

Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

Antiseizure Agents, Epidiolex and Fintepla

Epidiolex (Cannabidiol)

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Fintepla (Fenfluramine)

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Revision Notes

Combined existing Epidiolex criteria with Fintepla criteria approved by the DUR Board on July 22, 2022



Epidiolex (Cannabidiol)

Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
EPIDIOLEX 100MG/ML SOLUTION	45169



Epidiolex (Cannabidiol)

Clinical Criteria Logic

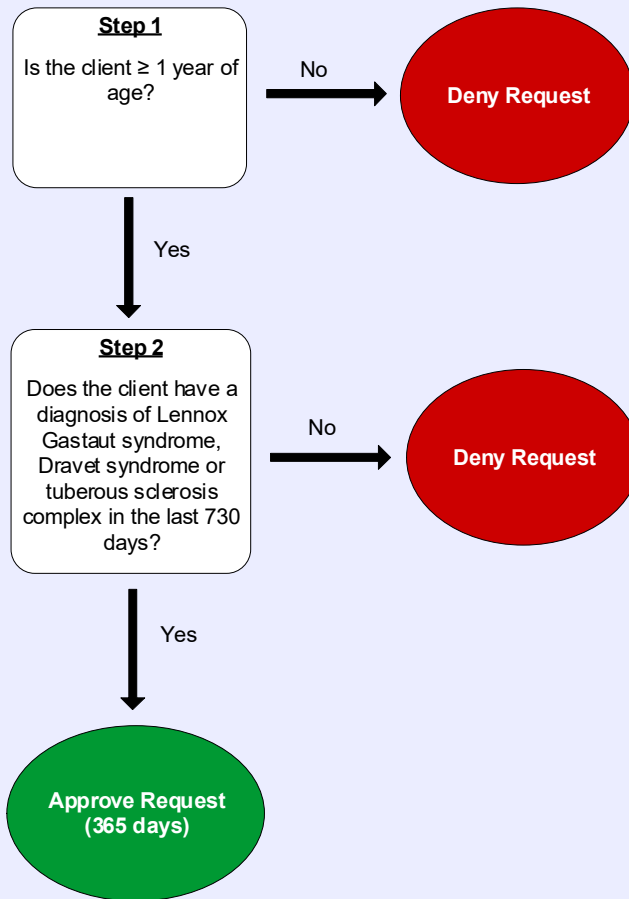
1. Is the client greater than or equal to (\geq) 1 year of age?
 Yes (Go to #2)
 No (Deny)

2. Does the client have a **diagnosis of Lennox-Gastaut syndrome, Dravet syndrome or tuberous sclerosis complex** in the last 730 days?
 Yes (Approve – 365 days)
 No (Deny)



Epidiolex (Cannabidiol)

Clinical Criteria Logic Diagram





Fintepla (Fenfluramine)

Drugs Requiring Prior Authorization

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Drugs Requiring Prior Authorization	
Label Name	GCN
FINTEPLA 2.2 MG/ML SOLUTION	48284



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Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 2 years of age?
 Yes (Go to #2)
 No (Deny)

