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**Market Applicability**

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*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:

A. The individual is 12 years of age or older, has a diagnosis of partial-onset seizures, and is using as adjunctive therapy; 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, Ila); OR
F. Medication is being used in treatment-resistant focal and generalized epilepsy (DrugPoints B, Ila);

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 black 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 had 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:

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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;

**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 10 years of age or 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
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| Applicable | X | X | NA | NA | X | X | NA | X | X | X | NA | NA | NA |   |

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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**

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 (levitiracetam) 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 Dilantin 30mg (brand only), Felbatol (brand only), Keppra IR (brand only), Trileptal (brand only), Peganon, Zonegran (brand only), Zarontin (brand only), Celontin, and Oxtellar XR, may be approved if the following criteria are met:

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;

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OR

XVII. 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); **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

XVIII. 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

XIX. 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;

OR

XX. 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;

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