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

DUOCONNECT START FORM AND DUOPA PRESCRIPTION

US-DUOP-181333

FAX: 1-(844)-844-2323
PHONE: 1-(844)-386-4968

1. PATIENT INFORMATION

Patient Name: _____
Gender: ☐ Male ☐ Female
Preferred Language: ☐ English ☐ Spanish
Address: _____
City / State / ZIP: _____
Preferred Phone #: _____
Additional Phone #: _____
E-mail: _____

Alternate Contact Name: _____
Alternate Contact Relationship: _____
Alternate Contact Phone #: _____
Patient Resides in a Facility (e.g., nursing home, hospital) ☐ Yes ☐ No
Name of Facility: _____
Facility Contact Name: _____
Facility Address: _____
Facility Phone #: _____

2. PATIENT CONSENT & SPECIALTY PHARMACY PREFERENCE

Please review the privacy notice on page 4 to understand how AbbVie uses your personal data.

Marketing Consent:

☐ I would like to receive communications related to AbbVie's products, clinical trial, research opportunities, and other services.

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

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

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 ☐ Accredo ☐ Pharmacy Solutions

3. INSURANCE INFORMATION

Please fax a copy of all insurance cards (front and back) with this form to: 1-(844)-844-2323.

Primary Insurance
Insurance Name(s): _____
Phone #(s): _____ Policy #(s): _____

Secondary Insurance
Insurance Name(s): _____
Phone #(s): _____ Policy #(s): _____

4. PROCEDURALIST INFORMATION

Proceduralist Name / Specialty: _____
Facility Name: _____
Address: _____
City / State / ZIP: _____
Office Contact Name: _____
Office Phone #: _____

5. PEG-J PROCEDURE

Consult Date (if applicable): _____
PEG-J Date: _____
Procedure Location: ☐ Proceduralist Office (Section 4)
☐ Other: _____

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 Indication and Important Safety Information on page 5 and full Prescribing Information at https://www.rxabbvie.com/pdf/duopa_pi.pdf.

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6. PRESCRIBER INFORMATION

Prescriber Name: _____
Prescriber Specialty: _____
Facility Name: _____
Address: _____
City / State / ZIP: _____
Prescriber E-mail: _____
NPI#: _____

Office Contact Name: _____
Office Phone #: _____
Office Fax #: _____
Office E-mail: _____
Referring Neurologist Name: _____
City / State / ZIP: _____

7. PRESCRIPTION INFORMATION (In states not permitting dual prescriptions or specific prescription requirements, please fax a separate prescription)

Patient Name: _____ Patient's Diagnosis ICD 10 Code: _____
DOB: _____ Drug Allergies: _____ ☐ NKDA

DUOPA CASSETTES

Number of boxes (7 cassettes per box):_____ Days Supply: 28 Refills: _____ SIG: _____

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 (include dose range, if applicable; see page 3 for examples of Dose Calculations):

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

SIG Directions: Use to infuse Duopa cassettes

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

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GENERAL DOSING CONSIDERATIONS[2]

- Prior to initiating Duopa, patients should be converted from all other forms of levodopa to oral carbidopa/levodopa immediate release (CLIR; 1:4 ratio)
- Duopa (carbidopa and levodopa) enteral suspension is administered over a 16-hour infusion period. The daily dose is determined by individualized patient titration and composed of a Morning Dose, a Continuous Dose, and Extra Doses
- At the end of the daily 16-hour infusion, patients disconnect the pump from the PEG-J and may take their nighttime dose of oral CLIR and other Parkinson's medications as prescribed
- Maximum recommended dose of Duopa: 2000 mg of levodopa (one cassette per day) administered over 16 hours
- Patients should be prescribed oral CLIR in the event that they are unable to administer Duopa for >2 hours during the daily dosing period

DAY 1: DOSE CALCULATIONS[2]

Step 1: Duopa Morning Dose

a. Determine the total amount of levodopa (in mg) in the first dose of oral CLIR that was taken by the patient on the previous day

b. Convert that oral levodopa dose from milligrams (mg) to milliliters (mL) by multiplying the oral dose by 0.8 and dividing by 20 mg/mL. This calculation provides the Morning Dose of Duopa in milliliters

c. Add 3 mL to the Morning Dose to fill (prime) the intestinal tube to obtain the Total Morning Dose

d. The Total Morning Dose is usually administered over 10 to 30 minutes

EXAMPLE

Patient's Usual Oral Morning Levodopa Dose = 200 mg

1. 200 mg × 0.8 Duopa Conversion Factor = 160 mg
2. $\frac{160\ \text{mg}}{20\ \text{mg/mL}}$ = 8 mL Duopa Morning Dose
3. 8 mL + 3 mL = 11 mL Total Morning Dose Volume

