ONFI® (clobazam) CIV 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).

For more information, please see the full Prescribing Information, including Boxed Warning, Medication Guide, and Instructions for Use, or visit ONFIHCP.com.

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

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

Indications and Usage

ONFI® (clobazam) CIV 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; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS

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 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.

The use of benzodiazepines, including ONFI, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death.

- Before prescribing ONFI and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.

Abrupt discontinuation or rapid dosage reduction of ONFI after continued use may precipitate acute withdrawal reactions, which can be life-threatening.

- To reduce the risk of withdrawal reactions, use a gradual taper to discontinue or reduce the dosage of ONFI.

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.

WARNING: Risks from Concomitant Use with Opioids

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.

WARNING: Abuse, Misuse, and Addiction

Abuse and misuse of benzodiazepines often (but not always) involves the use of doses greater than the maximum recommended dosage and commonly involves concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes, including respiratory depression, overdose, or death.

Use of ONFI, particularly in patients at elevated risk, necessitates counseling about the risks and proper use of ONFI along with monitoring for signs and symptoms of abuse, misuse, and addiction. Prescribe the lowest effective dosage; avoid or minimize concomitant use of Central Nervous System (CNS) depressants and other substances associated with abuse, misuse, and addiction (e.g., opioid analgesics, stimulants); and advise patients on the proper disposal of unused drug. If a substance use disorder is suspected, evaluate the patient and institute (or refer them for) early treatment, as appropriate.

WARNING: Dependence and Withdrawal Reactions

Patients at an increased risk of withdrawal reactions after benzodiazepine discontinuation or rapid dosage reduction include those who take higher dosages and those who have had longer durations of use.

The continued use of benzodiazepines, including ONFI, may lead to clinically significant physical dependence. Abrupt discontinuation or rapid dosage reduction of ONFI after continued use, or administration of flumazenil (a benzodiazepine antagonist) may precipitate **acute withdrawal reactions**, which can be life-threatening (e.g., seizures).

In some cases, benzodiazepine users have developed **protracted withdrawal syndrome** with withdrawal symptoms lasting weeks to more than 12 months.

Please see additional Important Safety Information on next page.

Lundbeck

ONFI® (clobazam) CIV Insurance Information Form

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

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

Important Safety Information continued

Potentiation of Sedation from Concomitant Use with 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.

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.

Drug Reaction with Eosinophilia and Systemic Symptoms

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as Multiorgan Hypersensitivity, has been reported in patients taking antiepileptic drugs, including ONFI. DRESS typically, although not exclusively, presents with fever, rash and/or lymphadenopathy, in association with other organ system involvement. Eosinophilia is often present. If such signs or symptoms are present, then the patient should be evaluated immediately. ONFI should be discontinued immediately and not restarted unless an alternative etiology for the signs or symptoms can be established.

Suicidal Behavior and Ideation

Antiepileptic drugs (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.

Neonatal Sedation and Withdrawal Syndrome

Use of ONFI late in pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) and/or withdrawal symptoms (hyperreflexia, irritability, restlessness, tremors, inconsolable crying, and feeding difficulties) in the neonate. Monitor neonates exposed to ONFI during pregnancy or labor for signs of sedation and monitor neonates exposed to ONFI during pregnancy for signs of withdrawal.

Pregnancy, Registry and Nursing Mothers

- Talk to your patients about enrolling in the North American Antiepileptic Drug Pregnancy Registry; encourage them to call 1-888-233-2334 or visit http://www.aedpregnancyregistry.org/.
- Published data from observational studies on the use of benzodiazepines during pregnancy do not report a clear association with benzodiazepines and major birth defects. Although early studies reported an increased risk of congenital malformations with diazepam and chlordiazepoxide, there was no consistent pattern noted. In addition, the majority of more recent case-control and cohort studies of benzodiazepine use during pregnancy, which were adjusted for confounding exposures to alcohol, tobacco and other medications, have not confirmed these findings.
- 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.
- ONFI is excreted in human milk. Because of the potential for serious adverse reactions from ONFI in nursing infants, discontinue nursing or discontinue the drug.

Overdosage Management

In managing benzodiazepine overdosage, employ general supportive measures, including intravenous fluids and airway maintenance. Flumazenil is contraindicated in patients who have received a

Please see additional Important Safety Information on next page.

Lundbeck

ONFI® (clobazam) CIV Insurance Information Form

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

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

Important Safety Information continued

benzodiazepine for control of a potentially life-threatening condition (e.g., status epilepticus). The risk of withdrawal seizures with flumazenil may be increased in patients with epilepsy. Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdosage management recommendations.

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, Medication Guide, and Instructions for Use, or visit ONFIHCP.com.

Lundbeck