United Healthcare Community Plan

UnitedHealthcare Community Plan of Pennsylvania
Medical Policy Update Bulletin: May 2022

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Take Note

InterQual® 2022 Clinical Criteria: Apr. 2022 Release

Effective May 1, 2022, the following Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines have been updated to reflect the applicable InterQual® clinical criteria reference(s) associated with the Apr. 2022 Release:

Policy Title	Policy Type
Abnormal Uterine Bleeding and Uterine Fibroids (for Pennsylvania Only)	Medical Policy
Airway Clearance Devices (for Pennsylvania Only)	Medical Policy
Articular Cartilage Defect Repairs (for Pennsylvania Only)	Medical Policy
Beds and Mattresses (for Pennsylvania Only)	Coverage Determination Guideline
Catheter Ablation for Atrial Fibrillation (for Pennsylvania Only)	Medical Policy
Chemotherapy Observation or Inpatient Hospitalization (for Pennsylvania Only)	Utilization Review Guideline
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Pennsylvania Only)	Medical Policy
Cosmetic and Reconstructive Procedures (for Pennsylvania Only)	Coverage Determination Guideline
Deep Brain and Cortical Stimulation (for Pennsylvania Only)	Medical Policy
Hysterectomy (for Pennsylvania Only)	Medical Policy
Implanted Electrical Stimulator for Spinal Cord (for Pennsylvania Only)	Medical Policy
Lower Extremity Invasive Diagnostic and Endovascular Procedures (for Pennsylvania Only)	Medical Policy
Manual Wheelchairs (for Pennsylvania Only)	Coverage Determination Guideline
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia (for Pennsylvania Only)	Coverage Determination Guideline
Obstructive and Central Sleep Apnea Treatment (for Pennsylvania Only)	Coverage Determination Guideline
Orthognathic (Jaw) Surgery (for Pennsylvania Only)	Coverage Determination Guideline
Patient Lifts (for Pennsylvania Only)	Coverage Determination Guideline
Pediatric Gait Trainers, Standing Systems, and Walkers (for Pennsylvania Only)	Coverage Determination Guideline
Plagiocephaly and Craniosynostosis Treatment (for Pennsylvania Only)	Medical Policy
Pneumatic Compression Devices (for Pennsylvania Only)	Medical Policy
Power Mobility Devices (for Pennsylvania Only)	Coverage Determination Guideline
Rhinoplasty and Other Nasal Surgeries (for Pennsylvania Only)	Coverage Determination Guideline
Speech Generating Devices (for Pennsylvania Only)	Coverage Determination Guideline
Surgery of the Elbow (for Pennsylvania Only)	Medical Policy

Take Note

Policy Title	Policy Type
Surgery of the Foot (for Pennsylvania Only)	Medical Policy
Surgery of the Hand or Wrist (for Pennsylvania Only)	Medical Policy
Surgery of the Hip (for Pennsylvania Only)	Medical Policy
Surgery of the Knee (for Pennsylvania Only)	Medical Policy
Surgery of the Shoulder (for Pennsylvania Only)	Medical Policy
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Pennsylvania Only)	Medical Policy
Surgical Treatment for Spine Pain (for Pennsylvania Only)	Medical Policy
Temporomandibular Joint Disorders (for Pennsylvania Only)	Medical Policy
Total Artificial Disc Replacement for the Spine (for Pennsylvania Only)	Medical Policy
Video Electroencephalographic (vEEG) Monitoring and Recording (for Pennsylvania Only)	Medical Policy
Wheelchair Options and Accessories (for Pennsylvania Only)	Coverage Determination Guideline
Wheelchair Seating (for Pennsylvania Only)	Coverage Determination Guideline

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Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Computed Tomographic Colonography (for Pennsylvania Only)	May 1, 2022	Application • Added language to indicate any requests for services that do not meet criteria set in the PARP will be evaluated on a case by case basis; refer to *Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101* Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information
Glaucoma Surgical Treatments (for Pennsylvania Only)	Jun. 1, 2022	Applicable Codes • Added CPT codes 0671T, 66989, and 66991 • Removed CPT codes 0191T and 0376T
Intensity-Modulated Radiation Therapy (for Pennsylvania Only)	May 1, 2022	Application • Added language to indicate any requests for services that do not meet criteria set in the PARP will be evaluated on a case by case basis; refer to *Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101* Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache) (for Pennsylvania Only)	Jun. 1, 2022	Applicable Codes • Revised description for CPT codes 64568 and 64575
Transcatheter Heart Valve Procedures (for Pennsylvania Only)	May 1, 2022	Application • Added language to indicate any requests for services that do not meet criteria set in the PARP will be evaluated on a case by case basis; refer to *Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101* Coverage Rationale • Added instruction to refer to the following sources for additional information pertaining to Volume Requirements consistent with the Centers for Medicare and Medicaid Services (CMS): ○ CMS National Coverage Determination 20.32: *Transcatheter Aortic Valve Replacement (TAVR)* ○ Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) *Transcatheter Valve Therapy (TVT) Registry* Definitions • Updated definition of “CMS Volume Requirements for Transcatheter Aortic Heart Valve Replacement (TAVR)”

