

UnitedHealthcare Commercial Medical Policy Update Bulletin: September 2026

In This Issue

Take Note

Page

- Annual ICD-10 and Quarterly CPT/HCPCS Code Updates 2
- Policy Updates Cancelled: Implanted Electrical Stimulator for the Spinal Cord..... 2

Medical Policy Updates

New

- Vascular Embolization: Select Procedures – Effective Dec. 1, 2026 3

Updated

- Genetic Testing for Neurological Disorders – Effective Sep. 1, 2026 4
- Preventive Care Services – Effective Oct. 1, 2026 4

Revised

- Obstructive and Central Sleep Apnea Treatment – Effective Nov. 1, 2026 5
- Transarterial Radioembolization (TARE)/Selective Internal Radiation Therapy(SIRT) for the Treatment of Malignant Cancers of the Liver – Effective Nov. 1, 2026..... 8
- Treatment of Temporomandibular Joint Disorders – Effective Oct. 1, 2026 9

Medical Benefit Drug Policy Updates

New

- Otarmeni™ (Lunsotogene Parvec-Cwha) – Effective Oct. 1, 2026 11

Revised

- Itvisma® (Onasemnogene Abeparvovec-Brve) – Effective Oct. 1, 2026 11
- Lumvoa™ (Veligrotug-Vvze) and Tepezza® (Teprotumumab-Trbw) – Effective Oct. 1, 2026 13
- Provider Administered Drugs – Site of Care – Effective Oct. 1, 2026 17
- Tziel® (Teplizumab-Mzwv) – Effective Oct. 1, 2026 19
- Xolair® (Omalizumab) – Effective Nov. 1, 2026 25
- Zolgensma® (Onasemnogene Abeparvovec-Xioi) – Effective Oct. 1, 2026 29

Take Note

Annual ICD-10 and Quarterly CPT/HCPCS Code Updates

Beginning **Oct. 1, 2026**, all applicable Medical Policies and Medical Benefit Drug Policies will be updated to reflect the annual ICD-10 and quarterly CPT/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](#)
- [Centers for Medicare & Medicaid Services: International Classification of Diseases, Tenth Revision \(ICD-10\) Codes](#)

Complete details on impacted policies and corresponding code edits will be provided in the October 2026 edition of the Medical Policy Update Bulletin.

Policy Updates Cancelled: Implanted Electrical Stimulator for the Spinal Cord

The Medical Policy titled *Implanted Electrical Stimulator for the Spinal Cord* will not be updated on Sep. 10, 2026, as previously announced. Details on upcoming changes to this policy will be provided in a future edition of the Medical Policy Update Bulletin.

Medical Policy Updates

New		
Policy Title	Effective Date	Coverage Rationale
Vascular Embolization: Select Procedures	Dec. 1, 2026	Notes: - This policy does not apply to members aged < 18 years. - This policy does not apply to indications involving acute/active bleeding (e.g., gastrointestinal bleed, hemoptysis, bleeding secondary to trauma, and other emergent causes resulting in hemodynamic instability). - For transarterial radioembolization/selective internal radiation therapy for treating malignancies involving the liver, refer to the Medical Policy titled Transarterial Radioembolization (TARE)/Selective Internal Radiation Therapy (SIRT) for the Treatment of Malignant Cancers of the Liver. Transarterial bland embolization or transarterial chemoembolization is proven and medically necessary for treating malignancies involving the liver when certain criteria are met. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Ablative or Transarterial Therapy, Liver. Click here to view the InterQual® criteria. Renal embolization is proven and medically necessary for any of the following indications: - Preoperative treatment of renal cell carcinoma - Palliation of symptomatic renal cell carcinoma - Treatment (as an alternative to surgery) of nonruptured angiomyolipomas that are considered to be at elevated risk for bleeding (e.g., large in size or with rapid growth, large intratumoral aneurysms, hypervascular tumors, female individual of reproductive age or pregnant) For vascular embolization for all other oncological indications, refer to the relevant NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for clinical criteria. Arterial embolization is unproven and not medically necessary for the following indications due to insufficient evidence of efficacy: - Hemorrhoids (hemorrhoidal/rectal arteries) - Musculoskeletal pain, including but not limited to the following: - Knee osteoarthritis (genicular artery) - Shoulder osteoarthritis - Adhesive capsulitis - Tendinitis - Plantar fasciitis

Medical Policy Updates

Updated		
Policy Title	Effective Date	Summary of Changes
Genetic Testing for Neurological Disorders	Sep. 1, 2026	Related Policies - Removed reference link to the Medical Policy titled: - Chromosome Microarray Testing (Non-Oncology Conditions) - Genetic Testing for Cardiac Disease Coverage Rationale - Replaced reference to “<i>multi-gene</i> Targeted Panel testing (five or more genes)” with “Targeted Panel testing of five or more genes” Definitions - Removed definition of: - Whole Exome Sequencing (WES) - Whole Genome Sequencing (WGS) Supporting Information - Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information
Preventive Care Services	Oct. 1, 2026	Related Policies - Removed reference link to the Medical Policy titled: - Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan – Site of Service - Screening Colonoscopy Procedures – Site of Service Coverage Rationale - Added language to clarify <i>certain</i> colonoscopies may require a site of service review - Removed reference link to the Medical Policy titled <i>Screening Colonoscopy Procedures – Site of Service</i> Applicable Codes - Updated list of applicable Pregnancy ICD-10 diagnosis codes to reflect annual edits; added O00.121, O00.122, O00.129, O00.131, O00.132, O00.139, O00.31, O00.32, O00.41, O00.42, O00.511, O00.512, O00.519, O00.521, O00.522, O00.529, O31.40X0, O31.40X1, O31.40X2, O31.40X3, O31.40X4, O31.40X5, O31.40X9, O31.41X0, O31.41X1, O31.41X2, O31.41X3, O31.41X4, O31.41X5, O31.41X9, O31.42X0, O31.42X1, O31.42X2, O31.42X3, O31.42X4, O31.42X5, O31.42X9, O31.43X0, O31.43X1, O31.43X2, O31.43X3, O31.43X4, O31.43X5, and O31.43X9 Preventive Care Services Sudden Cardiac Arrest (SCA) and Sudden Cardiac Death (SCD) – Risk Assessment and ECG Screening - Updated list of applicable ICD-10 diagnosis codes to reflect annual edits: - Added I42.00, I42.01, I42.09, I42.81, I42.89, I47.22, I49.81, I49.82, and I49.89 - Removed I42.0 and I49.8

