United Healthcare®

UnitedHealthcare Commercial

Medical Policy Update Bulletin: March 2022

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Policy Title	**Effective Date**	**Coverage Rationale**

Obstetrical Ultrasound	Jun. 1, 2022	The use of prenatal or obstetrical ultrasound is proven and medically necessary during pregnancy when the following criteria are met:
		• Up to three obstetrical ultrasounds are performed during routine pregnancy care which may include the following (see below for exception*):
		  ○ One ultrasound during the first trimester for indications that include but are not limited to the following:
		  ▪ To confirm the presence of an intrauterine pregnancy
		  ▪ To estimate gestational age
		  ○ One ultrasound during the second trimester (generally between 18-22 weeks) for indications that include but are not limited to the following:
		  ▪ To survey fetal anatomy
		  ▪ To determine an accurate estimation of gestational age
		  ○ One ultrasound during the third trimester for indications that include but are not limited to the following:
		  ▪ To determine fetal presentation
		  ▪ To assess fetal growth
		  ▪ To evaluate fetal condition in late registrants for prenatal care
		• Additional ultrasounds during the course of a High-Risk Pregnancy only when the treating provider will make therapeutic determinations based upon the results
		
		Three-Dimensional (3-D) Prenatal Ultrasounds are unproven and not medically necessary due to insufficient evidence of efficacy.
		
		The following are unproven and not medically necessary due to insufficient evidence of efficacy:
		• More than one Detailed Fetal Anatomic Ultrasound Examination per pregnancy
		• The use of prenatal or obstetrical ultrasound for the sole purpose of determination of sex of the fetus unless the determination of fetal sex is essential to the diagnosis of a condition.
		
		All other uses of prenatal obstetrical ultrasound are unproven and not medically necessary due to insufficient evidence of efficacy.
		
		*Exception: The limit of three obstetrical ultrasounds per pregnancy does not apply to obstetrical ultrasound procedures rendered in the emergency room, during outpatient Observation Care, or inpatient hospital setting.

Updated

Policy Title	Effective Date	Summary of Changes
Cardiovascular Disease Risk Tests	Apr. 1, 2022	**Applicable Codes** • Added CPT code 84999 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information
Deep Brain and Cortical Stimulation	Mar. 1, 2022	**Coverage Rationale** • Updated language to clarify responsive cortical stimulation is proven and medically necessary for treating *refractory* partial or focal seizure disorder **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information

Transcatheter Heart Valve Procedures	Mar. 1, 2022	**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)"
		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

Functional Endoscopic Sinus Surgery (FESS)	Apr. 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)*"
			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

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Functional Endoscopic Sinus Surgery (FESS) (continued)	Apr. 1, 2022	○ "Nasal lavage" with "nasal lavage/ *irrigation if appropriate*" **Supporting Information** • Updated *References* section to reflect the most current information	▪ 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 has the 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: – Bony remodeling – Bony thickening – Opacified sinus – Ostial obstruction (outflow tract obstruction) and mucosal thickening ○ Sino nasal 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

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Functional Endoscopic Sinus Surgery (FESS) (continued)	Apr. 1, 2022		○ Polyposis with obstructive symptoms (for Chronic Rhinosinusitis with polyps see 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.
Negative Pressure Wound Therapy	May 1, 2022	**Coverage Rationale** • Revised list of indications and devices that are unproven and not medically necessary: ○ Added "negative pressure wound therapy (NPWT) systems with instillation" ○ Replaced "NPWT for treating closed surgical *wounds*" with "NPWT for treating closed surgical *incisions*" **Definitions** • Updated definition of "National Pressure Injury Advisory Panel (NPIAP) Staging System" **Applicable Codes** • Removed instruction to refer to the Coverage Determination Guideline titled *Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements* for use of HCPCS codes K0743 and K0746 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References*	Notes: • The proven and medically necessary coverage statements in this policy apply to the use of negative pressure wound therapy (NPWT) in the outpatient setting. • The unproven and not medically necessary coverage statements in this policy apply to all settings. NPWT, in an outpatient setting or upon discharge from an inpatient setting, is proven and medically necessary for treating individuals who have undergone a complete wound therapy program and meet indication-specific criteria as noted below. A complete wound therapy program, meeting the following criteria, must have been tried or considered and ruled out prior to initiation of NPWT: • Documentation of evaluation, care and wound measurements; and • Application of dressings to maintain a moist wound environment; and • Debridement of necrotic tissue, if present; and • Evaluation of and provision for adequate nutritional status; and • Documentation, by provider, of indication for NPWT; and • Documentation, that open wound has not responded to conventional treatment after 30 days **Indications** • Pressure ulcer (Stage III or IV) with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Appropriate turning and positioning; and

