STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIHEPTANOIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIHEPTANOIN	DOJOLVI	46676		GPI-10 (8020008000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) and meet **ALL** of the following criteria?
   - The patient's diagnosis is confirmed by documentation of at least **TWO** of the following:
     - Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
     - Low enzyme activity in cultured fibroblasts
     - One or more known pathogenic mutations in *CPT2, ACADVL, HADHA, or HADHB*
   - The patient is symptomatic (e.g. rhabdomyolysis, cardiomyopathy) for LC-FAOD
   - Therapy is prescribed by or given in consultation with a gastroenterologist or physician specialist in medical genetics/inherited metabolic disorders
   - The patient had a trial of or contraindication to commercial MCT oil (medical food product)

   If yes, **approve for 4 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the patient had a positive clinical response (e.g., improved exercise tolerance) or stabilization of clinical status compared to baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for approval:
   A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
   B. Your diagnosis is confirmed by documentation of at least TWO of the following:
      1. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
      2. Low enzyme activity in cultured fibroblasts
      3. One or more known pathogenic mutations in *CPT2, ACADVL, HADHA, or HADHB*
   C. You are symptomatic for LC-FAOD (for example you have rhabdomyolysis [break down of muscle tissue] or cardiomyopathy [disease of the heart muscle])
   D. Therapy is prescribed by or given in consultation with a gastroenterologist (digestive tract doctor) or physician specialist in medical genetics/inherited metabolic disorders
   E. You have previously tried commercial MCT oil (a medical food product) unless there is a medical reason you are unable to (contraindication)
   (Initial denial text continued on next page)

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TRIHEPTANOIN

INITIAL CRITERIA (CONTINUED ON NEXT)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) **AND** meet the following criterion?
   - The patient had a positive clinical response (e.g. improved exercise tolerance) or stabilization of clinical status compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for renewal:
   A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
   B. You had a positive clinical response (such as improved exercise tolerance) or stabilization of clinical status compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dojolvi.

REFERENCES

- Dojolvi [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
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