United Healthcare Community Plan

UnitedHealthcare Community Plan
Medical Policy Update Bulletin: September 2025

In This Issue

Take Note

Medical Policy Updates

Updated

Revised

Retired

Medical Benefit Drug Policy Updates

Updated

In This Issue

Revised

Take Note

Annual ICD-10 and Quarterly CPT/HCPCS Code Updates

Beginning **Oct. 1, 2025**, 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 2025 edition of the Medical Policy Update Bulletin.

Medical Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Autologous Cellular Therapy	Nov. 1, 2025	**Applicable Codes** • Removed CPT code 27599 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information

Cochlear Implants	Sep. 1, 2025	**Medical Records Documentation Used for Reviews**
		• Added language to indicate:
		  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service
		  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews

Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Nov. 1, 2025	**Coverage Rationale** • Replaced references to “non-intensive *insulin* treatment plan” with “non-intensive treatment plan” **Applicable Codes** • Removed CPT code 0447T **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
Cosmetic and Reconstructive Procedures	Nov. 1, 2025	**Definitions** • Updated definition of “Microtia” **Applicable Codes** • Added CPT codes 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, and 15876 **Supporting Information** • Updated *References* section to reflect the most current information

Mandatory Medicaid Coverage of Routine Patient Costs in Qualifying Clinical Trials	Sep. 1, 2025	**Medical Records Documentation Used for Reviews**
		• Added language to indicate:
		  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service
		  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews
		Supporting Information
		• Updated *FDA* section to reflect the most current information

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes

Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache)	Sep. 1, 2025	**Definitions**
		• Added definition of:
		  ○ Migraine Disability Assessment Test (MIDAS)
		  ○ Migraine-Specific Quality of Life Questionnaire (MSQ)
		Supporting Information
		• Updated *Clinical Evidence* and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech)	Nov. 1, 2025	**Coverage Rationale**
		• Added language (relocated from *Benefit Considerations* section) to indicate the services must not be duplicate services of another service provided concurrently by any other type of therapy (such as speech, physical, and occupational therapy) and must provide different treatment goals, plans, and therapeutic modalities
		Speech and Language Considerations
		• Added language (relocated from *Benefit Considerations* section) to indicate:
		  ○ Bilingual and multilingual speakers are frequently misclassified as developmentally delayed; equivalent proficiency in both languages should not be expected
		  ○ Individuals with limited English proficiency must receive culturally and linguistically adapted norm referenced standardized
			Note: This Medical Policy does not apply to cognitive therapy. For outpatient cognitive therapy, refer to the Medical Policy titled Cognitive Rehabilitation.
			
			Habilitation, rehabilitation, and maintenance are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® LOC: Outpatient Rehabilitation & Chiropractic.
			
			Click here to view the InterQual® criteria.
			
			Note: Upon clinical review and when appropriate, UnitedHealthcare may authorize therapies based on the medical necessity criteria above for up to six months in accordance with generally accepted standards of practice. The services must not be duplicate services of another service provided concurrently by any other type of therapy (such as speech, physical, and occupational therapy), and must provide different treatment goals, plans, and therapeutic modalities.
			
			The documentation requirements outlined in the policy are used in addition to InterQual® to assess whether the individual meets the clinical criteria for coverage, but does not guarantee coverage of the service requested.
			
			Refer to the policy for complete details.

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech) (continued)	Nov. 1, 2025	testing in all languages the child is exposed to in order to compare potential deficits ○ For speech and language therapy services for an individual with limited English proficiency, all of the following criteria must be met: ▪ All speech deficits must be present in the language in which the individual has the highest proficiency ▪ Language deficits must be present in the language in which the individual has the highest proficiency ▪ Delivery of services must be in the language in which the individual has the highest receptive language proficiency ○ For individuals with dyslexia, test results substantiating a diagnosis of receptive or expressive language delay must be included with goals addressing the corresponding language deficits (ASLHA) **Supporting Information** ● Added *Clinical Evidence* section ● Updated *Description of Services* and *References* sections to reflect the most current information ● Removed *Benefit Considerations* section	

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment	Nov. 1, 2025	**Coverage Rationale** ***Surgical Treatment*** • Added notation to indicate polysomnography should be repeated if there has been clinically significant weight loss or gain, changes in cardiovascular disease, or there are persistent or recurrent symptoms since the last study • Revised coverage criteria for: Uvulopalatopharyngoplasty (UPPP), Mandibular Osteotomy (MO), and Maxillomandibular Osteotomy and Advancement (MMA) in an Adult Patient ○ Replaced criterion requiring "*diagnosis of* moderate to severe Obstructive Sleep Apnea (OSA) [Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) ≥ 15]" with "moderate to severe OSA [Apnea Hypopnea Index (AHI) ≥ *15* or Respiratory Disturbance Index (RDI) ≥ 15] *as determined by Polysomnography (Attended)*" Implantable Hypoglossal Nerve Stimulation with a U.S. Food and Drug Administration (FDA) Approved Device in Adolescents Aged 10-18 Years With Down Syndrome	**Non-Surgical Treatment** **Removable Oral Appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) as documented by a sleep study (e.g., Polysomnography or Home Sleep Apnea Testing).** Refer to the Medical Policy titled Sleep Studies for further information. For many individuals, Oral Appliance therapy (OAT) may be an effective alternative to failed positive airway pressure (PAP) therapy. Documentation of the following is required: • A patient presenting with symptoms of OSA has been seen in a face-to-face evaluation with a qualified physician (MD or DO) trained in sleep medicine or with an Advanced Practice Provider working under the direct supervision of a physician trained in sleep medicine prior to beginning treatment for OAT (AASM and AADSM, December 2012, AAO-HNS, November 2019) • A treating physician (MD or DO) or an Advanced Practice Provider must diagnose OSA and recommend course of treatment (AAO-HNS, November 2019) • If PAP therapy results in no therapeutic efficacy or patient intolerance or refusal, documentation from the patient's treating physician (MD or DO) or an Advanced Practice Provider must be supplied For information on snoring and Oral Appliances, refer to the Medical Policy titled Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements. For medical necessity clinical coverage criteria for removable Oral Appliances, refer to the InterQual® CP: Durable Medical Equipment, Noninvasive Airway Assistive Devices. Click here to view the InterQual® criteria. **Other Non-Surgical Procedures** **The following are unproven and not medically necessary due to insufficient evidence of efficacy:** • Devices for treating Positional OSA • Nasal dilator devices for treating OSA

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (continued)	Nov. 1, 2025	○ Replaced criterion requiring "diagnosis of severe OSA (as determined by a *Polysomnogram within 24 months* and an AHI ≥ 10 and RDI ≤ 50 events per hour)" with "diagnosis of severe OSA [as determined by *Polysomnography (Attended)* and an AHI ≥ 10 and RDI ≤ 50 events per hour]" **Definitions** • Added definition of "Respiratory Disturbance Index (RDI)" **Applicable Codes** • Added CPT/HCPCS codes 0964T, 0965T, 0966T, and E0490 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	• Intranasal expiratory resistance valve (e.g., Bongo Rx) • Removable Oral Appliances for treating Central Sleep Apnea • Prefabricated Oral Appliance/device • Non-surgical electrical muscular training • Mandibular vertical repositioning devices (e.g., Slow Wave) • Morning repositioning devices • Epigenetic appliances [e.g., Homeoblock™, DNA® (Daytime/Nighttime appliance)] • Advanced Lightwire Functional (ALF) appliances **Surgical Treatment** **Uvulopalatopharyngoplasty (UPPP), mandibular osteotomy (MO), and maxillomandibular osteotomy and advancement (MMA) are proven and medically necessary in an adult patient when all the following criteria are met:** • Moderate to severe OSA [Apnea Hypopnea Index (AHI) ≥ 15 or Respiratory Disturbance Index (RDI) ≥ 15] as determined by Polysomnography* (Attended) • Excessive daytime sleepiness documented with an Epworth Sleepiness Scale (ESS) > 10 or with another validated tool • PAP therapy resulted in no therapeutic efficacy or patient refusal or intolerance In addition, the following criteria needs to be met: • For MMA, craniofacial disproportion or deformities with evidence of maxillomandibular deficiency • For MO, retrolingual or lower pharyngeal function obstruction **Implantable hypoglossal nerve stimulation with a U.S. Food and Drug Administration (FDA) approved device is proven and medically necessary in an adult patient with moderate to severe OSA when all the following criteria are met:** • Body Mass Index (BMI) of less than or equal to 40 kg/m^2; and • AHI of ≥ 15 and ≤ 100 as determined by Polysomnography (Attended)*; and

