

# UnitedHealthcare Individual Exchange Medical Policy Update Bulletin: July 2025

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## Take Note

### 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
Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing for Infectious Diarrhea	Medical Policy	<ul style="list-style-type: none"> <li>• Removed CPT code 0369U</li> </ul>
Gonadotropin Releasing Hormone Analogs	Medical Benefit Drug Policy	<ul style="list-style-type: none"> <li>• Revised description for HCPCS code J1954</li> </ul>
Hearing Aids and Devices Including Wearable, Bone-Anchored, and Semi-Implantable	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT codes 0951T, 0952T, 0953T, 0954T, and 0955T</li> </ul>
Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT codes 0560U and 0561U</li> </ul>
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT codes 0562U, 0565U, 0566U, 0569U, 0571U, and 0572U</li> </ul>
Oncology Medication Clinical Coverage	Medical Benefit Drug Policy	<ul style="list-style-type: none"> <li>• Added HCPCS code J9289</li> <li>• Revised description for HCPCS codes J1954 and J9292</li> </ul>
Preimplantation Genetic Testing and Related Services	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT codes 0552U, 0553U, 0554U, and 0555U</li> </ul>
Respiratory Pathogen Nucleic Acid Detection Testing	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT codes 0556U, 0563U, and 0564U</li> </ul>
Ustekinumab	Medical Benefit Drug Policy	<ul style="list-style-type: none"> <li>• Added HCPCS codes Q5099 and Q5100</li> </ul>
Whole Exome and Whole Genome Sequencing (Non-Oncology Conditions)	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT code 0567U</li> </ul>

## Medical Policy Updates

Updated			
Policy Title	Effective Date	Summary of Changes	
Carrier Testing Panels for Genetic Diseases	Jul. 1, 2025	<p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>Updated definition of “Gene Panel”</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information</li> </ul>	
Cosmetic and Reconstructive Procedures	Aug. 1, 2025	<p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>Updated definition of “Microtia”</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Added CPT codes 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, and 15876</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>References</i> section to reflect the most current information</li> </ul>	
Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cardiovascular Disease Risk Tests	Aug. 1, 2025	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>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”</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Added CPT code 0541U</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> </ul>	<p><b>The following are unproven and not medically necessary due to insufficient evidence of efficacy:</b></p> <ul style="list-style-type: none"> <li>Arterial compliance testing, using waveform analysis as a method to determine risk for cardiovascular disease</li> <li>Carotid intima-media thickness (CIMT) measurement as an effective screening tool for the management of cardiovascular disease</li> <li>Advanced lipoprotein analysis [e.g., lipoprotein(a), subfractions or particle size] as method to determine risk for cardiovascular disease</li> <li>Lipoprotein-associated phospholipase A2 (Lp-PLA2) enzyme as a method to determine risk for cardiovascular disease or ischemic stroke</li> <li>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</li> <li>Multi-protein diagnostic biomarker: <ul style="list-style-type: none"> <li>Analysis of protein biomarkers by aptamer-based microarray and algorithm</li> <li>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</li> <li>3 proteins [high sensitivity (hs) troponin, adiponectin, and kidney injury molecule-1 (KIM-1)] with algorithm and reported as a risk score</li> </ul> </li> </ul>

## Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cardiovascular Disease Risk Tests (continued)	Aug. 1, 2025		<ul style="list-style-type: none"> <li>4 proteins [NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 (TIMP-1), and KIM-1] with algorithm and reported as a risk score</li> <li>7 proteins (IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3) with algorithm and reported as a risk score</li> </ul>
Obstructive and Central Sleep Apnea Treatment	Sep. 1, 2025	<p><b>Coverage Rationale</b></p> <p><b>Surgical Treatment</b></p> <ul style="list-style-type: none"> <li>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</li> <li>Revised coverage criteria for: <b>Uvulopalatopharyngoplasty (UPPP), Mandibular Osteotomy (MO), and Maxillomandibular Osteotomy and Advancement (MMA) in an Adult Patient</b> <ul style="list-style-type: none"> <li>Replaced criterion requiring “<i>diagnosis of moderate to severe Obstructive Sleep Apnea (OSA) [Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) ≥ 1]</i>” with “<i>moderate to severe OSA [Apnea Hypopnea Index (AHI) ≥ 15 or Respiratory Disturbance Index (RDI) ≥ 15] as determined by Polysomnography (Attended)</i>”</li> </ul> </li> </ul>	<p><b>Non-Surgical Treatment</b></p> <p><b>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).</b> Refer to the Medical Policy titled Sleep Studies for further information.</p> <p>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:</p> <ul style="list-style-type: none"> <li>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)</li> <li>A treating physician (MD or DO) or an Advanced Practice Provider must diagnose OSA and recommend course of treatment (AAO-HNS, November 2019)</li> <li>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</li> </ul> <p>For information on snoring and Oral Appliances, refer to the Medical Policy titled Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements.</p> <p>For medical necessity clinical coverage criteria for removable Oral Appliances, refer to the InterQual® CP: Durable Medical Equipment, Noninvasive Airway Assistive Devices.</p> <p><a href="#">Click here to view the InterQual® criteria.</a></p>

