

## Clinical Policy: Inebilizumab-cdon (Uplizna)

Reference Number: CP.PHAR.458

Effective Date: 06.11.20

Last Review Date: 08.25

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)  
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Inebilizumab-cdon (Uplizna®) is an anti-CD19-directed cytolytic antibody.

### FDA Approved Indication(s)

Uplizna is indicated for the treatment of:

- Neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive
- Immunoglobulin G4-related disease (IgG4-RD) in adult patients
- Generalized myasthenia gravis (gMG) in adult patients who are antiacetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Uplizna is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Neuromyelitis Optica Spectrum Disorder (must meet all):

1. Diagnosis of NMOSD;
2. Prescribed by or in consultation with a neurologist;
3. Age  $\geq$  18 years;
4. Member has positive serologic test for anti-AQP4 antibodies;
5. Member has experienced at least one relapse within the previous 12 months;
6. Member meets one of the following (a or b):
  - a. History of at least one relapse requiring rescue therapy<sup>†</sup> during the previous 12 months;
  - b. History of two relapses requiring rescue therapy<sup>†</sup> during the previous 24 months;

<sup>†</sup>Rescue therapies include: IV corticosteroids, IV immunoglobulin, and/or plasma exchange

7. Baseline expanded disability status scale (EDSS) score of  $\leq$  8;
8. Failure of rituximab (*Ruxience™ and Truxima® are preferred*)<sup>\*</sup> at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;<sup>^</sup>

<sup>\*</sup>Prior authorization may be required for rituximab

<sup>^</sup>For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395

9. At the time of request, member does not have active hepatitis B infection (positive results for hepatitis B surface antigen and anti-hepatitis B virus tests) or active or untreated latent tuberculosis;
10. Uplizna is not prescribed concurrently with rituximab, Bkemv<sup>TM</sup>, Soliris<sup>®</sup>, Enspryng<sup>®</sup>, Ephysql<sup>®</sup>, or Ultomiris<sup>®</sup>;
11. Dose does not exceed a loading dose of 300 mg on Day 1 and Day 15, followed by 300 mg every 6 months starting 6 months after the first infusion.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

**B. Immunoglobulin G4-Related Disease (must meet all):**

1. Diagnosis of IgG4-RD;
2. Provider attestation that diagnosis meets the American College of Rheumatology/European Union League Against Rheumatism (ACR/EULAR) IgG4-RD classification criteria (*see Appendix D*);
3. Prescribed by or in consultation with a rheumatologist, gastroenterologist, nephrologist, pulmonologist, or internist;
4. Age  $\geq$  18 years;
5. Documentation that the member has a history of IgG4-RD affecting at least two organs/sites;
6. Member is currently receiving glucocorticoid treatment for an IgG4-RD flare;\*

*\*For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*

7. At the time of request, member does not have active hepatitis B infection (positive results for hepatitis B surface antigen and anti-hepatitis B virus tests) or active or untreated latent tuberculosis;
8. Uplizna is not prescribed concurrently with rituximab;
9. Dose does not exceed a loading dose of 300 mg on Day 1 and Day 15, followed by 300 mg every 6 months starting 6 months after the first infusion.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

**C. Generalized Myasthenia Gravis (must meet all):**

1. Diagnosis of gMG;
2. Prescribed by or in consultation with a neurologist;
3. Age  $\geq$  18 years;
4. One of the following Myasthenia Gravis-Activities of Daily Living (MG-ADL) scores at baseline (a or b):
  - a.  $\geq 11$ ;
  - b. Between 6 to 10, with  $> 50\%$  of the score attributed to non-ocular items;
5. Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV;
6. Member has positive serologic test for one of the following (a or b):
  - a. Anti-AChR antibodies;
  - b. Anti-MuSK antibodies;

7. If member has positive serologic test for anti-AChR antibodies: Failure of a cholinesterase inhibitor (*see Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;\*  
*\*For Illinois HIM requests, the step therapy requirement above does not apply as of 1/1/2026 per IL HB 5395*
8. Failure of a corticosteroid (*see Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;\*  
*\*For Illinois HIM requests, the step therapy requirement above does not apply as of 1/1/2026 per IL HB 5395*
9. Failure of at least one non-steroidal immunosuppressive therapy (*see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated;\*  
*\*For Illinois HIM requests, the step therapy requirement above does not apply as of 1/1/2026 per IL HB 5395*
10. Uplizna is not prescribed concurrently with Imaavy™, Rystiggo®, Soliris®/Bkemv™/Ephysli®, Ultomiris®, Vyvgart®, Vyvgart® Hytrulo, or Zilbrysq®;
11. Dose does not exceed a loading dose of 300 mg on Day 1 and Day 15, followed by 300 mg every 6 months starting 6 months after the first infusion.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