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Negative Pressure Wound Therapy (continued)	May 1, 2022	sections to reflect the most current information	○ Use of a pressure-reducing support surface; and ○ Moisture and incontinence management ● Neuropathic ulcer (e.g., diabetic ulcer) with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Comprehensive diabetic management program; and ○ Reduction in pressure on ulcer ● Venous insufficiency ulcer with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Compression bandages and/or garments have been used consistently, for at least 30 days; and ○ Leg elevation and ambulation ● Open surgical wound with documentation of the following: ○ Post-operative dehiscence (separation of a previously closed surgical incision) with documentation of a complete wound therapy program, as outlined above; or ○ Open, non-healing amputation site in diabetics; or ○ Post-sternotomy infection (mediastinitis); or ○ Delayed healing or non-healing of skin graft is likely due to irregularly contoured or inadequate blood flow of the graft bed ● High-risk open fracture (Gustilo Grade III) The following indications and devices are unproven and not medically necessary due to insufficient evidence of efficacy: ● NPWT for treating all other indications, including but not limited to: ○ Closed surgical incisions ○ Pilonidal disease ● Disposable/single-use NPWT systems ● NPWT systems with instillation **Contraindications to NPWT** ● Active bleeding or exposed vasculature in wound ● Eschar or necrotic tissue present in wound ● Exposed bone, nerves or organs in vicinity of wound

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Negative Pressure Wound Therapy (continued)	May 1, 2022		• Malignancy present in wound • Uncontrolled soft tissue infection or osteomyelitis within vicinity of wound • Presence of an open fistula to body organs or cavities within vicinity of wound NPWT should be discontinued when any of the following criteria are present: • Documentation of weekly assessment of the wound's dimensions and characteristics by the provider indicate failure of progressive wound healing (i.e., wound is not diminishing in size [either surface area or depth] within 30 days); or • The depth of the wound is 1 mm or less; or • Uniform granulation tissue has been obtained
Obstructive and Central Sleep Apnea Treatment	May 1, 2022	Coverage Rationale *Nonsurgical Treatment* • Revised list of services/devices that are unproven and not medically necessary for treating Obstructive Sleep Apnea (OSA); added: ○ Non-surgical electrical muscular training ○ Morning repositioning devices *Surgical Treatment* • Revised coverage criteria for implantable hypoglossal nerve stimulation: ○ Added criterion requiring total AHI < 25% for central + mixed apneas ○ Replaced reference to "polysomnography" with "Polysomnography *(Attended)*" • Revised list of surgical procedures	**Nonsurgical Treatment** Removable Oral Appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) as documented by a sleep study (e.g., polysomnography or Home Sleep Apnea Testing). Refer to the Medical Policy titled Attended Polysomnography for Evaluation of Sleep Disorders for further information. For many individuals, oral appliance therapy (OAT) may be an effective alternative to failed continuous positive airway pressure (CPAP) therapy. Documentation of the following is required: • A patient presenting with symptoms of OSA be seen in a face-to-face evaluation with a qualified physician (MD or DO) trained in sleep medicine or with an Advanced Practice Provider working under the direct supervision of a sleep medicine physician prior to beginning treatment for OAT (AASM and AADSM, December 2012, AAO-HNS, November 2019) • A treating physician (MD or DO) or an Advanced Practice Provider must diagnose OSA and recommend course of treatment (AAO-HNS, November 2019) • If the patient refuses CPAP therapy, documentation of the refusal from the patient's treating physician (MD or DO) or an Advanced Practice Provider

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Obstructive and Central Sleep Apnea Treatment (continued)	May 1, 2022	that are unproven and not medically necessary for treating Obstructive Sleep Apnea (OSA); added "distraction osteogenesis for maxillary expansion (DOME)" **Definitions** • Added definition of "Polysomnogram (Attended)" **Applicable Codes** • Added CPT/HCPCS codes 21142 and E1399 • Added notation to indicate: ○ HCPCS code E0486 applies to the custom fabricated oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable and includes fitting and adjustment ○ Dental services (e.g., D9947, D9948 and D9949) are excluded from coverage under the medical plan; the member specific benefit plan document must be referenced prior to determining any coverage decision **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	must be supplied For information on snoring and Oral Appliances, refer to the Coverage Determination Guideline titled Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements. For medical necessity clinical coverage criteria for removable oral appliances, refer to the InterQual® 2021, Oct. 2021 Release, CP: Durable Medical Equipment, Noninvasive Airway Assistive Devices. Click here to view the InterQual® criteria. The following are unproven and not medically necessary due to insufficient evidence of efficacy: • Devices for treating Positional OSA • Nasal dilator devices for treating OSA • Removable Oral Appliances for treating Central Sleep Apnea • Prefabricated Oral Appliance/Device • Non-surgical electrical muscular training • Morning repositioning devices **Surgical Treatment** The following surgical procedures are proven and medically necessary for treating OSA as documented by polysomnography. For medical necessity clinical coverage criteria, InterQual® Client Defined 2021, CP: Procedures: • Mandibular Osteotomy (Custom) - UHG • Maxillomandibular Osteotomy and Advancement (Custom) - UHG • Uvulopalatopharyngoplasty (UPPP) (Custom) - UHG Click here to view the InterQual® criteria. Implantable hypoglossal nerve stimulation is proven and medically necessary in an adult patient with moderate to severe OSA when all of the following

