERPING1 or F12 gene 2. A C4 level below the lower limit of normal and one of the following (per laboratory standard): <ol style="list-style-type: none"> a. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal b. C1-INH functional level below the lower limit of normal

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REVISED			
Hereditary Angioedema (HAE), Treatment and Prophylaxis (continued)	Oct. 1, 2018	<p>following:</p> <ul style="list-style-type: none"> - Confirmed monoallelic mutation known to cause HAE in either the SERPING1 or F12 gene - A C4 level below the lower limit of normal and one of the following (per laboratory standard): <ul style="list-style-type: none"> • C1 inhibitor (C1-INH) antigenic level below the lower limit of normal • C1-INH functional level below the lower limit of normal ▪ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug ▪ Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Cinryze ○ Updated list of allowed specialist prescribers; added "rheumatologist" ○ Removed criterion requiring 	<p>and</p> <p>B. Prescribed by one of the following specialists:</p> <ol style="list-style-type: none"> 1. Immunologist 2. Allergist 3. Rheumatologist <p>and</p> <p>C. Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; and</p> <p>D. One of the following:</p> <ol style="list-style-type: none"> 1. Both of the following: <ol style="list-style-type: none"> a. Used for treatment of an acute HAE attack; and b. Not used in combination with other approved treatments for acute HAE attacks (e.g. Berinert, Firazyr, Kalbitor or Ruconest) or 2. All of the following: <ol style="list-style-type: none"> a. For prophylaxis against HAE attacks; and b. Not used in combination with other products indicated for the prophylaxis against HAE attacks (e.g. Haegarda, Takhzyro); and c. Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Cinryze.

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Hereditary Angioedema (HAE), Treatment and Prophylaxis (continued)	Oct. 1, 2018	<ul style="list-style-type: none"> one of the following: <ul style="list-style-type: none"> ▪ For continuation of prior therapy; or ▪ History of failure, contraindication, or intolerance of 17-alpha alkylated androgen (e.g., danazol, oxandrolone) or antifibrinolytics (e.g., aminocaproic acid, tranexamic acid) • Updated supporting information to reflect the most current clinical evidence and references 	
Maximum Dosage	Oct. 1, 2018	<ul style="list-style-type: none"> • Revised coverage rationale: <ul style="list-style-type: none"> ○ Updated list of applicable drug products; added pegfilgrastim-jmdb (Fulphila™) ○ Added HCPCS code based maximum dosage information for Fulphila™ (pegfilgrastim-jmdb): <ul style="list-style-type: none"> ▪ Maximum Dosage per Administration: 6 mg total dose ▪ HCPCS Code: Q5108 ▪ Maximum Allowed: 12 HCPCS units (0.5 mg per unit) ○ Added maximum allowed quantities for National Drug Code (NDC) billing for Fulphila™ (pegfilgrastim-jmdb): <ul style="list-style-type: none"> ▪ How Supplied: 6 mg/0.6 mL prefilled syringe ▪ National Drug Code: 	<p>This policy provides information about the maximum dosage per administration for certain medications administered by a medical professional.</p> <p>Drug Products:</p> <ul style="list-style-type: none"> • bevacizumab (Avastin®) • eculizumab (Soliris®) • infliximab (Remicade®) • infliximab-dyyb (Inflectra™) • infliximab-abda (Renflexis™) • omalizumab (Xolair®) • pegfilgrastim (Neulasta®) • pegfilgrastim-jmdb (Fulphila™) • rituximab (Rituxan®) • trastuzumab (Herceptin®) • ustekinumab (Stelara®) • vedolizumab (Entyvio®) • zoledronic acid (zoledronic acid, Reclast® and Zometa®) <p>Most medications have a maximum dosage based upon body surface area or patient weight or a set maximal dosage independent of patient body size, and are proven when used according to labeled indications or when otherwise supported by published clinical evidence.</p>

