UnitedHealthcare®

February 2019

medical policy update bulletin

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

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

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

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** > *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

Quality of Care Guideline (QOCG) Updates

UPDATED

Medical Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Electroencephalographic (EEG) Monitoring and Video Recording	Apr. 1, 2019	Electroencephalographic (EEG) monitoring and video recording is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, EEG, Video Monitoring, M-580 (ISC).

Policy Title	Effective Date	Summary of Changes
UPDATED		
Apheresis	Feb. 1, 2019	• Simplified coverage rationale (no change to guidelines) • Updated supporting information to reflect the most current FDA information

Chromosome Microarray Testing (Non-Oncology Conditions)	Apr. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated coverage rationale; replaced references to "Preimplantation Genetic *Diagnosis (PGD)* in embryos" and "Preimplantation Genetic *Screening (PGS)* in embryos" with "Preimplantation Genetic *Testing – (PGT)* in embryos"
		• Updated definitions:
		  ○ Added definition of "Preimplantation Genetic Testing (PGT)"
		  ○ Removed definition of:
		  ▪ Preimplantation Genetic Diagnosis (PGD)
		  ▪ Preimplantation Genetic Screening (PGS)
		• Updated list of applicable ICD-10 diagnosis codes; removed Z3A.00, Z3A.01, Z3A.08, Z3A.09, Z3A.10, Z3A.11, Z3A.12, Z3A.13, Z3A.14, Z3A.15, Z3A.16, Z3A.17, Z3A.18, Z3A.19, Z3A.20, Z3A.21, Z3A.22, Z3A.23, Z3A.24, Z3A.25, Z3A.26, Z3A.27, Z3A.28, Z3A.29, Z3A.30, Z3A.31, Z3A.32, Z3A.33, Z3A.34, Z3A.35, Z3A.36, Z3A.37, Z3A.38, Z3A.39, Z3A.40, Z3A.41, Z3A.42, and Z3A.49
		• Updated supporting information to reflect the most current description of services and references

Collagen Crosslinks and Biochemical Markers of Bone Turnover	Feb. 1, 2019	• Simplified coverage rationale (no change to guidelines) • Updated supporting information to reflect the most current clinical evidence, FDA information, and references

Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation	Feb. 1, 2019	• Updated coverage rationale; modified language pertaining to neuromuscular electrical stimulation (NMES) to clarify:
		  ○ NMES is proven and medically necessary for treating the following indications:
		  ▪ Disuse muscle atrophy if:
		  - The nerve supply to the muscle is intact; and
		  - The disuse muscle atrophy is not of neurological origin but originates from conditions such as

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UPDATED		
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation *(continued)*	Feb. 1, 2019	casting, splinting or contractures ▪ To improve wrist and finger function and prevent or correct shoulder subluxation in persons with partial paralysis following stroke • Updated supporting information to reflect the most current clinical evidence and references
Light and Laser Therapy for Cutaneous Lesions and Pilonidal Disease	Feb. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section
Manipulation Under Anesthesia	Feb. 1, 2019	• Simplified coverage rationale (no change to guidelines) • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Apr. 1, 2019	• Updated coverage rationale: ○ Replaced language indicating "the use of one of the [listed] gene expression tests *listed [in the policy]* is proven and medically necessary to make a treatment decision regarding adjuvant chemotherapy in females or males with non-metastatic breast cancer when *all of the [listed]* criteria are met" with "the use of one of the [listed] gene expression tests is *considered* proven and medically necessary to make a treatment decision regarding adjuvant chemotherapy in females or males with non-metastatic breast cancer when criteria are met *as summarized [in the policy]*" ○ Modified language to clarify services are unproven and not medically necessary (as described) *due to insufficient evidence of efficacy* • Updated list of applicable CPT codes; added 0013U, 0014U, and 0069U
Negative Pressure Wound Therapy	Feb. 1, 2019	• Updated coverage rationale: ○ Replaced reference to "members" with "individuals" ○ Removed duplicative language pertaining to outpatient application of treatment ○ Replaced language indicating "negative pressure wound therapy (NPWT) should be discontinued when the depth of the wound is *less than* 1 mm" with "NPWT should be discontinued when the depth of the wound is 1 mm *or less*"
Neurophysiologic Testing and Monitoring	Feb. 1, 2019	• Simplified coverage rationale (no change to guidelines)

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Policy Title	Effective Date	Summary of Changes
UPDATED		
Pharmacogenetic Testing	Apr. 1, 2019	• Simplified coverage rationale (no change to guidelines) • Updated list of applicable CPT codes; added 0078U

Sodium Hyaluronate	Feb. 1, 2019	• Updated and reformatted coverage rationale:
		  ○ Simplified content
		  ○ Added language to clarify hyaluronic acid gel preparations to improve the skin's *appearance*, contour and/or reduce depressions due to acne, scars, injury or wrinkles are considered cosmetic
		• Updated list of applicable ICD-10 diagnosis codes; removed coding clarification language
		• Updated supporting information to reflect the most current description of services

Transcatheter Heart Valve Procedures	Feb. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)
		• Added definition of:
		  ○ New York Heart Association (NYHA) Heart Failure Classification
		  ○ Predicted Risk of Mortality (PROM)
		• Updated supporting information to reflect the most current references

Transcranial Magnetic Stimulation	Feb. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Simplified coverage rationale (no change to guidelines)
		• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Cognitive Rehabilitation	Mar. 1, 2019	• Revised and reformatted coverage rationale:
		  ○ Simplified content
		  ○ Replaced language indicating:
		  ▪ "CR is proven and medically necessary when treating individuals following a TBI or *cerebral vascular accident*" with "CR is proven and medically
			Cognitive rehabilitation (CR) is proven and medically necessary when treating individuals following a traumatic brain injury (TBI) or stroke when ALL of the following criteria are met:
			• Individual has the ability to actively participate, and
			• Treatment regimen includes:
			  ○ Specific interventions for functional communication deficits, including pragmatic conversational skills, or
			  ○ Compensatory memory strategy training
			
			The following are unproven and not medically necessary due to insufficient evidence of efficacy:
			• Cognitive rehabilitation for any other condition or diagnosis

