Drug and Biologic Coverage Policy

Ocrelizumab

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Related Coverage Resources

Medication Administration Site of Care

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document (Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document) may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

Ocrelizumab (Ocrevus™) is considered medically necessary when ALL of the following criteria are met:

- Individual is 18 years of age or older
- Monotherapy treatment of ONE of the following:
  - Active Secondary Progressive Multiple Sclerosis (SPMS) (for example, SPMS with a documented relapse)
  - Clinically Isolated Syndrome
  - Primary Progressive Multiple Sclerosis
  - Progressive-relapsing Multiple Sclerosis
  - Relapsing-Remitting Multiple Sclerosis

Ocrelizumab (Ocrevus) is considered experimental, investigational or unproven for ANY other use.

Initial authorization is up to 12 months.

Reauthorization is up to 12 months when the initial authorization criteria are met.
When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

### FDA Approved Indications

#### FDA Approved Indication

Ocrevus is 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.

### Recommended Dosing

#### FDA Recommended Dosing

Administer Ocrevus under the close supervision of an experienced healthcare professional with access to appropriate medical support to manage severe reactions such as serious infusion reactions.

- **Initial dose:** 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion.
- **Subsequent doses:** single 600 mg intravenous infusion every 6 months.
- **Observe the patient for at least one hour after the completion of the infusion**

### General Background

#### Disease Overview

Multiple Sclerosis (MS) is a chronic disabling disease of the central nervous system (CNS) characterized by inflammation, demyelination, and degenerative changes. Patients experience relapses followed by remission of neurological symptoms. MS lesions occur in many different parts of the CNS and the symptoms and clinical course of the disease are highly variable. Some common signs and symptoms of the disease include vision problems (e.g., nystagmus), ambulation problems, pain, fatigue, spasticity, cognitive dysfunction, depression, ataxia, sensory loss, bladder disturbances, bowel dysfunction, dizziness, and vertigo. In general, patients with MS may have diminished ratings on vitality and physical functions. Most people with MS are diagnosed between the ages of 20 and 50 years, but MS can manifest in young children and older adults. Approximately 450,000 people are living with MS in the US. In relapsing forms of MS women are impacted two to three times more commonly than men, and MS appears more predominant among Caucasians. (Gajofatto, 2017; MS Coalition, 2017; National Multiple Sclerosis Society, 2012; Reich, 2018)

Four different clinical courses of MS have been delineated. A relapse is defined as the development of new or recurrung symptoms lasting at least 24 hours and separated from a previous attack by at least 1 month. Relapsing-remitting MS is characterized by acute attacks usually followed by almost complete recovery with limited progression. Disease progression is minimal between attacks. Approximately 85% of people are initially diagnosed with relapsing-remitting MS. Secondary-progressive MS begins as relapsing-remitting course but the disease transitions in many patients to a steadily progressive form with increased loss of function. Of the 85% of patients who initially have relapsing-remitting MS, more than 50% of patients will develop secondary-progressive MS within 10 years as will 90% of patients within 25 years. Primary progressive MS is noted by a steady decline in function from the onset without noted relapses. Around 10% to 15% of patients are diagnosed with primary progressive MS. Progressive-relapsing MS starts with disease progression at onset with occasional acute relapses and continued disease progression. Only a small minority of patients (< 5%) have progressive-relapsing MS. About 10% of the MS population has a benign disease course, which is generally determined retrospectively. Among those with relapsing forms of MS the severity, duration, and frequency of relapses vary widely among patients. The Expanded Disability Status Scale (EDSS) is the scale most often used to assess neurologic disability and evaluates cerebellar, pyramidal, brainstem, sensory, bowel, bladder, visual, and mental functional systems on a scale that ranges from 0 (normal neurologic examination) to 10 (death due to MS). MRI
evaluations are used to assess current MS disease activity, as well as to monitor for permanent neurologic damage. (Gajofatto, 2017; MS Coalition, 2017; National Multiple Sclerosis Society, 2012)

**Professional Societies/Organizations**

**American Academy of Neurology (AAN)**

The AAN practice guideline recommendations regarding disease-modifying therapies for adults with Multiple Sclerosis (MS) makes distinct recommendations of situations in which preferences may be considered, some of which are medication-related. Evidence supports higher efficacy of Lemtrada, Tysabri, Gilenya, and Ocrevus compared with previously self-injectable disease-modifying MS therapies. Subgroup analyses from Phase III pivotal trials with Lemtrada, Gilenya, and Tysabri demonstrate a reduction in MS relapses and MRI measures in patients with MS who have highly-active disease. Compared with beta interferon therapy, treatment with these agents led to more favorable outcomes in the cohort of patients with MS who have highly active disease. For patients with highly-active MS, use of Lemtrada, Gilenya, or Tysabri should be considered (Level B). With Aubagio, there may be a risk of teratogenicity from male sperm, which may last for 2 years following treatment cessation if the patient does not receive chelation therapy. Men with MS should be counseled regarding their reproductive plans before initiating Aubagio therapy (Level B). Tysabri has been associated with progressive multifocal leukoencephalopathy (PML). Regarding oral products, there are rare reports of PML with both Gilenya and Tecfidera. Patients who are considering therapy with Tysabri, Gilenya, Ocrevus, and Tecfidera should be informed about the risks of PML. (Rae-Grant, 2018a)

**The American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative**

No recommendations are available for Multiple Sclerosis.

**Centers for Medicare & Medicaid Services - National Coverage Determinations (NCDs)**

There are no CMS National Coverage Determinations for Ocrevus.

**Other Covered Uses**

AHFS Drug Information 2020 Edition does not support any off-label uses of Ocrevus.

**Experimental, Investigational, Unproven Uses**

Compendia and other published clinical studies do not currently support any uses other than the FDA indication. Criteria will be updated as new published data are available.

**Coding/Billing Information**

*Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.*

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J2350</td>
<td>Injection, ocrelizumab, 1 mg</td>
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**References**