Medical Policy Updates

Updated			
Policy Title	Effective Date	Summary of Changes	
Preventive Care Services (continued)	Oct. 1, 2026	Expanded Women’s Preventive Health Breast Cancer Screening for Women at Average Risk Breast MRI – To Complete the Screening Process - Added CPT/HCPCS codes 76014, 76015, 76016, 76017, 76018, 76019, and A9573 Average Risk Diagnosis Codes - Updated list of applicable ICD-10 diagnosis codes for Personal History, Genetic Susceptibility or Family History to reflect annual edits; added QA1.790, QA1.791, QA1.792, and QA1.798	
Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment	Nov. 1, 2026	Coverage Rationale Obstructive Sleep Apnea Other Surgical Procedures - Revised list of unproven and not medically necessary procedures; added “radiofrequency ablation of the soft palate and/or tongue base” Supporting Information - Updated <i>Clinical Evidence</i> section to reflect the most current information	Obstructive Sleep Apnea Diagnosis of Obstructive Sleep Apnea for Nonsurgical or Surgical Treatment - An individual presenting with symptoms of Obstructive Sleep Apnea (OSA) has been seen for an evaluation (in person or via telemedicine) with a qualified physician or with an Advanced Practice Provider working under the direct supervision of a physician prior to beginning treatment - A qualified physician or an Advanced Practice Provider working under the direct supervision of a physician will diagnose OSA and recommend the course of treatment Nonsurgical Treatment Removable Oral Appliances are proven and medically necessary for treating OSA meeting the diagnosis requirements above and which has been documented by a sleep study (e.g., Polysomnography (Attended), Home Sleep Apnea Testing). Refer to the Medical Policy titled Sleep Studies for further information. Oral Appliance therapy may be an effective alternative to failed Positive Airway Pressure (PAP) therapy. Documentation from the individual’s treating physician or Advanced Practice Provider that PAP therapy resulted in no therapeutic efficacy, or an individual is intolerant or has refused is required.

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (continued)	Nov. 1, 2026		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. <i>Other Nonsurgical Procedures</i> 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) • Prefabricated Oral Appliance/device • Nonsurgical 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 appliances <i>Surgical Treatment</i> Uvulopalatopharyngoplasty, mandibular osteotomy, and maxillomandibular osteotomy and advancement (MMA) are proven and medically necessary in an adult individual when all the following criteria are met: • Moderate to severe OSA meeting the diagnosis requirements above [Apnea-Hypopnea Index (AHI) ≥ 15 or Respiratory Disturbance Index ≥ 15], as determined by Polysomnography (Attended)* • Excessive daytime sleepiness documented with an Epworth Sleepiness Scale of > 10 or with another validated tool • PAP therapy resulted in no therapeutic efficacy or individual's refusal or intolerance In addition, the following criteria need to be met: • For MMA, craniofacial disproportion or deformities with evidence of maxillomandibular deficiency

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (continued)	Nov. 1, 2026		- For mandibular osteotomy, 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 individual with moderate to severe OSA meeting the diagnosis requirements above when all the following criteria are met: - Body Mass Index of ≤ 40 kg/m²; and - AHI of ≥ 15 and ≤ 100, as determined by Polysomnography (Attended)*; and - Total AHI of $< 25\%$ for central and 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 individual's 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 to 18 years with Down syndrome when all the following criteria are met: - Diagnosis of severe OSA meeting the diagnosis requirements above and [as determined by a Polysomnogram (Attended)* and an AHI ≥ 10 and Respiratory Disturbance Index ≤ 50 events per hour]; and - Body Mass Index of < 95th percentile for age; and - Total AHI of $< 25\%$ for central and 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 adherence; 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 nonconcentric palatal collapse; and - Used in accordance with FDA guidelines

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (continued)	Nov. 1, 2026		*Polysomnography should be repeated if there has been clinically significant weight loss or gain, changes in cardiovascular disease, or persistent or recurrent symptoms since the last study (Caples et al., 2021). 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): • Lingual suspension – Also referred to as tongue stabilization, tongue stitch, and tongue fixation • Isolated hyoid myotomy • Stand-alone uvulectomy • Transoral robotic surgery • Distraction osteogenesis for maxillary expansion • Radiofrequency ablation of the soft palate and/or tongue base Central Sleep Apnea Implantable phrenic nerve stimulation devices (e.g., the remede[®] System) for the treatment of Central Sleep Apnea are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy. Removable Oral Appliances for treating Central Sleep Apnea are unproven and not medically necessary due to insufficient evidence of efficacy.
Transarterial Radioembolization (TARE)/Selective Internal Radiation Therapy (SIRT) for the Treatment of Malignant Cancers of the Liver	Nov. 1, 2026	Coverage Rationale • Revised list of proven and medically necessary indications for Transarterial Radioembolization (TARE)/selective internal radiation therapy (SIRT) using yttrium-90 microspheres; replaced “metastasis from uveal/ocular melanoma when confined to the liver” with	Note: This policy applies to individuals 19 years of age or older. Transarterial Radioembolization (TARE)/selective internal radiation therapy (SIRT) is covered without further review for individuals younger than 19 years of age. Transarterial Radioembolization (TARE)/selective internal radiation therapy (SIRT) using yttrium-90 microspheres is proven and medically necessary for the following indications in individuals with an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2: • Liver-dominant primary hepatocellular carcinoma in individuals who are not surgical candidates • Primary hepatocellular carcinoma as a bridge to liver transplant

