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, including Boxed Warning for risks from concomitant use with opioids, 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

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS
See full Prescribing Information for complete boxed warning.

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.

- **Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.**
- **Limit dosages and durations to the minimum required.**
- **Follow patients for signs and symptoms of respiratory depression and sedation.**

Contraindication: Hypersensitivity

ONFI is contraindicated in patients with a history of hypersensitivity to the drug or its ingredients. Hypersensitivity reactions have included serious dermatological reactions.

Risks from Concomitant Use with Opioids (see Boxed Warning)

Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioids alone. If a decision is made to prescribe ONFI concomitantly with opioids, prescribe the lowest effective dosages and minimum durations of concomitant use. Advise both patients and caregivers about the risks of respiratory depression and sedation when ONFI is used with opioids.

Potentiation of Sedation from Concomitant Use with Central Nervous System (CNS) Depressants

ONFI has a CNS depressant effect. Caution patients or their caregivers against simultaneous use with other CNS depressant drugs or alcohol and that the effects of other CNS depressant drugs or alcohol may be potentiated.

Somnolence or Sedation

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. Monitor patients for somnolence and sedation, particularly with concomitant use of other CNS depressants. 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.

Withdrawal Symptoms

As with all antiepileptic drugs (AEDs), withdraw ONFI gradually to minimize the risk of precipitating seizures, seizure exacerbation, or status epilepticus. Withdrawal symptoms occurred following abrupt discontinuation of ONFI; the risk of withdrawal symptoms is greater with higher doses.

Serious Dermatological Reactions

Serious skin 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. Discontinue ONFI at the first sign of rash, unless the rash is clearly not drug-related.

Physical and Psychological Dependence

Carefully monitor patients with a history of substance abuse 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.

Suicidal Behavior and Ideation

AEDs, including ONFI, increase the risk of suicidal thoughts or behavior in patients. Inform patients, their caregivers, and families of the risk and advise them to monitor and report any emergence or worsening of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, 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.

Pregnancy, Registry and Nursing Mothers

- Based on animal data, ONFI may cause fetal harm and should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.
  - Encourage patients to call the toll-free number 1-888-233-2334 to enroll in the Pregnancy Registry or visit http://www.aedpregnancyregistry.org/.
- ONFI is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from ONFI, discontinue nursing or discontinue the drug.

Adverse Reactions

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, including Boxed Warning for risks from concomitant use with opioids; Medication Guide; and Instructions for Use.

Lundbeck
Your Partner in Epilepsy™

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