UnitedHealthcare®

December 2017

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.**

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

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** > *Menu > 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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REVISED

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UPDATED

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REVISED

Take Note

ANNUAL CPT® AND HCPCS CODE UPDATES

Beginning Jan. 1, 2018, all applicable Medical Policies, Medical Benefit Drug Policies, and Coverage Determination Guidelines will be modified to reflect the 2018 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 2018 code updates:

- American Medical Association. Current Procedural Terminology: CPT® 2018
- Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System: HCPCS Level II

Complete details on impacted policies and corresponding code edits will be provided in the January 2018 edition of the Medical Policy Update Bulletin.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
UPDATED			
Cardiovascular Disease Risk Tests	Jan. 1, 2018	• Updated list of applicable CPT codes; added 83701 and 83704 • Updated supporting information to reflect the most current FDA information	**Arterial compliance testing, using waveform analysis, is unproven and not medically necessary as a method to determine risk for cardiovascular disease**. There is insufficient evidence to conclude that noninvasive arterial compliance testing is effective as a screening tool for the early detection of cardiovascular disease (CVD). There is inadequate clinical evidence from prospective studies that the use of this technology alters patient management and improves clinical outcomes. Additional research involving larger, well-designed studies is needed to establish the role of arterial compliance in the early identification, prevention and management of CVD. **Carotid intima-media thickness (CIMT) measurement is unproven and not medically necessary as an effective screening tool for the management of cardiovascular disease**. The clinical evidence is insufficient to show an added benefit of CIMT testing beyond traditional lipid risk assessment. There is inadequate clinical evidence from prospective studies that the use of this technology alters patient management and improves clinical outcomes. Additional research involving larger, well-designed studies is needed to establish the role of arterial compliance in the early identification, prevention and management of CVD. **Advanced lipoprotein analysis (e.g., apolipoproteins, lipoprotein (a), subfractions or particle size) is unproven and not medically necessary as a method to determine risk of cardiovascular disease**. Studies report inconsistent results regarding the usefulness of advanced lipoprotein testing. Research has shown a lack of universal, standardized testing modalities and patient-selection criteria. Additional large, prospective studies are needed to establish whether measurement of these emerging markers will be more predictive of CVD than conventional lipid risk factors. **Tests that measure the lipoprotein-associated phospholipase A_2 (Lp-PLA_2) enzyme and other human A2 phospholipases such as secretory phospholipase A2 (sPLA2-IIA) are unproven and not medically necessary as a method to determine risk of cardiovascular disease or ischemic stroke**. Additional well-designed clinical trials are necessary to establish the clinical utility of Lp-PLA_2 and sPLA2-IIA for cardiovascular risk assessment and to determine the role of Lp-PLA_2 as a potential adjunct to traditional risk assessment in the management of stroke in adults.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
UPDATED			
Cardiovascular Disease Risk Tests *(continued)*	Jan. 1, 2018		**Tests that measure long-chain omega-3 fatty acids are unproven and not medically necessary as a method to determine risk for cardiovascular disease**. There is insufficient evidence to conclude that measuring long-chain omega-3 fatty acids is effective as a screening tool for the early detection of cardiovascular disease (CVD). There is inadequate clinical evidence from prospective studies that the use of this technology alters patient management and improves clinical outcomes. Additional research involving larger, well-designed studies is needed to establish the role of arterial compliance in the early identification, prevention and management of CVD. **Endothelial function assessment using tools such as peripheral arterial tonometry (PAT) or brachial artery pressure ultrasound is unproven and not medically necessary as a prognostic indicator to determine risk of cardiovascular disease**. There is insufficient evidence in the peer-reviewed medical literature to support the effectiveness and prognostic clinical utility of endothelial function assessment to establish the risk of cardiovascular disease. The majority of the identified studies reported some measure of statistical association of either PAT or brachial artery ultrasound with cardiovascular disease. However, these associations are insufficient to directly demonstrate their clinical utility to effectively predict cardiovascular morbidity. Well-designed studies that extend beyond measures of simple statistical association are needed to demonstrate the clinical usefulness of such assessment tools to effectively predict cardiovascular events and classify patients according to their individual cardiovascular risk.
Electrical and Ultrasound Bone Growth Stimulators	Jan. 1, 2018	• Updated list of applicable CPT codes; removed 20974 • Updated supporting information to reflect the most current FDA information	Two MCG™ Care Guidelines, 21st edition, 2017, are identified, one for electrical and electromagnetic bone growth stimulators, and one for ultrasonic bone growth stimulators. For information regarding medical necessity review of electrical and electromagnetic bone growth stimulators, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Bone Growth Stimulators, Electrical and Electromagnetic ACG: A-0565 (AC). For information regarding medical necessity review of ultrasonic bone growth stimulators, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Bone Growth Stimulators, Ultrasonic ACG: A-0414 (AC).

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
UPDATED			
Epidural Steroid and Facet Injections for Spinal Pain	Jan. 1, 2018	• Updated list of applicable ICD-10 codes; added M48.061 and M48.062	Epidural steroid injections in this policy apply to the lumbar spine only. This section does not address cervical or thoracic injections. The facet joint injections section of this policy addresses multiple sites, and is not limited to the lumbar spine. **Ultrasound Guidance** **The use of ultrasound guidance for epidural steroid injection(s) and facet joint injection(s) is unproven and not medically necessary**. There is insufficient clinical evidence regarding its safety and/or efficacy in published peer-reviewed medical literature. **Epidural Steroid Injections** **Epidural steroid injection is proven and medically necessary for the treatment of acute and sub-acute sciatica or radicular pain of the low back caused by spinal stenosis, disc herniation or degenerative changes in the vertebrae**. Epidural steroid injections have a clinically established role in the short-term management of low back pain when the following two criteria are met: • The pain is associated with symptoms of nerve root irritation and/or low back pain due to disc extrusions and/or contained herniations; and • The pain is unresponsive to conservative treatment, including but not limited to pharmacotherapy, exercise or physical therapy. **Epidural steroid injection is unproven and not medically necessary for all other indications of the lumbar spine**. There is a lack of evidence from randomized controlled trials indicating that epidural steroid injections effectively treat patients with lumbar pain not associated with sciatica or radicular pain. **Note**: This policy does not apply to obstetrical epidural anesthesia utilized during labor and delivery. **Facet Joint Injections** **Diagnostic facet joint injection and/or facet nerve block (e.g., medial branch block) is proven and medically necessary to localize the source of pain to the facet joint in persons with spinal pain**. **Therapeutic facet joint injection is unproven and not medically**

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UPDATED			
Epidural Steroid and Facet Injections for Spinal Pain *(continued)*	Jan. 1, 2018		**necessary for the treatment of chronic spinal pain**. Clinical evidence about the very existence of facet joint syndrome is conflicting, and evidence from studies is inadequate regarding the superiority of periodic facet joint injections compared to placebo in relieving chronic spinal pain (pain lasting more than 3 months). For additional information on facet joint injections as a diagnostic procedure prior to radiofrequency ablation, see *Clinical Evidence* section of the policy.
Femoroacetabular Impingement Syndrome	Dec. 1, 2017	• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes	**Information Pertaining to Medical Necessity Review (When Applicable)** **Surgical treatment for femoroacetabular impingement (FAI) syndrome is medically necessary in patients who meet ALL of the following criteria**:* • Pain unresponsive to non-surgical management (e.g., restricted activity, nonsteroidal anti-inflammatory drugs) • Moderate-to-severe persistent hip or groin pain that limits activity and is worsened by flexion activities (e.g., squatting or prolonged sitting) • Positive impingement sign (i.e., sudden pain on 90 degree hip flexion with adduction and internal rotation or extension and external rotation) • Radiographic confirmation of FAI (e.g., pistol-grip deformity, alpha angle greater than 50 degrees, coax profunda, and/or acetabular retroversion) • Do not have advanced osteoarthritis (i.e., Tönnis grade 2 or 3) and/or severe cartilage damage (i.e., Outerbridge grade III or IV) *(Tannast, 2007; Filigenzi, 2008; Zebala, 2007; Clohisy, 2010) Tonnis Classification of Osteoarthritis by Radiographic Changes: • Grade 0: No signs of osteoarthritis (OA) • Grade 1: Increased sclerosis of femoral head or acetabulum, slight joint space narrowing or slight slipping of joint margin, no or slight loss of head sphericity • Grade 2: Small cysts in femoral head or acetabulum, moderate joint space narrowing, moderate loss of head sphericity • Grade 3: Large cysts, severe joint space narrowing or obliteration of joint space, severe deformity of the head, avascular necrosis Outerbridge grades include: • Grade 0: Normal • Grade I: Cartilage with softening and swelling

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
UPDATED			
Femoroacetabular Impingement Syndrome *(continued)*	Dec. 1, 2017		• Grade II: Partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter • Grade III: Fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm • Grade IV: Exposed subchondral bone head
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Jan. 1, 2018	• Updated list of applicable CPT codes: ○ Added 0019U, 0021U, 81541*, and 81551* ○ Removed 0008M* *(*annual code edit)*	Refer to the policy for complete details on the coverage guidelines for *Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions*.
Occipital Neuralgia and Headache Treatment	Jan. 1, 2018	• Updated list of applicable ICD-10 diagnosis codes; added C76.0 • Added definition of "Cervicogenic Headache" • Updated supporting information to reflect the most current FDA information and references	**Injection of local anesthetics and/or steroids, used as occipital nerve blocks, is proven and medically necessary for treating pain due to malignancy involving the head and neck**. **Injection of local anesthetics and/or steroids, used as occipital nerve blocks, is unproven and not medically necessary for diagnosing and treating occipital neuralgia or headaches including migraine and cervicogenic headaches**. There is insufficient evidence that greater occipital nerve blocks can be used as a specific diagnostic test for occipital neuralgia or headaches. The efficacy of local injection therapies for occipital neuralgia or cervicogenic headache and other headaches has not been established in well-designed clinical trials. See the Medical Benefit Drug Policy titled *Botulinum Toxins A and B* for information regarding the use of botulinum toxin for treatment of headaches. **Surgery including but not limited to the following is unproven and not medically necessary for treating occipital neuralgia or cervicogenic headache**: • Occipital neurectomy • Partial posterior intradural C1-C3 rhizotomy • Rhizotomy of C1-C3 spinal dorsal roots • Surgical decompression of second cervical nerve root and ganglion • Surgical decompression of the greater occipital nerve The available evidence is insufficient to conclude that surgery is an effective

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UPDATED			
Occipital Neuralgia and Headache Treatment *(continued)*	Jan. 1, 2018		treatment for occipital neuralgia or cervicogenic headaches. The long-term efficacy of surgical procedures for occipital neuralgia or cervicogenic headaches has not been established in well-designed clinical trials. **Occipital neurectomy or surgical nerve decompression is unproven and not medically necessary for treating headaches**. The available evidence is insufficient to conclude that occipital neurectomy or nerve decompression including decompression of the supraorbital, supratrochlear, zygomaticotemporal, or greater occipital nerves is an effective treatment for headaches. The long-term efficacy of these procedures for headaches has not been established in well-designed clinical trials. **Radiofrequency ablation (thermal or pulsed) or denervation is unproven and not medically necessary for treating of occipital neuralgia or headaches including migraine, cluster and cervicogenic headache**. The available evidence from published studies is not sufficient to conclude that radiofrequency ablation or denervation is an effective treatment for occipital neuralgia or headaches. Well-designed studies are needed to evaluate the potential advantages of radiofrequency ablation for these conditions and to identify which patients would benefit from this procedure. **Neurostimulation or electrical stimulation is unproven and not medically necessary for treating of occipital neuralgia or headaches including migraine, cluster and cervicogenic headache**. The available studies were limited and had significant methodological flaws, making it difficult to draw conclusions regarding the efficacy of electrical stimulation for the treatment of headache or occipital neuralgia. There are no well-designed randomized controlled studies in the medical literature comparing neurostimulation to established treatment options or a sham procedure. Studies on larger populations with longer follow-up are needed to establish the benefits of neurostimulation and electrical stimulation for treating these conditions.
Prolotherapy for Musculoskeletal Indications	Jan. 1, 2018	• Updated list of applicable CPT codes to reflect annual code edits; added 0481T • Updated supporting information	**Prolotherapy is unproven and not medically necessary**. The available studies are limited to those that include short to medium term follow-up with no significant functional improvement compared to placebo. Additional studies are needed to further define treatment parameters and to

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Prolotherapy for Musculoskeletal Indications *(continued)*	Jan. 1, 2018	to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	determine whether a clinically significant improvement is achieved.

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REVISED			

Balloon Sinus Ostial Dilation	Jan. 1, 2018	• Revised coverage rationale:
		  ○ Removed age requirement of "older than 12 years" from coverage criteria for medically necessary treatment
		  ○ Removed language indicating balloon sinus ostial dilation is not medically necessary in children 12 years of age or younger
		• Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references
			Balloon sinus ostial dilation is medically necessary for treating 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 computed tomography (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 persons whose symptoms persist despite medical therapy with one or more of the following:
			  ○ Nasal lavage
			  ○ Antibiotic therapy, if bacterial infection is suspected
			  ○ Intranasal corticosteroids
			
			Balloon sinus ostial dilation is not medically necessary for treating nasal polyps or tumors.
			There is insufficient published clinical evidence to conclude that balloon sinus ostial dilation is safe and effective for treating nasal polyps or tumors.

Epiduroscopy, Epidural Lysis of Adhesions and Functional Anesthetic Discography	Jan. 1, 2018	**Notice of Revision**: The following summary of changes has been modified. Revisions to the original policy update announcement are outlined in red below. Please take note of the additional updates to be	**Epiduroscopy (including spinal myeloscopy) is unproven and not medically necessary for the diagnosis of any type of neck or back pain or spinal disorder**. There is insufficient evidence to conclude that epiduroscopy can improve patient management or disease outcomes. The available studies primarily evaluated the feasibility of the procedure and the ability to visualize normal

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REVISED			

Epiduroscopy, Epidural Lysis of Adhesions and Functional Anesthetic Discography *(continued)*	Jan. 1, 2018	implemented on **Jan. 1, 2018**.
		• Revised coverage rationale:
		  ○ Updated coverage statements; replaced language indicating "[the listed services] are unproven and not medically necessary for the diagnosis of *back pain*" with "[the listed services] are unproven and not medically necessary for the diagnosis of *any type of neck or back pain or spinal disorder*"
		  ○ Modified language pertaining to clinical evidence/study findings:
		  ▪ Replaced references to "back pain" with "neck or back pain or spinal disorder"
		  ▪ Removed language indicating no published studies have evaluated epidural lysis of adhesions relative to open surgical procedures for chronic back pain
		• Updated list of applicable CPT codes; removed 62292
		• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references
			and pathological structures with an epiduroscope. None of the studies systematically evaluated the accuracy of epiduroscopy for diagnosis of causes of neck or back pain and neurological signs.
			