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Cognitive Rehabilitation *(continued)*	Mar. 1, 2019	necessary when treating individuals following a TBI or *stroke when all of the [listed] criteria are met*" ▪ "Coma stimulation is unproven and not medically necessary when treating individuals who are comatose or in a Vegetative or Minimally Conscious State *who have sustained a brain injury*" with "coma stimulation is unproven and not medically necessary when treating individuals who are comatose or in a Vegetative or Minimally Conscious State" ○ Added criterion requiring the individual has the ability to actively participate in treatment • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	• Coma stimulation when treating individuals who are comatose or in a Vegetative or Minimally Conscious State
Home Hemodialysis	Mar. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed *Benefit Considerations* section • Revised coverage rationale: ○ Replaced language indicating: ▪ "Home hemodialysis	**Home hemodialysis without Skilled Care is proven and medically necessary as an alternative to facility-based hemodialysis for treating individuals with end-stage renal disease who meet ALL of the following criteria**: • Individual is stable on dialysis with no evidence of Skilled Care interventions being necessary during treatments; and • Individual undergoing hemodialysis or non-professional caregiver has the ability to perform and maintain home hemodialysis and has received comprehensive training regarding proper protocol; and

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Home Hemodialysis *(continued)*	Mar. 1, 2019	**without** *professional staff assistance* is proven *and/or* medically necessary as an alternative to facility-based hemodialysis for treating patients with end-stage renal disease who meet all of the [listed] criteria" with "home hemodialysis without *Skilled Care* is proven *and* medically necessary as an alternative to facility-based hemodialysis for treating individuals with end-stage renal disease who meet all of the [listed] criteria" ▪ "Home hemodialysis **with** *professional staff assistance* is proven *and/or* medically necessary as an alternative to facility-based hemodialysis for treating patients with end-stage renal disease who meet all of the [listed] criteria" with "Home hemodialysis with *Skilled Care* is proven *and* medically necessary as an alternative to facility-based hemodialysis for treating individuals with end-stage renal disease who	• Absence of complications and significant concomitant disease that would cause home hemodialysis to be unsafe or unsuitable; and • Presence of well-functioning vascular access. **Home hemodialysis with Skilled Care is proven and medically necessary as an alternative to facility-based hemodialysis for treating individuals with end-stage renal disease who meet ALL of the following criteria**: • Individual is stable on dialysis and not at increased risk as a result of having the procedure performed outside a dialysis center venue; and • Individual has well-functioning vascular access; and • Individual has medical contraindications to leaving home for hemodialysis; and • Individual undergoing hemodialysis or non-professional caregiver is not capable of performing home hemodialysis; and • Staff assisted home hemodialysis protocols generally match those provided in the hemodialysis center (i.e., at least 3 times per week, 3-4 hour treatments). The exact dialysis therapy employed is determined on an individual basis by the attending nephrologist.

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REVISED			
Home Hemodialysis *(continued)*	Mar. 1, 2019	meet all of the [listed] criteria" ○ Updated coverage criteria for: ▪ Home hemodialysis **without** Skilled Care; replaced criterion requiring "*patient* or non-professional caregiver has the ability to perform and maintain home hemodialysis and has received comprehensive training regarding proper protocol" with "*individual undergoing hemodialysis* or non-professional caregiver has the ability to perform and maintain home hemodialysis and has received comprehensive training regarding proper protocol" ▪ Home hemodialysis **with** Skilled Care; replaced criterion requiring "*patient* or non-professional caregiver is not capable of performing home hemodialysis" with "*individual undergoing hemodialysis* or non-professional caregiver is not capable of performing home hemodialysis"	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Home Hemodialysis *(continued)*	Mar. 1, 2019	○ Replaced references to "patient(s)" with "individual(s)" • Added definition of "Skilled Care" • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references	
Neuropsychological Testing Under the Medical Benefit	Mar. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Revised and reformatted coverage rationale: ○ Simplified content ○ Replaced language indicating: ▪ "Neuropsychological testing is proven and medically necessary for evaluating individuals with neurotoxin exposure with documented ***significant*** *prenatal alcohol, drug, or toxin exposure* when the result of testing will influence clinical decision making" with "neuropsychological testing is proven and medically necessary for evaluating individuals with neurotoxin exposure with documented *prenatal alcohol, drug, or toxin*	**Neuropsychological testing is proven and medically necessary for evaluating individuals with the following conditions when the result of testing will influence clinical decision making**: • Attention-deficit/hyperactivity disorder (ADHD) when all of the following are present: ○ Specific neurocognitive behavioral deficits related to ADHD need to be evaluated and ○ Testing has been recommended by a physician and is related or secondary to a known or suspected organic-medical condition resulting from brain injury or disease process (e.g., concussion, intractable seizure disorder, cancer treatment effects, genetic disorders, inborn errors of metabolism) *The scope of these criteria is applicable only to neuropsychological testing that is covered by the medical benefit. These criteria do not apply to evaluate or determine educational interventions.* • Confirmed space-occupying brain lesion including but not limited to the following: ○ Brain abscess ○ Brain tumors ○ Arteriovenous malformations within the brain • Dementia or symptoms of dementia such as memory impairment or memory loss (including extrapyramidal disorders such as Parkinson's disease) that is associated with a new onset or progressive memory loss and a decline in at least one of the following cognitive domains (DSM-5): ○ Complex attention ○ Executive function ○ Learning and memory ○ Language ○ Perceptual-motor

