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

Getting your patients started

DuoConnect complete

This checklist may help you complete and provide the necessary documentation required.

Please be sure to provide ALL required information listed below. Incomplete submissions may cause delays in your patients starting on Duopa.

Complete the DuoConnect Complete Enrollment and Prescription Form

- ❑ Provide all patient demographic information, including authorized caregiver's name and phone number
- ❑ Provide **all patient insurance information**, including secondary and tertiary insurance information (photocopies accepted)
- ❑ Ensure the patient signs and dates the consent and selects a specialty pharmacy preference
- ❑ If patient resides in a Facility, please provide the facility's information (e.g. Name, contact, phone number, address)
- ❑ Provide all proceduralist information
- ❑ Include physician demographics, signature and date where indicated
- ❑ Provide all prescription details, including:
  - ❑ ICD-10 Code
  - ❑ No. of cassette boxes
  - ❑ All pharmacy instructions (i.e., SIG lines)
  - ❑ Pump lock level (only if requesting a programmed pump)
  - ❑ Dose and flow rates
  - ❑ Separate or alternative prescription, per state laws

Prepare supporting documentation

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 (e.g., 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

Common missing information that can cause delays in treatment includes:

- Supportive documentation of "off" periods – must be noted in hours/days
- Documented bradykinesia
- Physician signature and date on the prescription

The Specialty Pharmacy and/or DuoConnect Complete will contact you with questions and/or clarifications.

If you have specific questions regarding clinical documentation, you may contact the Specialty Pharmacy:
▪ Accredo 888.200.2811 ▪ CVS 877.437.8469 ▪ Pharmacy Solutions 877.648.3738

Fax all information to DuoConnect Complete to 1.844.844.2323

- ❑ **Completed DuoConnect Complete Enrollment and Prescription Form**
  - ❑ **Must include HIPAA Authorization from page 4**
- ❑ **Patient Insurance Card(s)**
  - ❑ **Must include a picture of the front and back of each insurance card being used**
- ❑ **Supporting documentation**

Questions?
DuoConnect Complete is here to help

CALL 1.844.386.4968

Please see Indication & Important Safety Information on page 6.
Please see accompanying Full Prescribing Information or visit www.duopa.com.

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: Jane (First) Doe (Last)

Date of Birth: April (Month) / 17 (Date) / 1974 (Year)

Healthcare Provider Contact Information

Name: Susan Barber ABC Medical Center

Phone #: 555.912.7262

MINIMUM MEDICAL DOCUMENTATION THAT MUST BE SUBMITTED WITH THIS FORM

Clinical documentation is required. Please check each box and submit accompanying records.

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.

Please see Indication & Important Safety Information on page 6.
Please see accompanying Full Prescribing Information or visit www.duopa.com.

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

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: Jane (First) Doe (Last)

Date of Birth: April (Month) / 17 (Date) / 1974 (Year)

Gender: ☐ Male ☒ Female

Address: 1234 Spring Street

City/State/ZIP: Any Town, CA 12345

Phone #: 555.621.9981

Email: jane.doe@email.com

☐ Check here if patient is a veteran

☐ Check here if an interpreter is needed

Language:

Authorized Caregiver Contact Information:

Name: Jeff Doe

Relationship to patient: Spouse

Phone #: 555.687.9763

Email: jeff.doe@email.com

Facility Information:

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

Name of Facility: ABC Medical Center

Facility Contact Name: Susan Barber

Facility Phone #: 555.912.7262

☒ 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: Jane Doe Date: 3/17/2020

▼ 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: Andrew Jackson / GI

Facility Name: ABC Medical Center

Address: 123 Main Street

Office Phone #: 555.142.2246

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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Adding your authorized caregiver's information enables direct coordination.

The patient should check this box if they want to receive communications related to AbbVie's products, clinical trial(s), research opportunities, and other services.

Patient signature is required to release Personal Health Information.

Please fax a copy of the insurance cards.

The patient should check one of the boxes to identify their pharmacy preference.

In order to coordinate care, provide the proceduralist information here.

- Note: Proceduralist information is not required to enroll in DuoConnect Complete.

Please see Indication & Important Safety Information on page 6.
Please see accompanying Full Prescribing Information or visit www.duopa.com.