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Policy Title	Effective Date	Summary of Changes
Transcatheter Heart Valve Procedures (for Pennsylvania Only) (continued)	May 1, 2022	**Applicable Codes** • Added CPT code 33370 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ablative Treatment for Spinal Pain (for Pennsylvania Only)	Jun. 1, 2022	**Coverage Rationale** • Replaced reference to "Thermal Radiofrequency Ablation" with "*Conventional* (Thermal) Radiofrequency Ablation" • Removed language pertaining to documentation requirements ***Unproven and Not Medically Necessary*** • Replaced language indicating: ○ "Thermal Radiofrequency Ablation of facet joint nerves is unproven and not medically necessary for spinal segments that have been surgically fused" with "*Conventional* (Thermal) Radiofrequency Ablation of facet joint nerves is unproven and not medically necessary for spinal segments that have been *successfully* surgically fused" ○ "*Thermal Radiofrequency Ablation, including cooled* radiofrequency ablation, is	Conventional (Thermal) Radiofrequency Ablation of facet joint nerves is proven and medically necessary for the following: • Initial treatment of Chronic cervical (C3-4 joint and below), thoracic and lumbar pain when: ○ Clinical documentation shows a Functional Impairment due to facet pain; and ○ Clinical documentation of a diagnostic Facet Joint Injection and/or Facet Nerve Block (i.e., Medial Branch Block) to localize the source of spinal pain to the facet joint confirms the following: ▪ At least a 50% reduction in pain from baseline at the specific side and level of the proposed ablation; and ▪ The reduction in pain is sufficient to allow a measurable functional improvement; and ○ The diagnostic procedure is not performed on the same day as the ablation procedure • Repeat treatment of chronic cervical (C3 and below), thoracic and lumbar pain when: ○ History and physical examination confirm that the facet joint is the source of pain; and ○ Clinical documentation shows a Functional Impairment due to facet pain; and ○ Performed at a frequency of six months or longer (maximum of 2 times over a 12-month period per side and level); and

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ablative Treatment for Spinal Pain (for Pennsylvania Only) (continued)	Jun. 1, 2022	unproven and not medically necessary for treating sacroiliac pain" with "*all forms of* radiofrequency ablation are unproven and not medically necessary for treating sacroiliac pain" • Updated list of examples of other pain indications; removed "sacroiliac pain" **Definitions** • Updated definition of: ○ Conventional (Thermal) Radiofrequency Ablation ○ Cooled Radiofrequency Ablation ○ Pulsed Radiofrequency Ablation **Applicable Codes** • Added CPT codes 64628 and 64629 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	○ There has been a 50% or greater documented reduction in pain for at least 10 weeks following the previous ablation, as substantiated by a validated pain scale Conventional (Thermal) Radiofrequency Ablation of facet joint nerves is unproven and not medically necessary in the following circumstances due to insufficient evidence of efficacy: • The source of back pain at the proposed ablation level is from a cause other than facet joint syndrome that requires a different treatment approach. Examples include disc herniation, spinal stenosis, foraminal narrowing, vertebral fracture radiculopathy and spondylolisthesis; or • Spinal segments that have been successfully surgically fused; or • All other pain indications. Examples include, but are not limited to, occipital neuralgia, headache, or Complex Regional Pain Syndrome. All forms of radiofrequency ablation, are unproven and not medically necessary for treating sacroiliac pain. The following facet joint nerve ablation techniques are unproven and not medically necessary due to insufficient evidence of efficacy: • Pulsed Radiofrequency Ablation of the facet nerves of the cervical, thoracic or lumbar region, sacral nerve root or dorsal root ganglion • Endoscopic radiofrequency ablation/endoscopic rhizotomy • Cryoablation (cryodenervation, cryoneurolysis, cryosurgery or cryoanesthesia) • Cooled Radiofrequency Ablation • Chemical ablation (including, but not limited to, alcohol, phenol or sodium morrhuate) • Laser ablation (including pulsed, continuous or low level) • Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Abnormal Uterine Bleeding and Uterine Fibroids (for Pennsylvania Only)	Jun. 1, 2022	**Applicable Codes** • Removed CPT codes 58578 and 58999 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	**Levonorgestrel-Releasing Intrauterine Device** Levonorgestrel-releasing intrauterine devices (LNG-IUD) (e.g., Mirena®, Skyla®, Liletta® or Kyleena™) are proven and medically necessary for treating menorrhagia. Refer to the U.S. Food and Drug Administration (FDA) section for additional information. **Uterine Fibroids** Uterine artery embolization (UAE) is proven and medically necessary for treating symptomatic uterine fibroids when there is documentation of evaluation of abnormal uterine bleeding (AUB) including endometrial biopsy for individuals > 40 years of age and a pap smear screening consistent with current guidelines. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Uterine Artery Embolization (UAE). Click here to view the InterQual® criteria. UAE is unproven and not medically necessary for the purpose of preserving childbearing potential for women with symptomatic uterine fibroids due to insufficient evidence of efficacy. The following procedures are unproven and not medically necessary for treating uterine fibroids due to insufficient evidence of efficacy: • Magnetic resonance-guided focused ultrasound ablation (MRgFUS) • Ultrasound-guided radiofrequency ablation (e.g., Acessa™, Sonata®)

Discogenic Pain Treatment (for Pennsylvania Only)	Jun. 1, 2022	**Coverage Rationale**
		• Revised list of unproven and not medically necessary procedures:
		  ○ Added:
		  ▪ Annular closure devices (ACDs)
			The following procedures are unproven and not medically necessary due to insufficient evidence of efficacy:
			• Annular Closure Devices (ACDs)
			• Percutaneous discectomy and decompression procedures for treating discogenic pain
			• Percutaneous injection of allogeneic cellular/tissue based products
			• Thermal intradiscal procedures (TIPs) for treating discogenic pain

