

### Clinical Pharmacy Program Guidelines for Anticonvulsants

Program	Prior Authorization - Anticonvulsants
Medication	Aptiom (eslicarbazepine), Briviact (brivaracetam), Fycompa (perampanel), Vimpat (lacosamide), Gabitril (tiagabine), Banzel (rufinamide), Onfi (clobazam), Epidiolex (cannabidiol), Sympazan (clobazam), Sabril, (vigabatrin), Diacomit (stiripentol), Xcopri (cenobamate), Fintepla (fenfluramine)
Markets in Scope	Arizona, California, Colorado, Hawaii, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2016
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

#### 1. Background:

Aptiom (eslicarbazepine acetate), Briviact (brivaracetam), Vimpat (lacosamide) and Xcopri are indicated in the treatment of partial-onset seizures.

Banzel (rufinamide), Onfi (clobazam), and Sympazan (clobazam) are indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS). There is some clinical evidence to support the use of clobazam for refractory partial onset seizures.

Diacomit (stiripentol) is indicated for seizures associated with Dravet syndrome in patients taking clobazam.

Epidiolex (cannabidiol) is indicated for seizures associated with Lennox-Gastaut syndrome, Dravet syndrome or tuberous sclerosis complex.

Fintepla (fenfluramine) is indicated for the treatment of seizures associated with Dravet syndrome.

Fycompa (perampanel) is indicated for the treatment of partial-onset seizures with or without secondarily generalized seizures and as adjunctive therapy for the treatment of primary generalized tonic-clonic seizures.

Gabitril (tiagabine) is indicated as adjunctive therapy in the treatment of partial-onset seizures.

Sabril (vigabatrin) is indicated as adjunctive therapy for refractory complex partial seizures in patients who have inadequately responded to several alternative treatments and for infantile spasms for whom the potential benefits outweigh the risk of vision loss.

## 2. Coverage Criteria

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

1. **All** of the following:

a. One of the following:

- (1) For **Aptiom, Briviact Vimpat, or Xcopri**: 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 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 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, contraindication or intolerance of at least **two** of the following (any release formulation qualifies):

- (1) Divalproex
- (2) Lamotrigine
- (3) Topiramate
- (4) Valproic acid
- (5) Felbamate
- (6) Banzel
- (7) Clobazam

**-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.**

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

1. One of the following:
  - a. Diagnosis of seizures associated with Lennox-Gastaut syndrome

**-OR-**

- b. Both of the following:
  - Diagnosis of Dravet syndrome
  - Patient is currently taking Diacomit

**-OR-**

2. For continuation of prior therapy for a seizure disorder  
**Authorization will be issued for 12 months.**

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

1. Diagnosis of seizures associated with Lennox-Gastaut syndrome

**-OR-**

2. For continuation of prior therapy for a seizure disorder

**Authorization will be issued for 12 months.**

**E. Gabitril** will be approved based on **one** of the following:

1. **All** of the following:

a. Diagnosis of partial-onset seizures

**-AND-**

b. Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

**-AND-**

c. Not used as primary treatment

**-AND-**

d. History of greater than or equal to 8 week trial 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

**-OR-**

2. For continuation of prior therapy for a seizure disorder

**Authorization will be issued for 12 months.**

**F. Sympazan** will be approved based on **one** of the following criteria:

1. **ALL** of the following:

a. Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

**-AND-**

- b. **BOTH** of the following:
- i. Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
  - ii. Not used as primary treatment

-AND-

- c. History of greater than or equal to 8 week trial, contraindication or intolerance of at least **two** of the following (any release formulation qualifies):
- i. Divalproex
  - ii. Lamotrigine
  - iii. Topiramate
  - iv. Valproic acid
  - v. Felbamate
  - vi. Banzel

-AND-

- d. Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

-OR-

2. **ALL** of the following:
- a. Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)

-AND-

- b. **BOTH** of the following:
- i. Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
  - ii. Not used as primary treatment

-AND-

- c. History of greater than or equal to 8 week trial of at least **two** of the following (any release formulation qualifies):
- i. Carbamazepine
  - ii. Divalproex
  - iii. Gabapentin
  - iv. Lamotrigine
  - v. Levetiracetam