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Obstructive and Central Sleep Apnea Treatment (continued)	May 1, 2022		criteria are met:
			• Body Mass Index of (BMI) less than or equal to 32kg/m2; and
			• Apnea hypopnea Index (AHI) of ≥20 and ≤65 as determined with Polysomnography (Attended); and
			• Total AHI < 25% for central + mixed apneas; and
			• Absence of complete concentric collapse at the soft palate level; and
			• Failure or intolerance of Positive Airway Pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines)
			  ○ PAP failure is defined as an inability to eliminate OSA (AHI of greater than 20 despite PAP usage) and PAP intolerance is defined as:
			  ▪ Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night); or
			  ▪ Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it)
			
			Implantable neurostimulation devices for the treatment of Central Sleep Apnea (CSA) are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.
			
			The following surgical procedures are unproven and not medically necessary for treating OSA due to insufficient evidence of efficacy:
			• Laser-assisted uvulopalatoplasty (LAUP)
			• Lingual suspension - Also referred to as tongue stabilization, tongue stitch or tongue fixation
			• Palatal implants
			• Radiofrequency ablation of the soft palate and/or tongue base
			• Transoral robotic surgery (TORS)
			• Distraction osteogenesis for maxillary expansion (DOME)

Skin and Soft Tissue Substitutes	Apr.1, 2022	Coverage Rationale • Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any	**EpiFix or Grafix® (GrafixPL, GrafixPRIME and GrafixPL PRIME) (Non-Injectable)** EpiFix or Grafix is proven and medically necessary for treating diabetic foot ulcer when all of the following criteria are met:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (continued)	Apr. 1, 2022	indication; added: ○ Apis ○ Cygnus matrix ○ InnovaMatrix AC ○ Microlyte Matrix ○ Mirragen Advanced Wound Matrix ○ NovoSorb SynPath ○ Restrata ○ Symphony ○ TheraGenesis ○ XCelliStem **Applicable Codes** • Added HCPCS codes A2001, A2002, A2004, A2005, A2006, A2007, A2008, A2009, A2010, and Q4199 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	• Adequate circulation to the affected extremity as indicated by one or more of the following: ○ Pedal pulses palpable ○ Ankle-brachial index (ABI) between 0.7 and 1.2 ○ Dorsum transcutaneous oxygen test (TcPO2) ≥ 30 mm Hg within the last 60 days ○ Triphasic or biphasic Doppler arterial waveforms at the ankle of affected leg • Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days) • Individual has a diagnosis of Type 1 or Type 2 diabetes • Ulcer size ≥ 1 cm^2 and < 25 cm^2 • Ulcer has failed to demonstrate Measurable Signs of Healing with at least 4 weeks of standard wound care which includes all of the following: ○ Application of dressings to maintain a moist wound environment ○ Debridement of necrotic tissue, if present ○ Offloading • Individual does not have active Charcot deformity or major structural abnormalities of the affected foot • Individual does not have a known or suspected malignancy of the current ulcer being treated • Standard wound care continues • Ulcer being treated does not extend to tendon, muscle, capsule or bone ***EpiFix and Grafix Application Limitations*** • EpiFix is limited to one application per week for up to 12 weeks • Grafix is limited to one application per week for up to 12 weeks Due to insufficient evidence of efficacy, EpiFix and/or Grafix are unproven and not medically necessary for all other indications including but not limited to: • EpiFix application more frequently than once a week or beyond 12 weeks • Grafix application more frequently than once a week or beyond 12 weeks

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Skin and Soft Tissue Substitutes (continued)	Apr. 1, 2022		**TransCyte™** TransCyte is proven and medically necessary for treating surgically excised Full-Thickness Thermal Burn wounds and deep Partial-Thickness Thermal Burn wounds before autograft placement. TransCyte is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy. **Other Skin and Soft Tissue Substitutes** The following skin and soft tissue substitutes are unproven and not medically necessary for any indication* due to insufficient evidence of efficacy: • Affinity® • AlloGen™ • AlloSkin™ • AlloWrap® • Altiply® • Amnio Wound™ • Amnio Wrap2™ • AmnioAMP-MP™ • AmnioArmor™ • AmnioBand® • AmnioCore • Amniocyte Plus™ • AMNIOEXCEL®, AMNIOEXCEL Plus, or BioDExcel™ • AmnioFix® • AMNIOMATRIX® or BioDMatrix™ • Amnio-Maxx™ or Amnio-Maxx™ Lite • Amniorepair • Amniotext • Amniotext patch • Amnion Bio™ • AMNIPLY™

