United Healthcare®

UnitedHealthcare Commercial

Medical Policy Update Bulletin: May 2026

In This Issue

Medical Policy Updates

Page

Updated

Revised

Medical Benefit Drug Policy Updates

Updated

Revised

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions	May 1, 2026	**Applicable Codes** • Updated list of applicable CPT codes to reflect quarterly edits; added 0630U (effective Apr. 1, 2026)
Preimplantation Genetic Testing and Related Services	May 1, 2026	**Related Policies** • Added reference link to the Medical Policy titled *Whole Exome and Whole Genome Sequencing (Non-Oncology Conditions)* **Coverage Rationale** • Replaced language indicating "Preimplantation Genetic Testing (PGT) for monogenic/single gene defects (PGT-M) or inherited structural chromosome rearrangements (PGT-SR) is proven and medically necessary using polymerase chain reaction, next-generation sequencing (*e.g.*, chromosomal rearrangements), or chromosomal microarray for the [listed indications]" with "Preimplantation Genetic Testing (PGT) is proven and medically necessary *only* for monogenic/single-gene defects (PGT-M) or inherited structural chromosome rearrangements (PGT-SR) using polymerase chain reaction, next-generation sequencing (*i.e., for* chromosomal rearrangements), or chromosomal microarray for the [listed indications]" • Replaced reference to "gender" with "sex" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Pneumatic Compression Devices	Jun. 1, 2026	**Coverage Rationale** • Revised language pertaining to medical necessity clinical coverage criteria; replaced reference to the "InterQual® CP: Durable Medical Equipment, Pneumatic *and other Powered* Compression Devices" with "InterQual® CP: Durable Medical Equipment, Pneumatic Compression Devices"	**Advanced intermittent pneumatic compression devices (e.g., Flexitouch) for treating lymphedema of the head, face, or neck are considered unproven and not medically necessary.** **Pneumatic compression devices (high pressure, rapid inflation/deflation cycle) for treating peripheral arterial disease (PAD) are considered unproven and not medically necessary.** **Pneumatic compression devices are proven and medically necessary in certain circumstances for the treatment of lymphedema or chronic venous insufficiency with edema and nonhealing lower extremity ulcers.** For medical necessity clinical coverage criteria, refer to the

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Pneumatic Compression Devices (continued)	Jun. 1, 2026	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	InterQual® CP: Durable Medical Equipment, Pneumatic Compression Devices. Click here to view the InterQual® criteria. **Intermittent limb compression devices are proven and medically necessary in certain circumstances for the prevention of deep venous thrombosis.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Pneumatic Compression Devices. Click here to view the InterQual® criteria. **When the medical necessity criteria in the InterQual® subset are met, intermittent limb compression devices are proven and medically necessary for the prevention of deep venous thrombosis.**
Skin and Soft Tissue Substitutes	Jun. 1, 2026	**Coverage Rationale** • Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication; added: ○ Absolv3 Membrane ○ AlexiGuard DL-T, AlexiGuard SL-T, and AlexiGuard TL-T ○ AmchoMatrixDL ○ AmnioMatrixF3X and AmnioMatrixF4X ○ CHORIOFIX ○ CYGNUS® Solo ○ NuForm ○ Polygon3 Membrane ○ SimpliChor ○ Summit AC and Summit FX ○ XWRAP 2.0®, XWRAP Dual Plus®, XWRAP Fenestra®, XWRAP Fenestra Plus®, XWRAP Hydro®, XWRAP	**EPIFIX® or GRAFIX® (GRAFIX PL, GRAFIX PRIME, and GRAFIX PL PRIME) (Noninjectable)** **EPIFIX or GRAFIX is proven and medically necessary for treating a diabetic foot ulcer when all the following criteria are met:** • Adequate circulation to the affected extremity, as indicated by one or more of the following: ○ Pedal pulses palpable or pulses confirmed with Doppler examination ○ Ankle-Brachial Index between 0.7 and 1.2 • Glycated hemoglobin test < 12% (within the last 90 days) • Ulcer has failed to demonstrate adequate healing, with at least 4 weeks of standard wound care, which includes **all** the following: ○ Application of dressings to maintain a moist wound environment ○ Debridement of necrotic tissue if present ○ Offloading • No known contraindications, which may include but are not limited to the following: ○ Active Charcot deformity or major structural abnormalities of the affected foot ○ Chronic infection to the ulcer site ○ Known or suspected malignancy of the current ulcer being treated

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Skin and Soft Tissue Substitutes (continued)	Jun. 1, 2026	Hydro Plus®, and XWRAP Tribus® **Applicable Codes** • Added HCPCS codes Q4398, Q4399, Q4400, Q4401, Q4402, Q4403, Q4404, Q4405, Q4406, Q4407, Q4408, Q4409, Q4410, Q4411, Q4412, Q4413, Q4414, Q4415, Q4416, Q4417, and Q4420 • Revised description for HCPCS codes A2014 and A2037 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	○ Ulcer being treated does not extend to tendon, muscle, capsule, or bone **Due to insufficient evidence of efficacy, EPIFIX, and/or GRAFIX are unproven and not medically necessary for all other indications.** **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** Refer to the policy for a list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication due to insufficient evidence of efficacy. Refer to the Medical Policy titled Breast Reconstruction for information about coverage for skin and soft tissue substitutes used during postmastectomy breast reconstruction procedures. **Note**: Refer to the *Clinical Evidence* section of the policy for specific product information.
Sleep Studies	Jul. 1, 2026	**Coverage Rationale** ***Attended Full-Channel Polysomnography, Performed in a Healthcare Facility or Laboratory Setting*** Suspected Obstructive Sleep Apnea (OSA) • Revised coverage criteria for attended full-channel Polysomnography for evaluating individuals with suspected OSA;	**Home Sleep Apnea Testing** **Home Sleep Apnea Testing (HSAT), using a portable monitor, is medically necessary for evaluating adults with suspected Obstructive Sleep Apnea (OSA).** Where HSAT is indicated, an autotitrating Positive Airway Pressure (APAP) device is an option to determine a fixed PAP pressure. **Note**: Performing a repeat HSAT is not recommended when an initial test is negative, inconclusive or technically inadequate, due to the higher likelihood that a second test will also be negative, inconclusive or technically inadequate. Therefore, after a single negative, inconclusive or technically

