PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 8/20/2020
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

FINTEPLA® (fenfluramine) oral

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Fintepla (fenfluramine) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Neurologist

  2. Individual is 2 years of age or older

  3. A confirmed diagnosis of seizures associated with Dravet syndrome (DS) in a patient having at least six convulsive seizures per month while on stable antiepileptic medication therapy

  4. Individual has failure, intolerance, or contraindication to **TWO** the following:
     a. Valproate
     b. Clobazam
     c. Topiramate
     d. Levetiracetam

  5. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Echocardiogram as per REMS requirement

  6. Will not be used in patients with moderate to severe renal impairment

  7. Will not be used in patients with hepatic impairment

  8. There are **NO** contraindications
     a. Contraindications include:
        i. Concomitant use of, or within 14 days of the administration of monoamine oxidase inhibitors

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Fintepla (fenfluramine) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Neurologist

  2. Individual's condition responded while on therapy
     a. Response is defined as:
        i. Achieved and maintains a reduction in frequency of convulsive seizures
        ii. Longer interval between convulsive seizure over baseline of at least 5 days

  3. Individual has been adherent with the medication

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4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Serotonin syndrome
        ii. Valvular heart disease
        iii. Pulmonary arterial hypertension
        iv. Suicidal thoughts or behaviors
        v. Acute decreases in visual acuity or ocular pain

5. Will not be used in patients with moderate to severe renal impairment

6. Will not be used in patients with hepatic impairment

7. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Fintepla (fenfluramine) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 2 years of age and older.

The mechanisms by which fenfluramine exerts its therapeutic effects in the treatment of seizures associated with DS are unknown. Fenfluramine and the metabolite, norfenfluramine, increase extracellular levels of serotonin through interaction with serotonin transporter proteins, and exhibit agonist activity at serotonin 5HT-2 receptors.

DS, previously known as severe myoclonic epilepsy of infancy, is a rare early-onset epileptic encephalopathy characterized by refractory epilepsy and neurodevelopmental problems beginning in infancy. Patients present in the first year of life with a prolonged, often febrile, clonic seizure in the setting of normal cognitive and motor development prior to seizure onset. In most, febrile and afebrile seizures, including episodes of status epilepticus, recur repeatedly in the weeks to months after the initial event, and psychomotor impairment begins thereafter. Myoclonus, both epileptic and non-epileptic, occurs frequently. The majority of older children and young adults with DS have motor system dysfunction, gait and postural abnormalities, and cognitive and behavioral impairment.

DS seizures tend to be refractory to most anti-seizure drugs, and some patients derive benefit from a ketogenic diet and vagus nerve stimulation. The most commonly used anti-seizure drugs include valproate, clobazam, topiramate, levetiracetam, stirpentol, and cannabidiol. Most patients require two or more agents to achieve reasonable seizure control.

Valproate is considered a first-line agent for DS with clobazam added as a second agent if valproate does not control seizures despite adequate valproate dosing and serum levels. Topiramate is a broad spectrum antiseizure agent that is also used as added on therapy. Stiripentol and fenfluramine are also considered as add-on therapy.

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Clonazepam, levetiracetam, zonisamide, ethosuximide, and vegal nerve stimulation are considered third-line treatments for DS. Cannabidiol is also approved for treatment for DS.

Definitions:

Risk Evaluation and Mitigation Strategy (REMS) Program:
Use of Fintepla (fenfluramine) is subject to a Risk Evaluation and Mitigation Strategies (REMS) program that requires provider, patient, and dispensing pharmacy be enrolled into the program. Only providers and Pharmacies enrolled into the REMS may prescribe and dispense the drug, respectively, to individuals who are also in the program. A REMS program attempts to manage known or potentially serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) for some drugs to ensure that the benefits of a drug outweigh its risks.

Because of the risk for valvular heart disease and pulmonary arterial hypertension, Fintepla (fenfluramine) is available through a restricted REMS program

Requirements of the Fintepla (fenfluramine) REMS Program include the following:

- Prescribers must be certified by enrolling in the REMS program
- Prescribers must counsel patients receiving Fintepla (fenfluramine) about the risk of valvular heart disease and pulmonary arterial hypertension, how to recognize signs and symptoms of valvular heart disease and pulmonary arterial hypertension, the need for baseline (pretreatment) and periodic cardiac monitoring via echocardiogram during Fintepla (fenfluramine) treatment, and cardiac monitoring after treatment
- Patients must enroll in the REMS program and comply with ongoing monitoring requirements
- The pharmacy must be certified by enrolling in the REMS program and must only dispense to patients who are authorized to receive Fintepla (fenfluramine)
- Wholesalers and distributers must only distribute to certified pharmacies

Resources:

Fintepla (fenfluramine) product information, revised by manufacturer 06-2020, accessed 07-16-20 at DailyMed

Andrade DM and Nascimento FA. Dravet syndrome: Management and prognosis. In: UpToDate, Nordli DR (Ed), UpToDate, Waltham, MA.: UpToDate Inc. http://uptodate.com (Accessed on 07-16-2020)

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.