Reference number(s)
871-A

Initial Prior Authorization Seizure LGS, Dravet Anticonvulsants

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Banzel	rufinamide
Onfi	clobazam
Sympazan	clobazam

Indications

FDA-approved Indications

Banzel

Banzel is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in pediatric patients 1 year of age and older and in adults.

Onfi

Onfi (clobazam) is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older.

Sympazan

Sympazan is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older.

Compendial Uses

Onfi, Sympazan: Seizures associated with Dravet syndrome[4-6]

Coverage Criteria

Dravet Syndrome

Authorization may be granted when the requested drug is being prescribed for the treatment of seizures associated with Dravet syndrome when the following criteria is met:

- The request is for Onfi (clobazam) OR Sympazan (clobazam).

Lennox-Gastaut Syndrome

Authorization may be granted when the requested drug is being prescribed for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome when ONE of the following criteria are met:

- The request is for Banzel (rufinamide) and the following criteria is met:
  - The patient is 1 year of age or older.
- The request is for Onfi (clobazam) OR Sympazan (clobazam) and the following criteria is met:
  - The patient is 2 years of age or older.

Continuation of Therapy

Dravet Syndrome

Authorization may be granted when the requested drug is being prescribed for adjunctive treatment of seizures associated with Dravet syndrome when ALL of the following criteria are met:

- The request is for Onfi (clobazam) OR Sympazan (clobazam).
- The patient has achieved and maintained positive clinical response as evidenced by reduction in frequency or duration of seizures compared with seizure activity prior to initiation of the requested drug.

Lennox-Gastaut Syndrome

Authorization may be granted when the requested drug is being prescribed for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome when ALL of the following criteria are met:

- The patient meets ONE of the following:

  - The request is for Banzel (rufinamide) and the following criteria is met:
    - The patient is 1 year of age or older.
  - The request is for Onfi (clobazam) OR Sympazan (clobazam) and the following criteria is met:
    - The patient is 2 years of age or older.
- The patient has achieved and maintained positive clinical response as evidenced by reduction in frequency or duration of seizures compared with seizure activity prior to initiation of the requested drug.

Duration of Approval (DOA)

- 871-A: DOA: 36 months

References

1. Banzel [package insert]. Nutley, NJ: Eisai Inc.; December 2022.
2. Onfi [package insert]. Deerfield, IL: Lundbeck; March 2024.
3. Sympazan [package insert]. Warren, NJ: Aquestive Therapeutics.; March 2024.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed May 15, 2024.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/15/2024).
6. Wirrell EC, Hood V, Knupp KG, et al. International Consensus on Diagnosis and Management of Dravet Syndrome. Epilepsia. 2022;63(7):1761-1777.

Document History

Written by: UM Development (JK)

Date Written: 11/2011

Revised: (CT) 05/2012 (created MDC-1 document); (PL) 10/2012 (extended duration); (MS) 05/2013; (GS/CF) 05/2014; (CF) 05/2015; (MS) 05/2016 (no clinical changes); (JG) 05/2017 (no clinical changes), 05/2018 (no clinical changes); (ME) 11/2018 (add Sympazan); (CF) 05/2019 (no clinical changes, combined 718-A + 871-A, removed MDC from 718-A); (RP) 05/2020 (no clinical changes); (MAK) 05/2021 (no clinical changes); (DFW) 05/2022 (added Dravet Syndrome as compendia supported indication), 08/2022 (added COT requirements), 05/2023 (no clinical changes); (MRS) 05/2024 (off-cycle-added Banzel via UM opt consolidation effort, added COT for Banzel, updated title), 05/2024 (no clinical changes)

Reference number(s)
871-A

Reviewed: Medical Affairs: (KP) 11/2011; (MG) 05/2012; (DC) 05/2013; (LMS) 05/2014; (DNC) 05/2015; (AM) 11/2018; (GAD) 05/2019; (CHART) 05/28/2020, 05/27/2021, 05/26/2022, 08/25/2022, 06/01/2023, 05/30/2024

External Review: 12/2011, 06/2012, 10/2013, 10/2014, 10/2015, 10/2016, 07/2017, 10/2018, 12/2018 (FYI), 10/2019, 10/2020, 08/2021, 08/2022, 12/2022, 08/2023, 09/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome? [If Yes, then go to 2. If No, then go to 7.]	Yes	No
2	Which drug is being requested? [Please check which drug is being requested.] [] Banzel (rufinamide) (If checked, go to 3) [] Onfi (clobazam) (If checked, go to 4) [] Sympazan (clobazam) (If checked, go to 4)		
3	Is the patient 1 years of age or older? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
4	Is the patient 2 years of age or older? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Is this request for continuation of therapy? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Has the patient achieved and maintained positive clinical response as evidenced by reduction in frequency or duration of seizures compared with seizure activity prior to initiation of the requested drug? [No further questions]	Yes	No
7	Is the requested drug being prescribed for the treatment of seizures associated with Dravet syndrome? [If Yes, then go to 8. If No, then no further questions.]	Yes	No

8	Which drug is being requested? [Please check which drug is being requested.] [] Onfi (clobazam) (If checked, go to 9) [] Sympazan (clobazam) (If checked, go to 9) [] Other (If checked, no further questions)		
9	Is this request for continuation of therapy? [If Yes, then go to 10. If No, then no further questions.]	Yes	No
10	Has the patient achieved and maintained positive clinical response as evidenced by reduction in frequency or duration of seizures compared with seizure activity prior to initiation of the requested drug? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Go to 7	
2.	1=3 ;2=4 ;3=4		
3.	Go to 5	Deny	Your plan only covers this drug for seizures due to Lennox-Gastaut syndrome if you are 1 year old or older. We reviewed the information we had. Your request has been denied. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Age - Banzel]
4.	Go to 5	Deny	Your plan only covers this drug for seizures due to Lennox-Gastaut syndrome if you are 2 years old or older. We reviewed the information we had. Your request has been denied. For this drug, you may have to meet other criteria. You can request the drug

			policy for more details. You can also request other plan documents for your review. [Short Description: Age - Onfi, Sympazan]
5.	Go to 6	Approve, 36 Months	
6.	Approve, 36 Months	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Efficacy]
7.	Go to 8	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for A) Seizures due to Lennox-Gastaut syndrome when taken with other seizure drugs, and B) Seizures due to Dravet syndrome for Onfi (clobazam) or Sympazan (clobazam). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
8.	1=9 ;2=9 ;3=Deny		Your plan only covers this drug when it is used for certain health conditions. Covered uses are for A) Seizures due to Lennox-Gastaut syndrome when taken with other seizure drugs, and B) Seizures due to Dravet syndrome for Onfi (clobazam) or Sympazan (clobazam). Your plan does not cover this drug for Dravet syndrome. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing

			information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Dravet syndrome - wrong drug]
9.	Go to 10	Approve, 36 Months	
10.	Approve, 36 Months	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Efficacy]