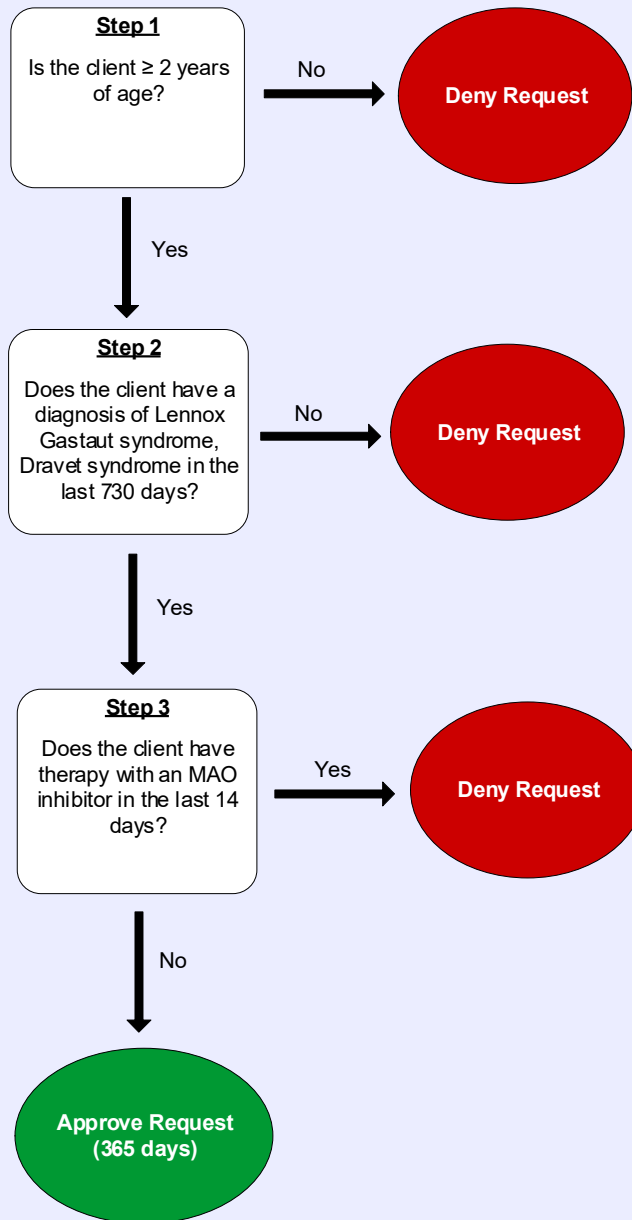
2. Does the client have a **diagnosis of Lennox-Gastaut syndrome or Dravet syndrome** in the last 730 days?
 Yes (Go to #3)
 No (Deny)

3. Has the client had therapy with an **MAO inhibitor** in the last 14 days?
 Yes (Deny)
 No (Approve – 365 days)



Fintepla (Fenfluramine)

Clinical Criteria Logic Diagram





Antiseizure Agents, Epidiolex and Fintepla Clinical Criteria Supporting Tables

Diagnosis of Lennox-Gastaut syndrome, Dravet syndrome or tuberous sclerosis complex	
Required diagnosis: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
G40411	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE WITH STATUS EPILEPTICUS
G40419	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE WITHOUT STATUS EPILEPTICUS
G40803	OTHER EPILEPSY INTRACTABLE, WITH STATUS EPILEPTICUS
G40804	OTHER EPILEPSY INTRACTABLE, WITHOUT STATUS EPILEPTICUS
G40811	LENNOX-GASTAUT SYNDROME NOT INTRACTABLE, WITH STATUS EPILEPTICUS
G40812	LENNOX-GASTAUT SYNDROME NOT INTRACTABLE, WITHOUT STATUS EPILEPTICUS
G40813	LENNOX-GASTAUT SYNDROME INTRACTABLE, WITH STATUS EPILEPTICUS
G40814	LENNOX-GASTAUT SYNDROME INTRACTABLE, WITHOUT STATUS EPILEPTICUS
G4083	DRAVET SYNDROME
G40833	DRAVET SYNDROME, INTRACTABLE, WITH STATUS EPILEPTICUS
G40834	DRAVET SYNDROME, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
Q851	TUBEROUS SCLEROSIS

Diagnosis of Lennox-Gastaut syndrome or Dravet syndrome	
Required diagnosis: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
G40411	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE WITH STATUS EPILEPTICUS
G40419	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE WITHOUT STATUS EPILEPTICUS
G40803	OTHER EPILEPSY INTRACTABLE, WITH STATUS EPILEPTICUS
G40804	OTHER EPILEPSY INTRACTABLE, WITHOUT STATUS EPILEPTICUS
G40811	LENNOX-GASTAUT SYNDROME NOT INTRACTABLE, WITH STATUS EPILEPTICUS