			Percutaneous and endoscopic epidural lysis of adhesions is unproven and not medically necessary for the treatment of any type of neck or back pain or spinal disorder.
			There is insufficient evidence to conclude that epidural lysis of adhesions can provide sustained reduction in chronic neck or back pain in patients with a presumptive diagnosis of epidural adhesions. Further validation with larger study populations and long term follow up is needed to verify the effectiveness of epidural adhesiolysis in the treatment of any type of neck or back pain or spinal disorder.
			
			Functional anesthetic discography (FAD) is unproven and not medically necessary for the diagnosis of any type of neck or back pain or spinal disorder.
			Although researchers are presently investigating the use of FAD for diagnosing discogenic pain, there is insufficient evidence at this time to draw conclusions.

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REVISED			
Functional Endoscopic Sinus Surgery (FESS)	Jan. 1, 2018	• Revised coverage rationale; removed language indicating drug eluting stents or drug eluting implants are unproven and not medically necessary for maintaining sinus ostial patency after sinus surgery • Removed definition of "Sinus Stents" • Updated list of applicable CPT codes: ○ Removed 0406T and 0407T ○ Revised description for 31254*, 31255*, and 31276* *(*annual code edit)* • Updated list of applicable HCPCS codes; removed S1090 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	**Functional endoscopic sinus surgery (FESS) is medically necessary for one or more of the following**: • Patients with chronic rhinosinusitis (defined as rhinosinusitis lasting longer than 12 weeks) with both of the following: ○ Chronic rhinosinusitis of the sinus to be operated on is confirmed on computed tomography (CT) scan by one or more of the following: ▪ Mucosal thickening ▪ Bony remodeling ▪ Bony thickening or ▪ Obstruction of the ostiomeatal complex ▪ Opacified sinus ○ Symptoms persist despite medical therapy with one or more of the following: ▪ Nasal lavage ▪ Antibiotic therapy, if bacterial infection is suspected ▪ Intranasal corticosteroids • Mucocele documented on CT scan • Concha bullosa documented on CT scan • Complications of sinusitis such as abscess • Tumor documented on CT scan (such as polyposis or malignancy) • Recurrent acute rhinosinusitis (RARS)
Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable	Jan. 1, 2018	• Replaced references to "totally implanted hearing systems" with "totally implanted *middle ear* hearing systems" • Revised benefit considerations: ○ Replaced reference to "bone anchored Hearing Aids" with "*fully or partially implantable* bone anchored Hearing Aids" ○ Removed language indicating partially implantable bone conduction hearing aids with magnetic coupling are excluded from coverage in plans that exclude unproven and/or	**Wearable Hearing Aids (Including Non-Implantable Bone Conduction Hearing Aids Utilizing a Headband)** **Hearing Aids required for the correction of a hearing impairment (a reduction in the ability to perceive sound which may range from slight to complete deafness) are proven and medically necessary**. **Bilateral or unilateral bone-anchored Hearing Aids utilizing a headband (without osseointegration) are proven and medically necessary for hearing loss in a patient who is not a candidate for an air-conduction Hearing Aid and when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions**. See the *FDA* section of the policy for more information. **Semi-Implantable Electromagnetic Hearing Aids (SEHA)** **A semi-implantable electromagnetic Hearing Aid is proven and**

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REVISED			
Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable *(continued)*	Jan. 1, 2018	non-medically necessary services • Revised coverage rationale: ○ Updated coverage criteria for bone-anchored Hearing Aids; replaced references to "unilateral/bilateral implantable bone-anchored Hearing Aids" with "unilateral/bilateral *fully or partially* implantable bone-anchored Hearing Aids" ○ Removed language indicating partially implantable magnetic bone conduction hearing devices are unproven and not medically necessary for hearing loss • Modified definition of "Frequency Modulated Systems (Auditory Trainers)"; previously listed as "Frequency *Modulation* Systems (Auditory Trainers)" • Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references	**medically necessary for Sensorineural Hearing Loss in a patient who is not a candidate for an air-conduction Hearing Aid and when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions**. See the *FDA* section of the policy for more information. **Bone Anchored Hearing Aids** ***Implantable Bone-Anchored Hearing Aid (BAHA) for Sensorineural Hearing Loss*** **A unilateral fully or partially implantable bone-anchored Hearing Aid is proven and medically necessary for Sensorineural Hearing Loss in one ear in a patient who is not a candidate for an air-conduction Hearing Aid and when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions**. See the *FDA* section of the policy for more information. **Unilateral or bilateral fully or partially implantable bone-anchored Hearing Aids are proven and medically necessary for sensorineural hearing loss in both ears when both of the following criteria are present**: • The poorer ear is not a candidate for an air-conduction Hearing Aid due to a speech reception threshold of 70 dB or more OR a word discrimination score of less than 60%; and • The better hearing ear has a speech reception threshold of 35 dB or less and a speech discrimination score of 60% or more. ***Implantable Bone-Anchored Hearing Aid (BAHA) for Conductive or Mixed Hearing Loss*** **A unilateral fully or partially implantable bone-anchored Hearing Aid is proven and medically necessary for Conductive or Mixed Hearing Loss in one or both ears in a patient who is not a candidate for an air-conduction Hearing Aid and when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions**. See the *FDA* section of the policy for more information. **Bilateral fully or partially implantable bone-anchored Hearing Aids are proven and medically necessary for Conductive or Mixed Hearing**

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REVISED			
Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable *(continued)*	Jan. 1, 2018		**Loss in both ears in a patient who is not a candidate for an air-conduction Hearing Aid and when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions**. See the *FDA* section of the policy for more information. **Totally Implanted Middle Ear Hearing Systems** **Totally implanted middle ear hearing systems are unproven and not medically necessary for hearing loss**. There is inadequate evidence demonstrating the efficacy of totally implanted middle ear hearing systems for treating hearing loss or deafness. Well-designed studies with larger patient populations and longer follow-up are required to demonstrate the safety and benefits of these devices. **Intraoral Bone Conduction Hearing Aids** **An intraoral bone conduction Hearing Aid is unproven and not medically necessary for treating hearing loss**. There is insufficient evidence to support the use of an intraoral bone conduction Hearing Aid to treat hearing loss. The quality of the studies was low due to small study populations, short follow-up, and lack of randomization and appropriate control groups. Future studies with larger populations of patients wearing the device for longer periods are needed to evaluate hearing benefits and device safety. **Laser or Light Based Hearing Aids** **Laser or light based Hearing Aids (e.g., Earlens Contact Hearing Device) are unproven and not medically necessary for treating hearing loss**. The evidence assessing the effectiveness of this device is limited. Additional studies with larger populations and long-term follow-up are needed to evaluate improvement of hearing with Hearing Aids that use light to transmit sound.
Omnibus Codes	Jan. 1, 2018	• Revised coverage rationale: **Retinal prosthetic devices for treating retinal disease** ○ Updated list of applicable CPT codes to reflect annual	Refer to the policy for complete details on the coverage guidelines for Omnibus Codes.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Omnibus Codes *(continued)*	Jan. 1, 2018	code edits; revised description for 0472T and 0473T **Implantable devices for monitoring left atrial pressure** ○ Removed content/language indicating implantable devices for monitoring left atrial pressure (CPT codes 0293T and 0294T*) are investigational, unproven and not medically necessary *(*codes retired effective Jan. 1, 2018)* **Transperineal placement of biodegradable material, peri-prostatic (via needle)** ○ Updated list of applicable CPT codes to reflect annual code edits: ▪ Added 55874 ▪ Removed 0438T **Autologous adipose-derived regenerative cell therapy for scleroderma of the hands** ○ Added language to indicate autologous adipose-derived regenerative cell therapy for scleroderma of the hands (CPT codes 0489T and 0490T*) is unproven and not medically necessary *(*new codes effective Jan. 1, 2018)* **Near-infrared spectroscopy (NIRS)** ○ Added language to indicate near-infrared spectroscopy (NIRS) for assessing tissue	

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REVISED			
Omnibus Codes *(continued)*	Jan. 1, 2018	oxygenation in lower extremity wounds (CPT code 0493T*) is unproven and not medically necessary *(*new code effective Jan. 1, 2018)* **Percutaneous cryoablative therapy of pulmonary tumors, including the pleura or chest wall when involved by tumor extension** ○ Updated list of applicable CPT codes to reflect annual code edits: ▪ Added 32994 ▪ Removed 0340T **Optical endomicroscopy** ○ Updated list of applicable CPT codes; added 43206 **Dermal/skin substitutes** ○ Updated list of applicable HCPCS codes to reflect annual code edits; revised description for Q4132, Q4133, Q4148, Q4156, Q4158, Q4162, and Q4163 • Updated supporting information to reflect the most current clinical evidence and references	
Proton Beam Radiation Therapy	Jan. 1, 2018	• Updated benefit considerations; replaced language indicating: ○ "If a member has benefits for out-of-network services, proton beam therapy (PBT) *would be* covered at the out-of-network benefit level; additional coverage for travel costs *would not be* allowed in this situation" with "if a	**Proton beam radiation therapy is proven and medically necessary for definitive therapy of the following indications**: • Intracranial arteriovenous malformations (AVMs) • Ocular tumors, including intraocular/uveal melanoma (includes the iris, ciliary body and choroid) • Skull-based tumors (e.g., chordomas, chondrosarcomas or paranasal sinus tumors) • Localized, unresectable hepatocellular carcinoma (HCC) in the curative setting when documentation is provided that sparing of the surrounding normal tissue cannot be achieved with standard radiation therapy

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Proton Beam Radiation Therapy *(continued)*	Jan. 1, 2018	member has benefits for out-of-network services, PBT *is* covered at the out-of-network benefit level; additional coverage for travel costs *are not* allowed in this situation" ○ "If a member does not have benefits for out-of-network services, no out-of-network benefit *would be* available for PBT as long as external beam radiation therapy is available within the network" with "if a member does not have benefits for out-of-network services, no out-of-network benefit *is* available for PBT as long as external beam radiation therapy is available within the network" • Revised coverage rationale: ○ Added language to indicate PBT is proven and medically necessary for Definitive Therapy of localized, unresectable hepatocellular carcinoma (HCC) in the curative setting when documentation is provided that sparing of the surrounding normal tissue cannot be achieved with standard radiation therapy techniques, including intensity-modulated radiation therapy (IMRT), and stereotactic body radiation therapy (SBRT),	techniques, including intensity-modulated radiation therapy (IMRT), and stereotactic body radiation therapy (SBRT), and selective internal radiation spheres, and transarterial therapy (for example, chemoembolization) is contraindicated or not technically feasible. **Proton beam radiation therapy is unproven and not medically necessary for treating ALL other indications, including but not limited to**: • Age-related macular degeneration (AMD) • Bladder cancer • Brain and spinal cord tumors • Breast cancer • Choroidal hemangioma • Esophageal cancer • Gynecologic cancers • Head and neck cancers • Lung cancer • Lymphomas • Pancreatic cancer • Prostate cancer • Vestibular tumors (e.g., acoustic neuroma or vestibular schwannoma) There is limited clinical evidence that directly compares PBT with other types of radiation therapy. Current published evidence does not allow for any definitive conclusions about the safety and efficacy of PBT to treat conditions other than those noted above as proven and medically necessary. **Proton beam radiation therapy may be covered for a diagnosis that is not listed above as proven, including recurrences or metastases in selected cases, when documentation is provided that sparing of the surrounding normal tissue cannot be achieved with standard radiation therapy techniques, including IMRT and stereotactic body radiation therapy (SBRT).** Requests for these exceptions will be evaluated on a case-by-case basis. **Proton beam radiation therapy used in conjunction with IMRT is unproven and not medically necessary**. Clinical evidence is insufficient to support the combined use of these

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Proton Beam Radiation Therapy *(continued)*	Jan. 1, 2018	and selective internal radiation spheres, and transarterial therapy (for example, chemoembolization) is contraindicated or not technically feasible ○ Removed language indicating PBT is unproven and not medically necessary for treating hepatocellular carcinoma • Updated list of applicable ICD-10 diagnosis codes; added C22.0 • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	technologies in a single treatment plan. Comparative effectiveness studies including randomized controlled trials are needed to demonstrate the safety and long-term efficacy of combined therapy.
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins	Feb. 1, 2018	• Revised coverage rationale; added language to indicate endovenous foam sclerotherapy of incompetent great saphenous veins and accessory saphenous veins is unproven and not medically necessary for treating venous reflux ○ There is insufficient evidence in the published clinical literature supporting the safety and efficacy of endovascular embolization using endovenous foam sclerotherapy for treating varicose veins ○ Further long-term results from large, well-designed studies are needed to support the clinical utility of	**Varicose Vein Ablative and Stripping Procedures** **Radiofrequency ablation, endovenous laser ablation, stripping, ligation and excision of the great saphenous vein and small saphenous veins are considered reconstructive and medically necessary when ALL of the following criteria are present**: • Junctional Reflux (see *Definitions* section of the policy): ○ Ablative therapy for the great or small saphenous veins will be considered reconstructive and therefore medically necessary only if junctional reflux is demonstrated in these veins; or ○ Ablative therapy for accessory veins will be considered reconstructive and medically necessary only if anatomically related persistent junctional reflux is demonstrated after the great or small saphenous veins have been removed or ablated. • Member must have one of the following functional impairments: ○ Skin ulceration; or ○ Documented episode(s) of frank bleeding of the varicose vein due to erosion of/or trauma to the skin; or ○ Documented superficial thrombophlebitis or documented venous stasis dermatitis; or ○ Moderate to severe pain causing functional/physical impairment.

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Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins *(continued)*	Feb. 1, 2018	this approach
		• Updated list of applicable CPT codes to reflect annual code edits; added 36465, 36466, 36482, and 36483
		• Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references
			• Venous Size:
			  ○ The great saphenous vein must be 5.5 mm or greater when measured at the proximal thigh immediately below the saphenofemoral junction via duplex ultrasonography.
			  ○ The small saphenous vein or accessory veins must measure 5 mm or greater in diameter immediately below the appropriate junction.
			• Duration of reflux, in the standing or reverse Trendelenburg position that meets the following parameters:
			  ○ Greater than or equal to 500 milliseconds (ms) for the great saphenous, small saphenous or principle tributaries.
			  ○ Perforating veins > 350 ms.
			  ○ Some duplex ultrasound readings will describe this as moderate to severe reflux which will be acceptable.
			
			Ablation of perforator veins is considered reconstructive and medically necessary when the following criteria are present:
			• Evidence of perforator venous insufficiency measured by recent duplex ultrasonography report (see criteria above); and
			• Perforator vein size is 3.5 mm or greater; and
			• Perforating vein lies beneath a healed or active venous stasis ulcer.
			
