Anticonvulsants
Utilization Management Criteria

Therapeutic Class:	Anticonvulsants
Non-Preferred Agents:	Dilantin capsule, infatab, suspension (oral); Divalproex sprinkle (oral); Depakote (oral); Depakote ER (oral); Phenytek (oral); Phenytoin EXT capsule (oral); Celontin (oral); Methsuximide (oral); Zarontin capsule, syrup (oral); Carbamazepine suspension (oral); Tegretol 200 mg tablet; Klonopin tablet (oral); Carbamazepine XR (oral); Carbamazepine ER (oral); Onfi tablet, suspension (oral); Vigabatrin powder pack, tablet (oral); Lamictal tablet, dispersible tablet, ODT, dose pack (oral); Lamictal XR dose pack, tablet (oral); Lamotrigine tablet dose pack, ODT; Lamotrigine XR tablet (oral); Felbatol suspension, tablet (oral); Equetro (oral); Felbamate suspension, tablet (oral); Topamax tablet, sprinkle (oral); Trileptal tablets (oral); Topiramate solution (oral); Oxcarbazepine suspension (oral); Keppra tablets, solution (oral); Keppra XR (oral); Levetiracetam ER (oral); Clonazepam ODT (oral); Rufinamide tablet, suspension (oral); Banzel tablet, suspension (oral); Diacomit capsule, powder pack (oral); Vimpat tablet, solution (oral); Eslicarbazepine tablet (oral); Aptiom (oral); Lacosamide solution unit dose (oral); Fycompa tablet, suspension (oral); Perampanel tablet (oral); Oxtellar XR (oral);Oxcarbazepine ER tablet (oral); Trokendi (topiramate) XR capsule (oral); Qudexy (topiramate) XR capsule (oral); Topiramate ER sprinkle (oral); Vimpat tablet dose pack (oral); Elepsia XR tablet (oral); Briviact tablet, solution (oral); Spritam (oral); Levetiracetam (Spritam) (AG) (oral); Sympazan (oral); Xcopri tablet, titration pak (oral); Fintepla solution (oral); Eprontia solution (oral); Zonisade suspension (oral); Motpoly XR (oral); Libervant film (buccal); Vigafyde solution (oral); Vigadrone powder pack, tablet (oral); Vigpoder powder pack (oral); Ztalmy (ganaxolone), Subvenite suspension, start kit (oral); Sezaby (IV)

Preferred Agents:	Carbamazepine tab chew, IR (oral); Carbatrol ER capsule (oral); Clobazam suspension (oral), tablet; Clonazepam IR tablet (not ODT or ER) (oral); Depakote Sprinkle capsule (not tablet) (oral); Diazepam rectal gel system (rectal); Divalproex Sod DR Tablet (not sprinkle) (oral); Divalproex Sod ER tablet (oral); Epidiolex solution (oral); Epitol tablet (oral); Ethosuximide capsule, solution (oral); Lacosamide tablet, solution (not cup); Lamotrigine chew dispers tab (not ODT) (oral); Lamotrigine tablet (not ER) (oral); Levetiracetam solution, IR tablet (not ER) (oral); Nayzilam nasal spray (nasal); Oxcarbazepine tablet (oral); Phenobarbital elixir, solution, tablet (oral); Phenytoin chew tablet, suspension (oral); Phenytoin sod ext 100 mg caps (not 200 mg, 300 mg) (oral); Primidone tablet (oral); Roweepra tablet (oral); Sabril 500 mg powder pack (oral); Sabril 500 mg tablet (oral); Subvenite tablet (not START KIT) (oral); Tegretol 100 mg/ 5 mL suspension (oral); Tegretol XR tablet (oral); Tiagabine tablet (oral); Topiramate sprinkle capsule, tablet (oral); Trileptal 300 mg/ 5 mL suspension (oral); Valproic acid capsule, solution (oral); Valtoco nasal spray (nasal); Zonisamide capsule (oral)
Implementation Date:	1/1/2026
Prepared For:	CT Medicaid
PDL Status:	Nonpreferred Agents
Background:	A number of anticonvulsant drugs are available for the treatment of various seizure disorders; these drugs are diverse in terms of their mechanisms of action, indicated populations, and warnings. Barbiturates (phenobarbital and primidone) and phenytoin are older agents used for the treatment of partial onset and tonic-clonic seizures. Partial (focal) seizures originate in one specific area of the brain and can cause symptoms like muscle twitching, unusual sensations, or confusion. The succinimides (ethosuximide and methsuximide) are used for absence seizures, a type of seizure that causes brief lapses in consciousness, often appearing as staring spells. Oral benzodiazepines are indicated for seizure disorders; however, only clonazepam, clobazam, and diazepam buccal film are specifically discussed within this review. Additional benzodiazepine formulations used for the acute outpatient treatment of seizures include intranasal formulations of diazepam and midazolam. The carbamazepine derivatives (carbamazepine, eslicarbazepine, and oxcarbazepine) and valproic acid derivatives (divalproex and valproic acid) can be used for a variety of

