

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2021 P 1078-19 |
| Program | Prior Authorization/Notification - Anticonvulsants |
| Medication | Aptiom (eslicarbazepine acetate), Banzel (rufinamide), Briviact (brivaracetam), Diacomit (stiripentol), Epidiolex (cannabidiol), Fintepla (fenfluramine), Fycompa (perampanel), Nayzilam (midazolam), Onfi (clobazam), Sabril (vigabatrin), Sympazan (clobazam)*, Valtoco (diazepam), Vimpat (lacosamide), Xcopri (cenobamate) |
| P&T Approval Date | 11/2012, 10/2013, 2/2014, 5/2014, 10/2014, 2/2015, 8/2015, 10/2015, 10/2016, 4/2017, 10/2017, 7/2018, 3/2019, 5/2019, 3/2020, 7/2020, 9/2020, 10/2020, 10/2021 |
| Effective Date | 1/1/2022; Oxford: 1/1/2022 |

1. Background:

Aptiom (eslicarbazepine acetate), Briviact (brivaracetam), Vimpat (lacosamide) and Xcopri are indicated in the treatment of partial-onset seizures. Vimpat is also indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic 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 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.

Nayzilam (midazolam) and Valtoco (diazepam) are indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern.

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.

Adjunctive therapy is defined as treatment administered in addition to another therapy.

2. Coverage Criteria:

A. Initial Authorization

1. **Aptiom, Briviact, or Xcopri** will be approved based on **ONE** of the following criteria:

- a. Diagnosis of partial-onset seizures
- b. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

2. **Banzel** will be approved based on **ONE** of the following criteria:

- a. **ALL** of the following:
 - i. Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)
 - ii. Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
 - iii. Not used as primary treatment

-OR-

- b. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

3. **Fycompa** will be approved based on **ONE** of the following:

- a. **ONE** of the following:
 - i. Diagnosis of partial-onset seizures with or without secondarily generalized seizures

-OR-

- ii. **ALL** of the following:
 - (a) Diagnosis of primary generalized tonic-clonic seizures
 - (b) Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)

(c) Not used as primary treatment

-OR-

b. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

4. **Onfi** or **Sympazan*** will be approved based on **ONE** of the following criteria:

a. **ALL** of the following:

i. **ONE** of the following:

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

(b) Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)

(c) Diagnosis of Dravet syndrome

-AND-

ii. **BOTH** of the following:

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

(b) Not used as primary treatment

-OR-

b. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

5. **Sabril** will be approved based on **ONE** of the following criteria:

a. **ALL** of the following:

i. Diagnosis of partial-onset seizures

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

iii. Not used as primary treatment

iv. Patient has had inadequate response to several (at least three) alternative anticonvulsants

-OR-

b. Diagnosis of infantile spasms

-OR-

c. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

6. **Diacomit** will be approved based on **ONE** of the following criteria:

a. Diagnosis of Dravet syndrome and currently taking clobazam

-OR-

b. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

7. **Epidiolex** will be approved based on **ONE** of the following criteria:

a. Diagnosis of Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex

-OR-

b. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

8. **Nayzilam** or **Valtoco** will be approved based on the following criterion:

a. Diagnosis of seizure clusters or acute repetitive seizures that are distinct from the patient's usual seizure pattern

Authorization will be issued for 12 months.

9. **Fintepla** will be approved based on **ONE** of the following criteria:

a. Diagnosis of Dravet syndrome

-OR-

b. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

10. **Vimpat** will be approved based on **ONE** of the following criteria:

- a. Diagnosis of partial-onset seizures
- b. For continuation of prior therapy for a seizure disorder
- c. **All** of the following:
 - i. Diagnosis of primary generalized tonic-clonic seizures
 - ii. Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
 - iii. Not used as primary treatment

Authorization will be issued for 12 months.

B. Reauthorization

1. **Aptiom, Banzel, Briviac, Diacomit, Epidiolex, Fintepla, Fycompa, Nayzilam, Onfi, Sabril, Sympazan*, Valtoco, Vimpat or Xcopri** will be approved based on the following criterion:

- a. Documentation of positive clinical response to therapy.

