Ocrelizumab (Ocrevus™)

Iowa Medicaid Program:	Prior Authorization	**Effective Date:** 10/20/2017
Revision Number:		**Last Review Date:** 10/20/2017
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:** 10/2018
Approved By:	Medicaid Medical Director	**Approved Date:** 11/27/2017

Ocrelizumab (Ocrevus™) is a CD20-directed cytolytic antibody indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis (MS).

The efficacy of Ocrevus™ in patients with relapsing MS was established in two identical, Phase III, multicenter, randomized, double-blind, double-dummy, active controlled, published, parallel group trials (OPERA I and OPERA II), that used Rebif® (interferon beta-1a subcutaneous [SC]) as an active comparator for up to 96 weeks. In these two trials (OPERA I n = 821 and OPERA II n = 825) the annualized relapse rate (ARR) among patients with relapsing MS was lower with Ocrevus™ in both studies compared with Rebif® (0.16 vs. 0.29; P < 0.001).

The efficacy of Ocrevus™ in patients with primary progressive MS was established in one Phase III, randomized, parallel-group, double-blind, placebo-controlled published trial (ORATORIO [n = 732]).3 Therapy duration was at least 120 weeks. Most patients (88 percent) had not previously used MS disease modifying therapy. In ORATORIO the primary endpoint was the percentage of patients with disability progression confirmed at 12 weeks in a time-to-event analysis that defined disability progression as an increase in the Expanded Disability Status Scale (EDSS) of at least 1.0 point from baseline that was sustained on subsequent visits for at least 12 weeks if the baseline score was 5.5 or less or an increase of at least 0.5 points that was sustained for at least 12 weeks if the baseline EDSS score was more than 5.5. The percentage of patients with primary progressive MS with 12-week confirmed disability progression was 32.9 percent with Ocrevus™ vs. 39.3 percent with placebo (P = 0.03). The percentage of patients with 24-week confirmed disability progression was 29.6 percent with Ocrevus™ vs. 35.7 percent with placebo (P = 0.04). By Week 120, performance on the timed 25-foot walk worsened by 38.9 percent with Ocrevus™ vs. 55.1 percent with placebo (P = 0.04). More favorable MRI results on several parameters were also observed with Ocrevus™ compared with placebo.

Criteria: Coverage for Ocrevus™ can be approved for those members meeting the following criteria:

1. RELAPSING MULTIPLE SCLEROSIS. Approval for one year when **ALL** criteria are met:
    a. The member is 18 years of age or greater; AND
    b. The member has a relapsing form of MS. This include relapsing-remitting MS (RRMS), secondary-progressive MS (SPMS) or progressive-relapsing MS (PRMS); AND
    c. The member has previously tried at least one MS therapy including Avonex (interferon beta-1a), Rebif (interferon beta-1a), Betaseron/Extavia (interferon beta-1b), Plegridy (peginterferon beta-1a), Copaxone/Glatopa (glatiramer acetate), Aubagio (terflunomide tablets), Gilenya (fingolimod) capsules), Tecfidera (dimethyl fumarate delayed-release capsules, Zinbryta (daclizumab), or Lemtrada (alemtuzumab; AND

   d. Ocrevus™ is prescribed by, or in consultation with a physician who specializes in the treatment of MS and/or is a neurologist.
2. PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS (MS). Treatment is approved for one year when the member meets **ALL** of the following criteria:
   a. The member is 18 years of age or older; AND
   b. Ocrevus™ is prescribed by or in consultation with a physician who specializes in the treatment of MS or is a board certified neurologist.
3. Contraindications for treatment include:
   a. Active Hepatitis B
   b. Current use of other disease-modifying agents used for MS.
4. Dosing: Intravenous infusion of 300 mg on day 1, followed by 300 mg 2 weeks later; subsequent doses of 600 mg are administered once every 6 months starting 6 months after the first 300 mg dose.

Codes:
NDC: 50242-150-01
HCPCS: C9494
CPT: 96413

References Used:
Ocrevus™ injection for intravenous infusion [prescribing information]. San Francisco, CA: Genentech, Inc; March 2017.

Hauser SL, Bar-Or A, Comig G, et al, for the OPERA I and OPERA II Clinical Investigators. Ocrelizumab versus interferon beta-1a in relapsing multiple sclerosis. N Engl J Med. 2016 Dec 21. [Epub ahead of print]

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:

C. David Smith, MD