Duopa
carbidopa/levodopa
enteral suspension
4.63 mg/20 mg per mL

DAP-080123-A08

ENROLLMENT AND PRESCRIPTION FORM

DuoCONNECT complete

FAX: 1.844.844.2323
PHONE: 1.844.386.4968

For detailed guidance on completing this form refer to the annotated instruction guide provided on the website.

The Healthcare Provider (HCP) and the patient or legally authorized person should fill out all patient information before the patient leaves the office.

Patient Information

Patient Name: _____ _____
First Last

Date of Birth: _____/_____/_____
Month Date Year

Healthcare Provider Contact Information

Name: _____

Phone #: _____

MINIMUM MEDICAL DOCUMENTATION THAT MUST BE SUBMITTED WITH THIS FORM

Duopa coverage consideration for motor fluctuations requires medical records from the last 6 months by a neurologist who prescribes and manages treatment with carbidopa-levodopa. Submit copies of the following records—each box must be checked by the healthcare provider to indicate the documentation was submitted:

☐ Evidence of an evaluation by a neurologist who prescribes and manages treatment with carbidopa-levodopa

☐ Diagnosis of idiopathic Parkinson's disease
- Include additional evidence of:
  - ☐ Presence of bradykinesia
  - ☐ Presence of at least one other cardinal symptom in addition to bradykinesia (i.e., tremor, rigidity, and/or postural instability)
  - ☐ Duration of patient's condition
  - ☐ Clinical course (worsening or improving)
  - ☐ Prognosis

☐ Motor complications documented with disabling "off" periods for a minimum of 3 hours/day
- Include additional evidence of:
  - ☐ Current treatment with carbidopa-levodopa
  - ☐ Previous/Current treatment of at least one other class of anti-Parkinson's therapy (i.e., COMT inhibitor or MAO-B inhibitor)
  - ☐ Other therapeutic interventions used and therapeutic outcomes
  - ☐ Concomitant medications related and unrelated to Parkinson's disease

☐ Documentation that patient is levodopa-responsive
  - ☐ Include additional evidence of clearly defined "on" periods

This form cannot be processed unless you complete this section and submit the minimum documentation. Requirements for coverage, including minimum documentation, may vary by payer. Updates by the healthcare provider may be needed if patient history changes.

INDICATION[1]

DUOPA (carbidopa and levodopa) enteral suspension is indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease.

SELECT IMPORTANT SAFETY INFORMATION[1]

DUOPA is **contraindicated** in patients who are currently taking or have taken (within 2 weeks) a **nonselective monoamine oxidase (MAO) inhibitor**, as concurrent use can cause hypertension. A percutaneous endoscopic gastrostomy with jejunal extension **(PEG-J) is contraindicated** with lack of transillumination/positive needle aspiration test; intestinal obstruction; sepsis; peritonitis; serious coagulation disorders; ascites; and neoplastic, inflammatory, and infiltrative diseases of the gastric and abdominal walls.

Please see accompanying full Prescribing Information or visit www.duopa.com.
Please see additional Important Safety Information on pages 4 and 5.

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1. PATIENT INFORMATION

The HCP and the patient or legally authorized person should fill out all patient information before the patient leaves the office.

Patient Name: _____ _____
First Last

Date of Birth: _____/_____/_____
Month Date Year

Gender: ☐ Male ☐ Female

Address: _____

City/State/ZIP: _____

Phone #: _____

Email: _____

☐ Check here if patient is a veteran

☐ Check here if an interpreter is needed
Language: _____

Authorized Caregiver Contact Information:

Name: _____

Relationship to patient: _____

Phone #: _____

Email: _____

Facility Information:

Patient Resides in a Facility (e.g., nursing home, hospital) ☐ Yes ☐ No

Name of Facility: _____

Facility Contact Name: _____

Facility Phone #: _____

☐ I consent to the collection, use, and disclosure of my health-related personal data to receive communications from AbbVie regarding its products, programs, services, clinical trials, research opportunities and for online targeted advertising, as further described in the **"How we may use Personal Data," "How we disclose Personal Data,"** and **"Cookies and similar tracking and data collection technologies"** sections of our **Privacy Notice**. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting **"Your Privacy Choices"** on AbbVie's website.

