

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Antiepileptics

Override(s)	Approval Duration
Prior Authorization Step Therapy Quantity Limit	1 year

Medications	Comment	Quantity Limit
Carbamazepine	Preferred	May be subject to quantity limit
Epitol		
Ethosuximide		
Felbamate		
Lamotrigine Chewable		
Lamotrigine IR		
Lamotrigine ODT		
Lamotrigine XR		
Levetiracetam immediate release *note: generic for Keppra IR, not generic for Spritam.		
Levetiracetam extended release		
Oxcarbazepine		
Phenytoin		
Primidone		
Roweepra (levetiracetam) immediate release *note: generic for Keppra IR, not generic for Spritam.		
Roweepra (levetiracetam) XR *note: generic for Keppra XR, not generic for Spritam.		
Tiagabine		
Topiramate		
Topiramate Sprinkle Cap		
Valproic acid/Valproate		
Zonisamide		

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Aptiom (eslicarbazepine)	Non-Preferred
Banzel (rufinamide)	
Briviact (brivaracetam)	
Celontin (methsuximide)	
Diacomit (stiripentol)	Non-Preferred (con't)
Dilantin (phenytoin) 30mg - brand	
Elepsia XR (levetiracetam extended release)	
Felbatol (felbamate) – brand	
Fycompa (perampanel)	
Fintepla (fenfluramine)	
Gabitril (tigabine) - brand	
Keppra IR (levetiracetam immediate release) – brand only	
Keppra XR (levetiracetam extended release) – brand only	
Lamictal IR (lamotrigine) – brand only	
Lamictal ODT (lamotrigine oral disintegrating tablet) - brand only	
Lamictal CD (lamotrigine chewable dispersible) - brand only	
Lamictal XR (lamotrigine extended-release) – brand only	
Onfi (clobazam)	
Oxtellar XR (oxcarbazepine)	
Peganone (ethotoin)	
Potiga (ezogabine)	
Qudexy XR (topiramate)	
Sabril (vigabatrin)	
Spritam (levetiracetam)	
Sympazan (clobazam)	

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Trileptal (oxcarbazepine) – brand only	
Trokendi XR (topiramate)	
Topamax (topiramate) – brand only	
Topamax Sprinkles (topiramate) – brand only	
Topiramate ER – brand only	
Vimpat (lacosamide)	
Xcopri (cenobamate), Xcopri (cenobamate) PAK	
Zarontin (ethosuximide) – brand only	
Zonegran (zonisamide) – brand only	

***Note: prior authorization of benefits ONLY applies to the non-preferred agents.**

APPROVAL CRITERIA

I. Requests for Gabitril (tigabine) may be approved if the following criteria are met:

- A. Individual is 12 years of age or older; **AND**
- B. Individual has a diagnosis of partial seizures; **AND**
- C. Individual is using as adjunctive therapy; **AND**
- D. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product or has been receiving the requested non-preferred product for 90 days or more or the preferred agent is not FDA approved for the prescribed indication;

OR

II. Requests for Keppra XR and levetiracetam extended-release may be approved if the following criteria are met:

- A. The individual is 12 years of age or older and has a diagnosis of partial-onset seizures; **AND**
- B. If a non-preferred product is requested, individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product or has been receiving

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the non-preferred product for 90 days or more or the preferred agent is not FDA approved for the prescribed indication;

OR

III. Requests for Lamictal IR, Lamictal ODT, and Lamictal CD may be approved if the following criteria are met:

- A. The individual is 18 years of age or older and has a diagnosis of Bipolar disorder; **OR**
- B. The individual is 2 years of age or older, has a diagnosis of Lennox-Gastaut syndrome, and is using as adjunct therapy; **OR**
- C. The individual is 2 years of age or older, has a diagnosis of a seizure disorder, and is using as adjunct therapy; **OR**
- D. Individual is 16 years of age or older, has a diagnosis of partial seizures, and is converting to monotherapy from one of the following single antiepileptic drugs (AEDs) or has been receiving the medication for 90 days or more:
 - 1. Carbamazepine; **OR**
 - 2. Phenytoin; **OR**
 - 3. Phenobarbital; **OR**
 - 4. Primidone; **OR**
 - 5. Valproic Acid; **OR**
- E. Medication is being used to treat intractable infantile spasms (DrugPoints B, IIa); **OR**
- F. Medication is being used in treatment-resistant focal and generalized epilepsy (DrugPoints B, IIa);

