Medical Coverage Policy | Infused Multiple Sclerosis Drugs_ Alemtuzumab(Lemtrada) and Ocrelizumab (Ocrevus)

EFFECTIVE DATE:06|01|2017
POLICY LAST UPDATED: 06|06|2017

OVERVIEW

Multiple sclerosis (MS) is an immune-mediated disease of the central nervous system. It is characterized by demyelation of nerves leading to decreased or improper nerve function. MS affects an estimated 2.3 million people worldwide, is more common among women than men, and has a mean age of onset of 28 to 31 years. MS is categorized into three different types depending on disease presentation. This policy documented the medical criteria for coverage of Alemtuzumab (Lemtrada) and Ocrelizumab (Ocrevus).

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products
Alemtuzumab (Lemtrada)

Alemtuzumab (Lemtrada) is medically necessary when the following criteria have been met:

1. ONE of the following:
    a. The patient is not currently being treated with a disease modifying agent (DMA) for the requested indication
    OR
    b. The patient is currently being treated with a DMA for the requested indication AND the DMA will be discontinued before starting the requested agent

    AND
2. The patient does not have any FDA labeled contraindications to therapy with the requested agent
    AND
3. ONE of the following:
    a. There is documentation that the patient is currently being treated with the requested agent
    OR
    b. The patient has a diagnosis of a relapsing form of multiple sclerosis and meets BOTH of the following:
        i. ONE of the following:
            1. The patient's medication history includes the use of TWO preferred* agents for the treatment of relapsing forms of MS (*If client has preferred agents: Aubagio, Avonex, Betaseron, Copaxone, Gilenya, Glatopa, Plegridy, Rebif, or Tecfidera)
            OR
            2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a preferred* agent for the treatment of relapsing forms of MS (*If client has preferred agents: Aubagio, Avonex, Betaseron, Copaxone, Gilenya, Glatopa, Plegridy, Rebif, or Tecfidera)
            OR
            3. The patient's medication history includes the use of Tysabri

        AND
        ii. The agent is prescribed by or in consultation with a neurologist experienced in multiple sclerosis

    AND
4. The patient will be receiving anti-viral prophylaxis for herpetic viral infections
    AND

5. The prescribed dose is within the FDA approved labeled dosage

Length of Approval: 12 months

Ocrevus® (ocrelizumab)

Ocrevus® (ocrelizumab) is medically necessary when ALL of the following are met:

1. ONE of the following:
    a. The patient is not currently being treated with a disease modifying agent (DMA) for the requested indication
    OR
    b. The patient is currently being treated with a DMA for the requested indication AND the DMA will be discontinued before starting the requested agent

    AND
2. The patient does not have any FDA labeled contraindications to therapy with the requested agent
    AND
3. ONE of the following:
    a. There is documentation that the patient is currently being treated with the requested agent
    OR
    b. The patient has a diagnosis of a relapsing form of multiple sclerosis and meets BOTH of the following:
        i. ONE of the following:
            1. The patient's medication history includes the use of TWO (preferred*) disease modifying agents for the treatment of relapsing forms of MS (*If client has preferred disease modifying agents: Aubagio, Avonex, Betaseron, Copaxone, Gilenya, Glatopa, Plegridy, Rebif, or Tecfidera)
            OR
            1. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to TWO (preferred*) disease modifying agents for the treatment of relapsing forms of MS (*If client has preferred agents: Aubagio, Avonex, Betaseron, Copaxone, Gilenya, Glatopa, Plegridy, Rebif, or Tecfidera)

        AND
        ii. The requested agent is prescribed by or in consultation with a neurologist experienced in multiple sclerosis

    OR
    b. The patient has a diagnosis of a primary progressive form of multiple sclerosis and meets the following:
        i. The requested agent is prescribed by or in consultation with a neurologist experienced in multiple sclerosis

    OR
    c. The patient has another FDA labeled diagnosis

    AND
4. If starting therapy, the patient has been tested for hepatitis B virus and determined to not have active hepatitis B viral infection
    AND
5. The prescribed dose is within the FDA approved labeling

Length of approval: 12 months.

Criteira for approval after initial 12-month approval
Ocrevus® (ocrelizumab) and Lemtrada™ (alemtuzumab) will be renewed when ALL of the following are met:

1. The patient has been previously approved for the requested drug
   AND
2. The patient has had clinical benefit from treatment with the requested agent
   AND
3. If requesting Lemtrada, the patient will be receiving anti-viral prophylaxis for herpetic viral infections
   AND
4. ONE of the following:
   a. The patient is not currently being treated with an additional disease modifying agent (DMA) for the requested indication
      OR
   b. The patient is currently being treated with an additional DMA for the requested indication AND the DMA will be discontinued before continuing with the requested agent
   AND
5. The patient does not have any FDA labeled contraindications to therapy with the requested agent
   AND
6. The prescribed dose is within FDA labeling

Length of Continued Approval: 12 months

PRIOR AUTHORIZATION
Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products.

POLICY STATEMENT
Alemtuzumab (Lemtrada) and Ocrelizumab (Ocrevus) may be considered medically necessary for patients 17 years of age or older for the treatment of relapsing forms of multiple sclerosis when the medical criteria has been met.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable infusion benefits/coverage.

