## ALASKA MEDICAID Prior Authorization Criteria

# Dojolvi<sup>TM</sup> (triheptanoin)

# FDA INDICATIONS AND USAGE<sup>1,2</sup>

Dojolvi<sup>TM</sup> is a medium-chain triglyceride indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).

#### APPROVAL CRITERIA<sup>1,2</sup>

- 1. Patient has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder based on at least TWO of the following (a, b, or c):
  - a. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma;
    OR
  - b. Enzyme activity assay (in cultured fibroblasts or lymphocytes) below the lower limit of the normal reference range for the reporting laboratory; **OR**
  - c. Genetic testing demonstrating pathogenic mutation in a gene associated with long-chain fatty acid oxidation disorders **AND**;
- 2. Is being prescribed by or in consultation with an endocrinologist or metabolic disease specialist **AND**;
- 3. The prescriber has submitted the patient's weight and total prescribed daily caloric intake **AND**:
- 4. The dose does not to exceed 35% of Daily Caloric Intake.

# **DENIAL CRITERIA**<sup>1</sup>

- 1. Failure to meet approval criteria **OR**;
- 2. Patient is concurrently using another medium chain triglyceride product.

## **CAUTIONS**<sup>1</sup>

• Avoid co-administration of Pancreatic Lipase Inhibitors due to potential for reduced clinical effect.

#### **DURATION OF APPROVAL**

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

#### **OUANTITY LIMIT**

Dojolvi<sup>TM</sup> Criteria Version: 1 Original: 10/08/20 Approval: 11/20/20 Effective: 1/11/21

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• 30 days – dose does not exceed 35% of the patient's caloric intake

## **REFERENCES / FOOTNOTES:**

- 1. Dojolvi [package insert]. Novato, CA Ultragenyx Pharmaceutical Inc. June 2020. https://www.ultragenyx.com/medicines/dojolvi-full-prescribing-information/. Accessed on 10/08/2020
- 2. FDA Approves Dojolvi (triheptanoin) for the Treatment of Long-Chain Fatty Acid Oxidation Disorders, https://www.drugs.com/newdrugs/fda-approves-dojolvitriheptanoin-long-chain-fatty-acid-oxidation-disorders-5283.html. Accessed 10/08/2020

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