Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Lemtrada (alemtuzumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 Year

Medications	Quantity Limit
Lemtrada (alemtuzumab)	3 vials per 12 months *Initiation of therapy: may approve 2 (two) additional vials (12 mg/1.2 mL) during the first treatment course in the first 12 months

APPROVAL CRITERIA

Requests for Lemtrada (alemtuzumab) may be approved if the following criteria are met:

I. Individual has a diagnosis of relapsing multiple sclerosis (RMS); **AND**
II. Individual has received prior treatment with at least two alternative drug therapies indicated for the treatment of multiple sclerosis (MS) (for example, interferons, glatiramer) and failed to achieve an adequate response; **AND**
III. Individual is human immunodeficiency virus (HIV) negative.

Lemtrada (alemtuzumab) may not be approved for the following:

I. All other indications not included above; **OR**
II. Individual is using to treat primary progressive MS (PPMS); **OR**
III. Individual is using to treat secondary progressive MS (SPMS); **OR**
IV. Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tecfidera and Tysabri).

Note:
Lemtrada has black box warnings for autoimmunity, infusion reactions and malignancies. Lemtrada causes serious autoimmune diseases such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels and urinalysis with urine counts periodically for 48 months after the last dose. Lemtrada causes serious, life-threatening infusion reactions. Lemtrada must be

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

administered in a setting equipped to manage anaphylaxis and serious infusion reactions. Individuals should be monitored for two hours after each infusion and informed infusion reactions can also occur after the monitoring period. Lemtrada may cause an increased risk of malignancies, including thyroid cancer, melanoma and lymphoproliferative disorders. Perform baseline and yearly skin exams. Because of these risks, Lemtrada is available only through restricted distribution under a Risk Evaluation Mitigation Strategy (REMS) Program.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 20, 2019.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
4. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: June 11, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 20, 2019.
5. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90: 777-788. Available from https://www.aan.com/Guidelines/home/GuidelineDetail/898. Accessed: July 20, 2019.