UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2017-9
Program	Prior Authorization/Medical Necessity - Single Source Brand Anticonvulsants
Medication/Therapeutic Class	Single Source Brand Anticonvulsants – Aptiom (eslicarbazepine), Briviact (brivaracetam), Epidiolex (cannabidiol), Fycompa (perampanel) and Vimpat (lacosamide)
P&T Approval Date	2/2014, 5/2014, 11/2014, 11/2015, 6/2016, 6/2017, 9/2018, 11/2018
Effective Date	2/1/2019; Oxford only: 2/1/2019

1. Background:

This program requires a member to try at least two antiepileptic medications prior to receiving coverage for Aptiom, Briviact, Fycompa, Vimpat or Epidiolex when it is used for seizures associated with Lennox-Gastaut syndrome. Epidiolex for seizures associated with Dravet syndrome does not require a trial of alternative antiepileptic medications.

2. Coverage Criteria [a]:

A. Aptiom, Briviact, Fycompa or **Vimpat** will be approved based on **one** of the following:

1. **All** of the following:
   a. One of the following:
      (1) For **Aptiom, Briviact** or **Vimpat**: diagnosis of partial-onset seizures
      (2) For **Fycompa**: diagnosis of partial-onset or primary generalized tonic-clonic seizures

-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
      (2) Divalproex
      (3) Gabapentin
      (4) Lamotrigine
      (5) Levetiracetam
      (6) Oxcarbazepine
      (7) Phenytoin
      (8) Pregabalin
      (9) Topiramate

(10) Valproic acid
(11) Zonisamide

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

1. Diagnosis of seizures associated with Dravet syndrome

-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], contraindication or intolerance of at least **two** of the following (any release formulation qualifies):

(1) Divalproex
(2) Lamotrigine
(3) Topiramate

(4) 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.

[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] Connecticut and Kentucky 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. Fycompa prescribing information. Eisia Inc., Woodcliff, NJ. AprilJuly 2017.

4. 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.
5. Perucca E, et al. The pharmacological treatment of epilepsy in adults. Lancet Neuol 2011; 10:446-56.
6. Vimpat prescribing information. UCB, Inc. Smyrna, GA. November 2017.
7. Aptiom prescribing information. Sunovion Pharmaceuticals Inc. Marlborough, MA. October 2017.
8. Briviact prescribing information. UCB, Inc. Smyrna, GA. May 2018.
9. Epidiolex prescribing information. Greenwich Biosciences, Inc. Carlsbad, CA. June 2018.

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.