United Healthcare®

UnitedHealthcare Individual Exchange
Medical Policy Update Bulletin: August 2025

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Medical Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Clinical Trials	Aug. 1, 2025	**Related Policies** • Added reference link to the Medicare Advantage Medical Policy titled *Experimental Procedures and Items, Investigational Devices, and Clinical Trials* **Definitions** • Updated definition of "Covered Health Care Service(s)" **Supporting Information** • Updated *FDA* section to reflect the most current information
Cochlear Implants	Aug. 1, 2025	**Medical Records Documentation Used for Review** • Updated list of Medical Records Documentation Used for Reviews; replaced: ○ "Treatments tried, failed, or contraindicated; include the dates and reason for discontinuation" with "treatments tried, failed, or contraindicated; include the dates, *duration*, and reason for discontinuation" ○ "*Other* applicable diagnostic tests" with "*all recent* applicable *imaging studies and* diagnostic tests"
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Sep. 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 *Benefit Considerations*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache)	Aug. 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
Surgery of the Hip	Aug. 1, 2025	**Medical Records Documentation Used for Review** • Updated list of Medical Records Documentation Used for Reviews; replaced "complete diagnostic imaging *report(s) that are separate and distinct from the professional component of an evaluation and management office visit*" with "complete diagnostic *interpretation of* imaging *findings including, at a minimum: relevant clinical information, detailed report of imaging findings, impression, and specialty(ies) of the provider(s) who interpreted the images*"
Surgery of the Knee	Aug. 1, 2025	**Medical Records Documentation Used for Review** • Updated list of Medical Records Documentation Used for Reviews; replaced "complete diagnostic imaging *report(s) that are separate and distinct from the professional component of an evaluation and management office visit*" with "complete diagnostic *interpretation of* imaging *findings including, at a minimum: relevant clinical*

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Surgery of the Knee (continued)	Aug. 1, 2025	*information, detailed report of imaging findings, impression, and specialty(ies) of the provider(s) who interpreted the images*"	
Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech)	Sep. 1, 2025	**Coverage Rationale** • Revised discharge criteria; replaced criterion requiring "functional abilities have become comparable to *those of others* of the same chronological age *and gender*" with "functional abilities have become comparable to *individuals* of the same chronological age" ***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 testing in all languages the child is exposed to in order to compare potential deficits ○ For speech and language therapy services for an	**Note**: This policy applies to benefit plans that have medical necessity requirements for habilitation, rehabilitation, and maintenance therapies. 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. The documentation requirements outlined below 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. **Initial Therapy Evaluation/Initial Therapy Visit Requests** The therapy evaluation report must include **all** of the following: • A statement of the individual's medical history; and • A comparison prior level of function to current level of function, as applicable; and • A description of the individual's functional impairment including its impact on their health, safety, and/or independence; and • A clear diagnosis including the appropriate ICD-10 code; and • Reasonable prognosis, including the individual's potential for meaningful and noteworthy progress; and • Baseline objective measurements (current versions of standardized assessments), including a description of the individual's current deficits and their severity level which include:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech) (continued)	Sep. 1, 2025	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	○ Current standardized assessment scores, age equivalents, percentage of functional delay, criterion-referenced scores, and/or other objective information as appropriate for the individual's condition or impairment ○ Standardized assessments administered must correspond to the delays identified and relate to the long- and short-term goals ○ Standardized assessments results will not be used as the sole determinant as to the medical necessity of the requested initial therapy visit ○ If the individual has a medical condition that prevents them from completing standardized assessment(s), alternative could include: ▪ The therapist provides in-depth objective clinical information using task analysis to describe the individual's deficit area(s) in lieu of standardized assessments ▪ The therapist should include checklists, caregiver reports or interviews, and clinical observation **Plan of Care** The initial authorization for therapy must also include a plan of care (POC). Providers must develop an individual's POC based on the results of the evaluation. The POC must include **all** the following: • Functional or physical impairment; and • Short and long-term therapeutic goals and objectives: ○ Treatment goals should be specific to the individual's diagnosed condition or functional or physical impairment ○ Treatment goals must be functional, measurable, attainable and time based ○ Treatment goals must relate to individual-specific functional skills and • Treatment frequency, duration, and anticipated length of treatment session(s) **Re-Evaluations** Re-evaluations must be completed at least once every twelve months or more frequently based on state regulatory requirements to support the need for on-going services. Re-evaluations performed more often than once should only be completed when the individual experiences a significant

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Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech) (continued)	Sep. 1, 2025		change in functional level in their condition or functional status. The documentation must be reflective of this change. Re-evaluations must include current standardized assessment scores, percentage of functional delay, criterion referenced scores or other objective information as appropriate for the individual's condition or impairment. The therapy re-evaluation report must include **all** of the following:
			• Date of last therapy evaluation; and
			• Number of therapy visits authorized, and number of therapy visits attended; and
			• Compliance to home program; and
			• Description of the individual's current deficits and their severity level documented using objective data; and
			• Objective demonstration of the individual's progress towards each treatment goal:
			  ○ Using consistent and comparable methods to report progress on short-term and long-term treatment goals established
			  ○ For all unmet goals, baseline, and current function so that the individual's progress towards goals can be measured
			and
			• An updated statement of the prescribed treatment modalities and their recommended frequency/duration; and
			• A brief prognosis with clearly established discharge criteria; and
			• An updated individualized POC must include updated measurable, functional, and time-based goals:
			  ○ The updated POC/progress summary must not be older than 90 days; and
			  ○ If the majority of the long and short-term goals were not achieved, the plan of care must include a description of the barriers or an explanation why the goal(s) needed to be modified or discontinued
			and
			• A revised POC that the treating therapist has not made a meaningful update to support the need for continued services will not be accepted, in addition, the notation of the percentage accuracy towards the individual's goals alone is not sufficient to establish a need for continued, medically necessary therapy

