Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Ocrevus (*ocrelizumab*) and Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) PA Criteria:

Ocrevus and Ocrevus Zunovo are indicated for the treatment of

- Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- Primary progressive MS, in adults**. No other disease-modifying MS medications are indicated for use in primary progressive MS.**

Ocrevus **and Ocrevus Zunovo** should be prescribed by, or in consultation with, a physician who specializes in the treatment of MS and/or a neurologist.

Select the formulation below:

☐ Ocrevus (for intravenous administration) OR ☐ Ocrevus Zunovo (for subcutaneous administration)

Select the diagnosis below:

☐ Primary progressive multiple sclerosis (PPMS) ICD-10 code:_____

☐ Relapsing forms of multiple sclerosis (MS) ICD-10 code:_____

☐ Other diagnosis: _____ ICD 10 code: _____

FDA-APPROVED INDICATIONS

1. RELAPSING REMITTING FORMS OF MULTIPLE SCLEROSIS (RRMS) (Approval: 12 Months)

Approve for 12 months if the patient meets **ALL** of the following criteria (**A, B, C, and D**):

☐ Yes ☐ No Age of patient is within the age range as recommended by the FDA label **AND**
☐ Yes ☐ No Relapsing form of multiple sclerosis (MS) [relapsing forms of MS are relapsing-remitting MS {RRMS}, secondary-progressive MS {SPMS} with relapses, or progressive-relapsing MS {PRMS}]; **AND**

☐ Yes ☐ No Previous trial in the last six months of at least two preferred MS drugs which are contraindicated or not tolerated *or* ineffective; **AND**

Please indicate which of the following describe the evidence of treatment ineffectiveness:

- ☐ Yes, ☐ No Increasing clinical relapses (defined as 2 or more relapses in a year, or one severe relapse associated with either poor recover or MRI lesion progression),
- ☐ Yes, ☐ No CNS lesion progression by MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions or T1 hypointense lesions),
- ☐ Yes, ☐ No Worsening disability (sustained worsening of Expanded Disability Status Scale (EDSS) score or neurological examination findings),
- ☐ Yes, ☐ No Continues to have worsening disability as evidenced by decreased mobility and/or ability to perform activities of daily living.
- ☐ Other (please explain):_____

☐ Yes ☐ No This is a particularly aggressive initial disease course, as defined by meeting at least one of the following:

☐Yes, ☐ No EDSS score of ≥ 4 within 5 years of onset; OR
☐Yes, ☐ No Multiple (two or more) relapses with incomplete resolution in the past year; OR
☐Yes, ☐ No At least 2 MRI studies showing new or enlarging T2 lesions or gadolinium-enhancing lesions despite treatment over 6 months; OR
☐Yes, ☐ No Presence of spinal or brainstem lesions on MRI.

2. PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS (PPMS) (Approval: 12 Months)

☐ Yes ☐ No Age of patient is within the age range as recommended by the FDA label
AND

Prescribing physician attests that patient is thought to have PPMS as evidenced by:

☐ Yes, ☐ No --Are there one or more brain T2 lesions in at least one area characteristic for MS (periventricular, juxacortical, cortical or infratentional?)
OR
☐ Yes, ☐ No --Are there two or more T2 lesions in the spinal cord?
OR
☐ Yes, ☐ No --Is there positive CSF (isoelectric focusing evidence of oligoclonal IgG bands or increased IgG index, or both)?

Please indicate the length of disease progression (retrospectively or prospectively determined):

☐ < 1 year **OR** ☐ ≥ 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Ocrevus **and Ocrevus Zunovo** have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

- ☐Yes, ☐ No -**Current Use of Ocrevus and Ocrevus Zunovo with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS)**
  - Ocrevus and Ocrevus Zunovo are not indicated for use in combination with other MS disease-modifying therapies and the safety and efficacy have not been adequately established.

- ☐Yes, ☐ No -***Active* Hepatitis B infection.**
  - Ocrevus **and Ocrevus Zunovo** are contraindicated in patients with active HBV confirmed by positive results for HBsAg and anti-HBV tests.
  - For patients who are negative for surface antigen (HBsAG) and positive for HB core antibody (HBcAb+) or are carriers of HBV (HbsAg+), consult liver disease experts before starting and during treatment.
  - Prior to initiating Ocrevus **or Ocrevus Zunovo**, perform Hepatitis–B Screening Date:_____

REAUTHORIZATION REQUESTS: (Approval 12 months)

- ☐ Yes, ☐ No Continues to meet initial authorization criteria as applicable;
  AND
- ☐ Yes, ☐ No Ocrevus **or Ocrevus Zunovo** was administered to patient in the past 6 months;
  AND
- ☐ Yes, ☐ No Documentation of positive response to therapy (e.g., improved or maintained disease control evidenced by decreased or stabilized Expanded Disability Scale (EDSS) score or reductions in relapses or MRI lesions;
  AND
- ☐ Yes, ☐ No Not using other MS disease-modifying therapies concurrently;
  AND
- ☐ Yes, ☐ No There were no documented severe and / or potentially life threatening adverse event that occurred during or following the previous infusion;
  AND
- ☐ Yes, ☐ No Does not have an active Hepatitis B infection

Ocrevus - How Supplied: Intravenous Solution: 300 mg /10 ml Vial

Ocrevus Dose: _____ Frequency: _____

OR

Ocrevus Zunovo How Supplied: Subcutaneous Injection: 920 mg ocrelizumab and 23,000 units hyaluronidase / 23 mL solution in a single-dose vial

Ocrevus Zunovo Dose: _____ Frequency: _____

Ocrevus Dosage and Administration:

- Initial Dose: 300 mg IV infusion on day 1, followed by a second 300 mg IV infusion 2 weeks later;
- Maintenance dose: 600 mg every 6 months (beginning 6 months after the first 300 mg dose)
- Pre-medicate with 100 mg of methylprednisolone (or an equivalent corticosteroid) administered IV approximately 30 minutes prior to each Ocrevus infusion to reduce the frequency and severity of infusion reactions. Pre-medicate with an antihistamine (e.g., diphenhydramine) approximately 30-60 minutes prior to each Ocrevus infusion to further reduce the frequency and severity of infusion reactions. The addition of an antipyretic (e.g., acetaminophen) may also be considered.
- Observe patient for at least 1 hour after infusion completion.

Ocrevus Zunovo Dosage and Administration:

- Dosing: 920 mg ocrelizumab/23,000 units of hyaluronidase administered as a single 23 mL subcutaneous injection every 6 months
- Administer as a subcutaneous injection in the abdomen over approximately 10 minutes.
- Do not administer 2 inches around the navel. Do not administer into areas where the skin is red, bruised, tender, or hard, or areas where there are moles or scars.
- Premedicate orally with 20 mg of dexamethasone (or an equivalent corticosteroid) and an antihistamine (e.g., desloratadine) at least 30 minutes prior to each injection to reduce the risk of local and systemic injection reactions. The addition of an antipyretic (e.g., acetaminophen) may be considered.
- Monitor the patient closely during injections.
    - For the initial dose, monitor the patient for at least one hour post-injection.
    - For subsequent doses, monitor the patient for at least 15 minutes post-injection.

To prevent medication errors, please verify the product (Ocrevus versus Ocrevus Zunovo) prior to administration. Ocrevus and Ocrevus Zunovo should be administered under the close supervision of an experienced healthcare professional with access to appropriate medical support to manage severe reactions such as serious infusion reactions.