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Maximum Dosage <i>(continued)</i>	Oct. 1, 2018	<p>67457-0833-06</p> <ul style="list-style-type: none"> ▪ Maximum Allowed: 0.6 mL • Updated list of applicable HCPCS codes; added Q5108 • Updated list of applicable NDCs; added 67457-0833-06 • Updated supporting information to reflect the most current references 	<p>The medications included in this policy when given beyond maximum dosages based upon body surface area or patient weight or a set maximal dosage independent of patient body size are not supported by package labeling or published clinical evidence and are unproven.</p> <p>This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (119 kg) and body surface area (2.45 meters²) in the U.S. (Fryar, 2012). In some cases, the maximum allowed units and/or vials may exceed the upper level limit as defined within this policy due to an individual patient body weight > 119 kg or body surface area > 2.45 meters².</p> <p>Refer to the policy for complete details on <i>Maximum Dosage</i> guidelines.</p>

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UPDATED			
Infertility Services	Oct. 1, 2018	<ul style="list-style-type: none"> Updated supporting information to reflect the most current references; no change to coverage rationale 	
Orthognathic (Jaw) Surgery	Oct. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language to clarify the listed MCG™ Care Guidelines should be referenced for <i>medical necessity clinical coverage criteria</i> 	
Speech Language Pathology Services	Oct. 1, 2018	<ul style="list-style-type: none"> Updated coverage rationale; modified language to clarify the listed MCG™ Care Guidelines should be referenced for <i>medical necessity clinical coverage criteria</i> 	
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Habilitative Services and Outpatient Rehabilitation Therapy	Nov. 1, 2018	<ul style="list-style-type: none"> Reorganized and renamed policy; combined content previously outlined in the Coverage Determination Guidelines titled: <ul style="list-style-type: none"> <i>Habilitative Services for Essential Health Groups</i> <i>Rehabilitation Services (Outpatient)</i> Revised coverage rationale: <ul style="list-style-type: none"> Updated indications of coverage for: <ul style="list-style-type: none"> Habilitative Services <ul style="list-style-type: none"> Replaced language indicating “for plans that provide <i>Essential Health Benefits</i>, benefits are provided for inpatient and outpatient habilitative services when all of the [listed] conditions are met” with “for plans that provide <i>coverage for habilitative services</i>, benefits are provided for inpatient and outpatient habilitative services 	<p><u>Indications for Coverage</u></p> <p><i>Habilitative Services</i></p> <p>Habilitative services are Medically Necessary, Skilled Care Services that are part of a prescribed treatment plan or maintenance program* to help a person with a disabling condition to keep, learn or improve skills and functioning for daily living. For information about skilled care, see the Coverage Determination Guideline titled <i>Skilled Care and Custodial Care Services</i>. (Large group plans that include coverage for habilitative services do not include coverage for maintenance programs, or services to keep skills and functioning for daily living.)</p> <p>Benefits for outpatient and inpatient habilitative services are limited to:</p> <ul style="list-style-type: none"> Physical therapy Occupational therapy Manipulative Treatment Speech therapy (see the Coverage Determination Guideline titled <i>Speech Language Pathology Services</i>) Post-cochlear implant aural therapy Cognitive therapy <p>*Certain plans may not include coverage for all of the above therapies, and state mandates may require coverage for thereapies not mentioned above. [For example, with respect to the treatment of autism and autism spectrum disorder, Maryland includes behavioral health treatment (including applied behavioral analysis), and psychological care within the scope of habilitative service]. Please see the member specific benefit plan document and state mandate requirements for details.</p>