<b>Revised</b>			
<b>Policy Title</b>	<b>Effective Date</b>	<b>Summary of Changes</b>	<b>Coverage Rationale</b>
Obstructive and Central Sleep Apnea Treatment (continued)	Sep. 1, 2025	<p><b>Implantable Hypoglossal Nerve Stimulation with a U.S. Food and Drug Administration (FDA) Approved Device in Adolescents Aged 10-18 Years with Down Syndrome</b></p> <ul style="list-style-type: none"> <li>Replaced criterion requiring “diagnosis of severe OSA (as determined by a <i>Polysomnogram within 24 months</i> and an AHI <math>\geq 10</math> and RDI <math>\leq 50</math> events per hour)” with “diagnosis of severe OSA [as determined by <i>Polysomnography (Attended)</i> and an AHI <math>\geq 10</math> and RDI <math>\leq 50</math> events per hour]”</li> </ul> <p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>Added definition of “Respiratory Disturbance Index (RDI)”</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Added CPT/HCPCS codes 0964T, 0965T, 0966T, and E0490</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>FDA</i> and <i>References</i> sections to reflect the most current information</li> </ul>	<p><b>Other Non-Surgical Procedures</b></p> <p>The following are unproven and not medically necessary due to insufficient evidence of efficacy:</p> <ul style="list-style-type: none"> <li>Devices for treating Positional OSA</li> <li>Nasal dilator devices for treating OSA</li> <li>Intranasal expiratory resistance valve (e.g., Bongo Rx)</li> <li>Removable Oral Appliances for treating Central Sleep Apnea</li> <li>Prefabricated Oral Appliance/device</li> <li>Non-surgical electrical muscular training</li> <li>Mandibular vertical repositioning devices (e.g., Slow Wave)</li> <li>Morning repositioning devices</li> <li>Epigenetic appliances [e.g., Homeoblock™, DNA® (Daytime/Nighttime appliance)]</li> <li>Advanced Lightwire Functional (ALF) appliances</li> </ul> <p><b>Surgical Treatment</b></p> <p><b>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:</b></p> <ul style="list-style-type: none"> <li>Moderate to severe OSA [Apnea Hypopnea Index (AHI) <math>\geq 15</math> or Respiratory Disturbance Index (RDI) <math>\geq 15</math>] as determined by Polysomnography (Attended)*</li> <li>Excessive daytime sleepiness documented with an Epworth Sleepiness Scale (ESS) <math>&gt; 10</math> or with another validated tool</li> <li>PAP therapy resulted in no therapeutic efficacy or patient refusal or intolerance</li> </ul> <p>In addition, the following criteria needs to be met:</p> <ul style="list-style-type: none"> <li>For MMA, craniofacial disproportion, or deformities with evidence of maxillomandibular deficiency</li> <li>For MO, retrolingual or lower pharyngeal function obstruction</li> </ul> <p><b>Implantable hypoglossal nerve stimulation with a U.S. Food and Drug Administration (FDA) approved device is proven and medically</b></p>

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Obstructive and Central Sleep Apnea Treatment (continued)	Sep. 1, 2025		<p><b>necessary in an adult patient with moderate to severe OSA when all the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• Body Mass Index of (BMI) less than or equal to 40kg/m<sup>2</sup>; and</li> <li>• AHI of ≥ 15 and ≤ 100 as determined by Polysomnography (Attended)*; and</li> <li>• Total AHI &lt; 25% for central + mixed Apneas, as evaluated by attended polysomnography; and</li> <li>• Absence of a complete blockage or complete concentric collapse of the soft palate confirmed by drug-induced sleep endoscopy; and</li> <li>• PAP therapy resulted in no therapeutic efficacy or patient refusal or intolerance; and</li> <li>• Used in accordance with FDA guidelines</li> </ul> <p><b>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:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of severe OSA [as determined by a Polysomnogram (Attended)* and an AHI ≥ 10 and RDI ≤ 50 events per hour]; and</li> <li>• BMI &lt; 95<sup>th</sup> percentile for age; and</li> <li>• Total AHI &lt; 25% for central + mixed Apneas; and</li> <li>• Contraindication for or not effectively treated with a prior adenotonsillectomy; and</li> <li>• Confirmed failure or intolerance of PAP therapy despite attempts to improve compliance; and</li> <li>• Absence of tracheostomy use during sleep; and</li> <li>• Absence of a complete blockage or concentric collapse of the soft palate level confirmed by drug induced sleep endoscopy; and</li> <li>• Individual and caregiver refusal of an MMA procedure for non-concentric palatal collapse; and</li> <li>• Used in accordance with FDA guidelines</li> </ul> <p><b>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.</b></p> <p>*Polysomnography should be repeated if there has been clinically significant weight loss or gain, changes in cardiovascular disease, or there are</p>

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Obstructive and Central Sleep Apnea Treatment (continued)	Sep. 1, 2025		<p>persistent or recurrent symptoms since the last study (Caples et al. 2021).</p> <p><b>Other Surgical Procedures</b></p> <p>The following surgical procedures are unproven and not medically necessary for treating OSA due to insufficient evidence of efficacy (not an all-inclusive list):</p> <ul style="list-style-type: none"> <li>• Laser-assisted uvulopalatoplasty (LAUP)</li> <li>• Lingual suspension - also referred to as tongue stabilization, tongue stitch, or tongue fixation</li> <li>• Isolated hyoid myotomy</li> <li>• Stand-alone uvulectomy</li> <li>• Palatal implants</li> <li>• Radiofrequency ablation of the soft palate and/or tongue base</li> <li>• Transoral robotic surgery (TORS)</li> <li>• Distraction osteogenesis for maxillary expansion (DOME)</li> </ul>
Panniculectomy Surgery	Aug. 1, 2025	<p><b>Title Change</b></p> <ul style="list-style-type: none"> <li>• Previously titled <i>Panniculectomy and Body Contouring Procedures</i></li> </ul> <p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>• Removed language indicating body contouring procedures, including but not limited to the following, are considered cosmetic and not medically necessary: <ul style="list-style-type: none"> <li>○ Abdominoplasty</li> <li>○ Lipectomy, including suction-assisted lipectomy (unless part of an approved procedure)</li> <li>○ Repair of diastasis recti</li> </ul> </li> <li>• Updated instruction to refer to the Medical Policy titled <i>Breast Reconstruction for information on liposuction when being performed post-mastectomy</i></li> </ul>	<p><b>Panniculectomy</b></p> <p><b>Panniculectomy is considered reconstructive and medically necessary in certain circumstances.</b> For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Panniculectomy, Abdominal.</p> <p><a href="#">Click here to view the InterQual® criteria.</a></p> <p><b>Panniculectomy is considered cosmetic and not medically necessary when performed for the following indications:</b></p> <ul style="list-style-type: none"> <li>• For any other condition that does not meet the InterQual® criteria</li> <li>• 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</li> <li>• When performed for primarily cosmetic purposes</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• For information on liposuction for lipedema, refer to the Medical Policy titled Liposuction for Lipedema.</li> <li>• For information on liposuction when being performed post-mastectomy, refer to the Medical Policy titled Breast Reconstruction.</li> </ul>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Panniculectomy Surgery (continued)	Aug. 1, 2025	<p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>Removed definition of:               <ul style="list-style-type: none"> <li>Abdominoplasty</li> <li>Diastasis Recti</li> <li>Functional or Physical or Physiological Impairment</li> <li>Suction Assisted Lipectomy</li> </ul> </li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Removed CPT codes 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, and 15876</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Added <i>Benefit Considerations</i> section</li> <li>Updated <i>Description of Services, Clinical Evidence, FDA, and References</i> sections to reflect the most current information</li> </ul>	
Skin and Soft Tissue Substitutes	Aug. 1, 2025	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication; added:               <ul style="list-style-type: none"> <li>Abiomend Hydromembrane</li> <li>Abiomend Membrane</li> <li>Abiomend Xplus Hydromembrane</li> <li>Abiomend Xplus Membrane</li> <li>AmchoPlast FD</li> <li>Amnio Burgeon Dual-Layer Membrane</li> <li>Amnio Burgeon Membrane and Hydromembrane</li> <li>Amnio Burgeon Xplus Membrane and Xplus Hydromembrane</li> </ul> </li> </ul>	<p><b>EpiFix or Grafix® (GrafixPL, GrafixPRIME, and GrafixPL PRIME) (Non-Injectable)</b></p> <p><b>EpiFix or Grafix is proven and medically necessary for treating a diabetic foot ulcer when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>Adequate circulation to the affected extremity as indicated by one or more of the following:               <ul style="list-style-type: none"> <li>Pedal pulses palpable or pulses confirmed with doppler examination</li> <li>Ankle-brachial index (ABI) between 0.7 and 1.2</li> </ul> </li> <li>Glycated hemoglobin test (HgA1c) &lt; 12% (within the last 90 days)</li> <li>Ulcer has failed to demonstrate adequate healing with at least 4 weeks of standard wound care which includes <b>all</b> of the following:               <ul style="list-style-type: none"> <li>Application of dressings to maintain a moist wound environment</li> <li>Debridement of necrotic tissue if present</li> <li>Offloading</li> </ul> </li> <li>No known contraindications which may include but are not limited to the following:               <ul style="list-style-type: none"> <li>Active Charcot deformity or major structural abnormalities of the affected foot</li> </ul> </li> </ul>