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Neuropsychological Testing Under the Medical Benefit *(continued)*	Mar. 1, 2019	*exposure* when the result of testing will influence clinical decision making" ▪ "Computerized cognitive testing including but not limited to Cognivue®, Mindstreams® Cognitive Health Assessment, and BrainCare™ is unproven and not medically necessary for diagnosing dementia or ***mild*** *cognitive impairment*" with "computerized cognitive testing including but not limited to Cognivue®, Mindstreams® Cognitive Health Assessment, and BrainCare™ is unproven and not medically necessary for diagnosing dementia or *cognitive impairment*"	○ Social cognition • Demyelinating disorders including multiple sclerosis • Intellectual disability or intellectual developmental disorder when all of the following are present: ○ The intellectual disability or intellectual developmental disorder is associated with a known or suspected medical cause (e.g., traumatic brain injury, in utero toxin exposure, early seizure disorder, sickle cell disease, genetic disorders) and ○ The intellectual disability or intellectual developmental disorder meets all of the following criteria (DSM-5): ▪ Deficits in intellectual function, such as reasoning, problem solving, planning, abstract thinking, judgment, academic learning, and learning from experience, confirmed by both clinical assessment and individualized, standardized intelligence testing, ▪ Deficits in adaptive functioning that result in failure to meet developmental and sociocultural standards for personal independence and social responsibility. Without ongoing support, the adaptive deficits limit functioning in one or more activities of daily life, such as communication, social participation, and independent living across multiple environments, such as home, school, work and community, and ▪ Onset of intellectual and adaptive deficits during the developmental period *The scope of these criteria is applicable only to neuropsychological testing that is covered by the medical benefit. These criteria do not apply to evaluate or determine educational interventions.* • Encephalopathy including acquired immunodeficiency syndrome (AIDS) encephalopathy, human immunodeficiency virus (HIV) encephalopathy, hepatic encephalopathy, Lyme disease encephalopathy including neuroborreliosis, Wernicke's encephalopathy and systemic lupus erythematosus (SLE) encephalopathy. • Neurotoxin exposure with at least one of the following: ○ Demonstrated serum levels of neurotoxins ○ Individual with documented prenatal alcohol, drug, or toxin exposure • Seizure disorder including individuals with epilepsy and individuals being considered for epilepsy surgery • Stroke • Traumatic brain injury (TBI): TBI is defined as a bump, blow, or jolt to the head or a penetrating head injury that disrupts the normal function

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Neuropsychological Testing Under the Medical Benefit *(continued)*	Mar. 1, 2019		of the brain. (Centers for Disease Control and Prevention). See the following website for more information: http://www.cdc.gov/TraumaticBrainInjury/index.html. (Accessed March 16, 2018) **The following are unproven and not medically necessary due to insufficient evidence of efficacy:** • Baseline neuropsychological testing in asymptomatic individuals at risk for sport-related concussions or brain injuries. • Computerized neuropsychological testing for evaluating concussions or brain injuries. • Neuropsychological testing for the following diagnoses alone without other proven conditions as noted above: ○ Headaches including migraine headache ○ History of myocardial infarction ○ Intermittent explosive disorder • Computerized cognitive testing including but not limited to Cognivue®, Mindstreams® Cognitive Health Assessment, and BrainCare™ for diagnosing dementia or cognitive impairment.
Outpatient Cardiac Telemetry	Mar. 1, 2019	• Revised coverage rationale: ○ Replaced language indicating "Outpatient Cardiac Telemetry is proven and medically necessary for suspected cardiac arrhythmia *not detected with standard cardiac event monitoring*" with "Outpatient Cardiac Telemetry is proven and medically necessary for suspected cardiac arrhythmia *and non-diagnostic Ambulatory Event Monitoring after a minimum of 30 days*" ○ Removed notation pertaining to standard cardiac event monitoring	**Outpatient Cardiac Telemetry is proven and medically necessary for ANY of the following indications**: • Suspected cardiac arrhythmia and non-diagnostic Ambulatory Event Monitoring after a minimum of 30 days • Cryptogenic stroke with suspected occult atrial fibrillation as the cause of the stroke • Monitoring arrhythmia status following an ablation procedure

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Outpatient Cardiac Telemetry *(continued)*	Mar. 1, 2019	• Added definition of:
		  ○ Ambulatory Event Monitoring/Electrocardiography (ECG)
		  ○ Attended Surveillance
		  ○ Outpatient Cardiac Telemetry
		• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references	

Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins	Mar. 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section
		• Revised and reformatted coverage rationale:
		  ○ Simplified content
		  ○ Updated coverage criteria for radiofrequency ablation, endovenous laser ablation, Stripping, Ligation and excision of the Great Saphenous Vein and Small Saphenous Veins; replaced criterion requiring "*member* must have severe pain causing Functional/Physical Impairment"" with "*individual* must have *moderate to* severe pain causing Functional or Physical Impairment"
		  ○ Replaced language indicating "endovenous mechanochemical ablation (MOCA) of Varicose Veins
			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, proven and medically necessary when ALL of the following criteria are present:
			• Junctional Reflux:
			  ○ Ablative therapy for the Great Saphenous Veins or Small Saphenous Veins only if Junctional Reflux is demonstrated in these veins; or
			  ○ Ablative therapy for Accessory Veins only if anatomically related persistent Junctional Reflux is demonstrated after the Great Saphenous Veins or Small Saphenous Veins have been removed or ablated.
			• Individual 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 or Physical Impairment.
			• 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

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REVISED			
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins *(continued)*	Mar. 1, 2019	*using a percutaneous infusion catheter* is unproven and not medically necessary *for treating Venous Reflux*" with "endovenous mechanochemical ablation (MOCA) of Varicose Veins is unproven and not medically necessary" • Updated definitions: ○ Replaced references to "*2017* Certificate of Coverage (COC)" with "*UnitedHealthcare Insurance Company* COC" ○ Added definition of "Moderate to Severe Pain" ○ Removed definition of: ▪ Duplicate Saphenous Vein ▪ High Quality Photograph ▪ Spectral Doppler Flow Imaging ○ Modified definition of "Cosmetic Procedures" • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references	meets the following parameters: ○ Greater than or equal to 500 milliseconds (ms) for the Great Saphenous vein, Small Saphenous Veins 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, proven 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 is unproven and not medically necessary due to insufficient evidence of efficacy**. **Ligation Procedures** **The following procedure is proven and medically necessary**: • Ligation at the saphenofemoral junction, as a stand-alone procedure, when used to prevent the propagation of an active clot to the deep venous system in individuals with ascending Superficial Thrombophlebitis who fail or are intolerant of anticoagulation therapy. **The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy**: • Ligation of the Great Saphenous Vein at the saphenofemoral junction, as a stand-alone procedure • Ligation of the Small Saphenous Vein at the saphenopopliteal junction, as a stand-alone procedure • Ligation at the saphenofemoral junction, as an adjunct to radiofrequency ablation or endovenous laser ablation of the main saphenous veins **The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy**: • Endovascular embolization of Varicose Veins using cyanoacrylate-based adhesive • Endovenous foam sclerotherapy of incompetent Great Saphenous Veins, lesser saphenous veins, and accessory saphenous veins

