

Pharmacy Policy

Dojolvi

Policy Number: 9.231

Revision Number: 1.0

Version Effective Date: 9/1/2021

Product Applicability All Plan+ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth- MCO

MassHealth- ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Dojolvi

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All medically excepted indications unless otherwise excluded
Exclusion	Pregnancy
Required Medical Information	<ol style="list-style-type: none"> 1. Member has a diagnosis of long-chain fatty acid oxidation disorder (LC-FAOD); AND 2. Results from genetic testing show CPT II, LCHAD, VLCAD and TFP deficiency (documentation required); AND 3. One of the following: <ul style="list-style-type: none"> • Chronic elevated creatine kinase (CK) • Episodic elevated CK with reported muscle dysfunction • Highly elevated CK but asymptomatic • Frequent Severe major medical episodes of hypoglycemia, rhabdomyolysis, or

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	<p>exacerbation of cardiomyopathy requiring emergency room visits or hospitalizations</p> <ul style="list-style-type: none"> • Severe susceptibility to hypoglycemia or recurrent symptomatic hypoglycemia requiring intervention • Evidence of functional cardiomyopathy documenting poor ejection fraction requiring ongoing management; AND <p>4. Trial of or contraindication to commercially available medium chain triglyceride (MCT)_oil</p>
Prescriber Restriction	Prescribed by or in consultation with a specialist in medical genetics or inherited metabolic disorders
Coverage Duration	Initial : 6 months Reauthorization: 12 months
Other criteria	<ol style="list-style-type: none"> 1. Member has a diagnosis of long-chain fatty acid oxidation disorder (LC-FAOD; AND 2. Member had a positive clinical response as shown by one of the following: <ul style="list-style-type: none"> • Decrease in frequency of rhabdomyolysis , hypoglycemia and exacerbation of cardiomyopathy • Increase in exercise tolerance and endurance • Gross motor development or motor function

Clinical Background Information and References

1. Dojolvi (triheptynoin) [prescribing information]. Novato, CA. Ultragenyx Pharmaceutical Inc. June 2020

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	9/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/13/2021	Policy created	9/1/2021	P&T Committee,

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Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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