Clinical Policy: Inebilizumab (BrandName)
Reference Number: CP.PHAR.458
Effective Date: FDA Approval Date
Last Review Date: 02.20
Line of Business: Commercial, HIM, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Inebilizumab (BrandName®) is an anti-CD19 monoclonal antibody.

FDA Approved Indication(s) [Pending]
Inebilizumab is indicated for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) 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 inebilizumab is medically necessary when the following criteria are met:

I. Initial Approval Criteria*
   *Criteria will mirror the clinical information from the prescribing information once FDA-approved
   A. Neuromyelitis Optica Spectrum Disorder (must meet all):
      1. Diagnosis of NMOSD,*
      2. Prescribed by or in consultation with a neurologist;
      3. Age ≥ 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† during the previous 12 months;
         b. History of two relapses requiring rescue therapy† during the previous 24 months;
            †Rescue therapies include: IV corticosteroids, IV immunoglobulin, and/or plasma exchange
      7. Baseline expanded disability status score (EDSS) score of ≤ 8;*
      8. Failure of rituximab (Rituxan®, Ruxience™, Truxima®) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;*Prior authorization may be required for rituximab
      9. Dose does not exceed a loading dose of 300 mg on Day 1 and Day 15.*
   Approval duration: 26 weeks
   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is
II. Continued Therapy*
   *Criteria will mirror the clinical information from the prescribing information once FDA-approved

A. Neuromyelitis Optica Spectrum Disorder (must meet all):
   1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
   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. If request is for a dose increase, new dose does not exceed 300 mg every 26 weeks.*
   Approval duration: 26 weeks

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 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.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   AQP-4: aquaporin-4
   EDSS: expanded disability status scale
   FDA: Food and Drug Administration
   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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rituxan®/Ruxience™/Truxima® (rituximab)*</td>
<td>375 mg/m² per week for 4 weeks as induction, followed by 375 mg/m² biweekly every 6 to 12 months</td>
<td>See regimen</td>
</tr>
</tbody>
</table>
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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 [Pending]
- Contraindication(s): pending
- Boxed warning(s): pending

Appendix D: General Information
- AQP-4-IgG-seropositive status is confirmed with the use of commercially available cell-binding kit assay (Euroimmun).

V. Dosage and Administration [Pending]

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>NMOSD*</td>
<td>Loading dose: 600 mg IV*</td>
<td>See regimen*</td>
</tr>
<tr>
<td></td>
<td>Maintenance dose: 300 mg IV every 26 weeks*</td>
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VI. Product Availability [Pending]
Pending

VII. References

Coding Implications [Pending]
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.

<table>
<thead>
<tr>
<th>HCPSC Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>Pending</td>
<td>Pending</td>
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Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>01.21.20</td>
<td>02.20</td>
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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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