VENTURA COUNTY
HEALTH CARE PLAN

FORMULARY EXCEPTION POLICY

POLICY: Multiple Sclerosis – Ampyra® (dalfampridine extended-release tablets – Acorda Therapeutics)

REVIEW DATE: 10/20/2020

Documentation: Documentation will be required for patients requesting brand Ampyra where noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or other information.

CRITERIA

1. **Multiple Sclerosis (MS).** Approve for the duration noted if the patient meets the following criteria (A and B):
   - **A)** Patient meets one of the following (i or ii):
     - **i.** Initial Therapy. Approve for 4 months if the patient meets all of the following (a, b, and c):
       - **a)** Patient is ≥ 18 years of age; AND
       - **b)** Ampyra is being used to improve or maintain mobility; AND
       - **c)** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; OR
     - **ii.** Patient Currently Receiving Ampyra. Approve for 1 year if the patient meets all of the following (a, b, c, and d):
       - **a)** Patient is ≥ 18 years of age; AND
       - **b)** Ampyra is being used to improve or maintain mobility; AND
       - **c)** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; AND
       - **d)** According to the prescriber the patient has responded to or is benefitting from therapy.
         Note: Examples of response or benefits include an increase in walking speed and/or improvement in strength, coordination, ambulation, or balance.
   - **B)** Patient meets both of the following criteria (i and ii):
     - **i.** Patient has tried generic dalfampridine **[documentation required]**; AND
     - **ii.** Brand Ampyra is being requested due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent product which, per the prescriber, would result in a significant allergy or serious adverse reactions **[documentation required]**.

HISTORY

Type of Revision	Summary of Changes	ReviewDate
New Policy	--	07/01/2019
Annual Revision	No criteria changes.	08/05/2020
Early Annual Revision	**Multiple Sclerosis:** Criteria are now broken down into patients receiving initial therapy and patients currently receiving Ampyra. Regarding initial approval, criteria are now to approve for 4 months (previously, the duration of approval was 1 year). Criteria were added that the agent is approved if the patient is ≥ 18 years of age. Also, regarding the criterion that requires that the patient is using Ampyra to improve mobility (in a patient with multiple sclerosis), the wording "or maintain (mobility)" was added. The approval duration for patients currently receiving Ampyra continues to be 1 year. Criteria for patients receiving initial therapy and for patients currently receiving Ampyra are the same except for patients currently receiving Ampyra, the patient has to demonstrate response or benefit from therapy, according to the prescriber. A note was added that examples of response or benefits include an increase in walking speed and/or improvement in strength, coordination, ambulation, or balance. In that criteria that addresses the multisource branded product, the phrase "prescribing physician" was changed to "prescriber".	10/20/2020