



Commercial & Healthcare Exchange PA Criteria

Effective: September 2nd, 2020

Prior Authorization: Dojolvi

Products Affected: Dojolvi (triheptanoin) oral solution

Medication Description: 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.

Covered Uses: 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

Prescriber Restrictions: 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

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