United Healthcare®

UnitedHealthcare Commercial
Medical Policy Update Bulletin: July 2025

In This Issue

Take Note

Medical Policy Updates

Updated

Revised

Retired

Medical Benefit Drug Policy Updates

New

Updated

In This Issue

Revised

Take Note

Coming Soon: New Policy Library for Surest

Beginning **Aug. 1, 2025**, the Medical Policies and Medical Benefit Drug Policies for **Surest**™ benefit plans will be housed in their own library on UHCprovider.com. At that time, the policies, along with their corresponding Medical Policy Update Bulletins, will be available for your reference at UHCprovider.com > Coverage and payments > Policies and protocols > For Commercial Plans > **UnitedHealthcare | Surest Medical & Drug Policies.**

Quarterly CPT/HCPCS Code Updates

Effective **Jul. 1, 2025**, the following Medical Policies and Medical Benefit Drug Policies have been updated to reflect the quarterly Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) code additions, revisions, and deletions. Refer to the following sources for information on the code updates:

- American Medical Association: Current Procedural Terminology: CPT®
- Centers for Medicare & Medicaid Services: Healthcare Common Procedure Coding System (HCPCS) Quarterly Update

Policy Title	Policy Type	Summary of Changes
Assisted Administration of Clotting Factors, Coagulant Blood Products, & Other Hemostatics (for Oxford Only)	Medical Benefit Drug Policy	• Added HCPCS code J7172
Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing for Infectious Diarrhea	Medical Policy	• Removed CPT code 0369U
Gonadotropin Releasing Hormone Analogs	Medical Benefit Drug Policy	• Revised description for HCPCS code J1954
Hearing Aids and Devices Including Wearable, Bone-Anchored, and Semi-Implantable	Medical Policy	• Added CPT codes 0951T, 0952T, 0953T, 0954T, and 0955T
Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions	Medical Policy	• Added CPT codes 0560U and 0561U
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions	Medical Policy	• Added CPT codes 0562U, 0565U, 0566U, 0569U, 0571U, and 0572U
Oncology Medication Clinical Coverage	Medical Benefit Drug Policy	• Revised description for HCPCS code J1954
Preimplantation Genetic Testing and Related Services	Medical Policy	• Added CPT codes 0552U, 0553U, 0554U, and 0555U
Provider Administered Drugs – Site of Care	Medical Benefit Drug Policy	• Revised description for HCPCS code Q9998

Take Note

Policy Title	Policy Type	Summary of Changes
Respiratory Pathogen Nucleic Acid Detection Testing	Medical Policy	• Added CPT codes 0556U, 0563U, and 0564U
Ustekinumab	Medical Benefit Drug Policy	• Added HCPCS codes Q5099 and Q5100
Whole Exome and Whole Genome Sequencing (Non-Oncology Conditions)	Medical Policy	• Added CPT code 0567U

Updated

Policy Title	Effective Date	Summary of Changes
Carrier Testing Panels for Genetic Diseases	Jul. 1, 2025	**Definitions** • Updated definition of "Gene Panel" **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
Cosmetic and Reconstructive Procedures	Aug. 1, 2025	**Definitions** • Updated definition of "Microtia" **Applicable Codes** • Added CPT codes 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, and 15876 **Supporting Information** • Updated *References* section to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cardiovascular Disease Risk Tests	Aug. 1, 2025	**Coverage Rationale** • Revised list of unproven and not medically necessary services; added "cardiovascular disease (HDL reverse cholesterol transport), cholesterol efflux capacity, LC-MS/MS, quantitative measurement of 5 distinct HDL-bound apolipoproteins (apolipoproteins A1, C1, C2, C3, and C4), with algorithm and reported as a risk score" **Applicable Codes** • Added CPT code 0541U **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	**The following are unproven and not medically necessary due to insufficient evidence of efficacy:** • Arterial compliance testing, using waveform analysis as a method to determine risk for cardiovascular disease • Carotid intima-media thickness (CIMT) measurement as an effective screening tool for the management of cardiovascular disease • Advanced lipoprotein analysis [e.g., lipoprotein(a), subfractions or particle size] as method to determine risk for cardiovascular disease • Lipoprotein-associated phospholipase A2 (Lp-PLA2) enzyme as a method to determine risk for cardiovascular disease or ischemic stroke • Endothelial function assessment using tools such as peripheral arterial tonometry (PAT) or brachial artery pressure ultrasound as a prognostic indicator to determine risk of cardiovascular disease • Multi-protein diagnostic biomarker: ○ Analysis of protein biomarkers by aptamer-based microarray and algorithm ○ Cardiovascular disease (HDL reverse cholesterol transport), cholesterol efflux capacity, LC-MS/MS, quantitative measurement of 5 distinct HDL-bound apolipoproteins (apolipoproteins A1, C1, C2, C3, and C4), with algorithm and reported as a risk score ○ 3 proteins [high sensitivity (hs) troponin, adiponectin, and kidney injury molecule-1 (KIM-1)] with algorithm and reported as a risk score ○ 4 proteins [NT-proBNP, osteopontin, tissue inhibitor of

