CADTH

CADTH COMMON DRUG REVIEW

CADTH Canadian Drug Expert Committee Recommendation

(Final)

LEVODOPA/CARBIDOPA INTESTINAL GEL (DUODOPA — ABBVIE CORPORATION)
Indication: Parkinson's disease

RECOMMENDATION
The CADTH Canadian Drug Expert Committee recommends that levodopa/carbidopa intestinal gel (LCIG) be reimbursed for the treatment of patients with advanced levodopa-responsive Parkinson disease (PD) who do not have satisfactory control of motor fluctuations and hyper-/dyskinesia despite optimized treatment with available combinations of PD medicinal products, and for whom the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the percutaneous endoscopic gastrostomy-jejunostomy tube required for administration, if the following conditions are met:

Conditions

- Patients treated with LCIG should be under the care of a neurologist with experience in the treatment of patients with PD who has completed the LCIG education program referenced in the product monograph.
- Reduced price.

Service Line: CADTH Drug Reimbursement Recommendation
Version: 1.0
Publication Date: TBC
Report Length: 9 Pages

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Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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Indication: Parkinson's disease

Recommendation:

The CADTH Canadian Drug Expert Committee (CDEC) recommends that levodopa/carbidopa intestinal gel (LCIG) be reimbursed for the treatment of patients with advanced levodopa-responsive Parkinson's disease (PD) who do not have satisfactory control of motor fluctuations and hyper-/dyskinesia despite optimized treatment with available combinations of PD medicinal products, and for whom the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the percutaneous endoscopic gastrostomy-jejunostomy (PEG-J) tube required for administration, if the following conditions are met:

Conditions:

- Patients treated with LCIG should be under the care of a neurologist with experience in the treatment of patients with PD who has completed the LCIG education program referenced in the product monograph.
- Reduced price.

Reasons for the Recommendation:

1. One phase III, double-blind, double-dummy, multi-centre, superiority randomized controlled trial (RCT) (Study 001/002; N = 71) demonstrated that LCIG was associated with a statistically significant and clinically meaningful reduction in patients' "off" time at week 12 compared with immediate-release (IR) oral levodopa/carbidopa (OLC) capsules. LCIG was also associated with significant improvement in the amount of "on" time without troublesome dyskinesia at week 12. The Unified Parkinson's Disease Rating Scale (UPDRS), Part II and Parkinson disease questionnaire (PDQ-39) Summary Index Score were used to assess PD symptoms at week 12; these tests showed statistically significant and clinically meaningful improvements in favour of LCIG. No important harm differences were reported between LCIG and IR OLC capsules.
2. One non-comparative, open-label, multi-centre, long-term safety study (Study 004; N = 354) designed to assess the safety of LCIG over 54 weeks demonstrated that LCIG use was not associated with important harms.
3. At the manufacturer's marketed price of $166 per cassette, the annual cost of LCIG ($60,590) is significantly greater than the publicly available annual cost of other comparable treatment options for advanced PD ($500 to $5,000). The cost-effectiveness of LCIG compared with relevant comparator treatments is unknown, as no economic model was provided to consider the new clinical information in the resubmission. Therefore, CDEC was uncertain whether using LCIG therapy offers reasonable value at the submitted price.

Of Note:

- CDEC noted that appropriately defined initiation and discontinuation criteria for the reimbursement of LCIG are essential to ensure that LCIG is used in patients who are most likely to benefit from it, and to prevent inappropriate use. The Committee recommends that a panel of clinical experts with experience in the treatment of patients with PD be convened to develop initiation and discontinuation criteria for LCIG.
- CDEC noted that due to insufficient information regarding cost-effectiveness, it was not possible to comment on what an appropriate price would be for LCIG to provide value to public drug plans. The Committee noted that the cost of LCIG cassettes alone is substantially greater than the estimated cost of deep brain stimulation (DBS) and the cost of available combinations of PD medicinal products, and that there are additional treatment costs associated with LCIG that need to be considered, including the costs of endoscopic insertion of the PEG-J tube, and the resources required for this procedure, and for subsequent maintenance.

- CDEC noted that LCIG is associated with implementation considerations that are not a feature of other treatments such as DBS. Specifically, LCIG must be stored in a refrigerator and protected from light, which introduces practical challenges. In addition, there is a high risk of wastage, because once a cassette is taken out of the refrigerator it must be used within 16 hours or discarded. The clinical expert noted that the majority of patients take approximately 1,000 mg LCIG per day, so approximately half of the cassette would be discarded.