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Habilitative Services and Outpatient Rehabilitation Therapy (continued)	Nov. 1, 2018	<p>when all of the [listed] conditions are met"</p> <ul style="list-style-type: none"> ▪ Replaced reference(s) to: <ul style="list-style-type: none"> - "[Services] provided in the <i>home</i>" with "[services] provided in the <i>member's residence</i>" - "Outpatient <i>rehabilitative services</i>" with "outpatient <i>rehabilitation</i>" - "Home health care <i>section of the plan</i>" with "home health care <i>benefit</i>" - "Cardiac and pulmonary therapy" with "Cardiac <i>Rehabilitation</i> and pulmonary therapy" <p>Rehabilitation Services – Outpatient</p> <ul style="list-style-type: none"> ▪ Replaced reference(s) to: <ul style="list-style-type: none"> - "<i>Rehabilitative services</i>" with "<i>rehabilitation therapy services</i>" (where applicable) - "[Services] provided in the <i>home</i>" with "[services] provided in the <i>member's residence</i>" - "Cerebral vascular accident" with 	<p>For plans that provide coverage for habilitative services, benefits are provided for inpatient and outpatient habilitative services when all of the following conditions are met:</p> <ul style="list-style-type: none"> • The covered member has a disabling condition • The treatment is prescribed by a Physician • The treatment is administered by a licensed speech-language pathologist, licensed audiologist, licensed occupational therapist, licensed physical therapist, Physician, or other provider who acts within the scope of his or her license will be considered on the same basis as a Physician, and • Treatment must be proven and not Experimental or Investigational. <p>Outpatient habilitative services are those that are either:</p> <ul style="list-style-type: none"> • Provided in a physician's office • Provided on an outpatient basis at a hospital or Alternate Facility (such as health care facility that provides outpatient rehabilitation), or • Provided in the member's residence from an independent physical or occupational therapist (a physical or occupational therapist that is not affiliated with a home health agency). <p>Certain states may require coverage of habilitative services in other locations. (For example, in Maryland, benefits for habilitative services may not be denied on the sole basis that the services are received in an educational setting.) Please see the member specific benefit plan document and state mandate requirements for details.</p> <p>Outpatient habilitative services provided in the member's residence from a home health agency are addressed under the home health care benefit. The home health care benefit only applies to habilitative services that are rendered by a home health agency.</p> <p>Inpatient habilitative services are those received while in an inpatient setting. Depending on where the inpatient habilitative services are provided, benefits are the same as the applicable inpatient benefit category (inpatient hospital, skilled nursing facility/inpatient rehabilitation facility).</p> <p>We may require that a treatment plan be provided, request medical records, clinical notes, or other necessary data to allow us to substantiate that initial or continued medical treatment is Medically Necessary. When the treating provider expects that continued treatment is or will be required to allow the</p>

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Habilitative Services and Outpatient Rehabilitation Therapy (continued)	Nov. 1, 2018	<p>“cerebral vascular accident (<i>stroke</i>)”</p> <ul style="list-style-type: none"> - “Home health care section of the <i>plan</i>” with “home health care section of the <i>member specific benefit plan document</i>” o Updated coverage limitations and exclusions for rehabilitation therapy: <ul style="list-style-type: none"> ▪ Added language to clarify <i>coverage is excluded for</i> confinement, treatment, services or supplies related to learning and intellectual disabilities ▪ Added language to indicate: <ul style="list-style-type: none"> - Coverage is excluded for services that are solely educational or vocational in nature or otherwise paid under state or federal law for purely educational services - Coverage is excluded for Custodial Care, respite care, day care, therapeutic recreation, vocational training and residential treatment - Certain state mandates do not 	<p>covered person to achieve progress that is capable of being demonstrated (measurable progress), we may request a treatment plan that includes:</p> <ul style="list-style-type: none"> • Diagnosis • Proposed treatment by type, frequency, and expected duration of treatment • Expected treatment goals • Frequency of treatment plan updates <p>Certain state mandates may limit the frequency for requesting plan treatment progress (for example Maryland is limited to no more than one request per year). See the member specific benefit plan document and state mandate requirements for details.</p> <p>Coverage of Durable Medical Equipment and prosthetic devices, when used as a component of habilitative services, are described under the Durable Medical Equipment (DME) Orthotics and Supplies or Prosthetic Devices benefit sections of the member specific benefit plan document, and may require a separate review. Check the member specific benefit plan document.</p> <p>Refer to the member specific benefit plan document for any applicable benefit visit limits for habilitative services.</p> <p>Cardiac Rehabilitation and pulmonary therapy are covered under the rehabilitation services benefit. These are not habilitative services.</p> <p>Rehabilitation Services - Outpatient</p> <p>Benefits for outpatient rehabilitation services include:</p> <ul style="list-style-type: none"> • Physical therapy • Occupational therapy • Manipulative Treatment • Speech therapy for disorders of speech, language, voice, communication and auditory processing only when the disorder results from injury, stroke, cancer, Congenital Anomaly or autism spectrum disorder (see the Coverage Determination Guideline titled <i>Speech Language Pathology Services</i>) • Pulmonary rehabilitation therapy • Cardiac Rehabilitation therapy • Post-cochlear implant aural therapy • Cognitive rehabilitation therapy when Medically Necessary following a

