

## Pharmacy Medical Necessity Guidelines: Dojolvi™ (triheptanoin)

Effective: October 19, 2020

Prior Authorization Required	✓	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p><b>Commercial Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans</li> <li>• CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <p><b>Tufts Health Public Plans Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)</li> <li><input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans</li> <li><input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan</li> </ul>		<p><b>Fax Numbers:</b></p> <p>RXUM: 617.673.0988</p>	

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

### OVERVIEW

#### **FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Dojolvi (triheptanoin) 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

### COVERAGE GUIDELINES

The plan may authorize the coverage of Dojolvi (triheptanoin) for Members, when the following criteria are met:

1. Documentation of a molecularly or genetically confirmed diagnosis of a long-chain fatty acid oxidation disorder
- AND**
2. 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

### LIMITATIONS

- None

### CODES

None

### REFERENCES

1. Dojolvi (triheptanoin) [prescribing information]. Novato, CA: Ultragenyx Pharmaceuticals Inc.; June 2020.
2. Gillingham MB, Heitner SB, Martin J, et al. Triheptanoin versus trioctanoin for long-chain fatty acid oxidation disorders: a double blinded, randomized controlled trial. J Inher Metab Dis. 2017;40(6):831-43.

### APPROVAL HISTORY

October 13, 2020: Reviewed by Pharmacy & Therapeutics Committee.

### BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical

Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

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