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sleep Studies (continued)	Jul. 1, 2026	replaced criterion requiring "results of previous (within the past 12 months) HSAT are negative, indeterminate, *or technically inadequate* to make a diagnosis of OSA" with "results of previous (within the past 12 months) HSAT are negative or indeterminate to make a diagnosis of OSA" Other Conditions • Revised list of conditions for which attended full-channel Polysomnography is medically necessary following an appropriate clinical assessment when OSA has been excluded or adequately treated; replaced "Parasomnia with documented disruptive, violent, or potentially injurious sleep behavior suspicious of Rapid Eye Movement Sleep Behavior Disorder (RBD)" with "Parasomnia with documented disruptive, violent, or potentially injurious sleep behaviors *or behaviors* suspicious of Rapid Eye Movement Sleep Behavior Disorder (RBD)" ***Attended PAP Titration*** • Revised list of sleep studies that are medically necessary when the criteria [listed in the policy] for attended full-channel Polysomnography is met; replaced "a full-night study for	inadequate HSAT result, performance of attended full-channel Polysomnography is strongly recommended (Kapur et al., 2017). **Attended Full-Channel Polysomnography, Performed in a Healthcare Facility or Laboratory Setting** ***Suspected Obstructive Sleep Apnea*** **Attended full-channel Polysomnography is medically necessary for evaluating individuals with suspected OSA when:** • Results of previous (within the past 12 months) HSAT are negative or indeterminate to make a diagnosis of OSA (Kapur et al., 2017; Centers for Medicare and Medicaid Services); or • Individual is a child or adolescent (i.e., less than 18 years of age); or • Individual is known to have one or more of the following comorbid medical conditions that prohibits the use of a HSAT: ○ Significant Chronic Pulmonary Disease as defined by a forced expiratory volume (FEV_1) % predicted of < 60% (Pellegrino et al., 2005) ○ Progressive neuromuscular disease/neurodegenerative disorder (examples include but are not limited to: Parkinson disease, myotonic dystrophy, amyotrophic lateral sclerosis, multiple sclerosis with associated pulmonary disease, and history of stroke with persistent neurological sequelae) ○ Moderate to severe heart failure [New York Heart Association class III or IV (NYHA, 1994) or left ventricular ejection fraction ≤ 40% (Yancy et al., 2013; Yancy et al., 2017)] ○ Body mass index (BMI) ≥ 50 (DeMaria et al., 2007; Blackstone and Cortés, 2010) ○ Obesity Hypoventilation Syndrome ○ Documented ongoing epileptic seizures in the presence of symptoms of sleep disorder ○ Chronic opiate medication use (> 3 months) (Dowell et al., 2022) Also, refer to the Repeat Testing section below.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Sleep Studies (continued)	Jul. 1, 2026	Positive Airway Pressure (PAP) titration, when *a split-night sleep study is inadequate or not feasible and* the individual has a confirmed diagnosis of OSA" with "a full-night study for PAP titration, when the individual has a confirmed diagnosis of OSA *or other sleep-disordered breathing*"
		Attended Repeat Testing
		• Replaced language indicating "repeat attended full-channel Polysomnography and repeat PAP titration are medically necessary in [the listed] circumstances" with "repeat attended full-channel Polysomnography and repeat PAP titration are medically necessary in [the listed] circumstances *when the criteria [listed in the policy] for an attended study are met*"
		• Revised list of circumstances for/in which repeat attended full-channel Polysomnography and repeat PAP titration are medically necessary; replaced "individuals who have experienced a clinically significant weight loss or gain (≥ 10%) *or changes in cardiovascular disease* since the last study" with "individuals who have experienced a clinically significant weight loss or gain (≥ 10%) since the last study"
			Other Conditions
			Attended full-channel Polysomnography is medically necessary following an appropriate clinical assessment either because OSA has been excluded, OSA has been adequately treated, or documented symptoms suggest one of the following conditions:
			• Periodic Limb Movement Disorder (PLMD) (not leg movements associated with another disorder such as sleep disordered breathing)
			• Restless Legs Syndrome (RLS)/Willis-Ekbom Disease that has not responded to treatment
			• Parasomnia with documented disruptive, violent, or potentially injurious sleep behaviors or behaviors suspicious of Rapid Eye Movement Sleep Behavior Disorder (RBD)
			• Narcolepsy, once other causes of Excessive Sleepiness have been ruled out by appropriate clinical assessment (also refer to the Daytime Sleep Studies section below)
			• Central Sleep Apnea
			Implantable Hypoglossal Nerve Stimulator
			Attended full-channel Polysomnography is medically necessary to rule out Central Sleep Apnea prior to implantation and/or calibration of an implantable hypoglossal nerve stimulator when the device is indicated. Refer to the Medical Policy titled Obstructive and Central Sleep Apnea Treatment for implantable hypoglossal nerve stimulator indications.
			Other Studies
			The following studies are not medically necessary due to insufficient evidence of efficacy:
			• Attended full-channel Polysomnography for evaluating any of the following conditions:
			  ○ Circadian Rhythm Disorders
			  ○ Depression
			  ○ Insomnia
			• Actigraphy for any sleep disorders

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sleep Studies (continued)	Jul. 1, 2026	**Definitions** • Updated definition of "Polysomnography (Attended)" **Supporting Information** • Updated *References* section to reflect the most current information	**Daytime Sleep Studies** **Note**: The following sleep studies may be performed during the night if necessary to match an individual's normal sleep pattern. **Multiple Sleep Latency Testing (MSLT) is medically necessary for evaluating suspected Narcolepsy or idiopathic Hypersomnia when other causes of Excessive Sleepiness have been excluded by appropriate clinical assessment.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures: • Sleep Studies • Sleep Studies (Pediatric) Click here to view the InterQual® criteria. **Maintenance of Wakefulness Testing (MWT) is medically necessary for evaluating the following:** • An adult who is unable to stay awake, resulting in a safety issue; or • Assessing response to treatment in adults with sleep disorders **MWT is unproven and not medically necessary in children and adolescents less than 18 years of age.** **Abbreviated daytime sleep studies (e.g., PAP-Nap) are not medically necessary due to insufficient evidence of efficacy.** **Attended PAP Titration** **When an individual meets the above criteria for an attended full-channel Polysomnography sleep study, the following are medically necessary:** • A split-night sleep study, performed in a healthcare facility or laboratory setting, for diagnosis and PAP titration; or • A full-night study for PAP titration when the individual has a confirmed diagnosis of OSA or other sleep-disordered breathing Also, refer to the Repeat Testing section below.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Sleep Studies (continued)	Jul. 1, 2026		**Attended Repeat Testing** **When the above criteria for an attended study are met, repeat attended full-channel Polysomnography and repeat PAP titration are medically necessary in the following circumstances:** • Individuals who have persistent, recurrent or new symptoms, despite documented appropriate current treatment or PAP therapy (e.g., equipment failure, improper mask fit, pressure leaks, unsuccessful titration, inadequate pressure, and medical problems including nasal congestion have been addressed and appropriately managed); or • Individuals who have experienced a clinically significant weight loss or gain (≥ 10%) since the last study (Caples et al., 2021; Peppard et al., 2000) **Repeat Testing for Oral Appliance Adjustments** Repeat testing and repositioning/adjustments for oral sleep appliances can be done in the home, unless the individual meets criteria for an attended sleep study.
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins	Jul. 1, 2026	**Coverage Rationale** • Revised language to indicate: ***Thermal and Nonthermal Treatments for Venous Insufficiency and Varicose Veins*** ○ Endovenous Ablation of the lower extremity superficial truncal or perforator veins for the treatment of Venous Insufficiency and Varicose Veins is reconstructive and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® Client Defined CP: Procedures, Endovenous Ablation, Lower Extremity	**Thermal and Nonthermal Treatments for Venous Insufficiency and Varicose Veins** **Endovenous Ablation of the lower extremity superficial truncal or perforator veins for the treatment of Venous Insufficiency and Varicose Veins is reconstructive and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined CP: Procedures, Endovenous Ablation, Lower Extremity Superficial Truncal or Perforator Vein (Custom) – UHG. Click here to view the InterQual® criteria. **The following procedures for the treatment of Venous Insufficiency and Varicose Veins are considered unproven and not medically necessary due to insufficient evidence of efficacy:** • Endovenous mechanochemical ablation (MOCA) • Endovenous Ablation of incompetent perforator veins using endovenous foam Sclerotherapy (e.g., noncompounded foam sclerosant) • Endovenous Ablation of recurrent or residual perforator vein following a prior vein procedure

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (continued)	Jul. 1, 2026	Superficial Truncal or Perforator Vein (Custom) – UHG ○ The following procedures for the treatment of Venous Insufficiency and Varicose Veins are considered unproven and not medically necessary due to insufficient evidence of efficacy: ▪ Endovenous mechanochemical ablation (MOCA) ▪ Endovenous Ablation of incompetent perforator veins using endovenous foam Sclerotherapy (e.g., noncompounded foam sclerosant) ▪ Endovenous Ablation of recurrent or residual perforator vein following a prior vein procedure ***Ligation Procedures*** ○ Ligation and division, with or without stripping or excision of lower extremity Superficial Veins, is reconstructive and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Ligation and Division +/- Stripping or Excision, Lower Extremity Superficial Vein	**Ligation Procedures** **Ligation and division, with or without stripping or excision of lower extremity Superficial Veins, is reconstructive and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Ligation and Division +/- Stripping or Excision, Lower Extremity Superficial Vein. Click here to view the InterQual® criteria. **Sclerotherapy of Superficial Veins** • Refer to the *Applicable Codes* section of the policy for Sclerotherapy (e.g., liquid, foam, ultrasound guided, endovenous chemical ablation, endovenous microfoam) • Refer to the *Benefit Considerations* section of the policy for cosmetic Sclerotherapy **Other Procedures** **Porcine bioprosthetic valve (e.g., VenoValve) implantation into the femoral vein for treatment of deep vein reflux associated with chronic Venous Insufficiency is unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy.**