Revised

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

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (continued)	Nov. 1, 2025		**necessary for treating OSA due to insufficient evidence of efficacy (not an all-inclusive list):** • Laser-assisted uvulopalatoplasty (LAUP) • Lingual suspension – also referred to as tongue stabilization, tongue stitch, or tongue fixation • Isolated hyoid myotomy • Stand-alone uvulectomy • Palatal implants • Radiofrequency ablation of the soft palate and/or tongue base • Transoral robotic surgery (TORS) • Distraction osteogenesis for maxillary expansion (DOME)

Panniculectomy Surgery	Nov. 1, 2025	**Title Change**
		• Previously titled *Panniculectomy and Body Contouring Procedures*
		Coverage Rationale
		• Removed language indicating body contouring procedures, including but not limited to the following, are considered cosmetic and not medically necessary:
		  ○ Abdominoplasty
		  ○ Lipectomy, including suction-assisted lipectomy (unless part of an approved procedure)
		  ○ Repair of diastasis recti
		• Updated instruction to refer to the Medical Policy titled *Breast Reconstruction for information on liposuction when being performed* post-mastectomy
		Definitions
		• Removed definition of:
		  ○ Abdominoplasty
		  ○ Diastasis Recti
			Panniculectomy
			Panniculectomy is considered reconstructive and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Panniculectomy, Abdominal.
			
			Click here to view the InterQual® criteria.
			
			Panniculectomy is considered cosmetic and not medically necessary when performed for the following indications:
			• For any other condition that does not meet the InterQual® criteria
			• In conjunction with abdominal or gynecologic surgery, including but not limited to hernia repair, bariatric surgery, C-section, or hysterectomy, unless the member meets the InterQual® CP: Procedures, Panniculectomy, Abdominal criteria
			• When performed for primarily cosmetic purposes
			
			Notes:
			• For information on liposuction for lipedema, refer to the Medical Policy titled Liposuction for Lipedema.
			• For information on liposuction when being performed post-mastectomy, refer to the Medical Policy titled Breast Reconstruction.

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Panniculectomy Surgery (continued)	Nov. 1, 2025	○ Functional or Physical or Physiological Impairment ○ Suction Assisted Lipectomy **Applicable Codes** • Removed CPT codes 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, and 15876 **Supporting Information** • Updated *Description of Services, Clinical Evidence, FDA*, and *References* sections to reflect the most current information	
Skin and Soft Tissue Substitutes	Nov. 1, 2025	**Coverage Rationale** • Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication; added: ○ AdvoGraft Dual and AdvoGraft One ○ AeroGuard and NeoGuard ○ AmchoPlast EXCEL ○ AmchoThick ○ AmnioDefend FT Matrix ○ AmnioPlast 3 ○ Duograft AA, duoGRAFT AC, and triGRAFT FT ○ Membrane Wrap-Lite ○ Renew FT Matrix **Applicable Codes** • Added HCPCS codes Q4368, Q4369, Q4370, Q4371, Q4372, Q4373, Q4375, Q4376, Q4377, Q4378, Q4379, Q4380, and Q4382	**EpiFix or Grafix® (GrafixPL, GrafixPRIME, and GrafixPL PRIME) (Non-Injectable)** **EpiFix or Grafix is proven and medically necessary for treating a diabetic foot ulcer when all of the following criteria are met:** • Adequate circulation to the affected extremity as indicated by one or more of the following: ○ Pedal pulses palpable or pulses confirmed with doppler examination ○ Ankle-brachial index (ABI) between 0.7 and 1.2 • Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days) • Ulcer has failed to demonstrate adequate healing with at least 4 weeks of standard wound care which includes **all** of the following: ○ Application of dressings to maintain a moist wound environment ○ Debridement of necrotic tissue if present ○ Offloading • No known contraindications which may include but are not limited to the following: ○ Active Charcot deformity or major structural abnormalities of the affected foot ○ Chronic infection to the ulcer site ○ Known or suspected malignancy of the current ulcer being treated ○ Ulcer being treated does not extend to tendon, muscle, capsule, or bone

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Skin and Soft Tissue Substitutes (continued)	Nov. 1, 2025	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	***EpiFix and Grafix Application Limitations*** • EpiFix is limited to one application per week for up to 12 weeks. • Grafix is limited to one application per week for up to 12 weeks. **Due to insufficient evidence of efficacy, EpiFix and/or Grafix are unproven and not medically necessary for all other indications including but not limited to:** • EpiFix application more frequently than once a week or beyond 12 weeks • Grafix application more frequently than once a week or beyond 12 weeks **TransCyte™** **TransCyte is proven and medically necessary for treating surgically excised Full-Thickness Thermal Burn wounds and deep Partial-Thickness Thermal Burn wounds before autograft placement.** **TransCyte is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy.** **Other Skin and Soft Tissue Substitutes** Other skin and soft tissue substitutes listed in the policy are unproven and not medically necessary for any indication due to insufficient evidence of efficacy. Refer to the Medical Policy titled Breast Reconstruction for information about coverage for skin and soft tissue substitutes used during post mastectomy breast reconstruction procedures. **Note**: Refer to the *Clinical Evidence* section of the policy for specific product information. Refer to the policy for complete details.
Surgery of the Shoulder	Nov. 1, 2025	**Coverage Rationale** • Revised language pertaining to medical necessity clinical coverage criteria:	**Surgery of the shoulder is proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the: • InterQual® CP: Procedures: ○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Shoulder (continued)	Nov. 1, 2025	○ Added reference to the InterQual® CP: Procedures, Removal and Replacement or Revision, Joint Replacement, Shoulder ○ Removed reference to the: ▪ InterQual® CP Procedures: – Arthrotomy, Shoulder – Removal and Replacement, Total Joint Replacement (TJR), Shoulder ▪ InterQual® Client Defined, CP: Procedures, Revision, Total Joint Replacement (TJR), Shoulder (Custom) - UHG **Medical Records Documentation Used for Reviews** • Added language to indicate: ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to	○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder (Adolescent) ○ Arthroscopy, Diagnostic, +/- Synovial Biopsy, Shoulder ○ Joint Replacement, Shoulder ○ Removal and Replacement or Revision, Joint Replacement, Shoulder Click here to view the InterQual® criteria. **Subacromial balloon spacers for the treatment of rotator cuff tears are unproven and not medically necessary due to insufficient evidence of efficacy.**

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Shoulder (continued)	Nov. 1, 2025	the guidelines titled Medical Records Documentation Used for Reviews **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Retired

Policy Title	Effective Date	Summary of Changes
Diagnostic Spinal Ultrasonography	Sep. 1, 2025	• Retired policy; diagnostic spinal ultrasonography no longer requires clinical review
Neuropsychological Testing Under the Medical Benefit	Sep. 1, 2025	• Retired policy; neuropsychological testing under the medical benefit no longer requires clinical review

Medical Benefit Drug Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Benlysta® (Belimumab)	Sep. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
Brineura® (Cerliponase Alfa)	Sep. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
Elevidys™ (Delandistrogene Moxparvovec-Rokl)	Sep. 1, 2025	**Application** ***North Carolina*** • Added instruction to refer to the state's Medicaid clinical policy
Enjaymo® (Sutimlimab-Jome)	Sep. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
Evkeeza® (Evinacumab-Dgnb)	Sep. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
FcRn Blockers (Rystiggo®, Vyvgart®, & Vyvgart Hytrulo®)	Sep. 1, 2025	**Application** ***Arizona*** • Added instruction to refer to the state's Medicaid clinical policy for all applicable drug products listed in the policy
Gene Therapies for Hemophilia B	Nov. 1, 2025	**Application** ***North Carolina*** • Removed language indicating this Medical Benefit Drug Policy does not apply to the state of **North Carolina**
Gonadotropin Releasing Hormone Analogs	Sep. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy and use the drug-specific criteria, if available for the specific product, otherwise this medical benefit drug policy applies
Luxturna® (Voretigene Neparvovec-Rzyl)	Nov. 1, 2025	**Application** ***North Carolina*** • Removed language indicating this Medical Benefit Drug Policy does not apply to the state of **North Carolina**

