UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Anticonvulsants

Program	Prior Authorization - Anticonvulsants
Medication	Aptiom (eslicarbazepine), Briviact (brivaracetam), Felbatol (felbamate), Fycompa (perampanel), Vimpat (lacosamide), Gabitril (tiagabine), Banzel (rufinamide), Onfi (clobazam)
Issue Date	6/2016
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

1. Background:

This program requires a member to try at least two antiepileptic medications prior to receiving coverage for Aptiom, Briviact, Fycompa or Vimpat.

2. Coverage Criteria

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 seizures with or without secondarily generalized seizures 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. Onfi, **Banzel, or Felbatol** will be approved based on the following:

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

Authorization will be issued for 12 months.

C. 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 failure, contraindication, or intolerance to two preferred anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)

-OR-

2. For continuation of prior therapy for a seizure disorder

Authorization will be issued for 12 months.

4. References:

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7. Aptiom prescribing information. Sunovion Pharmaceuticals Inc. Marlborough, MA. August 2015.
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19. Trileptal Prescribing Information. Novartis. East Hanover, NJ. February 2013.
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25. Talati R, et al. Effectiveness and Safety of Antiepileptic Medications in Patients with Epilepsy. Agency for Healthcare Research and Quality (US); December 2011.
26. U.S. Food and Drug Association Adverse Events Reporting System (FAERS). www.fda.gov.
27. Felbatol Prescribing Information. Meda Pharmaceuticals Inc. Sommerset, NJ. July 2011.
28. Mysoline Prescribing Information. Valeant Pharmaceuticals Inc. Bridgewater, NJ. September 2012.
29. Spritam Prescribing Information. Aprecia Pharmaceuticals Company. East Windsor, NJ. February 2016.

Program	Prior Authorization - Anticonvulsants
Change Control	
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.