	seizure types; these agents have additional indications that include neuropathic pain (carbamazepine), bipolar disorder (carbamazepine and divalproex), and migraine prophylaxis (divalproex). Finally, there are a number of newer anticonvulsant therapies indicated for a wide variety of seizure types and seizure disorders, including Lennox-Gastaut syndrome (LGS), Dravet syndrome, and cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder. LGS is a severe form of epilepsy that typically begins in childhood and involves multiple seizure types, including tonic (stiffening) and atonic (drop) seizures, often resulting in developmental delays. Dravet syndrome is another severe childhood epilepsy that involves prolonged, often fever-triggered seizures, along with other seizure types like myoclonic and absence seizures. CDKL5 deficiency disorder is a rare genetic disorder that causes early-onset seizures, is typically resistant to treatment, and is associated with severe neurodevelopmental impairment. Specific medications for these conditions include cannabidiol, felbamate, fenfluramine, lamotrigine, rufinamide, and topiramate for LGS; cannabidiol, fenfluramine, and stiripentol for Dravet syndrome; and ganaxolone for CDKL5 deficiency disorder. Among the newer agents, only topiramate and lamotrigine have additional non-seizure indications (migraine prophylaxis and bipolar disorder, respectively). Given the diversity in their specific indications, approved populations, and adverse events/warnings, making meaningful comparisons between agents in this class is difficult. Head-to-head trials in seizure disorders are generally lacking, particularly for newer drugs, and guidelines for epilepsy do not tend to recommend specific agents over others. Most drugs have at least one formulation approved for at least one seizure-related indication in pediatric patients; a notable exception to this is cenobamate, which is only approved for use in adults. The majority of drugs also have at least one formulation available generically. Some drugs have significant safety concerns associated with their use, requiring boxed warnings and/or Risk Evaluation and Mitigation Strategies (REMS). These safety concerns include serious dermatologic reactions and aplastic anemia with carbamazepine (boxed warning); risk of abuse/misuse with benzodiazepines (boxed warning); hepatotoxicity, pancreatitis, and teratogenic effects with valproic acid derivatives (boxed warnings); aplastic anemia and acute liver failure with felbamate (boxed warning); valvular heart disease and pulmonary hypertension with fenfluramine (boxed warning and REMS); serious dermatologic reactions with lamotrigine (boxed warning); serious psychiatric and behavioral reactions with perampanel (boxed warning); and irreversible vision loss with vigabatrin (boxed warning and REMS). Additionally, products containing levetiracetam or clobazam have a warning in their labeling for drug reaction with eosinophilia and systemic symptoms (DRESS), a multiorgan hypersensitivity reaction that can be fatal.