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (continued)	Jul. 1, 2026	***Other Procedures*** • Removed language indicating endovenous mechanochemical ablation (MOCA) of Varicose Veins is unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Transcatheter Procedures for Heart Valve Conditions	Jul. 1, 2026	**Coverage Rationale** ***Mitral*** • Replaced language indicating: ○ "Transcatheter mitral heart valve repair (e.g., annuloplasty), except where noted [as proven and medically necessary in the policy], is unproven and not medically necessary" with "transcatheter mitral heart valve repair *or reconstruction* (e.g., annuloplasty), except where noted [as proven and medically necessary in the policy], is unproven and not medically necessary" ○ "Transcatheter mitral heart valve r*econstruction or* replacement is unproven and not medically necessary" with "transcatheter mitral heart valve replacement is	**Aortic** **Transcatheter aortic heart valve replacement is proven and medically necessary when performed according to U.S. Food and Drug Administration (FDA)–labeled indications, contraindications, warnings, and precautions and all the following criteria are met:** • Diagnosis of severe calcific native aortic valve stenosis, as indicated by **one** of the following: ○ Mean aortic valve gradient of ≥ 40 mm Hg; or ○ Peak aortic jet velocity of ≥ 4.0 m/s; or ○ Aortic valve area of ≤ 1.0 cm^2 • Individual is symptomatic [New York Heart Association (NYHA) class II or greater] and symptoms are due to aortic valve stenosis • An interventional cardiologist and an experienced cardiothoracic surgeon have determined that the procedure is appropriate • Individual has engaged in a Shared Decision-Making conversation with an interventional cardiologist and an experienced cardiothoracic surgeon • Procedure is performed in a center that meets **all** the following criteria: ○ On-site heart valve surgery and interventional cardiology programs; and ○ Postprocedure intensive care unit, with personnel experienced in managing individuals who have undergone open heart valve procedures; and

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Transcatheter Procedures for Heart Valve Conditions (continued)	Jul. 1, 2026	unproven and not medically necessary“ • Added notation to indicate requests for transcatheter valve-in-valve replacement within a failed bioprosthetic mitral valve will be considered on a case-by-case basis ***Pulmonary*** • Added language to clarify transcatheter pulmonary heart valve replacement *(including valve-in-valve)* and related devices (e.g., Alterra) are proven and medically necessary when used according to FDA-labeled indications, contraindications, warnings, and precautions in individuals with right ventricular outflow tract dysfunction, with one of the [listed] clinical indications for intervention ***Tricuspid*** • Added language to indicate transcatheter tricuspid heart valve repair or reconstruction (e.g., annuloplasty), except where noted [as proven and medically necessary in the policy], is unproven and not medically necessary due to insufficient evidence of efficacy • Replaced language indicating “transcatheter tricuspid heart valve *reconstruction or* replacement is unproven and not medically necessary due to	○ Volume requirements consistent with the Centers for Medicare and Medicaid Services; for additional information, refer to the corresponding CMS National Coverage Determination and the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry **Transcatheter valve-in-valve replacement within a failed bioprosthetic aortic valve is proven and medically necessary for individuals at high or prohibitive surgical risk [Predicted Risk of Mortality (PROM) score of ≥ 8%] when performed according to FDA-labeled indications, contraindications, warnings, and precautions.** **Note**: Requests for transcatheter aortic heart valve replacement for low-flow/low-gradient aortic stenosis in individuals who do not meet the peak velocity, mean gradient, and valve area criteria listed above will be considered on a case-by-case basis. These requests will be evaluated using recommendations from the American College of Cardiology/American Heart Association Guideline for the Management of Patients With Valvular Heart Disease (Otto et al., 2021) when all the clinical evaluation has been facilitated by a transcatheter aortic heart valve replacement expert and after appropriate additional testing has been conducted. **Mitral** **Transcatheter edge-to-edge repair of the mitral heart valve is proven and medically necessary when used according to FDA-labeled indications, contraindications, warnings, and precautions in individuals with one of the following clinical indications for intervention:** • Primary (degenerative) mitral regurgitation (MR) when **all** the following criteria are met: ○ Moderate to severe or severe MR (grade ≥ 3); and ○ Symptomatic NYHA class III or IV; and ○ Prohibitive surgical risk, as defined by **one** of the following: ▪ PROM score of ≥ 8% for individuals deemed likely to undergo mitral valve replacement; or ▪ PROM score of ≥ 6% for individuals deemed likely to undergo mitral valve repair; or ▪ Predicted risk of death or major morbidity at 1 year of over 50%

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Transcatheter Procedures for Heart Valve Conditions (continued)	Jul. 1, 2026	insufficient evidence of efficacy" with "transcatheter tricuspid heart valve replacement *(including valve-in-valve)* is unproven and not medically necessary due to insufficient evidence of efficacy" ***Other Devices and Procedures*** • Revised list of unproven and not medically necessary devices/procedures; removed "valve-in-valve replacement within a failed bioprosthesis for mitral, pulmonary, or tricuspid valves" **Definitions** • Updated definition of "CMS Volume Requirements for Transcatheter Aortic Heart Valve Replacement" **Supporting Information** • Updated *Benefit Considerations*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	and ○ Care directed by a multidisciplinary heart team, which includes a heart failure specialist, interventional cardiologist, and cardiothoracic surgeon experienced in the evaluation and treatment of heart failure and mitral valve disease • Secondary (functional) MR when **all** the following criteria are met: ○ Moderate to severe or severe MR (grade ≥ 3) with left ventricular ejection fraction ≥ 20 and ≤ 50; and ○ Symptomatic NYHA class II to IV (ambulatory); and ○ Optimal evidence-based management, which includes pharmacological therapy plus cardiac resynchronization therapy, as indicated; and ○ High surgical risk (PROM score of ≥ 8%); and ○ Care directed by a multidisciplinary heart team, which includes a heart failure specialist, interventional cardiologist, and cardiothoracic surgeon experienced in the evaluation and treatment of heart failure and mitral valve disease **Transcatheter mitral heart valve repair or reconstruction (e.g., annuloplasty), except where noted above, is unproven and not medically necessary due to insufficient evidence of efficacy.** **Transcatheter mitral heart valve replacement is unproven and not medically necessary due to insufficient evidence of efficacy.** **Note**: Requests for transcatheter valve-in-valve replacement within a failed bioprosthetic mitral valve will be considered on a case-by-case basis. **Pulmonary** **Transcatheter pulmonary heart valve replacement (including valve-in-valve) and related devices (e.g., Alterra) are proven and medically necessary when used according to FDA-labeled indications, contraindications, warnings, and precautions in individuals with right ventricular outflow tract dysfunction, with one of the following clinical indications for intervention:** • Moderate or greater pulmonary regurgitation; and/or

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Transcatheter Procedures for Heart Valve Conditions (continued)	Jul. 1, 2026		• Pulmonary stenosis with a mean right ventricular outflow tract gradient of ≥ 35 mm Hg **Tricuspid** **Transcatheter edge-to-edge repair of the tricuspid heart valve is proven and medically necessary when used according to FDA-labeled indications, contraindications, warnings, and precautions and the individual meets all the following criteria:** • Symptomatic Severe Tricuspid Regurgitation • Receiving stable (≥ 30 days) guideline-directed medical therapy for heart failure • Symptomatic NYHA class II or greater • Pulmonary artery systolic pressure of < 70 mm Hg • Intermediate or greater risk for surgery, as determined by the local heart team, which includes board-certified specialists in cardiac surgery, interventional cardiology, echocardiology, and heart failure **Transcatheter tricuspid heart valve repair or reconstruction (e.g., annuloplasty), except where noted above, is unproven and not medically necessary due to insufficient evidence of efficacy.** **Transcatheter tricuspid heart valve replacement (including valve-in-valve) is unproven and not medically necessary due to insufficient evidence of efficacy.** **Other Devices and Procedures** **The following transcatheter heart valve devices and/or procedures are unproven and not medically necessary due to insufficient evidence of efficacy:** • Cerebral protection devices (e.g., SENTINEL™) • Transcatheter superior and inferior vena cava prosthetic valve implantation

Medical Benefit Drug Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**

Adakveo® (Crizanlizumab-Tmca)	May 1, 2026	**Template Update**
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Added *Application* section to indicate this policy applies to:
		  ○ UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans

Crysvita® (Burosumab-Twza)	May 1, 2026	**Template Update**
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Added *Application* section to indicate this policy applies to:
		  ○ UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans
		Supporting Information
		• Updated *CMS* and *References* sections to reflect the most current information

Ketalar® (Ketamine) and Spravato® (Esketamine)	May 1, 2026	**Template Update**
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Added *Application* section to indicate this policy applies to:
		  ○ UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans
		Supporting Information
		• Updated *References* section to reflect the most current information

