

Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Onfi (clobazam), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a neurologist
- Must be age 2 years or older
- Must have diagnosis of Lennox-Gastaut syndrome
- Must have had an inadequate response or intolerance to at least 2 generic antiepileptic medications such as lamotrigine, topiramate, felbamate
- Must be using clobazam (Onfi) as adjunctive therapy to other anti-epileptic drugs (AEDs)

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A
Quantity Level Limit	
Onfi tablets	60 tablets per 30 days
Onfi oral suspension	480 mL per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Onfi [package insert]. Deerfield, IL: Lundbeck, Inc; October 2011.
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3. Conry JA, Ng YT, Paolicchi JM, et al. Clobazam in the treatment of Lennox-Gastaut syndrome. *Epilepsia*. 2009;50:1158-1166.
4. Crumrine PK. Management of seizures in Lennox-Gastaut Syndrome. *Pediatr Drugs*. 2011;13:107-118.
5. Arzimanoglou A, French J, Blume WT, et al. Lennox-Gastaut syndrome: a consensus approach on diagnosis, assessment, management, and trial methodology. *Lancet Neurol*. 2009;8:82-93.



Onfi (clobazam)

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7. French JA, Kanner AM, Bautista J, et al. Efficacy and tolerability of the new antiepileptic drugs II: treatment of refractory epilepsy: report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2004;62:1261-1273.
8. Ng Y, Conry J, Drummond R, et al. Randomized, phase III study results of clobazam in Lennox-Gastaut syndrome. *Neurology*. 2011;77:1473-1481.
9. Machado V, Palmira A, Bastos F, Rotert R. Long-term control of epileptic drop attacks with the combination of valproate, lamotrigine, and a benzodiazepine: A "proof of concept," open label study. *Epilepsia*. 2011;52(7):1303-1310.
10. Lamictal [package insert]. Research Triangle Park, NC: GlaxoSmithKline;2014.
11. Topamax [package insert]. Titusville, NJ: Janssen Ortho, LLC; 2014.
12. Felbatol [package insert]. Somerset, NJ: Meda Pharmaceuticals, Inc.; July 2011.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual review</i>	<i>02/17, 02/18</i>

