Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

OCREVUS® (*ocrelizumab*) and OCREVUS ZUNOVO® (*ocrelizumab and hyaluronidase-ocsq*) PA CRITERIA:

OCREVUS® and OCREVUS ZUNOVO® are anti-CD20 monoclonal antibodies 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; and primary progressive MS, in adults. No other disease-modifying MS medications are indicated for use in primary progressive MS.

Prior authorization is required for OCREVUS® and OCREVUS ZUNOVO®. Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 12 Months

1. The patient meets the FDA-approved age requirements and dosing parameters for the indicated use; **AND**

2. The medication is prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of multiple sclerosis (MS); **AND**

3. There is no current use of OCREVUS® or OCREVUS ZUNOVO® with other disease-modifying agents used for MS (OCREVUS® and OCREVUS ZUNOVO® are not indicated for use in combination with other MS disease-modifying therapies as safety and efficacy have not been adequately established); **AND**

4. Hepatitis B screening has been completed, and the patient does not have active Hepatitis B infection (OCREVUS® and OCREVUS ZUNOVO® are contraindicated in patients with active HBV confirmed by a positive HBsAg and anti-HBV tests); **AND**

5. The patient has a diagnosis of one or more of the following:

    a. Relapsing form of MS (relapsing forms of MS include relapsing-remitting MS (RRMS), secondary-progressive MS (SPMS) with relapses, or progressive-relapsing MS (PRMS)); **AND**
        i. The patient is John Cunningham (JC) virus antibody positive; **OR**

ii. The patient has had a trial within the past six months of at least two preferred MS therapies, and each was contraindicated, not tolerated, or ineffective, such as:
    1. Increasing clinical relapses (defined as two or more relapses in a year, or one severe relapse associated with either poor recovery or MRI lesion progression); **OR**
    2. CNS lesion progression on MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions or T1 hypointense lesions); **OR**
    3. Worsening disability (sustained worsening of Expanded Disability Status Scale (EDSS) score or neurological examination findings); **OR**
    4. Continues to have worsening disability as evidenced by decreased mobility and/or ability to perform activities of daily living; **AND**
iii. This is a particularly aggressive initial disease course, as defined by meeting at least one of the following:
    1. EDSS score of ≥ 4 within 5 years of onset; **OR**
    2. Multiple (two or more) relapses with incomplete resolution in the past year; **OR**
    3. At least 2 MRI studies showing new or enlarging T2 lesions or gadolinium-enhancing lesions despite treatment over 6 months; **OR**
    4. Presence of spinal or brainstem lesions on MRI.

OR

b. Primary Progressive MS (PPMS); **AND**
    i. The prescribing physician attests that the patient has PPMS as evidenced by:
        1. One or more brain T2 lesions in at least one area characteristic for MS (periventricular, juxtacortical, cortical or infratentorial); **OR**
        2. Two or more T2 lesions in the spinal cord; **OR**
        3. Positive cerebrospinal fluid (CSF) (isoelectric focusing evidence of oligoclonal IgG bands or increased IgG index, or both).

Re-Authorization: 12 Months

1. Patient continues to meet initial authorization criteria as applicable; **AND**

2. OCREVUS® or OCREVUS ZUNOVO® was administered to the patient in the past 6 months; **AND**

3. Documentation of positive response to therapy is provided (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**

4. There were no documented severe or potentially life-threatening adverse events that occurred during or following the previous infusion.

Dosing:

- The recommended starting dose of OCREVUS® is 300 mg IV infusion on day 1, followed by a second 300 mg IV infusion 2 weeks later. The maintenance dose is 600 mg every 6 months (beginning 6 months after the first 300 mg dose).
- The recommended dose of OCREVUS ZUNOVO® is 920 mg ocrelizumab/23,000 units of hyaluronidase administered as a single 23 mL subcutaneous injection in the abdomen every 6 months.
- 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.

Formulation:

- OCREVUS® is available as a single-dose vial of 300 mg per 10 ml solution for intravenous administration.
- OCREVUS ZUNOVO® is available a single-dose vial of 920 mg ocrelizumab and 23,000 units hyaluronidase per 23 mL solution for subcutaneous injection.