Authorization will be issued for 12 months.

3. Additional Clinical Programs:

- *Typically excluded from coverage.
- 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.
- Medical Necessity may be in place.

4. References:

1. Banzel [package insert]. Woodcliff Lake, NJ: Eisai, Inc; April 2020.
2. Vimpat [package insert]. Smyrna, GA: UCB, Inc; November 2020.
3. Fycompa [package insert]. Woodcliff Lake, NJ: Eisai Inc; February 2021.
4. Aptiom [package insert]. Marlborough, MA; Sunovion Pharmaceuticals Inc; March 2019.
5. Onfi [package insert]. Deerfield, IL: Lundbeck; February 2021.
6. Briviac [package insert]. Smyrna, GA: UCB, Inc; August 2021.
7. Sabril [package insert]. Deerfield, IL: Lundbeck; August 2021.
8. Koeppen, D. et al. Clobazam in therapy-resistant patients with partial epilepsy: A double-blind placebo-controlled crossover study. *Epilepsia* 28(5);495-506. October 1987.

9. Micahel, B. Clobazam as an add-on in the management of refractory epilepsy. Cochrane Database of Systemic Reviews 2008.
10. Sympazan [package insert]. Warren, NJ: Aquestive Therapeutics; August 2020.
11. Diacomit [package insert]. Redwood City, CA: Biocodex Inc; May 2020.
12. Epidiolex [package insert]. Carlsbad, CA: Greenwich Biosciences, Inc; September 2021.
13. Nayzilam [package insert]. Smyrna, GA: UCB, Inc; February 2021.
14. Valtoco [package insert]. San Diego, CA: Neurelis, Inc; February 2021.
15. Xcopri [package insert]. Paramus, NJ: SK Life Science, Inc; March 2020.
16. Fintepla [package insert]. Emeryville, CA: Zogenix, Inc; June 2020.

| Program | Prior Authorization/Notification - Anticonvulsants |
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| Change Control | |
| Date | Change |
| 10/2013 | Revised diagnosis of Banzel to “Diagnosis of seizures associated with”. Removed age edit from Vimpat and Potiga. |
| 2/2014 | Added Fycompa to criteria. |
| 5/2014 | Added Aptiom to criteria. Revised program name to “Adjunctive Anticonvulsants” |
| 10/2014 | Updated Vimpat criteria to reflect new monotherapy indication. Changed program name to “Anticonvulsants” |
| 2/2015 | Added Onfi to Anticonvulsant guideline. (Onfi previously in 1073, moved to 1078.) |
| 8/2015 | Updated Fycompa criteria and background to reflect new indication for adjunctive therapy for primary generalized tonic-clonic seizures. Updated references. |
| 10/2015 | Updated Aptiom criteria to allow for new indication of monotherapy for partial-onset seizures. Updated references. |
| 10/2016 | Added Briviact to criteria. Administrative changes. |
| 4/2017 | Added Sabril to criteria. Updated requirements for Potiga to include inadequate response to prior therapy. Updated Onfi to include coverage for refractory partial onset seizures. Added criteria for continuation of therapy for all medications. Updated references. |
| 10/2017 | Updated Fycompa criteria to reflect new monotherapy indication. Removed Potiga due to market removal. |
| 7/2018 | Updated Briviact criteria to allow for new indication of monotherapy for partial-onset seizures. Updated references. |
| 12/2018 | Administrative change to add statement regarding use of automated processes. |
| 3/2019 | Sympazan added to criteria. |
| 5/2019 | Diacomit and Epidiolex added to criteria. |
| 3/2020 | Nayzilam and Valtoco added to criteria. Updated references. |
| 7/2020 | Added Dravet syndrome to covered indications for Onfi and Sympazan. Added Xcopri to criteria. |

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| 9/2020 | Added Fintepla to criteria. |
| 10/2020 | Updated approved indications for Epidiolex to include seizures associated with tuberous sclerosis complex. |
| 10/2021 | Updated Vimpat criteria to allow for adjunctive therapy for primary generalized tonic-clonic seizures. Updated references. |