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Cardiovascular Disease Risk Tests (continued)	Aug. 1, 2025		metalloproteinase-1 (TIMP-1), and KIM-1] with algorithm and reported as a risk score ○ 7 proteins (IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3) with algorithm and reported as a risk score
Obstructive and Central Sleep Apnea Treatment	Sep. 1, 2025	**Coverage Rationale** ***Surgical Treatment*** • Added notation to indicate polysomnography should be repeated if there has been clinically significant weight loss or gain, changes in cardiovascular disease, or there are persistent or recurrent symptoms since the last study • Revised coverage criteria for: Uvulopalatopharyngoplasty (UPPP), Mandibular Osteotomy (MO), and Maxillomandibular Osteotomy and Advancement (MMA) in an Adult Patient ○ Replaced criterion requiring "*diagnosis of* moderate to severe Obstructive Sleep Apnea (OSA) [Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) ≥ 1]" with "moderate to severe OSA [Apnea Hypopnea Index (AHI) ≥ *15* or Respiratory Disturbance Index (RDI) ≥ 15] *as determined by Polysomnography (Attended)*" Implantable Hypoglossal Nerve Stimulation with a U.S.	**Non-Surgical Treatment** **Removable Oral Appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) as documented by a sleep study (e.g., Polysomnography or Home Sleep Apnea Testing).** Refer to the Medical Policy titled Sleep Studies for further information. For many individuals, Oral Appliance therapy (OAT) may be an effective alternative to failed positive airway pressure (PAP) therapy. Documentation of the following is required: • A patient presenting with symptoms of OSA has been seen in a face-to-face evaluation with a qualified physician (MD or DO) trained in sleep medicine or with an Advanced Practice Provider working under the direct supervision of a physician trained in sleep medicine prior to beginning treatment for OAT (AASM and AADSM, December 2012, AAO-HNS, November 2019) • A treating physician (MD or DO) or an Advanced Practice Provider must diagnose OSA and recommend course of treatment (AAO-HNS, November 2019) • If PAP therapy results in no therapeutic efficacy or patient intolerance or refusal, documentation from the patient's treating physician (MD or DO) or an Advanced Practice Provider must be supplied For information on snoring and Oral Appliances, refer to the Medical Policy titled Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements. For medical necessity clinical coverage criteria for removable Oral Appliances, refer to the InterQual® CP: Durable Medical Equipment, Noninvasive Airway Assistive Devices. Click here to view the InterQual® criteria.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Obstructive and Central Sleep Apnea Treatment (continued)	Sep. 1, 2025	Food and Drug Administration (FDA) Approved Device in Adolescents Aged 10-18 Years with Down Syndrome ○ Replaced criterion requiring "diagnosis of severe OSA (as determined by a *Polysomnogram within 24 months* and an AHI ≥ 10 and RDI ≤ 50 events per hour)" with "diagnosis of severe OSA [as determined by *Polysomnography (Attended)* and an AHI ≥ 10 and RDI ≤ 50 events per hour]" **Definitions** • Added definition of "Respiratory Disturbance Index (RDI)" **Applicable Codes** • Added CPT/HCPCS codes 0964T, 0965T, 0966T, and E0490 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	**Other Non-Surgical Procedures** **The following are unproven and not medically necessary due to insufficient evidence of efficacy:** • Devices for treating Positional OSA • Nasal dilator devices for treating OSA • Intranasal expiratory resistance valve (e.g., Bongo Rx) • Removable Oral Appliances for treating Central Sleep Apnea • Prefabricated Oral Appliance/device • Non-surgical electrical muscular training • Mandibular vertical repositioning devices (e.g., Slow Wave) • Morning repositioning devices • Epigenetic appliances [e.g., Homeoblock™, DNA® (Daytime/Nighttime appliance)] • Advanced Lightwire Functional (ALF) appliances **Surgical Treatment** **Uvulopalatopharyngoplasty (UPPP), mandibular osteotomy (MO), and maxillomandibular osteotomy and advancement (MMA) are proven and medically necessary in an adult patient when all the following criteria are met:** • Moderate to severe OSA [Apnea Hypopnea Index (AHI) ≥ 15 or Respiratory Disturbance Index (RDI) ≥ 15] as determined by Polysomnography (Attended)* • Excessive daytime sleepiness documented with an Epworth Sleepiness Scale (ESS) > 10 or with another validated tool • PAP therapy resulted in no therapeutic efficacy or patient refusal or intolerance In addition, the following criteria needs to be met: • For MMA, craniofacial disproportion, or deformities with evidence of maxillomandibular deficiency • For MO, retrolingual or lower pharyngeal function obstruction **Implantable hypoglossal nerve stimulation with a U.S. Food and Drug Administration (FDA) approved device is proven and medically necessary in an adult patient with moderate to severe OSA when all the**

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Obstructive and Central Sleep Apnea Treatment (continued)	Sep. 1, 2025		**following criteria are met:** • Body Mass Index of (BMI) less than or equal to 40kg/m^2; and • AHI of ≥ 15 and ≤ 100 as determined by Polysomnography (Attended)*; and • Total AHI < 25% for central + mixed Apneas, as evaluated by attended polysomnography; and • Absence of a complete blockage or complete concentric collapse of the soft palate confirmed by drug-induced sleep endoscopy; and • PAP therapy resulted in no therapeutic efficacy or patient refusal or intolerance; and • Used in accordance with FDA guidelines **Implantable hypoglossal nerve stimulation with an FDA approved device is proven and medically necessary in adolescents aged 10-18 years with Down syndrome when all the following criteria are met:** • Diagnosis of severe OSA [as determined by a Polysomnogram (Attended)* and an AHI ≥ 10 and RDI ≤ 50 events per hour]; and • BMI < 95th percentile for age; and • Total AHI < 25% for central + mixed Apneas; and • Contraindication for or not effectively treated with a prior adenotonsillectomy; and • Confirmed failure or intolerance of PAP therapy despite attempts to improve compliance; and • Absence of tracheostomy use during sleep; and • Absence of a complete blockage or concentric collapse of the soft palate level confirmed by drug induced sleep endoscopy; and • Individual and caregiver refusal of an MMA procedure for non-concentric palatal collapse; and • Used in accordance with FDA guidelines **Implantable neurostimulation devices for the treatment of Central Sleep Apnea (CSA) are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.** *Polysomnography should be repeated if there has been clinically significant weight loss or gain, changes in cardiovascular disease, or there are persistent or recurrent symptoms since the last study (Caples et al. 2021).