			Endovenous mechanochemical ablation (MOCA) of varicose veins using a percutaneous infusion catheter is unproven and not medically necessary for treating venous reflux.
			There is insufficient evidence in the clinical literature supporting the safety and efficacy of MOCA for treating varicose veins. Further results from large, well-designed studies are needed to support the clinical utility of this approach.
			
			Ligation Procedures
			Ligation of the great saphenous vein at the saphenofemoral junction, as a stand-alone procedure, is unproven and not medically necessary for treating venous reflux.
			Ligation performed without stripping or ablation is associated with high long-term recurrence rates due to neovascularization.
			
			Ligation of the small saphenous vein at the saphenopopliteal junction, as a stand-alone procedure, is unproven and not medically necessary for treating venous reflux.

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Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins *(continued)*	Feb. 1, 2018		Ligation performed without stripping or ablation is associated with high long-term recurrence rates due to neovascularization. **Ligation at the saphenofemoral junction, as a stand-alone procedure, is proven and medically necessary, when used to prevent the propagation of an active clot to the deep venous system in patients with ascending superficial thrombophlebitis who fail or are intolerant of anticoagulation therapy**. **Ligation at the saphenofemoral junction, as an adjunct to radiofrequency ablation or endovenous laser ablation of the main saphenous veins, is unproven and not medically necessary for treating venous reflux**. Published clinical evidence has not demonstrated that the addition of saphenofemoral ligation to endovenous ablation procedures provides an additive benefit in resolving venous reflux or preventing varicose vein recurrence. Endovenous ablation is a clinically effective therapy for treating venous reflux. Adding ligation to the procedure adds clinical risk without adding clinical benefit. **Endovascular embolization of varicose veins using cyanoacrylate-based adhesive is unproven and not medically necessary for treating venous reflux.** There is insufficient evidence in the published clinical literature supporting the safety and efficacy of endovascular embolization using cyanoacrylate-based adhesive for treating varicose veins. Further long-term results from large, well-designed studies are needed to support the clinical utility of this approach. **Endovenous foam sclerotherapy of incompetent great saphenous veins and accessory saphenous veins is unproven and not medically necessary for treating venous reflux.** There is insufficient evidence in the published clinical literature supporting the safety and efficacy of endovascular embolization using endovenous foam sclerotherapy for treating varicose veins. Further long-term results from large, well-designed studies are needed to support the clinical utility of this approach.

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Transcatheter Heart Valve Procedures	Feb. 1, 2018	• Revised coverage rationale; added language to indicate 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
		  ○ Refer to the *Benefit Considerations* section of the policy for coverage of unproven services when certain conditions are met
		• Updated list of applicable CPT codes to reflect annual code edits; added 0483T and 0484T
		• Updated supporting information to reflect the most current clinical evidence, FDA information, and references
			Aortic Valve
			Transcatheter aortic heart valve replacement is proven and medically necessary for treating intermediate or higher risk* patients, 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:
			• Severe calcific native aortic valve stenosis as indicated by ONE of the following:
			  ○ Mean aortic valve gradient >40 mmHg; or
			  ○ Peak aortic jet velocity >4.0 m/s; or
			  ○ Aortic valve area of ≤ 0.8 cm2
			• Patient is symptomatic (New York Heart Association [NYHA] class II or greater) and symptoms are due to aortic valve stenosis
			• Patient 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.
			
			*** Society of Thoracic Surgeons (STS) risk categories are as follows (Nishimura et al., 2014)**:
			• Intermediate - predicted risk of mortality (PROM) score of 4-8%
			• High - PROM score of >8%
			
			For a complete list of indications, contraindications, warnings and precautions by device, see the *FDA* section of the policy.
			
			Pulmonary Valve
			Transcatheter pulmonary heart valve replacement is proven and medically necessary, when used according to FDA labeled indications, contraindications, warnings and precautions, in patients with right ventricular outflow tract (RVOT) dysfunction with one of the following clinical indications for intervention:
			• Moderate or greater pulmonary regurgitation, and/or
			• Pulmonary stenosis with a mean RVOT gradient ≥ 35 mmHg.
			
			Mitral Valve
			Transcatheter mitral valve replacement is unproven and not medically necessary.
			There is insufficient evidence in the clinical literature demonstrating the long-

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Transcatheter Heart Valve Procedures *(continued)*	Feb. 1, 2018		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. See *Benefit Considerations* for coverage of unproven services when certain conditions are met. **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. See *Benefit Considerations* for coverage of unproven services when certain conditions are met. **Percutaneous transcatheter mitral valve annuloplasty via the coronary sinus is unproven, not medically necessary and investigational due to lack of FDA approval**. 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. **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. **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.

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Vagus Nerve Stimulation	Jan. 1, 2018	• Revised coverage rationale:
		  ○ Replaced references to "vagus nerve stimulation" with "implantable vagus nerve stimulators"
		  ○ Added language to indicate transcutaneous (nonimplantable) vagus nerve stimulation is unproven and not medically necessary for treating all indications
		• Updated list of applicable HCPCS codes:
		  ○ Added E0770 and E1399
		  ○ Removed C1767 and C1778
		• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references
			Implantable Vagus Nerve Stimulators
			Implantable vagus nerve stimulators are proven and medically necessary for treating epilepsy in patients with ALL of the following (see below for implants that allow detection and stimulation of increased heart rate):
			• Medically refractory epileptic seizures with failure of two or more trials of single or combination antiepileptic drug therapy or intolerable side effects of antiepileptic drug therapy; and
			• The patient is not a surgical candidate or has failed a surgical intervention; and
			• No history of left or bilateral cervical vagotomy. The U.S. Food and Drug Administration (FDA) identifies a history of left or bilateral cervical vagotomy as a contraindication to vagus nerve stimulation.
			
			It is an expectation that the physician have experience and expertise in the use of vagus nerve stimulation.
			
			Vagus nerve stimulation implants that allow detection and stimulation of increased heart rate (e.g., AspireSR™ Model 106) are unproven and not medically necessary for treating epilepsy.
			There is limited evidence to determine if vagus nerve stimulation implants that allow detection and stimulation of increased heart rate are beneficial for improving health outcomes in patients with epilepsy. Larger, long-term studies are needed to determine if this device is safe and effective.
			
			Implantable vagus nerve stimulators are unproven and not medically necessary for treating ALL other indications, including but not limited to:
			• Alzheimer's disease
			• Anxiety disorder
			• Autism spectrum disorder
			• Back and neck pain
			• Bipolar disorder
			• Bulimia
			• Cerebral palsy
			• Chronic pain syndrome
			• Cluster headaches
			• Depression
			• Fibromyalgia

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Vagus Nerve Stimulation *(continued)*	Jan. 1, 2018		• Heart failure • Migraines • Morbid obesity • Narcolepsy • Obsessive-compulsive disorder • Paralysis agitans • Sleep disorders • Tourette's syndrome Available studies on the use of vagus nerve stimulators for treating severe, major depression or bipolar disorder refractory to medical therapy contain methodological flaws such as lack of control group, small sample size, potential bias, lack of randomization and blinding and lack of statistical power analysis. There is a substantial placebo effect associated with depression treatments and the lack of data from prospective randomized controlled or comparative clinical studies considerably limits the conclusions that can be drawn from the available evidence. Furthermore, preliminary analysis of a randomized controlled trial did not find a statistically significant difference between sham and active vagus nerve stimulation. Definitive patient selection criteria for vagus nerve stimulation in patients with treatment-resistant depression have not yet been established, and significant predictors of response have also not been identified. Early research has examined the use of vagus nerve stimulation for additional indications. However, because of limited studies, small sample sizes and weak study designs, there is insufficient data to conclude that vagus nerve stimulation is safe and/or effective for treating these indications. **Transcutaneous (Nonimplantable) Vagus Nerve Stimulation** **Transcutaneous (nonimplantable) vagus nerve stimulation is unproven and not medically necessary for treating all indications**. There is limited evidence to determine if transcutaneous vagus nerve stimulation improves health outcomes as a treatment for any condition. Further clinical trials demonstrating the clinical usefulness of this treatment are necessary before it can be considered proven for any condition.

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NEW		
Alpha$_1$-Proteinase Inhibitors	Feb. 1, 2018	**Alpha$_1$-proteinase inhibitors (Aralast NP™, Glassia™, Prolastin®-C and Zemaira®) are proven and medically necessary for chronic augmentation and maintenance therapy of patients with emphysema due to congenital deficiency of alpha$_1$-proteinase inhibitor (A$_1$-PI), also known as alpha$_1$-antitrypsin (AAT) deficiency**. I. The treatment of **emphysema due to congenital deficiency of alpha$_1$-proteinase inhibitor (A$_1$-PI)** in patients who meet all of the following criteria: A. For **initial therapy, all** of the following: 1. Diagnosis of congenital alpha1-antitrypsin deficiency confirmed by **one** of the following: a. Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous); **or** b. Other rare AAT disease-causing alleles associated with serum alpha$_1$-antitrypsin (AAT) level < 11 µmol/L [e.g., Pi (Malton, Malton)] **and** 2. Circulating serum concentration of alpha$_1$-antitrypsin (AAT) level < 11 µmol/L (which corresponds to < 80 mg/dl if measured by radial immunodiffusion or < 57 mg/dl if measured by nephelometry); **and** 3. Continued optimal conventional treatment for emphysema (e.g., bronchodilators, supplemental oxygen if necessary); **and** 4. Current nonsmoker; **and** 5. Diagnosis of emphysema confirmed with pulmonary function testing; **and** 6. Dosing is in accordance with the United States Food and Drug Administration approved labeling: dosage is 60 mg/kg body weight administered once weekly; **and** 7. Initial authorization will be for no more than 12 months. B. For **continuation therapy, all** of the following: 1. Diagnosis of congenital alpha1-antitrypsin deficiency confirmed by **one** of the following: a. Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous); **or** b. Other rare AAT disease-causing alleles associated with serum alpha$_1$-antitrypsin (AAT) level < 11 µmol/L [e.g., Pi (Malton, Malton)] **and** 2. Submission of medical records (e.g. chart notes, laboratory values) documenting a positive clinical response from pretreatment baseline to alpha1-proteinase inhibitor treatment; **and** 3. Current nonsmoker; **and** 4. Diagnosis of emphysema confirmed with pulmonary function testing; **and** 5. Dosing is in accordance with the United States Food and Drug Administration approved labeling: dosage is 60 mg/kg body weight administered once weekly; **and** 6. Reauthorization will be for no more than 12 months. **Alpha$_1$-proteinase inhibitor is unproven for:** I. Conditions other than emphysema associated with alpha1-antitrypsin deficiency II. Cystic fibrosis

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Ilaris® (Canakinumab)	Jan. 1, 2018	**Ilaris® (canakinumab) is proven and medically necessary for**: I. **The treatment of cryopyrin-associated periodic syndromes (CAPS)** in patients who meet all of the following criteria: A. For **initial therapy, all** of the following: 1. One of the following, as diagnosed by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of the following: a. Familial cold autoinflammatory syndrome (FCAS) b. Muckle-Wells syndrome (MWS) **and** 2. Ilaris dosing for FCAS/MWS is in accordance with the United States Food and Drug Administration approved labeling: Maximum dosing of 3mg/kg up to 150 mg every 8 weeks; **and** 3. Initial authorization will be for no more than 12 months. B. For **continuation therapy, all** of the following: 1. Patient is currently on Ilaris therapy for one of the following: a. FCAS b. MWS **and** 2. Ilaris dosing for FCAS/MWS is in accordance with the United States Food and Drug Administration approved labeling: Maximum dosing of 3mg/kg up to 150 mg every 8 weeks; **and** 3. Documentation of positive clinical response to Ilaris therapy; **and** 4. Reauthorization will be for no more than 12 months. II. **The treatment of tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS)** in patients who meet all of the following criteria: A. For **initial therapy, all** of the following: 1. Diagnosis of TRAPS by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of TRAPS; **and** 2. Ilaris dosing for TRAPS is in accordance with the United States Food and Drug Administration approved labeling: Maximum dosing of 4 mg/kg up to 300mg every 4 weeks; **and** 3. Initial authorization will be for no more than 12 months. B. For **continuation of therapy, all** of the following: 1. Patient is currently receiving Ilaris therapy for TRAPS; **and** 2. Documentation of a positive clinical response to therapy, defined as a decrease in frequency or severity of attacks; **and** 3. Ilaris dosing for TRAPS is in accordance with the United States Food and Drug Administration approved labeling: Maximum dosing of 4 mg/kg up to 300mg every 4 weeks; **and** 4. Reauthorization will be for no more than 12 months.

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Ilaris® (Canakinumab) *(continued)*	Jan. 1, 2018	III. **The treatment of hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS)/mevalonate kinase deficiency (MKD)** in patients who meet all of the following criteria: A. For **initial therapy, all** of the following: 1. One of the following, as diagnosed by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of the following: a. HIDS b. MKD **and** 2. Ilaris dosing for HIDS/MKD is in accordance with the United States Food and Drug Administration approved labeling: Maximum dosing of 4 mg/kg up to 300mg every 4 weeks; **and** 3. Initial authorization will be for no more than 12 months. B. For **continuation of therapy, all** of the following: 1. Patient is currently receiving Ilaris for one of the following: a. HIDS b. MKD **and** 2. Documentation of a positive clinical response to therapy, defined by a decrease in frequency or severity of attacks; **and** 3. Ilaris dosing for HIDS/MKD is in accordance with the United States Food and Drug Administration approved labeling: Maximum dosing of 4 mg/kg up to 300mg every 4 weeks; **and** 4. Reauthorization will be for no more than 12 months. IV. **The treatment of familial Mediterranean fever (FMF)** in patients who meet **all** of the following criteria: A. For **initial therapy, all** of the following: 1. Diagnosis of FMF by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of FMF; **and** 2. History of failure, contraindication, or intolerance to colchicine; **and** 3. Ilaris dosing for FMF is in accordance with the United States Food and Drug Administration approved labeling: Maximum dosing of 4 mg/kg up to 300mg every 4 weeks; **and** 4. Initial authorization will be for no more than 12 months. B. For **continuation of therapy, all** of the following: 1. Patient is currently receiving Ilaris for FMF; **and** 2. Documentation of a positive clinical response to therapy, defined by a decrease in index disease flare or normalization of CRP; **and** 3. Ilaris dosing for FMF is in accordance with the United States Food and Drug Administration approved labeling: Maximum dosing of 4 mg/kg up to 300mg every 4 weeks; **and** 4. Reauthorization will be for no more than 12 months. V. **The treatment of systemic juvenile idiopathic arthritis (SJIA)** in patients who meet **all** of the following