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Discogenic Pain Treatment (for Pennsylvania Only) (continued)	Jun. 1, 2022	▪ Percutaneous injection of allogeneic cellular/tissue-based products ○ Removed: ▪ Annulus fibrosus repair following spinal surgery **Applicable Codes** ● Added CPT codes 0627T, 0628T, 0629T, and 0630T **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Functional Endoscopic Sinus Surgery (FESS) (for Pennsylvania Only)	Jun. 1, 2022	**Coverage Rationale** ● Revised coverage criteria for Chronic Rhinosinusitis (CRS) with or without polyps; replaced criterion requiring: ○ "Intranasal corticosteroids" with "intranasal corticosteroids *(and/or oral corticosteroids when appropriate)*" ○ "Nasal lavage" with "nasal lavage/*irrigation if appropriate*" **Supporting Information** ● Updated *References* section to reflect the most current information	Functional Endoscopic Sinus Surgery (FESS) is proven and medically necessary when one or more of the following conditions are present: ● Chronic Rhinosinusitis (CRS) with or without polyps which has all of the following: ○ Lasted longer than 12 weeks ○ Persistence of symptoms despite administration of full courses of all of the following treatments: ▪ Intranasal corticosteroids (and/or oral corticosteroids when appropriate), and ▪ Antibiotic therapy if bacterial infection is suspected; and ▪ Nasal lavage/irrigation if appropriate ○ Confirmation of Chronic Rhinosinusitis on a computed tomography (CT) scan for each sinus to be treated meeting all of the following criteria: ▪ CT images are obtained after completion of medical management; and ▪ Documentation of which sinus disease and the extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System; and ▪ CT findings include one or more of the following:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Functional Endoscopic Sinus Surgery (FESS) (for Pennsylvania Only) (continued)	Jun. 1, 2022		– Bony remodeling – Bony thickening – Opacified sinus – Ostial obstruction (outflow tract obstruction) and mucosal thickening ○ Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis • Recurrent Acute Rhinosinusitis (RARS) with all of the following: ○ Four or more episodes per year with distinct symptom free intervals between episodes; and ○ Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis; and ○ CT scan evidence of one of the following: ▪ For the maxillary, frontal, or sphenoid sinuses, both of the following are present: – Ostial obstruction (outflow tract obstruction) in the sinus to be treated – Mucosal thickening in the sinus to be treated ▪ For the ethmoid sinus, mucosal thickening is present • Any of the following conditions confirmed on CT : ○ Complications of sinusitis such as abscess ○ Symptomatic concha bullosa ○ Symptomatic mucocele ○ Polyposis with obstructive symptoms (for Chronic Rhinosinusitis with polyps, refer to the above criteria) ○ Sinonasal tumor Functional Endoscopic Sinus Surgery (FESS) is unproven and not medically necessary for any condition other than those listed above due to insufficient evidence of efficacy. **Documentation Requirements** Medical notes documenting the following, when applicable:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Functional Endoscopic Sinus Surgery (FESS) (for Pennsylvania Only) (continued)	Jun. 1, 2022		• Chronic Rhinosinusitis (CRS) with the following: ○ Signs and symptoms ○ Treatments tried and failed including duration of treatments/medical therapies ○ Post medical management CT scan images: ▪ That show the abnormality for which surgery is being requested ▪ Are the optimal image to show the abnormality of the affected area with use of the Modified Lund-Mackay Scoring System to define the severity of Chronic Rhinosinusitis ▪ ▪ Note: Upon request, CT images may be required and must be labeled with the: – Date taken – Applicable case number obtained at time of notification, or the member's name and ID number on the images – Whether the imaging was taken pre-or post-medical therapy ▪ CT images can be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted ○ CT scan report documents all of the following: ▪ Which sinus has the disease ▪ The extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System • Recurrent Acute Rhinosinusitis with the following: ○ Number of episodes per year of acute rhinosinusitis ○ Signs and symptoms ○ CT scan images: ▪ That show the abnormality for which surgery is being requested ▪ Are the optimal image to show the abnormality of the affected area ▪ Note: Upon request, CT images may be required and must be labeled with the: – Date taken – Applicable case number obtained at time of notification, or the member's name and ID number on the images

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Functional Endoscopic Sinus Surgery (FESS) (for Pennsylvania Only) (continued)	Jun. 1, 2022		– Whether the images were taken pre- or post-medical therapy ▪ CT images can be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted ○ CT scan report documents all of the following: ▪ Which sinus has the disease ▪ The extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System
Manipulation Under Anesthesia (for Pennsylvania Only)	Jul. 1, 2022	**Coverage Rationale** • Replaced language indicating "manipulation under anesthesia (MUA) is proven and medically necessary for shoulder joint for adhesive capsulitis (frozen shoulder)" with "MUA is proven and medically necessary for shoulder joint for adhesive capsulitis (frozen shoulder) *when certain criteria are met*" • Added instruction to refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Manipulation Under Anesthesia, Shoulder for medical necessity clinical coverage criteria • Removed language indicating MUA is unproven and not medically necessary for any shoulder condition other than adhesive capsulitis (frozen shoulder) **Applicable Codes** • Removed pelvis ICD-10 diagnosis codes M99.14, S32.10XA, S32.111A, S32.112A, S32.119A,	Manipulation under anesthesia (MUA) is proven and medically necessary for: • Knee joint for arthrofibrosis following total knee arthroplasty, knee surgery, or fracture • Shoulder joint for adhesive capsulitis (frozen shoulder) when certain criteria are met. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Manipulation Under Anesthesia, Shoulder. Click here to view the InterQual® criteria. MUA is unproven and not medically necessary for all other conditions (whether for single or serial manipulations) including but not limited to the following, due to insufficient evidence of efficacy: • Ankle • Finger • Hip joint or adhesive capsulitis of the hip • Knee joint - any condition other than for arthrofibrosis following total knee arthroplasty, knee surgery, or fracture • Pelvis • Spine • Temporomandibular joint (TMJ) • Toe • Wrist This policy does not apply to the following:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Manipulation Under Anesthesia (for Pennsylvania Only) (continued)	Jul. 1, 2022	S32.121A, S32.122A, S32.129A, S32.131A, S32.132A, S32.139A, S32.14XA, S32.15XA, S32.16XA, S32.17XA, S32.19XA, S32.2XXA, S32.301A, S32.302A, S32.309A, S32.311A, S32.312A, S32.313A, S32.391A, S32.392A, S32.399A, S32.401A, S32.402A, S32.409A, S32.411A, S32.412A, S32.413A, S32.421A, S32.422A, S32.423A, S32.431A, S32.432A, S32.433A, S32.441A, S32.442A, S32.443A, S32.451A, S32.452A, S32.453A, S32.461A, S32.462A, S32.463A, S32.471A, S32.472A, S32.473A, S32.481A, S32.482A, S32.483A, S32.491A, S32.492A, S32.499A, S32.501A, S32.502A, S32.509A, S32.511A, S32.512A, S32.519A, S32.591A, S32.592A, S32.599A, S32.601A, S32.602A, S32.609A, S32.611A, S32.612A, S32.613A, S32.614A, S32.615A, S32.616A, S32.691A, S32.692A, S32.699A, S32.810A, S32.811A, S32.82XA, S32.89XA, S32.9XXA, and S33.2XXA **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	• Manipulation of the finger on the day following the injection of collagenase clostridium histolyticum (Xiaflex®) to treat Dupuytren's contracture • Closed reduction of a fracture or joint dislocation unless specified • Elbow joint for arthrofibrosis following elbow surgery or fracture

