UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1078-26
Program	Prior Authorization/Notification - Anticonvulsants
Medication	Aptiom® (eslicarbazepine acetate), Banzel® (rufinamide), Briviact® (brivaracetam), Diacomit® (stiripentol), Epidiolex® (cannabidiol), Fintepla® (fenfluramine), Fycompa® (perampanel), Libervant (diazepam)™, Nayzilam® (midazolam), Onfi® (clobazam), Sabril®* (vigabatrin), Sympazan® (clobazam), Valtoco® (diazepam), Vigadrone® (vigabatrin), Vigafyde™ (vigabatrin), Vigpoder™ (vigabatrin), Xcopri® (cenobamate), Ztalmy® (ganaxolone)
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, 5/2022, 10/2022, 12/2023, 2/2024, 9/2024, 3/2025, 6/2025
Effective Date	9/1/2025

1. Background:

Aptiom (eslicarbazepine acetate), Briviact (brivaracetam), 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 (cannabadiol) is indicated for seizures associated with Lennox-Gastaut syndrome, Dravet syndrome or tuberous sclerosis complex.

Fintepla (fenfluramine) is indicated for seizures associated with Lennox-Gastaut syndrome and 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.

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

Ztalmy (ganaxolone) is indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD).

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*, Vigadrone, Vigafyde or Vigpoder** 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 and less than or equal to two years old

-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. **Libervant, 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 Lennox-Gastaut syndrome or Dravet syndrome

   -OR-

   b. For continuation of prior therapy for a seizure disorder

   Authorization will be issued for 12 months.

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

    a. Diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder
    b. For continuation of prior therapy for a seizure disorder

    Authorization will be issued for 12 months.

B. Reauthorization

1. **Aptiom**, **Banzel, Briviact, Diacomit, Epidiolex, Fintepla, Fycompa, Libervant, Nayzilam, Onfi, Sabril*, Sympazan, Valtoco**, **Vigafyde, Vigpoder, Xcopri or Ztalmy** 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:

- 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.
  *Brand Sabril is typically excluded from coverage.

4. References:

1. Banzel [package insert]. Nutley, NJ: Eisai, Inc; December 2022.
2. Fycompa [package insert]. Coral Gables, FL: Eisai Inc; June 2023.
3. Aptiom [package insert]. Marlborough, MA; Sunovion Pharmaceuticals Inc; March 2019.
4. Onfi [package insert]. Deerfield, IL: Lundbeck; March 2024.
5. Briviact [package insert]. Smyrna, GA: UCB, Inc; May 2023.
6. Sabril [package insert]. Deerfield, IL: Lundbeck; October 2021.
7. 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.
8. Micahel, B. Clobazam as an add-on in the management of refractory epilepsy. Cochrane Database of Systemic Reviews 2008.
9. Sympazan [package insert]. Warren, NJ: Aquestive Therapeutics; March 2024.
10. Diacomit [package insert]. San Mateo, CA: Biocodex Inc; June 2024.
11. Epidiolex [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; March 2024.
12. Nayzilam [package insert]. Smyrna, GA: UCB, Inc; January 2023.
13. Valtoco [package insert]. San Diego, CA: Neurelis, Inc; August 2023.
14. Xcopri [package insert]. Paramus, NJ: SK Life Science, Inc; April 2024.
15. Fintepla [package insert]. Smyrna, GA: UCB, Inc; December 2023.
16. Ztalmy [package insert]. Radnor, PA; Marinus Pharmaceuticals, Inc.; April 2024.
17. Libervant [package insert]. Warren, NJ: Aquestive Therapeutics; April 2024.
18. Vigafyde [package insert]. Parsippany, NJ: Pyros Pharmaceuticals, Inc.; November 2024.
19. Vigpoder [package insert]. Parsippany, NJ: Pyros Pharmaceuticals, Inc.; July 2023.

Program	Prior Authorization/Notification - Anticonvulsants
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.
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.
5/2022	Updated Fintepla criteria to allow for Lennox-Gastaut syndrome. Updated references.
10/2022	Ztalmy added to criteria.
12/2023	Removed note that Sympazan is typically excluded from coverage. Updated references.
2/2024	Removed Vimpat from criteria.
9/2024	Added Libervant to criteria. Updated references.
3/2025	Added Vigafyde and Vigpoder to criteria. Noted that brand Sabril is typically excluded from coverage.
6/2025	Added Vigadrone to criteria. Added up to 2 years of age for infantile spasms.