Table 1. Anticonvulsant Agents

Drug (Route of Administration)	Indications										
	Absence (Petit Mal) Seizures	Myoclonic Seizures	Partial (Focal) Seizures	Tonic-Clonic (Grand Mal) Seizures	Acute Treatment of Intermittent Episodes of Frequent Seizure Activity	Neuropathic Pain	LGS	Dravet Syndrome	CDKL5 Deficiency Disorder	Migraine Prophylaxis	Bipolar Disorder
Barbiturates											
Phenobarbital[†] Phenobarbital (PO)[‡]	--	--	x*	x*	--	--	--	--	--	--	--
Primidone Mysoline®[G] (PO)	--	--	x*	x*	--	--	--	--	--	--	--
Hydantoins											
Phenytoin[#] Dilantin®[G] (PO)	--	--	x*	x*	--	--	--	--	--	--	--
Phenytoin[#] Phenytek®[G] (PO)	--	--	x*	x*	--	--	--	--	--	--	--
Succinimides											
Ethosuximide Zarontin®[G] (PO)	x*	--	--	--	--	--	--	--	--	--	--
Methsuximide Celontin®[G] (PO)	x*	--	--	--	--	--	--	--	--	--	--
Benzodiazepines											
Clobazam Onfi®[G] (PO)	--	--	--	--	--	--	x*[§]	--	--	--	--
Clobazam film Sympazan® (PO)	--	--	--	--	--	--	x*[§]	--	--	--	--
Clonazepam[+] Klonopin®[G] (PO)	x*	x*	--	--	--	--	x*	--	--	--	--
Diazepam[&] Diastat®[G] (PR) Valtoco® (IN)	--	--	--	--	x*	--	--	--	--	--	--
Libervant™ (PO)	--	--	--	--	x**	--	--	--	--	--	--
Midazolam Nayzilam® (IN)	--	--	--	--	x*	--	--	--	--	--	--

Drug (Route of Administration)	Indications										
	Absence (Petit Mal) Seizures	Myoclonic Seizures	Partial (Focal) Seizures	Tonic-Clonic (Grand Mal) Seizures	Acute Treatment of Intermittent Episodes of Frequent Seizure Activity	Neuropathic Pain	LGS	Dravet Syndrome	CDKL5 Deficiency Disorder	Migraine Prophylaxis	Bipolar Disorder
Carbamazepine Derivatives											
Carbamazepine Epitol®‖ (PO) Tegretol®G (PO)	--	--	x*	x*	--	x£	--	--	--	--	--
Carbamazepine XR Tegretol® XRG (PO)	--	--	x*	x*	--	x£	--	--	--	--	--
Carbamazepine XR Carbatrol®G (PO)	--	--	x*	x*	--	x£	--	--	--	--	--
Carbamazepine XR Equetro® (PO)	--	--	x*	x*	--	x£	--	--	--	--	x
Eslicarbazepine Aptiom® (PO)	--	--	x*	--	--	--	--	--	--	--	--
Oxcarbazepine Trileptal®G (PO)	--	--	x*	--	--	--	--	--	--	--	--
Oxcarbazepine XR Oxtellar XR® (PO)	--	--	x*	--	--	--	--	--	--	--	--
Valproic Acid and Derivatives											
Divalproex DR Depakote®G (PO)	x*††	--	x††	--	--	--	--	--	--	x	x
Divalproex ER Depakote ER®G (PO)	x*††	--	x††	--	--	--	--	--	--	x	x
Valproic acid Valproic acid (PO)‡	x*††	--	x††	--	--	--	--	--	--	--	--
Other Anticonvulsants											
Brivaracetam Briviact® (PO)	--	--	x*	--	--	--	--	--	--	--	--
Cannabidiol Epidiolex® (PO)	--	--	--	--	--	--	x*	x*&&	--	--	--
Cenobamate Xcopri® (PO)	--	--	x	--	--	--	--	--	--	--	--

Drug (Route of Administration)	Indications										
	Absence (Petit Mal) Seizures	Myoclonic Seizures	Partial (Focal) Seizures	Tonic-Clonic (Grand Mal) Seizures	Acute Treatment of Intermittent Episodes of Frequent Seizure Activity	Neuropathic Pain	LGS	Dravet Syndrome	CDKL5 Deficiency Disorder	Migraine Prophylaxis	Bipolar Disorder
Felbamate Felbatol®G (PO)	--	--	x*##	--	--	--	x§	--	--	--	--
Fenfluramine Fintepla® (PO)	--	--	--	--	--	--	x*	x*	--	--	--
Ganaxolone Ztalmy® (PO)	--	--	--	--	--	--	--	--	x*	--	--
Lacosamide Vimpat®G (PO)	--	--	x*	x*§	--	--	--	--	--	--	--
Lacosamide XR Motpoly XR™ (PO)	--	--	x*	x*§	--	--	--	--	--	--	--
Lamotrigine Lamictal®G (PO) Lamictal ODT®G (PO) Subvenite®‖ (PO)	--	--	x*	x*§	--	--	x*§	--	--	--	x
Lamotrigine XR Lamictal XR®G (PO)	--	--	x*	x*§	--	--	--	--	--	--	--
Levetiracetam Keppra®G (PO) Roweepra®‖ (PO) Spritam® (PO)	--	x*§	x*	x*§	--	--	--	--	--	--	--
Levetiracetam XR Keppra XR®G (PO) Elepsia XR® (PO)	--	--	x*++	--	--	--	--	--	--	--	--
Perampanel Fycompa® (PO)	--	--	x*	x*§	--	--	--	--	--	--	--
Rufinamide Banzel®G (PO)	--	--	--	--	--	--	x*§	--	--	--	--
Stiripentol Diacomit® (PO)	--	--	--	--	--	--	--	x*§‡‡	--	--	--
Tiagabine Gabitril®G (PO)	--	--	x*§	--	--	--	--	--	--	--	--