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

Sample

DuoConnect Complete Enrollment and Prescription Form

DuoConnect Complete

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 HEALTHCARE PROVIDER USE ONLY

5. PRESCRIBER INFORMATION

Prescriber Name: John Adams
Specialty: Neurology
Clinic Name: ABC Medical Center
Address: 123 Main Street
City/State/ZIP: Any Town, CA 12345

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: Jane (First) Doe (Last)

Patient Diagnosis (checkbox is required to confirm diagnosis for aPD):

Date of Birth: April (Month) / 17 (Date) / 1974 (Year)

☐ advanced Parkinson's Disease ICD-10 Code:

ICD-10 code is required.

☐ No Known Allergies (NKDA) Drug Allergies: None

DUOPA CASSETTES (Carbidopa 4.63 mg/Levodopa 20 mg/mL 100 mL Suspension)

Number of boxes (7 cassettes per box): 4 Days Supply: 28 Refills: 12 SIG: Administer 1 Duopa Cassette via PEG-J and CADD-Legacy 1400 Pump daily

Pharmacy instructions are required (e.g., Administer 1 Duopa Cassette via PEG-J and CADD-Legacy 1400 Pump daily).

PUMP Route of administration via pump (check one)

☐ Programmed CADD-Legacy® 1400 portable infusion pump for Duopa and pump bag

☒ Unprogrammed* (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

†To be completed only if requesting a programmed pump.

Only needed for programmed pumps —
LL1 with range: Allows limited dose adjustments by the patient
LL2: No patient access to the pump programming functions

Flow Rates: Required for programmed and unprogrammed pumps

Morning Dose	Continuous Dose	Extra Dose
Dose: 6.5 (includes 3ml tube prime)	Dose: 2.8 mL/hr	Dose: 1.0
Range: 6.0-7.0	Range: 2.5-3.0	Range: 1.0-1.5
Lockout Time: 20 hrs or ☐ 20 hrs. (default)		Lockout Time: 2 hrs

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.

	Qty	Refills	SIG
☒ Female-female Luer Lock	28	12	Use once daily
☒ 10 mL Male Luer Lock Syringe	28	12	Use once daily
☒ AA Batteries	8	12	Change once weekly
☒ Luer to ENFit™ Transition Connector (clear)	30	12	Use once daily or ☐ Not Ap

⚠ Warnings:
- Do not disclose to the patient the pump's security codes or any other information that would allow the patient complete access to all programming and operating functions. Improper programming could compromise patient treatment.
- Programming the pump at a delivery rate other than what is prescribed will cause over- or underdelivery of medication.

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

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

PRESCRIBER SIGNATURE AND DATE – STAMP SIGNATURE NOT ALLOWED

John Adams 3/17/2020

☒ 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 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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Number of boxes required for 1 cassette per day

1 box = 7-day supply

2 boxes = 14-day supply

4 boxes = 28-day supply

If you select the "programmed" option, the pump will arrive "pre-programmed" with the settings here. If no selection is made or if you select "unprogrammed," the Specialty Pharmacy will send an unprogrammed pump to the patient.

Flow rates are required regardless of "programmed" or "unprogrammed" request. Updates to prescription parameters may be taken by the pharmacy via verbal order.

Dose and dose ranges are provided as examples only. Dose and dose ranges are calculated based on what the HCP determines is appropriate for each patient. For Duopa dosing calculations, guidelines, and examples, please see page 4. Note: Administration of frequent extra doses may cause or worsen dyskinesias.

Please check box if patient will require connectors for ENFit tubing.

Signature of prescriber and date are required.

Pharmacy instructions are required. Indicate specific frequency of use (e.g., use one daily).

Pharmacy instructions are required. Indicate specific frequency of use (e.g., change once weekly).

Please see Indication & Important Safety Information on page 6.
Please see accompanying Full Prescribing Information or visit www.duopa.com.

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

Dosing

Duopa Dose Calculations

DuoCONNECT complete

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: Duopa Dose Calculations[2]

Step 1: 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: 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.

Recommended Tubing Sets

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

Please see Indication & Important Safety Information on page 6.
Please see accompanying Full Prescribing Information or visit www.duopa.com.

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

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.

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 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. Centers for Medicare & Medicaid Services. Updated June 16, 2023. Accessed October 19, 2023. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33794 **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.