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Habilitative Services and Outpatient Rehabilitation Therapy (continued)	Nov. 1, 2018	<p>allow visit limits or limits on the number of hours of treatment; see the member specific benefit plan document and state mandate requirements for details</p> <ul style="list-style-type: none"> ▪ Removed language indicating coverage is excluded for educational assessments and ongoing treatment, and vocational training ▪ Replaced language indicating: <ul style="list-style-type: none"> - "Coverage is excluded for services that are not <i>rehabilitative</i>" with "coverage is excluded for services that are not <i>considered to be rehabilitation therapy</i>" - "Maintenance therapy is not a rehabilitation service and is excluded from <i>coverage under the rehabilitation benefit</i>" with "maintenance therapy is not a rehabilitation <i>therapy service</i> and 	<p>post-traumatic brain injury or cerebral vascular accident (stroke).</p> <p>Certain plans may not include coverage for all of the above therapies and state mandates may require coverage for therapies not mentioned above. Please see the member specific benefit plan document and state mandate requirements for details.</p> <p>Benefits are provided for outpatient rehabilitation services when all of the following conditions are met:</p> <ul style="list-style-type: none"> • The treatment is administered by a Physician or a licensed therapy provider (i.e., licensed speech-language pathologist, licensed audiologist, licensed occupational therapist, licensed physical therapist, or other provider who acts within the scope of his or her license) • The treatment is not for maintenance/preventive purposes • The services are not considered to be habilitative. <p>Outpatient rehabilitation services are those that are either:</p> <ul style="list-style-type: none"> • Provided in a physician's office, • Provided on an outpatient basis at a hospital or Alternate Facility (such as health care facility that provides outpatient rehabilitative services), or • Provided in the member's residence from an independent physical or occupational therapist (a physical or occupational therapist that is not affiliated with a home agency). <p>Certain states may require coverage for therapies of rehabilitative services in other locations. Please see the member specific benefit plan document and state mandate requirements for details.</p> <p>Outpatient rehabilitation therapy services that are provided in the member's residence from a home health agency are addressed under the home health care section of the member specific benefit plan document. The home health care benefit only applies to rehabilitation therapy services that are rendered by a home health agency.</p> <p>Rehabilitation therapy services that are received while in an inpatient setting, e.g., inpatient hospital, inpatient rehabilitation facility or skilled nursing facility, are part of the applicable inpatient setting benefit. Depending on the inpatient setting, benefits are the same as the applicable inpatient benefit category (hospital inpatient, skilled nursing facility/inpatient rehabilitation</p>

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Habilitative Services and Outpatient Rehabilitation Therapy (continued)	Nov. 1, 2018	<p>is excluded from the rehabilitation <i>therapy</i> benefit”</p> <ul style="list-style-type: none"> - “Coverage is excluded for rehabilitation services that are done for preventive reasons” with “coverage is excluded for rehabilitation <i>therapy</i> services that are done for preventive reasons” • Updated definitions: <ul style="list-style-type: none"> ○ Removed definition of: <ul style="list-style-type: none"> ▪ Habilitative Services ▪ Rehabilitation Services – Outpatient Therapy ○ Revised definition of: <ul style="list-style-type: none"> ▪ Medically Necessary ▪ Skilled Care • Updated list of applicable CPT/HCPCS codes (and corresponding notations): <ul style="list-style-type: none"> ○ Added language to clarify <i>when indicated as habilitative codes</i>, the [listed] CPT and HCPCS codes only apply to habilitative services when billed with one of the habilitative diagnosis codes in the primary position on the claim ○ Removed notation pertaining to codes for rehabilitation services that can be billed by 	<p>facility benefit).</p> <p>Refer to the member specific benefit plan document for any applicable benefit visit limits for rehabilitation services.</p> <p>Pulmonary therapy does not include respiratory therapy. Respiratory therapy is a therapeutic service and not included in the benefit limits for pulmonary therapy.</p> <p>Coverage Limitations and Exclusions <i>The following limitations and exclusions apply to both habilitative services, and rehabilitation therapy:</i></p> <ul style="list-style-type: none"> • Coverage is excluded for services that are solely educational or vocational in nature or otherwise paid under state or federal law for purely educational services. • Coverage is excluded when the patient does not meet criteria for coverage as indicated in the <i>Indications for Coverage</i> section above and the member specific benefit plan document. • Coverage is excluded if the service is considered by UnitedHealthcare to be Unproven, Investigational or Experimental. • Coverage is excluded for Custodial Care, respite care, day care, therapeutic recreation, vocational training and residential treatment. • Coverage is excluded once the treatment plan goals are met. • Coverage is excluded for physiological modalities and procedures that result in similar or redundant therapeutic effects when performed on the same body region during the same visit or office encounter. An example includes, but is not limited to, the same day combined use of hot packs, ultrasound and iontophoresis in the treatment of strain. • Coverage is excluded for programs that do not require the supervision of Physician and/or a licensed therapy provider. • Coverage is excluded for Work Hardening (refer to the <i>Definitions</i> section of the policy). • Coverage is excluded for confinement, treatment, services or supplies that are required: a) only by a court of law, or b) only for insurance, travel, employment, and school or camp purposes. Please check the member specific plan benefit document and state mandates. • Coverage is excluded for services beyond any visit limits specified in the member specific benefit plan document. (Certain state mandates do not allow visit limits or limits on the number of hours of treatment. Please

