# SENTARA HEALTH PLANS

# PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST\*

<u>Directions:</u> 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; <u>fax to 1-800-750-9692</u>. No additional phone calls will be necessary if all information (<u>including phone and fax #s</u>) on this form is correct. <u>If information provided is not complete</u>, correct, or legible, authorization may be delayed.

<u>Drug Requested</u>: Fintepla® (fenfluramine)

Marahan Nama					
Member Name:					
Member Sentara #:	Date of Birth:				
Prescriber Name:					
	Date:				
Office Contact Name:					
Phone Number:					
DEA OR NPI #:					
DRUG INFORMATION: Author					
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<sup>®</sup> (unless contraindicated)

## **AND**

 $\square$  Medication must be used as adjunctive therapy to  $\ge 1$  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)

#### <u>AN</u>D

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<sup>®</sup>, and 3 to 6 months after the final dose of Fintepla<sup>®</sup>

### 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

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.

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	Member must	confinue to	i 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.\*

<sup>\*</sup>Approved by Pharmacy and Therapeutics Committee: 9/17/2020 REVISED/UPDATED/REFORMATTED: 42/7/2020; 5/43/2022; 6/3/2022 6/17/2022