## Medical Policy Updates

Revised			
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Skin and Soft Tissue Substitutes (continued)	Aug. 1, 2025	<ul style="list-style-type: none"> <li>○ AmnioCore SL</li> <li>○ ChoriPly</li> <li>○ CYGNUS Disk</li> <li>○ Dual Layer Amnio Burgeon X-Membrane</li> <li>○ EPIXPRESS</li> <li>○ Foundation Dermal Regeneration Scaffold (DRS) Solo</li> <li>○ Miro3D fibers</li> <li>○ MiroDry Wound Matrix</li> <li>○ Myriad Matrix</li> <li>○ Myriad Morcells</li> <li>○ PalinGen Dual-Layer Membrane</li> <li>○ Theracor P or Allacor P</li> <li>○ XWRAP Dual</li> <li>○ XWRAP Plus</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>● Added HCPCS codes A2030, A2031, A2032, A2033, A2034, A2035, Q4354, Q4355, Q4356, Q4357, Q4358, Q4359, Q4360, Q4361, Q4362, Q4364, Q4365, Q4366, and Q4367</li> <li>● Removed HCPCS codes Q4231</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>● Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> </ul>	<ul style="list-style-type: none"> <li>○ Chronic infection to the ulcer site</li> <li>○ Known or suspected malignancy of the current ulcer being treated</li> <li>○ Ulcer being treated does not extend to tendon, muscle, capsule, or bone</li> </ul> <p><b><i>EpiFix and Grafix Application Limitations</i></b></p> <ul style="list-style-type: none"> <li>● EpiFix is limited to one application per week for up to 12 weeks.</li> <li>● Grafix is limited to one application per week for up to 12 weeks.</li> </ul> <p><b>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:</b></p> <ul style="list-style-type: none"> <li>● EpiFix application more frequently than once a week or beyond 12 weeks</li> <li>● Grafix application more frequently than once a week or beyond 12 weeks</li> </ul> <p><b>TransCyte™</b></p> <p>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.</p> <p>TransCyte is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy.</p> <p><b>Other Skin and Soft Tissue Substitutes</b></p> <p>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.</p> <p>Refer to the policy for complete details.</p>
Surgery of the Foot	Aug. 1, 2025	<p><b>Related Policies</b></p> <ul style="list-style-type: none"> <li>● Added reference link to the Medical Policy titled <i>Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and</i></li> </ul>	<p><b>Surgery of the foot is proven and medically necessary in certain circumstances.</b> For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:</p> <ul style="list-style-type: none"> <li>● Arthrodesis or Arthroplasty, Interphalangeal Joint, Second-Fifth Toes</li> <li>● Exostectomy, First Metatarsophalangeal (MTP) Joint (Bunionectomy)</li> <li>● Osteotomy, Distal Transpositional, First Metatarsal (MT) (Bunionectomy)</li> </ul>

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Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Foot (continued)	Aug. 1, 2025	<p><i>Soft Tissue Wounds</i></p> <p><b>Coverage Rationale</b>  <b>Hallux Rigidus (Correction With Implant)</b></p> <ul style="list-style-type: none"> <li>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 (<i>Hemi-implant or Total Implant Arthroplasty</i>) is proven and medically necessary when all of the [listed] criteria are met”</li> </ul> <p><b>Definition</b></p> <ul style="list-style-type: none"> <li>Added definition of: <ul style="list-style-type: none"> <li>Hemi-Implant Arthroplasty</li> <li>Interposition Arthroplasty</li> <li>Total Implant Arthroplasty</li> </ul> </li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> </ul>	<ul style="list-style-type: none"> <li>Osteotomy, Proximal, First Metatarsal (MT) (Bunionectomy)</li> <li>Osteotomy, Proximal Phalanx, First Toe +/- Bunionectomy</li> <li>Plantar Fascial Release</li> </ul> <p><a href="#">Click here to view the InterQual® criteria.</a></p> <p><b>Hallux Limitus or Rigidus (Correction Without Implant)</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>Diagnosis of hallux limitus or hallux rigidus to include the following: <ul style="list-style-type: none"> <li>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)</li> </ul> </li> <li>Persistent pain despite a reasonable trial of conservative treatment including one or more of the following: <ul style="list-style-type: none"> <li>Orthotics, shoe modification (e.g., high and wide toe box, rocker bottom sole), and/or shoe inserts</li> <li>Medical therapy (NSAIDs, analgesics, or intra-articular injections)</li> <li>Activity modification</li> <li>Debridement of hyperkeratotic lesions, if present</li> </ul> </li> </ul> <p>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.</p> <p><b>Hallux Rigidus (Correction With Implant)</b></p> <p>Correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release with implant (<i>Hemi-implant or Total Implant Arthroplasty</i>) is proven and medically necessary when all of the following criteria are met:</p> <ul style="list-style-type: none"> <li>Diagnosis of hallux rigidus to include the following:</li> </ul>

## Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Foot (continued)	Aug. 1, 2025		<ul style="list-style-type: none"> <li>○ 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)</li> <li>● Persistent pain despite a reasonable trial of conservative treatment including one or more of the following:               <ul style="list-style-type: none"> <li>○ Orthotics, shoe modification (e.g., high and wide toe box, rocker bottom sole), and/or shoe inserts</li> <li>○ Medical therapy (NSAIDs, analgesics, or intra-articular injections)</li> <li>○ Activity modification</li> <li>○ Debridement of hyperkeratotic lesions, if present</li> </ul> </li> </ul> <p><b>Osteochondral Allograft or Autograft Transplantation</b>            Osteochondral allograft or autograft transplantation is unproven and not medically necessary for treating cartilage defects of the foot due to insufficient evidence of efficacy.</p>
Umbilical Cord Blood Harvesting and Storage for Future Use	Aug. 1, 2025	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>● Replaced language indicating “collection and storage of umbilical cord blood is unproven and not medically necessary for a <i>person</i> who is currently healthy but desiring to provide the opportunity for a <i>hypothetical</i>, future transplantation due to insufficient evidence of efficacy” with “<i>prophylactic</i> collection and storage of umbilical cord blood is unproven and not medically necessary for an <i>individual</i> who is currently healthy but desiring to provide the opportunity for a future <i>unspecified autologous or allogeneic stem cell</i> transplantation due to insufficient evidence of efficacy”</li> </ul>	<p><b>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.</b></p> <p>For additional information and coverage of umbilical cord blood stem cell transplantation, refer to the Optum Clinical Guideline titled Hematopoietic Stem Cell Transplantation.</p>

## 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	<b>Supporting Information</b> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> </ul>	
Retired			
Policy Title	Effective Date	Summary of Changes	
Intrauterine Fetal Surgery	Jul. 1, 2025	<ul style="list-style-type: none"> <li>Retired policy; intrauterine fetal surgery no longer requires clinical review</li> </ul>	
Macular Degeneration Treatment Procedures	Jul. 1, 2025	<ul style="list-style-type: none"> <li>Retired policy; macular degeneration treatment procedures no longer require clinical review</li> </ul>	
Pectus Deformity Repair	Jul. 1, 2025	<ul style="list-style-type: none"> <li>Retired policy; pectus deformity repair no longer requires clinical review</li> </ul>	

## Medical Benefit Drug Policy Updates

New		
Policy Title	Effective Date	Coverage Rationale
Kebilidi™ (Eladocagene Exuparvovec-Tneq)	Aug. 1, 2025	<p><b>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:</b></p> <ul style="list-style-type: none"> <li>• Submission of medical records documenting a diagnosis of AADC deficiency; <b>and</b></li> <li>• Submission of medical records documenting diagnosis has been confirmed by <b>all</b> of the following:               <ul style="list-style-type: none"> <li>○ Presence of biallelic mutations in the dopa decarboxylase (<i>DDC</i>) gene; <b>and</b></li> <li>○ 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); <b>and</b></li> <li>○ Decreased AADC enzyme activity in plasma per current laboratory standards</li> </ul> </li> <li><b>and</b></li> <li>• Patient has achieved skull maturity, as confirmed by neuroimaging, necessary for stereotactic neurosurgical administration of Kebilidi; <b>and</b></li> <li>• 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); <b>and</b></li> <li>• Patient is unable to ambulate independently; <b>and</b></li> <li>• Patient does not have an anti-adenovirus, serotype 2 (anti-AAV2) antibody titer higher than 1:1200 or &gt; 1 optical density value by enzyme-linked immunosorbent assay (ELISA); <b>and</b></li> <li>• Prescribed by a neurologist or neurosurgeon; <b>and</b></li> <li>• Patient has not previously received treatment with Kebilidi or other gene therapy for the treatment of AADC deficiency in their lifetime; <b>and</b></li> <li>• Dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>• Authorization will be issued for no more than one treatment per lifetime and for no longer than 60 days from approval</li> </ul>
Susvimo™ (Ranibizumab Injection)	Aug. 1, 2025	<p><b>Susvimo is proven and medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• For <b>initial therapy</b>, <b>all</b> of the following:               <ul style="list-style-type: none"> <li>○ <b>One</b> of the following diagnoses:                   <ul style="list-style-type: none"> <li>§ Neovascular (wet) age-related macular degeneration (AMD); <b>or</b></li> <li>§ Diabetic Macular Edema (DME)</li> </ul> </li> <li><b>and</b></li> <li>○ Patient has previously responded to at least <b>two</b> intravitreal injections of a VEGF inhibitor [e.g., Avastin (bevacizumab), Eylea (aflibercept), Eylea HD (aflibercept), Lucentis (ranibizumab), Pavblu (aflibercept-ayyh), Vabysmo (faricimab-svoa)]; <b>and</b></li> <li>○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>○ Initial authorization will be for no longer than 12 months</li> </ul> </li> <li>• For <b>continuation of therapy</b>, <b>all</b> of the following:               <ul style="list-style-type: none"> <li>○ Documentation of a positive clinical response; <b>and</b></li> <li>○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> </ul> </li> </ul>

## Medical Benefit Drug Policy Updates

New			
Policy Title	Effective Date	Coverage Rationale	
Susvimo™ (Ranibizumab Injection) (continued)	Aug. 1, 2025	<ul style="list-style-type: none"> <li>○ Reauthorization will be for no longer than 12 months</li> </ul>	
Updated			
Policy Title	Effective Date	Summary of Changes	
Niktimvo™ (Axatilimab-Csfr)	Jul. 1, 2025	<b>Coverage Rationale</b> <ul style="list-style-type: none"> <li>● Removed reference link to the Medical Benefit Drug Policy titled <i>Review at Launch for New to Market Medications</i></li> </ul>	
Off-Label/Unproven Specialty Drug Treatment	Aug. 1, 2025	<b>Coverage Rationale</b> <ul style="list-style-type: none"> <li>● Removed notation indicating 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)</li> </ul> <b>Definitions</b> <ul style="list-style-type: none"> <li>● Updated definition of “Serious Rare Disease”</li> </ul> <b>Supporting Information</b> <ul style="list-style-type: none"> <li>● Updated <i>References</i> section to reflect the most current information</li> </ul>	
Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Clotting Factors, Coagulant Blood Products, & Other Hemostatics	Aug. 1, 2025	<b>Coverage Rationale</b> <ul style="list-style-type: none"> <li>● Revised list of applicable products and corresponding brand names; added antithrombin-directed small interfering ribonucleic acid (siRNA) [brand name Qfitlia® (fitusiran)]</li> <li>● Added language to indicate:               <ul style="list-style-type: none"> <li>○ <b>Qfitlia (fitusiran)</b> has 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 <i>Review at Launch for New to Market</i></li> </ul> </li> </ul>	Refer to the policy for complete details.