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Habilitative Services and Outpatient Rehabilitation Therapy (continued)	Nov. 1, 2018	<p>both an occupational therapist and a physical therapist</p> <ul style="list-style-type: none"> Replaced reference to "aural rehabilitation" with "aural rehabilitation (<i>post-cochlear implant</i>)" Added language to indicate S8990 applies to the small group habilitative benefit only Revised description for 97116, 97542, and G0238 	<p>see the member specific benefit plan document and state mandate requirements for details.)</p> <ul style="list-style-type: none"> Coverage is excluded for gym and fitness club memberships and fees, health club fees, exercise equipment or supplies. Biofeedback services are excluded on most plans. Please check the member specific benefit plan document. <p>Additional limitations and exclusions for <i>habilitative services</i>:</p> <ul style="list-style-type: none"> A service that does not help the covered person to meet or maintain functional goals in a treatment plan within a prescribed time frame is not a habilitative service. large group plans that include coverage for habilitative services do not include coverage for maintenance programs, or services to keep skills and functioning for daily living. In the absence of a disabling condition, services to improve general physical condition are excluded from coverage. <p>Additional limitations and exclusions for <i>rehabilitation therapy</i>:</p> <ul style="list-style-type: none"> Coverage is excluded for services that are not considered to be rehabilitation therapy (see <i>Indications for Coverage</i> section above). Coverage is excluded if the services provided are considered non-skilled or custodial care. For additional information, see the Coverage Determination Guideline titled <u><i>Skilled Care and Custodial Care Services</i></u>. Maintenance therapy is not a rehabilitation therapy service and is excluded from the rehabilitation therapy benefit. (For additional information on maintenance therapy, see the <i>Habilitative Services</i> section above.) Coverage is excluded for rehabilitation therapy services that are done for preventive reasons. Confinement, treatment, services or supplies related to learning and intellectual disabilities. Coverage is excluded for general education and training (video or computerized interactive program). Viewing of films or videotapes, listening to audiotapes, and completing interactive computer programs. Services to improve general physical condition that are provided to reduce potential risk factors, where significant therapeutic improvement is not expected, are not Rehabilitation Services and are excluded from coverage.

