JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP016
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		Review Date	01/15/2020
	Subject **Lemtrada**	*Revision Date*	11/10/2021
		Page	1 of 3

This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Lemtrada

Table of Contents		Page Number
I.	POLICY	1
II.	POLICY CRITERIA	1
III.	AUTHORIZATION PERIOD/LIMITATIONS	1
IV.	EXCLUSIONS	2
V.	RECOMMENDED DOSAGE	2
VI.	CODES	2
VII.	REFERENCES	2
VIII.	APPROVALS	3

I. POLICY

Lemtrada (alemtuzumab) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

Lemtrada may be approved for patients who meet the following:

1. Patient is 17 years of age or older
2. Documented diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting MS [RRMS], secondary-progressive MS [SPMS] with relapses, progressive-relapsing MS [PRMS])
3. Patient has had inadequate response, or intolerance with two or more formulary (oral or subcutaneous products) indicated for treatment of MS (at least a 3-month trial per medication)
4. Patient has had inadequate response to a trial of Tysabri
5. Documentation of the following laboratory assessments within 6 months of Lemtrada request:
   a. Complete blood count (CBC)
   b. Serum creatinine level
   c. Urinalysis with urine cell counts
   d. Thyroid function test (e.g. TSH)
   e. Skin exam
6. Prescriber is, or in consultation with, a neurologist
7. Both the patient and prescriber are enrolled in the Lemtrada REMS program

III. AUTHORIZATION PERIOD/LIMITATIONS

- Initial approval of Lemtrada will be limited to one course of therapy for 5 consecutive days
- Twelve months after the first treatment course, a second course of therapy with Lemtrada for 3 consecutive days may be approved with documentation showing the following:
  - Patient is tolerating treatment and there continues to be a medical need for the medication

- Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient's condition)
- Documentation that the required laboratory assessment have been re-evaluated since the first course of treatment
- Patent has not received two or more treatment courses
- Patient is not currently taking any other disease modifying agents, immunosuppressants, or antineoplastics

IV. EXCLUSIONS

Lemtrada will **not** be covered for the following:

- Patients with chronic progressive MS
- Patients with uncontrolled active infections
- Any indications that are not FDA-approved, or guideline supported

Lemtrada is contraindicated in patients who are infected with Human Immunodeficiency Virus (HIV) because Lemtrada causes prolonged reductions of CD4+ lymphocyte counts.

V. RECOMMENDED DOSAGE

- Total duration of 24 months of therapy: 12 mg daily for 5 consecutive days (total 60 mg), followed 12 months later by 12 mg daily for 3 consecutive days (total 36 mg)

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CI
Lemtrada 12 MG/1.2ML SOLN Injection, alemtuzumab, 1 mg	J0202

VII. REFERENCES

1. Lemtrada [Prescribing Information]. Cambridge, MA: Genzyme Corporation; 2017 December
2. Coles AJ, Twyman CL, Arnold DL, et al. Alemtuzumab for patients with relapsing multiple sclerosis after disease modifying therapy: a randomized controlled phase 3 trial. Lancet 2012;380:1829-39

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
12/19/2018	Policy Creation
01/15/2020	No policy changes- presented policy for USFHP adoption effective 3/1/2020
11/10/2021	Removed Priority Partners as an applicable LOB

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