AND

- G. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product or has been receiving the non-preferred product for 90 days or more or the preferred agent is not FDA approved for the prescribed indication;

OR

IV. Requests for brand Lamictal XR may be approved if the following criteria are met:

- A. Individual is 13 years of age or older and has a diagnosis of partial seizures; **OR**
- B. Individual is 13 years of age or older, has a diagnosis of primary generalized tonic-clonic (PGTC) seizures, and is using as adjunctive therapy;

AND

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- C. Individual has trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product or has been receiving Lamictal XR (brand) for 90 days or more or the preferred agent is not FDA approved for the prescribed;

Note: Lamotrigine agents have a black box warning for serious skin rashes. Serious, life-threatening rashes (including Stevens-Johnson syndrome) requiring hospitalization and discontinuation of treatment have occurred. The rate of serious rash is greater in pediatric individuals than in adults. The risk of rash may also be increased by co-administration with valproate (includes valproic acid and divalproex sodium), exceeding the recommended initial dose, or exceeding the recommended dose escalation. Nearly all cases of life-threatening rashes associated with lamotrigine have occurred within 2 to 8 weeks of treatment initiation. Benign rashes also occur; however, it is not possible to predict which rashes prove to be serious or life-threatening. Therapy should ordinarily be discontinued at the first sign of rash, unless the rash is clearly not drug related.

OR

- V. Requests for Banzel (rufinamide) may be approved when the following criteria are met:

- A. Individual is 1 year of age or older and is using for the adjunctive treatments of seizures associated with Lennox-Gastaut Syndrome (LGS);

AND

- B. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on Banzel (rufinamide) for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

OR

- VI. Requests for Fycompa (perampanel) may be approved when the following criteria are met:

- A. Individual is 12 years of age or older, is using as adjunctive therapy, and has a diagnosis of primary generalized tonic clonic seizures;

OR

- B. Individual is 4 years of age or older, and has a diagnosis of partial-onset seizures (with or without secondarily generalized seizures);

AND

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- C. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on Fycompa (perampanel) for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

Note: Fycompa (perampanel) has a block box warning regarding serious or life-threatening psychiatric and behavioral adverse reactions. These include aggression, hostility, irritability, anger and homicidal ideation. These can occur in individuals with and without prior psychiatric history or concomitant medication use. Individuals should be advised to contact a healthcare provider immediately if any of these reactions or changes in mood, behavior, or personality occur while taking Fycompa. Individuals should be closely monitored during titration periods and at higher doses. Fycompa should be reduced if symptoms occur and discontinued immediately if symptoms are severe or worsening.

OR

VII. Requests for Onfi (clobazam) may be approved if the following criteria are met:

- A. Individual has a diagnosis of seizures associated with Lennox-Gastaut Syndrome (LGS) and is using as adjunctive therapy; **AND**
- B. One of the following:
1. Individual is between 2 and 64 years of age; **OR**
 2. Individual is 65 years of age or older and the physician has indicated the requested medication is not causing adverse effects; **OR**
 3. Individual has a contraindication or has a clinical reason not to use safer alternatives;

AND

- C. The individual has a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of an inadequate response or intolerance to one preferred product unless the individual has been on Onfi (clobazam) for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

OR

VIII. Requests for Potiga (ezogabine) may be approved when the following criteria are met:

- A. Individual is 18 years of age or older, using for the adjunctive treatment of partial-onset seizures, and benefits outweigh the risk of retinal abnormalities and potential decline in visual acuity;