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Transarterial Radioembolization (TARE)/Selective Internal Radiation Therapy (SIRT) for the Treatment of Malignant Cancers of the Liver (continued)	Nov. 1, 2026	“metastasis from uveal melanoma when confined to the liver” Definitions - Updated definition of “Transarterial Radioembolization (TARE)” Supporting Information - Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information	- Liver metastases from neuroendocrine tumors in individuals who are not surgical candidates when systemic therapy has failed to control symptoms - Liver metastases from colorectal carcinoma in individuals with chemotherapy-resistant or Refractory disease and with predominant hepatic metastases - Liver metastases from intrahepatic cholangiocarcinoma in individuals who are not surgical candidates - Metastasis from uveal melanoma when confined to the liver Transarterial Radioembolization (TARE)/selective internal radiation therapy (SIRT) using yttrium-90 microspheres is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy.
Treatment of Temporomandibular Joint Disorders	Oct. 1, 2026	Coverage Rationale - Replaced language indicating “the [listed] temporomandibular joint (TMJ) surgical services are proven and medically necessary in certain circumstances” with “temporomandibular joint (TMJ) arthroplasty is proven and medically necessary in certain circumstances” - Revised language pertaining to medical necessity clinical coverage criteria: - Added reference to the InterQual® CP: Procedures, Arthroplasty, Temporomandibular Joint (TMJ) - Removed reference to the: - InterQual® CP: Procedures: - Arthroscopy, Temporomandibular	The following nonsurgical services are proven and medically necessary for treating disorders of the temporomandibular joint (TMJ): - Arthrocentesis - Intra-articular injections of corticosteroids - Trigger point injections - Physical therapy - Occlusal splint (stabilization and repositioning splints) TMJ arthroplasty is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Arthroplasty, Temporomandibular Joint (TMJ). Click here to view the InterQual® criteria. The following services are unproven and not medically necessary for treating disorders of the TMJ due to insufficient evidence of efficacy (this list is not all inclusive): - Biofeedback - Jaw mobility mechanical stretching devices (e.g., TheraBite Jaw Motion Rehabilitation System®, Jaw Dynasplint® System) - Multiple occlusal splints (e.g., daytime and nighttime splints, maxillary and mandibular splints)

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Treatment of Temporomandibular Joint Disorders (continued)	Oct. 1, 2026	- Joint (TMJ) – Discectomy, Temporomandibular Joint (TMJ) – Reconstruction, Temporomandibular Joint (TMJ) ▪ InterQual® Client Defined, CP: Procedures, Arthroplasty, Temporomandibular Joint (TMJ) (Custom) - UHG Applicable Codes - Removed CPT codes 21060, 21247, 29800, and 29804 Supporting Information - Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information	Epigenetic appliances [e.g., Homeoblock™, DNA® (Daytime/Nighttime appliance), Advanced Lightwire Functional appliance] For information regarding intra-articular injections of sodium hyaluronate for TMJ disorders, refer to the Medical Benefit Drug Policy titled Sodium Hyaluronate. For information regarding botulinum toxin injections for TMJ disorders, refer to the Medical Benefit Drug Policies titled Botulinum Toxins A and B (for Commercial Only) and Botulinum Toxins A and B (for Individual Exchange Only).

Medical Benefit Drug Policy Updates

New			
Policy Title	Effective Date	Coverage Rationale	
Otarmeni™ (Lunsotogene Parvec-Cwha)	Oct. 1, 2026	Otarmeni is proven for the treatment of pediatric and adult patients with sensorineural hearing loss when all the following criteria are met: • Diagnosis of severe-to-profound or profound sensorineural hearing loss defined as any frequency > 90 decibel hearing level (dB HL); and • Molecularly confirmed biallelic variants in the <i>OTOF</i> gene; and • Preserved outer hair cell function; and • No prior cochlear implant in the same ear; and • Preoperative imaging demonstrates access to the inner ear is feasible (i.e., no abnormal mastoid pneumatization or clinically significant anatomic variations of the middle ear or inner ear); and • Dosing is in accordance with the U.S. Food and Drug Administration (FDA)–approved labeling; and • Authorization will be issued for no more than one treatment per ear per lifetime and for no longer than 60 days from approval	
Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Itvisma® (Onasemnogene Abeparvovec-Brve)	Oct. 1, 2026	Coverage Rationale • Revised coverage criteria; replaced criterion requiring “the patient is not to receive routine concomitant SMN modifying therapy [e.g., Evrysdi (risdiplam), Spinraza (nusinersen)] (patient’s medical record will be reviewed <i>and any current authorizations for SMN modifying therapy will be terminated upon Itvisma approval</i>)” with “the patient is not to receive routine concomitant SMN modifying therapy [e.g., Evrysdi (risdiplam), Spinraza (nusinersen)] (patient’s medical record will be reviewed)” Supporting Information • Updated <i>References</i> section to reflect the most current information	Itvisma is proven and medically necessary for one treatment per lifetime for the treatment of spinal muscular atrophy (SMA) in patients who meet all of the following criteria: • Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in one of the following: ○ Homozygous gene deletion or mutation of survival motor neuron 1 (<i>SMN1</i>) gene (e.g., homozygous deletion of exon 7 at locus 5q13); or ○ Compound heterozygous mutation of <i>SMN1</i> gene [e.g., deletion of <i>SMN1</i> exon 7 (allele 1) and mutation of <i>SMN1</i> (allele 2)] and • Submission of medical records (e.g., chart notes, laboratory values) confirming that patient has 2 or 3 <i>SMN2</i> gene copies; and • Patient is ≥ 2 years of age; and • Patient is not dependent on either of the following: ○ Invasive ventilation or tracheostomy ○ Use of non-invasive ventilation beyond use for naps and nighttime sleep and • Prescribed by a neurologist with expertise in the treatment of SMA; and

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Itvisma® (Onasemnogene Abeparvovec-Brve) (continued)	Oct. 1, 2026		• Patient is not to receive routine concomitant SMN modifying therapy [e.g., Evrysdi (risdiplam), Spinraza (nusinersen)] (patient's medical record will be reviewed); and • Patient does not have an elevated anti-AAV9 antibody titer above 1:50; and • Patient will receive prophylactic prednisolone (or glucocorticoid equivalent) prior to and following receipt of Itvisma in accordance with the U.S. Food and Drug Administration (FDA)–approved Itvisma labeling; and • Patient will receive Itvisma as a single-dose intrathecal injection in accordance with the FDA-approved labeling; and • Patient has never received gene therapy treatment [i.e., Zolgensma (onasemnogene abeparvovec-xioi), Itvisma] for SMA in the patient's lifetime; and • Provider does not request a planned inpatient admission for the sole purpose of administering Itvisma; and • Authorization will be issued for no more than one treatment per lifetime and for no longer than 45 days from approval Additional Information Relevant to the Review Process but not Impacting the Determination of Medical Necessity • Provider attests that the patient will be assessed via the Hammersmith Functional Motor Scale – Expanded (HFMSE) scale to establish a baseline functional assessment within the 2 weeks prior to Itvisma administration[†]; and • Provider attests that the patient, while under the care of the provider, will be assessed by (HFMSE) during subsequent office visits[†] [†]For quality purposes only, this information will not be considered as part of the individual coverage decision. Itvisma is not proven or medically necessary for: • The treatment of SMA for patients younger than 2 years of age; or • SMA without chromosome 5q mutations or deletions; or • The routine combination treatment of SMA with concomitant SMN modifying therapy