Drug (Route of Administration)	Indications										
	Absence (Petit Mal) Seizures	Myoclonic Seizures	Partial (Focal) Seizures	Tonic-Clonic (Grand Mal) Seizures	Acute Treatment of Intermittent Episodes of Frequent Seizure Activity	Neuropathic Pain	LGS	Dravet Syndrome	CDKL5 Deficiency Disorder	Migraine Prophylaxis	Bipolar Disorder
Topiramate Topamax®[G] (PO) Eprontia® (PO)	--	--	x*	x*	--	--	x*§	--	--	x*	--
Topiramate XR Qudexy XR®[G] (PO) Trokendi XR®[G] (PO)	--	--	x*	x*	--	--	x*§	--	--	x*	--
Vigabatrin Sabril®[G] (PO) Vigadrone®[‖] (PO) Vigpoder™ (PO)	--	--	x*§&&&	--	--	--	--	--	--	--	--
Zonisamide Zonegran® (PO) Zonisamide capsules®[‡] (PO) Zonisade® (PO)	--	--	x*§	--	--	--	--	--	--	--	--

[G]*Available generically.*
[‡]*Only available generically.*
[‖]*Branded generic product.*
**Adult and pediatric indication.*
[†]*Phenobarbital is also indicated as a sedative agent.*
[#]*Phenytoin is also indicated for prevention and treatment of seizures occurring during or following neurosurgery.*
[§]*Indicated as adjunctive therapy only.*
[+]*Clonazepam is also indicated for treatment of panic disorder in adults.*
[£]*Indicated to treat neuropathic pain associated with trigeminal neuralgia.*
[&]*Oral diazepam tablets, solution, and concentrate are approved for the adjunctive treatment of seizure disorders and are addressed in another therapeutic class review.*
[††]*Divalproex/valproic acid is indicated as monotherapy and adjunctive therapy for treatment of adults and pediatric patients with complex partial seizures that occur either in isolation or in association with other types of seizures. Also indicated for use as sole and adjunctive therapy for treatment of simple and complex absence seizures, and adjunctively in patients with multiple seizure types that include absence seizures.*
***Indicated in pediatric patients 2-5 years of age.*
[##]*Felbamate is not indicated as first-line antiepileptic treatment; it is recommended for use only in patients who respond inadequately to alternative treatments and whose epilepsy is so severe that a substantial risk of aplastic anemia and/or liver failure is deemed acceptable in relation to benefits.*
[++]*Elepsia XR is indicated as adjunctive therapy only.*
[&&]*Cannabidiol is approved for the treatment of seizures associated with Dravet syndrome and seizures associated with tuberous sclerosis complex in patients ≥1 year of age.*
[‡‡]*Stiripentol is approved for the treatment of seizures associated with Dravet syndrome in patients ≥6 months of age weighing ≥7 kg taking clobazam.*
[&&&]*Vigabatrin is also indicated as monotherapy for the treatment of infantile spasms in infants 1 month to 2 years of age when the potential benefit outweighs the risk of potential vision loss.*
Abbreviations: CDKL5, cyclin-dependent kinase-like 5; DR, delayed-release; ER/XR, extended-release; IN, intranasal; LGS, Lennox-Gastaut syndrome; PO, oral; PR, rectally.