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REVISED			
Prosthetic Devices, Wigs, Specialized, Microprocessor or Myoelectric Limbs	Nov. 1, 2018	<ul style="list-style-type: none"> Revised coverage rationale: <ul style="list-style-type: none"> Replaced references to “covered health service” with “covered health <i>care</i> service” Prosthetic Devices and Wigs <ul style="list-style-type: none"> Modified list of Prosthetic Devices that replace a limb or external body part; replaced language indicating “benefits include breast prosthesis and mastectomy bras; these items are always covered on an unlimited basis as to number of items and dollar amounts covered as required by the Women’s Health and Cancer Act of 1998” with “breast prosthesis [are covered] as required by the Women’s Health and Cancer Rights Act of 1998; benefits include mastectomy bras” Replaced language indicating “manufactured Prosthetic Devices must be approved by the Food and Drug Administration (FDA) and otherwise generally considered to be safe and effective for the purposes intended and the item must be reasonable and necessary for the individual member” with “manufactured Prosthetic Devices must be approved by the Food and Drug Administration (FDA) or otherwise generally 	<p>Indications for Coverage</p> <p>Prosthetic Devices and Wigs</p> <ul style="list-style-type: none"> A determination of coverage for the prostheses is based on the member’s potential functional abilities. Potential functional ability is based on the reasonable expectations of the Prosthetist, and treating physician, considering factors including, but not limited to: <ul style="list-style-type: none"> The member’s past history (including prior prosthetic use if applicable); and The member’s current condition including the status of the residual limb and the nature of other medical problems. Prosthetic Device coverage is limited to those Prosthetic Devices that replace a limb or external body part that are listed below: <ul style="list-style-type: none"> Artificial arms, legs, feet and hands. Artificial eyes, ears, and nose. Breast prosthesis as required by the <i>Women’s Health and Cancer Rights Act of 1998</i>. Benefits include mastectomy bras. Note: For lymphedema stockings for the arm, refer to the Coverage Determination Guideline titled <i>Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements</i>. Prosthetic Devices when covered, regardless of the setting or vendor from whom the Prosthetic Device is dispensed, are covered under the Prosthetic Devices section of the benefit document. Prosthetic Devices must be ordered by or under the direction of a physician. Manufactured Prosthetic Devices must be approved by the Food and Drug Administration (FDA) or otherwise generally considered to be safe and effective by Generally Accepted Standards of Medical Practice. Implantable devices/prostheses, such as artificial heart valves, are not prosthetics. If covered, these devices would be covered as a surgical service. Coverage is available for repair and replacement, when it is not due to theft, loss, misuse, malicious damage or gross neglect. Several states mandate coverage for prosthetics. Please check the member specific benefit document for coverage. <p>Specialized, Microprocessor or Myoelectric Limbs</p> <p>Computerized, bionic, microprocessor or myoelectric terms are considered the same for the purpose of this policy. Some states may require coverage of prosthetics that UnitedHealthcare may not otherwise consider covered.</p>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Prosthetic Devices, Wigs, Specialized, Microprocessor or Myoelectric Limbs (continued)	Nov. 1, 2018	<p>considered to be safe and effective <i>by Generally Accepted Standards of Medical Practice</i>"</p> <p>Specialized, Microprocessor or Myoelectric Limbs</p> <ul style="list-style-type: none"> ○ Removed language indicating: <ul style="list-style-type: none"> ▪ Evidence is insufficient to permit conclusions regarding the effect of a microprocessor-controlled prosthesis on health outcomes in limited community ambulators (K2) ▪ Evidence is also insufficient to permit conclusions regarding the effect of a next-generation microprocessor-controlled prosthesis on health outcomes; therefore, these are considered investigational and not covered ○ Modified coverage criteria for prosthetic limbs; replaced criterion requiring "[the] prosthetic will help the member regain or maintain <i>functional independence</i>" with "[the] prosthetic will help the member regain or maintain <i>function</i>" • Added definition of "Generally Accepted Standards of Medical 	<p>Lower Extremity Specialized, computerized or microprocessor limbs are based on a member's current functional capabilities and his/her expected functional rehabilitation potential. If more than one prosthetic limb meets a member's prosthetic rehabilitation needs, the least costly prosthetic will be approved.</p> <p>Prosthetic limbs are a covered health care service when criteria are met:</p> <ul style="list-style-type: none"> • Ordered by a physician; and • Member is evaluated for his/her individual needs by a healthcare professional with the qualifications and training and under the supervision of the ordering physician to make an evaluation (documentation should accompany the order); and • Ordering physician signs the final prosthetic proposal; and • The records must document the member's current functional capabilities and his/her expected functional rehabilitation potential, including an explanation for the difference, if that is the case. (It is recognized within the functional classification hierarchy that bilateral amputees often cannot be strictly bound by functional level classifications); and • Prosthetic replaces all or part of a missing limb; and • Prosthetic will help the member regain or maintain function; and • Member is willing and able to participate in the training for the use of the prosthetic (especially important in use of a computerized upper limb); and • Member is able to physically function at a level necessary for a computerized prosthetic or microprocessor, e.g., hand, leg or foot. <p>Coverage of computerized and specialized lower limb prostheses is based on maximum prosthetic function level of the member (see Lower Limb Rehabilitation Classification Levels 1-4 in <i>Definitions</i> section of the policy).</p> <ul style="list-style-type: none"> • Member meets criteria for prosthetic limbs above; and • Member has or is able to gain Lower Limb Rehabilitation Classification Levels 2-4 for prosthetic ambulation (see the <i>Definitions</i> section of the policy). <p><i>Refer to the policy for a list of applicable HCPCS Codes.</i></p> <p>Myoelectric Upper Limbs (arms, joints and hands) are covered when criteria are met:</p> <ul style="list-style-type: none"> • Member meets all the criteria for prosthetic limbs above; and

