SmartHealth Ascension

Alemtuzumab

(Lemtrada®) J0202 (1mg)

Covered with prior authorization

Alemtuzumab (Lemtrada®) may be authorized when the following criteria are met:

- Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including relapsing-remitting disease or active secondary progressive disease); **AND**
- Individual has received prior treatment with at least two alternative drug therapies indicated for the treatment of multiple sclerosis (e.g., dimethyl fumarate, interferons and glatiramer) and failed to achieve an adequate response; **AND**
- Individual is human immunodeficiency virus (HIV) negative.

Exclusion criteria
Requests may not be approved for the following:

- Treatment of clinically isolated syndrome (CIS)
- Treatment of primary progressive MS (PPMS)
- Treatment of non-active secondary progressive MS (SPMS)
- Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Kesimpta, Mavenclad, Mayzent, Ocrevus, Plegridy, Ponvory, Tecfidera, Tysabri, Vumerity and Zeposia)
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines
- Individual has an active acute or chronic infection at the initiation of therapy
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use

Initial authorization approval is up to 12 months.

Reauthorization approval is up to 12 months.

Reauthorization Criteria
Alemtuzumab is considered medically necessary for continued use when initial criteria are met **AND** the patient has experienced clinical benefit (disease stabilization or improvement) to therapy **AND** has not experienced an unacceptable toxicity.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Alemtuzumab (Lemtrada®) is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing, remitting disease and active secondary progressive disease, in adults.

References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. Lemtrada [Prescribing Information]. Cambridge, MA: Genzyme Corporation; 2022.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022

Criteria History/ Revision Information:

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.