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Obstructive and Central Sleep Apnea Treatment (continued)	Sep. 1, 2025		**Other Surgical Procedures** **The following surgical procedures are unproven and not medically necessary for treating OSA due to insufficient evidence of efficacy (not an all-inclusive list):** • Laser-assisted uvulopalatoplasty (LAUP) • Lingual suspension - also referred to as tongue stabilization, tongue stitch, or tongue fixation • Isolated hyoid myotomy • Stand-alone uvulectomy • Palatal implants • Radiofrequency ablation of the soft palate and/or tongue base • Transoral robotic surgery (TORS) • Distraction osteogenesis for maxillary expansion (DOME)
Panniculectomy Surgery	Aug. 1, 2025	**Title Change** • Previously titled *Panniculectomy and Body Contouring Procedures* **Coverage Rationale** • Removed language indicating body contouring procedures, including but not limited to the following, are considered cosmetic and not medically necessary: ○ Abdominoplasty ○ Lipectomy, including suction-assisted lipectomy (unless part of an approved procedure) ○ Repair of diastasis recti • Updated instruction to refer to the Medical Policy titled *Breast Reconstruction for information on liposuction when being performed* post-mastectomy **Definitions** • Removed definition of:	**Panniculectomy** **Panniculectomy is considered reconstructive and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Panniculectomy, Abdominal. Click here to view the InterQual® criteria. **Panniculectomy is considered cosmetic and not medically necessary when performed for the following indications:** • For any other condition that does not meet the InterQual® criteria • In conjunction with abdominal or gynecologic surgery, including but not limited to hernia repair, bariatric surgery, C-section, or hysterectomy, unless the member meets the InterQual® CP: Procedures, Panniculectomy, Abdominal criteria • When performed for primarily cosmetic purposes **Notes**: • For information on liposuction for lipedema, refer to the Medical Policy titled Liposuction for Lipedema. • For information on liposuction when being performed post-mastectomy, refer to the Medical Policy titled Breast Reconstruction.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Panniculectomy Surgery (continued)	Aug. 1, 2025	○ Abdominoplasty ○ Diastasis Recti ○ Functional or Physical or Physiological Impairment ○ Suction Assisted Lipectomy **Applicable Codes** • Removed CPT codes 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, and 15876 **Supporting Information** • Added *Benefit Considerations* section • Updated *Description of Services, Clinical Evidence, FDA*, and *References* sections to reflect the most current information	
Skin and Soft Tissue Substitutes	Aug. 1, 2025	**Coverage Rationale** • Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication; added: ○ Abiomend Hydromembrane ○ Abiomend Membrane ○ Abiomend Xplus Hydromembrane ○ Abiomend Xplus Membrane ○ AmchoPlast FD ○ Amnio Burgeon Dual-Layer Membrane ○ Amnio Burgeon Membrane and Hydromembrane ○ Amnio Burgeon Xplus Membrane and Xplus Hydromembrane ○ AmnioCore SL ○ ChoriPly ○ CYGNUS Disk	**EpiFix or Grafix® (GrafixPL, GrafixPRIME, and GrafixPL PRIME) (Non-Injectable)** **EpiFix or Grafix is proven and medically necessary for treating a diabetic foot ulcer when all of 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 (ABI) between 0.7 and 1.2 • Glycated hemoglobin test (HgA1c) < 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** of 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)	Aug. 1, 2025	○ Dual Layer Amnio Burgeon X-Membrane ○ EPIXPRESS ○ Foundation Dermal Regeneration Scaffold (DRS) Solo ○ Miro3D fibers ○ MiroDry Wound Matrix ○ Myriad Matrix ○ Myriad Morcells ○ PalinGen Dual-Layer Membrane ○ Theracor P or Allacor P ○ XWRAP Dual ○ XWRAP Plus **Applicable Codes** • Added HCPCS codes A2030, A2031, A2032, A2033, A2034, A2035, Q4354, Q4355, Q4356, Q4357, Q4358, Q4359, Q4360, Q4361, Q4362, Q4364, Q4365, Q4366, and Q4367 • Removed HCPCS codes Q4231 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	○ Ulcer being treated does not extend to tendon, muscle, capsule, or bone ***EpiFix and Grafix Application Limitations*** • EpiFix is limited to one application per week for up to 12 weeks. • Grafix is limited to one application per week for up to 12 weeks. **Due to insufficient evidence of efficacy, EpiFix and/or Grafix are unproven and not medically necessary for all other indications including but not limited to:** • EpiFix application more frequently than once a week or beyond 12 weeks • Grafix application more frequently than once a week or beyond 12 weeks **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** **Other skin and soft tissue substitutes listed in the policy 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 post mastectomy breast reconstruction procedures. **Note**: Refer to the *Clinical Evidence* section of the policy for specific product information.
Surgery of the Foot	Aug. 1, 2025	**Related Policies** • Added reference link to the Medical Policy titled	**Surgery of the foot is proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgery of the Foot (continued)	Aug. 1, 2025	*Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds* **Coverage Rationale** ***Hallux Rigidus (Correction With Implant)*** • Replaced language indicating "correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release with implant is proven and medically necessary when all of the [listed] criteria are met" with "correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release with implant *(Hemi-implant or Total Implant Arthroplasty)* is proven and medically necessary when all of the [listed] criteria are met" **Definition** • Added definition of: ○ Hemi-Implant Arthroplasty ○ Interposition Arthroplasty ○ Total Implant Arthroplasty **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	• Arthrodesis or Arthroplasty, Interphalangeal Joint, Second-Fifth Toes • Exostectomy, First Metatarsophalangeal (MTP) Joint (Bunionectomy) • Osteotomy, Distal Transpositional, First Metatarsal (MT) (Bunionectomy) • Osteotomy, Proximal, First Metatarsal (MT) (Bunionectomy) • Osteotomy, Proximal Phalanx, First Toe +/- Bunionectomy • Plantar Fascial Release Click here to view the InterQual® criteria. **Hallux Limitus or Rigidus (Correction Without Implant)** **Correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release without implant is proven and medically necessary when all of the following criteria are met:** • Diagnosis of hallux limitus or hallux rigidus to include the following: ○ Radiographic imaging to confirm a mild to moderate pathology (e.g., a grading scale such as the Coughlin and Shurnas or Hattrup Johnson Classification may be used) • Persistent pain despite a reasonable trial of conservative treatment including one or more of the following: ○ Orthotics, shoe modification (e.g., high and wide toe box, rocker bottom sole), and/or shoe inserts ○ Medical therapy (NSAIDs, analgesics, or intra-articular injections) ○ Activity modification ○ Debridement of hyperkeratotic lesions, if present **Correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release without implant is unproven and not medically necessary for severe hallux rigidus (e.g., a grading scale such as the Coughlin and Shurnas or Hattrup Johnson Classification may be used) due to insufficient evidence of efficacy.** **Hallux Rigidus (Correction With Implant)** **Correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release with implant (Hemi-**

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

Surgery of the Foot (continued)	Aug. 1, 2025		**implant or Total Implant Arthroplasty) is proven and medically necessary when all of the following criteria are met:**
			• Diagnosis of hallux rigidus to include the following:
			  ○ Radiographic imaging to confirm a moderate to severe pathology (e.g., a grading scale such as the Coughlin and Shurnas or Hattrup Johnson Classification may be used)
			• Persistent pain despite a reasonable trial of conservative treatment including one or more of the following:
			  ○ Orthotics, shoe modification (e.g., high and wide toe box, rocker bottom sole), and/or shoe inserts
			  ○ Medical therapy (NSAIDs, analgesics, or intra-articular injections)
			  ○ Activity modification
			  ○ Debridement of hyperkeratotic lesions, if present
			
			Osteochondral Allograft or Autograft Transplantation
			Osteochondral allograft or autograft transplantation is unproven and not medically necessary for treating cartilage defects of the foot due to insufficient evidence of efficacy.

Umbilical Cord Blood Harvesting and Storage for Future Use	Aug. 1, 2025	**Coverage Rationale** • Replaced language indicating "collection and storage of umbilical cord blood is unproven and not medically necessary for *a person* who is currently healthy but desiring to provide the opportunity for a *hypothetical*, future transplantation due to insufficient evidence of efficacy" with "*prophylactic* collection and storage of umbilical cord blood is unproven and not medically necessary for *an individual* who is currently healthy but desiring to provide the opportunity for a future *unspecified autologous or allogeneic stem cell*	**Due to insufficient evidence of efficacy, prophylactic collection and storage of umbilical cord blood is unproven and not medically necessary for an individual who is currently healthy but desiring to provide the opportunity for a future unspecified autologous or allogeneic stem cell transplantation.** For additional information and coverage of umbilical cord blood stem cell transplantation, refer to the Optum Clinical Guideline titled Hematopoietic Stem Cell Transplantation.