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Prosthetic Devices, Wigs, Specialized, Microprocessor or Myoelectric Limbs <i>(continued)</i>	Nov. 1, 2018	<p>Practice”</p> <ul style="list-style-type: none"> Updated supporting information to reflect the most current references 	<ul style="list-style-type: none"> Member has a congenital missing or dysfunctional arm and/or hand; or Member has a traumatic or surgical amputation of the arm (above or below the elbow); and The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a Myoelectric Prosthetic Device (usually 3-5 muscle groups must be activated to use a computerized arm/hand), no external switch; and A standard passive or body-powered Prosthetic Device cannot be used or is insufficient to meet the functional needs of the individual in performing activities of daily living (ADL’s); and The medical records must indicate the specific need for the technologic or design features. <p><u>Coverage Limitations and Exclusions</u></p> <ul style="list-style-type: none"> Coverage for wigs/scalp hair prosthesis is excluded unless specifically listed as a covered health care service. Some states mandate coverage. Check the member specific benefit document for coverage. When wigs are covered, the benefit does not include coverage for hair implants or hair plugs. Coverage is not available for prosthetics if the member is eligible through a governmental program for a prosthetic due to military service related injuries and/or primary insurance coverage, e.g., VA, Medicare or TriCare. Replacement of Prosthetic Devices due to misuse, malicious damage or gross neglect or to replace lost or stolen items. (Check member specific benefit document.) Repairs to Prosthetic Devices due to misuse, malicious damage or gross neglect. (Check member specific benefit document.) If more than one Prosthetic Device can meet the member’s functional needs, benefits are only available for the Prosthetic Device that meets the minimum specifications for the member’s needs. Coverage beyond any dollar or frequency limits specified in the member’s specific benefit documents.

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan – Site of Care	Jan. 1, 2019	<p>An advanced radiologic imaging procedure in the hospital outpatient department is considered medically necessary for individuals who meet ANY of the following criteria:</p> <ul style="list-style-type: none"> • Less than 10 years of age • Require obstetrical observation • Require perinatology services • Have a known contrast allergy • Have a known chronic disease with prior radiology imaging procedures for the diagnosis, management or surveillance of the disease at the hospital outpatient department • Have pre-procedure imaging where the surgery or procedure is being performed at the hospital <p>An advanced radiologic imaging procedure in the hospital outpatient department is considered medically necessary when there are no geographically accessible appropriate alternative sites for the individual to undergo the procedure, including but not limited to the following:</p> <ul style="list-style-type: none"> • Moderate or deep sedation or general anesthesia is required for the procedure; or • The equipment for the size of the individual is not available; or • Open magnetic resonance imaging is required because the member has a documented diagnosis of claustrophobia and/or severe anxiety <p>An advanced radiologic imaging procedure in the hospital outpatient department is considered medically necessary when imaging in a physician’s office or freestanding imaging center would reasonably be expected to delay care and adversely impact health outcome.</p> <p>All other advanced radiologic imaging procedures in the hospital outpatient department are considered not medically necessary when the above criteria are not met.</p>
Policy Title	Effective Date	Summary of Changes
UPDATED		
Chemotherapy Observation or Inpatient Hospitalization	Oct. 1, 2018	<ul style="list-style-type: none"> • Updated coverage rationale; modified language to clarify the listed MCG™ Care Guidelines should be referenced <i>for medical necessity clinical coverage criteria</i>

Quality of Care Guideline (QOCG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Hospital Readmissions	Oct. 1, 2019	<ul style="list-style-type: none">Updated guiding principles; removed reference to the 2011 Certificate of Coverage (no change to guidelines)