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Lumvoa™ (Veligrotug-Vvze) and Tepezza® (Teprotumumab-Trbw)	Oct. 1, 2026	Title Change - Previously titled <i>Tepezza</i>® (<i>Teprotumumab-Trbw</i>) Template Update - Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans - Added <i>Application</i> section to indicate this policy applies to: - UnitedHealthcare Commercial benefit plans - Individual Exchange benefit plans Coverage Rationale Lumvoa - Added language to indicate: - Lumvoa™ (veligrotug-vvze) 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 Medications</i> for additional details - Lumvoa is proven for the treatment of thyroid eye disease; Lumvoa is medically necessary when all of the following criteria are met: - Diagnosis of thyroid eye disease (TED) - Presence of moderately to severe disease, associated	Lumvoa™ (veligrotug-vvze) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the Medical Benefit Drug Policy titled Review at Launch for New to Market Medications for additional details. Thyroid Eye Disease Lumvoa and Tepezza are proven for the treatment of thyroid eye disease. Lumvoa and Tepezza are medically necessary when all of the following criteria are met: - Diagnosis of thyroid eye disease (TED); and - Presence of moderately to severe disease, associated with at least one of the following: Both of the following: - Presence of symptomatic, active disease; and One of the following: - Lid retraction ≥ 2 mm - Moderate or severe soft tissue involvement - Proptosis ≥ 3 mm above normal for race and sex - Diplopia or Both of the following: - Presence of stable, chronic (inactive) disease; and One of the following: - Greater than or equal to 3 mm in proptosis from before diagnosis of TED; or - Proptosis ≥ 3 mm above normal values for race and sex (i.e., 19 and 21 mm for white female and male patients, respectively; and 23 and 24 mm for black female and male patients, respectively) and One of the following: - Presence of either significant proptosis or diplopia; or Both of the following: - Absence of either significant proptosis or diplopia; and - History of intolerance, failure, or contraindication to oral or intravenous glucocorticoids (e.g., prednisone,

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Lumvoa™ (Veligrotug-Vvze) and Tepezza® (Teprotumumab-Trbw) (continued)	Oct. 1, 2026	with at least one of the following: – Both of the following: • Presence of symptomatic, active disease • One of the following: lid retraction $\geq$ 2 mm, moderate or severe soft tissue involvement, proptosis $\geq$ 3 mm above normal for race and sex, or diplopia – Both of the following: • Presence of stable, chronic (inactive) disease • One of the following: greater than or equal to 3 mm in proptosis from before diagnosis of TED or proptosis $\geq$ 3 mm above normal values for race and sex (i.e., 19 and 21 mm for white female and male patients, respectively; and 23 and 24 mm or black female and male patients, respectively)	methylprednisolone) (For Medicare reviews, refer to the CMS section of the policy.) and • One of the following: ○ Patient is euthyroid [defined as free triiodothyronine (T3) and thyroxine (T4) levels within the normal limits]; or ○ Presence of mild hypo- or hyperthyroidism [defined as free (T3) and (T4) levels less than 50% above or below the normal limits] and patient is undergoing treatment to correct the mild hypo- or hyperthyroidism to maintain a euthyroid state and • Prescribed by an endocrinologist or ophthalmologist; and • One of the following: ○ For Lumvoa, patient has not previously received Tepezza (teprotumumab-trbw); or ○ For Tepezza, patient has not previously received Lumvoa (veligrotug-vvze) and • Patient will not be using Lumvoa or Tepezza in combination with another biologic immunomodulator [e.g., rituximab (Rituxan®, Ruxience®, Truxima®, Riabni®), Actemra® (tocilizumab), Kevzara® (sarilumab)]; and • Dosing is in accordance with the U.S. Food and Drug Administration (FDA)–approved labeling; and • Authorization is limited to a maximum of 5 lifetime doses of Lumvoa and 8 lifetime doses of Tepezza Reauthorization/Continuation of Care Criteria Clinical benefit beyond 5 lifetime infusions of Lumvoa and 8 lifetime infusions of Tepezza has not been demonstrated in phase 3 clinical studies. Therefore, treatment exceeding these limits is considered unproven and not medically necessary.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Lumvoa™ (Veligrotug-Vvze) and Tepezza® (Teprotumumab- Trbw) (continued)	Oct. 1, 2026	▪ One of the following: – Presence of either significant proptosis or diplopia – Both of the following: • Absence of either significant proptosis or diplopia • History of intolerance, failure, or contraindication to oral or intravenous glucocorticoids (e.g., prednisone, methylprednisolone) ▪ One of the following: – Patient is euthyroid [defined as free triiodothyronine (T3) and thyroxine (T4) levels within the normal limits] – Presence of mild hypo- or hyperthyroidism [defined as free (T3) and (T4) levels less than 50% above or below the normal limits] and patient is undergoing treatment to correct the mild hypo- or hyperthyroidism to maintain a euthyroid state ▪ Prescribed by an endocrinologist or	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Lumvoa™ (Veligrotug-Vvze) and Tepezza® (Teprotumumab-Trbw) (continued)	Oct. 1, 2026	ophthalmologist ▪ Patient has not previously received Tepezza (teprotumumab-trbw) ▪ Patient will not be using Lumvoa in combination with another biologic immunomodulator [e.g., rituximab (Rituxan®, Ruxience®, Truxima®, Riabni®), Actemra® (tocilizumab), Kevzara® (sarilumab)] ▪ Dosing is in accordance with the U.S. Food and Drug Administration (FDA)–approved labeling ▪ Authorization is limited to a maximum of 5 lifetime doses of Lumvoa Tepezza • Revised coverage criteria: ○ Added criterion requiring the patient has not previously received Lumvoa (veligrotug-vvze) ○ Replaced criterion requiring “authorization <i>will be issued for</i> a maximum of 8 doses per lifetime” with “authorization <i>is limited to</i> a maximum of 8 lifetime doses” Reauthorization/Continuation of Care Criteria • Replaced language indicating “the clinical benefit of Tepezza has not been demonstrated beyond 8	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Lumvoa™ (Veligrotug-Vvze) and Tepezza® (Teprotumumab- Trbw) (continued)	Oct. 1, 2026	infusions in phase 3 clinical trials; <i>the continued use of Tepezza beyond 8 infusions in the patient's lifetime is unproven and not medically necessary</i> with "clinical benefit beyond 5 lifetime infusions of Lumvoa and 8 lifetime infusions of Tepezza has not been demonstrated in phase 3 clinical studies; <i>therefore, treatment exceeding these limits is considered unproven and not medically necessary</i>" Applicable Codes - Added HCPCS codes J3490 and J3590 Supporting Information - Updated <i>Background, Clinical Evidence, FDA, CMS, and References</i> sections to reflect the most current information	
Provider Administered Drugs – Site of Care	Oct. 1, 2026	Coverage Rationale - Combined and reorganized lists of applicable drug products, documentation requirements, applicable codes, and related policies in the <i>Provider Administered Drugs – Site of Care: Applicable Medications</i> list - Added language to indicate a medication will be subject to this <i>Provider Administered Drugs – Site of Care</i> policy when the medication is listed on the <i>Provider Administered Drugs – Site of Care: Applicable Medications</i> list	A medication will be subject to this Provider Administered Drugs – Site of Care policy when the medication is listed on the Provider Administered Drugs – Site of Care: Applicable Medications. This policy addresses the criteria for consideration of allowing hospital outpatient facility infusion services for specialty medications and intravenous Immune Globulin (IVIG) and subcutaneous Immune Globulin (SCIG) therapy. This includes claim submission for hospital-based services with the following CMS/AMA place of service codes: 19 Off Campus-Outpatient Hospital; and 22 On Campus-Outpatient Hospital Alternative Sites of Care, such as non-hospital outpatient infusion, physician office, ambulatory infusion suites, or home infusion services are well accepted places of service for medication infusion therapy. If an

