UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2017-20
Program	Prior Authorization/Medical Necessity - Single Source Brand Anticonvulsants
Medication/Therapeutic Class	Single Source Brand Anticonvulsants – Aptiom® (eslicarbazepine), Briviact® (brivaracetam), Epidiolex® (cannabidiol), Fintepla® (fenfluramine), Xcopri® (cenobamate) and Ztalmy® (ganaxolone)
P&T Approval Date	2/2014, 5/2014, 11/2014, 11/2015, 6/2016, 6/2017, 9/2018, 11/2018, 11/2019, 7/2020, 10/2020, 10/2021, 1/2022, 5/2022, 10/2022, 11/2022, 10/2023, 10/2024, 4/2025
Effective Date	7/1/2025

1. Background:

This program requires a member to try at least one antiepileptic medication prior to receiving coverage for Briviact and at least two antiepileptic medications prior to receiving coverage for Aptiom, Fintepla, Xcopri, and Ztalmy or for Epidiolex when it is used for seizures associated with Lennox-Gastaut syndrome. Epidiolex for seizures associated with Dravet syndrome or tuberous sclerosis complex do not require a trial of alternative antiepileptic medications.

2. Coverage Criteria[a]:

A. Aptiom, Xcopri or **Ztalmy** will be approved based on **one** of the following:

1. **All** of the following:

   a. One of the following:

      (1) For **Aptiom** or **Xcopri**: diagnosis of partial-onset seizures
      (2) For **Ztalmy**: diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder confirmed with genetic testing

-AND-

   b. History of greater than or equal to 8 week trial[b] of at least **two** of the following (any release formulation qualifies):

      (1) Carbamazepine (e.g. generic Tegretol)
      (2) Divalproex (e.g. generic Depakote)
      (3) Gabapentin (e.g. generic Neurontin)
      (4) Lamotrigine (e.g. generic Lamictal)
      (5) Levetiracetam (e.g. generic Keppra)
      (6) Oxcarbazepine (e.g. generic Trileptal)
      (7) Phenytoin (e.g. generic Dilantin)
      (8) Pregabalin (e.g. generic Lyrica)
      (9) Topiramate (e.g. generic Topamax)

(10) Valproic acid (e.g. generic Depakene)
(11) Zonisamide (generic Zonegran)

-AND-

c. **One** of the following:

(1) **Both** of the following:

(a) Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
(b) Lack of compliance as a reason for treatment failure has been ruled out

-OR-

(2) **Both** of the following:

(a) Documentation of failure due to intolerable side effects.
(b) Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

-OR-

2. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

B. Briviact will be approved based on **one** of the following:

1. **All** of the following:

a. Diagnosis of partial-onset seizures

-AND-

b. History of greater than or equal to 8 week trial[b] of at least **one** of the following (any release formulation qualifies):

(1) Carbamazepine (e.g. generic Tegretol)
(2) Divalproex (e.g. generic Depakote)
(3) Gabapentin (e.g. generic Neurontin)
(4) Lamotrigine (e.g. generic Lamictal)
(5) Levetiracetam (e.g. generic Keppra)
(6) Oxcarbazepine (e.g. generic Trileptal)
(7) Phenytoin (e.g. generic Dilantin)
(8) Pregabalin (e.g. generic Lyrica)
(9) Topiramate (e.g. generic Topamax)
(10) Valproic acid (e.g. generic Depakene)

(11) Zonisamide (generic Zonegran)

-AND-

c. **One** of the following:

(1) **Both** of the following:

(a) Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
(b) Lack of compliance as a reason for treatment failure has been ruled out

-OR-

(2) **Both** of the following:

(a) Documentation of failure due to intolerable side effects.
(b) Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

-OR-

2. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

C. Epidiolex will be approved based on **one** of the following:

1. Diagnosis of seizures associated with Dravet syndrome or tuberous sclerosis complex

-OR-

2. **All** of the following:

a. Diagnosis of seizures associated with Lennox-Gastaut syndrome

-AND-

b. History of greater than or equal to 8 week trial[b] of at least **two** generic anticonvulsants (e.g. divalproex, lamotrigine, topiramate, valproic acid)

-AND-

c. **One** of the following:

(1) **Both** of the following:

(a) Documented history of persisting seizures after titration to the highest

tolerated dose with each medication trial
(b) Lack of compliance as a reason for treatment failure has been ruled out

-OR-

(2) **Both** of the following:

(a) Documentation of failure due to intolerable side effects.
(b) Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