Medical Therapies for Enzyme Deficiencies	May 1, 2026	**Coverage Rationale** • Added language to indicate Loargys® (pegzilarginase-nbln) and Avlayah™ (tividenofusp alfa-eknm) have been added to the Review at Launch program and some members may not be eligible for coverage of this medication at this time; refer to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for additional details **Supporting Information** • Updated *CMS* and *References* sections to reflect the most current information

Qalsody® (Tofersen)	May 1, 2026	**Template Update**
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Added *Application* section to indicate this policy applies to:
		  ○ UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans

Updated

Policy Title	Effective Date	Summary of Changes
Qalsody® (Tofersen) (continued)	May 1, 2026	**Supporting Information** • Updated *References* section to reflect the most current information

Veopoz® (Pozelimab-Bbfg)	May 1, 2026	**Template Update**
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Added *Application* section to indicate this policy applies to:
		  ○ UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans
		Coverage Rationale
		• Updated list of examples of complement protein C5 inhibitors the patient must not be receiving in combination with Veopoz; replaced "*Soliris* (eculizumab)" with "eculizumab"

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Cosentyx® (Secukinumab)	Jun. 1, 2026	**Coverage Rationale**
		• Replaced references to "targeted immunomodulator" with "*systemic* targeted immunomodulator"
		Psoriatic Arthritis (PsA)
		• Updated list of examples of systemic targeted immunomodulators the patient must not be receiving in combination with Cosentyx for treatment of the same indication:
		  ○ Removed Olumiant (baricitinib)
		  ○ Replaced "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)"
		• Updated list of examples of systemic targeted immunomodulators U.S. FDA-approved for the treatment of PsA with which the patient has been previously treated for initial therapy; added:
		  ○ Orencia (abatacept)
		  ○ Taltz (ixekizumab)
			This policy refers to Cosentyx (secukinumab) for intravenous (IV) injection for administration by a healthcare professional. Cosentyx (secukinumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit, unless otherwise specified in the member's benefit plan documents. Exception: For members enrolled in UnitedHealthcare of California plans with a delegated provider group conducting the prior authorization review, the self-administered Cosentyx may be obtained under the medical benefit.
			General Requirements (Applicable to all Medical Necessity Requests/Reviews)
			• All requests for IV Cosentyx must include justification as to why the IV route is medically reasonable and necessary.
			• Prescriber must attest that the patient or caregiver are not able to be trained or are physically unable to administer Cosentyx FDA labeled for self-administration and the prescriber must submit medical records and/or justification explanation.
			Psoriatic Arthritis (PsA)
			Cosentyx is proven for the treatment of psoriatic arthritis (PsA) when all of the following criteria are met:
			• For **initial therapy**, **all** of the following:

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cosentyx® (Secukinumab) (continued)	Jun. 1, 2026	***Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)*** • Updated list of examples of systemic targeted immunomodulators the patient must not be receiving in combination with Cosentyx for treatment of the same indication; added Taltz (ixekizumab) • Updated list of examples of systemic targeted immunomodulators U.S. FDA-approved for the treatment of AS or nr-axSpA with which the patient has been previously treated for initial therapy: ○ Added: ▪ Cimzia (certolizumab) ▪ Enbrel (etanercept) ▪ Olumiant (baricitinib) ▪ Orencia (abatacept) ▪ Taltz (ixekizumab) ○ Replaced "Xeljanz/*Xeljanz XR* (tofacitinib)" with "Xeljanz (tofacitinib)" **Supporting Information** • Updated *References* section to reflect the most current information	○ Diagnosis of active psoriatic arthritis; **and** ○ Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for PsA; **and** ○ Patient is not receiving Cosentyx in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication; **and** ○ Initial authorization will be issued for 12 months • For **continuation of therapy**, **all** of the following: ○ Documentation of positive clinical response; **and** ○ Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for PsA; **and** ○ Patient is not receiving Cosentyx in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication; **and** ○ Authorization will be issued for 12 months **Cosentyx is medically necessary for the treatment of psoriatic arthritis (PsA) when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of active psoriatic arthritis; **and** ○ One of the following: ▪ History of failure to a 3-month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced; **or** ▪ Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx),

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cosentyx® (Secukinumab) (continued)	Jun. 1, 2026		Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] **and** ○ Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for PsA; **and** ○ Patient is not receiving Cosentyx in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication; **and** ○ Prescribed by or in consultation with **one** of the following: ▪ Rheumatologist; **or** ▪ Dermatologist **and** ○ Initial authorization will be issued for 12 months • For **continuation of therapy**, **all** of the following: ○ Documentation of positive clinical response; **and** ○ Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for PsA; **and** ○ Patient is not receiving Cosentyx in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Enbrel (etanercept), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication; **and** ○ Authorization will be issued for 12 months **Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)** **Cosentyx is proven for the treatment of ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) when all of**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cosentyx® (Secukinumab) (continued)	Jun. 1, 2026		**the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis; **and** ○ Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for AS or nr-axSpA; **and** ○ Patient is not receiving Cosentyx in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication; **and** ○ Initial authorization will be issued for 12 months • For **continuation of therapy**, **all** of the following: ○ Documentation of positive clinical response; **and** ○ Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for AS or nr-axSpA; **and** ○ Patient is not receiving Cosentyx in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication; **and** ○ Authorization will be issued for 12 months **Cosentyx is medically necessary for the treatment of ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis; **and** ○ One of the following: ▪ History of failure to **two** NSAIDs (e.g., ibuprofen, naproxen) at the maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced; **or** ▪ Patient has been previously treated with a systemic targeted

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cosentyx® (Secukinumab) (continued)	Jun. 1, 2026		immunomodulator FDA-approved for the treatment of ankylosing spondylitis or nr-axSpA [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] **and** ○ Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for AS or nr-axSpA; **and** ○ Patient is not receiving Cosentyx in combination with a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication; **and** ○ Prescribed by or in consultation with a rheumatologist; **and** ○ Initial authorization will be issued for 12 months • For **continuation of therapy**, **all** of the following: ○ Documentation of positive clinical response; **and** ○ Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for AS or nr-axSpA; **and** ○ Patient is not receiving Cosentyx in combination a systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication; **and** ○ Authorization will be issued for 12 months **Cosentyx (secukinumab) for intraveneous injection is unproven and not medically necessary for the following (Cosentyx for self-administered subcutaneous injection is obtained under the pharmacy benefit):** • Plaque psoriasis • Enthesitis-related arthritis • Hidradenitis suppurativa

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Hemgenix® (Etranacogene Dezaparvovec-Drlb)	Jun. 1, 2026	**Title Change**
		• Previously titled *Gene Therapies for Hemophilia B*
		Template Update
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Added *Application* section to indicate this policy applies to:
		  ○ UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans
		Coverage Rationale
		• Removed content/language pertaining to Beqvez (product discontinued)
		Applicable Codes
		• Removed HCPCS code J1414
		Supporting Information
		• Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
			Hemgenix is proven and medically necessary for the treatment of Hemophilia B (congenital factor IX deficiency) when all of the following criteria are met:
			• Patient is 18 years of age or older; **and**
			• **One** of the following:
			  ○ **Both** of the following:
			  ▪ Diagnosis of severe hemophilia B; **and**
			  ▪ Documentation of endogenous factor IX levels less than 1% of normal factor IX (< 0.01 IU/mL)
			  or
			  ○ **All** of the following:
			  ▪ Diagnosis of moderately severe hemophilia B; **and**
			  ▪ Documentation of endogenous factor IX levels ≥ 1% ≤ 2% (greater than or equal to 0.01 IU/mL to less than or equal to 0.02 IU/mL); **and**
			  ▪ **One** of the following:
			  – Patient has current or historical life-threatening hemorrhage; **or**
			  – Patient has repeated, serious spontaneous bleeding episodes
			  and
			• **One** of the following:
			  ○ Patient is currently receiving routine prophylaxis for hemophilia B with a non-factor replacement therapy [i.e., Alhemo (concizumab-mtci), Hympavzi (marstacimab-hncq), Qfitlia (fitusiran)]; **or**
			  ○ **Both** of the following:
			  ▪ Patient currently uses factor IX prophylaxis therapy; **and**
			  ▪ Patient has had a minimum of 50 exposure days to a factor IX agent
			  or
			  ○ Patient has been determined to be an appropriate candidate for Hemgenix by the Hemophilia Treatment Center based on willingness to adhere to initial and long-term monitoring and management
			  and
			• Patient does not have a history of inhibitors to factor IX greater than or equal to 0.6 Bethesda units (BU); **and**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Hemgenix® (Etranacogene Dezaparvovec-Drlb) (continued)	Jun. 1, 2026		• Patient does not screen positive for active factor IX inhibitors as defined as greater than or equal to 0.6 Bethesda units (BU) prior to administration of Hemgenix; **and** • Patient has not gone through Immune Tolerance Induction (ITI); **and** • Liver health assessments including enzyme testing [e.g., alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and total bilirubin] and hepatic ultrasound and/or elastography are performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations; **and** • **All** of the following: ○ Documentation that the patient has been evaluated for the presence of preexisting neutralizing antibodies to the adenovirus vector (e.g., AAV-5) used to deliver the therapy; **and** ○ Patient has had pre-existing anti-AAV5 neutralizing antibodies measured through the laboratory developed, CLIA-validated AAV5 Neutralizing Antibody Test made available through CSL Behring; **and** ○ The patient does not have high anti-AAV antibody (e.g., AAV-5) titers that may be associated with a lack of response to treatment based on published clinical evidence **and** • One of the following: ○ Patient is not HIV positive; **or** ○ Patient is HIV positive and is virally suppressed with anti-viral therapy (i.e., < 200 copies of HIV per mL) **and** • The patient's hepatitis B surface antigen is negative; **and** • One of the following: ○ Patient's hepatitis C virus (HCV) antibody is negative; **or** ○ Patient's HCV antibody is positive, and the patient's HCV RNA is negative **and** • The patient is not currently using antiviral therapy for hepatitis B or C; **and** • Patient has not previously received treatment with Hemgenix (etranacogene dezaparvovec-drlb) or another gene therapy [e.g., Beqvez (fidanacogene elaparvovec-dzkt)] for the treatment of