**D. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Neuromyelitis Optica Spectrum Disorder (must meet all):**

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

- b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy – including but not limited to improvement or stabilization in any of the following parameters:
  - a. Frequency of relapse;
  - b. EDSS;
  - c. Visual acuity;
3. Uplizna is not prescribed concurrently with rituximab, Bkemv, Soliris, Enspryng, Ephysqli, or Ultomiris;
4. If request is for a dose increase, new dose does not exceed 300 mg every 6 months.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

**B. Immunoglobulin G4-Related Disease (must meet all):**

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. Uplizna is not prescribed concurrently with rituximab;
4. If request is for a dose increase, new dose does not exceed 300 mg every 6 months.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

**C. Generalized Myasthenia Gravis (must meet all):**

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy as evidenced by a  $\geq$  2-point reduction from baseline in the MG-ADL total score;
3. Uplizna is not prescribed concurrently with Imaavy, Rystiggo, Soliris/Bkemv/ Ephysqli, Ultomiris, Vyvgart, Vyvgart Hytrulo, or Zilbrysq;
4. If request is for a dose increase, new dose does not exceed 300 mg every 6 months.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

**D. Other diagnoses/indications** (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

AChR: acetylcholine receptor

ACR: American College of Rheumatology

AQP-4: aquaporin-4

EDSS: expanded disability status scale

EULAR: European League Against  
Rheumatism

FDA: Food and Drug Administration

gMG: generalized myasthenia gravis

IgG4-RD: immunoglobulin G4-related disease

MG-ADL: Myasthenia Gravis-Activities of  
Daily Living

MGFA: Myasthenia Gravis Foundation of  
America

MuSK: muscle specific tyrosine kinase

NMOSD: neuromyelitis optica spectrum  
disorder

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
Rituxan® (rituximab), Riabni™ (rituximab- arrx), Ruxience™ (rituximab-pvvr),	<b>NMOSD</b> IV: 375 mg/m <sup>2</sup> per week for 4 weeks as induction, followed by 375 mg/m <sup>2</sup> biweekly every 6 to 12 months	See regimen

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Truxima® (rituximab-abbs)*		
<b>Corticosteroids for gMG</b>		
betamethasone	Oral: 0.6 to 7.2 mg PO per day	7.2 mg/day
dexamethasone	Oral: 0.75 to 9 mg/day PO	9 mg/day
methylprednisolone	Oral: 12 to 20 mg PO per day; increase as needed by 4 mg every 2-3 days until there is marked clinical improvement	40 mg/day
prednisone	Oral: 15 mg/day to 20 mg/day; increase by 5 mg every 2-3 days as needed	60 mg/day
<b>Cholinesterase Inhibitors for gMG</b>		
pyridostigmine (Mestinon®)	Oral immediate-release: 600 mg daily in divided doses (range, 60-1,500 mg daily in divided doses) Oral sustained release: 180-540 mg QD or BID	Immediate-release: 1,500 mg/day Sustained-release: 1,080 mg/day
neostigmine (Bloxiverz®)	Oral: 15 mg TID. The daily dosage should be gradually increased at intervals of 1 or more days. The usual maintenance dosage is 15-375 mg/day (average 150 mg) IM or SC: 0.5 mg based on response to therapy	Oral: 375 mg/day
<b>Nonsteroidal Immunosuppressants for gMG</b>		
azathioprine (Imuran®)	Oral: 50 mg QD for 1 week, then increase gradually to 2 to 3 mg/kg/day	3 mg/kg/day
mycophenolate mofetil (Cellcept®)*	Oral: Dosage not established. 1 gram BID has been used with adjunctive corticosteroids or other non-steroidal immunosuppressive medications	2 g/day
cyclosporine (Sandimmune®)*	Oral: initial dose of cyclosporine (non-modified), 5 mg/kg/day in 2 divided doses	5 mg/kg/day
Rituxan® (rituximab), Riabni™ (rituximab-arrx), Ruxience™ (rituximab-pvvr), Truxima® (rituximab-abbs)*	IV: 375 mg/m <sup>2</sup> once a week for 4 weeks; an additional 375 mg/m <sup>2</sup> dose may be given every 1 to 3 months afterwards	375 mg/m <sup>2</sup>

