MVP Health Care Medical Policy

Medicare Part B: Multiple Sclerosis Agents

Type of Policy:	**Drug and Medical Therapy**
Prior Approval Date:	**04/01/2025**
Approval Date:	**08/01/2025**
Effective Date:	**10/01/2025**
Related Policies:	N/A

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

Refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available

Codes Requiring Prior Authorization (covered under the medical benefit)

J0202 Lemtrada (alemtuzmab injection, 1mg)

J2323 Tysabri (natalizumab injection, 1 mg)

J2329 Briumvi (ublituximab, 150mg/6mL solution for infusion)

Codes Not Requiring Prior Authorization (covered under the medical benefit)

J2350 Ocrevus (ocrelizumab injection, 1mg)

J2351 Ocrevus Zunovo (ocrelizumab, subcutaneous infusion)

Overview

Multiple sclerosis (MS) is a chronic central nervous system disease that is an autoimmune disease. The body's own defense system attacks the myelin sheath which protects the nerve fibers in the central nervous system (CNS). Damage to the myelin sheath and nerve fibers may cause disruption to nerve impulses between the brain and spinal cord which can cause a variety of symptoms. The severity of symptoms and progression of disease is variable between individuals. FDA-approved drugs approved for multiple sclerosis included in this policy are indicated for functional improvement or disease modification.

FDA Approved Indications for MS:

Briumvi:

- Briumvi is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Lemtrada:

- is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of members with relapsing forms of multiple sclerosis. Because of its safety profile, the use of Lemtrada should generally be reserved for members who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Ocrevus and Ocrevus Zunovo:

- Is a CD20-directed cytolytic antibody indicated for the treatment of members with relapsing or primary progressive forms of MS

Tysabri:

- As monotherapy for the treatment of members with relapsing forms of multiple sclerosis to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations. TYSABRI is generally recommended for members who have had an inadequate response to, or are unable to tolerate, an alternate MS therapy.

Indications/Criteria

Agents for Disease Modification

Treatment will be considered for coverage for the treatment of the FDA approved indications for multiple sclerosis:

Preferred Agents:

Ocrevus (ocrelizumab) – see exclusion criteria
Ocrevus Zunovo

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Non-Preferred Agents (prior authorization required):
Tysabri (natalizumab), Lemtrada (alemtuzumab), Briumvi (ublituximab),

Non-Preferred Agents will be considered for coverage for the treatment of FDA approved indications for multiple sclerosis when all of the following are met:

- Prescribed by a neurologist.
- Greater than or equal to 18 years old.
- Monitoring and REMS requirements per the prescribing information are met.
- Neurology chart notes for the past 2 years, including all radiologic reports substantiate MS diagnosis consistent with prescribing information and detail previous treatment, if any.
- Documented failure or significant adverse effects to all preferred agents
    - Documented failure defined as:
        - At least 2 relapses within the past 12 months, AND
        - MRI identifying lesion progression.
- **Tysabri** (natalizumab) coverage will be limited to monotherapy for those members meeting all the above criteria and have had an inadequate response to, or are unable to tolerate, both preferred and non-preferred MS therapies described above AND
    1. A baseline MRI scan must be obtained prior to natalizumab
    2. Members must be evaluated at 3 and 6 months after the first infusion and every 6 months thereafter.
    3. Alternative treatment criteria for members currently with high disease activity, as defined by a high number of relapses while on treatment and the progression of gadolinium-positive lesions on MRI, will be reviewed on a case-by-case basis
- **Lemtrada** (alemtuzumab)-Must have inadequate response to all preferred MS therapies AND not have Human Immunodeficiency Virus (HIV)
- **Briumvi** (ublituximab) coverage will be considered for those members meeting all the above criteria for non-preferred agents and have had an inadequate response to, or are unable to tolerate ALL preferred MS therapies described above AND

- Hepatitis B virus screening and quantitative serum immunoglobulin screening required prior to first dose
- Member must be assessed for active infection prior to every infusion; if member has active infection, infusion must be delayed until infection is resolved.
- Pregnancy test results prior to each infusion for females of reproductive potential
- Member must not have received live vaccines within 4 weeks and non-live vaccines within 2 weeks of treatment with Briumvi.

Initial approval for up to 6 months for self-administered agents and up to 3 infusions in 3 months for Tysabri.

- **For continuation** of therapy for up to 6 months:
  - Continued benefit – decrease in number of relapses.
- Lemtrada (alemtuzumab)
  - **Initial approva**l will be for 12mg/day on 5 consecutive days.
  - **Second approval** will be 12 months after initial approval for 12mg/day on three consecutive days if documentation identifies benefit from initial treatment and no adverse reactions
- Briumvi
  - **Initial approval** for Briumvi will be 2 infusions within one month (150mg initially, followed by 450mg infusion 2 weeks later)
  - **Continuation** of therapy will be 1 infusion every 24 weeks for subsequent infusions if documentation identifies benefit from initial treatment and no adverse reactions

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Exclusions

Lemtrada

- Use beyond two years

Briumvi

- Active hepatitis B virus infection
- History of life-threatening infusion reaction to Briumvi

Ocrevus IV for the treatment of RMS (Relapsing Multiple Sclerosis)

- Doses above 600mg do not provide additional benefit and are not supported medical literature

Agents for Disease Modification exclusions:

- Combination use of disease modifying agents
- Doses exceeding prescribing information
- Members who have in the last 6 months experienced or may be expected to experience medical contraindications or are on concomitant therapy with an agent known to have a significant potential for adverse outcome when used in combination with the requested agent as noted in the prescribing literature.

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