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Ophthalmologic Complement Inhibitors	Sep. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
Roctavian® (Valoctocogene Roxaparvovec-Rvox)	Nov. 1, 2025	**Application** ***North Carolina*** • Removed language indicating this Medical Benefit Drug Policy does not apply to the state of **North Carolina**
Tepezza® (Teprotumumab-Trbw)	Sep. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
Tezspire® (Tezepelumab-Ekko)	Sep. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
Zolgensma® (Onasemnogene Abeparvovec-Xioi)	Sep. 1, 2025	**Application** ***North Carolina*** • Added instruction to refer to the state's Medicaid clinical policy

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Complement Inhibitors	Oct. 1, 2025	**Title Change** • Previously titled *Complement Inhibitors (PiaSky®, Soliris®, & Ultomiris®)* **Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy **Coverage Rationale** • Revised list of applicable complement inhibitor drug products; added:	This policy refers only to the following complement inhibitor drug products: • Bkemv™ (eculizumab-aeeb) • Epysqli® (eculizumab-aagh) • PiaSky® (crovalimab-akkz) • Soliris® (eculizumab) • Ultomiris® (ravulizumab-cwvz) Zilbrysq (zilucoplan) is a self-administered injection obtained under the member's pharmacy benefit. Any U.S. Food and Drug Administration (FDA) approved and launched eculizumab biosimilar product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Complement Inhibitors (continued)	Oct. 1, 2025	○ Bkemv (eculizumab-aeeb) ○ Epysqli (eculizumab-aagh) • Added language to indicate: ○ Any U.S. Food and Drug Administration (FDA) approved and launched eculizumab biosimilar product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare ○ Bkemv (eculizumab-aeeb) and Epysqli (eculizumab-aagh) are the preferred eculizumab products; coverage will be provided for Bkemv and Epysqli contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Coverage for Soliris (eculizumab) and other non-preferred eculizumab biosimilar products will be provided contingent on the *Preferred Product Criteria* and the *Diagnosis-Specific Criteria* [sections of the policy]; in order to continue coverage, members already on Soliris (eculizumab) or other non-preferred eculizumab biosimilar products will be required to change therapy to Bkemv (eculizumab-aeeb) or Epysqli	**Eculizumab Preferred Product** Bkemv (eculizumab-aeeb) and Epysqli (eculizumab-aagh) are the preferred eculizumab products. Coverage will be provided for Bkemv and Epysqli contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section. Coverage for Soliris (eculizumab) and other non-preferred eculizumab biosimilar products will be provided contingent on the *Preferred Product Criteria* and the *Diagnosis-Specific Criteria* sections. In order to continue coverage, members already on Soliris (eculizumab) or other non-preferred eculizumab biosimilar products will be required to change therapy to Bkemv (eculizumab-aeeb) or Epysqli (eculizumab-aagh) unless they meet the criteria in this section. ***Preferred Product Criteria*** **Treatment with Soliris or other non-preferred eculizumab biosimilar products is medically necessary for the indications specified in the policy when both of the following criteria are met:** • **One** of the following: ○ **Both** of the following: ▪ History of a trial of Bkemv or Epysqli resulting in minimal clinical response to therapy and residual disease activity; **and** ▪ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Soliris or other non-preferred eculizumab products, than experienced with Bkemv or Epysqli **or** ○ **Both** of the following: ▪ History of intolerance, contraindication, or adverse event to Bkemv or Epysqli; **and** ▪ Physician attests that, in their clinical opinion, the same intolerance, contraindication, or serious adverse event would not be expected to occur with Soliris or other non-preferred eculizumab products **and** • Patient has not had a loss of a favorable response after established maintenance therapy with Soliris or other eculizumab biosimilar products

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Complement Inhibitors (continued)	Oct. 1, 2025	(eculizumab-aagh) unless they meet the criteria in the *Preferred Product Criteria* section [of the policy] ○ Treatment with Soliris or other non-preferred eculizumab biosimilar products is medically necessary for the indications specified in the policy when both of the following criteria are met: ▪ One of the following: – Both of the following: • History of a trial of Bkemv or Epysqli resulting in minimal clinical response to therapy and residual disease activity • Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Soliris or other non-preferred eculizumab products, than experienced with Bkemv or Epysqli – Both of the following:	***Diagnosis-Specific Criteria*** **Bkemv, Epysqli, Soliris, and Ultomiris are proven and medically necessary for the treatment of atypical hemolytic uremic syndrome (aHUS) when all of the following criteria are met:** • **Initial Therapy** ○ Documentation supporting the diagnosis of aHUS by ruling out **both** of the following: ▪ Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS); **and** ▪ Thrombotic thrombocytopenia purpura (TTP) (e.g., rule out ADAMTS13 deficiency) **and** ○ Laboratory results, signs, and/or symptoms attributed to aHUS (e.g., thrombocytopenia, microangiopathic hemolysis, thrombotic microangiopathy, acute renal failure, etc.); **and** ○ Patient is treatment-naïve with the requested product; **and** ○ The requested product is dosed according to the U.S. FDA labeled dosing for aHUS; **and** ○ Prescribed by, or in consultation with, a hematologist or nephrologist; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Patient has previously been treated with the requested product; **and** ○ Documentation demonstrating a positive clinical response from baseline (e.g., reduction of plasma exchanges, reduction of dialysis, increased platelet count, reduction of hemolysis); **and** ○ The requested product is dosed according to the U.S. FDA labeled dosing for aHUS; **and** ○ Prescribed by, or in consultation with, a hematologist or nephrologist; **and** ○ Reauthorization will be for no more than 12 months **Bkemv, Epysqli, PiaSky, Soliris, and Ultomiris are unproven and not medically necessary for the treatment of Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS).**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Complement Inhibitors (continued)	Oct. 1, 2025	• History of intolerance, contraindication, or adverse event to Bkemv or Epysqli • Physician attests that, in their clinical opinion, the same intolerance, contraindication, or serious adverse event would not be expected to occur with Soliris or other non-preferred eculizumab products ▪ Patient has not had a loss of a favorable response after established maintenance therapy with Soliris or other eculizumab biosimilar products ○ Bkemv and Epysqli are proven and medically necessary for the treatment of the following indications when criteria listed in the policy are met: ▪ Atypical hemolytic uremic syndrome (aHUS)	**Bkemv, Epysqli, PiaSky, Soliris, and Ultomiris are proven and medically necessary for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) when all of the following criteria are met:** • **Initial Therapy** ○ Documentation supporting the diagnosis of PNH that includes **both** of the following: ▪ Flow cytometry analysis confirming presence of PNH clones; **and** ▪ Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.) **and** ○ The requested product is dosed according to the U.S. FDA labeled dosing for PNH; **and** ○ For PiaSky authorization only, **both** of the following: ▪ History of trial and failure, contraindication, or intolerance to **one** of the following: – Complement C5 inhibitor [i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Soliris (eculizumab), or Ultomiris (ravulizumab)]; **or** – Empaveli (pegcetacoplan); **or** – Fabhalta (iptacopan) **and** ▪ Patient is **not** receiving PiaSky in combination with a complement factor D inhibitor [e.g., Voydeya (danicopan)] **and** ○ Patient is **not** receiving the requested product in combination with any of the following for treatment of the same indication: ▪ A different complement C5 inhibitor [i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), PiaSky (crovalimab), Soliris (eculizumab), or Ultomiris (ravulizumab)]; **and** ▪ A complement C3 inhibitor [e.g., Empaveli (pegcetacoplan)]; **and** ▪ A complement factor B inhibitor [e.g., Fabhalta (iptacopan)] **and** ○ Prescribed by, or in consultation with, a hematologist or oncologist;