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Hemgenix® (Etranacogene Dezaparvovec-Drlb) (continued)	Jun. 1, 2026		hemophilia B; **and** • Hemgenix is prescribed and managed by a bleeding disorder specialist on staff at a Hemophilia Treatment Center (HTC) that holds Federal designation as evidenced by being listed within the CDC's HTC directory; **and** • Prescriber attests that the patient's ALT and AST as well as factor IX activity will be monitored weekly for at least 3 months following administration of Hemgenix and regularly thereafter per the monitoring schedule recommended in the prescribing information; **and** • Prescriber attests that counseling has been provided to the patient around the risks of alcohol consumption following administration of Hemgenix; **and** • Hemgenix dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Provider does not request a planned inpatient admission for the sole purpose of administering Hemgenix; **and** • Authorization will be issued for no more than one treatment per lifetime and for no longer than 45 days from approval **Additional information relevant to the review process for Hemgenix but not impacting the determination of medical necessity:** • Prescriber attests that the patient, while under the care of the prescriber, will be assessed for treatment efficacy including, but not limited to evaluation of factor IX expression, breakthrough bleeding episodes, factor IX product utilization, inhibitor development;* **and** • Prescriber acknowledges that UnitedHealthcare may request documentation, not more frequently than biannually, and not for a period to exceed 5 years of follow-up patient assessment(s) including, but not necessarily limited to, evaluation of factor IX expression, breakthrough bleeding episodes, factor IX product utilization, inhibitor development while the patient is under the care of the prescriber* *For quality purposes only, this information will not be considered as part of the individual coverage decision. **Hemgenix is unproven and not medically necessary in the following:** • The treatment of hemophilia A

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Hemgenix® (Etranacogene Dezaparvovec-Drlb) (continued)	Jun. 1, 2026		• The repeat administration of Hemgenix for the treatment of hemophilia B • The treatment of hemophilia B after previously receiving another factor IX gene therapy product • The routine combination treatment with chronically administered prophylactic therapy for hemophilia B • The treatment of hemophilia B in patients less than 18 years of age
Ilumya® (Tildrakizumab-Asmn)	Jun. 1, 2026	**Coverage Rationale** • Replaced references to: ○ "Targeted immunomodulator" with "*systemic* targeted immunomodulator" ○ "Biologic or targeted synthetic DMARD" with "systemic targeted immunomodulator" • Updated list of examples of systemic targeted immunomodulators the patient must not be receiving in combination with Ilumya for treatment of the same indication: ○ Added: ▪ Bimzelx (bimekizumab-bkzx) ▪ Sotyktu (deucravacitinib) ○ Removed: ▪ Olumiant (baricitinib) ▪ Orencia (abatacept) ▪ Rinvoq (upadacitinib) ▪ Simponi (golimumab) ▪ Xeljanz (tofacitinib) • Updated list of examples of systemic targeted immunomodulators U.S. FDA-approved for the treatment of plaque psoriasis with which the patient has been previously treated for initial therapy; added: ○ Bimzelx (bimekizumab-bkzx) ○ Cosentyx (secukinumab)	Ilumya to be used as a self-administered, subcutaneous injection for the treatment of plaque psoriasis should be obtained under the pharmacy benefit, unless otherwise specified in the member's benefit plan documents. Exception: For members enrolled in UnitedHealthcare of California plans with a delegated provider group conducting the prior authorization review, the self-administered Ilumya may be obtained under the medical benefit. **Ilumya (tildrakizumab) is proven for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met:** • For **initial therapy**: ○ Diagnosis of moderate to severe plaque psoriasis; **and** ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; **and** ○ Patient is not receiving Ilumya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization will be for no longer than 12 months • For **continuation of therapy**: ○ Documentation of positive clinical response to Ilumya therapy; **and** ○ Physician attestation that the patient is unable to self-administer

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ilumya® (Tildrakizumab-Asmn) (continued)	Jun. 1, 2026	○ Siliq (brodalumab) ○ Sotyktu (deucravacitinib) ○ Taltz (ixekizumab) **Supporting Information** • Updated *CMS* and *References* sections to reflect the most current information	or there is no competent caregiver to administer the drug; physician must submit explanation; **and** ○ Patient is not receiving Ilumya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Reauthorization will be for no longer than 12 months **Ilumya (tildrakizumab) is medically necessary for provider administration for the treatment of moderate to severe plaque psoriasis when the following criteria are met:** • For **initial therapy**, submission of medical records (e.g., chart notes, laboratory values) documenting all of the following: ○ Diagnosis of chronic moderate to severe plaque psoriasis; **and** ○ Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis; **and** ○ One of the following: ▪ Both of the following: – History of failure, contraindication, or intolerance to **one** of the following topical therapies: • Corticosteroids (e.g., betamethasone, clobetasol, desonide) • Vitamin D analogs (e.g., calcitriol, calcipotriene) • Tazarotene • Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) • Anthralin • Coal tar **and** – History of failure to a 3-month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ilumya® (Tildrakizumab-Asmn) (continued)	Jun. 1, 2026		**or** ▪ Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of plaque psoriasis [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] **and** ○ History of failure, contraindication, or intolerance to three of the following preferred biologic products: (For Medicare reviews, refer to the *CMS* section of the policy.*) ▪ One of the preferred adalimumab products* ▪ Cimzia (certolizumab) ▪ Cosentyx (secukinumab) ▪ Enbrel (etanercept) ▪ Skyrizi (risankizumab) ▪ Sotyktu (deucravacitinib) ▪ One of the preferred ustekinumab products* ▪ Tremfya (guselkumab) **and** ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug; physician must submit explanation; **and** ○ Patient is not receiving Ilumya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Prescribed by or in consultation with a dermatologist; **and** ○ Initial authorization will be for no longer than 12 months • For **continuation of therapy**: ○ Documentation of positive clinical response to Ilumya therapy;

