SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Multiple Sclerosis (MS) Drugs

Drug Requested: (Select drug below)

❑ **Bafiertam®** (monomethyl fumarate)	❑ **Mayzent®** (siponimod)
❑ **Extavia®** (interferon beta-1b)	❑ **Ponvory®** (ponesimod)
❑ **Gilenya® 0.5 mg** (fingolimod)	❑ **Vumerity®** (diroximel fumarate)
❑ **Kesimpta®** (ofatumumab)	❑ **Zeposia®** (ozanimod)
❑ **Mavenclad®** (cladribine)	

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

For approval, chart notes must be submitted with form.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

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❑ For Extavia® approval, the following criteria must be met:

❑ Member **MUST** have documented failure, contraindication or intolerance to **TWO** of the following disease modifying therapies (DMTs) indicated for the treatment of multiple sclerosis (MS) **(check each therapy tried)**:

❑ Avonex® (interferon beta-1a)	❑ Betaseron® (interferom beta-1b)
❑ Plegridy® (peginterferon beta-1a)	❑ Rebif® (interferon beta-1a)

❑ For Bafiertam™ and Ponvory™ approval, the following criteria must be met:

❑ Member **MUST** have documented failure, contraindication or intolerance to at least **TWO (2)** disease modifying therapies (DMTs) indicated for the treatment of multiple sclerosis (MS) **(check each therapy tried)**:

❑ dimethyl fumarate (Tecfidera®)	❑ Glatopa® or glatiramer acetate (Copaxone®)
❑ fingolimod (Gilenya®)	❑ teriflunomide (Aubagio®)
❑ Vumerity® (diroximel fumarate) ***requires PA***	❑ Zeposia® (ozanimod) ***requires PA***

❑ For Vumerity® and Zeposia approval, the following criteria must be met:

❑ Member **MUST** have documented failure, contraindication or intolerance to at least **ONE (1)** generic disease modifying therapies (DMTs) indicated for the treatment of multiple sclerosis (MS) **(check each therapy tried)**:

❑ dimethyl fumarate (Tecfidera®)	❑ Glatopa® or glatiramer acetate (Copaxone®)
❑ fingolimod (Gilenya®)	❑ teriflunomide (Aubagio®)

❑ For Gilenya® 0.5 mg capsules approval, the following criteria must be met:

❑ Member **MUST** have documented trial and failure of fingolimod 0.5 mg capsules (generic Gilenya®)

❑ Member **MUST** have documented trial and failure of **ONE (1)** additional preferred disease modifying therapy (DMT) indicated for the treatment of multiple sclerosis (MS):

- ❑ dimethyl fumarate (Tecfidera®)
- ❑ Glatopa® or glatiramer acetate (Copaxone®)
- ❑ teriflunomide (Aubagio®)

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❑ **For Mayzent® approval, all the following criteria must be met:**
Maximum Quantity limit: 1 tablet per day

- ❑ Medication is prescribed by a neurologist
- ❑ Member is 18 years of age or older
- ❑ Member **MUST** have **ONE (1)** of the following confirmed relapsing forms of multiple sclerosis (MS):
  - ❑ Relapsing-remitting MS (RRMS)
  - ❑ Active Secondary-progressive MS (SPMS)
  - ❑ Clinically Isolated Syndrome (CIS)
- ❑ Member **MUST** have documented failure, contraindication or intolerance to at least **TWO (2)** disease modifying therapies (DMTs) indicated for the treatment of multiple sclerosis (MS) **(check each therapy tried)**:

❑ dimethyl fumarate (Tecfidera®)	❑ Glatopa® or glatiramer acetate (Copaxone®)
❑ fingolimod (Gilenya®)	❑ teriflunomide (Aubagio®)
❑ Vumerity® (diroximel fumarate) ***requires PA***	❑ Zeposia® (ozanimod) ***requires PA***

- ❑ Prescriber attestation to **ALL** the following:
  - ❑ **NO** CYP2C9*3/*3 genotype
  - ❑ **NO** history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
  - ❑ **NO** history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless member has a pacemaker
  - ❑ **NO** concurrent use with other MS disease modifying agents
  - ❑ **NOT** given concurrently with live vaccines

❑ **For Mavenclad® approval, all the following criteria must be met:**
Maximum Quantity limit: 2 tablets per day; 20 tablets per year (40 tablets total)

Recommended Dosage for Mavenclad:

- Oral: 3.5 mg/kg over 2-year treatment course, administered as 1.75 mg/kg in each year. Divide the 1.75 mg/kg dose over 2 cycles, each cycle lasting 4 to 5 consecutive days; do not administer more than 2 tablets (20mg) /day. Following the administration of 2 treatment courses, do not administer additional Mavenclad treatment during the next 2 years**.**

Administration of First Treatment Course:

- First Course/First Cycle: start any time
- First Course/Second Cycle: administer 23 to 27 days after the last dose of First Course/First Cycle

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Administration of Second Treatment Course:

- Second Course/First Cycle: administer at least 43 weeks after the last dose of First Course/Second Cycle
- Second Course/Second Cycle: administer 23 to 27 days after the last dose of Second Course/First Cycle

