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

DUOCONNECT START FORM AND DUOPA PRESCRIPTION

DuoConnect complete
FAX: 1.844.844.2323
PHONE: 1.844.386.4968

Patient must be 18 years or older to enroll. For detailed guidance on completing this form refer to the instruction guide provided.

1. PATIENT INFORMATION

The HCP and the patient or legally authorized person should fill out this form completely before leaving the office. Please print clearly.

Patient Name: _____ _____
First Last

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

Gender: ☐ Male ☐ Female

Address: _____

City / State / ZIP: _____

Preferred Phone #: _____

☐ Check here if it is NOT ok to leave a message

E-mail: _____

Alternate 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 #: _____

2. PATIENT CONSENT

Please review DuoConnect Patient Support Program description and the privacy notice on page 3 to understand the program and how AbbVie uses your personal data.

By enrolling, you may receive your own Nurse Ambassador. Ambassadors do not give medical advice and are trained to direct patients to their health care professionals for treatment-related advice, including further referrals. To learn about AbbVie's privacy practices and your privacy choices, visit www.abbvie.com/privacy.html

☐ **Marketing Consent:** I would like to receive news and updates about AbbVie's products, clinical trials, research opportunities, programs, and other information that may be of interest to me.

HIPAA Consent: My signature below certifies that I agree to the Patient Authorization on page 3.

Patient / Legal Representative (indicate relationship) Signature: _____ Date: _____

3. INSURANCE INFORMATION

Please fax a copy of all insurance cards (front and back) with this form to the fax number indicated on top of form.

4. SPECIALTY PHARMACY PREFERENCE

In the event that none or more than one of the pharmacies are in network, the below preference will be followed.

☐ No Preference ☐ Pharmacy Solutions ☐ Accredo ☐ <variable>

▼ FOR HEALTHCARE PROVIDER USE ONLY ▼

5. PROCEDURALIST INFORMATION

Proceduralist Name / Specialty: _____

Office Phone #: _____

Facility Name: _____

Address: _____

Medicare Local Coverage Determination Criteria

Duopa is only covered for treatment of motor fluctuations in beneficiaries, who meet all of the following criteria.[1] Clinical documentation *in the form of patient history and progress notes dated and signed within the previous 6 months* must be provided with each Duopa prescription. Please be aware that coverage requirements vary by payor.

- Evaluation by neurologist who prescribes and manages treatment with carbidopa-levodopa; and
- Diagnosis of idiopathic Parkinson's disease based on the presence of bradykinesia and at least one other cardinal Parkinson's disease feature (tremor, rigidity, postural instability); and
- Levodopa responsive with clearly defined "on" periods; and
- Persistent motor complications with disabling "off" periods for a minimum of 3 hours / day, despite medical therapy with carbidopa-levodopa, and at least one other class of anti-Parkinson's disease therapy (i.e., COMT inhibitor or MAO-B inhibitor)

Please see accompanying Full Prescribing Information or visit www.duopa.com.
Please see Indication & Important Safety Information on pages 3 and 4.

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6. PRESCRIBER INFORMATION

Prescriber Name: _____
Specialty: _____
Clinic Name: _____
Address: _____
City / State / ZIP: _____
NPI#: _____
Office Contact Name: _____
Office Contact Phone #: _____
Office Contact E-mail: _____
Office Fax #: _____

7. PRESCRIPTION INFORMATION

(in states not permitting dual prescriptions or specific prescription requirements, please fax a separate prescription)

Patient Name: _____ (First) _____ (Last) Patient's Diagnosis ICD 10 Code: _____

Date of Birth: _____ (Month) / _____ (Date) / _____ (Year) Drug Allergies: _____

DUOPA CASSETTES (Carbidopa 4.63mg / Levodopa 20mg / ml 100ml 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
- ☐ Non-programmed* (default settings) CADD-Legacy® 1400 portable infusion pump for Duopa and pump bag
  *Pump to be programmed by prescriber or agent