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ilumya® (Tildrakizumab-Asmn) (continued)	Jun. 1, 2026		**and** ○ Physician attestation that the patient is unable to self-administer or there is no competent caregiver to administer the drug. Physician must submit explanation; **and** ○ Patient is not receiving Ilumya in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Reauthorization will be for no longer than 12 months *For a list of preferred products, reference drug coverage tools.
Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease	Jun. 1, 2026	**Template Update** • Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans • Added *Application* section to indicate this policy applies to: ○ UnitedHealthcare Commercial benefit plans ○ Individual Exchange benefit plans **Coverage Rationale** ***Preferred Product*** • Added language to indicate: Medical Necessity Plans ○ VPRIV is the preferred enzyme replacement therapy for Gaucher disease; coverage for VPRIV is contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy]	This policy refers to the following drug products, all of which are intravenous enzyme replacement therapies used in the treatment of Gaucher disease: • Cerezyme® (imiglucerase) • Elelyso® (taliglucerase) • VPRIV® (velaglucerase) **Preferred Product** ***Medical Necessity Plans*** VPRIV is the preferred enzyme replacement therapy for Gaucher Disease. Coverage for VPRIV is contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for Cerezyme or Elelyso is contingent on the Preferred Product Criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section. In order to continue coverage, members already on Cerezyme or Elelyso will be required to change therapy to VPRIV unless they meet the criteria below.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease (continued)	Jun. 1, 2026	○ Coverage for Cerezyme or Elelyso is contingent on the *Preferred Product Criteria* section [of the policy] and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ In order to continue coverage, members already on Cerezyme or Elelyso will be required to change therapy to VPRIV unless they meet the criteria in the *Preferred Product Criteria* section [of the policy] *Preferred Product Criteria* ○ Treatment with Cerezyme or Elelyso is medically necessary for the indications specified in this policy when one the criteria below are met: ▪ Both of the following: – History of a trial of adequate dose and duration of VPRIV, resulting in a failure to meet clinical goals (e.g., persistent anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly) – Physician attests that, in their clinical opinion, the clinical response would be expected to be superior than experienced with VPRIV ▪ Both of the following:	**Preferred Product Criteria** *(For Medicare reviews, refer to the CMS section of the policy.)* **Treatment with Cerezyme or Elelyso is medically necessary for the indications specified in this policy when one the criteria below are met:** • **Both** of the following: ○ History of a trial of adequate dose and duration of VPRIV, resulting in a failure to meet clinical goals (e.g., persistent anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly); **and** ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior than experienced with VPRIV **or** • **Both** of the following: ○ History of contraindication, intolerance, or adverse event(s) to VPRIV; **and** ○ Physician attests that, in their clinical opinion, the same contraindication, intolerance, or adverse event(s) would not be expected to occur with Cerezyme or Elelyso ***Non-Medical Necessity Plans*** Cerezyme, Elelyso, or VPRIV is to be approved contingent on the coverage criteria in the Diagnosis-Specific Criteria section. **Diagnosis-Specific Criteria** **Cerezyme, Elelyso, and VPRIV are proven for the treatment of Gaucher disease when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ **One** of the following: ▪ For Elelyso, diagnosis of type 1 Gaucher disease; **or** ▪ For Cerezyme or VPRIV, diagnosis of type 1 or type 3 Gaucher disease **and** ○ Dosing is in accordance with United States Food and Drug Administration (FDA) approved labeling; **and** ○ Initial authorization will be for no more than 12 months

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease (continued)	Jun. 1, 2026	– History of contraindication, intolerance, or adverse event(s) to VPRIV – Physician attests that, in their clinical opinion, the same contraindication, intolerance, or adverse event(s) would not be expected to occur with Cerezyme or Elelyso Non-Medical Necessity Plans ○ Cerezyme, Elelyso, or VPRIV is to be approved contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ***Diagnosis-Specific Criteria*** • Added language to indicate: ***Type 2 Gaucher Disease*** ○ Cerezyme, Elelyso, and VPRIV are unproven and not medically necessary for type 2 Gaucher disease ***Type 3 Gaucher Disease*** ○ Cerezyme and VPRIV are proven for the treatment of type 3 Gaucher disease when all of the following criteria are met: Initial Therapy ▪ Diagnosis of type 3 Gaucher disease ▪ Dosing is in accordance with U.S. FDA-approved labeling ▪ Initial authorization will be for no more than 12 months	• For **continuation of therapy**, **all** of the following: ○ Documentation of positive clinical response to therapy (e.g., reduced severity or resolution of anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly); **and** ○ Dosing is in accordance with FDA approved labeling; **and** ○ Continuation authorization will be for no more than 12 months **Cerezyme, Elelyso, or VPRIV are medically necessary for the treatment of type 1 Gaucher disease when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of type 1 Gaucher disease; **and** ○ Patient has symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly); **and** ○ Dosing is in accordance with FDA approved labeling; **and** ○ Initial authorization will be for no more than 12 months • For **continuation of therapy**, **all** of the following: ○ **One** of the following: ▪ Patient is on Cerezyme or Elelyso and meets the criteria in the Preferred Product Criteria section; **or** ▪ Patient is on VPRIV **and** ○ Documentation of positive clinical response to therapy (e.g., reduced severity or resolution of anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly); **and** ○ Dosing is in accordance with FDA approved labeling; **and** ○ Continuation authorization will be for no more than 12 months **Cerezyme or VPRIV is medically necessary for the treatment of type 3 Gaucher disease when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ **One** of the following: ○ **Both** of the following: – Diagnosis of type **3** Gaucher disease; **and** – Patient has symptomatic chronic neuronopathic disease (e.g., growth retardation, impaired development, moderate

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease (continued)	Jun. 1, 2026	Continuation of Therapy ▪ Documentation of positive clinical response to therapy (e.g., reduced severity or resolution of anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly) ▪ Dosing is in accordance with U.S. FDA-approved labeling ▪ Continuation authorization will be for no more than 12 months ○ Elelyso is unproven and not medically necessary for the treatment of type 3 Gaucher disease • Revised coverage criteria for: ***Type 1 Gaucher Disease*** Proven ○ Removed criterion requiring symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly) Medically Necessary *Initial Therapy* ○ Added criterion requiring the patient has symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly) ○ Removed criterion requiring: ▪ History of failure of VPRIV due to failure to meet clinical goals (e.g., persistent	to severe anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly) **or** ○ **One** of the following: – Patient has suspected type **3** Gaucher Disease and a sibling with chronic neuronopathic Gaucher Disease (type 3); **or** – Patient has **one** of the following high-risk genotypes for type 3 Gaucher Disease: • L444P/L444P (c.1448T > C homozygote); or • D409H/D409H (c.1342G > C homozygote); or • L444P/D409H (c.1448T > C/c.1342G > C heterozygote) **and** ○ Dose for the requested product does not exceed 60 units/kg every 2 weeks; **and** ○ Initial authorization will be for no more than 12 months • For **continuation of therapy**, **all** of the following: ○ **One** of the following: ▪ Patient is on Cerezyme and meets the criteria in the Preferred Product Criteria section; **or** ▪ Patient is on VPRIV **and** ○ Documentation of positive clinical response to therapy (e.g., reduced severity or resolution of anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly); **and** ○ Dose does not exceed 60 units/kg every 2 weeks; **and** ○ Continuation authorization will be for no more than 12 months **Cerezyme, Elelyso, and VPRIV are unproven and not medically necessary for type 2 Gaucher Disease.** **Elelyso is unproven and not medically necessary for the treatment of type 3 Gaucher disease.**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease (continued)	Jun. 1, 2026	anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly) despite VPRIV therapy ▪ History of failure of VPRIV due to hypersensitivity to VPRIV therapy *Continuation of Therapy* ○ Added criterion requiring one of the following: ▪ Patient is on Cerezyme or Elelyso and meets the criteria in the *Preferred Product Criteria* section [of the policy] ▪ Patient is on VPRIV ***Type 3 Gaucher Disease*** Medically Necessary *Initial Therapy* ○ Added criterion requiring one of the following: ▪ Both of the following: – Diagnosis of type 3 Gaucher disease – Patient has symptomatic chronic neuronopathic disease (e.g., growth retardation, impaired development, moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly) ▪ One of the following: – Patient has suspected type 3 Gaucher disease and a sibling with chronic	

