I. Medication Description

Lemtrada is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis. It is presumed that Lemtrada binds to CD52, a cell surface antigen present on T and B lymphocytes, and on natural killer cells, monocytes and macrophages. Following cell surface binding to T and B lymphocytes, Lemtrada results in antibody-dependent cellular cytolysis and complement-mediated lysis. Lemtrada is only available through restricted distribution under REMS program because of the risks of autoimmunity, infusion reactions, and malignancies.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is provided when the following criteria are met:

- Patient must be 18 years or older AND
- The patient has a relapsing form of multiple sclerosis AND
- It is confirmed that the patient is Human Immunodeficiency Virus (HIV) negative AND
- The patient has had an adequate trial with at least two alternative drug therapies indicated for the treatment of MS (e.g. glatiramer, interferons) and failed to achieve an adequate response or experienced intolerance to these drug therapies

IV. Quantity Limitations

- First treatment course: 12mg/day on 5 consecutive days (total of 60 mg)
- Second treatment course: 12 mg/day on 3 consecutive days (total of 36 mg), administered 12 months after the first treatment course.

V. Coverage Duration

Coverage is granted for up to one month, to accommodate one treatment course at a time.
VI. **Coverage Renewal Criteria**

Coverage is may be renewed for a second dose of Lemtrada only after 12 months have passed since the first treatment course.

VII. **Billing/Coding Information**

- Available as 12mg/1.2ml Solution for Injection
- J0202: 1 billable unit = 1mg
- Pertinent indications: Multiple sclerosis (G35)

VIII. **Summary of Policy Changes**

- 6/15/15: new policy
- 7/1/15: formulary distinctions made
- 12/15/15: no policy changes
- 1/1/16: drug code updated; approval duration limited to one treatment course at a time

IX. **References**


*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*