

## Pre - PA Allowance

None

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## Prior-Approval Requirements

**Age** 18 years of age or older

### Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including relapsing-remitting disease and active secondary progressive disease

**AND ALL** of the following:

1. Prescriber has reviewed baseline liver function tests (LFTs) and complete blood count (CBC) with differential including lymphocyte count
2. Female of reproductive potential: patient is not pregnant
3. Prescriber will advise females and males of reproductive potential to use effective contraception during Mavenclad dosing and for 6 months after the last dose in each treatment course
4. Prescriber agrees to delay the second treatment course until lymphocytes are greater than or equal to 800 cells per microliter
5. Patient **MUST** have tried **TWO** of the preferred MS medications (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

**AND NONE** of the following:

1. Diagnosis of clinically isolated syndrome (CIS)
2. Presence of current malignancy
3. HIV infection or active chronic infection (e.g., hepatitis or tuberculosis)
4. Concurrent use with other MS disease modifying agents
5. Given concurrently with live vaccines

## Prior - Approval Limits

*PA limit is 2 cycles per year, for a total of 4 cycles for 2 years.*

### Quantity

<b>Dose of MAVENCLAD per Cycle by Patient Weight in Each Treatment Course</b>
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<b>Weight Range</b>	<b>Dose in mg (Number of 10 mg Tablets)</b>		
<b>kg</b>	<b>First Cycle</b>	<b>Second Cycle</b>	<b>Total for 1 year</b>
40* to less than 50	40 mg (4 tablets)	40 mg (4 tablets)	8 tablets
50 to less than 60	50 mg (5 tablets)	50 mg (5 tablets)	10 tablets
60 to less than 70	60 mg (6 tablets)	60 mg (6 tablets)	12 tablets
70 to less than 80	70 mg (7 tablets)	70 mg (7 tablets)	14 tablets
80 to less than 90	80 mg (8 tablets)	70 mg (7 tablets)	15 tablets
90 to less than 100	90 mg (9 tablets)	80 mg (8 tablets)	17 tablets
100 to less than 110	100 mg (10 tablets)	90 mg (9 tablets)	19 tablets
110 and above	100 mg (10 tablets)	100 mg (10 tablets)	20 tablets

\*The use of MAVENCLAD in patients weighing less than 40 kg has not been investigated.

**Duration**            2 years

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## **Prior – Approval *Renewal* Requirements**

None

## **Prior - Approval *Renewal* Limits**

None

**Appendix 1 - List of Preferred Multiple Sclerosis (MS) Medications**

Medication Name	Route of Administration
dimethyl fumarate (generic Tecfidera)	Oral**
fingolimod (generic Gilenya)	Oral**
Mayzent	Oral**
teriflunomide (generic Aubagio)	Oral**
Zeposia	Oral**

\*\* indicates separate criteria will need to be met

Medication Name	Route of Administration
Avonex	Injectable
Betaseron	Injectable
glatiramer acetate (generic Copaxone)	Injectable
Glatopa	Injectable
Plegridy	Injectable
Rebif	Injectable