All authorizations must be prescribed in accordance with FDA approved labeling. Use of samples to initiate therapy does not meet step therapy and/or continuation of therapy prior authorization requirements. Prior therapies will be verified through pharmacy claims and/or submitted chart notes

General Approval Criteria:

- For specific formulation requests
    - **For brand requests when a therapeutically equivalent generic is preferred:** Provider must provide a documented medical reason the preferred generic formulation cannot be used
    - **For generic requests when a therapeutically equivalent brand is preferred:** Provider must provide a documented medical reason the preferred brand formulation cannot be used
    - **For non-preferred dosage or formulation requests:** Provider must provide a documented medical reason the preferred dosage or formulation cannot be used

Initial Therapy –One of the following must be met:

- Claim is for a preferred agent **OR**

For Diacomit (all of the following must be met):

- Prescribed by or in consultation with a neurologist or other specialist in the treated disease state
- Documented diagnosis of Dravet syndrome
- Patient aged 6 months and older
- Documented trial and failure (defined as 30 days) of **one** preferred treatment for Dravet syndrome (e.g., valproic acid, clobazam, epidiolex) **OR** documented contraindication and/or adverse drug event or adverse drug reaction (ADE/ADR) to therapy
- Must be taken concurrently with clobazam
- Therapy will deny if patient has a documented history of moderate to severe hepatic or renal impairment
- The following dosage limitations apply:
    - DIACOMIT 250 MG CAPSULE-12 capsules per day
    - DIACOMIT 250 MG POWDER PACKETS-12 packets per day
    - DIACOMIT 500 MG CAPSULE- 6 capsules per day
    - DIACOMIT 500 MG POWDER PACKET- 6 packets per day

For Fintepla :

- Prescribed by or in consultation with a neurologist or other specialist in the treated disease state **AND ONE** of the following:
- Documented diagnosis of Dravet syndrome **AND**:
    - Patient is aged 2 years or older
    - Documented trial and failure (defined as 30 days) of **one** preferred treatment for Dravet syndrome (e.g., valproic acid, clobazam, epidiolex) **OR** documented contraindication and/or ADE/ADR to therapy
    - Therapy will deny if patient has a documented history of monoamine oxidase inhibitor therapy in the last 45 days
    - The following dosage limitations apply:
        - With concomitant Diacomit: 17 mg per day
        - Without concomitant Diacomit: 26 mg per day **OR**

- Documented diagnosis of Lennox Gastaut Syndrome (LGS) **AND**:
    - Patient is aged 2 years or older
    - Documented trial and failure (defined as 30 days) of **one** preferred anti-epileptic agent approved for LGS and/or documented contraindication or ADE/ADR (e.g., epidiolex, generic clobazam, clonazepam, lamotrigine, topiramate)
    - Therapy will deny if patient has a documented history of MAOI therapy in the last 45 days
    - The following dosage limitations apply:
        - With concomitant Diacomit: 17 mg per day
        - Without concomitant Diacomit: 26 mg per day

For Requests to Treat Lennox-Gastaut Syndrome With Other Nonpreferred Agents (Felbatol, Banzel, Brand Onfi) (all of the following must be met):

- Prescribed by or in consultation with a neurologist or other specialist in the treated disease state
- Documented diagnosis of Lennox- Gastaut Syndrome
- Documented trial and failure (defined as 30 days) of **one** preferred anti-epileptic agent approved for LGS and/or documented contraindication or ADE/ADR (e.g., epidiolex, generic clobazam, clonazepam, lamotrigine, topiramate)
- **For Felbatol**:
    - Baseline CBC and LFT's (including AST and ALT) required prior to initiation of therapy
    - Patient does **NOT** have a history of any blood dyscrasias (e.g., aplastic anemia, bone marrow depression)
    - Patient does **NOT** have a history of hepatic dysfunction or active liver disease
    - Written acknowledgement required by physician that the risks to patient, parent or guardian was provided regarding Felbatol use
    - *For continuation of therapy: Documentation of routine CBC and LFT monitoring as clinically determined, patient continues to have no evidence of blood dyscrasia or hepatic dysfunction*

- **For Banzel**:
  - Patient aged 1 year and older
  - Therapy will be denied in patients with history of Familial Short QT syndrome(FSQTS)
    - Baseline ECG shows QTc>330 ms **AND** no personal or family history of FSQTS
- **For Brand Onfi**:
  - Documentation of why generic clobazam cannot be utilized