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease (continued)	Jun. 1, 2026	neuronopathic Gaucher disease (type 3) – Patient has one of the following high-risk genotypes for type 3 Gaucher disease: L444P/L444P (c.1448T>C homozygote), D409H/D409H (c.1342G>C homozygote), or L444P/D409H (c.1448T>C/c.1342G>C heterozygote) ○ Removed criterion requiring symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly) *Continuation of Therapy* ○ Added criterion requiring one of the following: ▪ Patient is on Cerezyme and meets the criteria in the *Preferred Product Criteria* section [of the policy] ▪ Patient is on VPRIV ○ Removed criterion for treatment with Cerezyme requiring one of the following: ▪ History of failure of VPRIV due to failure to meet clinical goals (e.g., persistent anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly) despite VPRIV therapy	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease (continued)	Jun. 1, 2026	▪ History of failure of VPRIV due to hypersensitivity to VPRIV therapy **Supporting Information** • Added *CMS* section • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Leqvio® (Inclisiran)	Jun. 1, 2026	**Coverage Rationale** • Added language to indicate Leqvio (inclisiran) is proven and medically necessary for the treatment of homozygous familial hypercholesterolemia (HoFH) in patients who meet all of the following criteria: ***Initial Therapy*** ○ Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by one of the following: ▪ Submission of medical records (e.g., chart notes, laboratory values) confirming genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the low-density lipoprotein receptor (*LDLR*), apolipoprotein B (*APOB*), proprotein convertase subtilisin kexin type 9 (*PCSK9*), or low-density lipoprotein receptor adaptor protein 1 (*LDLRAP1*) genes or ≥ 2 such variants at different loci	**Leqvio (inclisiran) is proven and medically necessary for the treatment of primary hyperlipidemia, including 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); **or** ▪ Atherosclerotic cardiovascular disease (ASCVD) (e.g., acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin); **or** ▪ Primary hyperlipidemia **and** ○ Submission of medical records (e.g., chart notes, laboratory values) confirming **one** of the following: (For Medicare reviews, refer to the *CMS* section of the policy.) ▪ Patient has been previously treated with PCSK9 therapy [e.g., Praluent (alirocumab), Repatha (evolocumab)]; **or** ▪ Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy (i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive a high-intensity statin at maximally tolerated dose; **or** ▪ **Both** of the following: – Patient is unable to tolerate high-intensity statin as evidenced by **one** of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Leqvio® (Inclisiran) (continued)	Jun. 1, 2026	▪ Submission of medical records (e.g., chart notes, laboratory values) confirming both of the following: – Untreated LDL-C greater than 400 mg/dL – One of the following: • Xanthoma before 10 years of age • Evidence of familial hypercholesterolemia in at least one parent ○ Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis) ○ Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a history of failure, contraindication, or intolerance to PCSK9 therapy [e.g., Praluent (alirocumab), Repatha (evolocumab)] ○ Prescribed by one of the following: ▪ Cardiologist ▪ Endocrinologist ▪ Lipid specialist ○ Leqvio will not be used in combination with PCSK9 inhibitor therapy [e.g., Praluent (alirocumab), Repatha (evolocumab)] or Juxtapid (lomitapide) ○ Leqvio dosing is in accordance with the U.S. FDA-approved labeling	• Myalgia [muscle symptoms without creatine kinase (CK) elevations]; **or** • Myositis [muscle symptoms with CK elevations < 10 times upper limit of normal (ULN)] **and** – Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy (i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin ≥ 10 mg, pravastatin ≥ 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or pitavastatin ≥ 1 mg) and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose **or** ▪ Patient is unable to tolerate low or moderate, and high-intensity statins as evidenced by **one** of the following: – **One** of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low or moderate, and high-intensity statins: • Myalgia (muscle symptoms without CK elevations); **or** • Myositis [muscle symptoms with CK elevations < 10 times upper limit of normal (ULN)] **or** – Patient has a contraindication to all statins; **or** – Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN **and** ○ Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a history of failure, contraindication, or intolerance to PCSK9 therapy [e.g., Praluent (alirocumab), Repatha (evolocumab)]; **and** ○ Patient has LDL-C greater than or equal to 55 mg/dL; **and** ○ Prescribed by one of the following: ▪ Cardiologist ▪ Endocrinologist ▪ Lipid specialist

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Leqvio® (Inclisiran) (continued)	Jun. 1, 2026	○ Initial authorization will be for no more than 12 months ***Continuation of Therapy*** ○ Documentation of a positive clinical response to Leqvio therapy ○ Prescribed by one of the following: ▪ Cardiologist ▪ Endocrinologist ▪ Lipid specialist ○ Leqvio will not be used in combination with PCSK9 inhibitor therapy [e.g., Praluent (alirocumab), Repatha (evolocumab)] or Juxtapid (lomitapide) ○ Leqvio dosing is in accordance with the U.S. FDA-approved labeling ○ Reauthorization will be for no more than 12 months **Supporting Information** • Updated *Clinical Evidence*, *FDA*, *CMS*, and *References* sections to reflect the most current information	**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 Leqvio therapy; **and** ○ Prescribed by one of the following: ▪ Cardiologist ▪ Endocrinologist ▪ Lipid specialist **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** ○ Reauthorization will be for no more than 12 months **Leqvio (inclisiran) is proven and medically necessary for the treatment of homozygous familial hypercholesterolemia (HoFH) in patients who meet all of the following criteria:** • For **initial therapy**, **all** of the following: ○ Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by **one** of the following: ▪ Submission of medical records (e.g., chart notes, laboratory values) confirming genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) genes or ≥ 2 such variants at different loci; **or** ▪ Submission of medical records (e.g., chart notes, laboratory values) confirming **both** of the following: – Untreated LDL-C greater than 400 mg/dL; **and**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Leqvio® (Inclisiran) (continued)	Jun. 1, 2026		– **One** of the following: • Xanthoma before 10 years of age; **or** • Evidence of familial hypercholesterolemia in at least one parent **and** ○ Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis); **and** ○ Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a history of failure, contraindication, or intolerance to PCSK9 therapy [e.g., Praluent (alirocumab), Repatha (evolocumab)]; **and** ○ Prescribed by **one** of the following: ▪ Cardiologist ▪ Endocrinologist ▪ Lipid specialist **and** ○ Leqvio will not be used in combination with PCSK9 inhibitor therapy [e.g., Praluent (alirocumab), Repatha (evolocumab)] or Juxtapid (lomitapide); **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 Leqvio therapy; **and** ○ Prescribed by one of the following: ▪ Cardiologist ▪ Endocrinologist ▪ Lipid specialist **and** ○ Leqvio will not be used in combination with PCSK9 inhibitor therapy [e.g., Praluent (alirocumab), Repatha (evolocumab)] or Juxtapid (lomitapide); **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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Orencia® (Abatacept) Injectionfor Intravenous Infusion	Jun. 1, 2026	**Template Update**
		• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
		• Added *Application* section to indicate this policy applies to:
		  ○ UnitedHealthcare Commercial benefit plans
		  ○ Individual Exchange benefit plans
		Coverage Rationale
		• Replaced references to "targeted immunomodulator" with "*systemic* targeted immunomodulator"
		• Revised coverage criteria for:
		Polyarticular Juvenile Idiopathic Arthritis
		  ○ Updated list of examples of systemic targeted immunomodulators the patient must not be receiving in combination with Orencia for treatment of the same indication; replaced "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)"
		Rheumatoid Arthritis
		  ○ Updated list of examples of systemic targeted immunomodulators the patient must not be receiving in combination with Orencia for treatment of the same indication; replaced "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)"
			Refer to the policy for complete details.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Orencia® (Abatacept) Injectionfor Intravenous Infusion (continued)	Jun. 1, 2026	○ Updated list of examples of systemic targeted immunomodulators U.S. FDA-approved for the treatment of rheumatoid arthritis with which the patient has been previously treated for initial therapy; replaced "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)" ***Psoriatic Arthritis*** ○ Updated list of examples of systemic targeted immunomodulators the patient must not be receiving in combination with Orencia for treatment of the same indication: ▪ Added Bimzelx (bimekizumab-bkzx) ▪ Removed Olumiant (baricitinib) ▪ Replaced "Xeljanz (tofacitinib)" with "Xeljanz/ *Xeljanz XR* (tofacitinib)" ○ Updated list of examples of systemic targeted immunomodulators U.S. FDA-approved for the treatment of psoriatic arthritis with which the patient has been previously treated for initial therapy: ▪ Added: – Bimzelx (bimekizumab-bkzx) – Cosentyx (secukinumab) – Rinvoq (upadacitinib) – Skyrizi (risankizumab)	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Orencia® (Abatacept) Injectionfor Intravenous Infusion (continued)	Jun. 1, 2026	– Taltz (ixekizumab) ▪ Replaced "Xeljanz (tofacitinib)" with "Xeljanz/ *Xeljanz XR* (tofacitinib)" **Supporting Information** • Updated *References* section to reflect the most current information	
Provider Administered Drugs – Site of Care	Aug. 1, 2026	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled *Oncology Medication Clinical Coverage* **Coverage Rationale** • Added language to indicate submission of medical records documenting that outpatient hospital facility-based administration of Darzalex Faspro, Imfinzi, Jemperli, Keytruda, Keytruda Qlex, Libtayo, Opdivo, Opdivo Qvantig, Opdualag, Phesgo, Tecentriq, Tecentriq Hybreza, or Yervoy is medically necessary for individuals who meet at least one of the following criteria: ○ The patient is receiving concurrent chemotherapy or other infusion therapy that would require member to be treated at an outpatient hospital facility ○ The patient is less than 19 years of age ○ The patient is pregnant ○ The patient has immunoglobulin A (IgA) deficiency with anti-IgA antibodies • Added list of medications that require healthcare provider administration when used as monotherapy and after	This policy addresses the criteria for consideration of allowing hospital outpatient facility infusion services for specialty medications and intravenous Immune Globulin (IVIG) and subcutaneous Immune Globulin (SCIG) therapy. This includes claim submission for hospital-based services with the following CMS/AMA place of service codes: • 19 Off Campus-Outpatient Hospital; **and** • 22 On Campus-Outpatient Hospital Alternative Sites of Care, such as non-hospital outpatient infusion, physician office, ambulatory infusion suites, or home infusion services are well accepted places of service for medication infusion therapy. If an individual does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used. **Submission of medical records documenting that outpatient hospital facility-based administration is medically necessary for individuals who meet at least one of the following criteria:** • The patient is medically unstable and is at risk of requiring medical services and equipment available only in an outpatient hospital setting (e.g., endotracheal tube, chest tube insertion equipment, cricothyroidotomy set, mechanical ventilator) during administration of the requested drug based on **one** of the following: ○ History of cardiopulmonary conditions that cause an increased risk of severe adverse reactions during or immediately following infusion; **or** ○ An inability to tolerate fluid volume load (for intravenous infusions only) despite using the minimum amount of fluid required for infusion (e.g., unstable renal function); **or** ○ Risk of becoming medically unstable due to concomitant use of medications or other drug-drug or drug-disease interaction(s)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (continued)	Aug. 1, 2026	at least 2 infusions administered in the hospital outpatient facility, or monotherapy after completion of therapy in combination with chemotherapy in the hospital outpatient facility: ○ Darzalex Faspro® (daratumumab and hyaluronidase-fihj) ○ Imfinzi® (durvalumab) ○ Jermperli® (dostarlimab) ○ Keytruda® (pembrolizumab) ○ Keytruda Qlex® (pembrolizumab and berahyaluronidase alfa-pmph) ○ Libtayo® (cemiplimab) ○ Opdivo® (nivolumab) ○ Opdivo Qvantig® (nivolumab and hyaluronidase-nvhy) ○ Opdualag® (nivolumab and relatlimab-rmbw) ○ Phesgo® (pertuzumab, trastuzumab, and hyaluronidase-zzxf) ○ Tecentriq® (atezolizumab) ○ Tecentriq Hybreza® (atezolizumab and hyaluronidase-tqjs) ○ Yervoy® (ipilimumab) **Documentation Requirements** • Revised list of specialty medications with associated documentation requirements; added ○ Darzalex Faspro® (daratumumab and hyaluronidase-fihj) ○ Imfinzi® (durvalumab) ○ Jemperli® (dostarlimab) ○ Keytruda® (pembrolizumab)	**or** • Treatment at an alternative Site of Care presents a health risk due to a clinically significant physical or cognitive impairment; **or** • Severe patent vascular access issues (for intravenous infusions only) that require specialized equipment only available in an outpatient hospital setting (e.g., ultrasound guidance); **or** • Previous episode(s) of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure), not including the first or second infusion, that have occurred while receiving requested therapy that was unresponsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual while administering at alternative Sites of Care; **or** • Initial infusion or re-initiation of previous therapy after more than 6 months (excludes drugs dosed at an interval of 6 months or greater) for a short duration of time (e.g., 4 weeks); **or** • **All** of the following: ○ Homecare or home infusion provider has deemed that the individual or home environment is not suitable for home infusion therapy; **and** ○ The prescriber is unable to administer in the office setting; **and** ○ There are no ambulatory infusion suite options available for this member **or** • **For IVIG or SCIG only**: Individual has immunoglobulin A (IgA) deficiency with anti-IgA antibodies; **or** • **For Darzalex Faspro, Imfinzi, Jemperli, Keytruda, Keytruda Qlex, Libtayo, Opdivo, Opdivo Qvantig, Opdualag, Phesgo, Tecentriq, Tecentriq Hybreza, Yervoy only**: ○ The patient is receiving concurrent chemotherapy or other infusion therapy that would require member to be treated at an outpatient hospital facility; **or** ○ The patient is less than 19 years of age; **or** ○ The patient is pregnant; **or** ○ The patient has immunoglobulin A (IgA) deficiency with anti-IgA antibodies