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Omnibus Codes (for Pennsylvania Only)	Jun. 1, 2022	Application ● Replaced reference to "Pennsylvania-specific Program Exception Policy" with "Pennsylvania Exceptions *in the Pennsylvania Code, Title 55, Chapter 1101*" Coverage Rationale ● Removed guidelines for Drug-Eluting Punctal Plugs or Implants into the Lacrimal Canaliculus (CPT code 0356T) ● Added guidelines for: *3D Volumetric Imaging and Reconstruction of Breast or Axillary Lymph Node Tissue (CPT code 0694T)* (new to policy) ○ Added language to indicate three-dimensional (3D) volumetric imaging and reconstruction of breast or axillary lymph node tissue is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy *Comprehensive Full-Body Motion Analysis (CPT code 0693T)* (new to policy) ○ Added language to indicate comprehensive full-body,	Refer to the policy for complete details

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Omnibus Codes (for Pennsylvania Only) (continued)	Jun. 1, 2022	computer-based, markerless 3D kinematic and kinetic motion analysis is unproven and not medically necessary for all indications due to insufficient evidence of safety and/or efficacy *External Upper Limb Tremor Stimulators of the Peripheral Nerves of the Wrist (CPT codes K1018 and K1019)* (new to policy) ○ Added language to indicate external upper limb tremor stimulators of the peripheral nerves of the wrist and the related monthly supplies to treat essential tremor are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy *PureWick™ Female External Catheter and the PureWick™ Urine Collection System (CPT code K1006)* (new to policy) ○ Added language to indicate the PureWick™ Female External Catheter and the PureWick™ Urine Collection System are unproven and not medically necessary for managing	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Omnibus Codes (for Pennsylvania Only) (continued)	Jun. 1, 2022	urinary incontinence due to insufficient evidence of efficacy *Radiofrequency (RF) Therapy (CPT codes 0672T, 53860, 53899, and 58999)* (new to policy) ○ Added language to indicate radiofrequency (RF) therapy, including but not limited to cryogen-cooled monopolar radiofrequency (CMRF), monopolar RF, multipolar RF, RF-lifting, and temperature controlled RF therapies for the treatment of stress urinary incontinence (SUI) is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy ○ Updated list of applicable CPT codes for: *Aquapheresis (Ultrafiltration) (CPT codes 0692T, 37799, and 90999)* ○ Added 0692T *PillCam Colon 2 Capsule Endoscopy System (CPT code 91113)* ○ Added 91113 ○ Removed 0355T *Transperineal Periurethral Balloon Continence Devices*	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Omnibus Codes (for Pennsylvania Only) (continued)	Jun. 1, 2022	*(CPT codes 53451, 53452, 53453, and 53454)* ○ Added 53451, 53452, 53453, and 53454 ○ Removed 0548T, 0549T, 0550T, and 0551T *UroCuff Test (CPT codes 53899 and 55899)* ○ Added 55899	
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Pennsylvania Only)	Jun. 1, 2022	Coverage Rationale *Documentation Requirements* ● Revised list of clinical information to be documented in the medical notes, when applicable, to reflect/include: ○ Diagnosis ○ History of the medical condition(s) requiring treatment or surgical intervention ○ Documentation of signs and symptoms; including onset, duration, frequency, and which extremity (right, left, or both) ○ Relevant medical history, including: ▪ DVT (deep vein thrombosis) ▪ Aneurysm ▪ Tortuosity ○ Physical exam, including: ▪ Which extremity (right, left, or both)	**Varicose Vein Ablative and Stripping Procedures** The initial and subsequent radiofrequency ablation, endovenous laser ablation, Stripping, Ligation and excision of the Great Saphenous Vein (GSV) and Small Saphenous Veins (SSV) are considered reconstructive, proven and medically necessary when all of the following criteria are present: ● Junctional Reflux: ○ Ablative therapy for the GSV or SSV 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 GSV or SSV have been removed or ablated ● Individual must have one of the following Functional or Physical 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 causing Functional or Physical Impairment; or ○ Moderate to Severe Pain causing Functional or Physical Impairment ● Venous Size: ○ The GSV must be 5.5 mm or greater when measured at the proximal thigh immediately below the sapheno-femoral junction via Duplex Ultrasonography (Navarro et al. 2002).

