Ongentys® (opicapone) capsules

PATIENT ASSISTANCE PROGRAM

INBRACE® SUPPORT PROGRAM

To be completed in full, signed, and dated, then faxed to 833-578-0346.
For additional assistance, call 833-ONGENTYS (833-664-3689), 8 AM – 8 PM EST, M – F.

- Only completed ONGENTYS® (opicapone) capsules Patient Assistance Program Applications will be reviewed for patient program eligibility. Please ensure all areas of the form are completed in full with all signatures.
- Applicants must reside in the continental United States or its territories, meet the program financial requirements, and must not have prescription coverage for ONGENTYS in order to qualify. Each applicant will be assessed for individual program eligibility upon receipt of this completed ONGENTYS Patient Assistance Program Application.

1 Patient Information

First Name:	Last Name:	DOB: / /
Address:	City:	State: ZIP:
Last 4 digits of the SSN:	US Resident: Yes ☐ No ☐	Gender: Male ☐ Female ☐
Preferred Phone:	Mobile Phone? Yes ☐ No ☐	Email:
Alternate Contact/Caregiver:	Alt Contact/Caregiver Phone:	

Patient Signature: Date:

By signing here, I authorize the use and disclosure of my Protected Health Information as explained on page 3.

(Optional) Ship Prescription to: ☐ Caregiver ☐ HCP office

☐ **I consent to have my prescription shipped to preference above.**

2 Patient Insurance Information–Please attach a copy of the patient's insurance card (check below if no insurance)

☐ Patient does not have insurance.	**Medical Insurance Name:**	**Prescription Insurance Name:**	
Phone:	Cardholder ID #:	Phone:	Cardholder ID #:
Policyholder Name & DOB: / /		BIN:	PCN:

3 Financial Information–If information is unavailable, ONGENTYS program specialists will contact the patient

Total Monthly Gross Household Income: $ | Household Size (select one): 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐

Select Your Sources of Income: Salary/Wages ☐ SS Pension/Unemployment ☐ Alimony/Child Support ☐ Retirement ☐ SSDI ☐ SSI ☐

No Household Income ☐ Other ☐: _____

Income subject to verification

4 Clinical Information

Primary Diagnosis Code Category: ☐ **Parkinson's Disease (G20)** ☐ Other diagnosis: Allergies:

5 Prescriber Information

Prescriber Name:			Prescriber NPI #:
Facility Name:			
Address:	City:	State:	ZIP:
Phone:	Fax:		
Office Contact Name:	Phone:	Fax:	Email Address:
Referring Pharmacy Name:	Address:		Phone:

6 Prescription for ONGENTYS Capsules

☐ ONGENTYS® (opicapone) 50 mg
Directions: Take 1 capsule by mouth at night without food
Dispense: One-month supply
Refills: _____

OR

☐ ONGENTYS® (opicapone) 50 mg
Directions: _____
Dispense: One-month supply
Refills: _____

7 Prescriber Certification

I certify that the information provided in this ONGENTYS® (opicapone) capsules Patient Assistance Program Application is complete and accurate to the best of my knowledge, I have prescribed ONGENTYS based on my judgment of medical necessity, and I will supervise the patient's medical treatment. I certify that I have obtained my patient's written authorization in accordance with applicable state and federal law including the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations to provide the individually identifiable health information on this form to agents and service providers of Neurocrine Biosciences, Inc. (including, but not limited to, ONGENTYS dispensing pharmacies) for benefits eligibility, coverage authorization and coordination, and dispensing of ONGENTYS. I authorize the forwarding of this prescription and information to the INBRACE Support Program Pharmacy. I understand that neither I nor the patient should seek reimbursement for any free or discounted product received under the program. The ONGENTYS Patient Assistance Program requires the healthcare provider or facility to retain proof of patient income on file in their office. For purposes of an audit, the ONGENTYS Patient Assistance Program could ask for a copy of the patient's IRS 1040 form or other proof of income. I agree to notify the service providers if I become aware at any time in the future of changes in my patient's circumstances that would affect his or her eligibility, including but not limited to changes in health insurance status or coverage, financial status, or United States residency status. I understand that Neurocrine Biosciences, Inc. reserves the right to change or terminate the ONGENTYS Patient Assistance Program at any time.

Prescriber Signature: Date:

*(Original signature required - *If required by applicable law, please attach copies of all prescriptions on official state prescription forms)*

Please see Indication and Important Safety Information on page 2.

