OVERVIEW

This coverage policy has been developed from HPSJ Coverage Criteria using the best practices guidelines as developed by the American Academy of Neurology and American Epilepsy Society.

### Available Agents for Epilepsy (Current as of 8/2018)

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Generic Name (Brand Name)</th>
<th>Available Strengths</th>
<th>Formulary Limits</th>
<th>Avg Cost/Rx</th>
<th>Notes/Restriction Language</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Barbiturates</strong></td>
<td>Primidone (Mysoline)</td>
<td>50mg, 250mg</td>
<td>--</td>
<td>$13.96</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>Phenobarbital (Luminal)</td>
<td>15mg, 16.2mg, 30mg, 32.4mg, 60mg, 64.8mg, 97.2mg, 100mg, 22mg/5mL Elixir</td>
<td>--</td>
<td>$35.48</td>
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<tr>
<td><strong>Succinimides</strong></td>
<td>Methsuximide (Celontin)</td>
<td>300mg</td>
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</tr>
<tr>
<td></td>
<td>Ethosuximide (Zarontin)</td>
<td>250mg, 250mg/5mL Soln</td>
<td>PL</td>
<td>$136.93</td>
<td>Restricted to Neurologists</td>
</tr>
<tr>
<td><strong>Benzodiazepines</strong></td>
<td>Clonazepam (Onfi)</td>
<td>10mg, 20mg</td>
<td>PL</td>
<td>$1,051.40</td>
<td>Restricted to Neurologists</td>
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<tr>
<td></td>
<td>Carbamazepine (Tegretol)</td>
<td>200mg</td>
<td>--</td>
<td>$77.78</td>
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<tr>
<td></td>
<td>Oxcarbazepine (Trileptal)</td>
<td>150mg, 300mg, 600mg, 300mg/5mL Susp.</td>
<td>--</td>
<td>$70.10</td>
<td>--</td>
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<tr>
<td><strong>Miscellaneous Anticonvulsants</strong></td>
<td>Acetazolamide (Diamox)</td>
<td>125mg, 250mg, 500mg ER.</td>
<td>--</td>
<td>$132.18</td>
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<tr>
<td></td>
<td>Lacosamide (Vimpat)</td>
<td>50mg, 10mg/mL soln, 200mg/20mL IV soln.</td>
<td>PL</td>
<td>$705.73</td>
<td>Restricted to Neurologists</td>
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<tr>
<td></td>
<td>Divalproex Sodium (Depakote)</td>
<td>125mg DR, 250mg DR, 250mg ER, 500mg ER, 125mg sprinkle caps.</td>
<td>--</td>
<td>$26.46</td>
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<tr>
<td></td>
<td>Valproic Acid (Depakene)</td>
<td>250mg, 250mg/5mL Soln</td>
<td>--</td>
<td>$104.58</td>
<td>--</td>
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<tr>
<td></td>
<td>Topiramate (Topamax)</td>
<td>15mg Sprinkle Cap, 25mg Sprinkle Cap, 25mg, 50mg, 100mg, 200mg.</td>
<td>Sprinkle: PA IR: No Limit</td>
<td>$393.41</td>
<td>Sprinkle Capsules are restricted to members with a documented inability to swallow.</td>
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<tr>
<td></td>
<td>Felbamate (Felbatol)</td>
<td>400mg, 600mg</td>
<td>PL</td>
<td>$342.66</td>
<td>Restricted to Neurologists</td>
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<td></td>
<td>Gabapentin (Neurontin)</td>
<td>200mg, 300mg, 600mg, 800mg, 250mg/5mL soln.</td>
<td>--</td>
<td>$22.30</td>
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<tr>
<td></td>
<td>Phenytoin (Dilantin)</td>
<td>50mg, 100mg 125mg/5mL.</td>
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<td>$31.15</td>
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<td>Pregabalin (Lyrica)</td>
<td>25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg.</td>
<td>PA</td>
<td>$1475.08</td>
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<td>Levetiracetam (Keppra)</td>
<td>250mg, 500mg, 750mg, 1000mg, 500mg ER, 750mg ER, 500mg/5mL Soln, 500mg/5mL IV Soln.</td>
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<td>IR: $44.48 ER: $100.47</td>
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<td>Lamotrigine (Lamictal)</td>
<td>5mg Chew Tab, 25mg Chew Tab, 25mg, 100mg, 150mg, 200mg.</td>
<td>--</td>
<td>IR: $12.68 ODT: $530.06 ER: $755.53</td>
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<td>Zonisamide (Zonegran)</td>
<td>25mg, 50mg, 100mg</td>
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<td>$47.14</td>
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</table>

PL = Restricted to Neurologist Providers, PA = PA required. ST = Step Therapy, IR = Immediate Release, ER = Extended Release, ODT = Orally Dissolving Tablet
EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

CCS Coverage Requirements for Members aged 0-20:
California Childrens’ Services covers HPSJ members with refractory epilepsy who are concurrently on two or more epileptic medications (not including rescue medication, such as Diastat, or other benzodiazepines).
For coverage through the CCS program, members must be seen by a CCS Panel Provider. Submit the member’s most recent 6 months of records to the CCS Program for review. Fax numbers are listed below.
San Joaquin County: (209)953-3632
Stanislaus County: (209)558-7862

Barbiturates
Primiridone (Mysoline), Phenobarbital (Luminal)
- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A

Succinimides
Methsuximide (Celontin)
- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A

Ethosuximide (Zarontin)
- Coverage Criteria: None
- Limits: Restricted to Neurologists
- Required Information for Approval: PA must be submitted by a neurologist.