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*\*Off-label*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): previous life-threatening reaction to infusion of Uplizna, active hepatitis B infection, active or untreated latent tuberculosis
- Boxed warning(s): none reported

*Appendix D: General Information*

- AQP-4-IgG-seropositive status is confirmed with the use of commercially available cell-binding kit assay (Euroimmun).
- The MG-ADL scale is an 8-item patient-reported scale that measures functional status in 8 domains related to MG – talking, chewing, swallowing, breathing, impairment of ability to brush teeth or comb hair, impairment of ability to arise from a chair, double vision, and eyelid droop. Each domain is given a score of 0-3, with 0 being normal and 3 being most severe impairment. A 2-point decrease in the MG-ADL score is considered a clinically meaningful response.
- ACR/EULAR IgG4-RD classification criteria (all of the following):
  - Meets entry requirements:
    - Characteristic clinical or radiologic involvement of a typical organ (e.g., pancreas, salivary glands, bile ducts, orbits, kidney, lung, aorta, retroperitoneum, pachymeninges, or thyroid gland [Riedel's thyroiditis])  
OR
    - Pathologic evidence of an inflammatory process accompanied by a lymphoplasmacytic infiltrate of uncertain etiology in one of these same organs
  - Does NOT meet any of the classification criteria exclusions:
    - Fever
    - No objective response to glucocorticoids
    - Leukopenia and thrombocytopenia with no explanation
    - Peripheral eosinophilia
    - Positive antineutrophil cytoplasmic antibody (specifically against proteinase 3 or myeloperoxidase)
    - Positive SSA/Ro or SSB/La antibody
    - Positive double-stranded DNA, RNP, or Sm antibody
    - Other disease-specific autoantibody
    - Cryoglobulinemia
    - Known radiologic findings suspicious for malignancy or infection that have not been sufficiently investigated
    - Rapid radiologic progression
    - Long bone abnormalities consistent with Erdheim-Chester disease
    - Splenomegaly
    - Cellular infiltrates suggesting malignancy that have not been sufficiently evaluated
    - Markers consistent with inflammatory myofibroblastic tumor
    - Prominent neutrophilic inflammation
    - Necrotizing vasculitis
    - Prominent necrosis
    - Primarily granulomatous inflammation
    - Pathologic features of macrophage/histiocytic disorder

- Multicentric Castleman's disease
- Crohn's disease or ulcerative colitis (if only pancreatobiliary disease is present)
- Hashimoto thyroiditis (if only the thyroid is affected)
- Achieves  $\geq 20$  classification criteria inclusion points:

Domain/Items	Numeric Weight
<i>Histopathology</i>	
Uninformative biopsy	0
Dense lymphocytic infiltrate	+4
Dense lymphocytic infiltrate and obliterative phlebitis	+6
Dense lymphocytic infiltrate and storiform fibrosis with or without obliterative phlebitis	+13
<i>Immunostaining</i>	
	0–16, as follows: <ul style="list-style-type: none"> <li>• 0, if the IgG4+:IgG+ ratio is 0–40% or indeterminate and the number of IgG4+ cells/hpf is 0–9</li> <li>• 7, if 1) the IgG4+:IgG+ ratio is <math>\geq 41\%</math> and the number of IgG4+ cells/hpf is 0–9 or indeterminate; or 2) the IgG4+:IgG+ ratio is 0–40% or indeterminate and the number of IgG4+ cells/hpf is <math>\geq 10</math> or indeterminate</li> <li>• 14, if 1) the IgG4+:IgG+ ratio is 41–70% and the number of IgG4+ cells/hpf is <math>\geq 10</math>; or 2) the IgG4+:IgG+ ratio is <math>\geq 71\%</math> and the number of IgG4+ cells/hpf is 10–50</li> <li>• 16, if the IgG4+:IgG+ ratio is <math>\geq 71\%</math> and the number of IgG4+ cells/hpf is <math>\geq 51</math></li> </ul>
<i>Serum IgG4 concentration</i>	
Normal or not checked	0
$>$ Normal but $< 2 \times$ upper limit of normal	+4
$2–5 \times$ upper limit of normal	+6