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Umbilical Cord Blood Harvesting and Storage for Future Use (continued)	Aug. 1, 2025	transplantation due to insufficient evidence of efficacy" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Retired		
Policy Title	**Effective Date**	**Summary of Changes**
Intrauterine Fetal Surgery	Jul. 1, 2025	• Retired policy; intrauterine fetal surgery no longer requires clinical review
Macular Degeneration Treatment Procedures	Jul. 1, 2025	• Retired policy; macular degeneration treatment procedures no longer require clinical review
Pectus Deformity Repair	Jul. 1, 2025	• Retired policy; pectus deformity repair no longer requires clinical review

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

Kebilidi™ (Eladocagene Exuparvovec-Tneq)	Aug. 1, 2025	**Kebilidi is proven and medically necessary for the treatment of aromatic L-amino acid decarboxylase (AADC) deficiency in patients who meet all of the following criteria:**
		• Submission of medical records documenting **all** of the following:
		  ○ Genetically confirmed AADC deficiency due to biallelic mutations in the dopa decarboxylase (*DDC*) gene; **and**
		  ○ Patient has one or more of the following typical clinical characteristics associated with AADC deficiency (e.g., hypotonia, oculogyric crises, dystonia, hypokinesia, autonomic dysfunction, developmental delay); **and**
		  ○ Decreased AADC enzyme activity in plasma per current laboratory standards; **and**
		• Patient has achieved skull maturity, as confirmed by neuroimaging, necessary for sterotactic neurosurgical administration of Kebilidi; **and**
		• Patient has persistent symptoms of AADC deficiency (e.g., hypotonia, oculogyric crises, dystonia, hypokinesia, autonomic dysfunction, developmental delay) despite use of standard medical therapy (e.g., dopamine agonists, monoamine oxidase inhibitors, pyridoxine, other forms of vitamin B6); **and**
		• Patient is unable to ambulate independently; **and**
		• Patient does not have an anti-adeno-associated virus, serotype 2 (anti-AAV2) antibody titer higher than 1:1200 or > 1 optical density value by enzyme-linked immunosorbent assay (ELISA); **and**
		• Prescribed by a neurologist or neurosurgeon; **and**
		• Patient has not previously received treatment with Kebilidi or other gene therapy for the treatment of AADC deficiency in their lifetime; **and**
		• Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
		• Authorization will be issued for no more than one treatment per lifetime and for no longer than 60 days from approval

Susvimo™ (Ranibizumab Injection)	Aug. 1, 2025	**Susvimo is proven and medically necessary when all of the following criteria are met:**
		• For **initial therapy**, **all** of the following:
		  ○ **One** of the following diagnoses:
		  ▪ Neovascular (wet) age-related macular degeneration (AMD); **or**
		  ▪ Diabetic Macular Edema (DME)
		  and
		  ○ Patient has previously responded to at least **two** intravitreal injections of a VEGF inhibitor [e.g., Avastin (bevacizumab), Eylea (aflibercept), Eylea HD (aflibercept), Lucentis (ranibizumab), Pavblu (aflibercept-ayyh), Vabysmo (faricimab-svoa)]; **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**, **all** of the following:
		  ○ Documentation of a positive clinical response; **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