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REVISED			
Total Artificial Disc Replacement for the Spine	Mar. 1, 2019	• Revised and reformatted coverage rationale: o Simplified content o Modified language pertaining to cervical artificial disc replacement to indicate: ▪ Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating one-level or two contiguous levels of cervical Degenerative Disc Disease (C3 to C7), in a Skeletally Mature individual with symptomatic radiculopathy and/or myelopathy when the following criteria are met: - Documented individual history of neck and/or upper extremity pain and/or a functional/neurological deficit associated with the cervical level to be treated - Imaging studies (i.e., computerized tomography [CT] scan or magnetic resonance imaging [MRI]) confirming herniated nucleus	**Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating one-level or two contiguous levels of cervical Degenerative Disc Disease (C3 to C7), in a Skeletally Mature individual with symptomatic radiculopathy and/or myelopathy when the following criteria are met**: • Documented individual history of neck and/or upper extremity pain and/or a functional/neurological deficit associated with the cervical level to be treated • Imaging studies (i.e., computerized tomography [CT] scan or magnetic resonance imaging [MRI]) confirming herniated nucleus pulposus or osteophyte formation • Failed at least six weeks of non-operative treatment prior to implantation **Cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent) is unproven and not medically necessary due to insufficient evidence of efficacy**. **Lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating single level lumbar Degenerative Disc Disease with symptomatic intractable discogenic low back pain in a Skeletally Mature individual when ALL of the following criteria are met**: • Advanced Degenerative Disc Disease (DDD) in only one vertebral level between L3 and S1 confirmed by complex imaging studies (i.e., computerized tomography [CT] scan or magnetic resonance imaging [MRI]) that indicate either moderate to severe Degenerative Disease or Modic Changes. • Symptoms correlate with imaging findings • No more than Grade 1 Spondylolisthesis at the involved level or any listhesis at two or more lumbar segments • Presence of symptoms for at least six months • Failed at least 6 months of conservative treatment immediately prior to implantation of artificial disc. Conservative treatment shall include all of the following, unless contraindicated: physical therapy, anti-inflammatory medications, analgesics, muscle relaxants, and epidural steroid injections • Age 18 to 60 years

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REVISED			
Total Artificial Disc Replacement for the Spine *(continued)*	Mar. 1, 2019	pulposus or osteophyte formation - Failed at least six weeks of non-operative treatment prior to implantation ▪ Cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent) is unproven and not medically necessary ○ Updated coverage criteria for lumbar artificial total disc replacement: ▪ Replaced criterion requiring: - "Presence of symptoms for at least *one year*" with "presence of symptoms for at least *six months*" - "Failed at least 6 months of conservative treatment *just* prior to implantation of artificial disc" with "failed at least 6 months of conservative treatment *immediately* prior to implantation of artificial disc" ▪ Modified list of examples	• Favorable face to face psychological evaluation confirming candidacy for surgery • There are no contraindications to lumbar artificial total disc replacement, including, but not limited to the following: ○ Moderate or severe facet arthropathy or pars defect at the operative level on a preoperative MRI scan, CT scan or plain radiograph ○ Lumbosacral spinal fracture ○ Scoliosis of the lumbosacral spine ○ Active systemic infection or infection localized to the site of implantation ○ Tumor in the peritoneum, retroperitoneum or site of implantation ○ Osteoporosis or osteopenia as defined by recent (within one year) DEXA scan ○ Isolated radicular compression syndromes, especially due to disc herniation ○ Spinal stenosis or radiculopathy ○ Previous lumbar spine surgery where the previous surgery destabilized the spine or where the spine at the level of the previous surgery is an alternate source of pain ○ Vascular, urological, or other peritoneal or retroperitoneal pathology that may preclude safe and adequate anterior spine exposure as required for the surgery **Lumbar artificial total disc replacement is unproven and not medically in the following situations due to insufficient evidence of efficacy**: • More than one spinal level • Prior history of lumbar fusion or when combined with a lumbar fusion at any level • Treating any other indications not listed above

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REVISED			
Total Artificial Disc Replacement for the Spine *(continued)*	Mar. 1, 2019	of contraindications to lumbar artificial total disc replacement; replaced: - "Radicular compression syndromes especially due to disc herniation" with "*isolated* radicular compression syndromes especially due to disc herniation" - "Previous lumbar spine surgery" with "previous lumbar spine surgery *where the previous surgery destabilized the spine or where the spine at the level of the previous surgery is an alternate source of pain*" • Added definition of: ○ Modic Changes ○ Skeletally Mature	
Whole Exome and Whole Genome Sequencing	Apr. 1, 2019	• Revised coverage rationale: ○ Modified list of unproven and not medically indications for Whole Exome Sequencing (WES); replaced "preimplantation genetic *diagnosis or screening* for embryos" with "Preimplantation Genetic *Testing (PGT)* for embryos" • Added definition of	Genetic counseling is strongly recommended prior to these tests in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person. **Whole Exome Sequencing (WES)** **Whole Exome Sequencing (WES) is proven and medically necessary for diagnosing or evaluating a genetic disorder when the results are expected to directly influence medical management and clinical outcomes AND ALL of the following criteria are met**: • Clinical presentation is nonspecific and does not fit a well-defined syndrome for which a specific or targeted gene test is available. If a

