



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

MULTIPLE SCLEROSIS ORAL AGENTS

Preferred disease modifying agents: Aubagio[®], **Dimethyl Fumarate**, and Gilenya[®]

Non-preferred disease modifying agents: Bafiertam[™], 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 Gilenya.
- Patient must have a diagnosis of a relapsing form of Multiple Sclerosis [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 Multiple Sclerosis verified by progress notes, discharge notes, or “health conditions.”
- Patient must have previous treatment with generic dalfampridine.

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**
- 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/>