By enrolling, you may receive your own Nurse Ambassador provided by AbbVie. Ambassadors do not work under the direction of your healthcare professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

Privacy Notice: AbbVie may collect your personal data through your online and offline interactions with us, including your contact, demographic, geolocation, and health-related data. For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit **https://abbv.ie/PrivacyPatient**.

Through my submission of the enrollment form, I consent to the collection, use, and disclosure of my personal health data, as described in the Privacy Notice above and in AbbVie's Privacy Notice in the **"How We May Disclose Personal Data"** section. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting **"Your Privacy Choices"** on AbbVie's website.

HIPAA Consent: My signature below certifies that I agree to the HIPAA Authorization on page 4.

Indicate relationship: ☐Patient ☐Authorized Caregiver

Signature: _____ Date: _____

▼ FOR HEALTHCARE PROVIDER USE ONLY ▼

2. INSURANCE INFORMATION

Please fax a copy of all insurance cards, front and back (prescription and medical insurance as needed), with this form to the fax number indicated in the top right corner of this form.

3. SPECIALTY PHARMACY PREFERENCE

Duopa may only be filled at one of the below pharmacies. Patient insurance pharmacy mandates will take precedence for filling pharmacy; however, if no mandate is required by insurance, please select pharmacy preference below:

☐ No Preference ☐ Accredo ☐ CVS ☐ Pharmacy Solutions

4. PROCEDURALIST INFORMATION

Proceduralist Name/Specialty: _____

Facility Name: _____

Address: _____

Office Phone #: _____

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Please see additional Important Safety Information on pages 4 and 5.

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DuoConnect complete

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PHONE: 1.844.386.4968

FOR HEALTHCARE PROVIDER USE ONLY

5. PRESCRIBER INFORMATION

Prescriber Name: _____
Specialty: _____
Clinic Name: _____
Address: _____
City/State/ZIP: _____

NPI #: _____
Office Contact Name: _____
Office Contact Phone #: _____
Office Contact E-mail: _____
Office Fax #: _____

6. DIAGNOSIS AND PRESCRIPTION INFORMATION

In states not permitting dual prescriptions or specific prescription requirements, please fax a separate prescription.

Patient Name: _____ (First) _____ (Last)
Date of Birth: ____ (Month) / ____ (Date) / ____ (Year)

Patient Diagnosis (checkbox is required to confirm diagnosis for aPD):
☐ advanced Parkinson's Disease ICD-10 Code: _____

☐ No Known Allergies (NKDA) Drug Allergies: _____

DUOPA CASSETTES (Carbidopa 4.63 mg/Levodopa 20 mg/mL 100 mL Suspension)
Number of boxes (7 cassettes per box): _____ Days Supply: 28 Refills: _____ SIG: _____

PUMP Route of administration via pump (check one)

☐ Programmed CADD-Legacy® 1400 portable infusion pump for Duopa and pump bag
Lock Level (check one):† ☐ LL1 with Range ☐ LL2
†To be completed only if requesting a programmed pump.

☐ Unprogrammed* (default settings) CADD-Legacy® 1400 portable infusion pump for Duopa and pump bag
*Pump to be programmed by prescriber or agent.

Flow Rates: Required for programmed and unprogrammed pumps

Morning Dose
Dose: _____mL
Range: _____
Lockout Time: _____ or ☐ 20 hrs. (default)

Continuous Dose
Dose: _____mL/hr
Range: _____

Extra Dose
Dose: _____mL
Range: _____
Lockout Time: _____

SUPPLIES If Luer to ENFit™ Transition Connector is needed, check the box and fill in the appropriate quantity and refills. All other supplies are standard.

☒ Female-female Luer Lock	Qty: 28	Refills: 12	SIG: Use once daily
☒ 10 mL Male Luer Lock Syringe	Qty: 28	Refills: 12	SIG: Use once daily
☒ AA Batteries	Qty: 8	Refills: 12	SIG: Change once weekly
☐ Luer to ENFit™ Transition Connector (clear)	Qty: _____	Refills: _____	SIG: _____ or ☐ Not Applicable

HCP ACKNOWLEDGEMENT: If the "Programmed" option above is selected, I acknowledge and agree that I am responsible for the accuracy of all information necessary for programming of the pump, including information provided in the section entitled "Flow Rates for Continuous Infusion". In addition, I am responsible for providing the Specialty Pharmacy with any additional instruction or information for such programming, as necessary, including prescription changes. If the "Unprogrammed" option above is selected, I acknowledge and agree that I am responsible for the programming of the pump. I agree to provide information in the section entitled: "Flow Rates for Continuous Infusion".