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Whole Exome and Whole Genome Sequencing *(continued)*	Apr. 1, 2019	"Preimplantation Genetic Testing (PGT)" • Updated list of applicable CPT codes; added 0012U, 0013U, and 0014U • Updated supporting information to reflect the most current references	specific genetic syndrome is suspected, a single gene or targeted gene panel should be performed prior to determining if WES is necessary; and • WES is ordered by a board-certified medical geneticist, neonatologist, neurologist, or developmental and behavioral pediatrician; and • **One** of the following: ○ The clinical presentation or clinical and family history strongly suggest a genetic cause for which a specific clinical diagnosis cannot be made with any clinically available targeted genetic tests; or ○ There is a clinical diagnosis of a genetic condition where there is significant genetic heterogeneity and WES is a more practical approach to identifying the underlying genetic cause than are individual tests of multiple genes; or ○ There is likely a genetic disorder and multiple targeted gene tests that have failed to identify the underlying cause. **Comparator (e.g., parents or siblings) WES is proven and medically necessary for evaluating a genetic disorder when the above criteria have been met and WES is performed concurrently or has been previously performed on the individual**. **WES is unproven and not medically necessary for all other indications, including but not limited to the following**: • Screening and evaluating disorders in individuals when the above criteria are not met • Prenatal genetic diagnosis or screening • Evaluation of fetal demise • Preimplantation Genetic Testing (PGT) in embryos • Molecular profiling of tumors for the diagnosis, prognosis or management of cancer Further studies are needed to evaluate the clinical utility of whole exome sequencing for other indications. **Whole Genome Sequencing (WGS)** **Whole Genome Sequencing (WGS) is unproven and not medically necessary for screening and evaluating any genetic disorder**. Although WGS has the potential to identify causal variants for a wide variety of conditions that may be missed with other technologies, as well as to identify predictive biomarkers, the information derived from WGS has not yet

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Whole Exome and Whole Genome Sequencing *(continued)*	Apr. 1, 2019		been translated into improved outcomes and changed medical management. Further studies are needed to establish the clinical utility of WGS.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Gamifant™ (Emapalumab-Lzsg)	Feb. 1, 2019	**Gamifant (emapalumab-lzsg) has been added to the Review at Launch program.** Some members may not be eligible for coverage of this medication at this time. Please reference the policy titled *Review at Launch for New to Market Medications* for additional details. **I. Emapalumab is proven for the treatment of primary hemophagocytic lymphohistiocytosis (HLH).** **Emapalumab is medically necessary for the treatment of primary HLH in patients who meet all of the following criteria**: A. Submission of medical records (e.g., chart notes, laboratory values) confirming **one** the following: 1. Confirmation of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D); **or** 2. Confirmation that 5 of the following clinical characteristics are present: a. Fever ≥ 101.3°F b. Splenomegaly c. **Two** of the following cytopenias in the peripheral blood: i. Hemoglobin <9 g/dL; **or** ii. Platelet count <100 x 10^9/L; **or** iii. Neutrophils <1 x 10^9/L) d. **One** of the following: i. Hypertriglyceridemia defined as fasting triglycerides ≥3 mmol/L or ≥265 mg/dL; **or** ii. hypofibrinogenemia defined as fibrinogen ≤1.5 g/L e. Hemophagocytosis in bone marrow or spleen or lymph nodes with no evidence of malignancy f. Low or absent natural killer cell activity (according to local laboratory reference) g. Ferritin ≥ 500 mg/L h. Soluble CD25 (i.e., soluble IL-2 receptor) ≥2,400 U/ml **and** B. Patient has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (i.e., etoposide + dexamethasone); **and** C. Emapalumab will be administered with dexamethasone; **and** D. Patient is a candidate for stem cell transplant; **and** E. Emapalumab is being used as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant; **and** F. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** G. Approval is for no more than 6 months. **II. Emapalumab is not proven or medically necessary for the treatment of secondary HLH.**

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Subcutaneous Implantable Hormone Pellets	Feb. 1, 2019	**I. Testopel (testosterone pellets) is proven for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone, including primary hypogonadism and hypogonadotropic hypogonadism.** **Testopel (testosterone pellets) is medically necessary for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone, including primary hypogonadism and hypogonadotropic hypogonadism when the following criteria are met:** A. For initial therapy, **one** of the following: 1. Two pre-treatment fasting morning serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab, taken at separate times (This may require treatment to be temporarily held. Document lab value and date for both levels) **or** 2. **Both** of the following: a. Patient has condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity); **and** b. **One** pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (<5 ng/dL or < 0.17 nmol/L) or less than the reference range for the lab (this may require treatment to be temporarily held) **or** 3. **All** of the following: a. Patient has history of **one** of the following: i. Bilateral orchiectomy; **or** ii. Panhypopituitarism (defined as two or more pituitary hormone insufficiencies prior to the diagnosis of hypogonadism); **or** iii. A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome) **and** b. Patient is not taking any of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Norditropin NordiFlex, Nutropin, Nutropin AQ, Omnitrope, Saizen, Tev-Tropin; **and** c. Patient was male at birth; **and** d. Diagnosis of hypogonadism; **and** e. **One** of the following; i. Significant reduction in weight (< 90% ideal body weight) (e.g., AIDS wasting syndrome); **or** ii. Osteopenia; **or** iii. Osteoporosis; **or** iv. Decreased bone density; **or** v. Decreased libido; **or** vi. Organic cause of testosterone deficiency (e.g., injury, tumor, infection, or genetic defects)

Policy Title	Effective Date	Coverage Rationale
NEW		
Subcutaneous Implantable Hormone Pellets *(continued)*	Feb. 1, 201	**and** 4. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** 5. Initial authorization will be for no more than 6 months for new starts, 12 months for patients continuing therapy. B. For continuation of therapy, **all** of the following: 1. **One** of the following: a. Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is within or below the normal male limits of the reporting lab; **or** b. Follow up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is outside of upper male limits of normal for the reporting lab and the dose is adjusted; **or** c. **Both** of the following i. Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity); **and** ii. **One** of the following: 1) Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is within or below the normal male limits of the reporting lab; **or** 2) Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is outside of upper male limits of normal for the reporting lab and the dose is adjusted **and** 2. Patient is not taking any of the following growth hormones, unless diagnosed with panyhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Norditropin NordiFlex, Nutropin, Nutropin AQ, Omnitrope, Saizen, Tev-Tropin; **and** 3. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** 4. Initial authorization will be for no more than 12 months. **II. Testopel (testosterone pellet) is medically necessary for Gender-Affirming Hormonal Therapy for Transgender Adults.** A. For initial therapy, **all** of the following: 1. Diagnosis of gender dysphoria, according to the current DSM (i.e., DSM-5) criteria, by a mental health professional; **and** 2. Medication is prescribed by or in consultation with an endocrinologist or a medical provider