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Clotting Factors, Coagulant Blood Products, & Other Hemostatics (continued)	Aug. 1, 2025	<p><i>Medications</i> for additional details</p> <ul style="list-style-type: none"> <li>○ <b>Fitusiran [Qfitlia]</b> is proven/medically necessary for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A/hemophilia B when all of the criteria [listed in the policy] are met</li> <li>● Revised coverage criteria for:               <ul style="list-style-type: none"> <li>○ <b><i>Emicizumab-kxwh [Hemlibra]</i></b> <ul style="list-style-type: none"> <li>○ Removed criterion requiring prescriber attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Adynovate, Afstyla, Altuviiio, Eloctate, Jivi) for the treatment of breakthrough bleeding episodes</li> </ul> </li> <li>○ <b><i>Marstacimab-hncq [Hypavzi]</i></b> <ul style="list-style-type: none"> <li>○ Removed criterion requiring prescriber attestation that the patient is not to receive extended half-life factor IX replacement products (e.g., Alprolix, Idelvion) for the treatment of breakthrough bleeding episodes</li> </ul> </li> </ul> </li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>● Added HCPCS code J7172</li> <li>● Removed HCPCS code C9304</li> </ul>	

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Clotting Factors, Coagulant Blood Products, & Other Hemostatics (continued)	Aug. 1, 2025	<p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Background, Clinical Evidence, FDA, and References</i> sections to reflect the most current information</li> </ul>	
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®)	Aug. 1, 2025	<p><b>Title Change</b></p> <ul style="list-style-type: none"> <li>Previously titled <i>Neonatal FC Receptor Blockers (Rystiggo®, Vyvgart®, &amp; Vyvgart® Hytrulo)</i></li> </ul> <p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Replaced references to: <ul style="list-style-type: none"> <li>“Neonatal FC receptor blocker” with “FcRn blocker”</li> <li>“Soliris (eculizumab)” with “eculizumab”</li> </ul> </li> <li>Added language to indicate: <ul style="list-style-type: none"> <li>This policy refers to the following drug products for administration by a healthcare professional: <ul style="list-style-type: none"> <li>§ Rystiggo (rozanolixizumab-noli) for intravenous (IV) route</li> <li>§ Vyvgart (efgartigimod alfa-fcab) for intravenous (IV) route</li> <li>§ Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) vial for subcutaneous (SC) route</li> </ul> </li> <li>Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) prefilled syringe for self-administered subcutaneous injection is obtained under the pharmacy benefit</li> </ul> </li> </ul>	<p>This policy refers to the following drug products for administration by a healthcare professional:</p> <ul style="list-style-type: none"> <li>Rystiggo (rozanolixizumab-noli) for intravenous (IV) route</li> <li>Vyvgart (efgartigimod alfa-fcab) for intravenous (IV) route</li> <li>Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) vial for subcutaneous (SC) route</li> </ul> <p>Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) prefilled syringe for self-administered subcutaneous injection is obtained under the pharmacy benefit.</p> <p><b>Myasthenia Gravis</b></p> <p><b>Rystiggo is proven and 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:</b></p> <ul style="list-style-type: none"> <li><b>Initial Therapy</b> <ul style="list-style-type: none"> <li>Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming <b>all</b> of the following: <ul style="list-style-type: none"> <li>§ Patient has not failed a previous course of Rystiggo therapy; <b>and</b></li> <li>§ Diagnosis of generalized myasthenia gravis (gMG); <b>and</b></li> <li>§ One of the following: <ul style="list-style-type: none"> <li>– Positive serologic test for anti-AChR antibodies; <b>or</b></li> <li>– Positive serologic test for anti-MuSK antibodies</li> </ul> </li> </ul> </li> <li><b>and</b></li> <li>§ Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; <b>and</b></li> <li>§ Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy</li> </ul> </li> <li><b>and</b></li> <li>○ <b>One</b> of the following:</li> </ul>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	<ul style="list-style-type: none"> <li>• Revised coverage criteria for:               <ul style="list-style-type: none"> <li><b>Rystiggo</b> <ul style="list-style-type: none"> <li>○ Added criterion requiring the patient is not receiving Rystiggo in combination with an immune globulin</li> <li>○ 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 <i>intravenous</i> 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”</li> </ul> </li> <li><b>Vyvgart and Vyvgart Hytrulo for the Treatment of Generalized Myasthenia Gravis</b> <ul style="list-style-type: none"> <li>○ Added criterion requiring:                   <ul style="list-style-type: none"> <li>§ The patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with an immune globulin</li> </ul> </li> </ul> </li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>§ If anti-acetylcholine receptor (AChR) antibody positive, one of the following:           <ul style="list-style-type: none"> <li>– 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.); <b>or</b></li> <li>– 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</li> </ul> </li> <li><b>or</b></li> <li>§ If anti-muscle-specific tyrosine kinase (MuSK) antibody positive:           <ul style="list-style-type: none"> <li>– 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.)</li> </ul> </li> <li><b>and</b></li> <li>○ Patient is not receiving Rystiggo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; <b>and</b></li> <li>○ Patient is <b>not</b> receiving Rystiggo in combination with another FcRn blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]; <b>and</b></li> <li>○ Patient is <b>not</b> receiving Rystiggo in combination with an immune globulin; <b>and</b></li> <li>○ Rystiggo is dosed according to the US FDA labeled dosing for gMG; <b>and</b></li> <li>○ Prescribed by, or in consultation with, a neurologist; <b>and</b></li> <li>○ Initial authorization will be for no more than 12 months</li> <li>• <b>Continuation of Therapy</b> <ul style="list-style-type: none"> <li>○ Patient has previously been treated with Rystiggo; <b>and</b></li> <li>○ Submission of medical records (e.g., chart notes, laboratory tests) demonstrating <b>all</b> of the following:               <ul style="list-style-type: none"> <li>§ Improvement and/or maintenance of at least a 2 point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline; <b>and</b></li> </ul> </li> </ul> </li> </ul>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	<p>§ The patient will be given Vyvgart or Vyvgart Hytrulo no sooner than 50 days after each treatment cycle</p> <ul style="list-style-type: none"> <li>○ 