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech) (continued)	Sep. 1, 2025		**Treatment Session Notes** All treatment session notes must include: • Date of treatment • Specific treatment(s) provided that match the CPT code(s) billed • Accurate documentation of the length of treatment session • The individual's response to treatment • Skilled ongoing reassessment of the individual's progress toward the goals • All progress toward the goals in objective, measurable terms using consistent and comparable methods • Any problems or changes to the POC • Individual or caregiver involvement in and feedback about home program activities • Signature and date of the treating provider **Group Therapy** The documentation must include **all** of the following: • Prescribing provider's order for group therapy; and • Individualized treatment plan that includes frequency and duration of the prescribed group therapy and individualized treatment goals; and • Name and signature of licensed therapist providing supervision over the group therapy session; and • Specific treatment techniques utilized during the group therapy session and how the techniques will restore function; and • Accurate documentation of the length of treatment session; and • Group therapy setting or location; and • Number of clients in the group **Feeding and Swallowing Disorders** For feeding and swallowing evaluations, **all** of the following must be submitted: • Interview/case history; and • Medical/clinical records including the potential impact of medications, if any; and • Physical examination; and

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Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech) (continued)	Sep. 1, 2025		• Previous screening and assessments; and
			• Collaboration with providers and other caregivers
			  ○ During assessment, therapists determine whether the individual is an appropriate candidate for treatment and/or management; this determination is based on findings that include medical stability, cognitive status, nutritional status, and psychosocial, environmental, and behavioral factors
			and
			• Assessment must result in one or more of the following outcomes:
			  ○ Description of the characteristics of swallowing function, including any breakdowns in swallow physiology
			  ○ Diagnosis of a swallowing disorder
			  ○ Determination of the safest and most efficient route (oral vs. non-oral) of nutrition and hydration intake
			  ○ Identification of the effectiveness of intervention and support
			  ○ Recommendations for intervention and support for oral, pharyngeal, and/or laryngeal disorders
			  ○ Prognosis for improvement and identification of other relevant factors, if appropriate
			
			Discharge Criteria
			Discharge criteria includes but is not limited to all of the following (as applicable):
			• Treatment goals and objectives have been met
			• Functional abilities have become comparable to individuals of the same chronological age
			• The desired level of function that has been agreed to by the individual and provider has been achieved
			• The skill of a therapist or other licensed healthcare professional (within the scope of his/her licensure) is not required
			• The individual exhibits behavior that interferes with improvement or participation in treatment and efforts to address these factors have not been successful
			• In some situations, the individual, family, or designated guardian may choose not to participate in treatment, may relocate, or may seek another provider if the therapeutic relationship is not satisfactory; therefore, discharge is also appropriate in the following situations,

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Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech) (continued)	Sep. 1, 2025		provided that the individual, family, and/or guardian have been advised of the likely outcomes of discontinuation: ○ There is a request to be discharged or request continuation of services with another provider ○ The individual is transferred or discharged to another location where ongoing service from the current provider is not reasonably available; efforts should be made to ensure continuation of services in the new locale ○ The individual is unable to tolerate treatment because of a serious medical, psychological, or other condition **Speech and Language Considerations** • 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 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; and ○ Language deficits must be present in the language in which the individual has the highest proficiency; and ○ 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
Implanted Spinal Drug Delivery Systems	Sep. 1, 2025	**Coverage Rationale** • Added language to indicate replacement of the device is considered medically necessary when the individual has met all of the criteria for initial placement and the existing device is non-functional and either cannot be	**Cancer-Related Pain** **Epidural or intrathecal drug infusion trial or catheter pump placement for cancer-related pain is proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Epidural or Intrathecal Catheter Placement. Click here to view the InterQual® criteria.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Implanted Spinal Drug Delivery Systems (continued)	Sep. 1, 2025	repaired or is no longer under warranty **Medical Records Documentation Used for Review** • Updated list of Medical Records Documentation Used for Reviews; replaced: ○ "Treatments tried, failed, or contraindicated; include the dates and reason for discontinuation" with "treatments tried, failed, or contraindicated; include the dates, *duration*, and reason for discontinuation" ○ "*Other* applicable diagnostic tests" with "*all recent* applicable *imaging studies and* diagnostic tests" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	**Spasticity** **Epidural or intrathecal drug infusion trial or catheter pump placement for severe spasticity is proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Epidural or Intrathecal Catheter Placement. Click here to view the InterQual® criteria. **Chronic Non-Malignant Pain** **Epidural or intrathecal catheter drug infusion trial for non-malignant pain is proven and medically necessary for the following:** • Chronic intractable pain of a non-malignant origin (e.g., failed back surgery syndrome, complex regional pain syndrome, neuropathic pain) when all of the following criteria are met: ○ Age > 18 years*; and ○ Etiology of pain is known and clearly documented; and ○ Further treatment or surgical intervention for underlying condition is not indicated or refused; and ○ Documentation of treatment failure due to intolerable side-effects or failure to provide analgesia safely after a minimum of a 6-month trial of conservative methods of pain management (e.g., pharmacological, physical therapy, behavioral health treatment); and ○ Documentation of the absence of underlying, untreated psychological or psychosocial issues that will interfere with successful pain treatment **Epidural or intrathecal catheter pump placement for non-malignant pain is proven and medically necessary when all of the following criteria are met:** • Completion of drug infusion trial that met above criteria; and • Documentation of a ≥ 50% reduction in pain during trial **Replacement of Device** **Replacement of the device is considered medically necessary when the individual has met all of the criteria for initial placement and the**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Implanted Spinal Drug Delivery Systems (continued)	Sep. 1, 2025		**existing device is non-functional and either cannot be repaired or is no longer under warranty.** *This policy does not address individuals who are younger than 18 years of age.
Surgery of the Shoulder	Sep. 1, 2025	**Coverage Rationale** • Revised language pertaining to medical necessity clinical coverage criteria: ○ 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 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	**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 ○ 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