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Complement Inhibitors (continued)	Oct. 1, 2025	▪ Generalized myasthenia gravis in patients who are anti-acetylcholine receptor (AChR) antibody positive ▪ Neuromyelitis optica spectrum disorder (NMOSD) ▪ Paroxysmal nocturnal hemoglobinuria (PNH) ○ Bkemv and Epysqli are unproven and not medically necessary for the treatment of the Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) • Revised coverage criteria for: ***Paroxysmal Nocturnal Hemoglobinuria (PNH)*** ○ Replaced criterion requiring: ▪ "The patient has a history of trial and failure, contraindication, or intolerance to *Soliris (eculizumab) or Ultomiris (ravulizumab)*" with " the patient has a history of trial and failure, contraindication, or intolerance to *a complement C5 inhibitor [i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Soliris (eculizumab), or Ultomiris (ravulizumab)]*"	**and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Patient has previously been treated with the requested product; **and** ○ Documentation demonstrating a positive clinical response from baseline (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc.); **and** ○ The requested product is dosed according to the U.S. FDA labeled dosing for PNH; **and** ○ Patient is **not** receiving the requested product in combination with any of the following for treatment of the same indication: ▪ A different complement C5 inhibitor [i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), PiaSky (crovalimab), Soliris (eculizumab), or Ultomiris (ravulizumab)]; **and** ▪ A complement C3 inhibitor [e.g., Empaveli (pegcetacoplan)]; **and** ▪ A complement factor B inhibitor [e.g., Fabhalta (iptacopan)] **and** ○ For PiaSky authorization only: Patient is **not** receiving PiaSky in combination with a complement factor D inhibitor [e.g., Voydeya (danicopan)]; **and** ○ Prescribed by, or in consultation with, a hematologist or oncologist; **and** ○ Reauthorization will be for no more than 12 months **Bkemv, Epysqli, Soliris, and Ultomiris 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:** • **Initial Therapy** ○ Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming **all** of the following: ▪ Patient has not failed a previous course of a complement C5 inhibitor therapy [i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Soliris (eculizumab), Ultomiris (ravulizumab), or Zilbrysq (zilucoplan)]; **and** ▪ Diagnosis of generalized myasthenia gravis (gMG); **and**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Complement Inhibitors (continued)	Oct. 1, 2025	▪ "The patient is not receiving the *PiaSky, Soliris, or Ultomiris* in combination with *another* complement *protein* C5 inhibitor" with "the patient is not receiving the *requested product* in combination with *a different* complement C5 inhibitor *[i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), PiaSky (crovalimab), Soliris (eculizumab), or Ultomiris (ravulizumab)] for treatment of the same indication*" ***Generalized Myasthenia Gravis in Patients who are Anti-Acetylcholine Receptor (AChR) Antibody Positive*** ○ Replaced criterion requiring: ▪ "The patient has not failed a previous course of *Soliris or Ultomiris* therapy" with "the patient has not failed a previous course of *a complement C5 inhibitor* therapy [*i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh),* Soliris (eculizumab), Ultomiris (ravulizumab), *or Zilbrysq (zilucoplan)*]"	▪ Positive serologic test for anti-AChR antibodies; **and** ▪ Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; **and** ▪ Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 6 at initiation of therapy **and** ○ **One** of the following: ▪ History of failure of at least **two** immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.); **or** ▪ Patient has a history of failure of **both** of the following: – At least **one** immunosuppressive therapy; **and** – Four or more courses of plasmapheresis/plasma exchanges and/or intravenous immune globulin over the course of at least 12 months without symptom control **and** ○ The requested product is initiated and titrated according to the U.S. FDA labeled dosing for gMG; **and** ○ Patient is not receiving the requested product in combination with any of the following for treatment of the same indication: ▪ A different complement C5 inhibitor [i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), PiaSky (crovalimab), Soliris (eculizumab), Ultomiris (ravulizumab), or Zilbrysq (zilucoplan)]; **and** ▪ An FcRn blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Rystiggo (rozanolixizumab-noli)]; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Patient has previously been treated with the requested product; **and** ○ Submission of medical records (e.g., chart notes, laboratory tests) demonstrating **all** of the following: ▪ Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Complement Inhibitors (continued)	Oct. 1, 2025	▪ "The patient is not receiving the *Soliris or Ultomiris* in combination with *another* complement inhibitor [i.e., Zilbrysq (zilucoplan)] or a *neonatal Fc receptor* blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Rystiggo (rozanolixizumab-noli)]" with "the patient is not receiving the *requested product* in combination with any of the following *for treatment of the same indication*: *a different* complement *C5* inhibitor *[i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), PiaSky (crovalimab), Soliris (eculizumab), Ultomiris (ravulizumab), or* Zilbrysq (zilucoplan)] or an *FcRn* blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Rystiggo (rozanolixizumab-noli)]" ***Neuromyelitis Optica Spectrum Disorder (NMOSD)*** ○ Replaced criterion requiring:	treatment baseline; **and** ▪ Reduction in signs and symptoms of myasthenia gravis; **and** ▪ Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting the requested product **Note**: Add on dose escalation of IST or additional rescue therapy from baseline, to treat myasthenia gravis or exacerbation of symptoms while on the requested product therapy, will be considered as treatment failure **and** ○ The requested product is dosed according to the U.S. FDA labeled dosing for gMG; **and** ○ Patient is not receiving the requested product in combination with any of the following for treatment of the same indication: ▪ A different complement C5 inhibitor [i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), PiaSky (crovalimab), Soliris (eculizumab), Ultomiris (ravulizumab), or Zilbrysq (zilucoplan)]; **and** ▪ An FcRn blocker [e.g., Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Rystiggo (rozanolixizumab-noli)]; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Reauthorization will be for no more than 12 months **Bkemv, Epysqli, Soliris, and Ultomiris are proven and medically necessary for the treatment of neuromyelitis optica spectrum disorder (NMOSD) when all of the following criteria are met:** ● **Initial Therapy** ○ Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) by a neurologist confirming **all** of the following: ▪ Past medical history of **one** of the following: – Optic neuritis; **or** – Acute myelitis; **or** – Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting; **or** – Acute brainstem syndrome; **or** – Symptomatic narcolepsy or acute diencephalic clinical

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Complement Inhibitors (continued)	Oct. 1, 2025	▪ "The patient has not failed a previous course of *Soliris or Ultomiris* therapy" with "the patient has not failed a previous course of *a complement C5 inhibitor* therapy *for treatment of NMOSD* [*i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh),* Soliris (eculizumab), or Ultomiris (ravulizumab)]" ▪ "The patient is not receiving *Soliris or Ultomiris* in combination with disease modifying therapies approved for the treatment of multiple sclerosis" with "the patient is not receiving *the requested product* in combination with disease modifying therapies *U.S. Food and Drug Administration (FDA)* approved for the treatment of multiple sclerosis" **Applicable Codes** • Added HCPCS codes Q5151 and Q5152 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	syndrome with NMOSD-typical diencephalic MRI lesions; **or** – Symptomatic cerebral syndrome with NMOSD-typical brain lesions **and** ▪ Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies; **and** ▪ Diagnosis of multiple sclerosis or other diagnoses have been ruled out **and** ○ Patient has not failed a previous course of a complement C5 inhibitor therapy for treatment of NMOSD [i.e., Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Soliris (eculizumab), or Ultomiris (ravulizumab)]; **and** ○ History of failure of, contraindication, or intolerance to rituximab therapy; **and** ○ **One** of the following: ▪ History of at least two relapses during the previous 12 months prior to initiating the requested product; **or** ▪ History of at least three relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating the requested product **and** ○ The requested product is initiated and titrated according to the U.S. FDA labeled dosing for NMOSD; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Patient is **not** receiving the requested product in combination with **any** of the following for treatment of the same indication: ▪ Disease modifying therapies FDA approved for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]; **or** ▪ Anti-IL6 therapy [e.g., Actemra (tocilizumab), Enspryng (satralizumab)]; **or** ▪ B-cell depletion therapy [e.g., rituximab, Uplizna (inebilizumab-cdon)] **and** ○ Initial authorization will be for no more than 12 months