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (continued)	Oct. 1, 2026	Definitions - Added definition of “Oncology Drugs” Applicable Codes - Replaced list of applicable CPT/HCPCS codes with instruction to refer to the <i>Provider Administered Drugs – Site of Care: Applicable Medications</i> for the list of applicable codes and corresponding medications - Revised list of Provider Administered Drugs – Site of Care: Applicable Medications; added: - Avlayah™ and Loargys® (HCPCS codes C9399, J3490, and J3590) - Bosaya® (HCPCS code Q5161) - Conexence® (HCPCS code Q5158) - Exdensur™ (HCPCS code J2361) - Ospomyv™ (HCPCS code Q5159) - Qivigy® (HCPCS code J1577)	individual does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used. Submission of medical records documenting that outpatient hospital facility-based administration is medically necessary for individuals who meet at least one of the following criteria: - The patient is medically unstable and is at risk of requiring medical services and equipment available only in an outpatient hospital setting (e.g., endotracheal tube, chest tube insertion equipment, cricothyrotomy set, mechanical ventilator) during administration of the requested drug based on one of the following: - History of cardiopulmonary conditions that cause an increased risk of severe adverse reactions during or immediately following infusion; or - An inability to tolerate fluid volume load (for intravenous infusions only) despite using the minimum amount of fluid required for infusion (e.g., unstable renal function); or - Risk of becoming medically unstable due to concomitant use of medications or other drug-drug or drug-disease interaction(s) or - Treatment at an alternative Site of Care presents a health risk due to a clinically significant physical or cognitive impairment; or - Severe patent vascular access issues (for intravenous infusions only) that require specialized equipment only available in an outpatient hospital setting (e.g., ultrasound guidance); or - Previous episode(s) of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure), not including the first or second infusion, that have occurred while receiving requested therapy that was unresponsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual while administering at alternative Sites of Care; or - Initial infusion or re-initiation of previous therapy after more than 6 months (excludes drugs dosed at an interval of 6 months or greater) for a short duration of time (e.g., 4 weeks); or All of the following:

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (continued)	Oct. 1, 2026		- Homecare or home infusion provider has deemed that the individual or home environment is not suitable for home infusion therapy; and - The prescriber is unable to administer in the office setting; and - There are no ambulatory infusion suite options available for this member or For IVIG or SCIG only: Individual has immunoglobulin A (IgA) deficiency with anti-IgA antibodies; or For Oncology Drugs only: - The patient is receiving concurrent chemotherapy or other infusion therapy that would require member to be treated at an outpatient hospital facility; or - The patient is less than 19 years of age; or - The patient is pregnant; or - The patient has immunoglobulin A (IgA) deficiency with anti-IgA antibodies Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative Site of Care. Note: If more than one of the above criteria are met, then the greatest of the applicable approval time periods will be allowed.
Tziel® (Teplizumab-Mzwv)	Oct. 1, 2026	Coverage Rationale Delay Onset of Stage 3 Type 1 Diabetes (T1D) in Adult and Pediatric Patients Aged 1 Year and Older with Stage 2 T1D - Replaced language indicating: "Tziel, administered as a one-time 14-day course of therapy, is proven to delay the onset of stage 3 type 1 diabetes in pediatric and adult patients that meet the [listed] criteria" with "Tziel is proven to delay the	Delay Onset of Stage 3 Type 1 Diabetes (T1D) in Adult and Pediatric Patients Aged 1 Year and Older With Stage 2 T1D Tziel is proven to delay the onset of stage 3 T1D in pediatric and adult patients with stage 2 T1D when all of the following criteria are met: - Patient is 1 year of age or older; and - Diagnosis of stage 2 type 1 diabetes confirmed by all of following: - Presence of at least two positive pancreatic islet autoantibodies - Dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) - Clinical history of patient does not suggest insulin resistance due to obesity, type 2 diabetes (T2D), or dysglycemia due to other forms