Benzodiazepines
Clobazam (Onfi)
- Coverage Criteria: None
- Limits: Restricted to Neurologists
- Required Information for Approval: PA must be submitted by a neurologist.

Miscellaneous Anticonvulsants
Acetazolamide (Diamox)
- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A

Lacosamide (Vimpat)
- Coverage Criteria: None
- Limits: Restricted to Neurologists
- Required Information for Approval: PA must be submitted by a neurologist.

Carbamazepine (Tegretol), Oxcarbazepine (Trileptal)
- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A
Neurologic Disorders – Epilepsy

Divalproex Sodium (Depakote), Valproic Acid (Depakene)
- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A

Topiramate (Topamax)
- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A

Topiramate (Topamax) Sprinkle Capsules (15mg and 25mg)
- Coverage Criteria: Restricted to members with a documented inability to swallow.
- Limits: None
- Required Information for Approval: Chart notes documenting an inability to swallow. Documentation of the member’s barium swallow or speech-language pathology notes preferred.

Feldaminate (Felbatol)
- Coverage Criteria: None
- Limits: Restricted to Neurologists
- Required Information for Approval: PA must be submitted by a Neurologist.

Gabapentin (Neurontin)
- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A

Pregabalin (Lyrica)
- Coverage Criteria: Lyrica is step therapy to treatment failure of a tricyclic antidepressant and gabapentin at dose larger than 1800mg/day for at least 8 weeks.
- Limits: None
- Required Information for Approval: Chart notes and pharmacy fill history documenting treatment failure of dose optimized Gabapentin, and at least one tricyclic antidepressant.

Phenytoin (Dilantin)
- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A

Vigabatrin (Sabril)
- Coverage Criteria: PA required. Sabril is restricted for use in Infantile Spasms or Complex Partial Seizures. For Complex Partial Seizures, Sabril is reserved as adjunct therapy for patients 10 years and older with documented dose-optimized treatment failure of three formulary anti-epileptic agents for complex partial seizures including at least one of the following: carbamazepine, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, topiramate, valproic acid, divalproex sodium, zonisamide or tiagabine. Must be prescribed by a neurologist.
- Limits:
  - Infantile Spasms:
    - Less than 2 years of age
    - Limited to 150mg/kg/day
Complex Partial Seizures:
- For patients age 17 and older: Limit 3g per day
- For patients age 10-16: Limit 2g per day

**Required Information for Approval:**
- Documentation of visual acuity exam prior to initiation regardless of indication being requested.
- Prescribed by neurologist.
- For Complex Partial Seizure only:
  - Prescription fill history of previous agents used/continued
  - Documentation of planned adjunct therapy.

**Approval Time Frame**
- Initial approval is for 4 weeks.
- Continuation of Therapy: Updated notes describing patient clinical course (clinical improvement of symptoms) will be required for renewal.

**Zonisamide (Zonegran)**
- **Coverage Criteria:** None
- **Limits:** None
- **Required Information for Approval:** N/A

**REFERENCES**

1. FDA news release. Sabril Approved by FDA to Treat Spasms in Infants and Epileptic Seizures. 
   [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm179855.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm179855.htm)
   Sabril (vigabatrin) [prescribing information]. Cincinnati, OH: Patheon; June 2016.
2. French JA, et al. A double-blind, placebo-controlled study of vigabatrin three g/day in patients 
   201 Oct;57(8):1416-1421.
   Neuropsychiatr Dis Treat 2010; 6: 731–740
   Neuropsychiatr Dis Treat. 2009; 5: 505–515
7. Appleton, Re, et al. Randomised, placebo-controlled study of vigabatrin as first-line treatment of 
8. Lux, Andrew. Et al. The united kingdom infantile spasms study comparing vigabatrin with 
   prednisolone or tetracosactide at 14 days: a multicentre, randomised controlled trial. The Lancet. 
   2004; 364, 1773–1778.
9. Sergott, Andrew, et al. Evidence-based review of recommendations for visual function testing in 
10. Ovation Pharmaceuticals. Sabril® (vigabatrin) Tablet and Powder for Oral Solution. For Adjunctive 
    Treatment of Refractory Complex Partial Seizures in Adults (NDA 20-427) For Monotherapy 

**REVIEW & EDIT HISTORY**

<table>
<thead>
<tr>
<th>Document Changes</th>
<th>Reference</th>
<th>Date</th>
<th>P&amp;T Chairman</th>
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<td>Update to Policy</td>
<td>Banzel Monograph.docx</td>
<td>9/24/2009</td>
<td>Allen Shek PharmD BCPS</td>
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<td>2/16/2016</td>
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