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (continued)	Apr. 1, 2022		• Apis • Architect® • Artacent® Cord • Artacent Wound or Artacent AC • ArthroFLEX® • Ascent™ • AxoBioMembrane™ • Axolotl™ Ambient or Axolotl Cryo • Axolotl Graft or Axolotl DualGraft • BellaCell HD™ • bio-ConneKt® • BioDfence™ or BioDFence DryFlex™ • Bioskin™ • Bioskin Flow • Biovance® • BioWound™, BioWound Plus, or BioWound Xplus • Cellesta™ or Cellesta Duo • Cellesta Cord • Cellesta Flowable Amnion • CLARIX® • CLARIX FLO® • Cogenex (amniotic membrane and flowable amnion) • Coll-e-Derm™ • Conexa™ • Corecyte™ • Coretext™ or Protext™ • CorMatrix® • Corplex™ • Corplex p • Cryo-Cord™ • Cygnus matrix or Cygnus™ • Cymetra™ • Cytal™

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (continued)	Apr. 1, 2022		• DermACELL®*, DermACELL AWM® or DermACELL AWM Porous (*see asterisked note below when DermACELL is used during breast reconstruction*) • Dermacyte® • Derma-Gide™ • DermaPure™ • DermaSpan™ • Dermavest® or Plurivest® • Derm-Maxx • EpiCord® • EpiFix®, injectable • Excellagen® • E-Z Derm® • FlowerAmnioFlo™ or FlowerFlo™ • FlowerAmnioPatch™ or FlowerPatch™ • FlowerDerm™ • Fluid Flow™ • Fluid GF™ • GammaGraft™ • Genesis Amniotic Membrane • Grafix Core • Guardian • Helicoll™ • hMatrix® • Hyalomatrix® • InnovaMatrix AC • Integra® Flowable Wound Matrix • IntéguPly® • Interfy™ • Keramatrix® • Kerasorb® • Kerecis™ Omega3 • Keroxx™

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (continued)	Apr. 1, 2022		• Matrion™ • MatriStem® • Mediskin™ • Membrane Graft™ • Membrane Wrap™ • MemoDerm™ • Microlyte Matrix • Mirragen Advanced Wound Matrix • MIRODERM™ • MyOwn Skin™ • NeoPatch™ • NEOX® • NEOX FLO® • Novachor™ • Novafix™ • Novafix™ DL • NovoSorb SynPath • NuDYN™ • NuShield® • PalinGen® Amniotic Tissue Allograft and PalinGen Flow products • Polycyte™ • PriMatrix® • Procenta® • ProgenaMatrix™ • ProMatrX™ • PuraPly®, PuraPly AM, or PuraPly XT • REGUaRD™ • Repriza® • Restorigin™ • Restrata • Revita™ • Revitalon® • SkinTE™

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (continued)	Apr. 1, 2022		• STRATTICE™ • Stravix™ or StravixPL™ • Surederm™ • Surfactor® • SurGraft™ • SurgiCORD™ • SurgiGRAFT™ • SurgiGRAFT-DUAL • Symphony • Talymed® • TenSIX® • TheraGenesis • TheraSkin® • Therion™ • TranZgraft® • TruSkin™ • Vendaje • Vim • WoundEx® • WoundEx™ Flow • WoundFix™, WoundFix Plus, or WoundFix Xplus • XCelliStem • Xcellerate™ • XCM BIOLOGIC® Tissue Matrix • XWRAP™ • Zenith Amniotic Membrane *Refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy and Poland Syndrome for information above coverage for skin and soft tissue substitutes used during post mastectomy breast reconstruction procedures.

New		
Policy Title	**Effective Date**	**Coverage Rationale**

Leqvio® (Inclisiran)	Mar. 1, 2022	Leqvio® (inclisiran) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the policy titled Review at Launch for New to Market Medications for additional details.
		