Lock Level (check one): ☐ LL1 with Range ☐ LL2

Flow Rates:

Morning Dose	Continuous Dose	Extra Dose
Dose: _____ mL	Dose: _____ mL / hr	Dose: _____ mL
Range: _____	Range: _____	Range: _____
Lockout Time: _____		Lockout Time: _____

SUPPLIES

☐ Female-female Luer Lock	Qty: _____	Refills: _____	SIG: _____
☐ 10 mL Male Luer Lock Syringe	Qty: _____	Refills: _____	SIG: _____
☐ AA Batteries	Qty: _____	Refills: _____	SIG: _____
☐ Luer to ENFit™ Transition Connector (clear)[6]	Qty: _____	Refills: _____	SIG: _____

HCP CONSENT: I acknowledge that I have assisted the patient in enrolling in the DuoConnect program and have received the necessary authorizations to release the patient's Health Information to AbbVie, its affiliates, and agents to determine my patient's eligibility and to administer the DuoConnect Program. I authorize DuoConnect to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan, and obtaining patient benefit information and the necessary prior authorization forms when dealing with the Health Plan and Pharmacy Benefits Managers (PBMs), if the Plan or PBM requires such authorization. I understand that a representative from the specialty pharmacy will contact the patient to obtain authorization prior to shipping the prescription.

PRESCRIBER SIGNATURE AND DATE – STAMP SIGNATURE NOT ALLOWED

☐ Dispense as written / Do not substitute _____ Date

☐ Substitution permitted / Brand exchange permitted _____ Date

Please see accompanying Full Prescribing Information or visit www.duopa.com.
Please see Indication & Important Safety Information on pages 3 and 4.

HIPAA AUTHORIZATION (Please read the following, then date and sign where indicated on page 1, section 2)

I authorize my healthcare providers, pharmacies, insurers, and laboratory testing facilities (my "Healthcare Companies") to disclose information about me, my medical condition, treatment, insurance coverage, and payment information in relation to my use of AbbVie products, to AbbVie, its affiliates, and agents / contractors (collectively "AbbVie"), to enroll me in and provide me with DuoConnect Services. I understand that information released under this Authorization will no longer be protected by HIPAA. I also 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 Companies will not condition my treatment, payment, enrollment, or eligibility for benefits on whether I sign this Authorization. This Authorization will expire in 10 years or a shorter period if required by state law, unless I cancel it sooner by calling 1.844.386.4968, or by writing 200 Pinecrest Plaza, Morgantown, WV 26505.

I understand that cancelling my Authorization will not affect any use of my information that occurred before my request was processed. I am entitled to a copy of this signed authorization.

DUOCONNECT PRIVACY NOTICE

By submitting this form you are referring the above patient to AbbVie's patient support program to determine eligibility and receive support related to an AbbVie product. AbbVie, its affiliates, collaborators, and agents will use this information to provide the patient support and perform research and analytics, on a de-identified basis, for management of the program. For more information, visit **www.abbvie.com/privacy.html**.

INDICATION[2]

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

IMPORTANT SAFETY INFORMATION[2, 4, 5]

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 Indication & Important Safety Information on pages 3 and 4.

IMPORTANT SAFETY INFORMATION[2, 4, 5]

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.

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 full Prescribing Information.

References: 1. Local coverage determination (LCD): External infusion pumps (L33794). https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD: Updated 1/1/2018. Accessed May 22, 2018. **2.** DUOPA [package insert]. North Chicago, IL: AbbVie Inc. **3.** CADD-Legacy® 1400 Pump Operator's Manual. St Paul, MN: Smiths Medical ASD, Inc; 2015 **4.** AbbVie J Intestinal Tube 9 FR for PEG 15 and 20 FR [instructions for use]. North Chicago, IL: AbbVie Inc. **5.** AbbVie PEG Percutaneous Endoscopic Gastrostomy Kit [instructions for use]. North Chicago, IL: AbbVie Inc. **6.** Enteral Luer to ENFit™ Transition Connector [Instructions for use].