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Subcutaneous Implantable Hormone Pellets *(continued)*	Feb. 1, 2019	knowledgeable in transgender hormone therapy; **and** 3. Patient is not taking any of the following any of the following growth hormones, unless diagnosed with panyhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Norditropin NordiFlex, Nutropin, Nutropin AQ, Omnitrope, Saizen, or Tev-Tropin; **and** 4. Authorization will be for no more than 12 months. B. For continuation of therapy, **all** of the following: 1. Diagnosis of gender dysphoria, according to the current DSM (i.e., DSM-5) criteria, by a mental health professional; **and** 2. Medication is prescribed by or in consultation with an endocrinologist or a medical provider knowledgeable in transgender hormone therapy; **and** 3. **One** of the following**:** a. Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is within or below the normal male limits of the reporting lab; **or** b. Follow up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is outside of upper male limits of normal for the reporting lab and the dose is adjusted; **or** c. **Both** of the following i. Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity); **and** ii. **One** of the following 1) Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is within or below the normal male limits of the reporting lab; **or** 2) Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is outside of upper male limits of normal for the reporting lab and the dose is adjusted **and** 4. Patient is not taking any of the following growth hormones, unless diagnosed with panyhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Norditropin NordiFlex, Nutropin, Nutropin AQ, Omnitrope, Saizen, or Tev-Tropin; **and** 5. Authorization will be for no more than 12 months. **III.Compounded Hormone Pellets** Compounded hormone pellets, including but not limited to compounded testosterone, estrogen, and

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		
Subcutaneous Implantable Hormone Pellets *(continued)*	Feb. 1, 20199	progesterone pellets are not proven nor medically necessary for any indication. Compounded drugs, including compounded testosterone, estrogen, or progesterone pellets are not FDA approved.
Subcutaneous Implantable Naltrexone Pellets	Feb. 1, 2019	**Compounded Implantable Drug Pellets:** Compounded drugs, including compounded naltrexone pellets are not FDA approved.[1] Compounded drug pellets, including but not limited to compounded naltrexone are not proven nor medically necessary for any indication. This policy does not apply to Vivitrol® (Naltrexone Powder for suspension for injection, extended-release).

Policy Title	Effective Date	Summary of Changes
UPDATED		
17-Alpha-Hydroxy-progesterone Caproate (Makena™ and 17P)	Feb. 1, 2019	• Updated supporting information to reflect the most current clinical evidence, FDA information, and references; no change to coverage rationale or lists of applicable codes

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Clotting Factors, Coagulant Blood Products & Other Hemostatics	Feb. 1, 2019	• Revised coverage rationale: ○ Updated list of applicable products; added Rebinyn® [coagulation Factor IX (recombinant), GlycoPEGylated] ○ Updated coverage criteria for hemophilia A: ▪ Removed language indicating antihemophilic factor (recombinant), pegylated [**Jivi**] is not medically necessary for treatment of hemophilia A for routine prophylactic treatment, perioperative	Refer to the policy for complete details on the coverage guidelines for Clotting Factors, Coagulant Blood Products & Other Hemostatics.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Clotting Factors, Coagulant Blood Products & Other Hemostatics *(continued)*	Feb. 1, 2019	management of surgical bleeding, or treatment of bleeding episodes ▪ Added language to indicate: - Antihemophilic factor (recombinant), FC fusion protein [**Jivi**] is proven when all of the following criteria are met: • Diagnosis of hemophilia A; and • One of the following: ○ Routine prophylactic treatment; or ○ Peri-operative management of surgical bleeding; or ○ Treatment of bleeding episodes; and • Patient has previously received Factor VIII replacement therapy; and • Patient is 12 years of age or older; and • Prescribed dosage and interval utilized is within range	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Clotting Factors, Coagulant Blood Products & Other Hemostatics *(continued)*	Feb. 1, 2019	as defined by the prescribing information - Antihemophilic factor (recombinant), FC fusion protein [**Jivi**] is medically necessary for the treatment of hemophilia A when all of the following criteria are met: • Diagnosis of hemophilia A; and • One of the following: ○ Routine prophylactic treatment; or ○ Peri-operative management of surgical bleeding; or ○ Treatment of bleeding episodes; and • Patient has previously received Factor VIII replacement therapy; and • Patient is 12 years of age or older; and • Patient is not a candidate for treatment with	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Clotting Factors, Coagulant Blood Products & Other Hemostatics *(continued)*	Feb. 1, 2019	shorter acting half-life Factor VIII (recombinant) products [e.g., Kogenate FS, Kovaltry, Novoeight, or Nuwiq] as attested by the prescribing physician; and • Patient is not to receive routine infusions more than 2 times per week - Coagulation factor IX (recombinant), GlycoPEGylated [**Rebinyn**] is not medically necessary for treatment of hemophilia B for the control and prevention of bleeding episodes, perioperative management, or routine prophylaxis of to prevent or reduce the frequency of bleeding episodes	
White Blood Cell Colony Stimulating Factors	Feb. 1, 2019	• Revised coverage rationale: ○ Updated list of applicable white blood cell colony stimulating factors (CSFs); added Udenyca	The policy refers to the following drug products: **White Blood Cell Colony Stimulating Factors (CSFs)** • Fulphila • Granix • Leukine

