AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Fintepla® (fenfluramine)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Recommended Dosage:

	Without concomitant stiripentol		With concomitant stiripentol and clobazam	
	Weight-based Dosage	**Maximum Total Daily Dosage**	**Weight-based Dosage**	**Maximum Total Daily Dosage**
Initial Dosage:	0.1 mg/kg twice daily	26 mg	0.1 mg/kg twice daily	17 mg
Day 7	0.2 mg/kg twice daily	26 mg	0.15 mg/kg twice daily	17 mg
Day 14	0.35 mg/kg twice daily	26 mg	0.2 mg/kg twice daily	17 mg

Quantity Limit: 360 mL per 30 days; 26 mg per day

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Medication must be prescribed by or in consultation with a neurologist

AND

- ❑ Member must be 2 years of age or older

AND

- ❑ Member must have **ONE** of the following diagnoses **(must submit chart notes to confirm diagnosis)**:
  - ❑ Seizures associated with Dravet syndrome (DS)
  - ❑ Seizures associated with Lennox-Gastaut syndrome (LGS)

AND

- ❑ Member must be refractory to the following treatment regimen(s) that are appropriate for the diagnosis indicated below **(verified by pharmacy paid claims)**:
  - ❑ **Dravet Syndrome**: **first-line therapy** clobazam or valproate **AND second-line therapy** Diacomit®
  - ❑ **Lennox Gastaut**: **first-line therapies** valproate and clobazam or valproate and lamotrigine **AND all second line-therapies**: topiramate, rufinamide and Epidiolex® (unless contraindicated)

AND

- ❑ Medication must be used as adjunctive therapy to ≥ 1 antiepileptic drug used for the treatment of Dravet Syndrome or Lennox-Gastaut syndrome (e.g., valproate, clobazam, levetiracetam, topiramate, zonisamide, clonazepam) **(verified by pharmacy paid claims)**

AND

- ❑ Provider has obtained and reviewed an echocardiogram assessment before initiating treatment with Fintepla® and will continue to obtain and review an echocardiogram assessment every 6 months during treatment with Fintepla®, and 3 to 6 months after the final dose of Fintepla®

AND

- ❑ Member will be monitored for the emergence of signs and symptoms of serotonin syndrome if there is known concomitant administration of Fintepla® and serotonergic drugs including: prescription medications (e.g., SSRIs, SNRIs, TCAs, trazodone), over-the-counter medications (e.g., dextromethorphan), or herbal supplements (e.g., St. John's Wort)

AND

- ❑ Prescriber must be enrolled in Fintepla® Risk Evaluation and Mitigation Strategy (REMS) program

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Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must continue to meet initial authorization criteria

AND

- ❑ Member has demonstrated a positive response to Fintepla® therapy, defined as: decrease from baseline and stabilization of seizure frequency/severity **(submit chart notes)**

AND

- ❑ Member must be absent of unacceptable toxicity from therapy (e.g., significant weight loss, sedation, diarrhea)

Medication being provided by Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee**: 9/17/2020
REVISED/UPDATED: ~~12/7/2020; 5/13/2022; 6/3/2022; 6/17/2022;~~ **10/27/2023**