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Policy Title	Effective Date	Coverage Rationale
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Ilaris® (Canakinumab) *(continued)*	Jan. 1, 2018	criteria: A. For **initial therapy, all** of the following: 1. Diagnosis of SJIA by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of SJIA; **and** 2. Ilaris dosing for SJIA is in accordance with the United States Food and Drug Administration approved labeling: Maximum dosing of 4 mg/kg up to 300mg every 4 weeks; **and** 3. Patient is not receiving Ilaris in combination with another biologic [e.g. Actemra]; **and** 4. Initial authorization will be for no more than 12 months. B. For **continuation of therapy, all** of the following: 1. Patient is currently receiving Ilaris for SJIA; **and** 2. Documentation of a positive clinical response to therapy; **and** 3. Ilaris dosing for SJIA is in accordance with the United States Food and Drug Administration approved labeling: Maximum dosing of 4 mg/kg up to 300mg every 4 weeks; **and** 4. Patient is not receiving Ilaris in combination with another biologic [e.g. Actemra]; **and** 5. Reauthorization will be for no more than 12 months. **Ilaris is not proven or medically necessary for the management or treatment of cardiovascular disease.**
Review at Launch for New to Market Medications	Jan. 1, 2018	This Medical Benefit Drug Policy applies to certain newly launched medical benefit medications that are healthcare provider administered, have not yet undergone review by UnitedHealthcare, and a utilization management strategy has not yet been put in place. A medication will be subject to **review at launch** when the medication is listed on the *Review at Launch Medication List*. A medication subject to review at launch will be: • Excluded from coverage until the date the medication is reviewed by UnitedHealthcare and a utilization management strategy has been communicated as may be required by law or by December 31 of the following calendar year, whichever is earliest; **or** • Reviewed against available clinical evidence, which includes applicable Medical Benefit Drug Policies. **Providers are strongly encouraged to seek a pre-determination on any new to market medications that are subject to review at launch to ensure coverage**. Please be aware if a pre-determination is not requested, UnitedHealthcare may later deny the service or item as not medically appropriate or not covered. If a provider knows or has reason to believe that a service or item may not be covered, the provider must request a pre-service organization determination from UnitedHealthcare prior to providing or referring for the service or item. A provider may not collect payment from our commercial members for services not covered under the applicable benefit plan, unless the member provided written consent before the service was rendered. See the UnitedHealthcare Care Provider Administrative Guide for more detail. Medical Benefit Drug Policies express UnitedHealthcare's determination of whether a health services is proven to be

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Review at Launch for New to Market Medications *(continued)*	Jan. 1, 2018	effective based on published clinical evidence. They are also used to decide whether a given health service is medically necessary. Services determined to be experimental, investigational, unproven or not medically necessary by the clinical evidence are typically not covered.

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Somatostatin Analogs	Feb. 1, 2018	• Changed policy title; previously titled *Sandostatin®/Sandostatin LAR® Depot (Octreotide Acetate)* • Added reference link to policy titled *Oncology Medication Clinical Coverage* • Revised coverage rationale: ○ Added language to indicate: ▪ Signifor (pasireotide diaspartate) is proven and medically necessary for the treatment of Cushing's disease when both of the following criteria are met: - Diagnosis of Cushing's disease; and - One of the following: • Inadequate response to pituitary surgery; or • Not a candidate for pituitary surgery ▪ Signifor LAR (pasireotide) is proven and medically necessary for the treatment of acromegaly when both of the	Please refer to the *Oncology Medication Clinical Coverage Policy* for updated information based on the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium for oncology indications. I. **Sandostatin (octreotide acetate) and Sandostatin LAR (octreotide acetate LAR) are proven for the treatment of ONE of the following:** A. Bleeding gastroesophageal varices associated with liver disease **Octreotide acetate is medically necessary for the treatment of bleeding esophageal varices when both of the following criteria are met:** 1. Diagnosis of bleeding esophageal varices associated with liver disease; **and** 2. Octreotide acetate will be used as an adjunct to endoscopic therapy. B. Diarrhea, chemotherapy and/or radiation-induced C. Diarrhea, refractory HIV/AIDS-related **Octreotide acetate is medically necessary for the treatment of refractory HIV/AIDS-related diarrhea when both of the following criteria are met:** 1. Diagnosis of HIV/AIDS-related diarrhea; **and** 2. History of failure, contraindication, or intolerance to standard therapy (e.g., loperamide, diphenoxylate/atropine). D. Malignant bowel disease II. **Sandostatin immediate release (IR) is proven and medically necessary for the treatment of acromegaly when BOTH of the following criteria are met**: A. Diagnosis of acromegaly by **one** of the following: 1. Serum GH level > 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis;

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Somatostatin Analogs *(continued)*	Feb. 1, 2018	following criteria are met: - Diagnosis of acromegaly by one of the following: • Serum GH level > 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis; or • Elevated serum IGF- 1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis and - One of the following: • Inadequate response to one of the following: ○ Surgery ○ Radiotherapy ○ Dopamine agonist (e.g., bromocriptine, cabergoline) therapy • Not a candidate for any of the following: ○ Surgery ○ Radiotherapy ○ Dopamine agonist (e.g., bromocriptine,	2. Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis; **and** B. **One** of the following: 1. Inadequate response to **one** of the following: a. Surgery b. Radiotherapy c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy 2. Not a candidate for **any** of the following: a. Surgery b. Radiotherapy c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy III. **Sandostatin LAR is proven and medically necessary for the treatment of acromegaly when ALL of the following criteria are met**: A. Diagnosis of acromegaly by **one** of the following: 1. Serum GH level > 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis; 2. Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis; **and** B. **One** of the following: 1. Inadequate response to one of the following: a. Surgery b. Radiotherapy c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy 2. Not a candidate for **any** of the following: a. Surgery b. Radiotherapy c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy **and** C. Initial treatment with octreotide immediate release (IR) has been shown to be effective and tolerated. IV. **Signifor (pasireotide diaspartate) is proven and medically necessary for the treatment of Cushing's disease when BOTH of the following criteria are met**:

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Somatostatin Analogs *(continued)*	Feb. 1, 2018	cabergoline) therapy ▪ Somatuline Depot (lanreotide) is proven and medically necessary for the treatment of acromegaly when both of the following criteria are met: - Diagnosis of acromegaly by one of the following: • Serum GH level > 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis; or • Elevated serum IGF- 1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis and - One of the following: • Inadequate response to one of the following: ○ Surgery ○ Radiotherapy ○ Dopamine agonist (e.g., bromocriptine, cabergoline) therapy	A. Diagnosis of Cushing's disease; **and** B. **One** of the following: 1. Inadequate response to pituitary surgery; **or** 2. Not a candidate for pituitary surgery. V. **Signifor LAR (pasireotide) is proven and medically necessary for the treatment of acromegaly when BOTH of the following criteria are met**: A. Diagnosis of acromegaly by **one** of the following: 1. Serum GH level > 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis; 2. Elevated serum IGF- 1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis; **and** B. **One** of the following: 1. Inadequate response to **one** of the following: a. Surgery b. Radiotherapy c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy 2. Not a candidate for **any** of the following: a. Surgery b. Radiotherapy c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy VI. **Somatuline Depot (lanreotide) is proven and medically necessary for the treatment of acromegaly when BOTH of the following criteria are met**: A. Diagnosis of acromegaly by **one** of the following: 1. Serum GH level > 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis; 2. Elevated serum IGF- 1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis; **and** B. **One** of the following: 1. Inadequate response to **one** of the following: a. Surgery b. Radiotherapy

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Somatostatin Analogs *(continued)*	Feb. 1, 2018	• Not a candidate for any of the following: ○ Surgery ○ Radiotherapy ○ Dopamine agonist (e.g., bromocriptine, cabergoline) therapy ○ Updated unproven/not medically necessary statements; replaced reference to "*Sandostatin*" with "*somatostatin analogs*" • Updated list of applicable HCPCS codes; added J1930 and J2502 • Updated list of applicable ICD-10 diagnosis codes: ○ Added C7A.010, C7A.011, C7A.012, C7A.019, C7A.020, C7A.021, C7A.022, C7A.024, C7A.025, C7A.026, C7A.029, C7A.092, C7A.094, C7A.095, C7A.096, C25.4, E22.0, E24.0, K56.50, K56.51, K56.52, K56.600, K56.601, K56.609, K56.690, K56.691, and K56.699 ○ Removed K56.5, K56.60, and K56.69 • Updated supporting information to reflect the most current background information, clinical evidence, FDA and CMS information, and references	c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy 2. Not a candidate for **any** of the following: a. Surgery b. Radiotherapy c. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy **Somatostatin analogs are unproven and not medically necessary for treating the following conditions:** • Chylothorax • Dumping syndrome • Pancreatitis • Persistent hyperinsulinemic hypoglycemia of infancy • Prevention of postoperative complications following pancreatic surgery • Short bowel syndrome

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
UPDATED			
Breast Reduction Surgery	Dec. 1, 2017	• Updated definitions: ○ Added language to indicate the definitions listed in the policy may not apply to all plans; refer to the member specific benefit plan document for applicable definitions ○ Added definition of "Cosmetic Procedures [2018 UnitedHealthcare Generic Certificate of Coverage (COC)]" ○ Modified definition of: ▪ Reconstructive Procedures ▪ Reconstructive Procedures (California only) • Updated supporting information to reflect the most current references	**California Mandate for Medically Necessary Surgery** The State of California requires that all breast reduction surgeries be reviewed for medical necessity. Benefits will be provided if the breast reduction meets the Criteria for a Coverage Determination as Reconstructive identified below. **Indications for Coverage** Breast reduction surgery following mastectomy to achieve symmetry is covered as part of the Women's Health and Cancer Rights Act (WHCRA). Please refer to the Coverage Determination Guideline titled *Breast Reconstruction Post Mastectomy*. Breast reconstruction may be covered under certain circumstances for the surgical treatment of gender dysphoria. Please refer to the member specific benefit plan document for coverage. **All plans cover breast reduction surgeries that qualify under the Women's Health and Cancer Rights Act of 1998**. If a surgery does not qualify under the Women's Health and Cancer Rights Act of 1998, certain plans may allow breast reduction surgery which we determine to treat a physiologic functional impairment. However, certain plans exclude breast reduction surgery even if it treats a physiologic functional impairment. Refer to the member specific benefit plan document to determine coverage. ***For Plans that Cover Breast Reduction Surgery that Treat a Physiologic Functional Impairment (Including California Reviews for Medical Necessity)*** **Criteria for a Coverage Determination as Reconstructive** Breast reduction surgery is considered reconstructive and medically necessary when the following criteria are met and a physiologic functional impairment is identified: • Macromastia is the primary etiology of the member's functional impairment or impairments (as defined in the *Definitions* section of the policy). The following are examples of functional impairments that must be attributable to Macromastia to be considered (not an all-inclusive list): ○ Severe skin excoriation/intertrigo unresponsive to medical management ○ Severe restriction of physical activities that meets the definition of

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
UPDATED			
Breast Reduction Surgery *(continued)*	Dec. 1, 2017		functional impairment below ○ Signs and symptoms of nerve compression that are unresponsive to medical management (e.g., ulnar paresthesias) ○ Acquired kyphosis that is attributed to Macromastia ○ Chronic breast pain due to weight of the breasts ○ Upper back, neck, or shoulder pain ○ Shoulder grooving from bra straps ○ Headache and • The amount of tissue to be removed plots above the 22nd percentile; or • If the amount of tissue to be removed plots between the 5th and 22nd percentiles, the procedure may be either reconstructive or cosmetic; the determination is based on the review of the information provided; and • The proposed procedure is likely to result in significant improvement of the functional impairment. The following documentation should be available for review: • Reduction mammoplasty documentation should include the evaluation and management note for the date of service and the note for the day the decision to perform surgery was made. The member's medical record must contain, and be available for review on request, the following information: ○ Height and weight ○ Body surface area (BSA) ○ Photographs that document Macromastia. **<u>Coverage Limitations and Exclusions</u>** Some states require benefit coverage for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a functional impairment. Please refer to the member specific benefit plan document. • Cosmetic Procedures are excluded from coverage. Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure. • Any procedure that does not meet the reconstructive criteria above in

Coverage Determination Guideline (CDG) Updates

<table>
<tr><th>Policy Title</th><th>Effective Date</th><th>Summary of Changes</th><th>Coverage Rationale</th></tr>
<tr><td colspan="4">UPDATED</td></tr>
<tr><td>Breast Reduction Surgery
(continued)</td><td>Dec. 1, 2017</td><td></td><td>
the Indications for Coverage section (e.g., psychological or social reasons, breast size asymmetry unless post mastectomy, exercise).
• Breast reduction surgery is cosmetic when done to improve appearance without improving a functional/physiologic impairment.
• The use of liposuction as the sole procedure for breast reduction surgery is considered cosmetic.

<u>Appendix</u>
This Schnur chart may be used to assess whether the amount of tissue (per breast) that will be removed is reasonable for the body habitus, and whether the procedure is cosmetic or reconstructive in nature.
• If the amount plots above the 22nd percentile and the member has a functional impairment, the procedure is reconstructive.
• If the amount plots below the 5th percentile, the procedure is cosmetic.
• If the amount plots between the 5th and 22nd percentiles, the procedure may be either reconstructive or cosmetic based on review of information.

To calculate body surface area (BSA), see:
• http://www.cornellpediatrics.org/ser_div/critical/calc/bsacalc.htm; or
• BSA = (W 0.425 x H 0.725) x 0.007184 (weight is in kilograms and height is in centimeters)

Modified Schnur Nomogram Chart
<table>
<tr><th>Body Surface (m2)</th><th>Lower 5th Percentile</th><th>Lower 22nd Percentile</th></tr>
<tr><td>1.35</td><td>127</td><td>199</td></tr>
<tr><td>1.40</td><td>139</td><td>218</td></tr>
<tr><td>1.45</td><td>152</td><td>238</td></tr>
<tr><td>1.50</td><td>166</td><td>260</td></tr>
<tr><td>1.55</td><td>181</td><td>284</td></tr>
<tr><td>1.60</td><td>198</td><td>310</td></tr>
<tr><td>1.65</td><td>216</td><td>338</td></tr>
<tr><td>1.70</td><td>236</td><td>370</td></tr>
<tr><td>1.75</td><td>258</td><td>404</td></tr>
<tr><td>1.80</td><td>282</td><td>441</td></tr>
<tr><td>1.85</td><td>308</td><td>482</td></tr>
</table>
</td></tr>
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Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
UPDATED			
Breast Reduction Surgery *(continued)*	Dec. 1, 2017		1.90 | 336 | 527 1.95 | 367 | 575 2.00 | 401 | 628 2.05 | 439 | 687 2.10 | 479 | 750 2.15 | 523 | 819 2.20 | 572 | 895 2.25 | 625 | 978 2.30 | 682 | 1,068 2.35 | 745 | 1,167 2.40 | 814 | 1,275 2.45 | 890 | 1,393 2.50 | 972 | 1,522 2.55 | 1,062 | 1,662
Clinical Trials	Dec. 1, 2017	• Updated definitions: ○ Added language to indicate the definitions listed in the policy may not apply to all plans; refer to the member specific benefit plan document for applicable definitions ○ Modified definition of: ▪ Covered Health Care Service(s) ▪ Experimental or Investigational Service(s)	**Indications for Coverage** Effective for plan years starting on or after January 1, 2014, the Patient Protection and Affordable Care Act ("PPACA") requires non-grandfathered health plans to cover "Routine Patient Costs" incurred by a "Qualifying Individual" who is participating in an "Approved Clinical Trial." Benefits include the reasonable and necessary items and services used to prevent, diagnose and treat complications arising from participation in a qualifying clinical trial. Benefits are available only when the Covered Person is clinically eligible for participation in the qualifying clinical trial as defined by the researcher. I. ***Approved Clinical Trial*** A. An "Approved Clinical Trial" is defined as: 1. Phase I, Phase II, Phase III, or Phase IV clinical trial; 2. Being conducted in relation to the prevention, detection or treatment for Cancer or other life threatening disease or condition; and 3. That meets the requirements under Section II below.