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Complement Inhibitors (continued)	Oct. 1, 2025		• **Continuation of Therapy** ○ Patient has previously been treated with the requested product; **and** ○ Documentation of positive clinical response from baseline as demonstrated by at least **both** of the following: ▪ Reduction in the number and/or severity of relapses or signs and symptoms of NMOSD; **and** ▪ Maintenance, reduction, or discontinuation of dose(s) of any baseline immunosuppressive therapy (IST) prior to starting the requested product **Note**: Add on dose escalation of IST or additional rescue therapy from baseline, to treat NMOSD or exacerbation of symptoms while on the requested product therapy, will be considered as treatment failure **and** ○ The requested product is dosed according to the U.S. FDA labeled dosing for NMOSD; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Patient is **not** receiving the requested product in combination with **any** of the following for treatment of the same indication: ▪ Disease modifying therapies FDA approved for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]; **or** ▪ Anti-IL6 therapy [e.g., Actemra (tocilizumab), Enspryng (satralizumab)]; **or** ▪ B-cell depletion therapy [e.g., rituximab, Uplizna (inebilizumab-cdon)] **and** ○ Reauthorization will be for no more than 12 months
Factor Mimetics and Rebalancing Agents for Hemophilia	Oct. 1, 2025	**Coverage Rationale** • Revised coverage criteria for initial therapy for: Emicizumab-kxwh (Hemlibra) ○ Added criterion to allow coverage when the patient has not developed high-titer factor VIII inhibitors [i.e., patient has **not** developed	This policy refers to the following products: • Antithrombin-directed small interfering ribonucleic acid (siRNA): Qfitlia® (fitusiran) • Bispecific factor IXa- and factor X-directed antibody: Hemlibra® (emicizumab-kxwh) • Tissue factor pathway inhibitor (TFPI) antagonist: Alhemo® (concizumab-mtci) and Hympavzi™ (marstacimab-hncq) Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Factor Mimetics and Rebalancing Agents for Hemophilia (continued)	Oct. 1, 2025	factor VIII inhibitors greater than or equal to 5 Bethesda units (BU)] ○ Removed criterion requiring: ▪ Documentation of endogenous factor VIII level less than 1% of normal factor VIII (< 0.01 i.u./mL) ▪ Both of the following: – Diagnosis of moderate hemophilia A – Documentation of endogenous factor VIII level ≥ 1% < 5% (greater than or equal to 0.01 i.u./mL to less than 0.05 i.u./mL) ▪ Both of the following: – Diagnosis of mild hemophilia A – Documentation of endogenous factor VIII level ≥ 5% (greater than or equal to 0.05 i.u./mL) ▪ Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Factor Mimetics and Rebalancing Agents for Hemophilia (continued)	Oct. 1, 2025	prophylactic factor VIII replacement products ○ Replaced criterion requiring: ▪ "Diagnosis of *severe* hemophilia A" with "diagnosis of hemophilia A" ▪ "The patient has developed high-titer factor VIII inhibitors [≥ 5 Bethesda units (BU)]" with "the patient has developed high-titer factor VIII inhibitors [*i.e., patient has developed factor VIII inhibitors* greater than or equal to 5 Bethesda units (BU)]" Marstacimab-hncq (Hympavzi) ○ Added criterion to allow coverage when the patient has not developed high-titer factor VIII/factor IX inhibitors [i.e., patient has **not** developed factor VIII/factor IX inhibitors greater than or equal to 5 Bethesda units (BU)] ○ Removed criterion requiring: ▪ Documentation of endogenous factor VIII/ factor IX level less than 1% of normal factor VIII/ factor IX (< 0.01 i.u./mL) ▪ Both of the following: – Diagnosis of moderate hemophilia A/B	

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Factor Mimetics and Rebalancing Agents for Hemophilia (continued)	Oct. 1, 2025	– Documentation of endogenous factor VIII/factor IX level ≥ 1% < 5% (greater than or equal to 0.01 i.u./mL to less than 0.05 i.u./mL) ▪ Both of the following: – Diagnosis of mild hemophilia A/B – Documentation of endogenous factor VIII/factor IX level ≥ 5% (greater than or equal to 0.05 i.u./mL) ▪ Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor VIII/ factor IX replacement products ▪ The patient does not have a history of inhibitors to factor VIII/ factor IX ○ Replaced criterion requiring "diagnosis of *severe* hemophilia A/B" with "diagnosis of hemophilia A/B"	

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Factor Mimetics and Rebalancing Agents for Hemophilia (continued)	Oct. 1, 2025	Fitusiran (Qfitlia) ○ Added criterion to allow coverage when the patient has not developed high-titer factor VIII/factor IX inhibitors [i.e., patient has **not** developed factor VIII/factor IX inhibitors greater than or equal to 5 Bethesda units (BU)] ○ Removed criterion requiring: ▪ Documentation of endogenous factor VIII/ factor IX level less than 1% of normal factor VIII/ factor IX (< 0.01 i.u./mL) ▪ Both of the following: – Diagnosis of moderate hemophilia A/B – Documentation of endogenous factor VIII/factor IX level ≥ 1% < 5% (greater than or equal to 0.01 i.u./mL to less than 0.05 i.u./mL) ▪ Both of the following: – Diagnosis of mild hemophilia A/B – Documentation of endogenous factor VIII/factor IX level ≥ 5% (greater than or equal to 0.05 i.u./mL) ▪ Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to	

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Factor Mimetics and Rebalancing Agents for Hemophilia (continued)	Oct. 1, 2025	meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor VIII/ factor IX replacement products ○ Replaced criterion requiring: ▪ "Diagnosis of *severe* hemophilia A/B" with "diagnosis of hemophilia A/B" ▪ "The patient has developed high-titer factor VIII/factor IX inhibitors [≥ 5 Bethesda units (BU)]" with "the patient has developed high-titer factor VIII/factor IX inhibitors [*i.e., patient has developed factor VIII/ factor IX inhibitors* greater than or equal to 5 Bethesda units (BU)]"	
Gamifant® (Emapalumab-Lzsg)	Oct. 1, 2025	**Coverage Rationale *Hemophagocytic Lymphohistiocytosis (HLH)*** • Revised medical necessity criteria; replaced criterion requiring: ○ "Confirmation of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D)" with "confirmation	**Gamifant is proven and medically necessary for the treatment of primary hemophagocytic lymphohistiocytosis (HLH) in patients who meet all of the following criteria:** • Submission of medical records (e.g., chart notes, laboratory values) confirming **one** the following: ○ Confirmation of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D, RAB27A, STX11, STXBP2); **or** ○ Confirmation that **five** of the following clinical characteristics are present: ▪ Fever

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gamifant® (Emapalumab-Lzsg) (continued)	Oct. 1, 2025	of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D, *RAB27A, STX11, STXBP2*)" ○ "Confirmation of fever ≥ *101.3°F*" with "confirmation of fever" ○ "Confirmation of low or absent natural killer cell activity *(according to local laboratory reference)*" with "confirmation of low or absent natural killer cell activity" ○ "The patient has refractory, recurrent, or progressive disease, or intolerance with conventional HLH therapy (*i.e., etoposide + dexamethasone*)" with "the patient has refractory, recurrent, or progressive disease, or intolerance with conventional HLH therapy (*e.g., etoposide, corticosteroids, cyclosporine, anti-thymocyte globulin, methotrexate*)" ○ "*Approval is* for no more than 6 months" with "*authorization will be* for no more than 6 months" • Replaced references to "stem cell transplant" with "*hematopoietic* stem cell transplant" ***Hemophagocytic Lymphohistiocytosis (HLH)/ Macrophage Activation Syndrome (MAS)***	▪ Splenomegaly ▪ **Two** of the following cytopenias in the peripheral blood: – Hemoglobin < 9 g/dL; **or** – Platelet count < 100 x 10^9/L; **or** – Neutrophils < 1 x 10^9/L ▪ **One** of the following: – Hypertriglyceridemia defined as fasting triglycerides ≥ 3 mmol/L or ≥ 265 mg/dL; **or** – Hypofibrinogenemia defined as fibrinogen ≤ 1.5 g/L ▪ Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy ▪ Low or absent natural killer cell activity ▪ Ferritin ≥ 500 mcg/L ▪ Soluble CD25 (i.e., soluble IL-2 receptor) ≥ 2,400 U/mL **and** • Patient has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (e.g., etoposide, corticosteroids, cyclosporine, anti-thymocyte globulin, methotrexate); **and** • Gamifant will be administered with dexamethasone; **and** • Patient is a candidate for hematopoietic stem cell transplant; **and** • Gamifant is being used as part of the induction or maintenance phase of hematopoietic stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant; **and** • Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Authorization will be for no more than 6 months **Gamifant is medically necessary for the treatment of hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in patients who meet all of the following criteria:** • **Initial Therapy** ○ Submission of medical records (e.g., chart notes, laboratory values) confirming the following: ▪ Confirmed or suspected diagnosis of systemic juvenile idiopathic arthritis (sJIA) or adult onset Still's disease (AOSD); **and** ▪ Diagnosis of active MAS with **both** of the following: – Ferritin > 684 ng/mL