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
White Blood Cell Colony Stimulating Factors *(continued)*	Feb. 1, 2019	○ Added language to indicate Udenyca is: ▪ Proven for: - Neutropenia associated with cancer chemotherapy – dose dense chemotherapy - Primary prophylaxis of chemotherapy-induced febrile neutropenia (FN) - Secondary prophylaxis of FN - Treatment of FN - Hematopoietic syndrome of acute radiation syndrome ▪ Medically necessary when the following criteria are met: **Neutropenia associated with cancer chemotherapy – dose dense chemotherapy** - One of the following: • Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer; or	• Neulasta • Neupogen • Nivestym • Udenyca • Zarxio For the coverage criteria below, in absence of specified drug products, the term "colony stimulating factors" or "CSFs" will be used in this policy where the coverage criteria apply to all products listed above. **White blood cell colony stimulating factors are proven for the following indications:** **I. Bone marrow/stem cell transplant (Leukine, Neupogen, Nivestym, Zarxio)** **Leukine, Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met**: A. **One** of the following: 1. Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT); **or** 2. Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; **or** 3. Patient has had a peripheral stem cell transplant (PSCT) and have received myeloablative chemotherapy; **and** B. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; **and** C. Prescribed by or in consultation with a hematologist or oncologist. **II. Acute myeloid leukemia (AML) induction or consolidation therapy (Leukine, Neupogen, Nivestym, Zarxio)** **Leukine, Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met**: A. Diagnosis of AML; **and** B. Patient has completed either induction or consolidation chemotherapy; **and** C. Medication is dosed in accordance with the United States Food and

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
White Blood Cell Colony Stimulating Factors *(continued)*	Feb. 1, 2019	• Patient is receiving a dose-dense chemotherapy regimen for which the incidence of febrile neutropenia (FN) is unknown; and - Medication is dosed in accordance with the United States Food and Drug Administration (FDA) approved labeling; and - Prescribed by or in consultation with a hematologist or oncologist **Primary prophylaxis of chemotherapy-induced FN** - One of the following: • Patient is receiving chemotherapy regimen(s) associated with > 20% incidence of FN; or • Both of the following: ○ Patient is receiving chemotherap y regimen(s)	Drug Administration approved labeling; **and** D. Prescribed by or in consultation with a hematologist or oncologist. **III. Neutropenia associated with cancer chemotherapy – dose dense chemotherapy (Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Udenyca, Zarxio)** **Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Udenyca, and Zarxio are medically necessary when all of the following criteria are met**: A. **One** of the following: 1. Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer; **or** 2. Patient is receiving a dose-dense chemotherapy regimen for which the incidence of febrile neutropenia (FN) is unknown; **and** B. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; **and** C. Prescribed by or in consultation with a hematologist or oncologist. **IV. Primary prophylaxis of chemotherapy-induced febrile neutropenia (FN) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Udenyca, Zarxio)** **White blood cell colony stimulating factors are medically necessary when all of the following criteria are met**: A. **One** of the following: 1. Patient is receiving chemotherapy regimen(s) associated with > 20% incidence of FN; **or** 2. Both of the following: a. Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN; **and** b. Patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia (see list of risk factors in the *Clinical Evidence* section of the policy); **and** B. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; **and** C. Prescribed by or in consultation with a hematologist or oncologist.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
White Blood Cell Colony Stimulating Factors *(continued)*	Feb. 1, 2019	associated with 10-20% incidence of FN; and ○ Patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia (see the list of risk factors in the *Clinical Evidence* section of the policy); and - Medication is dosed in accordance with the FDA approved labeling; and - Prescribed by or in consultation with a hematologist or oncologist **Secondary prophylaxis of FN** - Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC ≤ 500 cells/mm3); and - Patient has a history	**V. Secondary prophylaxis of febrile neutropenia (FN) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Udenyca, Zarxio)** **White blood cell colony stimulating factors are medically necessary when all of the following criteria are met**: A. Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC ≤ 500 cells/mm^3); **and** B. Patient has a history of FN during a previous course of chemotherapy; **and** C. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; **and** D. Prescribed by or in consultation with a hematologist or oncologist. **VI. Treatment of Febrile Neutropenia (Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Udenyca, Zarxio)** [off-label] **Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Udenyca, and Zarxio are medically necessary when all of the following criteria are met**: A. Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC ≤ 500 cells/mm^3); **and** B. Diagnosis of FN and patient is considered high risk for infection-associated complications; **and** C. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; **and** D. Prescribed by or in consultation with a hematologist or oncologist. **VII. Severe Chronic Neutropenia (SCN) (Neupogen, Nivestym, Zarxio)** **Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met**: A. Diagnosis of SCN (i.e., congenital, cyclic, and idiopathic neutropenias with chronic ANC ≤ 500 cells/mm^3); **and** B. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; **and** C. Prescribed by or in consultation with a hematologist or oncologist. **VIII. HIV-related neutropenia (Leukine, Neupogen, Nivestym, Zarxio)** [off-label]

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
White Blood Cell Colony Stimulating Factors *(continued)*	Feb. 1, 2019	of FN during a previous course of chemotherapy; and - Medication is dosed in accordance with the FDA approved labeling; and - Prescribed by or in consultation with a hematologist or oncologist **Treatment of FN** - Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC ≤ 500 cells/mm3); and - Diagnosis of FN and patient is considered high risk for infection-associated complications; and - Medication is dosed in accordance with the FDA approved labeling; and - Prescribed by or in consultation with a hematologist or oncologist **Hematopoietic syndrome of acute radiation syndrome** - Patient has been acutely exposed to myelosuppressive doses of radiation; and	**Leukine, Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met**: A. Diagnosis of HIV infection; **and** B. Patient has an ANC ≤ 1,000 (cells/mm^3); **and** C. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; **and** D. Prescribed by or in consultation with a hematologist, oncologist or infectious disease specialist. **IX. Hepatitis-C treatment related neutropenia (Neupogen, Nivestym, Zarxio)** [off-label] **Neupogen, Nivestym, and Zarxio are medically necessary when all of the following criteria are met**: A. **One** of the following: 1. **All** of the following: a. Diagnosis of Hepatitis C virus; **and** b. Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a); **and** c. Documentation of neutropenia (ANC ≤ 500 cells/mm^3) after dose reduction of Peg-Intron or Pegasys; **or** 2. **Both** of the following: a. Documentation of interferon-induced neutropenia (ANC ≤ 500 cells/mm^3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a); **and** b. **One** of the following: i. Diagnosis of HIV co-infection; **or** ii. Status post liver transplant; **or** iii. Diagnosis of established cirrhosis **and** B. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; **and** C. Prescribed by or in consultation with a hematologist, oncologist, infectious disease specialist, hepatologist, or gastroenterologist. **X. Hematopoietic syndrome of acute radiation syndrome (Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Udenyca, Zarxio)**

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
White Blood Cell Colony Stimulating Factors *(continued)*	Feb. 1, 2019	- Medication is dosed in accordance with the FDA approved labeling; and - Prescribed by or in consultation with a hematologist or oncologist • Updated supporting information to reflect the most current FDA information and references	**Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Udenyca, and Zarxio are medically necessary when all of the following criteria are met:** A. Patient has been acutely exposed to myelosuppressive doses of radiation; **and** B. Medication is dosed in accordance with the United States Food and Drug Administration approved labeling; **and** C. Prescribed by or in consultation with a hematologist or oncologist.

