Lemtrada

Description

Lemtrada (alemtuzumab)

Background
Lemtrada is multiple sclerosis (MS) disease-modifying agent. Lemtrada can potentially alter the course of disease by lessening the frequency of clinical exacerbations. 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. Lemtrada depletes circulating T and B lymphocytes after each treatment course. Lymphocyte counts then increase over time (1).

Regulatory Status
FDA-approved indication: Lemtrada is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). 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 (1).

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 (1).
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 (1).

Lemtrada is contraindicated for patients with Human Immunodeficiency Virus (HIV) infection. Lemtrada can cause prolonged reductions of CD4+ lymphocyte counts which can further disease progression in patients with HIV (1).

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 (1).

Live, attenuated vaccines are generally not recommended for a person with MS because their ability to cause disease has been weakened but not totally inactivated (2).

Safety and effectiveness of the Lemtrada in patients younger than 17 years of age have not been established (1).

Related policies
Acthar Gel, Ampyra, Aubagio, Gilenya, Mavenclad, Mayzent, MS Injectables, Ocrevus, Tecfidera, Tysabri

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lemtrada may be considered medically necessary for patients 17 years of age or older for the treatment of relapsing forms of multiple sclerosis and if the conditions indicated below are met.

Lemtrada may be considered investigational in patients less than 17 years of age and for all other indications.

Prior-Approval Requirements

Age 17 years of age and older

Diagnosis
Patient must have the following:

Relapsing Multiple Sclerosis (MS)

AND ALL of the following:
1. Inadequate response to at least two drugs indicated for the treatment of MS
2. Prescriber and patient must be enrolled in Lemtrada REMS program

AND NONE of the following:
1. Co-infection with HIV
2. Used in combination with another MS disease modifying agent
3. Used concurrently with live vaccines

Prior – Approval Renewal Requirements

Age 17 years of age and older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS)

AND ALL of the following:
1. Prescriber and patient must be enrolled in Lemtrada REMS program

AND NONE of the following:
1. Co-infection with HIV
2. Used in combination with another MS disease modifying agent
3. Used concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 2 years
Prior – Approval *Renewal* Limits
Same as above

**Rationale**

**Summary**
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 (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of the MS injectable drugs while maintaining optimal therapeutic outcomes.

**References**

**Policy History**

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<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>December 2014</td>
<td>Addition to PA</td>
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<tr>
<td>September 2016</td>
<td>Annual editorial review and reference update</td>
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<td>Policy code changed from 5.06.23 to 5.60.23</td>
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<tr>
<td>December 2016</td>
<td>Annual editorial review and reference update</td>
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<td>Addition of not given concurrently with live vaccines</td>
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<tr>
<td>March 2017</td>
<td>Annual review</td>
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<tr>
<td>June 2017</td>
<td>Annual review</td>
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<tr>
<td>November 2018</td>
<td>Annual review and reference update</td>
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<tr>
<td>March 2019</td>
<td>Addition of PA Renewal Requirements and changed PA duration from lifetime to 2 years</td>
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<tr>
<td>June 2019</td>
<td>Annual review and reference update</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.