

# ONFI® (clobazam) IV Insurance Information Form

This form is to be used to confirm insurance coverage for ONFI.



## 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: \_\_\_\_\_

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

### 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: \_\_\_\_\_

ONFI Prescribing Information: Is the patient currently taking ONFI?  Yes  No

Drug Strength: \_\_\_\_\_ Quantity Prescribed: \_\_\_\_\_

Directions for Use: \_\_\_\_\_ Estimated Duration of ONFI Therapy: \_\_\_\_\_

## Step 3: Prescriber Authorization

I certify that, to the full extent required by applicable law, I have obtained written permission from my patient named above (or from the patient's legal representative) to release to the ONFI Support Center ("the OSC"), the patient's personal health information, both as provided on this form and such other personal health information as the OSC may need (1) to perform a preliminary verification of the patient's insurance coverage for ONFI, (2) to assess the patient's eligibility for participation in ONFI patient support programs, (3) to enroll the patient with the OSC, and (4) to provide reimbursement support and other informational support for the patient in connection with the patient's ONFI prescription(s). I agree that the OSC may contact me, including without limitation via email, fax, and telephone, to seek additional information relating to this form, the ONFI patient support programs, and the OSC.

I understand that any ONFI provided at no charge to the patient is provided on a complimentary basis. I will not submit or cause to be submitted any claims for payment or reimbursement for such products to any third-party payor, including a federal health care program. If I am or become in possession of such product, I will not resell or attempt to resell the product.

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Please complete this form in its entirety and fax to the OSC at 1-855-547-8278.**

**If you have any questions or need additional information, please call the OSC 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.

Completion of this form allows the OSC to provide informational support for ONFI patients.



# 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 ( $\geq 10\%$  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.](#)

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