Reset Form

ONFI® (clobazam)℞ Support Center Assistance Form

This form is to be used for prior authorization assistance, bridge supply, and patient assistance.

Step 1: Patient Information

Name: _____
(First) (Middle) (Last)
Sex: ❑ Male ❑ Female Date of Birth: ____ / ____ / ____
Address: _____
City: _____ State: _____ Zip Code: _____
Phone: _____ Alternate Phone: _____
Parent/Legal Guardian: _____
Phone: _____ Alternate Phone: _____
Pharmacy Name: _____ Phone: _____

Patient Insurance: Complete the information below or include copies of insurance cards.

Primary Insurance

Name of Medical Plan: _____ Phone: _____
Relationship to Cardholder: ❑ Self ❑ Spouse ❑ Child ❑ Other: _____
Cardholder Name: _____ Plan Number: _____
Group Number: _____ ID Number: _____

Secondary Insurance

Name of Medical Plan: _____ Phone: _____
Relationship to Cardholder: ❑ Self ❑ Spouse ❑ Child ❑ Other: _____
Cardholder Name: _____ Plan Number: _____
Group Number: _____ ID Number: _____

Prescription Insurance

Name of Prescription Plan: _____ Phone: _____
Rx BIN: _____ Rx PCN: _____

Step 2: Prescriber Information

Prescriber Name: _____
(First) (Last)
Specialty: ❑ Neurology ❑ Other: _____
Prescriber Address: _____
Prescriber Address #2: _____ City: _____
State: _____ Zip Code: _____ Phone: _____
Fax: _____ NPI #: _____ DEA #: _____
Physician Office Contact: _____ Phone: _____
Physician E-mail: _____

Step 3: Clinical Information

Diagnosis: _____ ICD-10 Code: _____

Does the patient have seizures associated with Lennox-Gastaut syndrome (LGS) or has the patient been diagnosed with LGS in the past? ❑ Yes ❑ No

Anticonvulsant Medications Previously Tried and Failed With Reason for Discontinuation (provide the information below or include chart notes containing the required information):

	Medication	Reason	Start Date	End Date
1.				
2.				
3.				
4.				

Anticonvulsant Medications Currently Taking:

1. _____ 3. _____
2. _____ 4. _____

ONFI® (clobazam)℞ Prescribing Information

Is the patient currently taking ONFI? ❑ Yes ❑ No
Drug Strength: _____
Quantity Prescribed: _____
Directions for Use: _____
Estimated Duration of ONFI Therapy: _____

Step 4: Prescriber Authorization

I certify that ONFI therapy is medically necessary and that this information is accurate to the best of my knowledge. In accordance with 45 CFR 160, I authorize Lash Group, acting as the ONFI Support Center, to be my designated agent and to act as my business associate (as defined in 45 CFR 160.103) to use and disclose any information in this form to the insurer of the above-named patient and to obtain any information about the patient, including any protected health information (as defined in 45 CFR 160.103) from the insurer, including eligibility and other benefit coverage information, for my payment and/or health care operation purposes. As my business associate, Lash Group is required to comply with, and by its signature hereto, agrees that it will comply with, the applicable requirements of 45 CFR 164.504(e) regarding business associates, and that it will safeguard any protected health information that it obtains on my behalf, and will use and disclose this information only for the purposes specified herein or as otherwise permitted by law.

Prescriber Signature: _____ Date: _____

Please complete this form in its entirety and fax to the ONFI Support Center at 1-855-547-8278.

If you have any questions or need additional information, please call the ONFI Support Center at 1-855-345-ONFI (6634).

Please see Indication and Important Safety Information on next page.

Onfi®
(clobazam)
10 mg, 20 mg Tablets
2.5 mg/mL Oral Suspension

Indication and Important Safety Information

Indications and Usage

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

Important Safety Information

- ONFI is contraindicated in patients with a history of hypersensitivity to the drug or its ingredients. Hypersensitivity reactions have included serious dermatological reactions.
- ONFI causes somnolence and sedation. In clinical trials, somnolence or sedation was reported at all effective doses and was dose-related. In general, somnolence and sedation begin within the first month of treatment and may diminish with continued treatment. Prescribers should monitor patients for somnolence and sedation, particularly with concomitant use of other central nervous system (CNS) depressants. Prescribers should caution patients against engaging in hazardous activities that require mental alertness, such as operating dangerous machinery or motor vehicles, until the effect of ONFI is known.
- ONFI has a CNS depressant effect. Patients should be cautioned against the simultaneous use with other CNS depressant drugs or alcohol, and cautioned that the effects of other CNS depressant drugs or alcohol may be potentiated.
- As with all antiepileptic drugs (AEDs), ONFI should be gradually withdrawn to minimize the risk of precipitating seizures, seizure exacerbation, or status epilepticus. Withdrawal symptoms have been reported following abrupt discontinuation of ONFI; the risk of withdrawal symptoms is greater with higher doses.
- Serious dermatological reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported with ONFI in both children and adults during the post-marketing period. ONFI should be discontinued at the first sign of rash, unless the rash is clearly not drug-related.
- Patients with a history of substance abuse should be under careful surveillance when receiving ONFI or other psychotropic agents because of the predisposition of such patients to habituation and dependence. In clinical trials, cases of dependency were reported following abrupt discontinuation of ONFI. The risk of dependence increases with increasing dose and duration of treatment.
- AEDs, including ONFI, increase the risk of suicidal thoughts or behavior in patients. Patients, their caregivers, and families should be informed of the risk and advised to monitor and report any emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior, or thoughts of self-harm. If these symptoms occur, consider whether it may be related to the AED or illness, because epilepsy itself can increase these risks.
- Based on animal data, ONFI may cause fetal harm and should only be used during pregnancy or while nursing if the potential benefit justifies the potential risk.
- The most commonly observed adverse reactions reported in an LGS randomized, double-blind, placebo-controlled, parallel group clinical trial of patients who received clobazam as adjunctive therapy (≥10% in any treatment group and at least 5% greater than placebo, respectively) were somnolence or sedation (32% vs. 15%), somnolence (25% vs. 12%), pyrexia (17% vs. 3%), lethargy (15% vs. 5%), aggression (14% vs. 5%), drooling (14% vs. 3%), irritability (11% vs. 5%), ataxia (10% vs. 3%), and constipation (10% vs. 0%).

For more information, please see the full Prescribing Information, Medication Guide, and Instructions for Use.

Lundbeck
Your Partner in Epilepsy™