Retired		
Policy Title	**Effective Date**	**Summary of Changes**
Core Decompression for Avascular Necrosis	Aug. 1, 2025	• Retired policy; core decompression for avascular necrosis no longer requires clinical review

New

Policy Title	Effective Date	Coverage Rationale
Encelto™ (Revakinagene Taroretcel-Lwey)	Sep. 1, 2025	**Encelto is proven and medically necessary for one treatment per eye, per lifetime for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel) who meet all of the following:** • Patient is at least 18 years of age; **and** • Submission of medical records (e.g., chart notes) confirming diagnosis of non-proliferative macular telangiectasia type 2 (MacTel) in at least one eye; **and** • Patient will be monitored for signs and symptoms of retinal tears and/or retinal detachment (e.g., acute onset of flashing lights, floaters, and/or loss of visual acuity); **and** • Encelto is prescribed by an ophthalmologist; **and** • Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Authorization will be issued for no more than one treatment per eye per lifetime and for no longer than 60 days from approval

Updated

Policy Title	Effective Date	Summary of Changes
Skyrizi® (Risankizumab-Rzaa)	Aug. 1, 2025	**Coverage Rationale** • Updated list of examples of targeted immunomodulators the patient must not be receiving in combination with Skyrizi: ***Crohn's Disease (CD)*** ○ Added: ▪ Entyvio (vedolizumab) ▪ Omvoh (mirikizumab-mrkz) ▪ Tremfya (guselkumab) ○ Removed: ▪ Xeljanz (tofacitinib) ○ Replaced: ▪ "*Humira* (adalimumab)" with "adalimumab" ▪ "*Stelara* (ustekinumb)" with "ustekinumab" ***Ulcerative Colitis (UC)*** ○ Added: ▪ Entyvio (vedolizumab) ▪ Tremfya (guselkumab) ▪ Zeposia (ozanimod) ○ Removed: ▪ Cimzia (certolizumab) ▪ Enbrel (etanercept) ▪ Olumiant (baricitinib) ▪ Orencia (abatacept)

Updated

Policy Title	Effective Date	Summary of Changes
Skyrizi® (Risankizumab-Rzaa) (continued)	Aug. 1, 2025	○ Replaced: ▪ "*Stelara* (ustekinumab)" with "ustekinumab" ▪ "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)" ● Updated list of examples of targeted immunomodulators with which the patient received previous treatment: ***Crohn's Disease (CD)*** ○ Added: ▪ Entyvio (vedolizumab) ▪ Omvoh (mirikizumab-mrkz) ▪ Rinvoq (upadacitinib) ▪ Tremfya (guselkumab) ○ Replaced: ▪ "*Stelara* (ustekinumb)" with "ustekinumab" ***Ulcerative Colitis (UC)*** ○ Added: ▪ Entyvio (vedolizumab) ▪ Omvoh (mirikizumab-mrkz) ▪ Tremfya (guselkumab) ▪ Zeposia (ozanimod) ○ Replaced: ▪ "*Stelara* (ustekinumab)" with "ustekinumab" ▪ "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)" **Supporting Information** ● Added *Benefit Considerations* section ● Updated *References* section to reflect the most current information
Vyepti® (Eptinezumab-Jjmr)	Sep. 1, 2025	**Applicable Codes** ● Added ICD-10 diagnosis codes G43.A0, G43.A1, G43.B0, G43.B1, G43.D0, and G43.D1 **Supporting Information** ● Updated *Background*, *Clinical Evidence*, and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Complement Inhibitors	Sep. 1, 2025	**Title Change** ● Previously titled *Complement Inhibitors (PiaSky®, Soliris®, & Ultomiris®)*	**Bkemv (eculizumab-aeeb) and Epysqli (eculizumab-aagh) have been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time.** This policy refers only to the following complement inhibitor drug products: ● Bkemv (eculizumab-aeeb)

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

Complement Inhibitors (continued)	Sep. 1, 2025	**Coverage Rationale**
		• Revised list of applicable complement inhibitor drug products; added:
		  ○ Bkemv (eculizumab-aeeb)
		  ○ Epysqli (eculizumab-aagh)
		• Added language to indicate:
		  ○ Bkemv (eculizumab-aeeb) and Epysqli (eculizumab-aagh) have been added to the Review at Launch program and some members may not be eligible for coverage of this medication at this time; refer to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for additional details
		  ○ 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)
		  ▪ Generalized myasthenia gravis in patients who are anti-acetylcholine receptor (AChR) antibody positive
		  ▪ Neuromyelitis optica spectrum disorder (NMOSD)
		  ▪ Paroxysmal nocturnal hemoglobinuria (PNH)
			• 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.
			
			Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Complement Inhibitors (continued)	Sep. 1, 2025	○ Bkemv and Epysqli are unproven and not medically necessary for the treatment of the following indications when criteria listed in the policy are met Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) ● Revised coverage criteria for: ***Paroxysmal Nocturnal Hemoglobinuria (PNH)*** ○ Added criterion to allow coverage when 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)] ○ Replaced criterion requiring "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*"	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Complement Inhibitors (continued)	Sep. 1, 2025	***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)*]" ▪ "The patient is not receiving the *Soliris or Ultomiris* in combination with *another* complement *protein* C5 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*	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Complement Inhibitors (continued)	Sep. 1, 2025	*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: ▪ "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	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Complement Inhibitors (continued)	Sep. 1, 2025	the treatment of multiple sclerosis" with "the patient is not receiving *the requested product* in combination with disease modifying therapies *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	
Reblozyl® (Luspatercept-Aamt)	Sep. 1, 2025	**Coverage Rationale** • Added language to indicate UnitedHealthcare recognizes indications and uses of injectable oncology medications, including therapeutic radiopharmaceuticals, listed in the *NCCN Drugs and Biologics Compendium* with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and medically necessary, and Categories of Evidence and Consensus of 3 as unproven and not medically necessary • Removed language indicating Reblozyl is proven and/or medically necessary for the treatment of symptomatic anemia in erythropoiesis stimulating agent-naïve (ESA-naïve) patients	**Reblozyl is proven and/or medically necessary for the treatment of anemia in adult patients with beta thalassemia who meet all of the following criteria:** • **Initial Therapy** ○ Diagnosis of anemia due to beta thalassemia including beta^{+} thalassemia, beta^{0} thalassemia, and hemoglobin E/beta thalassemia; **and** ○ Patient is 18 years of age or older; **and** ○ Patient is transfusion dependent as evidenced by **both** of the following in the previous 24 weeks: ▪ Has required regular transfusion of at least six units of packed red blood cells (PRBC); **and** ▪ No transfusion free period greater than 35 days **and** ○ Prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of beta thalassemia; **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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	with myelodysplastic syndromes (MDS) ***Anemia in Adult Patients With Beta Thalassemia*** • Revised coverage criteria for: Initial Therapy ○ Replaced criterion requiring "diagnosis of beta thalassemia including beta+ thalassemia, beta0 thalassemia, and hemoglobin E/beta thalassemia" with "diagnosis of *anemia due to* beta thalassemia including beta+ thalassemia, beta0 thalassemia, and hemoglobin E/beta thalassemia" Continuation of Therapy ○ Added criterion requiring documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline) ○ Removed criterion requiring: ▪ Diagnosis of beta thalassemia including beta+ thalassemia, beta^0 thalassemia, and hemoglobin E/beta thalassemia ▪ Patient has experienced a reduction in transfusion requirements from pretreatment baseline of at least 2 units PRBC while receiving Reblozyl	• **Continuation of Therapy** ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline); **and** ○ Prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of beta thalassemia; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Reauthorization will be for no more than 12 months **Reblozyl is proven and medically necessary for the treatment of symptomatic anemia in patients with myelodysplastic syndromes who meet all of the following criteria:** • **Initial Therapy** ○ Diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS); **and** ○ Patient has lower risk disease defined as International Prognostic Scoring System (IPSS-R): Very Low, Low, or Intermediate; **and** ○ Patient does not have a confirmed mutation with deletion 5q [del(5q)]; **and** ○ **One** of the following: ▪ **Both** of the following: – Ring sideroblasts < 15% (or ring sideroblasts < 5% with an SF3B1 mutation); and – Serum erythropoietin ≤ 500 mU/mL **or** ▪ Ring sideroblasts ≥ 15% (or ring sideroblasts ≥ 5% with an SF3B1 mutation) **and** ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes; **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