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		

Clinical Trials	Feb. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated list of applicable HCPCS codes (covered when criteria are met) to reflect annual code edits; added G2000

Habilitative Services and Outpatient Rehabilitation Therapy	Feb. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated list of applicable CPT codes for speech therapy; removed 70371

Infertility Services	Feb. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated coverage rationale; modified language pertaining to benefit limitations and exclusions for donor eggs to clarify:
		  ○ The cost of donor eggs, including medical cost related to donor stimulation and egg retrieval is excluded
		  ○ Cost for fertilization (in vitro fertilization or intracytoplasmic sperm injection), embryo culture, and embryo transfer may be covered if the member has an Infertility benefit that allows for Assisted Reproductive Technology

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		

Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan – Site of Care	Apr. 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated list of applicable CPT codes; added 77046 and 77047

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Provider Administered Drugs – Site of Care Review Guidelines	Apr. 1, 2019	• Changed policy title; previously titled *Specialty Medication Administration – Site of Care Review Guidelines*
		• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section
		• Updated list of related policies; added reference link to the policy titled *Revcovi™ (Elapegademase-Lvlr)*
		• Revised coverage rationale:
		  ○ Modified criteria to indicate outpatient hospital facility-based intravenous medication infusion is medically necessary for individuals who meet at least one of the following criteria (submission of medical records is required):
		  ▪ Documentation that the individual is medically unstable for administration of the prescribed medication at the alternative sites of care as determined by
			This guideline addresses the criteria for consideration of allowing hospital outpatient facility specialty medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes:
			• 19 Off Campus-Outpatient Hospital; and
			• 22 On Campus-Outpatient Hospital.
			
			Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If an individual does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used.
			
			Outpatient hospital facility-based intravenous medication infusion is medically necessary for individuals who meet at least ONE of the following criteria (submission of medical records is required):
			1. Documentation that the individual is medically unstable for administration of the prescribed medication at the alternative sites of care as determined by any of the following:
			  a. The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; **or**
			  b. The individual's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative site of care; **or**
			  c. Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; **or**
			  d. Difficulty establishing and maintaining patent vascular access
			or

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Provider Administered Drugs – Site of Care Review Guidelines *(continued)*	Apr. 1, 2019	any of the following: - The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; or - The individual's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative site of care; or - Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; or - Difficulty establishing and maintaining patent vascular access **or** ▪ Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g.,	2. Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting. **or** 3. Initial infusion or re-initiation of therapy after more than 6 months. **or** 4. Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy (if the prescriber cannot infuse in the office setting). **Outpatient hospital facility-based infusion may be granted to initiate or re-initiate products for a short duration (e.g., 4 weeks).** **Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative site of care.** This policy applies to these specialty medications that require healthcare provider administration: • Actemra® (Tocilizumab) • Adagen® (Pegademase bovine) • Aldurazyme® (Laronidase) • Aralast NP™ (A1-PI) • Benlysta® (Belimumab) • Cerezyme® (Imiglucerase) • Crysvita® (Burosumab) • Elaprase® (Idursulfase) • Elelyso® (Taliglucerase) • Entyvio® (Vedolizumab) • Exondys 51™ (Eteplirsen) • Fabrazyme® (Agalsidase beta) • Glassia™ (A1-PI) • Ilaris® (Canakinumab) • Ilumya™ (Tildrakizumab-asmn)

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Provider Administered Drugs – Site of Care Review Guidelines *(continued)*	Mar. 1, 2019	anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting **or** ▪ Initial infusion or re-initiation of therapy after more than 6 months **or** ▪ Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy (if the prescriber cannot infuse in the office setting) ○ Added language to indicate: ▪ Outpatient hospital facility-based infusion may be granted to initiate or re-initiate products for a short duration (e.g., 4 weeks) ▪ Ongoing outpatient hospital facility-based infusion duration of therapy will be no more	• Inflectra™ (Infliximab-dyyb) • Kanuma® (Sebelipase alfa) • Lumizyme® (Alglucosidase alfa) • Mepsevii™ (Vestronidase alfa-vjbk) • Naglazyme® (Galsulfase) • Ocrevus™ (Ocrelizumab) • Onpattro™ (Patisiran) • Orencia® (Abatacept) • Prolastin®-C™ (A1-PI) • Radicava™ (edaravone) • Remicade® (Infliximab) • Renflexis™ (Infliximab-abda) • Revcovi™ (Elapegademase-lvlr) • Simponi Aria® (Golimumab) • Soliris® (Eculizumab) • Trogarzo™ (Ibalizumab) • Vimizim® (Elosulfase alfa) • VPRIV® (Velaglucerase) • Zemaira® (A1-PI)

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Provider Administered Drugs – Site of Care Review Guidelines *(continued)*	Mar. 1, 2019	than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative site of care ○ Updated list of medications that require healthcare provider administration; added Revcovi™ (elapegademase-lvlr) ○ Removed reference to the MCG™ Care Guidelines, 22nd edition, 2018, Home Infusion Therapy, CMT: CMT-0009(SR) • Updated supporting information to reflect the most current clinical evidence and references	

Quality of Care Guideline (QOCG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Hospital Readmissions	Feb. 1, 2019	• Reorganized policy template: ○ Simplified and relocated *Instructions for Use* ○ Removed language pertaining to *Essential Health Benefits for Individual and Small Groups*