Updated

Policy Title	Effective Date	Summary of Changes
Niktimvo™ (Axatilimab-Csfr)	Jul. 1, 2025	**Coverage Rationale** • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* **Supporting Information** • Updated *Benefit Considerations* section to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®)	Aug. 1, 2025	**Title Change** • Previously titled *Neonatal FC Receptor Blockers (Rystiggo®, Vyvgart®, & Vyvgart® Hytrulo)* **Coverage Rationale** • Replaced references to: ○ "*Neonatal* FC *receptor* blocker" with "*FcRn* blocker" ○ "*Soliris* (eculizumab)" with "eculizumab" • Added language to indicate: ○ This policy refers to the following drug products for administration by a healthcare professional: ▪ Rystiggo (rozanolixizumab-noli) for intravenous (IV) route ▪ Vyvgart (efgartigimod alfa-fcab) for intravenous (IV) route ▪ Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) vial for subcutaneous (SC) route ○ Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) prefilled syringe for self-administered subcutaneous	This policy refers to the following drug products for administration by a healthcare professional: • Rystiggo (rozanolixizumab-noli) for intravenous (IV) route • Vyvgart (efgartigimod alfa-fcab) for intravenous (IV) route • Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) vial for subcutaneous (SC) route Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) prefilled syringe for self-administered subcutaneous injection is obtained under the pharmacy benefit. **Rystiggo is proven for the treatment of generalized myasthenia gravis in patients who are anti-acetylcholine receptor (AChR) antibody positive or antimuscle-specific tyrosine kinase (MuSK) antibody positive. Rystiggo is medically necessary for the treatment of generalized myasthenia gravis in patients who are anti-AChR antibody positive or anti-MuSK antibody positive when all of the following criteria are met:** • **Initial Therapy** ○ Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming **all** of the following: ▪ Patient has not failed a previous course of Rystiggo therapy; **and** ▪ Diagnosis of generalized myasthenia gravis (gMG); **and** ▪ **One** of the following: – Positive serologic test for anti-AChR antibodies; **or** – Positive serologic test for anti-MuSK antibodies **and** ▪ Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; **and**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	injection is obtained under the pharmacy benefit • Revised coverage criteria for: ***Rystiggo*** ○ Added criterion requiring the patient is not receiving Rystiggo in combination with an immune globulin ○ Replaced criterion requiring "the patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or *intravenous* immune globulin over the course of at least 12 months without symptom control" with "the patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or immune globulin over the course of at least 12 months without symptom control" ***Vyvgart and Vyvgart Hytrulo for the Treatment of Generalized Myasthenia Gravis*** ○ Added criterion requiring: ▪ The patient is not receiving Vyvgart or Vyvgart Hytrulo in	▪ Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy **and** ○ **One** of the following: (for Medicare reviews, refer to the *CMS* section of the policy) ▪ If anti-acetylcholine receptor (AChR) antibody positive, one of the following: – History of failure of at least **two** immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.); **or** – Patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or immune globulin over the course of at least 12 months without symptom control ▪ If anti-muscle-specific tyrosine kinase (MuSK) antibody positive: – History of failure of at least one immunosuppressive agent over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.) **and** ○ Patient is **not** receiving Rystiggo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and** ○ Patient is **not** receiving Rystiggo in combination with another FcRn blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]; **and** ○ Patient is **not** receiving Rystiggo in combination with an immune globulin; **and** ○ Rystiggo is dosed according to the US FDA labeled dosing for gMG; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Patient has previously been treated with Rystiggo; **and** ○ Submission of medical records (e.g., chart notes, laboratory tests)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	combination with an immune globulin ▪ The patient will be given Vyvgart or Vyvgart Hytrulo no sooner than 50 days after each treatment cycle ○ Replaced criterion requiring "the patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or *intravenous* immune globulin over the course of at least 12 months without symptom control" with "the patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or immune globulin over the course of at least 12 months without symptom control" ***Vyvgart Hytrulo for the Treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)*** Initial Therapy ○ Added criterion requiring: ▪ Trial and failure (after a trial of at least two months), contraindication,	demonstrating **all** of the following: ▪ Improvement and/or maintenance of at least a 2 point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline; **and** ▪ Reduction in signs and symptoms of myasthenia gravis; **and** ▪ Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Rystiggo (**Note**: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Rystiggo therapy will be considered as treatment failure.) **and** ○ Patient is **not** receiving Rystiggo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and** ○ Patient is **not** receiving Rystiggo in combination with another FcRn blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]; **and** ○ Patient is **not** receiving Rystiggo in combination with an immune globulin; **and** ○ Rystiggo is dosed according to the US FDA labeled dosing for gMG; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Reauthorization will be for no more than 12 months **Vyvgart and Vyvgart Hytrulo are proven for the treatment of generalized myasthenia gravis in patients who are anti-acetylcholine receptor (AChR) antibody positive. Vyvgart and Vyvgart Hytrulo are medically necessary for the treatment of generalized myasthenia gravis in patients who are anti-AChR antibody positive when all of the following criteria are met:** • **Initial Therapy** ○ Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming **all** of the following: ▪ Patient has not failed a previous course of Vyvgart therapy; **and** ▪ Patient has not failed a previous course of Vyvgart Hytrulo therapy; **and**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	or intolerance to corticosteroids ▪ Trial and failure (after a trial of at least three months), contraindication, or intolerance to immune globulin (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin) based on both of the following: – Dose has been adjusted or escalated to the maximally allowable and/or tolerated dose – Failure to obtain an objective response to treatment in a disability assessment defined by one of the following: • Inflammatory Rasch-built Overall Disability Scale (I-RODS): increase ≥ 4 centile points in a 48-point scale • Inflammatory Neuropathy Cause and Treatment Disability Scale (INCAT): decrease ≥ 1 point	▪ Diagnosis of generalized myasthenia gravis (gMG); **and** ▪ Positive serologic test for anti-AChR antibodies; **and** ▪ Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; **and** ▪ Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy **and** ○ **One** of the following: (for Medicare reviews, refer to the *CMS* section of the policy) ▪ History of failure of at least **two** immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.); **or** ▪ Patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges and/or immune globulin over the course of at least 12 months without symptom control **and** ○ Patient will be given Vyvgart or Vyvgart Hytrulo no sooner than 50 days after each treatment cycle; **and** ○ Patient is **not** receiving Vyvgart or Vyvgart Hytrulo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and** ○ Patient is **not** receiving Vyvgart or Vyvgart Hytrulo in combination with another FcRn blocker [e.g., Rystiggo (rozanolixizumab-noli)]; **and** ○ Patient is **not** receiving Vyvgart or Vyvgart Hytrulo in combination with an immune globulin; **and** ○ Vyvgart or Vyvgart Hytrulo is dosed according to the US FDA labeled dosing for gMG; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Patient has previously been treated with Vyvgart or Vyvgart Hytrulo; **and**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	– Failure to obtain an objective response to treatment in an impairment assessment defined by one the following: • Grip strength using handheld dynamometry in Martin Vigorimeter: increase ≥ 8 kilopascals (or ≥ 1.2 pounds/inch^2) or Jamar hand grip dynamometer: increase ≥ 10% • Medical Research Council (MRC) sum score (0-60): increase ≥ 2 to 4 points • Modified INCAT Sensory Sum scale (mISS): decrease ≥ 2 points ▪ Immunological testing [e.g., nodal and paranodal antibodies, serum protein electrophoresis and immunofixation, spot urine immunofixation for light chains, measurement of serum	○ Submission of medical records (e.g., chart notes, laboratory tests) demonstrating **all** of the following: ▪ Improvement and/or maintenance of at least a 2 point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline; **and** ▪ Reduction in signs and symptoms of myasthenia gravis; **and** ▪ Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart or Vyvgart Hytrulo (**Note**: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Vyvgart or Vyvgart Hytrulo therapy will be considered as treatment failure.) **and** ○ Patient is **not** receiving Vyvgart or Vyvgart Hytrulo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; **and** ○ Patient is **not** receiving Vyvgart or Vyvgart Hytrulo in combination with another FcRn blocker [e.g., Rystiggo (rozanolixizumab-noli)]; **and** ○ Patient is **not** receiving Vyvgart or Vyvgart Hytrulo in combination with an immune globulin; **and** ○ Vyvgart or Vyvgart Hytrulo is dosed according to the US FDA labeled dosing for gMG; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Reauthorization will be for no more than 12 months **Vyvgart Hytrulo is proven for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). Vyvgart Hytrulo is medically necessary for the treatment of CIDP when all of the following criteria are met:** • **Initial Therapy** ○ Patient has not failed a previous course of Vyvgart Hytrulo therapy; **and** ○ Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP); **and** ○ Diagnosis of CIDP is categorized as **one** of the following: ▪ Typical CIDP; **or**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	free light chains (SFLC), anti-MAG antibody] has excluded other possible relevant neuropathies (e.g., anti-MAG IgM neuropathy, multiple myeloma, AL-amyloidosis, POEMS syndrome) ○ Removed criterion requiring trial and failure (after a trial of at least three months), contraindication, or intolerance to two of the following therapies used for CIDP: ▪ Corticosteroids ▪ Immune globulin (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin) ▪ Plasma exchange ○ Replaced criterion requiring: ▪ "Electrodiagnostic testing has confirmed *a diagnosis of CIDP*" with "electrodiagnostic testing has confirmed *at least two motor nerve abnormalities*" ▪ "Electrodiagnostic testing allows only for a diagnosis of possible CIDP" with "electrodiagnostic testing allows only for a	▪ **One** of the following CIDP variants: – Distal CIDP – Multifocal CIDP – Focal CIDP – Motor CIDP – Sensory CIDP **and** ○ **One** of the following: ▪ Electrodiagnostic testing has confirmed at least two motor nerve abnormalities; **or** ▪ **All** of the following: – Electrodiagnostic testing allows only for a diagnosis of possible CIDP having only one motor nerve abnormality; **and** – **Two** of the following, consistent with EFNS/PNS guidelines, support a diagnosis of possible CIDP ○ Objective response to treatment with immunomodulatory agents (e.g., corticosteroids, immune globulin, plasma exchange) ○ Imaging with ultrasound or MRI ○ Cerebrospinal fluid (CSF) analysis ○ Nerve Biopsy **and** – Immunological testing [e.g., nodal and paranodal antibodies, serum protein electrophoresis and immunofixation, spot urine immunofixation for light chains, measurement of serum free light chains (SFLC), anti-MAG antibody] has excluded other possible relevant neuropathies (e.g., anti-MAG IgM neuropathy, multiple myeloma, AL-amyloidosis, POEMS syndrome) **and** ○ Trial and failure (after a trial of at least two months), contraindication, or intolerance to corticosteroids (for Medicare reviews, refer to the *CMS* section of the policy); **and** ○ Trial and failure (after a trial of at least three months), contraindication, or intolerance to Immune globulin (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin) based on **both** of