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gamifant® (Emapalumab-Lzsg) (continued)	Oct. 1, 2025	• Added language to indicate Gamifant is medically necessary for the treatment of HLH MAS in patients who meet all of the following criteria: Initial Therapy ○ Submission of medical records (e.g., chart notes, laboratory values) confirming the following: ▪ Confirmed or suspected diagnosis of systemic juvenile idiopathic arthritis (sJIA) or adult onset Still's disease (AOSD) ▪ Diagnosis of active MAS with both of the following: – Ferritin > 684 ng/mL – Two of the following laboratory criteria: platelet count ≤ 181 x 10^9/L, AST > 48 U/L, triglycerides > 156 mg/dL, fibrinogen level ≤ 360 mg/dL ○ Patient has had an inadequate response to high-dose intravenous glucocorticoids ○ Dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling ○ Initial authorization will be for no more than 12 months	– **Two** of the following laboratory criteria: • Platelet count ≤ 181 x 10^9/L; or • AST > 48 U/L • Triglycerides > 156 mg/dL • Fibrinogen level ≤ 360 mg/dL **and** ○ Patient has had an inadequate response to high-dose intravenous glucocorticoids; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Documentation of a positive clinical response to Gamifant; **and** ○ Dosing is in accordance with the FDA approved labeling; **and** ○ Reauthorization will be for no more than 12 months **Gamifant is not proven or medically necessary for the treatment of secondary HLH.**

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gamifant® (Emapalumab-Lzsg) (continued)	Oct. 1, 2025	**Continuation of Therapy** ○ Documentation of a positive clinical response to Gamifant ○ Dosing is in accordance with the U.S. FDA approved labeling ○ Reauthorization will be for no more than 12 months **Applicable Codes** • Added ICD-10 diagnosis codes D76.2 and D76.3 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Gonadotropin Releasing Hormone Analogs	Oct. 1, 2025	**Application** ***Kentucky*** • Added language to indicate the gender dysphoria and gender-affirming hormonal therapy criteria in this policy are not applicable for the state of **Kentucky**; this Medical Benefit Drug Policy applies for all other indications **Coverage Rationale** • Revised list of applicable gonadotropin releasing hormone analog (GnRH analog) drug products; added Lutrate Depot (leuprolide acetate)	Refer to the Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage for updated information based on the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications. This policy refers to the following gonadotropin releasing hormone analog (GnRH analog) drug products: • Camcevi™ (leuprolide mesylate) • Eligard® (leuprolide acetate) • Fensolvi (leuprolide acetate) • Firmagon (degarelix) • Leuprolide acetate depot • Lupron Depot (leuprolide acetate) • Lupron Depot-Ped (leuprolide acetate) • Lutrate Depot (leuprolide acetate) • Supprelin LA (histrelin acetate) • Trelstar (triptorelin pamoate) • Triptodur (triptorelin) • Zoladex (goserelin acetate) Refer to the policy for complete details.

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Maximum Dosage and Frequency	Oct. 1, 2025	**Coverage Rationale**
		• Revised list of applicable drug products; added:
		  ○ denosumab-bbdz (Jubbonti® & Wyost®)
		  ○ ustekinumab-stba (Steqeyma®)
		  ○ ustekinumab-kfce (Yesintek™)
		Maximum Allowed Quantities by HCPCS Units
		• Added maximum allowed quantities for:
		  ○ Jubbonti (denosumab-bbdz) (HCPCS code Q5136)
		  ○ Steqeyma (ustekinumab-stba) (HCPCS code Q5099)
		  ○ Wyost (denosumab-bbdz) (HCPCS code Q5136)
		  ○ Yesintek (ustekinumab-kfce) (HCPCS code Q5100)
		Maximum Allowed Quantities for National Drug Code (NDC) Billing
		• Added maximum allowed quantities for:
		  ○ Jubbonti (denosumab-bbdz) (NDC 61314-0240-63)
		  ○ Steqeyma (ustekinumab-stba) (NDCs 72606-0027-01, 72606-0028-01, and 72606-0029-01)
		  ○ Wyost (denosumab-bbdz) (NDC 61314-0228-94)
		  ○ Yesintek (ustekinumab-kfce) (NDCs 83257-0023-41, 83257-0024-11, 83257-0025-41, and 83257-0026-11)
			This policy provides information about the maximum dosage per administration and dosing frequency for certain medications administered by a medical professional. Most medications have a maximum dosage and frequency based upon body surface area, or patient weight, or a set maximal dosage and frequency independent of patient body size.
			Drug Products
			• abatacept (Orencia®)
			• abobotulinumtoxinA (Dysport®)
			• aflibercept (Eylea®)
			• aflibercept (Eylea® HD)
			• aflibercept-ayyh (Pavblu™)
			• atezolizumab (Tecentriq®)
			• avelumab (Bavencio®)
			• axatilimab-csfr (Niktimvo™)
			• benralizumab (Fasenra®)
			• bevacizumab (Avastin®)
			• bevacizumab-adcd (Vegzelma®)
			• bevacizumab-awwb (Mvasi™)
			• bevacizumab-bvzr (Zirabev®)
			• bevacizumab-maly (Alymsys®)
			• brolucizumab-dbll (Beovu®)
			• canakinumab (Ilaris®)
			• cemiplimab-rwlc (Libtayo®)
			• certolizumab pegol (Cimzia®)
			• crovalimab-akkz (PiaSky™)
			• daxibotulinumtoxinA-lanm (Daxxify®)
			• denosumab (Prolia® & Xgeva®)
			• denosumab-bbdz (Jubbonti® & Wyost®)
			• durvalumab (Imfinzi®)
			• eculizumab (Soliris®)
			• edaravone (Radicava®)
			• efgartigimod alfa-fcab (Vyvgart®)
			• pegfilgrastim-apgf (Nyvepria™)
			• pegfilgrastim-cbqv (Udenyca®)
			• pegfilgrastim-fpgk (Stimufend®)
			• pegfilgrastim-jmdb (Fulphila™)
			• pegfilgrastim-pbbk (Fylnetra®)
			• pegfilgrastim-bmez (Ziextenzo®)
			• pegloticase (Krystexxa®)
			• pembrolizumab (Keytruda®)
			• ranibizumab (Lucentis®)
			• ranibizumab (Susvimo™)
			• ranibizumab-nuna (Byooviz™)
			• ranibizumab-eqrn (Cimerli™)
			• ravulizumab-cwvz (Ultomiris®)
			• reslizumab (Cinqair®)
			• rimabotulinumtoxinB (Myobloc®)
			• risankizumab-rzaa (Skyrizi®)
			• rituximab (Rituxan®)
			• rituximab-pvvr (Ruxience™)
			• rituximab-abbs (Truxima®)
			• rituximab-arrx (Riabni®)
			• rituximab and hyaluronidase (Rituxan Hycela®)
			• rozanolixizumab-noli (Rystiggo®)
			• spesolimab-sbzo (Spevigo®)
			• testosterone cypionate (Depo-Testosterone®)
			• testosterone enanthate
			• testosterone pellets (Testopel®)

