

Prior Authorization Criteria  
Anti- Epileptic Drugs

1. Is the diagnosis for an OHP funded condition of epilepsy?
  - a. Yes – Go to question 2
  - b. No – Deny Cat 1 – for non-funded condition  
Deny Cat 3 -- for non FDA approved use of medication
  
2. Is the request for **eslicarbazepine (Aptiom) brivaracetam (Briviact) or lacosamide (Vimpat)**?
  - a. Yes- Go to question 3
  - b. No- Go to question 5 **\*\*Note- Lyrica (pregabalin) has separate criteria \*\***
  
3. Does the member have a documented diagnosis of focal or partial onset seizures by a neurologist?
  - a. Yes – Go to question 4
  - b. No – Deny Cat 3 – *These medications are only FDA approved for use in the treatment of partial onset seizures.*
  
4. Has the member had an inadequate response or intolerance to at least two other medications indicated for focal / partial onset seizures after using regularly (80% of the time or more) for at least 6 months?
  - Tiagabine (Gabitril)
  - Lamotrigine (Lamictal)
  - Pregabalin (Lyrica)
  - Levetiracetam (Keppra)
  - Gabapentin (Neurontin)
  - Carbamazepine (Tegretol)
  - Topiramate (Topamax)
  - Oxcarbazepine (Trileptal)
  - Zonisamide (Zonegran)
  - a. Yes – Go to question 20
  - b. No- Deny Cat 5 – *Member has not has inadequate response or intolerance to preferred medications.*
  
5. Is the request for **Perampanel (Fycompa)**?
  - a. Yes – Go to question 6
  - b. No – Go to question 8
  
6. Does the member have a documented diagnosis by a neurologist of focal /partial-onset seizures OR a diagnosis of tonic-clonic seizures where this will be adjunct therapy in a member over 12?
  - a. Yes- Go to question 7
  - b. No – Deny Cat 3- *This medication is being prescribed outside of FDA approved use.*

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7. Has the member had an inadequate response to at least 2 alternative, preferred agents after an adequate trial with demonstrated compliance? (seizures continue despite reaching therapeutic dose of medication)
    - a. Yes – Go to question 20
    - b. No- Deny Cat 5 – *Member has not had an adequate trial of preferred first line agents.*
  8. Is the request for an extended release form of **levetiracetam, oxcarbazepine or topiramate**?
    - a. Yes – Go to question 9
    - b. No – Go to question 10
  9. Is there documentation that treatment with the immediate release form of the medication is not sufficient for seizure control?
    - a. Yes – Go to question 20
    - b. No – Deny Cat 5 or Cat 15- *Member must demonstrate that the preferred immediate release form of the drug is inadequate for seizure control.*
  10. Is the request for **rufinamide (Banzel)** or **clobazam (Onfi)**?
    - a. Yes – Go to question 11
    - b. No – Go to question 13
  11. Does the member have a diagnosis of Lennox-Gastaut syndrome (LGS) made by a neurologist with the intention to use medication as an adjunct therapy?
    - a. Yes – Go to question 12
    - b. No – Deny Cat 3 – *Medication is being prescribed outside of FDA approved use.*
  12. Has the member had an inadequate response to at least 2 preferred, alternative agents
    - Valproic acid derivative (Depakene, Depakote)
    - Topiramate (Topamax)
    - Lamotrigine (Lamictal)
    - Felbamate (Felbatol) **\*\*only if benefit justifies risk of using this medication \*\***
- \*\*Do not make use of this drug a condition of approval, but if member has used this, it will help meet criteria.**
- a. Yes – Go to question 20
  - b. No - Deny Cat 5 – *Member has not had an adequate trial of preferred first line agents.*
13. Is the request for **vigabatrin (Sabril)**?
  - a. Yes – Go to question 14
  - b. No – Go to question 17
14. Is the request for adjunct therapy in a member who is at least 10 years of age and with focal/complex partial seizures that is refractory to treatment with at least 3 other AEDs?
  - a. Yes – Go to question 16
  - b. No – Go to question 15