HCP Privacy Notice: AbbVie may collect your personal data through your online and offline interactions with us, including your contact, demographic, geolocation, and professional data. For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit https://abbv.ie/PrivacyHCP.

PRESCRIBER SIGNATURE AND DATE – STAMP SIGNATURE NOT ALLOWED

_____ _____ _____ _____
☐ Dispense as written/Do not substitute Date ☐ Substitution permitted/Brand exchange permitted Date

I authorize DuoConnect Complete to act on my behalf for the limited purposes of transmitting this prescription by any means allowed under applicable law to the appropriate pharmacy designated by the patient utilizing their benefit plan.

Please see accompanying full Prescribing Information or visit www.duopa.com.
Please see additional Important Safety Information on pages 4 and 5.

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HIPAA AUTHORIZATION

Please read the following, then date and sign where indicated on page 2, section 1. **This page must be included when faxed.**

I authorize my health care providers and staff, health plan, and pharmacies (collectively, my "Healthcare Providers") to disclose individually identifiable information about me, my health or condition(s), treatment and care that I have received, my insurance coverage, my payment information, and my medication history and prescriptions (collectively, "Protected Health Information") to AbbVie Inc. and/or its designated affiliates, agents, representatives, and service providers (collectively, "AbbVie") in order for AbbVie to (i) enroll me in, provide, operate and administer the DuoConnect Complete Program; (ii) provide me with information concerning the Program; and (iii) develop, evaluate, and improve products, services, materials, and programs related to my condition or treatment. I understand that Protected Health Information disclosed to AbbVie under this Authorization will no longer be protected by HIPAA and may be subject to redisclosure by AbbVie. I understand that if my Healthcare Companies use or disclose my Personal Information for marketing purposes, they may receive financial remuneration. I understand that I am not required to sign this Authorization and that my Healthcare Providers will not otherwise condition my treatment, payment, health insurance enrollment, or eligibility for health care benefits to which I am otherwise entitled on whether I sign this Authorization. However, I understand that if I do not sign this Authorization, I cannot take part in the Program. I understand that this Authorization will expire once I am no longer participating in the Program, unless I cancel it sooner. I understand that I may cancel this Authorization at any time by making a data subject rights request at **https://abbviemetadata.my.site.com/AbbvieDSRM** or by writing to privacydsr@abbvie.com. However, I understand that if I cancel this Authorization, it will end my enrollment in the Program. I understand that cancelling this Authorization will not affect any use or disclosure of my Protected Health Information that has already taken place in reliance on this Authorization.

Note: You have a right to receive a copy of this Authorization. You may print a copy of or save this Authorization and retain a copy for your records.

IMPORTANT SAFETY INFORMATION[1]

DUOPA is **contraindicated** in patients who are currently taking or have taken (within 2 weeks) a **nonselective monoamine oxidase (MAO) inhibitor,** as concurrent use can cause hypertension. A percutaneous endoscopic gastrostomy with jejunal extension **(PEG-J) is contraindicated** with lack of transillumination / positive needle aspiration test; intestinal obstruction; sepsis; peritonitis; serious coagulation disorders; ascites; and neoplastic, inflammatory, and infiltrative diseases of the gastric and abdominal walls.

Because **DUOPA is administered using a PEG-J or naso-jejunal tube, gastrointestinal complications** can occur, including abscess; bezoar; ileus; implant site erosion / ulcer; intestinal hemorrhage, ischemia, obstruction, or perforation; intussusception; pancreatitis; peritonitis; pneumonia (including aspiration pneumonia); pneumoperitoneum; post-operative wound infection; and sepsis, any of which may require surgery or be fatal. Instruct patients to immediately report abdominal pain, prolonged constipation, nausea, vomiting, fever, or melanotic stool.