Diagnosis of Lennox-Gastaut syndrome or Dravet syndrome	
Required diagnosis: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
G40812	LENNOX-GASTAUT SYNDROME NOT INTRACTABLE, WITHOUT STATUS EPILEPTICUS
G40813	LENNOX-GASTAUT SYNDROME INTRACTABLE, WITH STATUS EPILEPTICUS
G40814	LENNOX-GASTAUT SYNDROME INTRACTABLE, WITHOUT STATUS EPILEPTICUS
G4083	DRAVET SYNDROME
G40833	DRAVET SYNDROME, INTRACTABLE, WITH STATUS EPILEPTICUS
G40834	DRAVET SYNDROME, INTRACTABLE, WITHOUT STATUS EPILEPTICUS

MAO inhibitors	
Look back timeframe: 14 days	
LABEL NAME	GCN
AZILECT 0.5 MG TABLET	27081
AZILECT 1 MG TABLET	24654
EMSAM 12MG/24 HOURS PATCH	26614
EMSAM 6MG/24 HOURS PATCH	26612
LINEZOLID 100MG/5ML SUSP	26871
LINEZOLID 600MG TABLET	26870
LINEZOLID 600MG/300ML IV SOLN	26873
MARPLAN 10 MG TABLET	16416
NARDIL 15 MG TABLET	16417
PARNATE 10 MG TABLET	16418
PHENELZINE SULFATE 15 MG TAB	16417
SELEGILINE 5MG CAPSULE	15603
SELEGILINE 5MG TABLET	15600
TRANLYCYPROMINE 10MG TABLET	16418
XADAGO 100 MG TABLET	40008
XADAGO 50 MG TABLET	40007
ZELAPAR 1.25MG ODT TABLET	22783
ZYVOX 100 MG/5 ML SUSPENSION	26871
ZYVOX 600 MG TABLET	26870
ZYVOX 600 MG/300 ML IV SOLN	26873



Antiseizure Agents, Epidiolex and Fintepla Clinical Criteria References

1. 2019 ICD-10-CM Diagnosis Codes. 2019. Available at www.icd10data.com. Accessed on January 25, 2019.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2022. Available at www.clinicalpharmacology.com. Accessed on May 24, 2022.
3. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on May 24, 2022.
4. Epidiolex Prescribing Information. Carlsbad, CA. Greenwich Biosciences. February 2022.
5. American Academy of Neurology and the American Epilepsy Society. Treatments for Refractory Epilepsy; Guideline Summary for Clinicians.
6. Kanner AM, Ashman E, Harden C, 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.
7. Wirrell EC, laux L, Donner E, et al. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations From a North American Consensus Panel. *Ped Neur* 2017;68:18-34.
8. Fintepla Prescribing Information. Emeryville, CA. Zogenix Inc. March 2022.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
01/25/2019	<ul style="list-style-type: none"> Initial publication and presentation to the DUR Board
02/04/2019	<ul style="list-style-type: none"> Updated to include DUR Board recommendations
03/28/2019	<ul style="list-style-type: none"> Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.) on each 'Drug Requiring PA' table
08/20/2020	<ul style="list-style-type: none"> Updated age to greater than or equal to 1 year of age on criteria logic and logic diagram, pages 3-4 Added diagnosis for tuberous sclerosis complex in criteria logic and logic diagram, pages 3-4 Added ICD-10 codes for Dravet syndrome and tuberous sclerosis complex to supporting tables, page 5 Updated references page 6
02/18/2021	<ul style="list-style-type: none"> Annual review by staff Updated references
02/25/2021	<ul style="list-style-type: none"> Added the following diagnosis (ICD-10) codes: G40411, G40419, G40803 and G40804
07/05/2022	<ul style="list-style-type: none"> Annual review by staff Updated references
07/25/2022	<ul style="list-style-type: none"> Combined existing Epidiolex criteria with Fintepla criteria approved by the DUR Board on 7/22/2022