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

Getting your patients started

DuoConnect Complete is here to help your patients get started on Duopa.
This checklist will 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 Start Form and Duopa Prescription

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

Prepare supporting documentation

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.

Be sure to provide ALL the clinical documentation outlined below:

- **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)**

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**
- **Pharmacy Solutions 877.648.3738**
- **CVS 877-437-8469**

Send all information to DuoConnect Complete through the DuoConnect Complete portal or fax to 1.844.844.2323

- ❑ **Completed DuoConnect Complete Start Form**
- ❑ **Patient Insurance Card(s)**
- ❑ **Duopa Prescription and supporting documentation**

Questions?
DuoConnect Complete is here to help

CALL 1.844.386.4968
8:00 a.m. – 8:00 p.m. EST (Monday—Friday)

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

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Sample

DuoConnect Complete Start Form

DuoConnect Complete

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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: 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
Preferred Phone #: 555.621.9981
☐ Check here if it is NOT ok to leave a message
E-mail: jane.doe@email.com

Alternate 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

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: Jane Doe Date: 3/11/2020

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 ☐ CVS

FOR HEALTHCARE PROVIDER USE ONLY

5. PROCEDURALIST INFORMATION

Proceduralist Name / Specialty: Andrew Jackson / GI
Facility Name: ABC Medical Center
Office Phone #: 555.142.2246
Address: 123 Main Street

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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Adding an alternate contact enables coordination with them directly.

This box should be checked to receive communications related to AbbVie's products, clinical trial, 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 begin DuoConnect services.

Please see Indication & Important Safety Information on page 6.
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Sample
Duopa Prescription

Duo CONNECT complete

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DUOCONNECT START FORM AND DUOPA PRESCRIPTION

Duo CONNECT complete
FAX: 1.844.844.2323
PHONE: 1.844.386.4968

▼ FOR HEALTHCARE PROVIDER USE ONLY ▼

6. 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 #:

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

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

ICD 10 code is required.

Date of Birth: April (Month) / 17 (Date) / 1974 (Year) Drug Allergies: None

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

DUOPA CASSETTES (Carbidopa 4.63mg / Levodopa 20mg / ml 100ml 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

Number of boxes required for 1 cassette per day

1 box = 7 day supply

2 boxes = 14-day supply

4 boxes = 28-day supply

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

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

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

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

You can specify Lock Level 1 or 2 —
LL1 with range: Allows limited dose adjustments by the patient
LL2: No patient access to the pump programming functions

Flow Rates:	Morning Dose	Continuous Dose	Extra Dose
	Dose: 6.5 (includes 3ml tube prime) mL	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		Lockout Time: 2 hrs

For Duopa dosing calculations, guidelines and examples, please see page 4

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. Note: Administration of frequent extra doses may cause or worsen dyskinesias.

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)[6]	Qty: 30	Refills: 12	SIG:	Use once daily

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

HCP CONSENT: I acknowledge that I have assisted the patient in enrolling in the DuoConnect program and have received the necessary authorizations to 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 the benefit plan, and obtaining patient benefit information and the necessary prior authorization forms when dealing with the Health Plan and Pharmacy Benefit Managers (PBMs), if the Plan or PBM requires such authorization. I understand that a representative from the specialty pharmacy will contact the patient to authorization prior to shipping the prescription.

PRESCRIBER SIGNATURE AND DATE – STAMP SIGNATURE NOT ALLOWED

Signature of prescriber and date is required.

John Adams 3/17/2020

☒ Dispense as written / Do not substitute — Date

☐ Substitution permitted / Brand exchange permitted — Date

Warnings:
- Do not disclose to the patient the pumps 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.

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

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Please see Indication & Important Safety Information on page 6.
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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: 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.

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.

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DUOCONNECT START FORM AND DUOPA PRESCRIPTION

DuoCONNECT complete
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PHONE: 1.844.386.4968

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.

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DuoCONNECT complete

Indication[2]

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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].