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Pennsylvania Only) (continued)	Jun. 1, 2022	▪ Vein(s) that will be treated [e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.] ▪ Vein diameter including the specific anatomic location where the measurement was taken (e.g., proximal thigh, proximal calf, etc.) ▪ Duration of reflux including the position of member at the time of measurement and the anatomic location where the measurement was taken [e.g., standing, saphenofemoral junction (SFJ)] ○ Severity of pain or other symptoms that interfere with activities of daily living related to vein disease ○ Functional disability(ies), as documented on a validated functional disability scale, (interfering with the ability to stand or sit for long periods of time, such as, preparing meals, performing work functions, driving, walking, etc.) ○ Diagnostic study/imaging reports	○ The SSV or Accessory Veins must measure 5 mm or greater in diameter immediately below the sapheno-popliteal 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 GSV, SSV Veins or principal tributaries ○ Perforating veins > 350ms ○ Some Duplex Ultrasound readings will describe this as moderate to severe reflux which will be acceptable Refer to Coding Clarification. Adherence to American Medical Association (AMA) coding guidance is required when requesting coverage of endovenous ablation procedures. Note that only one primary code may be requested for the initial vein treated, and only one add-on code per extremity may be requested for any subsequent vein(s) treated. 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 (refer to 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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Pennsylvania Only) (continued)	Jun. 1, 2022	○ Pulses ○ Prior conservative treatments tried, failed, or contraindicated. Include the dates and reason for discontinuation ○ Proposed treatment plan with procedure code, including specific vein(s) that will be treated (e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.), which extremity (left, right, or both) and date of procedure for each vein to be treated ○ In addition to the above, additional documentation requirements may apply for CPT codes 37761, 37765, 37766, and 37785; refer to the Utilization Review Guideline titled *Outpatient Surgical Procedures – Site of Service (for Pennsylvania Only)* **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information	The following procedure is proven and medically necessary in certain circumstances: ● Ligation, subfascial, endoscopic surgery for treatment of perforating veins associated with chronic Venous Insufficiency. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Ligation, Subfascial, Endoscopic, Perforating Vein. Click here to view the InterQual® criteria. The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy: ● Ligation of the GSV at the saphenofemoral junction, as a stand-alone procedure ● Ligation of the SSV 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 **Ambulatory Phlebectomy** Ambulatory phlebectomy for treating varicose veins is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Ambulatory Phlebectomy, Varicose Vein for: ● Hook Phlebectomy ● Microphlebectomy ● Mini Phlebectomy ● Stab Avulsion ● Stab Phlebectomy Click here to view the InterQual® criteria. **Other Procedures** The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Pennsylvania Only) (continued)	Jun. 1, 2022		• Endovascular embolization of Varicose Veins using cyanoacrylate-based adhesive
			• Endovenous low-nitrogen foam sclerotherapy of incompetent GSV, lesser saphenous veins, and accessory saphenous veins
			
			Documentation Requirements
			Medical notes documenting the following, when applicable:
			• Diagnosis
			• History of the medical condition(s) requiring treatment or surgical intervention
			• Documentation of signs and symptoms; including onset, duration, frequency, and which extremity (right, left, or both)
			• Relevant medical history, including:
			  ○ DVT (deep vein thrombosis)
			  ○ Aneurysm
			  ○ Tortuosity
			• Physical exam, including:
			  ○ Which extremity (right, left, or both)
			  ○ Vein(s) that will be treated [e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.]
			  ○ Vein diameter including the specific anatomic location where the measurement was taken (e.g., proximal thigh, proximal calf, etc.)
			  ○ Duration of reflux including the position of member at the time of measurement and the anatomic location where the measurement was taken [e.g., standing, saphenofemoral junction (SFJ)]
			• Severity of pain or other symptoms that interfere with activities of daily living related to vein disease
			• Functional disability(ies), as documented on a validated functional disability scale, (interfering with the ability to stand or sit for long periods of time, such as, preparing meals, performing work functions, driving, walking, etc.)
			• Diagnostic study/imaging reports
			• Pulses
			• Prior conservative treatments tried, failed, or contraindicated. Include the

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Pennsylvania Only) (continued)	Jun. 1, 2022		dates and reason for discontinuation • Proposed treatment plan with procedure code, including specific vein(s) that will be treated (e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.), which extremity (left, right, or both) and date of procedure for each vein to be treated In addition to the above, additional documentation requirements may apply for the following codes. Review the below listed policies in conjunction with the guidelines in this document. • For CPT codes 37761, 37765, 37766, and 37785, refer to the Utilization Review Guideline titled Outpatient Surgical Procedures – Site of Service (for Pennsylvania Only).
Surgical Treatment for Spine Pain (for Pennsylvania Only)	Jun. 1, 2022	Coverage Rationale • Replaced language indicating "a surgical spine procedure that is performed to alleviate symptoms or prevent clinical deterioration of a congenital or idiopathic deformity or bone disease is proven and medically necessary if not addressed in the [InterQual® criteria listed in the policy]" with "a surgical spine procedure that is performed to alleviate symptoms or prevent clinical deterioration of a congenital or idiopathic deformity or bone disease *other than scoliosis* is proven and medically necessary if not addressed in the [InterQual® criteria listed in the policy]" • Added language to indicate: ○ Interspinous process fusion devices are proven and	Spinal procedures for the treatment of spine pain are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures: • Decompression +/- Fusion, Cervical • Decompression +/- Fusion, Lumbar • Decompression +/- Fusion, Thoracic • Fusion, Cervical Spine • Fusion, Lumbar Spine • Fusion, Thoracic Spine Click here to view the InterQual® criteria. The following techniques for lumbar interbody fusion (LIF) are proven and medically necessary: • Anterior LIF(ALIF) including lateral approaches, e.g., extreme lateral interbody fusion (XLIF®), Direct lateral interbody fusion (DLIF) • Posterior LIF (PLIF), including transforaminal lumbar interbody fusion (TLIF) The following indications for a surgical spine procedure that is performed to alleviate symptoms or prevent clinical deterioration are considered proven and medically necessary if not addressed in the above criteria:

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for Pennsylvania Only) (continued)	Jun. 1, 2022	medically necessary when used in conjunction with any of the following procedures: ▪ Open laminar and/or facet decortication and fusion ▪ Autograft inter-and extra-spinous process decortication and fusion ▪ Interbody fusion of the same motion segment ○ Dividing treatment of symptomatic, multi-site spinal pathology via anterior or posterior approach into serial, multiple, or staged sessions when one session can address all sites is unproven and not medically necessary ● Removed language indicating interlaminar lumbar instrumented fusion (ILIF) utilizing an interspinous process fusion device is unproven and not medically necessary ● Revised list of documentation requirements: ○ Added: ▪ Smoking history/status, including date of last smoking cessation ▪ Degree and progression of curvature (for scoliosis)	● Congenital or idiopathic deformity or bone disease other than scoliosis ● Muscular dystrophy ● Laminectomy procedure to provide surgical exposure to treat lesions within the spinal canal Interspinous process fusion devices is proven and medically necessary when used in conjunction with any of the following procedures: ● Open laminar and/or facet decortication and fusion ● Autograft inter-and extra-spinous process decortication and fusion ● Interbody fusion of the same motion segment The following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy (this includes procedures that utilize interbody cages, screws, and pedicle screw fixation devices): ● Laparoscopic anterior lumbar interbody fusion (LALIF) ● Transforaminal lumbar interbody fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization) ● Axial lumbar interbody fusion (AxiaLIF®) ● Spinal decompression and interspinous process decompression systems for the treatment of lumbar spinal stenosis (e.g., Interspinous process decompression (IPD), Minimally invasive lumbar decompression (mild®) ● Dividing treatment of symptomatic, multi-site spinal pathology via anterior or posterior approach into serial, multiple, or staged sessions when one session can address all sites ● Spinal stabilization systems ○ Stabilization systems for the treatment of degenerative spondylolisthesis ○ Total facet joint arthroplasty, including facetectomy, laminectomy, foraminotomy, vertebral column fixation ○ Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement for the treatment of back pain ● Stand-alone facet fusion without an accompanying decompressive procedures; this includes procedures performed with or without bone

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical Treatment for Spine Pain (for Pennsylvania Only) (continued)	Jun. 1, 2022	▪ Quantification of relevant muscle strength ▪ Results of biopsy(ies) ▪ Results of bone aspirate ▪ List of conditions included in diagnostic image reports (when applicable): – Disc herniation – Discitis – Epidural abscess – Nerve root compression – Quantification of subluxation, translation by flexion, angulation when appropriate – Segment (s) instability – Spinal cord compression ○ Replaced language indicating "diagnostic image(s) *are* required" with "diagnostic image(s) *may be* required *upon request*" **Definitions** ● Added definition of "Staged Multi-Session" **Applicable Codes** ● Added CPT codes 63052 and 63053 ● Removed CPT codes 63194, 63195, 63196, 63198, and 63199	grafting and/or the use of posterior intrafacet implants such as fixation systems, facet screw systems or anti-migration dowels For information on vertebral body tethering, refer to the Medical Policy titled Vertebral Body Tethering for Scoliosis (for Pennsylvania Only). **Documentation Requirements** Medical notes documenting the following, when applicable: ● Condition requiring procedure ● History and co-morbid medical condition(s) ○ Smoking history/ status, including date of last smoking cessation ● Member's symptoms, pain, location, and severity including functional impairment that is interfering with activities of daily living (meals, walking, getting dressed, driving) ● Failure of Conservative Therapy through lack of clinically significant improvement between at least two measurements, on a validated pain or function scale or quantifiable symptoms despite concurrent Conservative Therapies (refer to definition), if applicable ● Progressive deficits with clinically significant worsening based on at least two measurements over time, if applicable ● Disabling Symptoms, if applicable ● Upon request, we may request the specific diagnostic image(s) that shows the abnormality for which surgery is being requested which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be needed to select the optimal image(s) ○ Note: When requested, diagnostic images must be labeled with the: ▪ Date taken ▪ Applicable case number obtained at time of notification, or the member's name and ID number on the image(s) ○ Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted ● Diagnostic image(s) report(s), including presence or absence of: ○ Segment (s) instability

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical Treatment for Spine Pain (for Pennsylvania Only) (continued)	Jun. 1, 2022	• Revised description for CPT codes 22600, 22610, 22612, 22614, 22633, 22634, 63048, and 63197 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	○ Spinal cord compression ○ Disc herniation ○ Nerve root compression ○ Quantification of subluxation, translation by flexion, angulation when appropriate ○ Discitis ○ Epidural abscess • Physical exam, including neurologic exam, including degree and progression of curvature (for scoliosis), if applicable ○ Degree and progression of curvature (for scoliosis) ○ Quantification of relevant muscle strength • Whether the surgery will be performed with direct visualization or only with endoscopic visualization • Complete report(s) of diagnostic tests ○ Results of biopsy(ies) ○ Results of bone aspirate • Describe the surgical technique(s) planned [e.g., AxiaLIF®, XLIF, ILIF, OLIF, LALIF, image-guided minimally invasive lumbar decompression (mild®), percutaneous endoscopic discectomy with or without laser, etc.]

Medical Benefit Drug Policy Updates

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Alpha$_1$-Proteinase Inhibitors	May 1, 2022	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. ● The treatment of emphysema due to congenital deficiency of alpha$_1$-proteinase inhibitor (A1-PI) in patients who meet all of the following criteria: ○ For initial therapy, all of the following: ▪ Diagnosis of congenital alpha$_1$-antitrypsin deficiency confirmed by one of the following: – Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous); or – Other rare AAT deficiency disease-causing alleles associated with serum AAT level < 11 µmol/L [e.g., Pi (Malton, Malton)]; and ▪ Circulating serum concentration of AAT < 11 µmol/L (which corresponds to < 80 mg/dl if measured by radial immunodiffusion or < 57 mg/dl if measured by nephelometry); and ▪ Continued optimal conventional treatment for emphysema (e.g., bronchodilators, supplemental oxygen if necessary); and ▪ Current nonsmoker; and ▪ Diagnosis of emphysema confirmed with pulmonary function testing; and ▪ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ▪ Initial authorization will be for no more than 12 months ○ For continuation of therapy, all of the following: ▪ Diagnosis of congenital alpha$_1$-antitrypsin deficiency confirmed by one of the following: – Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous); or – Other rare AAT deficiency disease-causing alleles associated with serum AAT level < 11 µmol/L [e.g., Pi(Malton, Malton)]; and ▪ Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response from pretreatment baseline to alpha$_1$-proteinase inhibitor treatment; and ▪ Current nonsmoker; and ▪ Diagnosis of emphysema confirmed with pulmonary function testing; and ▪ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ▪ Reauthorization will be for no more than 12 months Alpha$_1$-proteinase inhibitors are unproven for:

Medical Benefit Drug Policy Updates

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Alpha$_1$-Proteinase Inhibitors (continued)	May 1, 2022	• Conditions other than emphysema associated with alpha$_1$-antitrypsin deficiency • Cystic fibrosis
Enjaymo™ (Sutimlimab-Jome)	Jun. 1, 2022	Enjaymo is medically necessary for the treatment of CAD in patients who meet all of the following criteria: • For initial therapy, all of the following: ○ Diagnosis of CAD by, or in consultation with, a hematologist with expertise in the diagnosis of CAD; and ○ Confirmation of the CAD diagnosis based on all of the following: ▪ Evidence of chronic hemolysis (e.g., elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased indirect bilirubin, increased reticulocyte count); and ▪ Positive polyspecific direct antiglobin test (DAT); and ▪ Positive monospecific DAT specific for C3d; and ▪ Immunoglubulin G (IgG) DAT ≤ 1+; and ▪ Cold agglutinin titer ≥ 64 at 4°C and ○ Cold agglutinin syndrome secondary to other factors has been ruled out (e.g., infection, rheumatologic disease, systemic lupus erythematosus, overt hematologic malignancy, other autoimmune disorders); and ○ Patient has a baseline hemoglobin level ≤ 10 g/dL; and ○ Enjaymo is prescribed by a hematologist; and ○ Enjaymo dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Patient is not receiving Enjaymo in combination with a complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravilizumab-cwzb), Empaveli (pegcetacoplan)]; and ○ Initial authorization will be for no more than 6 months. • For continuation of therapy, all of the following: ○ Documentation of positive clinical response to therapy (e.g., increase in hemoglobin, decreased transfusion requirements, decreased markers of hemolysis, improvement in anemia-related symptoms); and ○ Enjaymo is prescribed by, or in consultation with, a hematologist; and ○ Enjaymo dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Patient is not receiving Enjaymo in combination with a complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravilizumab-cwzb), Empaveli (pegcetacoplan)]; and ○ Reauthorization will be for no more than 12 months. Requests outside of this criteria will be reviewed for medical necessity on a case by case basis.

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Rituximab (Riabni™, Rituxan®, Ruxience®, & Truxima®)	Jun. 1, 2022	Applicable Codes • Revised description for HCPCS code Q5115

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Immune Globulin (IVIG and SCIG) (for Pennsylvania Only)	Jun. 1, 2022	Coverage Rationale • Removed language pertaining to the states of Arizona, California, Florida, Hawaii, Maryland, Michigan, Mississippi, Nebraska, New Jersey, New York, Ohio, Rhode Island, Tennessee, Texas, Virginia, and Washington *Proven and Medically Necessary* • Revised coverage criteria for feto-neonatal alloimmune thrombocytopenia (AIT); replaced criterion requiring "fetus or newborn is considered to be at high risk for developing intracranial hemorrhage or other severe complication of AIT" with "fetus or newborn is considered to be at *standard or* high risk for developing intracranial hemorrhage or other severe complication of AIT" • Added language to indicate immune globulin is proven for vasculitides and antineutrophil antibody syndromes; immune globulin is medically necessary for the treatment of anti-neutrophil	Refer to the policy for complete details

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (for Pennsylvania Only) (continued)	Jun. 1, 2022	cytoplasmic antibody (ANCA)-associated vasculitis when all of the following criteria are met: Initial Treatment ○ Diagnosis of anti-neutrophil cytoplasmic antibody-associated vasculitis confirmed by specialist; and ○ Both of the following: ▪ Continued symptoms or findings after corticosteroid therapy or corticosteroids contraindicated or not tolerated ▪ Continued symptoms or findings after immunosuppressive therapy or immunosuppressive therapy contraindicated or not tolerated ○ Risk of thrombosis, renal dysfunction, and acute renal failure discussed with patient or caregiver ○ One of the following: ▪ Patient does not have previous treatment with immune globulin ▪ Patient does have previous treatment with immune globulin which was	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (for Pennsylvania Only) (continued)	Jun. 1, 2022	stopped for any reason other than anaphylaxis or inadequate response ○ IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 days Continuation of Treatment ○ Diagnosis of anti-neutrophil cytoplasmic antibody-associated vasculitis confirmed by specialist ○ Patient meets all of the following: ▪ Manageable or no side effects ▪ Improvement in clinical condition ▪ Complete response not yet achieved ○ IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 days *Unproven and Not Medically Necessary* ● Revised list of unproven and not medically necessary indications; removed “vasculitides and antineutrophil antibody syndromes” Supporting Information ● Updated *References* section to reflect the most current information	

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Vyvgart™ (Efgartigimod Alfa-Fcab)	Jun. 1, 2022	Coverage Rationale • Revised coverage criteria for continuation of therapy; replaced criterion requiring "improvement and/or maintenance of at least a *3* point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline" with "improvement and/or maintenance of at least a *2* point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline"	**Myasthenia Gravis** Vyvgart™ is proven and medically necessary when the following criteria are met: • Initial Therapy: ○ Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG) by a neurologist or in consultation with a neurologist confirming all of the following: ▪ Patient has not failed a previous course of Vyvgart™ therapy; and ▪ Positive serologic test for anti-AChR antibodies; and ▪ One of the following: – History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation – History of positive anticholinesterase test, e.g., edrophonium chloride test – Patient has demonstrated improvement in MG signs on oral cholinesterase inhibitors as assessed by the treating neurologist and ▪ Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; and ▪ Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy and ○ Both of the following: ▪ History of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, methotrexate, cyclosporine, mycophenylate, etc.); and ▪ Patient has required 2 or more courses of plasmapheresis/plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control and

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Vyvgart™ (Efgartigimod Alfa-Fcab) (continued)	Jun. 1, 2022		○ Patient is currently on a stable dose (at least 2 months) of immunosuppressive therapy; and ○ Patient is not receiving Vyvgart™ in combination with Soliris (eculizumab); and ○ Vyvgart™ is initiated and titrated according to the U.S. FDA labeled dosing for gMG, up to a maximum of 1200 mg per dose; and ○ Prescribed by or in consultation with a neurologist; and ○ Initial authorization will be for no more than 6 months. • Continuation of Therapy: ○ Patient has previously been treated with Vyvgart™; and ○ Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by all of the following: ▪ Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline. ▪ Reduction in signs and symptoms of myasthenia gravis ▪ Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart™. Note: add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Vyvgart™ therapy will be considered as treatment failure. and ○ Patient is not receiving Vyvgart™ in combination with Soliris (eculizumab); and ○ Vyvgart™ is dosed according to the U.S. FDA labeled dosing for gMG: up to a maximum of 1200 mg per dose; and ○ Prescribed by or in consultation with a neurologist; and ○ Reauthorization will be for no more than 12 months.