		Leqvio (inclisiran) is proven and medically necessary for the treatment of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) in patients who meet all of the following criteria:
		• For initial therapy, all of the following:
		  ○ Diagnosis of one of the following:
		  ▪ Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following*:
		  – Both of the following:
		  • Pre-treatment LDL-C greater than or equal to 190 mg/dL (greater than or equal to 155 mg/dL if less than 16 years of age); and
		  • One of the following:
		  ○ Family history of myocardial infarction in first-degree relative < 60 years of age; or
		  ○ Family history of myocardial infarction in second-degree relative < 50 years of age; or
		  ○ Family history of LDL-C greater than or equal to 190 mg/dL in first- or second-degree relative; or
		  ○ Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative; or
		  ○ Family history of tendinous xanthomata and/or arcus cornealis in first- or second degree relative
		  or
		  – Both of the following:
		  • Pre-treatment LDL-C greater than or equal to 190 mg/dL (greater than or equal to 155 mg/dL if less than 16 years of age); and
		  • One of the following:
		  ○ Functional mutation in LDL, apoB, or PCSK9 gene*; or
		  ○ Tendinous xanthomata; or
		  ○ Arcus cornealis before age 45
		  or
		  ▪ Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following:
		  – Acute coronary syndromes; or
		  – History of myocardial infarction; or
		  – Coronary or other arterial revascularization; or
		  – Stroke; or

New

Policy Title	Effective Date	Coverage Rationale
Leqvio® (Inclisiran) (continued)	Mar. 1, 2022	– Transient ischemic attack; or – Peripheral arterial disease presumed to be of atherosclerotic origin and ○ Prescribed by a lipid specialist (e.g., cardiologist, endocrinologist, lipid specialist/lipidologist); and ○ One of the following: (for Medicare reviews, refer to the CMS section of the policy) ▪ Despite adherence to PCSK9 therapy (defined by at least 12 consecutive weeks of use), one of the following: – Both of the following: • Patient has clinical ASCVD; and • Patient failed to achieve LDL-C goal of < 70 mg/dL or – Both of the following: • Patient has severe primary hypercholesterolemia (HeFH) (pre-treatment LDL-C ≥ 190 mg/dL); and • Patient failed to achieve LDL-C goal of < 100 mg/dL or ▪ Patient has a history of intolerance or contraindication to PCSK9 therapy and ○ Patient will continue other traditional low-density lipoprotein-cholesterol (LDL-C) lowering therapies (e.g., maximally tolerated statins, ezetimibe) in combination with Leqvio; and ○ Leqvio will not be used in combination with PCSK9 inhibitor therapy; and ○ Leqvio 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: ○ Documentation of a positive clinical response to therapy from pre-treatment baseline (e.g., achieved LDL-C goal of < 100 mg/dL or achieved a 50% reduction in LDL-C levels); and ○ Patient continues treatment with other traditional low-density lipoprotein-cholesterol (LDL-C) lowering therapies (e.g., statin, ezetimibe) in combination with Leqvio; and ○ Leqvio will not be used in combination with PCSK9 therapy; and ○ Leqvio dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months. *Results of prior genetic testing can be submitted as confirmation of diagnosis of HeFH, however please note that UnitedHealthcare does not currently cover genetic testing for evidence of an LDL-receptor mutation, familial defective apo B-100 or a PCSK9 mutation.

New		
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Tezspire™ (Tezepelumab)	Mar. 1, 2022	Tezspire (tezepelumab) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the policy titled Review at Launch for New to Market Medications for additional details. Tezspire is proven for add-on maintenance treatment for patients that meet the following criteria: • For initial therapy, both of the following: ○ Diagnosis of severe asthma; and ○ Will be used as add-on maintenance therapy; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization will be for no more than 6 months. • For continuation of therapy, all of the following: ○ Documentation of positive clinical response; and ○ Used in combination with an inhaled corticosteroid (ICS)-containing controller medication; and ○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)] ▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] 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. Tezspire is medically necessary when all of the following criteria is met: • For initial therapy, all of the following: ○ Diagnosis of severe asthma; and ○ Classification of asthma as uncontrolled or inadequately controlled as defined by at least one of the following: ▪ Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20); or ▪ Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months; or ▪ Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment); or ▪ Airflow limitation (e.g., after appropriate bronchodilator withhold FEV1 less than 80% predicted (in the face of reduced FEV1/FVC defined as less than the lower limit of normal); or ▪ Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma and

New

Policy Title	Effective Date	Coverage Rationale
Tezspire™ (Tezepelumab) (continued)	Mar. 1, 2022	○ Used in combination with one of the following: ▪ One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA) product [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]; or ▪ Combination therapy including both of the following: – One high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco®), mometasone furoate (Asmanex®), beclomethasone dipropionate (QVAR®)]; and – One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi®) or indacaterol (Arcapta®), leukotriene receptor antagonist – montelukast (Singulair®), theophylline] and ○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)] ▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] ○ Tezspire dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Tezspire is prescribed by a pulmonologist or allergist/immunologist; and ○ Initial authorization will be for no more than 6 months. ● For continuation of therapy, all of the following: ○ Documentation of a positive clinical response as demonstrated by at least one of the following: ▪ Reduction in the frequency of exacerbations ▪ Decreased utilization of rescue medications ▪ Increase in percent predicted FEV1 from pretreatment baseline ▪ Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.) and ○ Used in combination with an ICS-containing controller medication; and ○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)] ▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] and ○ Tezspire dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months.