BACKGROUND
Alemtuzumab (Lemtrada)
Lemtrada is indicated for the treatment of patients with relapsing forms of multiple sclerosis to decrease the frequency of clinical exacerbations and/or delay the accumulation of physical disability who had an inadequate response to two or more drugs indicated for the treatment of MS. Lemtrada is a monoclonal antibody that targets CD52, a protein abundant on T and B cells. Circulating T and B cells are thought to be responsible for the damaging inflammatory process in MS. Safety and effectiveness of the Lemtrada in patients younger than 17 years of age have not been established. (2)

Regulatory Status
U.S. Food and Drug Administration (FDA)-approved indication: Lemtrada is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who had an inadequate response to two or more drugs indicated for the treatment of MS.

The Lemtrada label includes a boxed warning citing the risk of autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after last dose

should be monitored. Lemtrada also carries a boxed warning for infusion reactions, which must be administered in an appropriate setting to manage anaphylaxis or serious infusion reactions. (2)

Lemtrada carries another boxed warning for an increased risk of malignancy, including thyroid cancer, melanoma, and lymphoproliferative disorders. Baseline and yearly skin exams should be done. (2)

Lemtrada is contraindicated for patients with HIV infection. Lemtrada can cause prolonged reductions of CD4+ lymphocyte counts which can further disease progression in patients with HIV. (2)

The Lemtrada is available only through a restricted distribution program under a REMS program. The Lemtrada REMS Program, a comprehensive risk management program with frequent monitoring, is being implemented to help mitigate the serious risks associated with the medications use.

Safety and effectiveness of the Lemtrada in patients younger than 17 years of age have not been established.

Typical dosing is the first dose is 12mg per day for 5 days. Subsequent dose is no sooner than 12 months and is dosed 12mg per day for 3 days.

Ocrelizumab (Ocrevus)
On March 28, 2017 the U.S. Food and Drug Administration approved Ocrevus (ocrelizumab) to

"Multiple sclerosis can have a profound impact on a person's life," said Billy Dunn, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research. "This therapy not only provides another treatment option for those with relapsing MS, but for the first time provides an approved therapy for those with primary progressive MS."

MS is a chronic, inflammatory, autoimmune disease of the central nervous system that disrupts communication between the brain and other parts of the body. It is among the most common causes of neurological disability in young adults and occurs more frequently in women than men. For most people with MS, episodes of worsening function (relapses) are initially followed by recovery periods (remissions). Over time, recovery may be incomplete, leading to progressive decline in function and increased disability. Most people experience their first symptoms of MS between the ages of 20 and 40.

PPMS is characterized by steadily worsening function from the onset of symptoms, often without early relapses or remissions. The U.S. Centers for Disease Control and Prevention estimates that approximately 15 percent of patients with MS have PPMS.

The efficacy of Ocrevus for the treatment of relapsing forms of MS was shown in two clinical trials in 1,656 participants treated for 96 weeks. Both studies compared Ocrevus to another MS drug, Rebif (interferon beta-1a). In both studies, the patients receiving Ocrevus had reduced relapse rates and reduced worsening of disability compared to Rebif.

In a study of PPMS in 732 participants treated for at least 120 weeks, those receiving Ocrevus showed a longer time to the worsening of disability compared to placebo.

Ocrevus should not be used in patients with hepatitis B infection or a history of life-threatening infusion-related reactions to Ocrevus. Ocrevus must be dispensed with a patient Medication Guide that describes important information about the drug's uses and risks. Ocrevus can cause infusion-related reactions, which can be serious. These reactions include, but are not limited to, itchy skin, rash, hives, skin redness, flushing, low blood pressure, fever, tiredness, dizziness, headache, throat irritation, shortness of breath, swelling of the throat, nausea, and fast heartbeat. Additionally, Ocrevus may increase the risk for malignancies, particularly breast cancer. Delay Ocrevus treatment for patients with active infections. Vaccination with live or live attenuated vaccines is not recommended in patients receiving Ocrevus.

In addition to the infusion-related reactions, the most common side effect of Ocrevus seen in the clinical trials for relapsing forms of MS was upper respiratory tract infection. The most common side effects in the study of PPMS were upper respiratory tract infection, skin infection, and lower respiratory tract infection.

The FDA granted this application breakthrough therapy designation, fast track designation, and priority review granted approval of Ocrevus to Genentech, Inc.

CODING

Blue CHiP for Medicare and Commercial Products

The following code for Lemtrada™ is medically necessary when criteria is met.
J0202 Injection, alemtuzumab, 1 mg (Lemtrada™)

The following codes for Ocrevus are medically necessary when criteria is met:
For claims with date of service prior to 10/1/2017
claims must be filed with the unlisted HCPCS code and the NDC number

For claims with date of service 10/1/2017 and after
C9494 Injection ocrelizumab, 1mg (Ocrevus® (ocrelizumab)

For claims with date of service 1/1/2018 and after
J2350 Injection, ocrelizumab, 1 mg

RELATED POLICIES

None

PUBLISHED

Provider Update, August 2017
Provider Update, June 2017
Provider Update, April 2016
Provider Update, October 2015

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