15. Is the member between the ages of 1 month to 2 years of age with infantile spasms diagnosed by a neurologist in whom the potential benefits outweigh the risk of vision loss AND is dosing within FDA approved dosing for weight and age?
- Yes – May approve for 1 month trial
  - No – Deny Cat 3 – *Medication is being prescribed outside FDA approved use.*
16. Has member had a baseline ophthalmologic exam, including visual field evaluation and dilated indirect ophthalmoscopy of the retina?
- Yes – May approve for a maximum of 3 months- **\*\*ongoing monitoring for vision loss must be done every 3 months\*\***
  - No – Deny- Cat 5 Not medically appropriate - *Vigabatrin causes permanent bilateral concentric visual field constriction in >30% of patients ranging in severity from mild to severe and can result in disability. In some cases, vigabatrin can damage the central retina and may decrease visual acuity. Assessment of member prior to treatment is essential for evaluation of visual acuity during treatment.*
17. Is the request for **Felbamate (Felbatrol)**?
- Yes – Go to question 18
  - No- Forward request to pharmacist or medical director to evaluate appropriateness of requested medication use in a seizure disorder.
18. Is the medication being used for partial onset/ focal seizures in a member 14 years or older OR for Lennox Gastaut syndrome in a member aged 2 to 14 years?
- Yes – Go to question 19
  - No – Deny Cat 3 – *Medication is being used outside of FDA approved prescribing.*
19. Has the member had an inadequate response to at least 3 other AEDs with at least 80% compliance over at least 6 months?  
AND  
Does the member have no signs of liver disease and normal liver function tests?  
AND  
Are the provider and member aware of the significant risks of aplastic anemia and hepatic failure associated with the use of this medication and attest that the epilepsy is severe enough to warrant the risk?
- Yes – May approve for 6 months
  - No – Deny Cat 5 – not medically appropriate- *The use of felbamate is associated with a marked increase in the incidence of aplastic anemia and hepatic failure. Accordingly, felbamate should only be used in patients whose refractory epilepsy is so severe that the risk of adverse outcome is deemed acceptable in light of the benefits conferred by its use*

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20. Does the use of the medication match the FDA approved indication and age as noted in the table below?

- a. Yes- May approve for up to 12 months as medically appropriate
- b. No – Deny Cat 3- *Medication is being used outside of FDA approved prescribing.*

<b>Medication</b>	<b>FDA approved indication for use</b>
Brivaracetam (Briviact)	Partial onset/ Focal seizures in ages 16 and up
Carbamazepine (Tegretol, Eptol)	Partial onset/ Focal, tonic clonic or mixed
Clobazam (Onfi)	Adjunct only in Lennox Gastaut - ages 2 +
Eslicarbazepine (Aptiom)	Partial onset / Focal – ages 4 years and up
Ethosuximide (Zarontin)	Absence seizures in ages 2 years and up
Felbamate (Felbatol)- 2 <sup>nd</sup> line only	Partial onset/ Focal & Lennox Gastaut ages 2 +
Gabapentin (Neurontin)	Partial onset/ Focal in ages 3 and up
Lacosamide (Vimpat)	Partial onset/ Focal in ages 4 and up
Lamotrigine – (Lamictal) DMAP agent	Partial onset/ tonic clonic ages 13 and up
Levetiracetam (Keppra)	Myoclonic-age 12 + Partial onset/ focal 1 month and up or Tonic clonic in ages 6 and up
Oxcarbazepine (Trileptal)	Partial onset/ Focal in ages 2 and up
Perampanel (Fycompa)	Adjunct only in partial onset/ Focal or tonic clonic ages 12 years and up.
Phenobarbital	Partial/focal, tonic clonic and status epilepticus
Phenytoin (Dilantin)	Complex partial/focal and tonic clonic
Pregabalin (Lyrica)	Adjunct only for partial onset/ focal in adults
Primidone (Mysoline)	Partial onset/focal, tonic clonic, psychomotor
Rufinamide (Banzel)	Adjunct only in Lennox Gastaut in ages 1 year +
Tiagabine (Gabitril)	Adjunct only in partial onset/ focal in ages 12 +
Topiramate (Topamax)	Infantile spasms – Adjunct only in partial/focal or tonic clonic in ages 2 and up
Valproate (Depakote) – DMAP agent	Broad spectrum
Vigabatrin (Sabril) – agent of last resort- used in refractory cases only due to risks	Infantile spasms in 1 month to 2 years of age Adjunct only in refractory complex partial seizures in ages 10 years and up
Zonisamide (Zonergan)	Adjunct only for Partial/ Focal seizures in ages 16 years and up

**Renewal Criteria-**

1. Has member demonstrated 80% or better compliance with therapy (if prescribed medication is adjunct therapy, must be compliant with other AEDs as well) and has member achieved adequate seizure control?
  - a. Yes- Go to question 2
  - b. No – Forward to pharmacist or medical director for evaluation of medical appropriateness of continued therapy. Consider amended approval for monitoring of compliance.
  
2. Has the member had appropriate monitoring as indicated below to ensure continued use of the AED is safe?

Brivaracetam (Briviact)	CBC, hepatic and renal function
Clobazam (Onfi)	Behavioral changes, respiratory depression
Eslicarbazepine (Aptiom)	LFTs, NA+ and CL- levels
Felbamate (Felbatol)	LFTs, CBC, behavioral changes
Lacosamide (Vimpat)	Baseline ECG - Monitor CV function
Perampanel (Fycompa)	Suicidality, weight
Rufinamide (Banzel)	Rash, serum levels of other AEDs
Vigabatrin (Sabril)	Ophthalmologic examination by an ophthalmic professional with the ability to perform dilated indirect ophthalmoscopy of the retina, assessment should include visual acuity and visual field every 3 months

- a. Yes- May approve for up to 12 months \*Vigabatrin approved for a maximum of 3 months\*
- b. No- Forward to pharmacist or MD for evaluation of appropriateness of continued therapy.