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Clinical Trials *(continued)*	Dec. 1, 2017		For purposes of this benefit, a "life-threatening disease or condition" is one from which the likelihood of death is probable unless the course of the disease or condition is interrupted. B. Additional Clinical Trials: Coverage of Routine Patient Costs incurred by members participating in the following types of clinical trials is not currently mandated by PPACA. However, UnitedHealthcare's standard clinical trial benefit would also include coverage of the Routine Patient Costs when a member is participating in a: 1. Phase I, Phase II or Phase III clinical trial; 2. Being conducted in relation to the detection or treatment of non-life threatening: a. Cardiovascular disease (cardiac/stroke); b. Surgical musculoskeletal disorders of the spine, hip and knees; and/or c. Other clinical trials: Certain plans may allow clinical trials relating to other diseases or disorders which are not life-threatening. 3. That meets the requirements under Section II below. II. ***Criteria For Approved Clinical Trials*** A. The clinical trial must be described in paragraph 1, 2 or 3 below. 1. The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following: a. National Institutes of Health (NIH) [includes National Cancer Institute (NCI)] b. Centers for Disease Control and Prevention (CDC) c. Agency for Healthcare Research and Quality (AHRQ) d. Centers for Medicare and Medicaid Services (CMS) e. A cooperative group or center of any of the entities described above or the Department of Defense (DOD) or the Veterans Administration (VA) f. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants g. The Department of Veterans Affairs, the Department of Defense or the Department of Energy as long as the study or

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Clinical Trials *(continued)*	Dec. 1, 2017		investigation has been reviewed and approved through a system of peer review that is determined by the Secretary of Health and Human Services to meet both of the following criteria: i. Comparable to the system of peer review of studies and investigations used by the National Institutes of Health; ii. Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review; or 2. The study or investigation is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration; or 3. The study or investigation is a drug trial that is exempt from having such an investigational new drug application. B. Additional Requirements 1. The clinical trial must have a written protocol that describes a scientifically sound study that has been approved by all relevant institutional review boards (IRBs) before participants are enrolled in the trial. We may, at any time, request documentation about the trial. 2. The subject or purpose of the trial must be the evaluation of an item or service that meets the definition of a Covered Health Service and is not otherwise excluded under the Policy. III. ***Qualified Individual*** A. To be a qualified individual, an individual must be: 1. Covered under the health plan; and 2. Eligible to participate in an approved clinical trial according to the trial protocol when: a. The individual was referred to the clinical trial by an in-network health care professional who has concluded that the individual's participation would be appropriate because the individual is eligible for the trial according to its protocol; or b. The individual provides the plan with medical and scientific information that establishes that participation would be appropriate because the individual is eligible for the trial according to its protocol.

Coverage Determination Guideline (CDG) Updates

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Clinical Trials *(continued)*	Dec. 1, 2017		IV. ***Routine Patient Costs During Clinical Trials Include***: A. Covered Health Services for which Benefits are typically provided absent a clinical trial. B. Covered Health Services required solely for: 1. The provision of the Experimental or Investigational service(s) or item (e.g., the infusion administration services to deliver an investigational drug); and/or 2. The clinically appropriate monitoring of the effects of the service or item (e.g., lab tests and imaging done at a frequency consistent with signs and symptoms and other standards of care for that diagnosis or treatment type); and/or 3. The prevention of complications. C. Covered Health Services needed for reasonable and necessary care arising from the provision of an Experimental or Investigational Service(s) or item. ***Network Plans*** If one or more network providers are participating in a clinical trial, then UnitedHealthcare may require that the Qualified Individual participate in the clinical trial using a network provider, as long as the network provider will accept the qualifying individual as a participant in the trial. However, if an Approved Clinical Trial is conducted outside of the Qualified Individual's state of residence, then UnitedHealthcare may not deny or otherwise limit payment for Routine Patient Services solely on the basis that the trial is conducted out-of-state. **Coverage Limitations and Exclusions** Benefits for clinical trials do not include: • The Experimental or Investigational Service(s) or item that is used in the clinical trial is not covered, except for the following: ○ Certain Category B devices (see definition below) ○ Certain promising interventions for patients with terminal illnesses ○ Other items and services that, in our determination, meet specified criteria in accordance with our medical and drug policies • Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient. Examples include, but are not limited to:

Coverage Determination Guideline (CDG) Updates

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Clinical Trials *(continued)*	Dec. 1, 2017		○ Laboratory tests and imaging studies done at a frequency dictated by the study protocol and not consistent with signs and symptoms and other standards of care for that diagnosis or treatment type • A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis • Items and services provided by the research sponsors free of charge for any person enrolled in the trial • Travel and transportation expenses are excluded from coverage. These include, but are not limited to, the following examples: ○ Fees for all types of transportation (examples include, but are not limited to: personal vehicle, taxi, medical van, ambulance, commercial airline, and train) ○ Rental car expenses ○ Mileage reimbursement for driving a personal vehicle ○ Lodging ○ Meals • Routine patient costs obtained out-of-Network where non-network benefits do not exist under the plan. • Clinical Trials that do not meet the requirements listed in the *Indications for Coverage* section above. An example includes, but is not limited to, Phase 0 drug clinical trials.
Cosmetic and Reconstructive Procedures	Jan. 1, 2018	• Updated definitions: ○ Added language to indicate the definitions listed in the policy may not apply to all plans; refer to the member specific benefit plan document for applicable definitions ○ Modified definition of: ▪ Congenital Anomaly ▪ Cosmetic Procedures ▪ Cosmetic Procedures (California only) ▪ Injury ▪ Reconstructive Procedures ▪ Reconstructive	Some states require benefit coverage for services that UnitedHealthcare considers Cosmetic Procedures, such as repair of external congenital anomalies in the absence of a Functional Impairment. Please refer to the member specific benefit plan document. **Indications for Coverage** ***Criteria for a Procedure to be Considered Reconstructive and Medically Necessary*** • There is documentation that the physical abnormality and/or physiological abnormality is causing a Functional Impairment (as defined in the *Definitions* section of the policy) that requires correction. • The proposed treatment is of proven efficacy and is deemed likely to significantly improve or restore the patient's physiological function. • Microtia repair (as defined in the *Definitions* section of the policy) is reconstructive; although no Functional Impairment may be documented for Microtia, this has been deemed reconstructive surgery.

Coverage Determination Guideline (CDG) Updates

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Cosmetic and Reconstructive Procedures *(continued)*	Jan. 1, 2018	Procedures (California only) • Updated list of applicable CPT codes to reflect annual code edits: ○ Added 15730 and 15733 ○ Removed 15732 ○ Revised description for 36468	**Coverage Limitations and Exclusions** Some states require benefit coverage for services that UnitedHealthcare considers Cosmetic Procedures, such as repair of external congenital anomalies in the absence of a Functional Impairment. Please refer to the member specific benefit plan document. • Cosmetic Procedures are excluded from coverage. Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a Reconstructive Procedure. • Any procedure that does not meet the reconstructive criteria above in the Indications for Coverage section is excluded from coverage.
Gynecomastia Treatment	Dec. 1, 2017	• Updated definitions: ○ Added language to indicate the definitions listed in the policy may not apply to all plans; refer to the member specific benefit plan document for applicable definitions ○ Modified definition of: ▪ Congenital Anomaly ▪ Cosmetic Procedures ▪ Cosmetic Procedures (California only) ▪ Reconstructive Procedures ▪ Reconstructive Procedures (California only)	**Indications for Coverage** ***Criteria for a Coverage Determination that Surgery is Reconstructive and Medically Necessary*** **Mastectomy or suction lipectomy for treatment of Benign Gynecomastia for a male patient under age 18 is considered reconstructive and medically necessary when all the following criteria are met**: • Gynecomastia or breast enlargement with moderate to severe chest pain that is causing a Functional/Physical Impairment as defined in the *Definitions* section of the policy. The inability to participate in athletic events, sports or social activities is not considered to be a functional/physical or physiological impairment. • No prior history of prescribed medications and appropriate screening(s) of non-prescription and/or recreational drugs or substances that have a known side effect of gynecomastia (examples include but are not limited to the following: testosterone, marijuana, asthma drugs, phenothiazines, anabolic steroids, cimetidine and calcium channel blockers). • The breast enlargement must be present for at least 2 years. If so, lab tests which might include, but are not limited to the following must be performed: ○ Thyroid function studies ○ Testosterone ○ Beta subunit HCG

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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Gynecomastia Treatment *(continued)*	Dec. 1, 2017		**Mastectomy or suction lipectomy for treatment of Benign Gynecomastia for a male patient age 18 and up is considered reconstructive and medically necessary when all the following criteria are met**: • Discontinuation of medications, nutritional supplements, and non-prescription medications or substances (examples include but are not limited to the following, testosterone, marijuana, asthma drugs, phenothiazines, anabolic steroids, cimetidine and calcium channel blockers) that have a known side effect of gynecomastia or breast enlargement and the breast size did not regress after discontinuation of use as appropriate. • Gynecomastia or breast enlargement with moderate to severe chest pain that is causing a Functional/Physical Impairment as defined below in the *Definitions* section. The inability to participate in athletic events, sports or social activities is not considered to be a functional/physical or physiological impairment. • Review of test results that have been performed to rule out certain diseases or other causes of gynecomastia (examples include but are not limited to blood tests, e.g., hormone levels estrogen, testosterone, liver and kidney function studies/enzymes). • Glandular breast tissue is the primary cause of gynecomastia as opposed to fatty deposits and is documented on physical exam and/or mammography. ***Additional Information*** In most cases, breast enlargement and/or Benign Gynecomastia spontaneously resolves by age 18 making treatment unnecessary. Gynecomastia during puberty is not uncommon and in 90% of cases regresses within 3 years of onset. If a tumor or neoplasm is suspected, a breast ultrasound and/or mammogram may be performed. As indicated, a breast biopsy may also be performed. **Coverage Limitations and Exclusions** • Treatment of Benign Gynecomastia when specifically excluded in the member specific benefit plan document. • Treatment of Benign Gynecomastia when not specifically excluded in the member specific benefit plan document and the above criteria is not met.

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Gynecomastia Treatment *(continued)*	Dec. 1, 2017		• Most medical and surgical treatments for Benign Gynecomastia are considered cosmetic. Medical treatments and surgery to alter a perceived abnormal appearance, or for psychological reasons, are considered cosmetic and are not covered. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of Benign Gynecomastia does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure.
Home Health Care	Dec. 1, 2017	• Updated definitions: ○ Added language to indicate the definitions listed in the policy may not apply to all plans; refer to the member specific benefit plan document for applicable definitions ○ Modified definition of: ▪ Home Health Agency ▪ Intermittent Care • Updated supporting information to reflect the most current references	**Indications for Coverage** The services being requested must meet all of the following: • Be ordered and directed by a treating practitioner or specialist (M.D., D.O., P.A. or N.P); and • The care must be delivered or supervised by a licensed professional in order to obtain a specified medical outcome; and • Services must be of Skilled Care in nature (refer to the Coverage Determination Guideline titled *Skilled Care and Custodial Care Services* and the *Definitions* section of the policy); and • Services must be intermittent and part time (typically provided for less than 4 hours per day; refer to the member specific benefit plan document for intermittent definitions, if provided); and • Services are provided in the home in lieu of Skilled Care in another setting (such as but not limited to a nursing facility, acute inpatient rehabilitation or a hospital); and • Services must be clinically appropriate and not more costly than an alternative health services; and • A written treatment plan must be submitted with the request for specific services and supplies. Periodic review of the written treatment plan may be required for continued Skilled Care needs and progress toward goals; and • Services are not provided for the comfort and convenience of the member or the member's family; and • Services are not Custodial Care in nature. ***Medical Necessity Plans*** Use the criteria above where applicable. ***Additional Information*** • Medical supplies and medications that are used in conjunction with a

Coverage Determination Guideline (CDG) Updates

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Home Health Care *(continued)*	Dec. 1, 2017		home health care visit are covered as part of that visit. Some examples are, but not limited to, surgical dressing, catheters, syringes, irrigation devices. Reimbursement for home health care visits and supplies are contractually determined. • Eligible physical, occupational and speech therapy received in the home from a Home Health Agency is covered under the Home Health Care section of the COC. The Home Health Care section only applies to services that are rendered by a Home Health Agency. • Eligible physical, occupational and speech therapy received in the home from an independent physical, occupational or speech therapist (a therapist that is not affiliated with a Home Health Agency) is covered under the Rehabilitation Services-Outpatient Therapy section of the COC. **Coverage Limitations and Exclusions** • Home health care does not include Custodial Care, domiciliary care, private duty nursing, respite care, or rest cures and therefore these services are not covered (check the member specific benefit plan document). • Services of personal care attendants (these are not home health aides). • We will determine if benefits are available by reviewing both the skilled nature of the service and the need for Physician-directed medical management. A service will not be determined to be "skilled" simply because there is not an available caregiver. • Covered pharmaceuticals, drugs, and DME provided in connection with home health services may be subject to separate benefit categories. Please reference the Durable Medical Equipment and the Pharmaceutical Products benefit sections of the member specific benefit plan document. • Homemaker services such as home meal delivery services (e.g., Meals-on-Wheels) or transportation services (e.g., Dial-a-Ride) are excluded. • Private Duty Nursing (refer to the Coverage Determination Guideline titled *Private Duty Nursing Services (PDN)*). • Services of an independent nurse hired directly by the family/patient are excluded. • Home health services beyond benefit limits, e.g., visits. • For Intermittent Care, exceptions may be made in certain circumstances when the need for more care is finite and predictable.
Orthognathic (Jaw) Surgery	Dec. 1, 2017	• Updated definitions: ○ Added language to indicate the definitions listed in the	**Indications for Coverage** Orthognathic (jaw) surgery is a standard exclusion from coverage in most fully-insured plans. The following list represents the covered *exceptions* to