- vi. Oxcarbazepine
- vii. Phenytoin
- viii. Pregabalin
- ix. Topiramate
- x. Valproic acid
- xi. Zonisamide

**-AND-**

d. Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

**-OR-**

3. **All** of the following:

- a. Diagnosis of Dravet syndrome

**-AND-**

- b. Patient is currently taking Diacomit

**-AND-**

- c. Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

**-OR-**

4. For continuation of prior therapy for a seizure disorder

**Authorization will be issued for 12 months.**

**G. Sabril Oral Solution** will be approved based on **one** of the following criteria:

- 1. Diagnosis of infantile spasms

**-OR-**

2. **All** of the following:

- a. Diagnosis of complex partial seizures

**-AND-**

- b. Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

**-AND-**

- c. Not used as primary treatment

**-AND-**

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

- i. Carbamazepine
- ii. Divalproex
- iii. Gabapentin
- iv. Lamotrigine
- v. Levetiracetam
- vi. Oxcarbazepine
- vii. Phenytoin
- viii. Pregabalin
- ix. Topiramate
- x. Valproic acid
- xi. Zonisamide

**-OR-**

3. For continuation of prior therapy for a seizure disorder

**Authorization will be issued for 12 months.**

**H. Sabril Tablets** will be approved based on **one** of the following criteria:

1. **All** of the following:

- a. Diagnosis of complex partial seizures

**-AND-**

- b. Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

**-AND-**

- c. Not used as primary treatment

**-AND-**



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

- i. Carbamazepine
- ii. Divalproex
- iii. Gabapentin
- iv. Lamotrigine
- v. Levetiracetam
- vi. Oxcarbazepine
- vii. Phenytoin
- viii. Pregabalin
- ix. Topiramate
- x. Valproic acid
- xi. Zonisamide

**-OR-**

2. For continuation of prior therapy for a seizure disorder

**Authorization will be issued for 12 months.**

**I. Diacomit** will be approved based on **one** of the following:

1. Diagnosis of Dravet syndrome and currently taking clobazam

**-OR-**

2. For continuation of prior therapy for a seizure disorder

**Authorization will be issued for 12 months.**

**J. 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 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. For continuation of prior therapy for a seizure disorder

**Authorization will be issued for 12 months.**

**3. Additional Clinical Rules:**

- 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:**

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**Community Plan**

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18. Nayzilam [package insert]. Smyrna, GA: UCB, Inc.; May 2019.
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21. Gabatril [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; May 2018.
22. Fintepla [package insert]. Emeryville, CA: Zogenix, Inc; June 2020.

Program	Prior Authorization - Anticonvulsants
<b>Change Control</b>	
Date	Change
6/2016	C&S – new program
8/2016	Removed Felbatol criteria (Section D) and Multi-Source Brand Anticonvulsants and Modified Release Products Section. Added criteria for Onfi and Banzel suspensions.
6/2017	Annual review. Updated policy template.
9/2017	Removed clinical criteria other than diagnosis check for Onfi and Banzel. Added diagnosis check for Felbatol to allow for Dx to Rx implementation. Updated Fycompa criteria to reflect new indication. Removed Potiga due to market removal of the medication.
3/2018	Added continuation of therapy language for Gabitril to match what we have for other non-preferred anticonvulsants.



Community Plan

5/2018	Felbatol moved into its own section to allow for approval for partial-onset seizures or LGS. Gabitril: removed not used as primary treatment requirement as this was duplicative.
11/2018	Addition of Epidiolex to program.
3/2019	Added Sympazan to the policy. Moved Sabril from its own policy into this policy. Updated step therapy drugs for alignment throughout the policy.
5/2019	Added Diacomit to the policy. Added Felbamate and Banzel as step therapy options for Lennox-Gastaut syndrome. Added Diacomit.
11/2019	Added clobazam as a step therapy option for LGS. Added step through generic clobazam for Sympazan.
7/2020	Added Dravet syndrome to covered indications for Onfi and Sympazan. Added Xcopri to criteria. Removed Felbatol.
9/2020	Added Fintepla to criteria.
10/2020	Updated Fintepla to align with E&I SSB Anticonvulsants. Updated Epidiolex criteria to include seizures associated with tuberous sclerosis complex.