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	diagnosis of possible CIDP having only one motor nerve abnormality" ▪ "Two *supportive* criteria [e.g., objective response to treatment, imaging, cerebrospinal fluid (CSF), nerve biopsy] consistent with EFNS/PNS guidelines *confirm* diagnosis of CIDP" with "two *of the following* [criteria] consistent with EFNS/PNS guidelines *support a* diagnosis *of possible* CIDP: objective response to treatment *with immunomodulatory agents (e.g., corticosteroids, immune globulin, plasma exchange)*, imaging *with ultrasound or MRI*, cerebrospinal fluid (CSF) *analysis*, and/or nerve biopsy" Continuation of Therapy ○ Added criterion requiring the patient is not receiving Vyvgart Hytrulo in combination with an immune globulin **Supporting Information** • Updated *References* section to reflect the most current information	the following (for Medicare reviews, refer to the *CMS* section of the policy): ▪ Dose has been adjusted or escalated to the maximally allowable and/or tolerated dose; **and** ▪ **Both** of the following: – Failure to obtain an objective response to treatment in a disability assessment defined by **one** of the following: • Inflammatory Rasch-built Overall Disability Scale (I-RODS): increase ≥ 4 centile points in a 48-point scale; **or** • Inflammatory Neuropathy Cause and Treatment Disability Scale (INCAT): decrease ≥ 1 point **and** – Failure to obtain an objective response to treatment in an impairment assessment defined by **one** the following: • Grip strength using handheld dynamometry in Martin Vigorimeter: increase ≥ 8 kilopascals (or ≥ 1.2 pounds/inch^2) or Jamar hand grip dynamometer: increase ≥ 10%; **or** • Medical Research Council (MRC) sum score (0-60): increase ≥ 2 to 4 points; **or** • Modified INCAT Sensory Sum scale (mISS): decrease ≥ 2 points **and** ○ Patient is **not** receiving Vyvgart Hytrulo in combination with an immune globulin; **and** ○ Vyvgart Hytrulo is dosed according to the US FDA labeled dosing for CIDP; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Patient has previously been treated with Vyvgart Hytrulo; **and** ○ Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]; **and** ○ Patient is **not** receiving Vyvgart Hytrulo in combination with an immune globulin; **and**

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025		○ Vyvgart Hytrulo is dosed according to the US FDA labeled dosing for CIDP; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Reauthorization will be for no more than 12 months
Immune Globulin (IVIG and SCIG)	Aug. 1, 2025	**Coverage Rationale** • Added language to indicate immune globulin is proven for measles (rubeola) post-exposure prophylaxis; immune globulin is medically necessary for the prevention of measles (rubeola) post-exposure prophylaxis when all of the following criteria are met: ○ Patient has been exposed to measles (rubeola) less than 6 days previously ○ Patient weight is greater than 30 kg (for patients ≤ 30 kg, administer Intramuscular immune globulin) ○ One of the following nonimmune or severely immunocompromised individuals who are not already receiving immune globulin therapy: ▪ Patient is a pregnant woman without evidence of measles immunity ▪ Patient has received hematopoietic stem cell transplant (HSCT) and has finished all immunosuppressive treatment within 12	Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2025	months ▪ Patient is a HSCT recipient with chronic graft-versus-host disease (GVHD) ▪ Patient has received chimeric antigen receptor T-cell (CAR T) therapy within 12 months ▪ Patient has acute lymphoblastic leukemia (ALL) and is completing or has completed chemotherapy within the last 6 months ▪ Patient with HIV infection and severe immunosuppression defined as a current CD4+ T-lymphocyte percentage < 15% (all ages) or a CD4+ T-lymphocyte count < 200 lymphocyte cells/mm3 (age > 5 years only) ▪ Patient with a primary immunodeficiency (refer to the disease list within the policy) ○ Request is for an initial, one-time dose, not to exceed 400 mg/kg **Applicable Codes** • Added ICD-10 diagnosis codes B05.0, B05.1, B05.2, B05.3, B05.4, O98.511, O98.512, O98.513, and O98.519	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2025	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Intracanalicular and Intravitreal Corticosteroid Implants	Aug. 1, 2025	**Coverage Rationale**
		• Revised authorization guidelines; replaced language indicating "authorization is for no more than *one month*" with "authorization is for no more than *60 days*"
		• Revised coverage criteria for Iluvien; added criterion requiring chronic non-infectious uveitis affecting the posterior segment of the eye
		Supporting Information
		• Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
			This policy provides information about the use of certain specialty pharmacy medications administered by the intracanalicular and intravitreal route for certain ophthalmologic conditions.
			
			This policy refers to the following intracanalicular and intravitreal corticosteroid implant products:
			• Dextenza® (dexamethasone ophthalmic insert)
			• Iluvien® (fluocinolone acetonide intravitreal implant)
			• Ozurdex® (dexamethasone intravitreal implant)
			• Retisert® (fluocinolone acetonide intravitreal implant)
			• Yutiq® (fluocinolone acetonide intravitreal implant)
			
			Dextenza is proven and medically necessary when all of the following criteria are met:
			• **One** of the following diagnoses:
			  ○ Ocular inflammation and pain following ophthalmic surgery; **or**
			  ○ Ocular itching associated with allergic conjunctivitis
			and
			• Prescribed by or in consultation with an ophthalmologist; **and**
			• Dose does not exceed one insert per eye; **and**
			• Authorization is for no more than 60 days
			
			Iluvien is proven and medically necessary when all of the following criteria are met:
			• **One** of the following:
			  ○ Chronic non-infectious uveitis affecting the posterior segment of the eye; **or**
			  ○ **Both** of the following:
			  ▪ Diagnosis of diabetic macular edema (DME); **and**
			  ▪ **Both** of the following:
			  – Member has been previously treated with a course of corticosteroids; **and**

