

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Epilepsy	P&T DATE:	9/11/2018
THERAPEUTIC CLASS:	Neurologic Disorders	REVIEW HISTORY:	2/17, 2/16
LOB AFFECTED:	Medi-Cal	(MONTH/YEAR)	

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

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)

Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Formulary Limits	Avg Cost/Rx	Notes/Restriction Language
Barbiturates	Primidone (Mysoline)	50mg, 250mg	--	\$13.96	--
	Phenobarbital (Luminal)	15mg, 16.2mg, 30mg, 32.4mg, 60mg, 64.8mg, 97.2mg, 100mg, 20mg/5mL Elixir	--	\$35.48	--
Succinimides	Methsuximide (Celontin)	300mg	--	--	--
	Ethosuximide (Zarontin)	250mg, 250mg/5mL Soln	PL	\$136.93	Restricted to Neurologists
Benzodiazepines	Clobazam (Onfi)	10mg, 20mg	PL	\$1,051.40	Restricted to Neurologists
	Clonazepam (Klonopin)	ODT: 0.125mg, 0.25mg, 0.5mg, 1mg, 2mg Tablet: 0.5mg, 1mg, 2mg	--	\$4.41	--
Miscellaneous Anticonvulsants	Acetazolamide (Diamox)	125mg, 250mg, 500mg ER.	--	\$132.18	--
	Lacosamide (Vimpat)	50mg, 10mg/mL soln, 200mg/20mL IV soln.	PL	\$705.73	Restricted to Neurologists
	Carbamazepine (Tegretol)	200mg	--	\$77.78	--
	Oxcarbazepine (Trileptal)	150mg, 300mg, 600mg, 300mg/5mL Susp.	--	\$70.10	--
	Divalproex Sodium (Depakote)	125mg DR, 250mg DR, 250mg ER, 500mg ER, 125mg sprinkle caps.	--	\$26.46	--
	Valproic Acid (Depakene)	250mg, 250mg/5mL Soln	--	\$104.58	--
	Topiramate (Topamax)	15mg Sprinkle Cap, 25mg Sprinkle Cap, 25mg, 50mg, 100mg, 200mg,	Sprinkle Cap: PA IR: No Limit	IR: \$22.69 Sprinkle: \$78.00	Sprinkle Capsules are restricted to members with a documented inability to swallow.
	Felbamate (Felbatol)	400mg, 600mg	PL	\$342.66	Restricted to Neurologists
	Gabapentin (Neurontin)	200mg, 300mg, 600mg, 800mg, 250mg/5mL soln.	--	\$22.30	--
	Phenytoin (Dilantin)	50mg, 100mg 125mg/5mL	--	\$31.15	--
	Pregabalin (Lyrica)	25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg.	PA	\$393.41	Step therapy to treatment failure of a tricyclic antidepressant and gabapentin at dose larger than 1800mg/day for at least 8 weeks.
	Tiagabine (Gabitril)	2mg, 4mg, 12mg, 16mg	PL	\$1475.08	Restricted to Neurologists
	Levetiracetam (Keppra)	250mg, 500mg, 750mg, 1000mg, 500mg ER, 750mg ER, 500mg/5mL Soln, 500mg/5mL IV Soln.	--	IR: \$44.48 ER: \$100.47	--
	Lamotrigine (Lamictal)	5mg Chew Tab, 25mg Chew Tab, 25mg, 100mg, 150mg, 200mg.	--	IR: \$12.68 ODT: \$530.06 ER: \$575.53	--
	Zonisamide (Zonegran)	25mg, 50mg, 100mg	--	\$47.14	--

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 Children's 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 Paneled 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

Primidone (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.

Clonazepam (Klonopin)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A

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

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.

Felbamate (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

Phenytoin (Dilantin)

- 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.

Tiagabine (Gabitril)

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

Lamotrigine (Lamictal)

- 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/tried.
 - 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>
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 with uncontrolled complex partial seizures. Vigabatrin Protocol 024 Investigative Cohort. *Neurology* 1996 Jan;46(1):54-61.
3. Dean C, et al. Dose-Response Study of Vigabatrin as add-on therapy in patients with uncontrolled complex partial seizures. *Epilepsia* 1999 Jan;40(1):74-82
4. Elterman RD, et al. Randomized trial of vigabatrin in patients with infantile spasms. *Neurology* 201 Oct;57(8):1416-1421.
5. Jason TL, et al. Clinical profile of vigabatrin as monotherapy for treatment of infantile spasms. *Neuropsychiatr Dis Treat* 2010; 6: 731–740
6. Waterhouse EJ, et al. Treatment of refractory complex partial seizures: role of vigabatrin. *Neuropsychiatr Dis Treat.* 2009; 5: 505–515
7. Appleton, Re, et al. Randomised, placebo-controlled study of vigabatrin as first-line treatment of infantile spasms. *Epilepsia.* 1999; 40.11: 1627-1633.
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 patients treated with vigabatrin. *Neuro-Ophthalmology.* 2010, 34(1), 20-35
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 Treatment of Infantile Spasms (NDA 22-006). Advisory Committee Briefing Document.

REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Potential Generics 2007 and 2008.doc	5/10/2007	Allen Shek PharmD BCPS
Update to Policy	Banzel Monograph.docx	9/24/2009	Allen Shek PharmD BCPS
Update to Policy	Formulary realignment 2-2010.xlsx	3/5/2010	Allen Shek PharmD BCPS
Update to Policy	Formulary realignment 5-11.xlsx	5/16/2011	Allen Shek PharmD BCPS
Update to Policy	Formulary realignment 09-17-2013	9/16/2013	Allen Shek PharmD BCPS
Update to Policy	HPSJ Coverage Policy - Neurologic Disorders - Epilepsy 2016-02.docx	2/16/2016	Johnathan Yeh PharmD
Update to Policy	HPSJ Coverage Policy - Neurologic Disorders - Epilepsy 2017-02.docx	2/2017	Johnathan Yeh PharmD
Update to Policy	HPSJ Coverage Policy - Neurologic Disorders - Epilepsy 2018-09.docx	9/2018	Johnathan Yeh, PharmD