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Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	***Symptomatic Anemia in Patients With Myelodysplastic Syndromes*** • Revised language to indicate Reblozyl is proven and medically necessary for the treatment of symptomatic anemia in patients with myelodysplastic syndromes who meet all of the following criteria: Initial Therapy ○ Diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) ○ Patient has lower risk disease as defined as International Prognostic Scoring System (IPSS-R): Very Low, Low, Intermediate ○ Patient does not have a confirmed mutation with deletion 5q [del(5q)] ○ One of the following: ▪ Both of the following: – Ring sideroblasts < 15% (or ring sideroblasts < 5% with an SF3B1 mutation) – Serum erythropoietin ≤ 500 mU/mL ▪ Ring sideroblasts ≥ 15% (or ring sideroblasts ≥ 5% with an SF3B1 mutation) ○ Prescribed by, or in consultation with, a	• **Continuation of Therapy** ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline); **and** ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes; **and** ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Reauthorization will be for no more than 12 months **Reblozyl is proven and medically necessary for the treatment of anemia in patients with myelodysplastic syndrome/myeloproliferative overlap neoplasm (MDS/MPN) who meet all of the following criteria:** • **Initial Therapy** ○ Diagnosis of anemia due to myelodysplastic syndrome/myeloproliferative overlap neoplasm (MDS/MPN); **and** ○ Presence of a SF3B1 mutation; **and** ○ Thrombocytosis defined as platelet count ≥ 450 x 10^9/L; **and** ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of MDS/MPN; **and** ○ Dosing is in accordance with the FDA approved labeling; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline); **and** ○ Reblozyl is prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of MDS/MPN; **and** ○ Dosing is in accordance with the FDA approved labeling; **and** ○ Reauthorization will be for no more than 12 months **Reblozyl is proven and medically necessary for the treatment of myelofibrosis-associated anemia who meet all of the following criteria:** • **Initial Therapy** ○ Diagnosis of myelofibrosis-associated anemia; **and**

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Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes ○ Dosing is in accordance with the U.S. FDA approved labeling ○ Initial authorization will be for no more than 12 months Continuation of Therapy ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline) ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes ○ Dosing is in accordance with the FDA approved labeling ○ Reauthorization will be for no more than 12 months ***Anemia in Patients With Myelodysplastic Syndrome/ Myeloproliferative Overlap Neoplasm (MDS/MPN)*** • Added language to indicate Reblozyl is proven and medically necessary for the treatment of anemia in patients with myelodysplastic syndrome/ myeloproliferative overlap	○ **One** of the following: ▪ **Both** of the following**:** – Symptomatic splenomegaly and/or constitutional symptoms; **and** – Used in combination with a JAK inhibitor [e.g., Inrebic (fedratinib), Jakafi (ruxolitinib), Ojjaara (momelotinib), Vonjo (pacritinib)] **or** ▪ No splenomegaly or constitutional symptoms **and** ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelofibrosis; **and** ○ Dosing is in accordance with the FDA approved labeling; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline); **and** ○ Reblozyl is prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelofibrosis; **and** ○ Dosing is in accordance with the FDA approved labeling; **and** ○ Reauthorization will be for no more than 12 months **Reblozyl is not proven or medically necessary for the treatment of:** • Alpha thalassemia • Beta thalassemia in pediatric patients • Non-transfusion dependent beta thalassemia • Sickle beta thalassemia [hemoglobin S (HbS)/beta thalassemia] UnitedHealthcare recognizes indications and uses of injectable oncology medications, including therapeutic radiopharmaceuticals, listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and medically necessary, and Categories of Evidence and Consensus of 3 as unproven and not medically necessary.

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Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	neoplasm (MDS/MPN) who meet all of the following criteria: Initial Therapy ○ Diagnosis of anemia due to myelodysplastic syndrome/ myeloproliferative overlap neoplasm (MDS/MPN) ○ Presence of a SF3B1 mutation ○ Thrombocytosis defined as platelet count ≥ 450 x 109/L ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of MDS/MPN ○ Dosing is in accordance with the U.S. FDA approved labeling ○ Initial authorization will be for no more than 12 months Continuation of Therapy ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline) ○ Reblozyl is prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of MDS/MPN ○ Dosing is in accordance with the U.S. FDA approved labeling	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	○ Reauthorization will be for no more than 12 months ***Myelofibrosis-Associated Anemia*** ● Added language to indicate Reblozyl is proven and medically necessary for the treatment of myelofibrosis-associated anemia who meet all of the following criteria: Initial Therapy ○ Diagnosis of myelofibrosis-associated anemia ○ One of the following: ▪ Both of the following: – Splenomegaly and constitutional symptoms well controlled on current JAK inhibitor [e.g., Inrebic (fedratinib), Jakafi (ruxolitinib), Ojjaara (momelotinib),Vonjo (pacritinib)] – Used in combination with a JAK inhibitor [e.g., Inrebic (fedratinib), Jakafi (ruxolitinib), Ojjaara (momelotinib),Vonjo (pacritinib)] ▪ No splenomegaly or constitutional symptoms ○ Prescribed by, or in consultation with, a hematologist, oncologist, or	

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Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	other specialist with expertise in the diagnosis and management of myelofibrosis ○ Dosing is in accordance with the U.S. FDA approved labeling ○ Initial authorization will be for no more than 12 months Continuation of Therapy ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline) ○ Reblozyl is prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelofibrosis ○ Dosing is in accordance with the U.S. FDA approved labeling ○ Reauthorization will be for no more than 12 months **Supporting Information** • Updated *Clinical Evidence* section to reflect the most current information	
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®)	Sep. 1, 2025	**Coverage Rationale** • Revised coverage criteria; replaced criterion requiring "the patient is not receiving any of [the listed therapies] in combination with Cinqair/Fasenra/Nucala" with "the patient is not receiving any of [the listed therapies] in	This policy refers to the following drug products for administration by a healthcare professional: • Cinqair® (reslizumab) for intravenous (IV) route • Fasenra® (benralizumab) for subcutaneous (SC) route • Nucala® (mepolizumab) for subcutaneous (SC) route Fasenra® (benralizumab) and Nucala® (mepolizumab) for self-administered