Neurocrine® BIOSCIENCES

IMPORTANT INFORMATION
INDICATION & USAGE

ONGENTYS® (opicapone) capsules is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS

ONGENTYS is contraindicated in patients with:

- Concomitant use of non-selective monoamine oxidase (MAO) inhibitors.
- Pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms.

WARNINGS & PRECAUTIONS

Cardiovascular Effects with Concomitant Use of Drugs Metabolized by Catechol-O-Methyltransferase (COMT)

Possible arrhythmias, increased heart rate, and excessive changes in blood pressure may occur with concomitant use of ONGENTYS and drugs metabolized by COMT, regardless of the route of administration (including inhalation). Monitor patients treated concomitantly with ONGENTYS and drugs metabolized by COMT.

Falling Asleep During Activities of Daily Living and Somnolence

Patients treated with dopaminergic medications and medications that increase levodopa exposure, including ONGENTYS, have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes has resulted in accidents. If a patient develops daytime sleepiness or somnolence, consider discontinuing ONGENTYS or adjusting other dopaminergic or sedating medications and advise patients to avoid driving and other potentially dangerous activities.

Hypotension/Syncope

Monitor patients for hypotension and advise patients about the risk for syncope. If these adverse reactions occur, consider discontinuing ONGENTYS or adjusting the dosage of other medications that can lower blood pressure.

Dyskinesia

ONGENTYS potentiates the effects of levodopa which may result in dyskinesia or exacerbate pre-existing dyskinesia. Reducing the patient's levodopa dosage or the dosage of another dopaminergic drug may reduce dyskinesia that occurs during treatment with ONGENTYS.

WARNINGS & PRECAUTIONS (cont'd)

Hallucinations and Psychosis

Consider stopping ONGENTYS if hallucinations or psychotic-like behaviors occur. Patients with a major psychotic disorder should ordinarily not be treated with ONGENTYS.

Impulse Control/Compulsive Disorders

Patients may experience intense urges (eg, gambling, sexual, spending money, binge eating) and the inability to control them. It is important for prescribers to specifically ask patients or their caregivers about the development of new or increased urges.

Re-evaluate the patient's current therapies for Parkinson's disease and consider stopping ONGENTYS if a patient develops such urges while taking ONGENTYS.

Withdrawal-Emergent Hyperpyrexia and Confusion

A symptom complex resembling neuroleptic malignant syndrome (elevated temperature, muscular rigidity, altered consciousness, and autonomic instability) has been reported in association with rapid dose reduction or withdrawal of drugs that increase central dopaminergic tone. There were no reports of neuroleptic malignant syndrome in ONGENTYS controlled clinical studies. When discontinuing ONGENTYS, monitor patients and consider adjustment of other dopaminergic therapies as needed.

ADVERSE REACTIONS

The most common adverse reactions (incidence at least 4% and greater than placebo) were dyskinesia, constipation, blood creatine kinase increased, hypotension/syncope, and weight decreased.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying ONGENTYS full Prescribing Information or at https://www.neurocrine.com/assets/ONGENTYS-PI.pdf.

AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

I authorize Neurocrine, companies working with Neurocrine, and my healthcare provider and pharmacy to use and disclose to Neurocrine, and companies working with Neurocrine, my Protected Health Information ("PHI"), such as information provided on the ONGENTYS® (opicapone) capsules Patient Assistance Program Application and the Patient Information provided in Section 1, my prescription, insurance, medical therapy information, and other PHI in connection with financial assistance services, reimbursement support, medication compliance and persistence, and other treatment-related services, as well as any information or materials related to such services (collectively called "Support Services"). I authorize the disclosure of my PHI to specific individuals who are identified on the ONGENTYS Patient Assistance Program Application. I understand that the companies working with Neurocrine, including my pharmacy, may receive payment for the use and disclosure of my PHI. I understand that I do not have to agree to the use and disclosure of my PHI in order to receive ONGENTYS, but without this authorization I may not be able to receive the Support Services. While my PHI will be protected and used and disclosed only for the intended purposes, I understand that once it is disclosed, it may be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further redisclosure. I understand that this authorization shall continue in effect for a period of ten years unless a shorter period is required by law. I understand that I may revoke this authorization to use or disclose my PHI by contacting an INBRACE Support Program representative by telephone (833-664-3689) or by mailing a letter to Neurocrine, Attn: INBRACE Support Program, 12780 El Camino Real, San Diego, CA 92130.