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Tziel® (Teplizumab-Mzwv) (continued)	Oct. 1, 2026	onset of stage 3 T1D in pediatric and adult patients <i>with stage 2 T1D</i> when all of the [listed] criteria are met” “Tziel is medically necessary when all of the [listed] criteria are met” with “Tziel is medically necessary <i>to delay the onset of stage 3 T1D in pediatric and adult patients with stage 2 T1D</i> when all of the [listed] criteria are met” - Revised coverage criteria: Proven - Replaced criterion requiring: “Clinical history of patient does not suggest type 2 diabetes (T2D)” with “clinical history of patient does not suggest <i>insulin resistance due to obesity, T2D, or dysglycemia due to other forms of diabetes [e.g., genetic forms of diabetes, maturity-onset diabetes of the young (MODY), latent autoimmune diabetes in adults (LADA), diabetes secondary to medications or surgery]</i>” “Authorization will be issued for no more than <i>14 doses</i>” with “authorization will be issued for no more than <i>one 14-dose treatment course per lifetime</i>”	of diabetes [e.g., genetic forms of diabetes, maturity-onset diabetes of the young (MODY), latent autoimmune diabetes in adults (LADA), diabetes secondary to medications or surgery] and - Dosing is in accordance with the U.S. Food and Drug Administration (FDA)–approved labeling; and - Patient has not been previously treated with Tziel; and - Authorization will be issued for no more than one 14-dose treatment course per lifetime Tziel is medically necessary to delay the onset of stage 3 T1D in pediatric and adult patients with stage 2 T1D when all of the following criteria are met: - Patient is 1 year of age or older; and - Diagnosis of stage 2 type 1 diabetes confirmed by all of the following: - Presence of at least two of the following pancreatic islet autoantibodies: - Glutamic acid decarboxylase 65 (GAD) autoantibodies - Insulin autoantibody (IAA) - Insulinoma-associated antigen 2 autoantibody (IA-2A) - Zinc transporter 8 autoantibody (ZnT8A) - Islet cell autoantibody (ICA) and - Presence of dysglycemia without overt hyperglycemia defined by one of the following: - Fasting plasma glucose ≥ 100 mg/dL and < 126 mg/dL; or 2-hour post-prandial plasma glucose level ≥ 140 mg/dL and < 200 mg/dL; or - A1C ≥ 5.7 and $< 6.5\%$ or $\geq 10\%$ increase in A1C and - Patient does not have symptoms associated with stage 3 type 1 diabetes (e.g., increased urination, excessive thirst, weight loss); and - Clinical history of patient does not suggest insulin resistance due to obesity, type 2 diabetes (T2D), or dysglycemia due to other forms of diabetes [e.g., genetic forms of diabetes, maturity-onset

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Tziel® (Teplizumab-Mzwv) (continued)	Oct. 1, 2026	Medically Necessary - Added criterion requiring clinical history of patient does not suggest insulin resistance due to obesity, type 2 diabetes (T2D), or dysglycemia due to other forms of diabetes [e.g., genetic forms of diabetes, maturity-onset diabetes of the young (MODY), latent autoimmune diabetes in adults (LADA), diabetes secondary to medications or surgery] - Removed criterion requiring diagnosis of T2D has been ruled out - Replaced criterion requiring “authorization will be issued for no more than one treatment course (<i>i.e.</i>, 14 doses) per lifetime” with “authorization will be issued for no more than one 14-dose treatment course per lifetime” Delay Decline in Beta Cell Function in Pediatric Patients Aged 8 to 17 Years with Recently Diagnosed Stage 3 T1D - Added language to indicate: - Tziel is proven to delay the decline in beta cell function in pediatric patients with recently diagnosed stage 3 T1D when all of the following criteria are met: - Patient is aged 8 to 17 years	diabetes of the young (MODY), latent autoimmune diabetes in adults (LADA), diabetes secondary to medications or surgery] and - Prescribed by or in consultation with an endocrinologist; and - Dosing is in accordance with the FDA-approved labeling; and - Patient has not been previously treated with Tziel; and - Authorization will be issued for no more than one 14-dose treatment course per lifetime Delay Decline in Beta Cell Function in Pediatric Patients Aged 8 to 17 Years With Recently Diagnosed Stage 3 T1D Tziel is proven to delay the decline in beta cell function in pediatric patients with recently diagnosed stage 3 T1D when all of the following criteria are met: - Patient is aged 8 to 17 years; and - Recent diagnosis (<i>i.e.</i>, within the last 8 weeks) of stage 3 T1D; and - Diagnosis of stage 3 T1D confirmed by all of the following: - Presence of at least one positive pancreatic islet cell autoantibody; and - Peak C-peptide ≥ 0.2 pmol/mL on a mixed-meal tolerance test (MMTT); and - Clinical history of patient does not suggest insulin resistance due to obesity, type 2 diabetes (T2D), or dysglycemia due to other forms of diabetes [e.g., genetic forms of diabetes, maturity-onset diabetes of the young (MODY), latent autoimmune diabetes in adults (LADA), diabetes secondary to medications or surgery] and - Dosing is in accordance with the FDA-approved labeling; and - Patient has not been previously treated with Tziel; and - Authorization will be issued for no more than two 12-dose treatment courses per lifetime Tziel is medically necessary to delay the decline in beta cell function in pediatric patients with recently diagnosed stage 3 T1D when all of the following criteria are met:

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Tziel® (Teplizumab-Mzwv) (continued)	Oct. 1, 2026	▪ Recent diagnosis (i.e., within the last 8 weeks) of stage 3 T1D ▪ Diagnosis of stage 3 T1D confirmed by all of the following: – Presence of at least one positive pancreatic islet cell autoantibody – Peak C-peptide ≥ 0.2 pmol/mL on a mixed-meal tolerance test (MMTT) – Clinical history of patient does not suggest insulin resistance due to obesity, T2D, or dysglycemia due to other forms of diabetes (e.g., genetic forms of diabetes, MODY, LADA, diabetes secondary to medications or surgery) ▪ Dosing is in accordance with the U.S. Food and Drug Administration (FDA)–approved labeling ▪ Patient has not been previously treated with Tziel ▪ Authorization will be issued for no more than two 12-dose treatment courses per lifetime ○ Tziel is medically necessary to delay the decline in beta cell	• Patient is aged 8 to 17 years; and • Recent diagnosis (i.e., within the last 8 weeks) of stage 3 T1D; and • Diagnosis of stage 3 T1D confirmed by all of the following: ○ Presence of at least one of the following pancreatic islet autoantibodies: ▪ Glutamic acid decarboxylase 65 (GAD) autoantibodies ▪ Insulin autoantibody (IAA) ▪ Insulinoma-associated antigen 2 autoantibody (IA-2A) ▪ Zinc transporter 8 autoantibody (ZnT8A) ▪ Islet cell autoantibody (ICA) and ○ Peak C-peptide ≥ 0.2 pmol/mL on a mixed-meal tolerance test (MMTT); and ○ Clinical history of patient does not suggest insulin resistance due to obesity, type 2 diabetes (T2D), or dysglycemia due to other forms of diabetes [e.g., genetic forms of diabetes, maturity-onset diabetes of the young (MODY), latent autoimmune diabetes in adults (LADA), diabetes secondary to medications or surgery] and • Prescribed by or in consultation with an endocrinologist; and • Dosing is in accordance with the FDA-approved labeling; and • Patient has not been previously treated with Tziel; and • Authorization will be issued for no more than two 12-dose treatment courses per lifetime

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Tziel® (Teplizumab-Mzwv) (continued)	Oct. 1, 2026	function in pediatric patients with recently diagnosed stage 3 T1D when all of the following criteria are met: ▪ Patient is aged 8 to 17 years ▪ Recent diagnosis (i.e., within the last 8 weeks) of stage 3 T1D ▪ Diagnosis of stage 3 T1D confirmed by all of the following: – Presence of at least one of the following pancreatic islet autoantibodies: • Glutamic acid decarboxylase 65 (GAD) autoantibodies • Insulin autoantibody (IAA) • Insulinoma-associated antigen 2 autoantibody (IA-2A) • Zinc transporter 8 autoantibody (ZnT8A) • Islet cell autoantibody (ICA) – Peak C-peptide ≥ 0.2 pmol/mL on a MMTT – Clinical history of patient does not suggest insulin resistance due to	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Tziel® (Teplizumab-Mzwv) (continued)	Oct. 1, 2026	obesity, T2D, or dysglycemia due to other forms of diabetes (e.g., genetic forms of diabetes, MODY, LADA, diabetes secondary to medications or surgery) - Prescribed by or in consultation with an endocrinologist - Dosing is in accordance with the FDA-approved labeling - Patient has not been previously treated with Tziel - Authorization will be issued for no more than two 12-dose treatment courses per lifetime Applicable Codes - Added ICD-10 diagnosis codes E10.10, E10.11, E10.21, E10.22, E10.29, E10.311, E10.319, E10.3211, E10.3212, E10.3213, E10.3219, E10.3291, E10.3292, E10.3293, E10.3299, E10.3311, E10.3312, E10.3313, E10.3319, E10.3391, E10.3392, E10.3393, E10.3399, E10.3411, E10.3412, E10.3413, E10.3419, E10.3491, E10.3492, E10.3493, E10.3499, E10.3511, E10.3512, E10.3513, E10.3519, E10.3521, E10.3522, E10.3523, E10.3529, E10.3531, E10.3532, E10.3533, E10.3539, E10.3541, E10.3542, E10.3543,	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Tziel® (Teplizumab-Mzwv) (continued)	Oct. 1, 2026	E10.3549, E10.3551, E10.3552, E10.3553, E10.3559, E10.3591, E10.3592, E10.3593, E10.3599, E10.36, E10.37X1, E10.37X2, E10.37X3, E10.37X9, E10.39, E10.40, E10.41, E10.42, E10.43, E10.44, E10.49, E10.51, E10.52, E10.59, E10.610, E10.618, E10.620, E10.621, E10.622, E10.628, E10.630, E10.638, E10.641, E10.649, E10.65, E10.69, E10.8, E10.9, E10.A0, E10.A1, and E10.A2 - Removed ICD-10 diagnosis codes E10.8 and E10.9 Supporting Information - Updated <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information	
Xolair® (Omalizumab)	Nov. 1, 2026	Template Update - Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans - Added <i>Application</i> section to indicate this policy applies to: - UnitedHealthcare Commercial benefit plans - Individual Exchange benefit plans Coverage Rationale - Added language to indicate: - Omlyclo® (omalizumab-igec) has been added to the Review at Launch program and some members may not be eligible for coverage of this medication at	This policy refers to Xolair (omalizumab) subcutaneous injection for administration by a healthcare professional. Xolair (omalizumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Refer to the policy for complete details.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Xolair® (Omalizumab) (continued)	Nov. 1, 2026	this time; refer to the Medical Benefit Drug Policy titled <i>Review at Launch for New to Market Medications</i> for additional details - Replaced language indicating: <i>Moderate to Severe Persistent Asthma</i> “Xolair for provider administration is proven for patients with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen, symptoms inadequately controlled with inhaled corticosteroids, and a <i>baseline plasma immunoglobulin E (IgE) level greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL</i>” with “Xolair for provider administration is proven for patients with moderate to severe persistent asthma with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids” <i>Nasal Polyps</i> “Xolair (<i>omalizumab</i>) for provider administration is proven for patients with nasal polyps <i>who have a diagnosis of nasal polyps, had</i> inadequate	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Xolair® (Omalizumab) (continued)	Nov. 1, 2026	response to nasal corticosteroids (e.g., <i>fluticasone, mometasone, triamcinolone</i>), and continues current maintenance therapy” with “Xolair for provider administration is proven as <i>add-on maintenance treatment</i> for patients with <i>chronic rhinosinusitis with nasal polyps (CRSwNP)</i> with an inadequate response to nasal corticosteroids” <i>IgE Mediated Food Allergy</i> ○ “Xolair (<i>omalizumab</i>) for provider administration is proven for patients with IgE-mediated food allergy who <i>have a diagnosis of IgE-mediated food allergy, are aged ≥ 1 year, and Xolair will be used in conjunction with food allergen avoidance</i>” with “Xolair for provider administration is proven for patients with IgE-mediated food allergy <i>for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods, to be used in conjunction with food allergen avoidance</i>” ● Revised coverage criteria for: <i>Moderate to Severe Persistent Asthma</i> ○ Updated list of examples of anti-interleukin 5 therapy products	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Xolair® (Omalizumab) (continued)	Nov. 1, 2026	the patient must not be receiving in combination with Xolair; added Exdensur (depemokimab) Chronic Urticaria - Replaced reference to “Xolair (omalizumab)” with “Xolair” - Added criterion for initial therapy requiring the patient remains symptomatic despite at least a 2-week trial of up dosing a 2nd generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)], up to 4-fold, after being unresponsive to at least a 2-week trial of a standard-dosed 2nd generation H1-antihistamine - Updated list of examples of anti-interleukin 5 therapy products the patient must not be receiving in combination with Xolair; added Exdensur (depemokimab) and Nucala (mepolizumab) Nasal Polyps - Updated list of examples of anti-interleukin 5 therapy products the patient must not be receiving in combination with Xolair; added Exdensur (depemokimab) IgE Mediated Food Allergy - Updated list of examples of anti-interleukin 5 therapy products the patient must not be receiving in combination with	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Xolair® (Omalizumab) (continued)	Nov. 1, 2026	Xolair; added Exdensusur (depemokimab) Supporting Information Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information	
Zolgensma® (Onasemnogene Abeparvovec-Xioi)	Oct. 1, 2026	Template Update - Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans - Added <i>Application</i> section to indicate this policy applies to: - UnitedHealthcare Commercial benefit plans - Individual Exchange benefit plans Coverage Rationale - Revised coverage criteria; replaced criterion requiring “the patient is not to receive routine concomitant SMN modifying therapy [e.g., Evrysdi (risdiplam), Spinraza (nusinersen)] (patient’s medical record will be reviewed <i>and any current authorizations for SMN modifying therapy will be terminated upon Zolgensma approval</i>)” with “the patient is not to receive routine concomitant SMN modifying therapy [e.g., Evrysdi (risdiplam), Spinraza (nusinersen)] (patient’s medical record will be reviewed)” Supporting Information - Updated <i>References</i> section to reflect the most current information	Zolgensma is proven and medically necessary for one treatment per lifetime for the treatment of spinal muscular atrophy (SMA) in patients who meet all of the following criteria: - Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in one of the following: - Homozygous gene deletion or mutation of survival motor neuron 1 (SMN1) gene (e.g., homozygous deletion of exon 7 at locus 5q13); or - Compound heterozygous mutation of SMN1 gene [e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2)] and One of the following: - Diagnosis of symptomatic SMA by a neurologist with expertise in the diagnosis of SMA; or Both of the following: - Diagnosis of SMA based on the results of SMA newborn screening; and - Submission of medical records (e.g., chart notes, laboratory values) confirming that patient has 4 copies or less of SMN2 gene and - For use in a neonatal patient born prematurely, the full-term gestational age has been reached; and - Patient is less than 2 years of age; and - Patient is not dependent on either of the following: - Invasive ventilation or tracheostomy - Use of non-invasive ventilation beyond use for naps and nighttime sleep and