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Maximum Dosage and Frequency (continued)	Oct. 1, 2025	***Maximum Allowed Frequencies***
		• Added maximum allowed frequencies for:
		  ○ Jubbonti (denosumab-bbdz)
		  ○ Wyost (denosumab-bbdz)
		Applicable Codes
		• Added HCPCS codes Q5099, Q5100, and Q5136
		Supporting Information
		• Updated *References* section to reflect the most current information
			• efgartigimod alfa and hyaluronidase-qvfc (Vyvgart® Hytrulo)
			• eflapegrastim-xnst (Rolvedon™)
			• emicizumab-kxwh (Hemlibra®)
			• eptinezumab-jjmr (Vyepti®)
			• faricimab-svoa (Vabysmo™)
			• golimumab (Simponi Aria®)
			• guselkumab (Tremfya®)
			• inclisiran (Leqvio®)
			• incobotulinumtoxinA (Xeomin®)
			• infliximab (Remicade®)
			• infliximab-axxq (Avsola™)
			• infliximab-dyyb (Inflectra®)
			• infliximab-abda (Renflexis®)
			• ipilimumab (Yervoy®)
			• mepolizumab (Nucala®)
			• mirikizumab-mrkz (Omvoh®)
			• nivolumab (Opdivo®)
			• ocrelizumab (Ocrevus®)
			• omalizumab (Xolair®)
			• onabotulinumtoxinA (Botox®)
			• patisiran (Onpattro®)
			• pegcetacoplan (Syfovre™)
			• pegfilgrastim (Neulasta®)
			• testosterone undecanoate (Aveed®)
			• tezepelumab-ekko (Tezspire®)
			• tildrakizumab-asmn (Ilumya™)
			• tocilizumab (Actemra®)
			• tocilizumab-aazg (Tyenne®)
			• tocilizumab-bavi (Tofidence™)
			• tofersen (Qalsody®)
			• trastuzumab (Herceptin®)
			• trastuzumab-anns (Kanjinti™)
			• trastuzumab-dkst (Ogivri™)
			• trastuzumab-dttb (Ontruzant®)
			• trastuzumab-pkrb (Herzuma®)
			• trastuzumab-qyyp (Trazimera™)
			• ustekinumab (Stelara®)
			• ustekinumab-aauz (Otulfi™)
			• ustekinumab-aekn (Selarsdi)
			• ustekinumab-auub (Wezlana™)
			• ustekinumab-kfce (Yesintek™)
			• ustekinumab-stba (Steqeyma®)
			• ustekinumab-ttwe (Pyzchiva®)
			• vedolizumab (Entyvio®)
			• vutrisiran (Amvuttra™)
			• zoledronic acid (zoledronic acid, Reclast®)
			The use of medications included in this policy, when given within the maximum dosage and/or frequency based upon body surface area or patient weight or a set of maximal dosage and/or frequency independent of patient body size, are proven when used according to labeled indications or when otherwise supported by published clinical evidence [e.g., well-designed systematic reviews (with or without meta-analyses) of multiple well-designed randomized controlled trials, the National Comprehensive Cancer Network (NCCN) guidelines].

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Oct. 1, 2025		**The use of medications included in this policy, when given beyond maximum dosages and/or frequency based upon body surface area or patient weight or a set maximal dosage independent of patient body size, are not supported by package labeling or published clinical evidence and are unproven.** **Continued use of a medication or dosages used beyond labeled indication or other published clinical evidence [e.g., well-designed systematic reviews (with or without meta-analyses) of multiple well-designed randomized controlled trials, NCCN guidelines] is considered not medically necessary.** This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (140 kg) and body surface area (2.71 meters^2) in the U.S. (adult male, 30 to 39 years, Fryar, 2021). In some cases, the maximum allowed units and/or vials may exceed the upper-level limit as defined within this policy due to an individual patient body weight > 140 kg or body surface area > 2.71 meters^2. Refer to the policy for complete details.
Oncology Medication Clinical Coverage	Oct. 1, 2025	**Coverage Rationale** • Revised list of UnitedHealthcare preferred and non-preferred oncology products: ○ Added: ▪ Tecentriq (atezolizumab) + Mvasi (bevacizumab-awwb) (preferred for hepatocellular carcinoma: combination systemic therapy) ▪ Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs) + Mvasi (bevacizumab-awwb) (preferred for hepatocellular carcinoma:	**Description** This policy provides parameters for coverage of injectable oncology medications (including, but not limited to, octreotide acetate, leuprolide acetate, leucovorin, and levoleucovorin), including therapeutic radiopharmaceuticals, covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). The Compendium lists the appropriate drugs and biologics for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category. Refer to the Medical Benefit Drug Policy titled White Blood Cell Colony Stimulating Factors or Erythropoiesis-Stimulating Agents, for information on those agents. This policy does not provide coverage criteria for chimeric antigen receptor (CAR) T-cell or tumor-infiltration lymphocyte (TIL) cell products. Coverage determinations are based on the member's benefits and the OptumHealth Transplant Solutions criteria for

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Oncology Medication Clinical Coverage (continued)	Oct. 1, 2025	combination systemic therapy) ▪ Imjudo (tremelimumab-actl) + Imfinzi (durvalumab) (preferred for hepatocellular carcinoma: combination systemic therapy) ▪ Tecentriq (atezolizumab) + any of the following: Avastin (bevacizumab), Zirabev (bevacizumab-bvzr), Alymsys (bevacizumab-maly), Vegzelma (bevacizumab-adcd) (non-preferred for hepatocellular carcinoma: combination systemic therapy) ▪ Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs) + any of the following: Avastin (bevacizumab), Zirabev (bevacizumab-bvzr), Alymsys (bevacizumab-maly), Vegzelma (bevacizumab-adcd) (non-preferred for hepatocellular carcinoma: combination systemic therapy) ▪ Opdivo (nivolumab) + Yervoy (ipilimumab) (non-preferred for hepatocellular carcinoma:	covered transplants in the Clinical Guideline titled Chimeric Antigen Receptor T-Cell (CAR T) Therapy or Tumor-Infiltrating Lymphocyte (TIL) Cell Therapy. **Coverage Rationale** The Oncology Products table in the policy lists the UnitedHealthcare preferred oncology products and respective non-preferred products. Coverage will be provided for the UnitedHealthcare preferred oncology product contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section. Coverage for any respective non-preferred oncology product will be provided contingent on the criteria in the *Preferred Product Criteria* and the *Diagnosis-Specific Criteria* sections. ***Preferred Product Criteria*** **Treatment with the respective non-preferred product specified in the Oncology Products table in the policy is medically necessary for oncology indications when both of the following are met:** • History of intolerance or contraindication to one of UnitedHealthcare's preferred oncology products; and • Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with the respective non-preferred product **Oncology Products** Refer to the policy for a list of UnitedHealthcare preferred and non-preferred oncology products and corresponding indications. Any U.S. Food and Drug Administration approved product that may belong to the UnitedHealthcare Preferred or Non-Preferred Oncology Product categories, but not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare P&T committee.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Oncology Medication Clinical Coverage (continued)	Oct. 1, 2025	combination systemic therapy) ○ Replaced indication listed as "head and neck cancers: recurrent, unresectable, oligometastatic, or metastatic disease, nasopharyngeal" with "head and neck cancers: *cancer of the nasopharynx*, recurrent, unresectable, oligometastatic, or metastatic disease, nasopharyngeal"	***Diagnosis-Specific Criteria*** **Injectable Oncology Medications** UnitedHealthcare recognizes indications and uses of injectable oncology medications, including therapeutic radiopharmaceuticals, in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven and not medically necessary. (However, refer to the *Benefit Considerations* section of the policy.) UnitedHealthcare will cover all chemotherapy agents for individuals under the age of 19 years for oncology indications. The majority of pediatric patients receive treatments on national pediatric protocols that are quite similar in concept to the NCCN patient care guidelines. Refer to the *Preferred Product Criteria* section of the policy for the UnitedHealthcare preferred oncology products and indications.
Testosterone Replacement or Supplementation Therapy	Oct. 1, 2025	**Application** ***Kentucky*** • Added language to indicate the gender-affirming hormonal therapy criteria in this policy are not applicable for the state of **Kentucky**; this Medical Benefit Drug Policy applies for all other indications **Coverage Rationale** • Added language to indicate: ○ Coverage for Azmiro will be provided contingent on the *Preferred Product Criteria* and the *Diagnosis-Specific Criteria* [sections in the policy]; in order to continue coverage, members already on Azmiro will be required to change therapy to a generic	This policy refers to the following testosterone products: • Testosterone cypionate (Azmiro™, Depo-Testosterone®) • Testosterone enanthate • Testosterone pellets (Testopel®) • Testosterone undecanoate (Aveed®) Coverage for Azmiro will be provided contingent on the *Preferred Product Criteria* and the *Diagnosis-Specific Criteria*. In order to continue coverage, members already on Azmiro will be required to change therapy to a generic testosterone cypionate product (i.e., generic Depo-Testosterone) unless they meet the criteria in this section. **Preferred Product Criteria** **Treatment with Azmiro is medically necessary for the indications specified in the policy when one of the following criteria are met:** • **Both** of the following: ○ History of a trial to **one** other testosterone cypionate product resulting in minimal clinical response to therapy; **and** ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Azmiro, than experienced with

