Physician Administered Drug Prior Authorization Criteria for Ocrevus®

Prior Authorization Criteria
Version 1, (10/23/2017)
Ocrevus® ocrelizumab
Ocrevus® is a CD-20 directed cytolytic antibody.

Indications[1]: Ocrevus® is used for:

- Treatment of patients with relapsing or primary progressive forms of multiple sclerosis (RRMS, PPMS, currently only FDA-approved drug for PPMS).

Criteria for Approval[1-4]:

- Member must have clear, documented indication for therapy
- Member screened for and is without active hepatitis B viral infection prior to initial dose

Additionally:

For PPMS:

- Only FDA-approved agent for PPMS

For RRMS:

- Member has had an adequate trial with one Montana Health Care Programs preferred drug, in this case interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®), glatiramer acetate (Copaxone®), or fingolimod (Gilenya®), and the preferred drug(s) was ineffective or caused intolerable side effects. An adequate trial is 8 weeks of therapy where member is compliant and adherent to the regimen.

Quantity Limit[1]:

- Product comes as 300 mg/10 mL, single-dose vial
- Member receives initial dose of 300 mg (IV), with a second 300 mg dose two weeks later
- Subsequent doses are 600 mg every 6 months

Criteria for Renewal Authorization Approval[1]:

- Member has been adherent to this regimen, with no adverse events warranting discontinuation of therapy

Criteria for Denial[1-4]:

- Unclear indication
- Active hepatitis B virus infection
- History of life-threatening infusion reaction to ocrelizumab
- The member has not completed an adequate trial with the preferred drugs (RRMS only)

Clinical Monitoring[1-4]:

- All live and live-attenuated vaccines should be administered 6 weeks prior to therapy initiation
- Women of childbearing potential should use contraception while receiving ocrelizumab and for 6 months after the last infusion of ocrelizumab.
- Monitor for infusion reactions during infusion and for at least 1 hr. following end of infusion
- Monitor for hepatitis B virus reactivation
- Monitor for significantly worsening infection, malignancy, and progressive multifocal leukoencephalopathy

References:

1. Ocrevus® [package insert]. South San Francisco, CA: Genentech, Inc.; 2017 March.
2. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; October 23, 2017
3. Olek, MJ. Treatment of progressive multiple sclerosis in adults. Gonzalex-Scarano F, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on October 23, 2017)
4. http:/search.ebscohost.com/login.aspx?direct=true&db=dme&AN=233015&site=dynamed-live&scope=site.