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	combination with Cinqair/ Fasenra/Nucala *for treatment of the same indication*" • Removed language indicating Nucala is unproven and not medically necessary for the treatment of chronic obstructive pulmonary disease (COPD) • Added language to indicate: ○ Nucala, for provider administration, is proven for patients who meet the following criteria: ▪ Diagnosis of chronic obstructive pulmonary disorder (COPD) defined by both of the following: – Post-bronchodilator forced expiratory volume (FEV1)/forced vital capacity (FVC) ratio less than 0.7 – Post-bronchodilator FEV1 % predicted greater than or equal to 30% and less than or equal to 70% ▪ Patient has an eosinophilic phenotype defined by a baseline (pre-mepolizumab treatment) peripheral blood eosinophil level ≥ 300 cells/µL ▪ Patient has uncontrolled or inadequately controlled	subcutaneous injection are obtained under the pharmacy benefit. Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	COPD demonstrated by both of the following: – One of the following: • Two or more COPD exacerbations in the previous year requiring treatment with systemic corticosteroids and/or antibiotics • One or more COPD exacerbation(s) that resulted in hospitalization or observation for over 24 hours in an emergency department or urgent care facility in the past year – COPD exacerbation(s) occurred while receiving maintenance therapy with one of the following: • Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta) • Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an ICS ▪ Symptoms of chronic productive cough for at least 3 months in the past year ▪ Nucala will be used as add-on maintenance therapy in combination with one of the following: – Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	– Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an ICS ▪ One of the following: – Physician attestation that the patient or caregiver is not competent or is physically unable to administer the Nucala product FDA labeled for self-administration – Patient has documented history of severe hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, or hypotension) to Nucala within the past 6 months and requires administration and direct monitoring by a healthcare professional – Patient is new to therapy with Nucala and requires initial dose to be directly	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	monitored by a healthcare professional before continued self-administration (note: Authorization will be for 1 dose) ▪ Patient is not receiving Nucala in combination with any of the following for treatment of the same indication: – Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)] – Anti-IgE therapy [e.g., Xolair (omalizumab)] – Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] – Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] ▪ Dosing is in accordance with the U.S. FDA approved labeling ▪ Prescribed by an allergist/immunologist/ pulmonologist ▪ Initial authorization will be for no more than 12 months	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	○ For patients currently on Nucala for the treatment of (COPD) authorization for continued use will be approved based on all of the following criteria: ▪ Documentation of positive clinical response to Nucala therapy ▪ Nucala is being used in combination with maintenance therapy [e.g., Advair/AirDuo (fluticasone/salmeterol), Bevespi Aerosphere (glycopyrrolate/ formoterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/formoterol), Trelegy Ellipta (fluticasone furoate/ umeclidinium/vilanterol)] ▪ Patient is not receiving Nucala in combination with any of the following for treatment of the same indication: – Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)] – Anti-IgE therapy [e.g., Xolair (omalizumab)] – Anti-interleukin 4	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	therapy [e.g., Dupixent (dupilumab)] – Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] ▪ 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 J44.0, J44.1, and J44.9 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®)	Sep. 1, 2025	**Coverage Rationale** • Added language to indicate rituximab is proven for the treatment of immunoglobulin G4-related disease (IgG4-RD); rituximab is medically necessary for the treatment of IgG4-RD when all of the following criteria are met: ***Initial Therapy*** ○ Diagnosis of IgG4-RD ○ Confirmation of IgG4-RD by a positive assessment using the ACR/EULAR classification criteria,	This policy refers only to the following drug products, rituximab injections for intravenous infusion for non-oncology conditions: • Riabni® (rituximab-arrx) • Rituxan® (rituximab) • Rituxan Hycela® (rituximab and hyaluronidase human) • Ruxience® (rituximab-pvvr) • Truxima® (rituximab-abbs) • Any FDA-approved rituximab biosimilar product not listed here “Rituximab” will be used to refer to all rituximab products without hyaluronidase. Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®) (continued)	Sep. 1, 2025	demonstrated by all of the following: ▪ Involvement of at least 1 or more organ(s) in a manner consistent with IgG4-RD ▪ Exclusion criteria is negative and consistent with an IgG4-RD diagnosis (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations) ▪ Inclusion criteria is positive and signifies a diagnosis of IgG4-RD (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations) ○ Prescribed by, or in consultation with, a specialist with expertise in the treatment of IgG4-RD ○ Patient is not receiving rituximab in combination with a disease modifying therapy for the treatment of IgG4-related disease [e.g., Uplizna (inebilizumab-cdon)] ○ Initial authorization will be for no more than 12 months ***Continuation of Therapy*** ○ Documentation of positive clinical response ○ Prescribed by, or in consultation with, a specialist	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®) (continued)	Sep. 1, 2025	with expertise in the treatment of IgG4-RD ○ Patient is not receiving rituximab in combination with a disease modifying therapy for the treatment of IgG4-related disease [e.g., Uplizna (inebilizumab-cdon)] ○ Reauthorization will be for no more than 12 months **Applicable Codes** • Added ICD-10 diagnosis code D89.84 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Susvimo® (Ranibizumab Injection)	Sep. 1, 2025	**Coverage Rationale** • Revised list of applicable diagnoses for which Susvimo is proven and medically necessary; added diabetic retinopathy (DR) **Applicable Codes** • Added ICD-10 diagnosis codes E08.319, E08.3291, E08.3292, E08.3293, E08.3299, E08.3391, E08.3392, E08.3393, E08.3399, E08.3491, E08.3492, E08.3493, E08.3499, E08.3521, E08.3522, E08.3523, E08.3529, E08.3531, E08.3532, E08.3533, E08.3539, E08.3541, E08.3542, E08.3543, E08.3549, E08.3551, E08.3552, E08.3553, E08.3559, E08.3591, E08.3592, E08.3593, E08.3599, E09.319, E09.3291, E09.3292,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Susvimo® (Ranibizumab Injection) (continued)	Sep. 1, 2025	E09.3293, E09.3299, E09.3391, E09.3392, E09.3393, E09.3399, E09.3491, E09.3492, E09.3493, E09.3499, E09.3521, E09.3522, E09.3523, E09.3529, E09.3531, E09.3532, E09.3533, E09.3539, E09.3541, E09.3542, E09.3543, E09.3549, E09.3551, E09.3552, E09.3553, E09.3559, E09.3591, E09.3592, E09.3593, E09.3599, E10.319, E10.3291, E10.3292, E10.3293, E10.3299, E10.3391, E10.3392, E10.3393, E10.3399, E10.3491, E10.3492, E10.3493, E10.3499, E10.3521, E10.3522, E10.3523, E10.3529, E10.3531, E10.3532, E10.3533, E10.3539, E10.3541, E10.3542, E10.3543, E10.3549, E10.3551, E10.3552, E10.3553, E10.3559, E10.3591, E10.3592, E10.3593, E10.3599, E11.319, E11.3291, E11.3292, E11.3293, E11.3299, E11.3391, E11.3392, E11.3393, E11.3399, E11.3491, E11.3492, E11.3493, E11.3499, E11.3521, E11.3522, E11.3523, E11.3529, E11.3531, E11.3532, E11.3533, E11.3539, E11.3541, E11.3542, E11.3543, E11.3549, E11.3551, E11.3552, E11.3553, E11.3559, E11.3591, E11.3592, E11.3593, E11.3599, E13.319, E13.3291, E13.3292, E13.3293, E13.3299, E13.3391, E13.3392, E13.3393, E13.3399, E13.3491, E13.3492, E13.3493, E13.3499, E13.3521, E13.3522,	