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Testosterone Replacement or Supplementation Therapy (continued)	Oct. 1, 2025	testosterone cypionate product (i.e., generic Depo-Testosterone) unless they meet the criteria in the *Preferred Product Criteria* section [of the policy] ○ Treatment with Azmiro is medically necessary for the indications specified in the policy when one of the following criteria are met: ▪ Both of the following: – History of a trial to one other testosterone cypionate product resulting in minimal clinical response to therapy – Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Azmiro, than experienced with other testosterone cypionate products ▪ Both of the following: – History of intolerance, contraindication, or adverse event to one other testosterone cypionate product – Physician attests that, in their clinical	other testosterone cypionate products **or** • **Both** of the following: ○ History of intolerance, contraindication, or adverse event to **one** other testosterone cypionate product; **and** ○ Physician attests that, in their clinical opinion, the same intolerance, contraindication, or serious adverse event would not be expected to occur with Azmiro **Diagnosis-Specific Criteria** **Injectable testosterone and Testopel (testosterone pellets) are medically necessary for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone, including primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired), when the following criteria are met:** • **One** of the following: ○ Patient has history of **one** of the following: ▪ Bilateral orchiectomy; **or** ▪ Panhypopituitarism; **or** ▪ A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome) **or** ○ **All** of the following: ▪ **One** of the following: – Two pre-treatment early morning serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab, taken at separate times; **or** – **Both** of the following: • Patient has condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity); **and** • **One** pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (< 5 ng/dL or < 0.17 nmol/L) or less than the reference range for the lab **or** – **Both** of the following:

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Testosterone Replacement or Supplementation Therapy (continued)	Oct. 1, 2025	opinion, the same intolerance, contraindication, or serious adverse event would not be expected to occur with Azmiro	• Patient is currently on testosterone therapy; **and** • **One** of the following: ○ Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is within or below the normal male limits of the reporting lab; **or** ○ Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is outside of upper male limits of normal for the reporting lab and the dose is adjusted **and** ▪ Patient was male at birth; **and** ▪ Diagnosis of hypogonadism **and** ○ Dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; **and** ○ Authorization will be for no more than 12 months **Injectable testosterone and Testopel (testosterone pellets) may be covered for gender-affirming hormonal therapy for transgender adults when the following criteria are met:** • **All** of the following: ○ Diagnosis of gender dysphoria, according to the current DSM (i.e., DSM-5-TR) criteria, by a mental health professional; **and** ○ Medication is prescribed by or in consultation with an endocrinologist or a medical provider knowledgeable in transgender hormone therapy; **and** ○ Authorization will be for no more than 12 months

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Testosterone Replacement or Supplementation Therapy (continued)	Oct. 1, 2025		**Compounded Hormone Products (e.g., Pellets)** Compounded drugs, including compounded testosterone, estrogen, or progesterone pellets are not FDA approved. Compounded hormone products (e.g., pellets), including but not limited to compounded testosterone, estrogen, and progesterone pellets, are considered experimental and investigational and not covered for any indication.
Ustekinumab	Nov. 1, 2025	**Coverage Rationale** • Revised list of applicable ustekinumab products for injection; added Starjemza (ustekinumab-hmny) • Added language to indicate: ○ Coverage for Starjemza will be provided contingent on the criteria in the *Preferred Product Criteria* section [of the policy] and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy]; in order to continue coverage, members already on Starjemza will be required to change therapy to Otulfi or Yesintek unless they meet the criteria in the *Preferred Product Criteria* section [of the policy] ○ Treatment with Starjemza is medically necessary for the indications specified in this policy when both of the following criteria are met: ▪ One of the following: – Both of the following: • Documentation of a trial of at least 14 weeks of	This policy refers to ustekinumab injection. Ustekinumab for self-administered subcutaneous injection is obtained under the pharmacy benefit. This policy refers to the following ustekinumab products: • Imuldosa™ (ustekinumab-srlf) • Otulfi® (ustekinumab-aauz) • Pyzchiva® (ustekinumab-ttwe) • Selarsdi™ (ustekinumab-aekn) • Starjemza® (ustekinumab-hmny) • Stelara® (ustekinumab) • Steqeyma® (ustekinumab-stba) • Wezlana™ (ustekinumab-auub) • Yesintek™ (ustekinumab-kfce) • Any FDA-approved ustekinumab biosimilar not listed here Refer to the policy for complete details.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ustekinumab (continued)	Nov. 1, 2025	Otulfi or Yesintek resulting in minimal clinical response to therapy and residual disease activity • Provider attests that in their clinical opinion, the clinical response would be expected to be superior with Imuldosa or Starjemza than experienced with Otulfi or Yesintek – Both of the following: • Documentation of intolerance, contraindication, or adverse event to Otulfi or Yesintek • Provider attests that in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Imuldosa or Starjemza	

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ustekinumab (continued)	Nov. 1, 2025	▪ Patient has not had a loss of a favorable response after established maintenance therapy with Steqeyma, Yesintek, or other ustekinumab product **Supporting Information** • Updated *References* section to reflect the most current information	
White Blood Cell Colony Stimulating Factors	Oct. 1, 2025	**Coverage Rationale** • Revised list of applicable white blood cell colony stimulating factors (CSFs); added Ryzneuta® (efbemalenograstim alfa-vuxw) • Added language to indicate: ○ Coverage for Ryzneuta will be provided contingent on the criteria in the *Preferred Product Criteria* section [of the policy] and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Treatment with Ryzneuta is medically necessary for the indications specified in the policy when one of the following is met: ▪ Both of the following: – History of a trial of adequate dose and duration of Neulasta or Udenyca, resulting in minimal clinical response	This policy refers to the following white blood cell colony stimulating factors (CSFs): • Long-acting pegfilgrastim agents: ○ Fulphila® (pegfilgrastim-jmdb) ○ Fylnetra® (pegfilgrastim-pbbk) ○ Neulasta® (pegfilgrastim) ○ Nyvepria™ (pegfilgrastim-apgf) ○ Udenyca® (pegfilgrastim-cbqv) ○ Stimufend® (pegfilgrastim-fpgk) ○ Ziextenzo® (pegfilgrastim-bmez) • Short-acting filgrastim agents: ○ Granix® (tbo-filgrastim) ○ Neupogen® (filgrastim) ○ Nivestym® (filgrastim-aafi) ○ Nypozi™ (filgrastim-txid) ○ Releuko® (filgrastim-ayow) ○ Zarxio® (filgrastim-sndz) • Leukine® (sargramostim) • Rolvedon® (eflapegrastim-xnst) • Ryzneuta® (efbemalenograstim alfa-vuxw) • Any FDA-approved white blood cell colony stimulating factor product not listed here Refer to the policy for complete details.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Oct. 1, 2025	– Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Ryzneuta than experienced with Neulasta or Udenyca ▪ Both of the following: – History of intolerance, contraindication, or Adverse Event to Neulasta or Udenyca – Physician attests that, in their clinical opinion, the same intolerance, contraindication, or Adverse Event would not be expected to occur with Ryzneuta ○ Ryzneuta is proven and medically necessary for the following indications when criteria in the policy are met: ▪ Hematopoietic syndrome of acute radiation syndrome ▪ Primary prophylaxis of chemotherapy-induced Febrile Neutropenia (FN) ▪ Secondary prophylaxis of Febrile Neutropenia (FN) ▪ Treatment of Febrile Neutropenia	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Oct. 1, 2025	**Applicable Codes** • Added HCPCS code J9361 **Supporting Information** • Updated *Background*, *FDA*, and *References* sections to reflect the most current information	
Xolair® (Omalizumab)	Oct. 1, 2025	**Coverage Rationale** • Revised coverage criteria; replaced criterion requiring "the patient is not receiving any of [the listed therapies] in combination with Xolair" with "the patient is not receiving any of [the listed therapies] in combination with Xolair *for treatment of the same indication*" **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	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.

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 Community Plan 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 Community Plan Medical Policies and Medical Benefit Drug Policies is available at **UHCprovider.com** > Policies and Protocols > Community Plan Policies > Medical & Drug Policies.