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Zolgensma® (Onasemnogene Abeparvovec-Xioi) (continued)	Oct. 1, 2026		• Zolgensma is prescribed by a neurologist with expertise in the treatment of SMA; and • Patient is not to receive routine concomitant SMN modifying therapy [e.g., Evrysdi (risdiplam), Spinraza (nusinersen)] (patient's medical record will be reviewed); and • Patient does not have an elevated anti-AAV9 antibody titer above 1:50; and • Patient will receive prophylactic prednisolone (or glucocorticoid equivalent) prior to and following receipt of Zolgensma in accordance with the U.S. Food and Drug Administration (FDA)–approved Zolgensma labeling; and • Patient will receive Zolgensma intravenously in accordance with the FDA-approved labeling; and • Patient has never received Zolgensma treatment in the patient's lifetime; and • Provider does not request a planned inpatient admission for the sole purpose of administering Zolgensma; and • Authorization will be issued for no more than one treatment per lifetime and for no longer than 45 days from approval or until 2 years of age, whichever is first Additional Information Relevant to the Review Process but not Impacting the Determination of Medical Necessity • Physician attests that the patient, while under the care of the physician, will be assessed by one of the following exam scales during subsequent office visits:[†] ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) scale during subsequent office visits while the patient is 2 to 3 years of age or younger; or ○ Hammersmith Functional Motor Scale Expanded (HFMSE) during subsequent office visits while the patient is 2 to 3 years of age or older and

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Zolgensma® (Onasemnogene Apeparvovec-Xioi) (continued)	Oct. 1, 2026		- Physician attests that the patient will be assessed via the CHOP INTEND scale to establish a baseline functional assessment within the following timelines:[†] - For patients greater than 2 months of age at the time of Zolgensma administration, a baseline CHOP INTEND score will be assessed within the 2 weeks prior to Zolgensma administration; or - For patients less than or equal to 2 months of age at the time of Zolgensma administration, a baseline CHOP INTEND score will be assessed within the 2 weeks prior to or the 2 weeks following Zolgensma administration [†]For quality purposes only, this information will not be considered as part of the individual coverage decision. Zolgensma is not proven or medically necessary for: - The treatment of pre-symptomatic patients diagnosed by newborn screening who have more than 4 copies of the SMN2 gene; or - The treatment of symptomatic later-onset SMA older than 2 years of age; or - SMA without chromosome 5q mutations or deletions; or - The routine combination treatment of SMA with concomitant SMN modifying therapy

General Information

The inclusion of a health service (e.g., test, drug, device, or procedure) in this bulletin indicates only that UnitedHealthcare is adopting a new policy and/or updated, revised, replaced, or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the health service. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a health service must be determined in accordance with the member's benefit plan and any applicable federal or state regulatory requirements. Additionally, UnitedHealthcare reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Medical Policy Update Bulletin was developed to share important information regarding 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](#).