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intracanalicular and Intravitreal Corticosteroid Implants (continued)	Aug. 1, 2025		– Member did not have a clinically significant rise in intraocular pressure **and** • Prescribed by or in consultation with an ophthalmologist; **and** • Dose does not exceed one implant per eye; **and** • Authorization is for no more than 60 days **Ozurdex is proven and medically necessary when all of the following criteria are met:** • Diagnosis of **one** of the following: o Macular edema following branch retinal vein occlusion (BRVO); **or** o Macular edema following central retinal vein occlusion (CRVO); **or** o Non-infectious uveitis affecting the posterior segment of the eye; **or** o Diabetic macular edema (DME) **and** • Prescribed by or in consultation with an ophthalmologist; **and** • Dose does not exceed one implant per eye; **and** • Authorization is for no more than 60 days **Retisert is proven and medically necessary when all of the following criteria are met:** • Diagnosis of chronic non-infectious uveitis affecting the posterior segment of the eye; **and** • Prescribed by or in consultation with an ophthalmologist; **and** • Dose does not exceed one implant per eye; **and** • Authorization is for no more than 60 days **Yutiq is proven and medically necessary when all of the following criteria are met:** • Diagnosis of chronic non-infectious uveitis affecting the posterior segment of the eye; **and** • Prescribed by or in consultation with an ophthalmologist; **and** • Dose does not exceed one implant per eye; **and** • Authorization is for no more than 60 days **Intracanalicular and intravitreal corticosteroid implant products are unproven and not medically necessary for the treatment any other**

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intracanalicular and Intravitreal Corticosteroid Implants (continued)	Aug. 1, 2025		**indication due to insufficient evidence of efficacy including but not limited to the following:** • Cystoid macular edema after cataract surgery • Radiation retinopathy
Leqvio® (Inclisiran)	Aug. 1, 2025	**Coverage Rationale** • Revised coverage criteria: ***Initial Therapy*** ○ Added criterion: ▪ To allow coverage when the patient has been previously treated with PCSK9 therapy [e.g., Praluent (alirocumab), Repatha (evolocumab)] ▪ Requiring Leqvio is prescribed by a cardiologist, endocrinologist, or lipid specialist ○ Replaced criterion requiring: ▪ "One of the [listed circumstances]" with "*submission of medical records (e.g., chart notes, laboratory values) confirming* one of the [listed circumstances]" ▪ "The patient has a history of failure, contraindication, or intolerance to PCSK9 therapy [e.g., Praluent (alirocumab), Repatha (evolocumab)]" with "*submission of medical records (e.g., chart notes,*	**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: ▪ 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: • Myalgia [muscle symptoms without creatine kinase (CK) elevations]; **or** • Myositis [muscle symptoms with CK elevations < 10 times upper limit of normal (ULN)] **and**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Leqvio® (Inclisiran) (continued)	Aug. 1, 2025	*laboratory values) confirming that* the patient has a history of failure, contraindication, or intolerance to PCSK9 therapy [e.g., Praluent (alirocumab), Repatha (evolocumab)]" ○ Removed criterion requiring: ▪ The patient has been receiving at least 12 consecutive weeks of ezetimibe therapy as adjunct to maximally tolerated statin therapy ▪ The patient has a history of contraindication or intolerance to ezetimibe ***Continuation of Therapy*** ○ Added criterion requiring Leqvio is prescribed by a cardiologist, endocrinologist, or lipid specialist	– 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 ○ 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

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Leqvio® (Inclisiran) (continued)	Aug. 1, 2025		• 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 ○ 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
Off-Label/Unproven Specialty Drug Treatment	Aug. 1, 2025	**Coverage Rationale** ***Description*** • Added review requirements for provider administered or supervised specialty drugs or patient self-administered • specialty drugs covered under the medical benefit to indicate: ○ When there is a corresponding UnitedHealthcare drug policy that does not address the requested indication or when there is not a UnitedHealthcare drug policy, review requires Drug Policy Interpretation Service (DPIS) research; DPIS staff will: ▪ Review clinical evidence to support clinical coverage issues that are not addressed in drug policy ▪ Research and summarize the evidence that will focus on the efficacy of	**Description** This policy provides parameters for coverage of off-label and unproven indications of FDA-approved medications covered under the medical benefit for one of the following: • Provider administered or supervised specialty drug or patient self-administered specialty drug covered under the medical benefit with a corresponding UnitedHealthcare policy that does not address the requested indication ○ Review under this section requires Drug Policy Interpretation Service (DPIS) research. DPIS staff will: ▪ Review clinical evidence to support clinical coverage issues that are not addressed in drug policy ▪ Research and summarize the evidence that will focus on the efficacy of the proposed drug for a specific diagnosis based on the best available clinical evidence that is published in the peer-reviewed medical literature and/or compendia ▪ Summarize the findings to assist the Medical Director in a coverage decision • Provider administered or supervised specialty drug or patient self-administered specialty drug covered under the medical benefit with a corresponding UnitedHealthcare policy that lists the drug as unproven for the requested indication ○ Review under this section requires notification to the health plan and approval of a benefit exception for what would otherwise be considered unproven services. • Provider administered or supervised specialty drug or patient self-

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Off-Label/Unproven Specialty Drug Treatment (continued)	Aug. 1, 2025	the proposed drug for a specific diagnosis based on the best available clinical evidence that is published in the peer-reviewed medical literature and/or compendia ▪ Summarize the findings to assist the Medical Director in a coverage decision ○ When there is a corresponding UnitedHealthcare policy that lists the drug as unproven for the requested indication, review requires notification to the health plan and approval of a benefit exception for what would otherwise be considered unproven services ***Indications of Coverage*** • Replaced language indicating "a specialty drug may be determined medically necessary for the requested off-label or unproven indication when the patient *has not been in or* is not currently in an eligible clinical trial" with "a specialty drug may be determined medically necessary for the requested off-label or unproven indication when the patient is not currently in an eligible clinical trial" • Removed notation indicating	administered specialty drug covered under the medical benefit without a UnitedHealthcare drug policy ○ Review under this section requires DPIS research; DPIS staff will: ▪ Review clinical evidence to support clinical coverage issues that are not addressed in drug policy ▪ Research and summarize the evidence that will focus on the efficacy of the proposed drug for a specific diagnosis based on the best available clinical evidence that is published in the peer-reviewed medical literature and/or compendia ▪ Summarize the findings to assist the Medical Director in a coverage decision This policy does **not** address coverage of: • Self-administered medications covered under the pharmacy benefit; refer to pharmacy benefit coverage. • Oncology medications (including but not limited to octreotide acetate, leuprolide acetate, leucovorin and levoleucovorin), including therapeutic radiopharmaceuticals, covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®); refer to the Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage for more information. • Vaccines; refer to the Medical Benefit Drug Policy titled Preventive Vaccines (Immunizations) and the Medical Policy titled Preventative Care Services for additional information on vaccines covered as preventive services. **Indications of Coverage** **A specialty drug may be determined medically necessary for the requested off-label or unproven indication when all of the criteria are met:** • The drug is approved by the U.S. Food and Drug Administration; **and** • The requested drug has not been excluded from coverage by UnitedHealthcare due to lack of efficacy, clinical benefit, or administrative program (e.g., exclusion at launch, plan document); **and** • **One** of the following: ○ The requested drug is considered "unproven" per UnitedHealthcare drug policy, where applicable

