UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1078-12
Program	Prior Authorization/Notification - Anticonvulsants
Medication	Aptiom (eslicarbazepine acetate); Banzel (rufinamide); Briviact (brivaracetam), Fycompa (perampanel); Onfi (clobazam); Sabril (vigabatrin), Vimpat (lacosamide)
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
Effective Date	10/1/2018; Oxford: 10/1/2018

1. Background:

Aptiom (eslicarbazepine acetate) and Vimpat (lacosamide) are indicated as monotherapy or adjunctive therapy in the treatment of partial-onset seizures.

Banzel (rufinamide) and Onfi (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 Onfi for refractory partial onset seizures.

Briviact (brivaracetam) is indicated for the treatment of partial-onset seizures.

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.

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 (5). Coverage will not be provided for Banzel, or Briviact as primary treatment.

2. Coverage Criteria:

A. <u>Initial Authorization</u>

1. **Aptiom** or **Vimpat** will be approved based on **<u>ONE</u>** 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. **Briviact** will be approved based on **ONE** of the following criteria:

   a. Diagnosis of partial onset seizures

   -OR-

   b. For continuation of prior therapy for a seizure disorder

5. **Onfi** 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)

-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

6. **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.

B. Reauthorization

1. **Aptiom**, **Banzel, Briviact, Fycompa, Onfi, Sabril** or **Vimpat** 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.

4. References:

1. Banzel prescribing information. Eisai, Inc. Woodcliff Lake, NJ. June 2015.
2. Vimpat prescribing information. UCB, Inc. Smyma, GA. June 2015.
3. Fycompa prescribing information. Eisai Inc., Woodcliff Lake, NJ. July 2017.
4. Glossary of Terms. Epilepsy Foundation Web site. http://www.epilepsy.com/get-help/toolbox/glossaryAccessed August 30, 2016.
5. Aptiom prescribing information. Sunovion Pharmaceuticals Inc. Marlborough, MA. September 2016.
6. Onfi Prescribing Information. Lundbeck, Deerfield, IL. February 2017.
7. Briviact prescribing information. UCB, Inc. Smyrna, GA. May 2018.
8. Sabril prescribing information. Lundbeck, Deerfield, IL. January 2017.
9. 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.
10. Micahel, B. Clobazam as an add-on in the management of refractory epilepsy. Cochrane Database of Systemic Reviews 2008.

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.