

## Commercial & Healthcare Exchange PA Criteria

Effective: September 2<sup>nd</sup>, 2020

**Prior Authorization:** Dojolvi

**Products Affected:** Dojolvi (triheptanoin) oral solution

<u>Medication Description</u>: Triheptanoin is a medium-chain triglyceride consisting of 3 odd-chain 7-carbon length fatty acids (heptanoate) that provide a source of calories and fatty acids to bypass the long-chain fatty acid oxidation disorder enzyme deficiencies for energy production and replacement.

<u>Covered Uses</u>: Dojolvi is 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).

Exclusion Criteria: N/A

**Required Medical Information:** Diagnosis

**Age Restrictions:** N/A

<u>Prescriber Restrictions</u>: Prescribed by or in consultation with a metabolic disease specialist or a physician who specializes in the management of long-chain fatty acid oxidation disorders.

**Coverage Duration:** 12 months

## Other Criteria:

- A. Patient has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder based on at least TWO of the following (TWO of i, ii, or iii):
  - i. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma; OR
  - ii. Enzyme activity assay (in cultured fibroblasts or lymphocytes) below the lower limit of the normal reference range for the reporting laboratory; OR
  - iii. Genetic testing demonstrating pathogenic mutation in a gene associated with long-chain fatty acid oxidation disorders

## References:

- 1. Dojolvi [package insert]. Novato, CA Ultragenyx Pharmaceutical Inc. 2020
- 2. Micromedex® Healthcare Series; Thomson Micromedex, Greenwood Village, Co. 2019
- 3. Dojolvi, Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed 8/11/2020
- 4. FDA Approves Dojolvi (triheptanoin) for the Treatment of Long-Chain Fatty Acid Oxidation Disorders, https://www.drugs.com/newdrugs/fda-approves-dojolvi-triheptanoin-long-chain-fatty-acid-oxidation-disorders-5283.html. Accessed 8/11/2020

Last Res. September 2020





Rev #	# Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/1/2020