Multiple Sclerosis, Injectable Drugs

Goal(s):

- Promote safe and effective use of injectable or infused disease-modifying drugs for multiple sclerosis.

Length of Authorization:

- Up to 12 months

Requires PA:

- Non-preferred injectable or infused multiple sclerosis pharmacy or physician administered claims.
- Note: Tysabri® (natalizumab) should be reviewed under separate Tysabri® PA criteria.
- Note: Requests for Arzerra™ (ofatumumab) should be reviewed under the Oncology PA.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for an FDA-approved form of multiple sclerosis (see Table 1)?	**Yes:** Go to #3.	**No:** Pass to RPH; Deny for medical appropriateness.
3. Is this a request for continuation of therapy?	**Yes**: Go to **Renewal Criteria**	**No:** Go to #4
4. Is the drug prescribed by or in consultation with a neurologist?	**Yes**: Go to # 5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the patient on concurrent treatment with a disease modifying drug (i.e., glatiramer, interferon, mitoxantrone, natalizumab, ofatumumab, ocrelizumab, or peginterferon) to treat MS?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #6
6. Is there documentation of recommended baseline testing to mitigate safety concerns (Table 2)?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
7. Has the patient failed trials for at least 2 drugs indicated for the treatment of MS?	**Yes:** Document drug and dates trialed: 1._____(dates) 2._____(dates) Go to #8	**No:** Pass to RPh. Deny; medical appropriateness.
8. Is the request for a drug with potential risks during pregnancy (e.g., ofatumumab or mitoxantrone)?	**Yes**: Go to #9	**No**: Approve for up to 1 year
9. Is the patient of childbearing potential?	**Yes:** Go to #10	**No:** Approve for up to 12 months
10. Is the patient pregnant or actively trying to conceive?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #11
11. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant?	**Yes:** Approve for up to 1 year	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Has the patient's condition improved as assessed by the prescribing physician and physician attests to patient's improvement?	**Yes:** Approve for 12 months. Document baseline assessment and physician attestation received.	**No:** Pass to RPh; Deny; medical appropriateness.

Table 1. FDA-Approved Indications for Injectable MS Drugs

Generic Name	Brand Name	FDA Indication			
		CIS	RRMS	SPMS	PPMS
Alemtuzumab	LEMTRADA		X	X	
Glatiramer acetate	GLATOPA, COPAXONE	X	X	X	
Interferon beta-1a	AVONEX, REBIF	X	X	X	
Interferon beta-1b	BETASERON, EXTAVIA	X	X	X	
Mitoxantrone	NOVANTRONE		X	X	
Ocrelizumab	OCREVUS	X	X	X	X
Ofatumumab	KESIMPTA	X	X	X	

Abbreviations: CIS = clinically isolated syndrome; PPMS = primary progressive multiple sclerosis; RRMS = relapsing-remitting multiple sclerosis; SPMS = secondary progressive multiple sclerosis

Table 2. FDA-recommended Baseline Safety Assessments

	LFTs	CBC	Thyroid Function Tests	Hepatitis B Virus Screening	Other Screening
Alemtuzumab	X	X	X		VZV and TB Screening, SCr, UA, up to date with all vaccinations
Glatiramer acetate					
Interferon beta-1a	X	X	X		
Interferon beta-1b	X	X	X		
Mitoxantrone	X	X			ECG and LVEF
Ocrelizumab				X	Serum immunoglobulins, up to date with all vaccinations
Ofatumumab				X	Serum immunoglobulins, up to date with all vaccinations

Abbreviations: CBC = complete blood count; ECG = electrocardiogram; FDA = U.S. Food and Drug Administration; JCV = John Cunningham Virus; LFTs = liver function tests; LVEF= left ventricular ejection fraction; PML = progressive multifocal leukoencephalopathy; Scr = serum creatinine; TB = tuberculosis; UA = urinalysis; VZV = varicella zoster virus

P&T / DUR Action: *10/22 (DM)*
Implementation: *1/1/23*