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Susvimo® (Ranibizumab Injection) (continued)	Sep. 1, 2025	E13.3523, E13.3529, E13.3531, E13.3532, E13.3533, E13.3539, E13.3541, E13.3542, E13.3543, E13.3549, E13.3551, E13.3552, E13.3553, E13.3559, E13.3591, E13.3592, E13.3593, and E13.3599 **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Uplizna® (Inebilizumab-Cdon)	Sep. 1, 2025	**Coverage Rationale** ***Neuromyelitis Optica Spectrum Disorder (NMOSD)*** • Revised coverage criteria; replaced criterion requiring "the patient is not receiving any of [the listed therapies] in combination with Uplizna" with "the patient is not receiving any of [the listed therapies] in combination with Uplizna *for treatment of the same indication*" ***Immunoglobulin G4-Related Disease (IgG4-RD)*** • Added language to indicate Uplizna (inebilizumab-cdon) is proven and medically necessary for the treatment of IgG4-RD when all the following criteria are met: ***Initial Therapy*** ○ Diagnosis of IgG4-RD ○ Confirmation of IgG4-RD by a positive assessment using the ACR/EULAR	**Uplizna (inebilizumab-cdon) is proven and medically necessary for the treatment of neuromyelitis optica spectrum disorder (NMOSD) when all the following criteria are met:** • For **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 – Acute myelitis – Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting – Acute brainstem syndrome – Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions – 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** ○ **One** of the following: ▪ History of failure of rituximab therapy; **or** ▪ **Both** of the following: – History of intolerance or contraindication to rituximab; **and**

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Uplizna® (Inebilizumab-Cdon) (continued)	Sep. 1, 2025	classification criteria, demonstrated by all of the following: ▪ Involvement of at least 1 or more organ(s) in a manner consistent with IgG4-RD ▪ Exclusion criteria is negative and consistent with an IgG4-RD diagnosis (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations) ▪ Inclusion criteria is positive and signifies a diagnosis of IgG4-RD (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations) ○ Both of the following: ▪ History of failure, contraindication, or intolerance to glucocorticoids ▪ One of the following: – History of failure of rituximab therapy – Both of the following: • History of intolerance or contraindication to rituximab • Physician attests that, in their clinical opinion,	– Physician attests that, in their clinical opinion, the same intolerance or severe adverse event would not be expected to occur with Uplizna **and** ○ **One** of the following: ▪ History of one or more relapses that required rescue therapy during the previous 12 months prior to initiating Uplizna; **or** ▪ History of two or more relapses that required rescue therapy during the previous 24 months, prior to initiating Uplizna **and** ○ Uplizna is initiated according to the U.S. FDA labeled dosing for NMOSD; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Patient is **not** receiving Uplizna in combination with **any** of the following for treatment of the same indication: ▪ Multiple sclerosis disease modifying therapies [e.g., dimethyl fumarate, fingolimod, Ocrevus (ocrelizumab), etc.] ▪ Complement inhibitors [e.g., eculizumab, PiaSky (crovalimab), Ultomiris (ravulizumab)] ▪ Anti-IL6 therapy (e.g., tocilizumab) ▪ Anti-CD20 therapy (e.g., rituximab) **and** ○ Initial authorization will be for no more than 12 months • For **continuation of therapy**: ○ Documentation of positive clinical response; **and** ○ Uplizna is dosed according to the U.S. FDA labeled dosing for NMOSD; **and** ○ Patient is **not** receiving Uplizna in combination with **any** of the following for treatment of the same indication: ▪ Multiple sclerosis disease modifying therapies [e.g., dimethyl fumarate, fingolimod, Ocrevus (ocrelizumab), etc.] ▪ Anti-IL6 therapy (e.g., tocilizumab) ▪ Complement inhibitors [e.g., eculizumab, PiaSky (crovalimab), Ultomiris (ravulizumab)] ▪ Anti-CD20 therapy (e.g., rituximab) **and** ○ Reauthorization will be for no more than 12 months

