PrDOJOLVI®

Triheptanoin Oral Liquid

SASKATCHEWAN

Ultragenyx Canada would like to announce that PrDOJOLVI® (triheptanoin) is eligible for public reimbursement in Saskatchewan for patients with LC-FAOD based on the reimbursement criteria detailed below through the Saskatchewan Exception Drug Status (EDS) program.

DOJOLVI® (triheptanoin) is indicated as a source of calories and fatty acids for the treatment of adult and pediatric patients with long-chain fatty acid oxidation disorders (LC-FAOD).

Please consult the Product Monograph at https://dojolvihcp.ca/wp-content/uploads/pdfs/Dojolvi_Final_PM.pdf for important information on contraindications, warnings and precautions, the conditions of clinical use, adverse reactions, drug interactions, and dosing instructions.

The Product Monograph is also available by calling us at 1-833-388-5872.

The DOJOLVI® Reimbursement Criteria for the Saskatchewan Exception Drug Status (EDS) Program Are as Follows:

Initiation Criteria

For the treatment of patients with an acute life-threatening long-chain fatty acid oxidation disorder (LC-FAOD) in whom:

- Alternative therapy to conventional even-chain medium-chain triglyceride (MCT) supplementation is required; and
- Triheptanoin treatment will be prescribed and monitored by a clinician experienced in the management of LC-FAOD (i.e., metabolic or genetic specialist physician); and
- One of the following are met:
  - The patient has a confirmed diagnosis of LC-FAOD and is experiencing acute life-threatening events*; or
  - The patient lacks a confirmed diagnosis of LC-FAOD but is presenting with acute life-threatening events* consistent with LC-FAOD

* Acute life-threatening events associated with LC-FAOD may include:

- A catastrophic presentation with acute or recurrent rhabdomyolysis with severe pain, compartment syndrome, acute renal failure requiring hospitalization and life-saving interventions including dialysis, treatment of hyperkalemia, and surgical treatment of compartment syndrome.
- Severe hypoglycemia, recurrent or acute, with or without seizures
- Cardiomyopathy with or without arrhythmia

A description of the patient's baseline acute life-threatening events, response to conventional even-chain MCT supplementation, and individualized treatment goals for triheptanoin treatment must be submitted with the initial coverage request.

Approval duration: 12 months

Renewal Requests

Patients who exhibit continued benefit with triheptanoin will be considered for renewal. Requesters must include a description of the patient's current response to triheptanoin therapy and clearly outline how this response meets the clinical treatment goals established at initiation.

Renewal duration: up to 12 months

For more information on applying for DOJOLVI coverage, we can arrange an appointment at your convenience, or you can visit the UltraCare website. You can also find the UltraCare Enrolment Form on the UltraCare website.