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Orthognathic (Jaw) Surgery *(continued)*	Dec. 1, 2017	policy may not apply to all plans; refer to the member specific benefit plan document for applicable definitions ○ Modified definition of: ▪ Congenital Anomaly ▪ Cosmetic Procedures ▪ Cosmetic Procedures (California only) ▪ Reconstructive Procedures • Updated list of applicable CDT codes; revised description for D7780 and D7950 • Updated supporting information to reflect the most current references	the orthognathic (jaw) surgery exclusion. **The following are eligible for coverage as reconstructive and medically necessary**: • Acute traumatic injury and Post-Surgical Sequela (see Post-Surgical Sequela in *Definitions* section of the policy) • Cancerous or non-cancerous tumors and cysts, Cancer and Post-Surgical Sequela (see Cancer Sequela and Post-Surgical Sequela in *Definitions* section below) **The following are eligible for coverage when the criteria are met (refer to Criteria section below)**: • Obstructive sleep apnea (also see Medical Policy titled *Obstructive Sleep Apnea Treatment*) • Cleft lip/palate (for cleft lip/palate related jaw surgery) • Congenital anomalies that meet the criteria for reconstructive. Depending on a patient-specific clinical review, examples include: Pierre Robin Syndrome, Hemifacial Microsomia, and Treacher Collins Syndrome. ***Criteria*** All orthognathic (jaw) surgeries are subject to some level of review. For the above covered exceptions that require review, the following criteria should be applied. **Orthognathic (jaw) surgery is a reconstructive procedure and medically necessary and is considered covered when both the skeletal deformity AND the functional impairment criteria below are met**: • The presence of any of the following facial skeletal deformities associated with masticatory malocclusion: ○ *Anteroposterior Discrepancies* ▪ Maxillary/Mandibular incisor relationship: overjet of 5mm or more, or a 0 to a negative value (norm 2mm) ▪ Maxillary/Mandibular anteroposterior molar relationship discrepancy of 4mm or more (norm 0 to 1mm) ▪ These values represent two or more standard deviation from published norms ○ *Vertical Discrepancies* Presence of a vertical facial skeletal deformity which is two or more standard deviations from published norms for accepted skeletal

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UPDATED			
Orthognathic (Jaw) Surgery *(continued)*	Dec. 1, 2017		landmarks: ▪ Open bite: - No vertical overlap of anterior teeth - Unilateral or bilateral posterior open bite greater than 2mm ▪ Deep overbite with impingement or irritation of buccal or lingual soft tissues of the opposing arch ▪ Supraeruption of a dentoalveolar segment due to lack of occlusion ○ *Transverse Discrepancies* ▪ Presence of a transverse skeletal discrepancy which is two or more standard deviations from published norms ▪ Total bilateral maxillary palatal cusp to mandibular fossa discrepancy of 4mm or greater, or a unilateral discrepancy of 3mm or greater, given normal axial inclination of the posterior teeth ○ *Asymmetries* ▪ Anteroposterior, transverse or lateral asymmetries greater than 3mm with concomitant occlusal asymmetry • In addition to meeting the skeletal deformity requirement above, the patient must also have one or more of the following functional impairments: ○ Masticatory (chewing) and swallowing dysfunction due to skeletal malocclusion (e.g., inability to incise/and or chew solid foods, choking on incompletely masticated solid foods, damage to soft tissue during mastication, malnutrition) ○ Documentation of speech deficits to support existence of speech impairment due to skeletal malocclusion ○ Moderate to severe obstructive sleep apnea, as measured by polysomnography (AASM Obstructive Sleep Apnea; and Practice Parameters for the Surgical Modifications of the Upper Airway for Obstructive Sleep Apnea in Adults), is defined as: ▪ Moderate for AHI or RDI ≥ 15 and ≤ 30 ▪ Severe for AHI or RDI > 30/hr; AND oropharyngeal narrowing secondary to maxillomandibular deficiency is the primary cause of moderate to severe obstructive sleep apnea [see MCG™ Care Guidelines, 21st edition, 2017, Maxillomandibular Osteotomy and Advancement A-0248 (ACG)] **Obstructive Sleep Apnea**

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Orthognathic (Jaw) Surgery *(continued)*	Dec. 1, 2017		For medical necessity plans, in addition to the criteria above, please also refer to the following:
			• Maxillomandibular advancement surgery (MMA):
			  ○ For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Maxillomandibular Osteotomy and Advancement, A-0248 (ACG).
			• Multilevel procedures whether done in a single surgery or phased multiple surgeries:
			  ○ There are a variety of procedure combinations, including mandibular osteotomy and genioglossal advancement with hyoid myotomy (GAHM). For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, Mandibular Osteotomy, A-0247 (ACG).
			
			California Only
			This is the mandated language for Reconstructive Procedures:
			• Reconstructive procedures to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease. Reconstructive procedures include surgery or other procedures which are associated with an Injury, Sickness or Congenital Anomaly. The primary result of the procedure is not a changed or improved physical appearance for cosmetic purposes only, but rather to improve function and/or create a normal appearance, to the extent possible.
			
			Coverage Limitations and Exclusions
			Except where state mandated, the following are not covered:
			• Cosmetic and non-reconstructive jaw surgery and jaw alignment procedures (Orthognathic Surgery) that do not meet the criteria in the *Indications for Coverage* section above are excluded from coverage.
			• Surgery for torus mandibularis and torus palatinus for fabrication of dentures is not covered.
			• Pre and post-surgical orthodontic treatment.
			
			Additional Information
			Some states may require orthognathic (jaw) surgery for cleft lip and cleft palate, or for services that UnitedHealthcare considers cosmetic procedures, such as repair of external congenital anomalies in the absence of a functional impairment. Please refer to the member specific benefit plan document.

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REVISED			
Blepharoplasty, Blepharoptosis and Brow Ptosis Repair	Jan. 1, 2018	• Revised coverage rationale for upper eyelid blepharoplasty: ○ Modified criterion pertaining to documentation requirements; removed language indicating clinical photographs must display the extra skin, but not the lid margin, is elevated to show: ▪ It reverses the Visual Field obstruction ▪ Lateral hooding (if present) resolves • Modified definition of "Marginal Reflex Distance -1 (MRD-1)"; previously listed as "*Margin* Reflex Distance -1 (MRD-1)"	Refer to the policy for complete details on the coverage guidelines for *Blepharoplasty, Blepharoptosis and Brow Ptosis Repair*.
Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements	Jan. 1, 2018	• Updated list of related policies; removed reference links to policies titled: ○ Standing Systems and Gait Trainers ○ Wearable Cardioverter Defibrillators • Replaced references to "health services" with "health care services" • Revised coverage rationale: Indications for Coverage ○ Updated coverage guidelines for *Contact Lenses & Scleral Bandages (Shells)* to indicate: ▪ Contact lenses or scleral shells that are used to treat an injury or disease (e.g., corneal abrasion,	Refer to the policy for complete details on the coverage guidelines for *Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements*.

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Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements *(continued)*	Jan. 1, 2018	keratoconus or severe dry eye), are not considered DME and may be covered as a therapeutic service; in these situations, contact lenses and scleral shells are not subject to a plan's contact lens exclusion ○ Updated coverage guidelines for *Repair and Replacement*: ▪ Added language to indicate: - Vendors/manufacturers are responsible for repairs, replacements, and maintenance for rented equipment and for purchased equipment covered by warranty - Frequency and timeframe limits for DME repair or replacement are specified in the member specific benefit plan documents ▪ Removed language indicating repairs, replacements and maintenance for rented items/devices are the contractual responsibility of the item/device provider	

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Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements *(continued)*	Jan. 1, 2018	Coverage Limitations and Exclusions ○ Modified language pertaining to accessories to DME items or devices which are primarily for the comfort or convenience of the member and excluded from coverage; added list of examples of home/vehicle accommodations (e.g., ramps, stair lifts and stair glides, wheelchair lifts, bathroom modifications, door modifications) ○ Added language to indicate the following items are excluded from coverage: ▪ Diagnostic or monitoring equipment purchased for home use unless otherwise described as a Covered Health Care Service (e.g., blood pressure monitor, oximeters) - Powered exoskeleton devices - Prescribed or non-prescribed publicly available devices, software applications and/or monitors that can be used for non-medical purposes (e.g., Smartphone applications, software applications)	

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Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements *(continued)*	Jan. 1, 2018	• Updated definitions: ○ Added language to indicate the definitions listed in the policy may not apply to all plans; refer to the member specific benefit plan document for applicable definitions ○ Modified definition of: ▪ Covered Health Care Service(s) ▪ Durable Medical Equipment ▪ Medically Necessary	
Habilitative Services for Essential Health Groups	Jan. 1, 2018	• Updated list of related policies; added reference link to policy titled *Skilled Care and Custodial Care Services* • Reorganized and revised coverage rationale: ○ Replaced references to "member specific benefit document" with "member specific benefit *plan* document" **Indications for Coverage** ○ Added language to clarify benefits for outpatient and inpatient Habilitative Services are limited to the services listed in the policy ○ Updated list of benefits for outpatient and inpatient Habilitative Services; replaced "cognitive *rehabilitation* therapy" with "cognitive therapy" ○ Added language to indicate:	**Indications for Coverage** Benefits for outpatient and inpatient Habilitative Services are limited to: • Physical therapy • Occupational therapy • Manipulative Treatment • Speech therapy (see the Coverage Determination Guideline titled *Speech Language Pathology Services*) • Post-cochlear implant aural therapy • Cognitive therapy 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 *Skilled Care and Custodial Care Services*. (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.) *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

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Habilitative Services for Essential Health Groups *(continued)*	Jan. 1, 2018	▪ 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 ▪ 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 ○ Removed language indicating: ▪ Medically necessary, skilled, maintenance therapy is included in the Habilitative Services benefit ▪ Certain state mandates may require that additional services be included within the definition of Habilitative Services ○ Updated list of benefit coverage conditions for plans that provide Essential Health Benefits: ▪ Added "treatment must be proven and not	service]. Please see the member specific benefit plan document and state mandate requirements for details. For plans that provide Essential Health Benefits, benefits are provided for inpatient and outpatient Habilitative Services when all of the following conditions are met: • The covered member has a disabling condition • The treatment is presscribed 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. Outpatient Habilitative Services are those that are either: • 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 home from an independent physical or occupational therapist (a physical or occupational therapist that is not affiliated with a Home Health Agency). Certain states may require coverage of Habilitative Services in other locations. (For example, in Maryland, benefits for Habiliative 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. Outpatient Habilitative Services provided in the home from a Home Health Agency are addressed under the Home Health Care section of the plan. The Home Health Care benefit only applies to Habilitative Services that are rendered by a Home Health Agency. 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.)

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Habilitative Services for Essential Health Groups *(continued)*	Jan. 1, 2018	experimental or investigational" ▪ Replaced "treatment is *ordered* by a Physician" with "treatment is *prescribed* by a Physician" ○ Replaced language indicating: ▪ "Certain plans may not include coverage for all of the therapies [listed in the policy]" with "certain plans may not include coverage for all of the therapies [listed in the policy] *and state mandates may require coverage for therapies not [listed in the policy]*" ▪ "For plans that provide Essential Health Benefits, benefits are provided for Habilitative Services when the conditions [listed in the policy] are met" with "for plans that provide Essential Health Benefits, benefits are provided for *inpatient and outpatient* Habilitative Services when *all of* the conditions [listed in the policy] are met" ▪ "Coverage for durable medical equipment and prosthetic devices, when	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 Covered Person to achieve progress that is capable of being demonstrated (measurable progress), we may request a treatment plan that includes: • Diagnosis • Proposed treatment by type, frequency, and expected duration of treatment • Expected treatment goals • Frequency of treatment plan updates 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.) Please see the member specific benefit plan document and state mandate requirements for details. 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 plan document, and may require a separate review. Check the member specific benefit plan document. ***Additional Information*** • Refer to the member specific benefit plan document for any applicable benefit visit limits for Habilitative Services. • Cardiac and pulmonary therapy are covered under the Rehabilitation Services benefit. These are not Habilitative Services. **Coverage Limitations and Exclusions** • 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. • 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. • Coverage is excluded when the patient does not meet criteria for coverage as indicated in the *Indications for Coverage* 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.

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Habilitative Services for Essential Health Groups *(continued)*	Jan. 1, 2018	used as a part of habilitative services, may require separate review" with "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 plan document and* may require a separate review" ○ Modified language to clarify: ▪ Outpatient Habilitative Services are those that are provided: - In a physician's office - On an outpatient basis at a Hospital or Alternate Facility (such as health care facility that provides outpatient rehabilitative services) - In the home from an independent physical or occupational therapist (a physical or occupational therapist that is not affiliated with a	• Coverage is excluded for Custodial Care, respite care, day care, therapeutic recreation, vocational training and residential treatment. • In the absence of a disabling condition, services to improve general physical condition are excluded from coverage. • 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 (see *Definitions* 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 see the member specific benefit plan document and state mandate requirements for details.) • 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. • 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.

