Clinical Policy: Anticonvulsant Agents

Reference Number: OH.PHAR.PPA.35
Effective date: 11.2019
Last review date: 6.2022
Line of Business:Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Central Nervous System (CNS) Agents: Anticonvulsants

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Banzel Carbamazepine Clobazam Clonazepam Divalproex Divalproex ER Eprontia solution **(PA required for 12 years and older)** Ethosuximide Gabapentin Lamotrigine Levetiracetam IR Tablet Levetiracetam Solution Oxcarbazepine Phenobarbital Phenytoin Pregabalin Primidone Topiramate Valproic Acid Zonisamide	Fycompa Vimpat	Aptiom Briviact Celontin Clonazepam ODT Elepsia XR Felbamate Fintepla Lamotrigine ER Lamotrigine ODT Levetiracetam ER Tablet Oxtellar XR Peganone Rufinamide Spritam Sympazan Tiagabine Topiramate ER Topiramate ER Sprinkle Cap Topiramate Sprinkle Cap Trokendi XR Vigabatrin Vigabatrin Powder **(PA is required for patients over 2 years of age)** Xcopri

ANTICONVULSANTS: CANNABINOID

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
EPIDIOLEX® (cannabidiol)†	

†Excluded from Grandfathering. Re-authorization requires documented reduction in average number of seizure days per month (measured monthly or quarterly).

ANTICONVULSANTS: STIRIPENTOL

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DIACOMIT® (stiripentol)	

†Excluded from Grandfathering. Re-authorization requires documented reduction in average number of seizure days per month (measured monthly or quarterly).

Central Nervous System (CNS) Agents: Anticonvulsants Rescue

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Diastat Nayzilam **(PA required for younger than 12)** Valtoco **(PA required for younger than 6)**	Diazepam Gel

• Sabril® powder requires prior authorization for age ≥ 2

• The following are anticonvulsant agents requiring step therapy: perampanel (Fycompa®), lacosamide (Vimpat®)

FDA Approved Indication(s)

• Refer to Clinical Pharmacology or other appropriate clinical resource for FDA approved indications

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that the medications listed in the above tables are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Seizures (must meet all):

1. Failure to no less than TWO preferred products for a 30 day trial of each unless one of the following:
   a. Allergy to two preferred medications
   b. Contraindication to or drug interaction with two preferred medications
   c. History of unacceptable/toxic side effects to two preferred medications
   d. The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated
2. Prescriptions submitted with the prescriber NPI of a physician who has registered a neurology specialty with Ohio Medicaid AND for products that are used

only for seizures, require a trial of ONE preferred product for 30 days unless one of the following:

a. Allergy to one preferred medication
b. Contraindication to or drug interaction with one preferred medication
c. History of unacceptable/toxic side effects to one preferred medication
d. The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated

*** This provision applies only to the standard tablet/capsule dosage form, and does not apply to brand products with available generic alternatives.**

3. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days of at least ONE preferred product.

Approval duration: 12 months

B. Lennox-Gastaut syndrome, Dravet syndrome or tuberous sclerosis complex

1. If medication is Epidiolex (must meet all):
   a. Diagnosis of Lennox-Gastaut syndrome, Dravet syndrome or tuberous sclerosis complex;
   b. Member has trialed and failed (inadequate seizure control or intolerance) 3 prior anticonvulsant therapies for 30 days each unless history of unacceptable/toxic side effects, contraindication or allergy to preferred medications (**Note:** not required to be met for a diagnosis of Dravet Syndrome)
   c. Prescriber has obtained serum transaminases (ALT and AST) and total bilirubin levels prior to starting therapy
   d. Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)
   e. Dose does not exceed 20 mg/kg/day (titration based on response/tolerability) for Lennox -Gastaut syndrome or Dravet syndrome
   f. Dose does not exceed 25mg/kg/day (titration based on response/tolerability) for tuberous sclerosis complex

2. If medication is Diacomit (must meet all):
   a. Diagnosis of Dravet syndrome;
   b. Medication is prescribed by a neurologist or in consultation with a neurologist;
   c. Prescriber must include management plans for patients with neutrophil counts <1500 cells/mm3 or platelet count less than 150,000/µL;
   d. Member must be concurrently managed with clobazam;
   e. Dose does not exceed 50 mg/kg/day or 3000mg/day.
   f. Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)
   g. Members with phenylketonuria (PKU) will not be authorized for suspension dosage form without evidence of total daily amount of phenylalanine.

Approval duration:
Initial: 180 days
Subsequent: 12 months

C. Status epilepticus

1. Trial and failure of at least one preferred medication unless one of the following:
   a. Allergy to medications not requiring prior approval
   b. Contraindication to or drug interaction with medications not requiring prior approval
   c. History of unacceptable/toxic side effects to medications not requiring prior approval

Approval duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
• Dosing varies by drug product. See FDA approved dosing and administration.

Appendix C: Contraindications / Boxed Warnings
• Refer to Clinical Pharmacology or other appropriate clinical resource for contraindications or black box warnings

IV. Dosage and Administration

A. Varies by drug product. See FDA approved dosing and administration.

V. Product Availability

A. Varies by drug product. Refer to Clinical Pharmacology or other appropriate clinical resource for product availability

VI. References

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.2019	
Annual review: Added anticonvulsant rescue section for status epilepticus. Updated preferred/non-preferred chart	11.21	
Quarter 2 2022 review: Added Eprontia solution to No PA required "preferred". Eprontia solution: a PA is required for patients 12 years and older	6.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.