Utilization Review Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes
Chemotherapy Observation or Inpatient Hospitalization (for Pennsylvania Only)	May 1, 2022	**Coverage Rationale** • Updated list of clinical conditions or complications of cancer chemotherapy which may require an observation stay; replaced "comorbidities *that require an observation or overnight stay*" with "comorbidities" • Replaced reference to "InterQual® *2021*, Apr. *2021* Release" with "InterQual® *2022*, Apr. *2022* Release" **Supporting Information** • Updated *References* section to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (for Pennsylvania Only)	Jun. 1, 2022	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled: ○ *Amondys 45™ (Casimersen) (for Pennsylvania Only)* ○ *Exondys 51® (Eteplirsen) (for Pennsylvania Only)* ○ *Immune Globulin (IVIG and SCIG) (for Pennsylvania Only)* ○ *Medical Therapies for Enzyme Deficiencies* ○ *Vyondys 53™ (Golodirsen) (for Pennsylvania Only)* **Application and Coverage Rationale** • Revised list of medications that require healthcare provider administration; added: ○ Aldurazyme® (laronidase) ○ Amondys 45™ (casimersen) ○ Asceniv™ (IV) ○ Bivigam® (IV) ○ Carimune® NF (IV) ○ Cutaquig® (SC)	This guideline addresses the criteria for consideration of allowing hospital outpatient facility 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 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): • 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: ○ 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

Utilization Review Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (for Pennsylvania Only) (continued)	Jun. 1, 2022	○ Cuvitru® (SC) ○ Elaprase® (idursulfase) ○ Exondys 51® (eteplirsen) ○ Fabrazyme® (agalsidase beta) ○ Flebogamma® DIF (IV) ○ Gammagard® Liquid (IV, SC) ○ Gammagard® S/D (IV) ○ Gammaked™ (IV, SC) ○ Gammaplex® (IV) ○ Gamunex®-C (IV, SC) ○ Hizentra® (SC) ○ HyQvia® (SC) ○ Kanuma® (sebelipase alfa) ○ Lumizyme® (alglucosidase alfa) ○ Mepsevii™ (vestronidase alfa-vjbk) ○ Naglazyme® (galsulfase) ○ Octagam® (IV) ○ Panzyga® (IV) ○ Privigen® (IV) ○ Revcovi® (elapegademase-lvlr) ○ Vimizim® (elosulfase alfa) ○ Viltepso™ (viltolarsen) ○ Vyondys 53™ (golodirsen) ○ Xembify® (SC) **Applicable Codes** • Added CPT codes 90283 and 90284 • Added HCPCS codes J0180, J0221, J1322, J1426, J1427, J1428, J1429, J1458, J1459, J1554, J1555, J1556, J1557, J1558, J1559, J1561, J1566,	due to a clinically significant physical or cognitive impairment; or ○ Difficulty establishing and maintaining patent vascular access; or ○ To initiate or re-initiate products for a short duration (e.g., 4 weeks); or • Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting; or • Initial infusion 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) 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 medications that require healthcare provider administration: • Actemra® (Tocilizumab) • Aldurazyme® (laronidase) • Amondys 45™ (casimersen) • Asceniv™ (IV) • Avsola™ (Infliximab-axxq) • Bivigam® (IV) • Carimune® NF (IV) • Cutaquig® (SC) • Cuvitru® (SC) • Elaprase® (idursulfase)

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Provider Administered Drugs – Site of Care (for Pennsylvania Only) (continued)	Jun. 1, 2022	J1568, J1569, J1572, J1575, J1599, J1743, J1931, J2840, J3397, and J3590	• Entyvio® (Vedolizumab) • Exondys 51® (eteplirsen) • Fabrazyme® (agalsidase beta) • Flebogamma® DIF (IV) • Gammagard® Liquid (IV, SC) • Gammagard® S/D (IV) • Gammaked™ (IV, SC) • Gammaplex® (IV) • Gamunex®-C (IV, SC) • Hizentra® (SC) • HyQvia® (SC) • Ilumya™ (Tildrakizumab-asmn) • Inflectra® (Infliximab-dyyb) • Kanuma® (sebelipase alfa) • Lumizyme® (alglucosidase alfa) • Mepsevii™ (vestronidase alfa-vjbk) • Naglazyme® (galsulfase) • Octagam® (IV) • Orencia® (Abatacept) • Panzyga® (IV) • Privigen® (IV) • Remicade® (Infliximab) • Renflexis® (Infliximab-abda) • Revcovi® (elapegademase-lvlr) • Simponi Aria® (Golimumab) • Vimizim® (elosulfase alfa) • Viltepso™ (viltolarsen) • Vyondys 53™ (golodirsen) • Xembify® (SC)

General Information

The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare is adopting 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. 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.

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.

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 Community Plan of Pennsylvania Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline, and Utilization Review Guideline updates. When information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

Policy Update Classifications

New

New clinical coverage criteria 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; 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

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

The complete library of UnitedHealthcare Community Plan of Pennsylvania Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines is available at UHCprovider.com/Pennsylvania > Medicaid (Community Plan) > Current Policies and Clinical Guidelines > UnitedHealthcare Community Plan of Pennsylvania Medical & Drug Policies and Coverage Determination Guidelines.