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Uplizna® (Inebilizumab-Cdon) (continued)	Sep. 1, 2025	the same intolerance or severe adverse event would not be expected to occur with Uplizna ○ Uplizna is initiated according to the U.S. FDA labeled dosing for IgG4-RD ○ Prescribed by, or in consultation with, a specialist with expertise in the treatment of IgG4-RD ○ Patient is not receiving Uplizna in combination with a disease modifying therapy for the treatment of IgG4-related disease (e.g., rituximab) ○ Initial authorization will be for no more than 12 months ***Continuation of Therapy*** ○ Documentation of positive clinical response ○ Uplizna is dosed according to the U.S. FDA labeled dosing for IgG4-RD ○ Prescribed by, or in consultation with, a specialist with expertise in the treatment of IgG4-RD ○ Patient is not receiving Uplizna in combination with a disease modifying therapy for the treatment of IgG4-related disease (e.g., rituximab) ○ Reauthorization will be for no	**Uplizna (inebilizumab-cdon) is proven and medically necessary for the treatment of Immunoglobulin G4-related disease (IgG4-RD) when all the following criteria are met:** • For **initial therapy**: ○ Diagnosis of Immunoglobulin G4-related disease (IgG4-RD); **and** ○ Confirmation of IgG4-RD by a positive assessment using the ACR/EULAR classification criteria, demonstrated by **all** of the following: ▪ Involvement of at least 1 or more organ(s) in a manner consistent with IgG4-RD; **and** ▪ Exclusion criteria is negative and consistent with an IgG4-RD diagnosis (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations); **and** ▪ Inclusion criteria is positive and signifies a diagnosis of IgG4-RD (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations) **and** ○ **Both** of the following: ▪ History of failure, contraindication, or intolerance to glucocorticoids; **and** ▪ **One** of the following: – History of failure of rituximab therapy; **or** – **Both** of the following: • History of intolerance or contraindication to rituximab; **and** • Physician attests that, in their clinical opinion, the same intolerance or severe adverse event would not be expected to occur with Uplizna **and** ○ Uplizna is initiated according to the U.S. FDA labeled dosing for IgG4-RD; **and** ○ Prescribed by, or in consultation with, a specialist with expertise in the treatment of IgG4-RD; **and** ○ Patient is **not** receiving Uplizna in combination with a disease modifying therapy for the treatment of IgG4-related disease (e.g., rituximab); **and**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Uplizna® (Inebilizumab-Cdon) (continued)	Sep. 1, 2025	more than 12 months **Applicable Codes** • Added ICD-10 diagnosis code D89.84 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	○ Initial authorization will be for no more than 12 months • For **continuation of therapy**: ○ Documentation of positive clinical response; **and** ○ Uplizna is dosed according to the U.S. FDA labeled dosing for IgG4-RD; **and** ○ Prescribed by, or in consultation with, a specialist with expertise in the treatment of IgG4-RD; **and** ○ Patient is **not** receiving Uplizna in combination with a disease modifying therapy for the treatment of IgG4-related disease (e.g., rituximab); **and** ○ Reauthorization will be for no more than 12 months

General Information

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

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

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Medical Policy Update Bulletin was developed to share important information regarding changes to our Individual Exchange Medical Policies and Medical Benefit Drug Policies. When information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

Policy Update Classifications

New

New clinical coverage criteria have been adopted for a health service (e.g., test, drug, device, or procedure)

Updated

An existing policy has been reviewed and changes have not been made to the clinical coverage criteria; however, items such as the clinical evidence, FDA information, and/or list(s) of applicable codes may have been updated

Revised

An existing policy has been reviewed and revisions have been made to the clinical coverage criteria

Replaced

An existing policy has been replaced with a new or different policy

Retired

The health service(s) addressed in the policy are no longer being managed or are considered to be proven/medically necessary and are therefore not excluded as unproven/not medically necessary services, unless coverage guidelines or criteria are otherwise documented in another policy

The complete library of UnitedHealthcare Individual Exchange Medical Policies and Medical Benefit Drug Policies is available at **UHCprovider.com/policies** > For Individual Exchange Plans > Medical & Drug Policies.