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”</li> </ul> <p><b><i>Vyvgart Hytrulo for the Treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)</i></b></p> <p><b>Initial Therapy</b></p> <ul style="list-style-type: none"> <li>○ Added criterion requiring: <ul style="list-style-type: none"> <li>§ Trial and failure (after a trial of at least two months), contraindication, or intolerance to corticosteroids</li> </ul> </li> </ul>	<p>§ Reduction in signs and symptoms of myasthenia gravis; <b>and</b></p> <p>§ Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Rystiggo. <b>Note:</b> 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</p> <p><b>and</b></p> <ul style="list-style-type: none"> <li>○ Patient is not receiving Rystiggo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; <b>and</b></li> <li>○ Patient is <b>not</b> receiving Rystiggo in combination with another FcRn blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]; <b>and</b></li> <li>○ Patient is <b>not</b> receiving Rystiggo in combination with an immune globulin; <b>and</b></li> <li>○ Rystiggo is dosed according to the US FDA labeled dosing for gMG; <b>and</b></li> <li>○ Prescribed by, or in consultation with, a neurologist; <b>and</b></li> <li>○ Reauthorization will be for no more than 12 months</li> </ul> <p><b>Vyvgart and Vyvgart Hytrulo are proven and 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:</b></p> <ul style="list-style-type: none"> <li>• <b>Initial Therapy</b> <ul style="list-style-type: none"> <li>○ Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming <b>all</b> of the following: <ul style="list-style-type: none"> <li>§ Patient has not failed a previous course of Vyvgart therapy; <b>and</b></li> <li>§ Patient has not failed a previous course of Vyvgart Hytrulo therapy; <b>and</b></li> <li>§ Diagnosis of generalized myasthenia gravis (gMG); <b>and</b></li> <li>§ Positive serologic test for anti-AChR antibodies; <b>and</b></li> <li>§ Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; <b>and</b></li> <li>§ Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy</li> </ul> </li> </ul> </li> </ul>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	<p>§ 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:</p> <ul style="list-style-type: none"> <li>– Dose has been adjusted or escalated to the maximally allowable and/or tolerated dose</li> <li>– Failure to obtain an objective response to treatment in a disability assessment defined by one of the following: <ul style="list-style-type: none"> <li>• Inflammatory Rasch-built Overall Disability Scale (I-RODS): increase <math>\geq 4</math> centile points in a 48-point scale</li> <li>• Inflammatory Neuropathy Cause and Treatment Disability Scale (INCAT): decrease <math>\geq 1</math> point</li> </ul> </li> <li>– Failure to obtain an objective response to</li> </ul>	<p><b>and</b></p> <ul style="list-style-type: none"> <li>○ <b>One</b> of the following: <ul style="list-style-type: none"> <li>§ History of failure of at least <b>two</b> immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.); <b>or</b></li> <li>§ 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</li> </ul> </li> <li><b>and</b></li> <li>○ Patient will be given Vyvgart or Vyvgart Hytrulo no sooner than 50 days after each treatment cycle; <b>and</b></li> <li>○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; <b>and</b></li> <li>○ Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with another FcRn blocker [e.g., Rystiggo (rozanolixizumab-noli)]; <b>and</b></li> <li>○ Patient is <b>not</b> receiving Vyvgart or Vyvgart Hytrulo in combination with an immune globulin; <b>and</b></li> <li>○ Vyvgart or Vyvgart Hytrulo is dosed according to the US FDA labeled dosing for gMG; <b>and</b></li> <li>○ Prescribed by, or in consultation with, a neurologist; <b>and</b></li> <li>○ Initial authorization will be for no more than 12 months</li> <li>• <b>Continuation of Therapy</b> <ul style="list-style-type: none"> <li>○ Patient has previously been treated with Vyvgart or Vyvgart Hytrulo; <b>and</b></li> <li>○ Submission of medical records (e.g., chart notes, laboratory tests) demonstrating <b>all</b> of the following: <ul style="list-style-type: none"> <li>§ Improvement and/or maintenance of at least a 2 point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline; <b>and</b></li> <li>§ Reduction in signs and symptoms of myasthenia gravis; <b>and</b></li> <li>§ Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart or</li> </ul> </li> </ul> </li> </ul>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	<p>treatment in an impairment assessment defined by one the following:</p> <ul style="list-style-type: none"> <li>Grip strength using handheld dynamometry in Martin Vigorimeter: increase <math>\geq 8</math> kilopascals (or <math>\geq 1.2</math> pounds/inch<sup>2</sup>) or Jamar hand grip dynamometer: increase <math>\geq 10\%</math></li> <li>Medical Research Council (MRC) sum score (0-60): increase <math>\geq 2</math> to 4 points</li> <li>Modified INCAT Sensory Sum scale (mISS): decrease <math>\geq 2</math> points</li> </ul> <p>§ 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</p>	<p>Vyvgart Hytrulo. <b>Note:</b> 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</p> <p><b>and</b></p> <ul style="list-style-type: none"> <li>Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with a complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]; <b>and</b></li> <li>Patient is not receiving Vyvgart or Vyvgart Hytrulo in combination with another FcRn blocker [e.g., Rystiggo (rozanolixizumab-noli)]; <b>and</b></li> <li>Patient is <b>not</b> receiving Vyvgart or Vyvgart Hytrulo in combination with an immune globulin; <b>and</b></li> <li>Vyvgart or Vyvgart Hytrulo is dosed according to the US FDA labeled dosing for gMG; <b>and</b></li> <li>Prescribed by, or in consultation with, a neurologist; <b>and</b></li> <li>Reauthorization will be for no more than 12 months</li> </ul> <p><b>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:</b></p> <ul style="list-style-type: none"> <li><b>Initial Therapy</b> <ul style="list-style-type: none"> <li>Patient has not failed a previous course of Vyvgart Hytrulo therapy; <b>and</b></li> <li>Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP); <b>and</b></li> <li>Diagnosis of CIDP is categorized as one of the following:           <ul style="list-style-type: none"> <li>§ Typical CIDP; <b>or</b></li> <li>§ <b>One</b> of the following CIDP variants:               <ul style="list-style-type: none"> <li>– Distal CIDP; <b>or</b></li> <li>– Multifocal CIDP; <b>or</b></li> <li>– Focal CIDP; <b>or</b></li> <li>– Motor CIDP; <b>or</b></li> <li>– Sensory CIDP</li> </ul> </li> </ul> </li> </ul> </li> <li><b>and</b></li> <li><b>One</b> of the following:</li> </ul>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	