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Habilitative Services for Essential Health Groups *(continued)*	Jan. 1, 2018	Home Health Agency) ▪ 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) ▪ Outpatient Habilitative Services provided in the home from a Home Health Agency are addressed under the Home Health Care section of the plan; the Home Health Care benefit only applies to Habilitative Services that are rendered by a Home Health Agency ▪ 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)	

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Habilitative Services for Essential Health Groups *(continued)*	Jan. 1, 2018	▪ 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 Covered Person to achieve progress that is capable of being demonstrated (measurable progress), we may request a treatment plan that includes: - Diagnosis - Proposed treatment by type, frequency, and expected duration of treatment - Expected treatment goals - Frequency of treatment plan updates **Additional Information** ○ Added instruction to refer to the member specific benefit plan document for information on benefit visit limits for Habilitative	

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REVISED			
Habilitative Services for Essential Health Groups *(continued)*	Jan. 1, 2018	Services **Coverage Limitations and Exclusions** ○ Added reference link to definition of "Work Hardening" ○ Added language to indicate 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 • Updated definitions: ○ Added definition of: ▪ Medically Necessary ▪ Skilled Care ○ Modified definition of: ▪ Custodial Care ▪ Experimental or Investigational Service(s) ▪ Habilitative Services ▪ Unproven Service(s) ▪ Work Hardening • Updated list of applicable CPT/HCPCS codes: ○ Added 97127*, 97763* and G0515* ○ Removed 97532* and 97762* ○ Revised description for 64550*, 97112, 97530, 97542, 97750, 97760*, 97761*, V5362 and V5363 *(*annual code edit)* • Removed list of applicable places of service (POS)	

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Habilitative Services for Essential Health Groups *(continued)*	Jan. 1, 2018	• Updated supporting information to reflect the most current references	
Infertility Services	Jan. 1, 2018	• Reorganized and revised coverage rationale: ○ Replaced language indicating: ▪ "Infertility *treatments* [listed in the policy] *must be provided under the direction* of a Physician" with "*services for the treatment of* Infertility *when provided by or under the care or supervision* of a Physician *are limited to the procedures* [listed in the policy]" ▪ "If a female member is pregnant and functioning as a Surrogate, coverage *would be* provided for maternity *related care*" with "if a female member is pregnant and functioning as a Surrogate, coverage *is* provided for maternity *services*" ○ Modified eligibility criteria to clarify the member must: ▪ Be a female under age 44 ▪ Not be able to become pregnant after the	**Indications for Coverage** Therapeutic (medical or surgical) procedures to correct a physical condition, which is the underlying cause of the Infertility, are a covered health service (e.g., for the treatment of a pelvic mass or pelvic pain, thyroid disease, pituitary lesions, etc.). Services for the treatment of Infertility when provided by or under the care or supervision of a Physician are limited to the following procedures: • Ovulation induction (or controlled ovarian stimulation); • Insemination procedures: Artificial Insemination (AI) and Intra Uterine Insemination (IUI); • Assisted Reproductive Technologies (ART). To be eligible for Benefits, you must meet all of the following: • You are a female under age 44. • You are not able to become pregnant after the following periods of time of regular, unprotected intercourse or therapeutic donor insemination: ○ One year, if you are a female under age 35. ○ Six months, if you are a female age 35 or older. • You have Infertility not related to voluntary sterilization or to failed reversal of voluntary sterilization. ***Surrogate/Gestational Carrier*** A member with an Infertility benefit that is using a Surrogate/Gestational Carrier because of a known medical cause of Infertility (this does not include a member who has had a voluntary sterilization or a failed reversal of a sterilization procedure) will have coverage for the following services. These services will be paid per the member's coverage. • Female member's ovary stimulation and retrieval of eggs are covered when a member is using a Surrogate (host uterus). **Please note**: The implantation of eggs or oocytes or donor sperm into a host uterus is not covered even if the member has the Infertility benefit. • Male member retrieval of sperm.

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Infertility Services *(continued)*	Jan. 1, 2018	following periods of time of regular, unprotected intercourse or therapeutic donor insemination: - One year, if a female under age 35 - Six months, if a female age 35 or older ▪ Have Infertility not related to voluntary sterilization or to failed reversal of voluntary sterilization ○ Added language to indicate: ▪ When the member's plan includes benefits for Infertility, long-term storage (greater than one year) of reproductive materials such as sperm, eggs, embryos, ovarian tissue and testicular tissue, is not covered ▪ When the members plan does not include benefits for Infertility, all health care services and related expenses for infertility treatments, including assisted reproductive technology, regardless of the reason for the treatment are not covered ▪ Surrogate parenting is excluded on all plans	**When applying the Infertility benefit, consider the following**: • Female Infertility: Infertility caused by a problem that results in the inability to produce an egg, if an embryo is unable to travel to the womb, or there is a process that prevents use of the womb for reproduction. • Male Infertility: Infertility caused by problems due to inability to ejaculate or insufficient number or motility of sperm. Please check the member specific benefit plan document for inclusion or exclusion. Some states mandate benefit coverage for Infertility services. Please check state mandates. **Benefit Limitations and Exclusions** **When the member's plan includes benefits for Infertility, the following services are not covered**: • Assisted Reproductive Technologies, ovulation induction and insemination procedures are excluded from coverage unless the member has a benefit for Infertility and the criteria listed in the Indications for Coverage has been met. • Cryo-preservation and other forms of preservation of reproductive materials, e.g., sperm, oocytes (eggs), embryos or ovarian. • Long-term storage (greater than one year) of reproductive materials such as sperm, eggs, embryos, ovarian tissue and testicular tissue. • Preservation of reproductive materials prior to cancer treatments and elective preservation of reproductive materials are not covered. This includes all services related, including but not limited to drug therapy, retrieval, cryopreservation and storage. • Donor services for donor sperm, ovum or oocytes (eggs), or embryos. ○ Donor eggs - All aspects of a donor egg cycle including stimulation, retrieval, fertilization, embryo culture and embryo transfer (fresh or frozen) are excluded from coverage unless otherwise specified in the plan language. ○ Donor sperm - The cost of procurement and storage of donor sperm is excluded. However, the thawing and insemination are covered if the member has an Infertility benefit that allows for artificial donor insemination. • In-vitro fertilization that is not an Assisted Reproductive Technology for the treatment of Infertility. This would include but is not limited to

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Infertility Services *(continued)*	Jan. 1, 2018	(even when the plan provides benefits for Infertility); services and treatments for a gestational carrier of a pregnancy that is not our member and all related services including, but not limited to donor eggs and donor sperm ▪ Refer to the pharmacy benefit administrator for self-injectable medication benefit information ○ Removed language indicating surrogate parenting, including fees incurred for the use of a surrogate/gestational carrier (i.e., host uterus), is excluded on all plans (even when the plan provides benefits for Infertility) • Modified definition of "Infertility" • Updated supporting information to reflect the most current references	elective fertility preservation, embryo accumulation/banking. • Any Infertility services or supplies beyond the benefit maximum (dollars or procedures). • Infertility treatment when the cause of the Infertility was a procedure that produces sterilization, e.g., vasectomy or tubal ligation. (Check the member specific benefit plan document). **When the member's plan does not include benefits for Infertility, the following services are not covered**: • All health care services and related expenses for infertility treatments, including assisted reproductive technology, regardless of the reason for the treatment. • Storage and retrieval of all reproductive materials. Examples include eggs, sperm, testicular tissue and ovarian tissue. • In vitro fertilization regardless of the reason for treatment. **The following services are excluded on all plans (even when the plan provides benefits for Infertility)**: • Surrogate Parenting: Services and treatments for a gestational carrier of a pregnancy that is not our member and all related services including, but not limited to: donor eggs and donor sperm. • Unproven tests or procedures for Infertility. Refer to the Medical Policy titled *Infertility Diagnosis and Treatment*. • Self-injectable drugs for Infertility. Refer to the exclusion for self-injectable drugs in the member specific benefit plan document. Refer to the pharmacy benefit administrator for self-injectable medication benefit information. ***Additional Information*** • As a standard, coverage is provided for maternity services (prenatal, delivery and postnatal pregnancy) for our members. If a female member is pregnant and functioning as a Surrogate, coverage is provided for maternity services. Coverage is not provided for maternity services for a Surrogate that is not a member (see Surrogate parenting exclusion above). • Surrogate parenting including fees incurred for the use of a Surrogate/Gestational Carrier (i.e., host uterus). • Advanced Reproductive Technology Services (IVF, GIFT, ZIFT, PROS, and TET) requested for reasons other than Infertility, must be reviewed in

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Infertility Services *(continued)*	Jan. 1, 2018		accordance with the member specific benefit plan document (case by case determination).
Preventive Care Services	Jan. 1, 2018	• Revised coverage rationale/indications for coverage: **For Plan Years that begin on or after August 1, 2012** ○ Removed language indicating prostate specific antigen (PSA) screening is covered under the Preventive Care Services benefit **Men's Health** ○ Removed language indicating prostate cancer screening for men age 40 and older is covered under the Preventive Care Services benefit **Additional Preventive Care Services** ○ Removed language indicating prostate cancer screening for men age 40 and older is covered under the Preventive Care Services benefit **Travel Immunizations** ○ Added language to indicate benefits for Preventive Care Services include immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from ACIP with respect to	Refer to the policy for complete details on the coverage guidelines for *Preventive Care Services*.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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Preventive Care Services *(continued)*	Jan. 1, 2018	the individual involved ○ Replaced language indicating "immunizations that are specific to travel are not required by PPACA and are excluded from *coverage*" with "immunizations that are specific to travel are not required by PPACA and are excluded from *the Preventive Care Services benefit*" • Revised list of applicable procedure and diagnosis codes for: **Preventive Care Services** ○ Updated table sub-headings; added language to clarify a date in the "Service" column indicates when the *listed* rating was released, not when the benefit is effective *Diabetes Screening* ○ Updated service description; added instruction to refer to the Behavioral Counseling in Primary Care to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Cardiovascular Risk Factors section of the policy for information on intensive behavioral counseling interventions *Rubella Screening By History of Vaccination or by Serology* ○ Removed coverage guidelines and list of applicable codes (no longer	

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Preventive Care Services *(continued)*	Jan. 1, 2018	in the current USPSTF recommendations) *Screening Mammography* ○ Updated service description; added instruction to refer to the *Expanded Women's Preventive Health*: *Breast Cancer Screening for Average-Risk Women* section of the policy for additional information *Cervical Cancer Screening, Pap Smear* ○ Updated service description; added instruction to refer to the *Expanded Women's Preventive Health: Screening for Cervical Cancer* section of the policy for additional information ○ Updated list of applicable CPT codes for Code Group 2; removed 88154 (discontinued Jan. 1, 2018) *Colorectal Cancer Screening* ○ Updated list of applicable CPT codes for Code Group 4 (Anesthesia): ▪ Added 00812 (new code effective Jan. 1, 2018) ▪ Removed 00810 (discontinued Jan. 1, 2018) *Wellness Examinations* ○ Updated service description/language pertaining to Health Resources and Services Administration (HRSA)	

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Preventive Care Services *(continued)*	Jan. 1, 2018	coverage requirements: ▪ Replaced references to "Health and Human Services (HHS)" with "Health Resources and Services Administration (HRSA)" ▪ Modified list of applicable services; replaced "contraceptive methods counseling" with "contraceptive methods counseling *and follow-up care*" *Prostate Cancer Screening* ○ Removed coverage guidelines and list of applicable codes (no longer in the current USPSTF recommendations) *Screening for Visual Impairment in Children* ○ Updated service description: ▪ Removed January 2011 USPSTF 'B' rating ▪ Added September 2017 USPSTF 'B' rating to indicate the USPSTF recommends vision screening at least once in all children age 3–5 years to detect amblyopia or its risk factors *Fluoride Application in Primary Care* ○ Updated service description: ▪ Removed March 2014 Bright Futures	

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Preventive Care Services *(continued)*	Jan. 1, 2018	recommendation (for age 6 months–6 years) ▪ Added April 2017 Bright Futures recommendation (for age 6 months–5 years) to indicate for those at high risk, consider application of fluoride varnish for caries prevention every 3 to 6 months ○ Updated preventive benefit instructions; changed age requirement from "0–6 years (ends on 7th birthday)" to "0–5 years (ends on 6th birthday)" *Lead Screening (Bright Futures)* ○ Updated service description; added language to indicate Bright Futures recommends: ▪ Screening lab work: Conduct risk assessment or screening, as appropriate, at the intervals of 12 months and 24 months ▪ Risk assessment and screening: If positive, at age 6 months, 9 months, 12 months, 18 months, 24 months, 3 years, 4 years, 5 years, and 6 years ○ Updated preventive benefit instructions for lead screening and blood draw; changed age requirement from "prenatal–21 years	

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Preventive Care Services *(continued)*	Jan. 1, 2018	(ends on 21st birthday)" to "6 months–6 years (ends on 7th birthday)" **Preventive Immunizations** *Seasonal Influenza ('flu')* ○ Updated list of applicable CPT codes; added 90756 (new code effective Jan. 1, 2018) **Expanded Women's Preventive Health** ○ Updated table heading/introduction; replaced language indicating "[the listed guidelines] are the requirements of *Health and Human Services (HHS) for plan years that begin on or after Aug. 1, 2012*" with "[the listed guidelines] are the requirements of the *Health Resources and Services Administration (HRSA)*" ○ Updated table sub-headings; added language to clarify a date in the "Service" column indicates when the listed rating was issued *Well-Woman Visits* ○ Updated service description: ▪ Removed language pertaining to August 2012 HHS coverage requirements ▪ Added language pertaining to December 2016 HRSA coverage requirements to indicate	

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Preventive Care Services *(continued)*	Jan. 1, 2018	the HRSA recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services including preconception, and many services necessary for prenatal and interconception care are obtained; the primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors *Screening for Gestational Diabetes Mellitus* (previously titled *Screening for Gestational Diabetes*) ○ Updated service description: ▪ Removed language pertaining to August 2012 HHS coverage requirements ▪ Added language pertaining to December 2016 HRSA coverage requirements to indicate: - The HSA recommends screening pregnant women for gestational diabetes	

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Preventive Care Services *(continued)*	Jan. 1, 2018	mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes - Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100-g oral glucose tolerance test if results on the initial oral glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity; this recommendation also suggests that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices *Human Papillomavirus DNA Testing (HPV)* ○ Relocated content to section titled *Screening for Cervical Cancer* *Counseling for Sexually Transmitted Infections*	

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Preventive Care Services *(continued)*	Jan. 1, 2018	○ Updated service description: ▪ Removed language pertaining to August 2012 HHS coverage requirements ▪ Added language pertaining to December 2016 HRSA coverage requirements to indicate the HRSA recommends directed behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for sexually transmitted infections (STIs) - This recommendation further recommends that health care providers use a woman's sexual history and risk factors to help identify those at an increased risk of STIs; risk factors may include age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner	

Coverage Determination Guideline (CDG) Updates

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Preventive Care Services *(continued)*	Jan. 1, 2018	with an STI, and a lack of or inconsistent condom use - For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgement *Education, Risk Assessment, and Screening for Human Immunodeficiency Virus Infection* (previously titled *Counseling and Screening for Human Immune-deficiency Virus*) ○ Updated service description: ▪ Removed language pertaining to August 2012 HHS coverage requirements ▪ Added language pertaining to December 2016 HRSA coverage requirements to indicate the HRSA recommends prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan - All women should be	

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Preventive Care Services *(continued)*	Jan. 1, 2018	tested for HIV at least once during their lifetime; additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents and women with an increased risk of HIV infection - Screening for HIV is recommended for all pregnant women upon initiation of prenatal care with retesting during pregnancy based on risk factors; rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status (screening during pregnancy enables prevention of vertical transmission) *Contraceptive Methods (Including Sterilizations)* ○ Updated service description: ▪ Removed language pertaining to August 2012 HHS coverage requirements	

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Preventive Care Services *(continued)*	Jan. 1, 2018	▪ Added language pertaining to December 2016 HRSA coverage requirements to indicate the HRSA recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes - Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method) - The Women's Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and	

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Preventive Care Services *(continued)*	Jan. 1, 2018	sterilization procedures be available as part of contraceptive care - Instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method ▪ Modified notation to indicate certain employers may qualify for an exemption from covering contraceptive methods and sterilizations on account of religious *or moral* objections *Breastfeeding Services and Supplies* (previously titled *Breastfeeding Support, Supplies, and Counseling)* ○ Updated service description: ▪ Removed language pertaining to August 2012 HHS coverage requirements ▪ Added language pertaining to December 2016 HRSA coverage requirements to indicate the HRSA recommends comprehensive lactation support services	