Nonpreferred Rescue Agent (Libervant Film) (all of the following must be met):

- Prescribed by or in consultation with a neurologist or other specialist in the treated disease state
- Diagnosis of seizure disorder
- Patient aged 2- 5 years old
- Documented trial of **one** preferred (1 claim) rescue agent (e.g., Nayzilam, Valtoco, diazepam rectal) and/or documentation of contraindication and/or ADE/ADR to preferred rescue agents

For Ztalmy (ganaxolone) (all of the following must be met):

- Prescribed by or in consultation with a neurologist or other specialist in the treated disease state
- Documented diagnosis of CDKL5 deficiency disorder with documentation of genetic testing confirming presence of pathogenic or likely pathogenic variant in the *CDKL5* gene
- Patient aged 2 years or older
- Claim does not exceed maximum dosage limitations:
  - For participants without severe hepatic impairment:
    - Weight≤28 kg: 63 mg/kg/day;
    - Weight> 28 kg: 1,800 mg/day
  - For participants with severe hepatic impairment
    - Weight ≤ 28 kg: 21 mg/kg/day
    - Weight > 28 kg: 600 mg/day

For Treatment of Bipolar Disorder:

- *Requests for a nonpreferred agent to treat bipolar disorder require documentation of diagnosis of bipolar disorder with no other additional PA criteria required*

All other nonpreferred agents in this class:

- Prescribed by or in consultation with a neurologist or other specialist in the treated disease state **AND**
- Documented diagnosis of seizure disorder **OR**
- Documentation of neuropathic pain **OR**
- Documentation of chronic migraine **AND**
- Documented trial and failure of **one** preferred agent (30 day trial)

Initial PA length: 1 year

Continuation Therapy: Documented compliance on current therapy regimen **AND** Documented continued clinical benefit **AND**

- For specific formulation requests
  - **For brand requests when a therapeutically equivalent generic is preferred:** Provider must provide a documented medical reason the preferred generic formulation cannot be used
  - **For generic requests when a therapeutically equivalent brand is preferred:** Provider must provide a documented medical reason the preferred brand formulation cannot be used
  - **For non-preferred dosage or formulation requests:** Provider must provide a documented medical reason the preferred dosage or formulation cannot be used

Continuation Length: 1 year

References:

1. Drugs@FDA: FDA Approved D rug Products. Accessed July 2025. https://www.accessdata.fda.gov/scripts/cder/daf/
2. DailyMed: National Library of Medicine. Accessed July 2025. https://dailymed.nlm.nih.gov/dailymed/index.cfm
3. Facts and Comparisons eAnswers online. Waltham, MA: UpToDate Inc.; 2025. Accessed July 2025. Available https://www.wolterskluwer.com/en/solutions/uptodate/enterprise/lexidrug-facts-and-comparisons
4. Drugs@FDA: FDA approved drug products. Accessed January 2025. https://www.accessdata.fda.gov/scripts/cder/daf/.
5. US Food and Drug Administration. Purple Book: Database of Licensed Biological Products. US Food and Drug Administration. Updated April 27, 2023. Accessed January 2025. https://purplebooksearch.fda.gov/
6. Chung SS, French JA, Kowalski J, et al. Randomized phase 2 study of adjunctive cenobamate in patients with uncontrolled focal seizures. Neurology. 2020;94(22):e2311-e2322.

7. Krauss GL, Klein P, Brandt C, et al. Safety and efficacy of adjunctive cenobamate (YKP3089) in patients with uncontrolled focal seizures: a multicentre, double-blind, randomised, placebo-controlled, dose-response trial. Lancet Neurol. 2020;19(1):38-48.

8. Brigo F, Lattanzi S. Cenobamate add-on therapy for drug-resistant focal epilepsy. Cochrane Database Syst Rev. 2024;8(8):CD014941. Published 2024 Aug 1.

9. Panebianco M, Bresnahan R, Marson AG. Lamotrigine add-on therapy for drug-resistant focal epilepsy. Cochrane Database Syst Rev. 2023;12(12):CD001909. Published 2023 Dec 11.

