BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Fintepla

Policy Number: 9.224
Version Number: 1.0
Version Effective Date: 6/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth - MCO ☐ MassHealth - ACO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Fintepla (fenfluramine) 2.2mg/ml solution**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	1. Diagnosis of Dravet Syndrome; **AND** 2. Member is 2 years of age or older; **AND** 3. Will be prescribed by a Neurologist; **AND**

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	4. Member will be using Fintepla as adjunctive therapy **AND** 5. Member had an inadequate response, intolerance, adverse reaction, or contraindication to at least TWO of the following anticonvulsants: clobazam, clonazepam, levetiracetam, stiripentol, topiramate, valproic acid, and zonisamide A**ND** 6. Dose does not exceed maximum daily limits of 17mg per day with concomitant Diacomit (stiripentol) plus clobazam or 26mg per day without concomitant Diacomit therapy **AND** 7. Member has received a baseline echocardiogram **AND** 8. Member's weight will be monitored during therapy.
Age Restriction	2 years of age or older
Prescriber Restriction	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other criteria	Reauthorization: 1. Member has experienced a reduced seizure burden or improvement in quality of life **AND** 2. Echocardiogram will be repeated at least every 6 months **AND** 3. Members weight will continue to be monitored to ensure appropriate dosing **AND** 4. Dose does not exceed maximum daily limits of 17mg per day with concomitant Diacomit plus clobazam or 26mg per day without concomitant Diacomit

Applicable Coding:

None

Clinical Background Information and References

1. Fintepla (fenfluramine) [prescribing information]. Emeryville CA, 94608: Zogenix Inc.; June 2020.

2. Andrade D, Nascimento, F; Dravet sundrome: Management and prognosis. August 2020. Accessed January 2021.

3. Lagae L, Sullivan J, Knupp K, et al; Fenfluramine hydrochloride for the treatment of seizures in Dravet syndrome: a randomized, double-blind, placebo-controlled trial. Lancet. 2019; 394(10216):2243-2254.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
02/11/2021	6/01/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
2/11/2021	Policy created	6/1/2021	P&T Committee

Next Review Date:

February 2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits;

adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.