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Vyvgart™ (Efgartigimod Alfa-Fcab)	Mar. 1, 2022	Vyvgart™ (efgartigimod alfa-fcab) 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. Vyvgart is proven for the treatment of generalized myasthenia gravis. Vyvgart is medically necessary when all of 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: (for Medicare reviews, refer to the CMS section of the policy) ▪ 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 ○ 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 US FDA labeled dosing for gMG, up to a maximum of 1200 mg per dose; and

New

Policy Title	Effective Date	Coverage Rationale
Vyvgart™ (Efgartigimod Alfa-Fcab) (continued)	Mar. 1, 2022	○ 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 3 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 US 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.

Updated

Policy Title	Effective Date	Summary of Changes
Oncology Medication Clinical Coverage	Mar. 1, 2022	Applicable Codes ● Added HCPCS codes A9513, A9590, A9606, A9699, J9311, and Q5123 ● Removed HCPCS codes J3315, J9155, J9202, J9218, and J9219

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Benlysta® (Belimumab)	Apr. 1, 2022	Coverage Rationale ● Revised coverage criteria; added criterion requiring the patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia)	This policy refers only to Benlysta (belimumab) injection for intravenous infusion for the treatment of systemic lupus erythematosus (SLE) and active lupus nephritis (LN). Benlysta (belimumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit and is indicated for systemic lupus erythematosus and active lupus nephritis.

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

Benlysta® (Belimumab) (continued)	Apr. 1, 2022	Supporting Information
		• Updated *References* section to reflect the most current information
		• Removed *CMS* section
			Benlysta (belimumab) is proven and medically necessary for the treatment of systemic lupus erythematosus when all of the following criteria are met:
			• For initial therapy, all of the following:
			  ○ Diagnosis of active systemic lupus erythematosus, without severe active central nervous system lupus; and
			  ○ Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]; and
			  ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; and
			  ○ Patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); and
			  ○ Benlysta is initiated and titrated according to US Food and Drug Administration labeled dosing for SLE; and
			  ○ Initial authorization is for no more than 12 months.
			• For continuation of therapy, all of the following:
			  ○ Patient has previously received Benlysta injection for intravenous infusion; and
			  ○ Documentation of positive clinical response; and
			  ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants; that is not a biologic; and
			  ○ Patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); and
			  ○ Benlysta is dosed according to US Food and Drug Administration labeled dosing for SLE; and
			  ○ Authorization is for no more than 12 months.
			
			Benlysta (belimumab) is proven and medically necessary for the treatment of active lupus nephritis when all of the following criteria are met:
			• For initial therapy, all of the following:
			  ○ Diagnosis of active lupus nephritis, without severe active central nervous system lupus; and

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Benlysta® (Belimumab) (continued)	Apr. 1, 2022		○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; and ○ Patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); and ○ Benlysta is initiated and titrated according to US Food and Drug Administration labeled dosing; and ○ Initial authorization is for no more than 12 months. ● For continuation of therapy, all of the following: ○ Patient has previously received Benlysta injection for intravenous infusion; and ○ Documentation of positive clinical response; and ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants; that is not a biologic; and ○ Patient is not receiving Benlysta in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab-fnia); and ○ Benlysta is dosed according to US Food and Drug Administration labeled dosing; and ○ Authorization is for no more than 12 months. Benlysta is unproven and not medically necessary for: ● Antineutrophil cytoplasmic antibody-associated vasculitis ● Rheumatoid arthritis ● Severe active central nervous system (CNS) lupus ● Sjögren's syndrome ● Use in combination with other biologics ● Waldenström macroglobulinemia