Dose of MAVENCLAD per Cycle by Patient Weight in Each Treatment Course

Weight Range	Dose in mg (Number of 10 mg Tablets) per Cycle	
kg	First Cycle	Second Cycle
40* to less than 50	40 mg (4 tablets)	40 mg (4 tablets)
50 to less than 60	50 mg (5 tablets)	50 mg (5 tablets)
60 to less than 70	60 mg (6 tablets)	60 mg (6 tablets)
70 to less than 80	70 mg (7 tablets)	70 mg (7 tablets)
80 to less than 90	80 mg (8 tablets)	70 mg (7 tablets)
90 to less than 100	90 mg (9 tablets)	80 mg (8 tablets)
100 to less than 110	100 mg (10 tablets)	90 mg (9 tablets)
110 and above	100 mg (10 tablets)	100 mg (10 tablets)

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

All the following criteria must be met:

- ❑ Medication is prescribed by a neurologist
- ❑ Member is 18 years of age or older
- ❑ Prescriber **MUST** provide member's most current weight: _____ **AND** date weight was taken: _____
- ❑ Member **MUST** have one of the following confirmed relapsing forms of multiple sclerosis (MS):
  - ❑ Relapsing-remitting MS (RRMS)
  - ❑ Active Secondary-progressive MS (SPMS)
- ❑ Member **MUST** have documented failure, contraindication or intolerance to at least **TWO (2)** disease modifying therapies (DMTs) indicated for the treatment of multiple sclerosis (MS) **(check each therapy tried)**:

❑ dimethyl fumarate (Tecfidera®)	❑ Glatopa® or glatiramer acetate (Copaxone®)
❑ fingolimod (Gilenya®)	❑ teriflunomide (Aubagio®)
❑ Vumerity® (diroximel fumarate) ***requires PA***	❑ Zeposia® (ozanimod) ***requires PA***

- ❑ Prescriber **MUST** submit baseline liver function tests (LFTs) and complete blood count (CBC) with differential including lymphocyte count. Lymphocytes must be within normal limits before 1st treatment course and must be at least 800 cells per microliter before 2nd treatment course **(submit lab documentation)**

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- ❑ Prescriber attestation to **ALL** the following:
  - ❑ Member has **NOT** previously received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine
  - ❑ Member does **NOT** have clinically isolated syndrome (CIS)
  - ❑ **NO** current diagnosis of malignancy
  - ❑ Negative pregnancy test in a woman of child-bearing age
  - ❑ Member does **NOT** have active chronic infection (e.g. hepatitis or tuberculosis or HIV infection)
  - ❑ Member does **NOT** have concurrent use of other MS disease modifying agents
  - ❑ Medication will **NOT** be given concurrently with live vaccines

❑ For Kesimpta®, all the following criteria must be met:

Recommended Dosage and Quantity Limit: SubQ: **Initial:** 20 mg once weekly for 3 doses (weeks 0, 1, and 2); **Maintenance:** 20 mg once monthly starting at week 4**. Maximum Quantity Limit:** 1 prefilled pen/syringe per 28 days

- ❑ Medication is prescribed by a neurologist
- ❑ Member is 18 years of age or older
- ❑ Member **MUST** have one of the following confirmed relapsing forms of multiple sclerosis (MS):
  - ❑ Relapsing-remitting MS (RRMS)
  - ❑ Active Secondary-progressive MS (SPMS)
  - ❑ Clinically Isolated Syndrome (CIS)
- ❑ Member **MUST** have documented failure, contraindication or intolerance to at least **TWO (2)** disease modifying therapies (DMTs) indicated for the treatment of multiple sclerosis (MS) **(check each therapy tried)**:

❑ dimethyl fumarate (Tecfidera®)	❑ Glatopa® or glatiramer acetate (Copaxone®)
❑ fingolimod (Gilenya®)	❑ teriflunomide (Aubagio®)
❑ Vumerity® (diroximel fumarate) ***requires PA***	❑ Zeposia® (ozanimod) ***requires PA***

- ❑ Prescriber attestation to **ALL** the following:
  - ❑ Testing for quantitative serum immunoglobulins prior to initiation of therapy
  - ❑ The member does **NOT** have an active infection with hepatitis B virus
  - ❑ Medication will **NOT** be given concurrently with live vaccines
  - ❑ Member does **NOT** have concurrent use of other MS disease modifying agents

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

__Previous therapies will be verified through pharmacy paid claims or submitted chart notes.__

***Approved by the Pharmacy and Therapeutic Committee**: ~~4/10/2007; 8/20/2015; 3/19/2020;~~ **9/21/2023**
REVISED/UPDATED/REFORMATTED: ~~6/3/2011; 8/15/2011, 5/17/2012; 7/3/2012; 4/7/2014; 5/8/2014; 6/2/2014; 8/8/2014; 10/30/2014; 3/19/2015; 5/27/2015; 10/26/2015; 12/22/2015; 6/28/2016; 7/21/2016; 8/22/2016; 9/22/2016; 12/11/2016; 5/29/2017; 6/28/2017; 8/5/2017; 4/18/2019; 5/15/2019; 8/12/2019; 6/4/2020; 11/5/2020; 1/27/2021; 44/1/2021; 6/14/2021; 9/14/2021; 10/8/2021; 8/4/2022; 10/13/2023;~~ **12/11/2023**