STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENFLURAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENFLURAMINE HCL	FINTEPLA	02116		GPI-10 (7260002810)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to TWO of the following: valproic acid derivative, clobazam, topiramate

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to valproic acid or derivatives
   - The patient had a trial of or contraindication to TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.**
   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 **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:
   A. You have seizures associated with ONE of the following:
      1. Dravet syndrome (a rare type of seizure)
      2. Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)
   B. **If you have Dravet syndrome, approval also requires:**
      1. You are 2 years of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
      3. You had a trial of or contraindication (harmful for) to TWO of the following: valproic acid derivative, clobazam, topiramate

   (Initial denial text continued on next page)

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FENFLURAMINE

INITIAL CRITERIA (CONTINUED)

C. **If you have Lennox-Gastaut syndrome, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (a type of brain doctor)
   3. You had a trial of or contraindication (harmful for) to valproic acid or derivatives
   4. You had a trial of or contraindication (harmful for) to TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

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

NOTE: For the diagnosis of Lennox-Gastaut syndrome (LGS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome **AND** meet the following criterion?
   - The patient has shown continued clinical benefit (e.g., reduction of seizures, reduced length of seizures, seizure control maintained)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.** 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 **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:
   A. You have seizures associated with Dravet syndrome (a rare type of seizure)
   B. You have shown continued clinical benefit (such as reduction of seizures, reduced length of seizures, seizure control maintained) while on therapy

   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.

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FENFLURAMINE

RATIONALE

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

REFERENCES

- Fintepla [Prescribing Information]. Emeryville, CA: Zogenix, Inc., March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22

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