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®)	Apr. 1, 2022	Coverage Rationale *Eosinophilic Granulomatosis with Polyangiitis (EGPA), Severe Asthma, and Hypereosinophilic Syndrome (HES)* • Revised medical necessity criteria; added criterion requiring the patient is not receiving Cinqair/ Fasenra/ Nucala in combination with a thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] *Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)* • Revised coverage criteria: Proven Criteria ○ Added criterion requiring the patient is not receiving Nucala in combination with a thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] Medically Necessary: Initial Therapy Criteria ○ Added criteria requiring: ▪ Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) defined by all of the following: – Two or more of the following symptoms for longer than 12	This policy provides information about the use of certain specialty pharmacy medications administered by either the subcutaneous (SC) or intravenous (IV) route. This policy refers to the following drug products: • Cinqair® (reslizumab) • Fasenra® (benralizumab) • Nucala® (mepolizumab) Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Apr. 1, 2022	weeks duration: • Nasal mucopurulent discharge • Nasal obstruction, blockage, or congestion • Facial pain, pressure, and/or fullness • Reduction or loss of sense of smell – One of the following findings using nasal endoscopy and/or sinus computed tomography (CT): • Purulent mucus or edema in the middle meatus or ethmoid regions • Polyps in the nasal cavity or the middle meatus • Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Apr. 1, 2022	– One of the following: • Presence of bilateral nasal polyposis • Patient has previously required surgical removal of bilateral nasal polyps – One of the following: • Patient has required prior sinus surgery; or • Patient has required systemic corticosteroids (e.g., prednisone, methyl-prednisolone) for CRSwNP in the previous 2 years; or • Patient has been unable to obtain symptom relief after trial of two of the following classes of agents: ○ Nasal saline irrigations ○ Intranasal cortico-	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Apr. 1, 2022	steroids (e.g., fluticasone, mometasone, triamcinolone) ○ Anti-leukotriene agents (e.g., montelukast, zafirlukast, zileuton) ▪ Patient will receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone) ▪ One of the following: – Physician attestation that the patient or caregiver are not competent or are physically unable to administer the Nucala product FDA labeled for self-administration – Patient has documented history of severe hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, or	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Apr. 1, 2022	hypotension) to Nucala within the past 6 months and requires administration and direct monitoring by a healthcare professional – Patient is new to therapy with Nucala and requires initial dose to be directly monitored by a healthcare professional before continued self-administration (Note: authorization will be for 1 dose) – Patient is ≤ 11 years of age ▪ Patient is not receiving Nucala in combination with a thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] ○ Removed criteria requiring: ▪ Diagnosis of chronic rhinosinusitis with polyps (CRSwNP) ▪ Patient remains symptomatic despite at least an 8-week trial of, or	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Apr. 1, 2022	history of contraindication or intolerance to nasal corticosteroids [e.g., Flonase (fluticasone), Rhinocort (budesonide), Nasonex (mometasone)] ▪ Patient is currently on and will continue current maintenance therapy ▪ Patient has had at least 1 surgery for the removal of nasal polyps within the previous 10 years ▪ Patient has nasal obstruction symptoms with a visual analog scale (VAS) score of > 5 ▪ Patient has a bilateral nasal polyp score (NPS) ≥ 5 with NPS ≥ 2 in each nostril Reauthorization/ Continuation of Care Criteria ○ Removed list of examples of positive clinical response ○ Added criteria requiring: ▪ One of the following: – Physician attestation that the patient or caregiver are not competent or are physically unable to administer the Nucala	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Apr. 1, 2022	product FDA labeled for self-administration; – Patient has documented history of severe hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, or hypotension) to Nucala within the past 6 months and requires administration and direct monitoring by a healthcare professional – Patient is ≤ 11 years of age ▪ The patient is not receiving Nucala in combination with a thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] ○ Replaced criterion requiring "patient will continue to receive Nucala as add-on maintenance therapy" with "patient will continue to receive Nucala as add-on maintenance therapy *in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)*"	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Apr. 1, 2022	Supporting Information • Updated *CMS* and *References* sections to reflect the most current information	
Ryplazim® (Plasminogen, Human-Tvmh)	Apr. 1, 2022	Coverage Rationale • Revised coverage criteria for initial therapy: ○ Replaced criterion requiring "diagnosis of hypo-plasminogenemia as measured by plasminogen activity level ≤ *50*% of laboratory standard" with "diagnosis of hypo-plasminogenemia as measured by plasminogen activity level ≤ *45*% of laboratory standard" ○ Removed criterion requiring an abnormal plasminogen antigen plasma level < 9 mg/dL as confirmed by an enzyme-linked immunosorbent assay	Ryplazim (plasminogen, human-tvmh) is proven and medically necessary for the treatment of plasminogen deficiency type 1 (hypoplasminogenemia) when the following criteria are met: • For initial therapy, all of the following: ○ Diagnosis of hypoplasminogenemia as measured by plasminogen activity level ≤ 45% of laboratory standard; and ○ Presence of clinical signs and symptoms of the disease (e.g., ligneous conjunctivitis, gingivitis, tonsillitis, abnormal wound healing, etc.); and ○ Prescribed by or in consultation with a hematologist; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization will be for no more than 6 months. • For continuation of therapy, all of the following: ○ Patient has previously received treatment with Ryplazim therapy; and ○ Patient has experienced a positive clinical response to Ryplazim therapy (e.g., improved (reduction) in lesion number/size, improvement in wound-healing, plasminogen activity trough level has increased by at least 10 percentage points from baseline; etc.); and ○ Prescribed by or in consultation with a hematologist; 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. Ryplazim is unproven and not medically necessary for the treatment of idiopathic pulmonary fibrosis.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ryplazim® (Plasminogen, Human-Tvmh) (continued)	Apr. 1, 2022		
Xolair® (Omalizumab)	Apr. 1, 2022	Coverage Rationale *Moderate to Severe Persistent Asthma* • Revised coverage criteria; added criterion requiring the patient is not receiving Xolair in combination with a thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] *Chronic Urticaria* • Revised coverage criteria; added criterion requiring the patient is not receiving Xolair in combination with any of the following: ○ Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)] ○ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] ○ Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] *Nasal Polyps* • Revised medical necessity criteria: Initial Therapy ○ Added criterion requiring: ▪ Diagnosis of chronic rhinosinusitis with nasal	This policy refers to Xolair (omalizumab) subcutaneous injection for administration by a healthcare professional. Xolair (omalizumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Xolair® (Omalizumab) (continued)	Apr. 1, 2022	polyps (CRSwNP) defined by all of the following: – Two or more of the following symptoms for longer than 12 weeks duration: • Nasal mucopurulent discharge • Nasal obstruction, blockage, or congestion • Facial pain, pressure, and/or fullness • Reduction or loss of sense of smell – One of the following findings using nasal endoscopy and/or sinus computed tomography (CT): • Purulent mucus or edema in the middle meatus or ethmoid regions; or • Polyps in the nasal cavity or the middle meatus; or • Radiographic imaging demonstrating	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Xolair® (Omalizumab) (continued)	Apr. 1, 2022	mucosal thickening or partial or complete opacification of paranasal sinuses – One of the following: • Presence of bilateral nasal polyposis; or • Patient has previously required surgical removal of bilateral nasal polyps – One of the following: • Patient has required prior sinus surgery; or • Patient has required systemic corticosteroids (e.g., prednisone, methyl-prednisolone) for CRSwNP in the previous 2 years; or • Patient has been unable to obtain symptom relief after trial of two of	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Xolair® (Omalizumab) (continued)	Apr. 1, 2022	the following classes of agents: ○ Nasal saline irrigations ○ Intranasal cortico-steroids (e.g., fluticasone, mometasone, triamcinolone) ○ Anti-leukotriene agents (e.g., montelukast, zafirlukast, zileuton) ▪ Patient will receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone) ▪ Patient is not receiving Xolair in combination with: – Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)] – Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Xolair® (Omalizumab) (continued)	Apr. 1, 2022	○ Removed criterion requiring: ▪ Diagnosis of nasal polyps ▪ Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to nasal corticosteroids [e.g., Flonase® (fluticasone), Rhinocort® (budesonide), Nasonex® (mometasone)] ▪ Patient currently on and will continue current maintenance therapy ▪ Patient has bilateral polyps as determined by a nasal polyp score (NPS) ≥ 5 with NPS ≥ 2 in each nostril ▪ Patient has a weekly average of nasal congestion score (NCS) > 1 ○ Replaced criterion requiring "Xolair is prescribed by an allergist/ immunologist/ *ENT*/ pulmonologist" with "Xolair is prescribed by an allergist/ immunologist/ *otolaryng-ologist*/ pulmonologist" Reauthorization/ Continuation of Care Criteria ○ Removed list of examples of positive clinical response	