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AND

- B. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on Potiga (ezogabine) for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

Note: Potiga (ezogabine) has black box warnings for retinal abnormalities and potential vision loss. Potiga can cause retinal abnormalities with fundoscopic features similar to those seen in retinal pigment dystrophies, which are known to result in damage to the photoreceptors and vision loss. Some individuals with retinal abnormalities have been found to have abnormal visual acuity. It is not possible to determine whether Potiga caused this decreased visual acuity, because baseline assessments are not available for these individuals. Potiga has an associated REMS program which is considered by the FDA to be necessary for safe and effective use. More information is available from the product Web site at <http://www.potiga.com> or by contacting GlaxoSmithKline by calling 1-888-825-5249.

OR

IX. Requests for Sabril (vigabatrin) may be approved when the following criteria are met:

- A. Individual is between the ages of 1 month and 2 years, is using for infantile spasms, and benefits outweigh the risk of vision loss; **OR**
- B. Individual is 2 years of age and older, using as adjunctive therapy for refractory complex partial seizures, and the benefits outweigh the risk of vision loss;

AND

- C. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on Sabril (vigabatrin) for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

Note: Sabril (vigabatrin) has a black box warning for vision loss. Sabril causes permanent bilateral concentric visual field constriction. Because assessing vision loss is difficult in infants and children, the frequency and extent of vision loss is poorly characterized in these individuals. For this reason, the risk is primarily based on the adult experience. Because of the risk of permanent vision loss, Sabril is available only through a special restricted program under a risk evaluation and mitigation strategy (REMS) called the SHARE program. Further information is available at <http://www.sabril.net> or by calling 1-888-457-4273.

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OR

X. Requests for Vimpat (lacosamide) oral solution or tablets may be approved if the following criteria are met:

- A. Individual is 4 years of age or older; **AND**
- B. Individual has a diagnosis of partial-onset seizures; **AND**
- C. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on Vimpat (lacosamide) for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

OR

XI. Requests for Vimpat (lacosamide) injection may be approved if the following criteria are met:

- A. Individual is 17 years of age or older; **AND**
- B. Individual has a diagnosis of partial-onset seizures; **AND**
- C. Individual is unable to take oral medications (e.g. unable to swallow tablets); **AND**
- D. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on Vimpat (lacosamide) for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

Requests for Vimpat (all dose forms) may **not** be approved for the following:

- A. Individual has severe hepatic impairment.

OR

XII. Requests for Trokendi XR, Qudexy XR may be approved if the following criteria are met:

- A. Individual has a diagnosis of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome (LGS);
- OR**
- B. Individual is 12 years of age or older and using for migraine headache prophylaxis;

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AND

- C. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on the requested non-preferred product for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

OR

- XIII. Requests for Topamax (brand only), Topamax Sprinkles (brand only) and Topiramate ER (brand only) may be approved if the following criteria are met:

- A. Individual has a diagnosis of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome (LGS); **OR**
 B. Individual is 12 years of age or older and using for migraine headache prophylaxis;
OR
 C. Individual is using for the management of alcohol dependence (AHFS);

AND

- D. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on the requested non-preferred product for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

OR

- XIV. Requests for Spritam (levetiracetam) may be approved when the following criteria are met:

- A. Individual is 4 years of age and older; **AND**
 B. Individual weighs more than 20 kg; **AND**
 C. Individual is using to treat partial onset seizures;

OR

- D. Individual is 12 years of age or older; **AND**
 E. Individual is using to treat juvenile myoclonic epilepsy;

OR

- F. Individual is 6 years of age or older; **AND**

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- G. Individual weighs more than 20 kg; **AND**
- H. Individual is using to treat primary generalized tonic-clonic seizures; **AND**
- I. Individual has idiopathic generalized epilepsy;

AND

- J. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on Spritam (levetiracetam) for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

OR

- XV. Requests for Aptiom (eslicarbazepine) may be approved if the following criteria are met:

- A. Individual is 4 years of age or older; **AND**
- B. Individual is using to treat partial-onset seizures; **AND**
- C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on Aptiom (eslicarbazepine) for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

OR

- XVI. Requests for Oxtellar XR (oxcarbazepine extended-release) may be approved if the following criteria are met:

- A. Individual is 6 years of age or older; **AND**
- B. Individual is using to treat partial-onset seizures; **AND**
- C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on Oxtellar XR (oxcarbazepine extended-release) for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

OR

- XVII. Requests for Dilantin 30mg (brand only), Felbatol (brand only), Keppra IR (brand only), Trileptal (brand only), Peganon, Zonegran (brand only), Zarontin (brand only), and Celontin, may be approved if the following criteria are met:

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- A. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on the requested non-preferred product for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

OR

- XVIII. Requests for Briviact (brivaracetam) injection may be approved when the following criteria are met:

- A. Individual is 16 years of age or older; **AND**
 B. Individual has been diagnosed with partial-onset seizures; **AND**
 C. Individual is using as monotherapy or adjunctive therapy; **AND**
 D. Individual is unable to take oral medications (e.g. unable to swallow tablets or oral solution); **AND**
 E. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on the requested non-preferred product for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

OR

- XIX. Requests for Briviact (brivaracetam) oral tablets and solution may be approved when the following criteria are met:

- A. Individual is 4 years of age or older; **AND**
 B. Individual has been diagnosed with partial-onset seizures; **AND**
 C. Individual is using as monotherapy or adjunctive therapy; **AND**
 D. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on the requested non-preferred product for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication;

OR

- XX. Requests for Diacomit (stiripentol) may be approved if the following are met:

- A. Individual is 2 years of age or older; **AND**
 B. Individual is diagnosed with seizures associated with Dravet Syndrome; **AND**
 C. Individual is taking in combination with clobazam; **AND**
 D. Individual has responded inadequately to previous antiepileptic drugs;

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OR

- XXI. Requests for Sympazan (clobazam) may be approved if the following criteria are met:
- A. Individual is 2 years of age or older; **AND**
 - B. Individual has a diagnosis of Lennox-Gastaut Syndrome (LGS); **AND**
 - C. Individual is using as adjunctive treatment for seizures associated with LGS; **AND**
 - D. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on the requested non-preferred product for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication.

Note: Sympazan (clobazam) carries a black box warning for concomitant use with opioids as it may result in profound sedation, respiratory depression, coma, and death.

OR

- XXII. Requests for Elepsia XR (levetiracetam extended-release) may be approved if the following criteria are met:
- A. Individual is 12 years of age or older; **AND**
 - B. Individual is using as adjunctive treatment for the treatment of partial-onset seizures; **AND**
 - C. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on the requested non-preferred product for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication.

Requests for Elepsia XR may **not** be approved for the following:

- A. Individual with moderate or severe renal impairment.

OR

- XXIII. Requests for Xcopri (cenobamate), Xcopri (cenobamate) PAK may be approved if the following criteria are met:
- A. Individual is 18 years of age or older; **AND**
 - B. Individual has a diagnosis of partial-onset seizures; **AND**
 - C. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one preferred product unless the individual has been on the requested non-preferred

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product for greater than or equal to 90 days or the preferred agent is not FDA approved for the prescribed indication.

Requests for Xcopri (cenobamate), Xcopri (cenobamate) PAK may not be approved for the following:

- A. Individual has severe hepatic impairment defined as Child-Pugh Class C; **OR**
- B. Individual has familial short QT syndrome.

OR

XXIV. Requests for Fintepla (fenfluramine) may be approved if the following criteria are met:

- A. Individual is 2 years of age or older; **AND**
- B. Individual has a diagnosis of seizures associated with Dravet Syndrome.

Requests for Fintepla (fenfluramine) may not be approved for the following:

- A. Individual is using for weight loss/reduction. **OR**
- B. Individual is using within 14 days of administration of monoamine oxidase inhibitors (MAOIs)

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 9, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

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