Psychotherapeutic and Neurological Agents – MISC: Multiple Sclerosis Agents
Ocrelizumab (Ocrevus)

Medical policy no. 62.40.50.60    Effective Date: July 1, 2019

Note:
- For non-preferred agents in this class/category, patients must have had an inadequate response or have had a documented intolerance due to severe adverse reaction or contraindication to at least TWO* preferred agents.
  *If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed
- If a new-to-market drug falls into an existing class/category, the drug will be considered non-preferred and subject to this class/category prior authorization (PA) criteria

Background:
Multiple sclerosis (MS) is a chronic, inflammatory disease which involves the damage and destruction of nerve fibers and myelin, the fatty substance that insulates nerve fibers. This damage can lead to distorted or interrupted signaling between the brain and spinal cord, which can cause a variety of symptoms that worsen over time.

There are four defined clinical courses of MS: relapsing-remitting (RRMS), primary progressive (PPMS), secondary progressive (SPMS), and progressive relapsing (PRMS). RRMS involves defined relapses of declining neurologic symptoms followed by periods of remission. In patients with PPMS, there is typically an absence of attacks prior to disease progression. PPMS is defined by gradual deterioration from disease onset without acute attacks.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>ocrelizumab</td>
<td>Ocrevus may be considered medically necessary when used for the treatment of relapsing remitting multiple sclerosis (RRMS) or primary progressive multiple sclerosis (PPMS)</td>
</tr>
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Clinical policy:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Clinical Criteria (Initial Approval)</th>
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</thead>
</table>
| Relapsing Remitting Multiple Sclerosis (RRMS)   | 1. Diagnosis of RRMS; AND  
2. Patient is 18 years of age or older; AND  
3. The patient must have an inadequate response to two or more medications FDA-approved for the same indication and/or medications that are considered the standard of care; AND  
4. The patient is not concurrently taking other disease-modifying therapies for multiple sclerosis (MS); AND  
5. Test results for hepatitis B viral infection are negative; AND  
6. Dose does not exceed FDA or compendia supported limitations; AND  
7. For patients previously treated with disease-modifying drugs with long-lasting treatment effects (e.g., natalizumab, alemtuzumab), an |
appropriate wash-out period has elapsed prior to planned treatment with ocrelizumab; **AND**
8. For patients with Expanded Disability Status Scale (EDSS) 6.5 or greater:
   a. Imaging evidence of active disease; **AND**
   b. Documentation of at least ONE relapsing event in the last 2 years; **AND**
   c. Documentation that the provider has discussed the benefits and risks of continuing disease-modifying therapy.

If ALL criteria are met, the request will be approved for 12 months

**Criteria (Reauthorization)**

Documentation of clinical benefit as determined by prescriber.

If ALL criteria are met, the request will be approved for 12 months

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### Primary Progressive Multiple Sclerosis (PPMS)

**Clinical Criteria (Initial Approval)**

1. Patient has a diagnosis of PPMS according to the revised McDonald Criteria; **AND**
2. Patient is 18 years of age or older; **AND**
3. Documentation of oligoclonal IgG bands in cerebral spinal fluid; **AND**
4. T2 lesions on brain or spinal cord imaging; **AND**
5. Ambulatory stage of disease (EDSS < 7); **AND**
6. The patient is not concurrently taking other disease-modifying therapies for multiple sclerosis (MS); **AND**
7. Test results for hepatitis B viral infection are negative; **AND**
8. Dose does not exceed FDA or compendia supported limitations.

If ALL criteria are met, the request will be approved for 12 months

**Criteria (Reauthorization)**

Documentation of clinical benefit as determined by prescriber.

If ALL criteria are met, the request will be approved for 12 months

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### Dosage and quantity limits

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dose and Quantity Limits</th>
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| ocrelizumab (Ocrevus) | Initial:  
• 300mg intravenous course on days 1 and 15  
Maintenance:  
• 600mg intravenous every 6 months |

### Coding:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J2350</td>
<td>Injection, ocrelizumab, 1 mg</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G35</td>
<td>Multiple Sclerosis</td>
</tr>
</tbody>
</table>
References

1. Product Information: OCREVUSTM intravenous injection, ocrelizumab intravenous injection. Genentech, Inc (per manufacturer), South San Francisco, CA, 2017
7. Montalban X, et al. Baseline Demographics and Disease Characteristics from ORATORIO, a Phase III Trial Evaluating Ocrelizumab in Patients with Primary Progressive Multiple Sclerosis (P7.017). Neurology April 6, 2015 vol. 84 no. 14 Supplement P7.017

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action and Summary of Changes</th>
</tr>
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<tbody>
<tr>
<td>05.06.2019</td>
<td>New Policy</td>
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