Step 2: Duopa Continuous Dose

a. Determine the amount of levodopa that the patient received from oral CLIR doses throughout the previous day (16 waking hours), in milligrams. Do not include the doses of oral CLIR taken at night when calculating the levodopa amount

b. Subtract the first morning oral levodopa dose in milligrams taken by the patient on the previous day (determined in Step 1a) from the total oral levodopa dose in milligrams taken over 16 waking hours (determined in Step 2a). Divide the result by 20 mg/mL. This is the dose of Duopa administered as a Continuous Dose (in mL) over 16 hours

c. The hourly infusion rate (mL per hour) is obtained by dividing the Continuous Dose by 16 (hours)

EXAMPLE

Previous Day's Oral Levodopa Dose = 1200 mg
First Morning Oral Levodopa Dose = 200 mg

1. 1200 mg – 200 mg = 1000 mg
2. $\frac{1000\ \text{mg}}{20\ \text{mg/mL}}$ = 50 mL 16-hour Continuous Dose
3. $\frac{50\ \text{mL}}{16\ \text{hr}}$ = 3.125 mL/hr Hourly Infusion Rate

Extra Doses

Duopa has an Extra Dose function that can be used to manage acute "off" symptoms that are not controlled by the Morning Dose and the Continuous Dose administered over 16 hours. The Extra Dose function should be set at 1 mL (20 mg of levodopa) when starting Duopa. Limit use to every 2 hours. Administration of frequent Extra Doses may cause or worsen dyskinesia.

Lockout Times[3]

The lockout time is the minimum amount of time which must elapse between the start of one dose and the start of the next.

Recommend Tubing Sets

AbbVie PEG 15 or 20 Fr and AbbVie J tubing are the recommended tubing sets for long-term PEG-J DUOPA administration.

For complete pump programming instructions please refer to the CADD-Legacy 1400 Pump Operations Manual.

Please see Indication and Important Safety Information on page 5 and full Prescribing Information at https://www.rxabbvie.com/pdf/duopa_pi.pdf.

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 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.

DUOCONNECT PATIENT SUPPORT PROGRAM DESCRIPTION AND PRIVACY NOTICE

The DuoConnect Program is an AbbVie-sponsored coordination of care program designed to provide personalized patient support. In order for you to participate, AbbVie, its affiliates, and agents (collectively "AbbVie") will use and disclose your personal information, including your health information, collected on the enrollment form on page 1 and through participation in DuoConnect for the following purposes:

1. To enroll you in and provide you with DuoConnect Programs and related support services, including: reimbursement support services, financial assistance (if eligible), peer mentor services, nursing services at home and by phone, services to help you and your physicians coordinate the shipment of your medication, and other support services ("DuoConnect Services").
2. To perform research and data analytics to develop and evaluate products, services, materials, and treatments.
3. To contact you or your alternate contact (if listed) with: (a) informational materials related to Parkinson's disease, relevant patient programs, Duopa, and the use of your prescribed AbbVie products; and, (b) if you have checked the "Marketing Consent" box on page 1, marketing materials related to AbbVie's products, clinical trial, research opportunities, and other services.

AbbVie may combine the information it receives about you with information from other sources. However, AbbVie will not sell or rent any information that can identify you to third parties for their own purposes or otherwise use or disclose any information that can identify you for any purpose not authorized above.

If you have questions about this Privacy Notice, want to update your information, terminate your DuoConnect enrollment, or opt-out of AbbVie marketing, please call 1-844-386-4968 or write to 200 Pinecrest Plaza, Morgantown, WV 26505.

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.

Because **DUOPA is administered using a PEG-J or naso-jejunal tube, gastrointestinal complications** can occur, including bezoar; ileus; implant site erosion / ulcer; intestinal hemorrhage, ischemia, obstruction, or perforation; intussusception; pancreatitis; peritonitis; pneumoperitoneum; and wound infection, 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 patients for drowsiness or sleepiness in DUOPA-treated patients, 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.

Parkinson's disease patients have a higher risk of developing **melanoma** than the general population and should be monitored periodically for melanoma.

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 at https://www.rxabbvie.com/pdf/duopa_pi.pdf.

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].