Domain/Items	Numeric Weight
> 5× upper limit of normal	+11
<i>Bilateral lacrimal, parotid, sublingual, and submandibular glands</i>	
No set of glands involved	0
One set of glands involved	+6
Two or more sets of glands involved	+14
<i>Chest</i>	
Not checked or neither of the items listed is present	0
Peribronchovascular and septal thickening	+4
Paravertebral band-like soft tissue in the thorax	+10
<i>Pancreas and biliary tree</i>	
Not checked or none of the items listed is present	0
Diffuse pancreas enlargement (loss of lobulations)	+8
Diffuse pancreas enlargement and capsule-like rim with decreased enhancement	+11
Pancreas (either of above) and biliary tree involvement	+19
<i>Kidney</i>	
Not checked or none of the items listed is present	0
Hypocomplementemia	+6
Renal pelvis thickening/soft tissue	+8
Bilateral renal cortex low-density areas	+10
<i>Retroperitoneum</i>	
Not checked or neither of the items listed is present	0
Diffuse thickening of the abdominal aortic wall	+4
Circumferential or anterolateral soft tissue around the infrarenal aorta or iliac arteries	+8

## V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NMOSD, IgG4-RD, gMG	Loading dose: 300 mg IV, followed by a second 300 mg IV dose 2 weeks later  Maintenance dose: 300 mg IV every 6 months, starting 6 months after the first infusion	See regimen

## VI. Product Availability

Solution for injection in a single-dose vial: 100 mg/10 mL

## VII. References

- Uplizna Prescribing Information. Gaithersburg, MD: Viela Bio, Inc.; December 2025. Available at: <https://www.uplizna.com>. Accessed December 16, 2025.
- Cree BA, Bennet JL, Kim HJ, et al. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N-MOmentum): A double-blind, randomised placebo-controlled phase 2/3 trial. Lancet. 2019; 394(10206): P1352-1363.

3. Sellner J, Boggild M, Clanet M, et al. EFNS guidelines on diagnosis and management of neuromyelitis optica. European Journal of Neurology. 2010; 17: 1019–1032.
4. Kumpfel T, Giglhuber K, Aktas O, et al. Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management. Journal of Neurology. 2023; 271: 141-176.
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6. Wallace ZS, Naden RP, Chari S, et al. The 2019 American College of Rheumatology/European League Against Rheumatism classification criteria for IgG4-related disease. Arthritis Rheumatol. 2020; 72(1): 7-19.
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8. Nowak RJ, Benatar M, Ciafaloni E, et al. A phase 3 trial of inebilizumab in generalized myasthenia gravis. N Engl J Med. 2025; 392(23): 2309-2320.
9. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016; 87(4); 419-425.
10. Narayanaswami P, Sanders DB, Wolfe G, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2020; 96(3): 114-122.
11. Treatment strategy. Myasthenia Gravis Foundation of America. Available at: <https://myasthenia.org/Newly-Diagnosed/Treatment-Strategy>. Accessed December 16, 2025.
12. Muppudi S, Silvestri N, Tan R, et al. The evolution of Myasthenia Gravis-Activities of Daily Living (MG-ADL) scale utilization to measure myasthenia gravis symptoms and treatment response (1817). Neurology. 2021; 96(15 Suppl): 1817.

### **Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<b>HCPCS Codes</b>	<b>Description</b>
J1823	Injection, inebilizumab-cdon, 1 mg

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>	<b>P&amp;T Approval Date</b>
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	10.20.20	02.21
1Q 2022 annual review: no significant changes; specified that Truxima is also a preferred rituximab product; updated HCPCS code; references reviewed and updated.	09.15.21	02.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Per February SDC and prior clinical guidance, added stepwise redirection requirement if member has failed rituximab, then member must use Enspryng.	02.17.22	05.22
Per August SDC and prior clinical guidance, removed redirection to Enspryng. Template changes applied to other diagnoses/indications and continued therapy section.	08.23.22	11.22
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.03.22	02.23
3Q 2023 annual review: no significant changes; references reviewed and updated.	04.18.23	08.23
3Q 2024 annual review: no significant changes; added Bkemv and Ultomiris to the list of therapies that Uplizna should not be prescribed concurrently with; references reviewed and updated.	05.15.24	08.24
3Q 2025 annual review: for NMOSD, added Ephysqli to the list of therapies that Uplizna should not be prescribed concurrently with, and revised continued approval duration from 6 to 12 months as NMOSD is a chronic condition; RT4: added criteria for the newly approved indication of IgG4-RD; references reviewed and updated. Added step therapy bypass for IL HIM per IL HB 5395.	06.24.25	08.25
RT4: added criteria for the newly approved indication of gMG; for NMOSD and IgG4-RD, extended initial approval durations for Medicaid and HIM from 6 to 12 months and revised all approval durations for Commercial to “6 months or to the member’s renewal date, whichever is longer”.	12.16.25	

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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