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Off-Label/Unproven Specialty Drug Treatment (continued)	Aug. 1, 2025	evidence limited to case studies or case series is not sufficient to meet the standard of this criterion (for peer-reviewed articles presented in a major peer-reviewed medical journal) **Definitions** • Updated definition of "Serious Rare Disease" **Supporting Information** • Updated *References* section to reflect the most current information	○ The indication for the requested drug is not addressed by a UnitedHealthcare drug policy, where applicable ○ A UnitedHealthcare drug policy does not exist for the requested drug **and** • The requested drug is intended to treat a chronic and seriously debilitating, or Serious Rare Disease; **and** • The patient has not failed a previous course or trial of the requested drug; **and** • The patient is not currently in an eligible clinical trial; **and** • Documented history of failure, contraindication, or intolerance to standard, conventional therapies to treat or manage the disease or condition, where available; **and** • Diagnosis is clinically supported as a use by at least **one** of the following: ○ **One** of the following compendia: ▪ The American Hospital Formulary Service Drug Information (AHFS-DI) under the Therapeutic Uses section; **or** ▪ The Elsevier Gold Standard's Clinical Pharmacology under the Indications section; **or** ▪ DRUGDEX System by Micromedex® has a Strength of Recommendation rating of Class I, Class IIa, or Class IIb under the Therapeutic Uses section **or** ○ Clinical indications supported by InterQual® Specialty Rx; **or** ○ Two (2) articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is validated and uncontested contradictory evidence presented in a major peer-reviewed medical journal (Examples of accepted journals include, but are not limited to, Journal of American Medical Association, New England Journal of Medicine, and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials.)
Provider Administered Drugs – Preferred Products	Jul. 1, 2025	**Coverage Rationale** • Revised list of non-preferred medical drug products; removed the following Par Sterile Products (NDCs inactive):	This policy provides parameters for coverage of preferred medications covered under the medical benefit. **Medical Necessity Plans** The Preferred Drug Products table below lists the UnitedHealthcare preferred

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Preferred Products (continued)	Jul. 1, 2025	○ Treprostinil 20mg/20mL Solution for Injection (42023-0206-01) ○ Treprostinil 50mg/20mL Solution for Injection (42023-0207-01) ○ Treprostinil 100mg/20mL Solution for Injection (42023-0208-01) ○ Treprostinil 200mg/20mL Solution for Injection (42023-0209-01) **Supporting Information** • Updated *Benefit Considerations* section to reflect the most current information	products and respective non-preferred products. Coverage will be provided for the UnitedHealthcare preferred product contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for any respective non-preferred product will be provided contingent on the criteria in the Preferred Drug Products Criteria and the Diagnosis-Specific Criteria sections. Members new to therapy will be required to utilize the UnitedHealthcare preferred product unless they meet the criteria in this section. ***Preferred Product Criteria*** **Treatment with the respective non-preferred product specified in the Non- Preferred Drug Products table below is medically necessary for proven indications when both of the following are met:** • History of intolerance or contraindication to one of the UnitedHealthcare's preferred products; and • Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with the respective non-preferred product. **Medical Drug Products** Below are UnitedHealthcare preferred medical drug products with a brand/generic alternative non-preferred products: **UnitedHealthcare Preferred Drug Products** • Treprostinil 20mg/20mL Solution for Injection (00781-3420) (Sandoz Inc. a Novartis Company) • Treprostinil 50mg/20mL Solution for Injection (00781-3425) (Sandoz Inc. a Novartis Company) • Treprostinil 100mg/20mL Solution for Injection (00781- **UnitedHealthcare Non-Preferred Drug Products** • Remodulin (treprostinil) 1mg/mL Solution for Injection (66302-0101) (United Therapeutics Corporation) • Remodulin (treprostinil) 2.5mg/mL Solution for Injection (66302-0102) (United Therapeutics Corporation) • Remodulin (treprostinil) 5mg/mL Solution for Injection (66302-

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Preferred Products (continued)	Jul. 1, 2025		3427) (Sandoz Inc. a Novartis Company) • Treprostinil 200mg/20mL Solution for Injection (00781-3430) (Sandoz Inc. a Novartis Company) • Treprostinil 20mg/20mL Solution for Injection (00781-3420) (Sandoz Inc. a Novartis Company) • Treprostinil 50mg/20mL Solution for Injection (00781-3425) (Sandoz Inc. a Novartis Company) • Treprostinil 100mg/20mL Solution for Injection (00781-3427) (Sandoz Inc. a Novartis Company) • Treprostinil 200mg/20mL Solution for Injection (00781-3430) (Sandoz Inc. a Novartis Company) 0105) (United Therapeutics Corporation) • Remodulin (treprostinil) 10mg/mL Solution for Injection (66302-0110) (United Therapeutics Corporation) • Treprostinil 20mg/20mL Solution for Injection (00703-0666) (Teva Pharmaceuticals USA) • Treprostinil 50mg/20mL Solution for Injection (00703-0676) (Teva Pharmaceuticals USA) • Treprostinil 100mg/20mL Solution for Injection (00703-0686) (Teva Pharmaceuticals USA) • Treprostinil 200mg/20mL Solution for Injection (00703-0696) (Teva Pharmaceuticals USA) • Treprostinil 20mg/20mL Solution for Injection (43598-0649-11) (Dr. Reddy's Laboratories, Inc.) • Treprostinil 50mg/20mL Solution for Injection (43598-0646-11) (Dr. Reddy's Laboratories, Inc.) • Treprostinil 100mg/20mL Solution for Injection (43598-0647-11) (Dr. Reddy's Laboratories, Inc.) • Treprostinil 200mg/20mL Solution for Injection (43598-0648-11) (Dr. Reddy's Laboratories, Inc.)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Provider Administered Drugs – Preferred Products (continued)	Jul. 1, 2025		***Diagnosis-Specific Criteria*** Refer to the drug-specific coverage policy if noted in the *Related Policies* section.

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.