<p>excluded other possible relevant neuropathies (e.g., anti-MAG IgM neuropathy, multiple myeloma, AL-amyloidosis, POEMS syndrome)</p> <ul style="list-style-type: none"> <li>○ 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: <ul style="list-style-type: none"> <li>§ Corticosteroids</li> <li>§ Immune globulin (i.e., intravenous immunoglobulin or subcutaneous immunoglobulin)</li> <li>§ Plasma exchange</li> </ul> </li> <li>○ Replaced criterion requiring: <ul style="list-style-type: none"> <li>§ “Electrodiagnostic testing has confirmed a <i>diagnosis of CIDP</i>” with “electrodiagnostic testing has confirmed <i>at least two motor nerve abnormalities</i>”</li> <li>§ “Electrodiagnostic testing allows only for a diagnosis of possible CIDP” with “electrodiagnostic testing allows only for a diagnosis of possible CIDP having only one</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>§ Electrodiagnostic testing has confirmed at least two motor nerve abnormalities; <b>or</b></li> <li>§ <b>All</b> of the following: <ul style="list-style-type: none"> <li>– Electrodiagnostic testing allows only for a diagnosis of possible CIDP having only one motor nerve abnormality; <b>and</b></li> <li>– Two of the following, consistent with EFNS/PNS guidelines, support a diagnosis of possible CIDP <ul style="list-style-type: none"> <li>○ Objective response to treatment with immunomodulatory agents (e.g., corticosteroids, immune globulin, plasma exchange)</li> <li>○ Imaging with ultrasound or MRI</li> <li>○ Cerebrospinal fluid (CSF) analysis</li> <li>○ Nerve Biopsy</li> </ul> </li> </ul> </li> <li><b>and</b></li> <li>– 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)</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>○ Trial and failure (after a trial of at least two months), contraindication, or intolerance to corticosteroids; <b>and</b></li> <li>○ 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 <b>both</b> of the following: <ul style="list-style-type: none"> <li>§ Dose has been adjusted or escalated to the maximally allowable and/or tolerated dose; <b>and</b></li> <li>§ <b>Both</b> of the following: <ul style="list-style-type: none"> <li>– Failure to obtain an objective response to treatment in a disability assessment defined by <b>one</b> of the following: <ul style="list-style-type: none"> <li>· Inflammatory Rasch-built Overall Disability Scale (I-RODS): increase ≥ 4 centile points in a 48-point scale;</li> </ul> </li> </ul> </li> </ul> </li> </ul> <p><b>or</b></p>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®) (continued)	Aug. 1, 2025	<p>motor nerve abnormality”</p> <p>§ “Two <i>supportive</i> criteria [e.g., objective response to treatment, imaging, cerebrospinal fluid (CSF), nerve biopsy] consistent with EFNS/PNS guidelines <i>confirm</i> diagnosis of CIDP” with “two of the following [criteria] consistent with EFNS/PNS guidelines <i>support</i> a diagnosis of <i>possible</i> 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”</p> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>○ Added criterion requiring the patient is not receiving Vyvgart Hytrulo in combination with an immune globulin</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>● Updated <i>References</i> section to reflect the most current information</li> </ul>	<ul style="list-style-type: none"> <li>· Inflammatory Neuropathy Cause and Treatment Disability Scale (INCAT): decrease ≥ 1 point</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>– Failure to obtain an objective response to treatment in an impairment assessment defined by <b>one</b> the following: <ul style="list-style-type: none"> <li>· Grip strength using handheld dynamometry in Martin Vigorimeter: increase ≥ 8 kilopascals (or ≥ 1.2 pounds/inch<sup>2</sup>) or Jamar hand grip dynamometer: increase ≥ 10%; <b>or</b></li> <li>· Medical Research Council (MRC) sum score (0-60): increase ≥ 2 to 4 points; <b>or</b></li> <li>· Modified INCAT Sensory Sum scale (mISS): decrease ≥ 2 points</li> </ul> </li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>○ Patient is <b>not</b> receiving Vyvgart Hytrulo in combination with an immune globulin; <b>and</b></li> <li>○ Vyvgart Hytrulo is dosed according to the US FDA labeled dosing for CIDP; <b>and</b></li> <li>○ Prescribed by, or in consultation with, a neurologist; <b>and</b></li> <li>○ Initial authorization will be for no more than 12 months</li> </ul> <ul style="list-style-type: none"> <li>● <b>Continuation of Therapy</b> <ul style="list-style-type: none"> <li>○ Patient has previously been treated with Vyvgart Hytrulo; <b>and</b> Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]; <b>and</b></li> <li>○ Patient is <b>not</b> receiving Vyvgart Hytrulo in combination with an immune globulin; <b>and</b></li> <li>○ Vyvgart Hytrulo is dosed according to the US FDA labeled dosing for CIDP; <b>and</b></li> <li>○ Prescribed by, or in consultation with, a neurologist; <b>and</b></li> <li>○ Reauthorization will be for no more than 12 months</li> </ul> </li> </ul>
Immune Globulin (IVIG and SCIG)	Aug. 1, 2025	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>● Added language to indicate immune globulin is proven for</li> </ul>	<p>This policy refers to FDA approved intravenous (IV) and subcutaneous (SC) immune globulin (IG) products including but not limited to the following (List not all inclusive):</p>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2025	<p>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:</p> <ul style="list-style-type: none"> <li>○ Patient has been exposed to measles (rubeola) less than 6 days previously</li> <li>○ Patient weight is greater than 30 kg (for patients ≤ 30 kg, administer Intramuscular immune globulin)</li> <li>○ One of the following nonimmune or severely immunocompromised individuals who are not already receiving immune globulin therapy:               <ul style="list-style-type: none"> <li>§ Patient is a pregnant woman without evidence of measles immunity</li> <li>§ Patient has received hematopoietic stem cell transplant (HSCT) and has finished all immunosuppressive treatment within 12 months</li> <li>§ Patient is a HSCT recipient with chronic graft-versus-host disease (GVHD)</li> <li>§ Patient has received chimeric antigen receptor T-cell (CAR T) therapy</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Alyglo™ (IV)</li> <li>• Asceniv™ (IV)*</li> <li>• Bivigam® (IV)</li> <li>• Cutaquig® (SC)*</li> <li>• Cuvitru® (SC)</li> <li>• Flebogamma® DIF (IV)</li> <li>• Gammagard® Liquid (IV, SC)</li> <li>• Gammagard® S/D (IV)</li> <li>• Gammaked™ (IV, SC)</li> <li>• Gammaplex® (IV)</li> <li>• Gamunex®-C (IV, SC)</li> <li>• Hizentra® (SC)</li> <li>• HyQvia® (SC)</li> <li>• Octagam® (IV)</li> <li>• Panzyga® (IV)*</li> <li>• Privigen® (IV)</li> <li>• Xembify® (SC)</li> </ul> <p>Refer to the policy for complete details.</p>