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Xolair® (Omalizumab) (continued)	Apr. 1, 2022	○ Added criterion requiring: ▪ Patient will continue to receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone) ▪ Patient is not receiving Xolair in combination with: – Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)] – Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] **Supporting Information** ● Updated *References* section to reflect the most current information	

Coverage Determination Guideline Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements	Mar. 1, 2022	Coverage Rationale *Coverage Limitations and Exclusions* • Replaced language indicating "cranial molding helmets and cranial banding are excluded from coverage, except when *used to avoid the need for surgery and/or to facilitate a successful surgical outcome*" with "cranial molding helmets and cranial banding are excluded from coverage, except when *they meet medical criteria"*

Utilization Review Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes

Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan – Site of Service	Apr. 1, 2022	**Documentation Requirements**
		• Updated list of applicable CPT codes with associated documentation requirements:
		  ○ Added 71271
		  ○ Removed 77021
		Applicable Codes
		• Added CPT code 71271
		• Removed CPT code 77021
		Supporting Information
		• Updated *References* section to reflect the most current information

Retired

Policy Title	Effective Date	Summary of Changes
Pediatric Outpatient Intensive Feeding Programs	Mar. 1, 2022	• Policy retired; for services related to treating a pediatric feeding disorder, refer to the Coverage Determination Guideline titled Habilitative Services and Outpatient Rehabilitation Therapy

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 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 Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines is available at UHCprovider.com > Policies and Protocols > Commercial Policies > Medical & Drug Policies and Coverage Determination Guidelines.