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (continued)	Aug. 1, 2026	○ Keytruda Qlex® (pembrolizumab and berahyaluronidase alfa-pmph ○ Libtayo® (cemiplimab) ○ Opdivo Qvantig® (nivolumab and hyaluronidase) ○ Opdivo® (nivolumab) ○ Opdualag® (nivolumab and relatlimab-rmbw) ○ Phesgo® (pertuzumab, trastuzumab, and hyaluronidase-zzxf) ○ Tecentriq® (atezolizumab) ○ Tecentriq Hybreza® (atezolizumab and hyaluronidase-tqjs) ○ Yervoy® (ipilimumab) **Applicable Codes** • Added HCPCS codes J9022, J9024, J9119, J9144, J9173, J9228, J9271, J9272, J9277, J9289, J9298, J9299, and J9316 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	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. **Note**: If more than one of the above criteria are met, then the greatest of the applicable approval time periods will be allowed. Refer to the policy for a list of medications that require healthcare provider administration.
Ustekinumab	Jun. 1, 2026	**Coverage Rationale** ***Preferred Product*** • Added language to indicate Starjemza is a preferred ustekinumab product; coverage will be provided contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] • Removed language indicating: ○ Coverage for Starjemza will be provided contingent on the criteria in the *Preferred Product*	This policy refers to the following ustekinumab products for injection by a healthcare professional: • Imuldosa (ustekinumab-srlf) • Otulfi (ustekinumab-aauz) • Pyzchiva (ustekinumab-ttwe) • Selarsdi (ustekinumab-aekn) • Stelara (ustekinumab) • Starjemza (ustekinumab-hmny) • Steqeyma (ustekinumab-stba) • Wezlana (ustekinumab-auub) • Yesintek (ustekinumab-kfce)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ustekinumab (continued)	Jun. 1, 2026	*Criteria* section [of the policy] and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Treatment with Starjemza is medically necessary for the indications specified in this policy when the preferred product criteria [listed in the policy] are met • Replaced language indicating "in order to continue coverage, members already on Imuldosa, Otulfi, Pyzchiva, Selarsdi, *Starjemza*, Stelara, or other non-preferred ustekinumab products will be required to change therapy to Steqeyma, Wezlana, or Yesintek unless they meet the criteria in the *Preferred Product Criteria* section [of the policy]" with "in order to continue coverage, members already on Imuldosa, Otulfi, Pyzchiva, Selarsdi, Stelara, or other non-preferred ustekinumab products will be required to change therapy to *Starjemza*, Steqeyma, Wezlana, or Yesintek unless they meet the criteria in the *Preferred Product Criteria* section [of the policy]" • Revised preferred product criteria; removed criterion requiring the patient has not had a loss of a favorable response after established maintenance therapy with Steqeyma, Wezlana, Yesintek, or other ustekinumab product	• Any FDA-approved ustekinumab biosimilar product not listed here Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ustekinumab (continued)	Jun. 1, 2026	***Diagnosis-Specific Criteria*** • Replaced references to "targeted immunomodulator" with "*systemic* targeted immunomodulator" • Revised coverage criteria; replaced criterion requiring "the patient is not receiving ustekinumab in combination with a targeted immunomodulator" with "the patient is not receiving ustekinumab in combination with a *systemic* targeted immunomodulator *for treatment of the same indication*" **Supporting Information** • Updated *CMS* section to reflect the most current information	

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 changes to our Medical Policies and Medical Benefit Drug Policies. 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 and Medical Benefit Drug Policies is available at **UHCprovider.com/policies** > For Commercial Plans > Medical & Drug Policies.