10. Vossler DG, Knake S, O'Brien TJ, et al. Efficacy and safety of adjunctive lacosamide in the treatment of primary generalized tonic-clonic seizures: a double-blind, randomized, placebo-controlled trial. J Neurol Neurosurg Psychiatry. 2020;91(10):1067-1075.

11. Knupp KG, Scheffer IE, Ceulemans B, et al. Efficacy and safety of fenfluramine for the treatment of seizures associated with Lennox-Gastaut syndrome: a randomized clinical trial. JAMA Neurol. 2022;79(6):554-564.

12. Knight EMP, Amin S, Bahi-Buisson N, et al. Safety and efficacy of ganaxolone in patients with CDKL5 deficiency disorder: results from the double-blind phase of a randomised, placebo-controlled, phase 3 trial. Lancet Neurol. 2022;21(5):417-427.

13. Olson HE, Amin S, Bahi-Buisson N, et al. Long-term treatment with ganaxolone for seizures associated with cyclin-dependent kinase-like 5 deficiency disorder: Two-year open-label extension follow-up. Epilepsia. 2024;65(1):37-45.

14. Detyniecki K, Van Ess PJ, Sequeira DJ, Wheless JW, Meng TC, Pullman WE. Safety and efficacy of midazolam nasal spray in the outpatient treatment of patients with seizure clusters-a randomized, double-blind, placebo-controlled trial. Epilepsia. 2019;60(9):1797-1808.

15. Guerrini R, Chiron C, Vandame D, Linley W, Toward T. Comparative efficacy and safety of stiripentol, cannabidiol and fenfluramine as first-line add-on therapies for seizures in Dravet syndrome: A network meta-analysis. Epilepsia Open. 2024;9(2):689-703.

16. Nevitt SJ, Sudell M, Cividini S, Marson AG, Tudur Smith C. Antiepileptic drug monotherapy for epilepsy: a network meta-analysis of individual participant data. Cochrane Database Syst Rev. 2022;4(4):CD011412.

17. Kharel S, Ojha R, Khanal S. Levetiracetam versus oxcarbazepine as monotherapy in newly diagnosed focal epilepsy: A systematic review and meta-analysis. Brain Behav. 2022;12(11):e2779.

18. Zhang L, Wang J, Wang C. Efficacy and safety of antiseizure medication for Lennox-Gastaut syndrome: a systematic review and network meta-analysis. Dev Med Child Neurol. 2022;64(3):305-313.

19. Brigo F, Jones K, Eltze C, Matricardi S. Anti-seizure medications for Lennox-Gastaut syndrome. Cochrane Database Syst Rev. 2021;4(4):CD003277.

20. Pack AM, Oskoui M, Williams Roberson S, et al. Teratogenesis, perinatal, and neurodevelopmental outcomes after in utero exposure to antiseizure medication: practice guideline from the AAN, AES, and SMFM. Neurology. 2024;102(11):e209279.

21. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2018;91(2):74-81.

22. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2018;91(2):82-90.

23. Wirrell EC, Laux L, Donner E, et al. Optimizing the diagnosis and management of Dravet syndrome: recommendations from a North American consensus panel. Pediatr Neurol. 2017;68:18-34.e3.

24. Glauser T, Shinnar S, Gloss D, et al. Evidence-based guideline: treatment of convulsive status epilepticus in children and adults: report of the Guideline Committee of the American Epilepsy Society. Epilepsy Curr. 2016;16(1):48-61.

25. Gronseth G, Cruccu G, Alksne J, et al. Practice parameter: the diagnostic evaluation and treatment of trigeminal neuralgia (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology and the European Federation of Neurological Societies. Neurology. 2008;71(15):1183-1190.

26. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59(1):1-18.

27. Oskoui M, Pringsheim T, Billinghurst L, et al. Practice guideline update summary: Pharmacologic treatment for pediatric migraine prevention: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society. Headache. 2019;59(8):1144-1157.

28. Yatham LN, Kennedy SH, Parikh SV, et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) and International Society for Bipolar Disorders (ISBD) 2018 guidelines for the management of patients with bipolar disorder. Bipolar Disord. 2018;20(2):97-170.

Revision History

Date	Version	Revisions
11/7/2025	V1	Document approved by DSS