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Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Immune Globulin (IVIG and SCIG) (continued)	Aug. 1, 2025	<p style="margin-left: 20px;">within 12 months</p> <p>§ Patient has acute lymphoblastic leukemia (ALL) and is completing or has completed chemotherapy within the last 6 months</p> <p>§ Patient with HIV infection and severe immunosuppression defined as a current CD4+ T-lymphocyte percentage &lt; 15% (all ages) or a CD4+ T-lymphocyte count &lt; 200 lymphocyte cells/mm<sup>3</sup> (age &gt; 5 years only)</p> <p>§ Patient with a primary immunodeficiency (refer to the disease list within the policy)</p> <ul style="list-style-type: none"> <li>○ Request is for an initial, one-time dose, not to exceed 400 mg/kg</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>• Added ICD-10 diagnosis codes B05.0, B05.1, B05.2, B05.3, B05.4, O98.511, O98.512, O98.513, and O98.519</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>• Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> </ul>	
Intracanalicular and Intravitreal Corticosteroid Implants	Aug. 1, 2025	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>• Revised authorization guidelines; replaced language indicating “authorization is for no more than</li> </ul>	This policy provides information about the use of certain specialty pharmacy medications administered by the intracanalicular and intravitreal route for certain ophthalmologic conditions.

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Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intracanalicular and Intravitreal Corticosteroid Implants (continued)	Aug. 1, 2025	<p><i>one month</i>" with "authorization is for no more than 60 days"</p> <ul style="list-style-type: none"> <li>Revised coverage criteria for <b>Iluvien</b>; added criterion requiring chronic non-infectious uveitis affecting the posterior segment of the eye</li> </ul> <p><b>Applicable Codes</b>  <b>Non-Infectious Uveitis Affecting the Posterior Segment of the Eye</b></p> <ul style="list-style-type: none"> <li>Added ICD-10 diagnosis codes H30.141, H30.142, H30.143, H30.149, H30.21, H30.22, H30.23, H30.811, H30.812, H30.813, and H30.819</li> </ul> <p><b>Ocular Inflammation and Pain Following Ophthalmic Surgery</b></p> <ul style="list-style-type: none"> <li>Removed ICD-10 diagnosis codes G89.18 and H05.00</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information</li> </ul>	<p>This policy refers to the following <b>intracanalicular and intravitreal corticosteroid implant products</b>:</p> <ul style="list-style-type: none"> <li>Dextenza® (dexamethasone ophthalmic insert)</li> <li>Iluvien® (fluocinolone acetonide intravitreal implant)</li> <li>Ozurdex® (dexamethasone intravitreal implant)</li> <li>Retisert® (fluocinolone acetonide intravitreal implant)</li> <li>Yutiq® (fluocinolone acetonide intravitreal implant)</li> </ul> <p><b>Dextenza is proven and medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li><b>One</b> of the following diagnoses: <ul style="list-style-type: none"> <li>Ocular inflammation and pain following ophthalmic surgery; <b>or</b></li> <li>Ocular itching associated with allergic conjunctivitis</li> </ul> <b>and</b> </li> <li>Prescribed by or in consultation with an ophthalmologist; <b>and</b></li> <li>Dose does not exceed one insert per eye; <b>and</b></li> <li>Authorization is for no more than 60 days</li> </ul> <p><b>Iluvien is proven and medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li><b>One</b> of the following: <ul style="list-style-type: none"> <li>Chronic non-infectious uveitis affecting the posterior segment of the eye; <b>or</b></li> <li><b>Both</b> of the following: <ul style="list-style-type: none"> <li>§ Diagnosis of diabetic macular edema (DME); <b>and</b></li> <li>§ <b>Both</b> of the following: <ul style="list-style-type: none"> <li>Member has been previously treated with a course of corticosteroids; <b>and</b></li> <li>Member did not have a clinically significant rise in intraocular pressure</li> </ul> </li> </ul> </li> </ul> <b>and</b> </li> <li>Prescribed by or in consultation with an ophthalmologist; <b>and</b></li> <li>Dose does not exceed one implant per eye; <b>and</b></li> <li>Authorization is for no more than 60 days</li> </ul> <p><b>Ozurdex is proven and medically necessary when all of the following criteria are met:</b></p>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intracanalicular and Intravitreal Corticosteroid Implants (continued)	Aug. 1, 2025		<ul style="list-style-type: none"> <li>• Diagnosis of <b>one</b> of the following:               <ul style="list-style-type: none"> <li>○ Macular edema following branch retinal vein occlusion (BRVO); <b>or</b></li> <li>○ Macular edema following central retinal vein occlusion (CRVO); <b>or</b></li> <li>○ Non-infectious uveitis affecting the posterior segment of the eye; <b>or</b></li> <li>○ Diabetic macular edema (DME)</li> </ul> </li> <li>• <b>and</b></li> <li>• Prescribed by or in consultation with an ophthalmologist; <b>and</b></li> <li>• Dose does not exceed one implant per eye; <b>and</b></li> <li>• Authorization is for no more than 60 days</li> </ul> <p><b>Retisert is proven and medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of chronic non-infectious uveitis affecting the posterior segment of the eye; <b>and</b></li> <li>• Prescribed by or in consultation with an ophthalmologist; <b>and</b></li> <li>• Dose does not exceed one implant per eye; <b>and</b></li> <li>• Authorization is for no more than 60 days</li> </ul> <p><b>Yutiq is proven and medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of chronic non-infectious uveitis affecting the posterior segment of the eye; <b>and</b></li> <li>• Prescribed by or in consultation with an ophthalmologist; <b>and</b></li> <li>• Dose does not exceed one implant per eye; <b>and</b></li> <li>• Authorization is for no more than 60 days</li> </ul> <p><b>Intracanalicular and intravitreal corticosteroid implant products are unproven and not medically necessary for the treatment any other indication due to insufficient evidence of efficacy including, but not limited to the following:</b></p> <ul style="list-style-type: none"> <li>• Cystoid macular edema after cataract surgery</li> <li>• Radiation retinopathy</li> </ul>

## 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 Individual Exchange 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 Individual Exchange Medical Policies and Medical Benefit Drug Policies is available at [UHCprovider.com/policies](https://UHCprovider.com/policies) > For Individual Exchange Plans > [Medical & Drug Policies](#).