Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	December 7, 2016 December 19, 2016, May 23, 2018, October 29, 2018, October 25, 2019, January 29, 2020, March 12, 2020, September 21, 2020, October 26, 2020, September 17, 2021, April 5, 2022, June 16, 2022, September 8, 2022, January 27, 2023, February 5, 2024

MULTIPLE SCLEROSIS ORAL AGENTS

Preferred disease modifying agents: Dimethyl Fumarate, Fingolimod (Gilenya®) and Terflunomide (Aubagio®)

Non-preferred disease modifying agents: Aubagio®, Bafiertam™, Gilenya®, Mavenclad®, Mayzent®, Ponvory™, Tascenso ODT™, Tecfidera®, Vumerity™, and Zeposia® (see separate criteria)

Preferred walking improvement agent: Dalfampridine

Non-Preferred walking improvement agent: Ampyra®

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

INITIAL REVIEW CRITERIA:

Disease Modifying Agents:

- Patient must be ≥ 18 years old or ≥ 10 years old for Fingolimod (Gilenya).
- Patient must have a diagnosis of a relapsing form of Multiple Sclerosis (MS) [e.g., relapsing remitting disease (RRMS), active secondary progressive disease (SPMS), or clinically isolated syndrome (CIS); verified by progress notes, discharge notes, or "health conditions".
- Patient must be used as single agent therapy with the exception of Ampyra.
- Patient must have a previous trial with insufficient response, adverse reaction, or contraindication to preferred disease modifying agent(s), including the preferred generic when brand is requested.

Ampyra:

- Patient must be ≥ 18 years.
- Must have a diagnosis of MS verified by progress notes, discharge notes, or "health conditions."
- Patient must have previous treatment with generic dalfampridine.

Mavenclad:

- Patient must be ≥ 18 years.
- Patient must have a diagnosis of MS verified by progress notes, discharge notes, or "health conditions."
- Patient must have previous treatment with a preferred disease modifying agent (e.g., Fingolimod, Dimethyl Fumarate or Terflunomide).
- Mavenclad is not being used to treat CIS. CIS refers to the first clinical onset of potential MS.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	December 7, 2016 December 19, 2016, May 23, 2018, October 29, 2018, October 25, 2019, January 29, 2020, March 12, 2020, September 21, 2020, October 26, 2020, September 17, 2021, April 5, 2022, June 16, 2022, September 8, 2022, January 27, 2023, February 5, 2024

- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/