-OR-

3. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

D. Fintepla will be approved based on **one** of the following:

1. **All** of the following:

a. Diagnosis of seizures associated with Dravet syndrome

-AND-

b. History of greater than or equal to 8 week trial[b] of at least **two** of the following (any release formulation qualifies):

(1) Divalproex (e.g. generic Depakote)
(2) Levetiracetam (e.g. generic Keppra)
(3) Topiramate (e.g. generic Topamax)
(4) Valproic acid (e.g. generic Depakene)
(5) Zonisamide (generic Zonegran)

-AND-

c. **One** of the following:

(1) **Both** of the following:

(a) Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
(b) Lack of compliance as a reason for treatment failure has been ruled out

-OR-

(2) **Both** of the following:

(a) Documentation of failure due to intolerable side effects.
(b) Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

-OR-

2. **All** of the following:

   a. Diagnosis of seizures associated with Lennox-Gastaut syndrome

   -AND-

   b. History of greater than or equal to 8 week trial[b] of at least **two** of the following (any release formulation qualifies):

      (1) Divalproex (e.g. generic Depakote)
      (2) Lamotrigine (e.g. generic Lamictal)
      (3) Topiramate (e.g. generic Topamax)
      (4) Valproic acid (e.g. generic Depakene)

   -AND-

   c. **One** of the following:

      (1) **Both** of the following:

         (a) Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
         (b) Lack of compliance as a reason for treatment failure has been ruled out

      -OR-

      (2) **Both** of the following:

         (a) Documentation of failure due to intolerable side effects.
         (b) Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

-OR-

3. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization

management programs may apply.
[b] For Connecticut, Kentucky and Mississippi business, only a 30 day trial will be required.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Anon; Drugs for Epilepsy, Treatment Guidelines from The Medical Letter, 2013; 11:9-19.
2. Britton JW. Antiepileptic drug withdrawal: literature review. Mayo Clin Proc. 2002;77(12):1378.
3. Kwan P, et al. Definition of drug resistant epilepsy; consensus proposal by the ad hoc Task Force of the ILAE Commission on Therapeutic Strategies. Epilepsia. 2010; 51(6);1069.
4. Perucca E, et al. The pharmacological treatment of epilepsy in adults. Lancet Neuol 2011; 10:446-56.
5. Aptiom [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc; March 2019.
6. Briviact [package insert]. Smyrna, GA: UCB, Inc; May 2023.
7. Epidiolex [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; March 2024.
8. Xcopri [package insert]. Paramus, NJ: SK Life Science, Inc; April 2024.
9. Fintepla [package insert]. Smyrna, GA: UCB, Inc; December 2023.
10. Ztalmy [package insert]. Radnor, PA; Marinus Pharmaceuticals, Inc.; April 2024.

Program	Prior Authorization/Medical Necessity - Single Source Brand Anticonvulsants
Change Control	
Date	Change
2/2014	New program
5/2014	Addition of Aptiom to program
11/2014	Updated to clarify trial period for Connecticut and Kentucky to comply with state regulations.
11/2015	Annual review. Modified criteria to separate out failure due to lack of efficacy and adverse events. Changed authorization period. Updated references.
6/2016	Updated to include diagnosis criteria and added Briviact. Added Maryland requirements. Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
6/2017	Annual review. References updated. State mandate reference language updated.
9/2018	Annual review. References updated.
11/2018	Addition of Epidiolex to program.
11/2019	Annual review. References updated.

7/2020	Addition of Xcopri to program.
10/2020	Addition of Fintepla to program. Updated Epidiolex criteria to include seizures associated with tuberous sclerosis complex.
10/2021	Updated Vimpat criteria to allow for primary generalized tonic-clonic seizures. References updated.
1/2022	Changed Briviact to require a trial of one generic anticonvulsant prior to coverage.
5/2022	Updated Fintepla to include Lennox-Gastaut syndrome criteria. Moved Vimpat to Multi-Source Brand Anticonvulsants criteria due to generic launch. Updated references. Updated state mandate language.
10/2022	Added Ztalmy to program.
11/2022	Removed specific medications for Epidiolex step requirement.
10/2023	Changed Fycompa to require a trial of one generic anticonvulsant prior to coverage.
10/2024	Annual review. Updated CT/KY/MS state mandate footnote. Updated references.
4/2025	Moved Fycompa to Multi-Source Brand Anticonvulsants criteria due to a generic launch. Aligned trial/failure language for consistency.