

CLES/Duopa therapy for Parkinson's disease

Use within the VA System

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Carbidopa/ Levodopa Enteral Suspension (Duopa) National Drug Monograph March 2016

- VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives
- Updated pdf available at: www.pbm.va.gov or <http://vaww.pbm.va.gov>

CLES - Efficacy

- Safely and effectively treats motor and some non-motor features of PD leading to improved quality of life and reduced off-time without worsening troublesome dyskinesia
- Compared with oral CL-IR from baseline, patients who were levodopa-responsive and had persistent motor fluctuations despite optimized treatment with oral carbidopa-levodopa demonstrated:
 - improved “Off” time (LSM difference -1.91 hours/day; P=0.0015)
 - increased in “On” time without troublesome dyskinesia (LSM difference 1.86 hours/day, P=0.0059)

Olanow CW, Kieburtz K, Odin P, et al. Lancet Neurol.2014;13(2):141–149.

CLES - Safety

- The most common adverse reactions for CLES (incidence $\geq 7\%$ over oral immediate-release carbidopa-levodopa) were:
 - complication of device insertion, incision site erythema, oropharyngeal pain
 - nausea
 - depression
 - peripheral edema
 - hypertension
 - upper respiratory tract infection, atelectasis
- Peripheral neuropathy, not uncommon in PD, may be worsened with CLES. This may be due to higher doses of levodopa required due to discontinuation of other dopamine sparing therapies.

Fernandez HH, Standaert DG, Hauser RA, et al. *Mov Disord.* 2015;30(4):500–509.
Slevin JT, Fernandez HH, Zadikoff C, et al. *J Parkinson's Dis.* 2015;5(1):165–174.

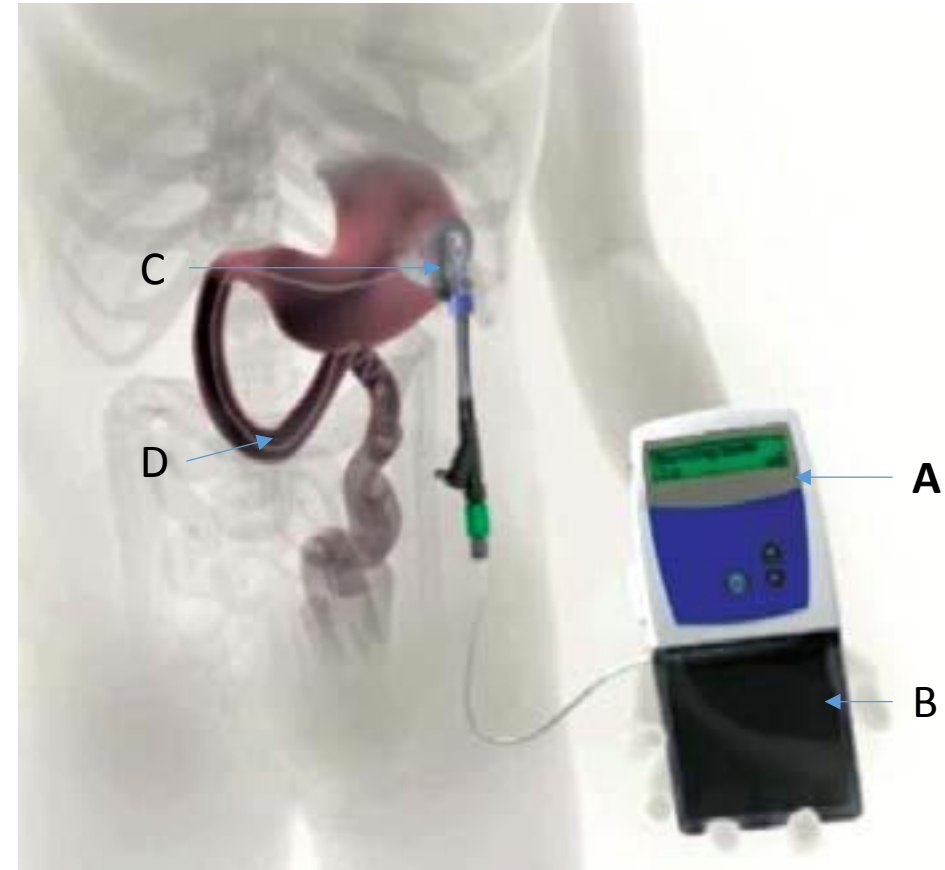
CLES – Potential Impact

- There are 51,625 unique patients in VA diagnosed with PD.
- Development of wearing off and other motor fluctuations is a phenomenon of disease progression. As the disease progresses, the plasma half-life of LD becomes more critical in maintaining clinical effects and motor benefit. The aim of CLES is to “smooth” out these fluctuations.
- Patients with advanced PD can be considered for therapies such as deep brain stimulation (DBS), CLES therapy, or apomorphine infusion (experimental in the US).
- Patients to consider for CLES include those who have been levodopa responsive and are not candidates for deep brain stimulation due to age, cognitive deficits or other medical or psychiatric complications.

CLES - Hardware

- Carbidopa-levodopa enteral suspension and infusion system delivers medication directly to the jejunum for up to 16H.
- Requires a percutaneous endoscopic gastrostomy with jejunal tube for drug delivery
- Bypasses the stomach and is intended to avoid the effects of slowed or delayed gastric emptying

- A. Infusion pump
- B. Duopa cassette
- C. PEG tube
- D. Jejunal tube



CLES - Hardware

- Duopa consists of
 - 100-ml cassette containing carbidopa and levodopa suspension (4.63 mg/20mg per ml)
 - CADD-Legacy[®] 1400 portable infusion pump
- Cassette
 - Must be refrigerated at 36°F – 46°F. Do not freeze.
 - Designated for single use and should not be used longer than 16 hours
 - Should sit at room temperature for 20 minutes prior to use
- A carrying case is provided with the pump

Members of the Duopa Team

- An MDS
- A proceduralist skilled in PEG-J placement
- A nurse, PA-C and/or other health care provider
- Available AbbVie resources include a 24/7 patient call center:
 - Nurse Case Manager provides one-on-one support with patient on-boarding, reimbursement, coordination of Duopa shipments, on-going f/u.
- Home nurse visits for training support:
 - “Welcome Visit”: Before procedure, reviews procedure, initial titration, stoma and tubing care.
 - F/U Visit 1: 24 hrs after d/c, reviews pump operation and daily routine.
 - F/U Visit 2: After titration begins reviews the daily routine, battery and cartridge replacement, as well as on-going pump care.

At UKMC/VAMC-Lexington

- Identify potential patient
- Conversion to C/L (1:4) IR tablets
- Arrange initial AbbVie Home Nurse Visit
- Appointment with Proceduralist
- 23hr Admission for procedure that takes place in the PM
- Evaluation by Proceduralist and d/c in AM, if cleared, to MDS Clinic
- Calculate and administer starting dose, titrate over the day; spend night at home or hotel
- Patient initiates pump in AM and returns to clinic for additional titration through the day
- D/c home to continue titration; return following week