Please see accompanying full Prescribing Information or visit www.duopa.com.
Please see additional Important Safety Information on page 5.

IMPORTANT SAFETY INFORMATION[1] (continued)

Patients treated with levodopa (a component of DUOPA) have reported **falling asleep while engaged in activities of daily living**, including the operation of motor vehicles, which sometimes resulted in accidents. Although many of these patients reported somnolence while on levodopa, some perceived that they had no warning signs (sleep attack), such as excessive drowsiness, and believed they were alert immediately prior to the event. For this reason, prescribers should reassess DUOPA-treated patients for drowsiness or sleepiness, especially since some of the events occur well after the start of treatment. Advise patients about the potential to develop drowsiness with DUOPA and ask about factors that may increase risk of **somnolence**. Consider discontinuing DUOPA in patients who report significant daytime sleepiness or episodes of falling asleep during activities that require active participation. For these patients, if a decision is made to continue DUOPA, advise them to avoid driving and other potentially dangerous activities that might result in harm if the patients become somnolent.

Monitor patients for **orthostatic hypotension**, especially after starting DUOPA or increasing the dose.

There is an increased risk for **hallucinations, psychosis, and confusion** in patients taking DUOPA. Hallucinations associated with levodopa may present shortly after the initiation of therapy and may be responsive to dose reduction of levodopa. Patients with a major psychotic disorder should not be treated with DUOPA.

Patients may experience **intense urges** while on DUOPA. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to ask patients or their caregivers specifically about the development of new or increased gambling urges, sexual urges, uncontrolled spending, binge or compulsive eating, or other urges while on DUOPA. Consider reducing the dose or discontinuing DUOPA if a patient develops such urges.

Depression has been reported in patients treated with DUOPA. Monitor patients for depression and concomitant suicidal tendencies.

Withdrawal-emergent hyperpyrexia and confusion, a symptom complex that resembles neuroleptic malignant syndrome (characterized by elevated temperature, muscular rigidity, altered consciousness, and autonomic instability), with no other obvious etiology, has been reported in association with rapid dose reduction, withdrawal, or change in dopaminergic therapy. Avoid sudden discontinuation or rapid dose reduction of DUOPA.

DUOPA may cause or exacerbate **dyskinesias**, which may require a dose reduction of DUOPA or other Parkinson's disease medications.

Generalized polyneuropathy has been reported in patients receiving DUOPA. Assess patients for the signs and symptoms of peripheral neuropathy before and periodically after starting DUOPA, especially patients with pre-existing neuropathy, patients taking medications, or those who have medical conditions associated with neuropathy.

Myocardial infarction and arrhythmia were reported in patients taking carbidopa-levodopa. Ask patients about symptoms of ischemic heart disease and arrhythmia, especially those with a history of myocardial infarction or cardiac arrhythmias.

DUOPA may increase the risk for **elevated blood urea nitrogen (BUN) and creatine phosphokinase (CPK).** Patients taking levodopa may have **increased levels of catecholamines** and their metabolites in plasma and urine, giving false positive results that suggest the diagnosis of pheochromocytoma.

Monitor patients with **glaucoma** after starting DUOPA, as it may cause increased intraocular pressure.

Drug Interactions: Monitor patients taking **selective MAO-B inhibitors** and carbidopa-levodopa for orthostatic hypotension. Concurrent administration with **antihypertensives** may result in postural hypotension, necessitating a dose reduction of the antihypertensive. Co-administration with **dopamine D2 antagonists, isoniazid,** or **iron salts** may reduce effectiveness of DUOPA.

The **most common adverse events** for DUOPA, with an incidence at least 7% greater than oral carbidopa-levodopa immediate release (CLIR), were (DUOPA vs CLIR): complication of device insertion (57% vs 44%), nausea (30% vs 21%), depression (11% vs 3%), peripheral edema (8% vs 0%), hypertension (8% vs 0%), upper respiratory tract infection (8% vs 0%), oropharyngeal pain (8% vs 0%), atelectasis (8% vs 0%), and incision site erythema (19% vs 12%).

Please see accompanying full Prescribing Information or visit www.duopa.com.
Please see additional Important Safety Information on page 4.

Reference: 1. DUOPA [package insert]. North Chicago, IL: AbbVie Inc.