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Preventive Care Services *(continued)*	Jan. 1, 2018	(including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding *Screening and Counseling for Interpersonal and Domestic Violence* ○ Updated service description: ▪ Removed language pertaining to August 2012 HHS coverage requirements ▪ Added language pertaining to December 2016 HRSA coverage requirements to indicate the HRSA recommends screening adolescents and women for interpersonal and domestic violence, at least annually, and, when needed, providing or referring for initial intervention services - Interpersonal and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion),	

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Preventive Care Services *(continued)*	Jan. 1, 2018	reproductive coercion, neglect, and the threat of violence, abuse, or both - Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and referral to appropriate supportive services *Breast Cancer Screening for Average-Risk Women* (new to policy) ○ Added service description/language pertaining to December 2016 HRSA coverage requirements to indicate the HRSA recommends average-risk women initiate mammography screening no earlier than age 40 and no later than age 50 ▪ Screening mammography should occur at least biennially and as frequently as annually ▪ Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening ▪ These screening recommendations are for	

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Preventive Care Services *(continued)*	Jan. 1, 2018	women at average risk of breast cancer; women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation ○ Added instruction to refer to the *Preventive Care Services: Screening Mammography* section of the policy for details on applicable codes and corresponding preventive benefit instructions *Screening for Cervical Cancer* [previously titled *Human Papillomavirus DNA Testing (HPV)*] ○ Updated service description: ▪ Removed language pertaining to August 2012 HHS coverage requirements ▪ Added language pertaining to December 2016 HRSA coverage requirements to indicate the HRSA recommends cervical cancer screening for average-risk women age 21–65 years - For women age 21–29 years, HRSA recommends cervical cancer screening	

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Preventive Care Services *(continued)*	Jan. 1, 2018	using cervical cytology (Pap test) every 3 years; co-testing with cytology and human papillomavirus testing is not recommended for women younger than 30 years - Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years - Women who are at average risk should not be screened more than once every 3 years ○ Updated list of applicable CPT codes for Human Papillomavirus DNA Testing (HPV); added 0500T (new code effective Jan. 1, 2018) ○ Updated code information/preventive benefit instructions; added instruction to refer to the *Preventive Care Services: Cervical Cancer Screening, Pap Smear* section of the policy for information pertaining to cervical cytology (Pap test) • Updated supporting information	

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Preventive Care Services *(continued)*	Jan. 1, 2018	to reflect the most current references	
Rehabilitation Services (Outpatient)	Jan. 1, 2018	• Reorganized and revised coverage rationale: ○ Replaced references to "member specific benefit document" with "member specific benefit *plan* document" **Indications for Coverage** ○ Updated list of benefits for outpatient Rehabilitation Services; replaced: ▪ "Speech therapy" with "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" ▪ "Cognitive rehabilitation therapy" with "cognitive rehabilitation therapy when medically necessary following a post-traumatic brain injury or cerebral vascular accident" ○ Replaced language indicating: ▪ "Certain *states* may not include coverage for all	**Indications for Coverage** Benefits for outpatient rehabilitation services include: • 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 Speech Language Pathology Services) • Pulmonary rehabilitation therapy • Cardiac rehabilitation therapy • Post-cochlear implant aural therapy • Cognitive rehabilitation therapy when Medically Necessary following a post-traumatic brain Injury or cerebral vascular accident Certain plans may not include coverage for all of the above therapies and state mandates may may require coverage for therapies not mentioned above. Please see the member specific benefit plan document and state mandate requirements for details. Benefits are provided for outpatient Rehabilitative Services when all of the following conditions are met: • 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/preventitive purposes • The services are not considered Habilitative (see definition of *Habilitative Services* and the Coverage Determination Guideline titled *Habilitative Services for Essential Health Groups*) Outpatient Rehabilitative Services are those that are either: • Provided in a physician's office, • Provided on an outpatient basis at a Hospital or Alternate Facility (such

Coverage Determination Guideline (CDG) Updates

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Rehabilitation Services (Outpatient) *(continued)*	Jan. 1, 2018	of the [listed] therapies; see the member specific benefit plan document for details" with "certain *plans* may not include coverage for all of the [listed] therapies *and state mandates may require coverage for therapies not mentioned [in the policy]*; see the member specific benefit plan document *and state mandate requirements* for details" ▪ "Rehabilitation Services *are a Covered Health Service* when all of the *criteria* [listed in the policy] are met" with "*benefits are provided for outpatient* Rehabilitative Services when all of the *conditions* [listed in the policy] are met" ○ Updated list of benefit coverage conditions for outpatient Rehabilitative Services: ▪ Added "treatment is not for maintenance/ preventative purposes" ▪ Replaced "treatment is *provided* by a physician or a licensed therapy provider" *with* "treatment is *administered* by a	as health care facility that provides outpatient rehabilitative services), or • Provided in the home from an independent physical or occupational therapist (a physical or occupational therapist that is not affiliated with a Home Health Agency). Certain states may 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. Outpatient Rehabilitative Services provided in the home from a Home Health Agency are addressed under the Home Health Care section of the plan. The Home Health Care benefit only applies to Rehabilitative Services that are rendered by a Home Health Agency. ***Additional Information*** • Rehabilitation services 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 facility benefit). • Refer to the member specific benefit plan document for any applicable benefit visit limits for Rehabilitation Services. • Pulmonary therapy does not include respiratory therapy. Respiratory therapy is a therapeutic service and not included in the benefit limits for pulmonary therapy. **Coverage Limitations and Exclusions** • Coverage is excluded when the patient does not meet criteria for coverage as indicated in the *Indications for Coverage* section above and 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 services that are not Rehabilitative (see definition of *Rehabilitation Services – Outpatient Therapy*). • Coverage is excluded if the services provided are considered non-skilled or custodial care. For additional information, see the Coverage Determination Guideline titled *Skilled Care and Custodial Care Services*. • Services to improve general physical condition that are provided to

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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Rehabilitation Services (Outpatient) *(continued)*	Jan. 1, 2018	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"* ○ Modified language to clarify: ▪ Outpatient Rehabilitative Services are those that are provided: - In a physician's office - On an outpatient basis at a Hospital or Alternate Facility (such as health care facility that provides outpatient rehabilitative services) - In the home from an independent physical or occupational therapist (a physical or occupational therapist that is not affiliated with a Home Health Agency) ▪ Certain states may require coverage for therapies of rehabilitative services in other locations; see the	reduce potential risk factors, where significant therapeutic improvement is not expected, are not Rehabilitation Services and are excluded from coverage. • Maintenance therapy is not a Rehabilitation Service and is excluded from coverage under the Rehabilitation benefit. For maintenance therapy, see the Coverage Determination Guideline titled *Habilitative Services for Essential Health Groups* for plans that cover Habilitative Services. • Coverage is excluded for Rehabilitation Services that are done for preventive reasons. • Coverage is excluded after 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 educational assessments and ongoing treatment, and vocational training. • Coverage is excluded for Work Hardening (see *Definitions* section of the policy). • Confinement, treatment, services or supplies related to learning and intellectual disabilities. • 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. • Coverage is excluded for services beyond any visit limits specified in the member specific benefit plan document. • 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 member specific benefit plan document. • 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.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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Rehabilitation Services (Outpatient) *(continued)*	Jan. 1, 2018	member specific benefit plan document and state mandate requirements for details ▪ Outpatient Rehabilitative Services provided in the home from a Home Health Agency are addressed under the Home Health Care section of the plan; the Home Health Care benefit only applies to Rehabilitative Services that are rendered by a Home Health Agency ○ Removed language indicating inpatient rehabilitative services are those received while in an inpatient setting; depending on where the inpatient rehabilitative services are provided, benefits are the same as the applicable inpatient benefit category (inpatient hospital, skilled nursing facility/inpatient rehabilitation facility) **Additional Information** ○ Added instruction to refer to the member specific benefit plan document for information on benefit visit limits for Rehabilitation Services **Coverage Limitations and Exclusions** ○ Replaced language indicating	

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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Rehabilitation Services (Outpatient) *(continued)*	Jan. 1, 2018	"maintenance therapy is not a Rehabilitation Service and is excluded from coverage" with "maintenance therapy is not a Rehabilitation Service and is excluded from coverage *under the Rehabilitation benefit*" • Updated definitions: ○ Added language to indicate the definitions listed in the policy may not apply to all plans; refer to the member specific benefit plan document for applicable definitions ○ Added definition of: ▪ Medically Necessary ▪ Skilled Care ○ Modified definition of: ▪ Alternate Facility ▪ Cardiac Rehabilitation ▪ Cognitive Rehabilitation ▪ Experimental or Investigational Service(s) ▪ Habilitative Services ▪ Pulmonary Rehabilitation ▪ Unproven Service(s) ▪ Work Hardening • Updated list of applicable CPT/HCPCS codes: ○ Added reference link to policy titled *Speech Language Pathology Services* for information on speech therapy codes ○ Added 97127*, 97763*, and G0515*	

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Rehabilitation Services (Outpatient) *(continued)*	Jan. 1, 2018	○ Removed 97532* and 97762* ○ Revised description for 64550*, 97112, 97530, 97542, 97750, 97760*, 97761*, G0237, G0238, and S9473 (*annual code edit) • Updated supporting information to reflect the most current references	

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
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Site of Service Guidelines for Certain Outpatient Surgical Procedures	Jan. 1, 2018	• Reformatted and reorganized policy; transferred content to new template
		• Revised coverage rationale:
		  ○ Removed footnotes pertaining to clinical descriptions/definitions from list of examples of *Certain Qualifying Conditions*
		  ○ Updated list of services requiring prior authorization in the outpatient hospital setting; removed abdominal paracentesis (CPT code 49083)
		• Modified definition of:
		  ○ Brittle Diabetes
		  ○ Obstructive Sleep Apnea (OSA)
		  ○ Poorly Controlled
		• Updated list of CPT codes requiring prior authorization in the outpatient hospital setting; removed 49083
		• Updated supporting information to reflect the most current references
			With the exception of the qualifying conditions below, certain elective procedures should be performed in an Ambulatory Surgical Center (ASC).
			
			The following will be taken into account to determine whether the elective procedure is being performed in a cost effective setting:
			• Member's specific benefit plan
			• Geographic availability of an in network provider
			• Ambulatory surgical care (ASC) capability
			• Physician privileging
			• Significant member comorbidities (see list of examples of Qualifying Conditions below)
			• American Society of Anesthesiologist (ASA) physical status (PS), classification system
			
			Potential Documentation Requirements
			• Physician office notes
			• Physician privileging
			• ASA score
			
			Certain Qualifying Conditions
			Some patients may require more complex care due to factors such as age or medical conditions. Also, some ASCs may have specific guidelines that prohibit members who are above a certain weight or have certain health conditions from receiving care in those facilities.
			
			Patients with severe systemic disease and some functional limitation (ASA PS classification III or higher) may be appropriate to have the procedure in an outpatient hospital setting (not an all-inclusive list):
			• Morbid obesity (>BMI.40)
			• Diabetes (brittle diabetes)
			• Resistant hypertension (poorly controlled)
			• Chronic obstructive pulmonary disease (COPD) (FEV1 < 50%)
			• Advance liver disease (MELD Score > 8)
			• Alcohol dependence (at risk for withdrawal syndrome)
			• End stage renal disease (hyperkalemia (above reference range peritoneal or hemodialysis)
			• Uncompensated chronic heart failure (CHF) (NYHA class III or IV)
			• History of myocardial infarction (MI) (recent event (< 3 mo.))

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
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Site of Service Guidelines for Certain Outpatient Surgical Procedures *(continued)*	Jan. 1, 2018		• History of cerebrovascular accident (CVA) or transient ischemic attack (TIA) (recent event (< 3 mo.)) • Coronary artery disease (CAD/peripheral vascular disease (PVD) (ongoing cardiac ischemia requiring medical management recently placed drug eluting stent (within 1 year)) • Sleep apnea (moderate to severe obstructive sleep apnea (OSA) • Implanted pacemaker • Personal history or family history of complication of anesthesia such as malignant hyperthermia • Pregnancy • Bleeding disorder requiring replacement factor or blood products or special infusion products to correct a coagulation defect (DDAVP is not blood product and is OK) • Prolonged surgery (>3 hrs.) • Anticipated need for transfusion • Recent history of drug abuse (especially cocaine) • Patients with drug eluting stents (DES) placed within one year or bare metal stents (BMS) or plain angioplasty within 90 days unless acetylsalicylic acid (ASA) and antiplatelet drugs will be continued by agreement of surgeon, cardiologist and anesthesia • Ongoing evidence of myocardial ischemia • Poorly controlled asthma (FEV1 < 80% despite medical management) • Significant valvular heart disease • Cardiac arrhythmia (symptomatic arrhythmia despite medication) ***Elective Procedures List*** Prior authorization is required for the following procedures if performed in an outpatient hospital setting (see *Applicable Codes* table).
Specialty Medication Administration – Site of Care Review Guidelines	Jan. 1, 2018	• Reformatted and reorganized policy; transferred content to new template • Updated list of related policies; added reference links to policies titled: ○ Ilaris® (Canakinumab) ○ Ocrevus™ (Ocrelizumab) • Updated benefit considerations; added language to indicate:	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: • 22 On Campus-Outpatient Hospital; and • 19 Off 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 a patient does not meet

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Utilization Management Guiding Principles
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Specialty Medication Administration – Site of Care Review Guidelines *(continued)*	Jan. 1, 2018	○ This guideline applies to members who have medical necessity language in their Certificate of Coverage (COC) or Summary Plan Document with benefits available for health care services if medically necessary and have been approved for the requested medication clinical use ○ This guideline applies to UnitedHealthcare Commercial plans ○ This guideline does not apply to Medicare or Medicaid plans • Revised coverage rationale: ○ Updated list of applicable specialty medications that require healthcare provider administration; added Ilaris® (canakinumab) and Ocrevus™ (ocrelizumab) • Updated supporting information to reflect the most current references	criteria for outpatient hospital facility infusion, alternative sites of care may be used. **Outpatient hospital facility-based intravenous medication infusion is medically necessary for persons 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 patient, 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) • Entyvio® (Vedolizumab) • Exondys 51™ (Eteplirsen) • Ilaris® (Canakinumab) • Inflectra™ (Infliximab-dyyb) • Ocrevus™ (Ocrelizumab) • Orencia® (Abatacept) • Radicava™ (edaravone) • Remicade® (Infliximab) • Renflexis™ (Infliximab-abda) • Simponi Aria® (Golimumab) • Soliris® (Eculizumab) Medical necessity criteria for administration of intravenous infusion therapy at home are addressed in MCG™ Care Guidelines, 21st edition, 2017, Home

Utilization Review Guideline (URG) Updates

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Specialty Medication Administration – Site of Care Review Guidelines *(continued)*	Jan. 1, 2018		Infusion Therapy, CMT: CMT-0009(SR).