

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

## Lemtrada (alemtuzumab)

DRUG.00074

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

Lemtrada (alemtuzumab) may be approved for the single-agent treatment of relapsing-remitting multiple sclerosis (RRMS) when the following criteria are met:

- I. Individual has received prior treatment with at least two alternative drug therapies indicated for the treatment of MS (for example, interferons, glatiramer) and failed to achieve an adequate response or experienced intolerance of these drug therapies; **AND**
- II. Individual is human immunodeficiency virus (HIV) negative.

Lemtrada (alemtuzumab) may **not** be approved when the above criteria are not met and including, but not limited to, the following diagnoses:

- I. Primary progressive MS (PPMS);
- II. Secondary progressive MS (SPMS);
- III. Combination treatment with other disease modifying biologic MS drug therapies (for example, interferons, glatiramer, daclizumab, natalizumab and ocrelizumab).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

### Key References:

1. Alemtuzumab. In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated December 15, 2017. Available at: <http://www.micromedexsolutions.com>. Accessed on December 22, 2017.
2. Alemtuzumab Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised December 01, 2010. Accessed on December 22, 2017.

PAGE 1 of 2 04/02/2018

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0063-18

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

3. Lemtrada®. [Product Information] Cambridge, MA. Updated December, 2017. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/103948s51591bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103948s51591bl.pdf). Accessed on December 22, 2017.
4. Porfirio GJ, Torloni MR. Alemtuzumab for multiple sclerosis. Cochrane Database Syst Rev. 2016;(4):CD011203.
5. Tramacere I, Giovane C, Salanti G, et al. Immunomodulators and immunosuppressants for relapsing-remitting multiple sclerosis: a network meta-analysis. Cochrane Database Syst Rev. 2015;(2):CD011381.
6. U.S. Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS). BLA 103948 LEMTRADA® (alemtuzumab) CD52-directed cytolytic antibody. Available at: <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=IndvRemsDetails.page&REMS=340>. Accessed on December 22, 2017.
7. Zhang J, Shi S, Zhang Y, et al. Alemtuzumab versus interferon beta 1a for relapsing-remitting multiple sclerosis. Cochrane Database Syst Rev. 2017;(11):CD010968.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.