ALASKA MEDICAID
Prior Authorization Criteria

Vumerity™ (diroximel fumerate)

FDA INDICATIONS AND USAGE[1]

Vumerity™ (diroximel fumerate) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), which includes clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults.

APPROVAL CRITERIA[1,2,3]

1. Patient is 18 years of age or older **AND**;
2. Patient has a diagnosis multiple sclerosis (MS) to include one of the following,
    a. clinically isolated syndrome **OR**;
    b. relapsing-remitting disease **OR**;
    c. active secondary progressive disease **AND**;
3. Is being prescribed by or in consultation with a neurologist or a provider that specializes in multiple sclerosis **AND**;
4. The patient has had a complete blood cell count and liver function testing, showing results deemed appropriate for treatment **AND**;
5. Serum aminotransferase, alkaline phosphatase, and total bilirubin levels must be documented **AND;**
6. The prescriber has counseled patients of reproductive potential to use effective contraception during and for 6 months after the last dose **AND;**
7. The patient has had an adequate trial and failure of at least one drug with the same specific indication form of MS.

DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Patient has moderate to severe renal impairment **OR**;
3. Patient is taking dimethyl fumarate.

CAUTIONS[1]

- Monitor for anaphylaxis and angioedema after the first dosage and throughout treatment.
- Progressive multifocal leukoencephalopthy has occurred in patient being treated with dimethyl fumarate.
- Lymphocyte counts may decrease with the use of Vumerity™.
- Liver injury has been reported and should be monitored.
- Patients should avoid alcohol.
- Administration with a high-fat, high-calorie meal or snack should be avoided.

DURATION OF APPROVAL

- Initial Approval: up to 30 days
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 120 – 231mg capsules per month

REFERENCES / FOOTNOTES:

1. Vumerity™ [prescribing information]. Waltham, MA: Alkermes, Inc.; October 2019.Accessed on 12/6/2019 at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5532591/
2. Dargahi N, Katsara M, Tselios T, Androutsou ME, de Courten M, Matsoukas J, et al. Multiple sclerosis: Immunopathology and treatment update. Brain Sciences July 2017; 7. Accessed on 12/6/2019 at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5532591/
3. Tintore, M, Vidal-Jordana, A, Sastre-Garriga, J. Treatment of multiple sclerosis: success from bench to bedside. Nat Rev Neurol. January 15, 2019:53-58.