Discussion Points:

- CDEC noted that in 2009, the Canadian Expert Drug Advisory Committee (CEDAC) recommended that Duodopa not be reimbursed due to the high incremental cost per quality-adjusted life-year (QALY) estimate reported by the manufacturer, as well as the low quality of two clinical trials that were considered by CEDAC (DIREQT trial [N = 25] and NPP-001-99 trial [n = 16]). These two trials were limited by open-label designs, high proportions of withdrawals, small sample sizes, and patient populations that were not representative of those who are most likely to use Duodopa. CDEC considered the additional clinical evidence to sufficiently address the limitations in clinical evidence that were noted in the previous CEDAC recommendation.
- CDEC considered the unmet needs of patients with PD, noting that PD is a progressive disease, and that over time, patients become less responsive to oral treatment options. Subcutaneous administration of apomorphine (an agent previously reviewed by CADTH; in January 2018, CDEC recommended reimbursement with criterion and conditions) may be an option for the acute, intermittent treatment of hypomobility "off" episodes ("end-of-dose wearing-off" and unpredictable "on/off" episodes) for patients who are receiving optimized PD therapy. For patients who remain unsatisfactorily controlled with these treatment options, disease management is a significant challenge and the options for therapy are invasive and complex. DBS is a treatment option available to patients disabled by unpredictable motor complications; however, the procedure requires neurosurgical resources that may not be universally available. As well, the procedure may be contraindicated in some patients.
- CDEC discussed the place in therapy of LCIG and the appropriateness of considering DBS a relevant comparator. Although there are several factors that influence a clinician's decision to treat a patient with DBS or LCIG, both treatment options are considered for patients who do not have satisfactory control of motor fluctuations despite optimized therapy.
- CDEC discussed the efficacy of LCIG based on the results of the long-term safety study, Study 004. The results from this study were suggestive of improvements in daily normalized "off" time (adjusted least squares mean [LSM] change of –4.4 hours, standard error [SE] 2.9) and "on" time (4.8 hours [SE 3.4]) at week 54 compared with baseline (6.75 hours standard deviation [SD] 2.35 hours and 7.65 hours [SD 2.45], respectively) for patients receiving LCIG. However, the interpretation of these results is limited by the non-comparative nature of the study and the lack of control for multiple statistical testing.

Background:

LCIG infused directly into the proximal small intestine is intended to mitigate the unpredictability of the absorption rate of intermittent OLC dosing and the variable gastric emptying rates associated with PD by providing relatively constant plasma concentrations of levodopa. LCIG has a Health Canada–approved indication for patients with advanced levodopa-responsive PD who do not have satisfactory control of severe, debilitating motor fluctuations and hyper-/dyskinesia despite optimized treatment with available combinations of PD medicinal products and for whom the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the PEG-J tube required for administration. LCIG dosing should be individualized for each patient and adjusted for optimal clinical response, defined as maximizing functional "on" time during the day (with as little dyskinesia as possible) by minimizing the number and duration of "off" episodes (bradykinesia). Treatment is administered over approximately 16 hours and is composed of three individually adjusted doses: the morning bolus dose, the continuous maintenance dose, and extra bolus doses. The LCIG (20 mg/mL levodopa and 5 mg/mL carbidopa monohydrate solution) is packaged in a 100 mL cassette containing 2,000 mg levodopa and 500 mg carbidopa. The cassettes are for single use only and should not be reused once opened. In addition, a single cassette should not be used for longer than 16 hours despite the possibility of medicinal product remaining.

Submission History:

The original CADTH Common Drug Review (CDR) of LCIG was based on the initial conditional marketing authorization of this product (i.e., Notice of Compliance with conditions [NOC/c]), and included two randomized, open-label crossover trials evaluating the effects of LCIG in patients with advanced PD and severe motor complications. The DIREQT trial (n = 25) compared LCIG with patients' pre-study conventional therapy. Treatment sequences were three weeks. The primary outcomes in the DIREQT trial were UPDRS item scores and time spent in various motor states as assessed by video recording. Quality of life (QoL) was also measured in the DIREQT trial. In the NPP-001-99 trial (n = 16), LCIG was compared with long-acting levodopa/carbidopa, and the short-acting formulation was given to patients as needed. Long-acting levodopa/carbidopa is not considered an appropriate comparator in this patient population. The quality of two trials considered by CEDAC was limited by open-label designs, high proportions of withdrawals in trials of small sample size, and patient populations that were not representative of those who are most likely to use LCIG. Therefore, given concerns with the quality of these trials, the relevance of the results was limited. The manufacturer's (Solvay Pharma Inc.) reported incremental cost per QALY estimate for LCIG of [redacted] to [redacted] compared with conventional oral drug therapies. The manufacturer (Solvay Pharma Inc.) requested that specific results from the economic evaluation remain confidential pursuant to the CDR Confidentiality Guidelines at the time of the review. Other published cost per QALY estimates for LCIG were reported at approximately $1 million dollars. LCIG received a CEDAC recommendation of "do not list" in 2009.

The basis of the resubmission by the Drug Policy Advisory Committee Formulary Working Group (DPAC-FWG) is the new clinical information that became available for the treatment of PD with LCIG since the original CDR review. The CDR-participating drug plans expressed the need for an updated review and a formulary reimbursement recommendation from CDEC to address the use of LCIG for the treatment of PD. In response to the DPAC-FWG formally requesting the manufacturer of LCIG (Abbvie Corporation) to file a resubmission for the review of LCIG through the CDR process, the manufacturer indicated that it did not plan to file a CDR resubmission for LCIG. Consequently, the CDR-participating drug plans submitted a resubmission for the review of LCIG. The conditions of the initial market authorization have since been removed based on the Duodopa Phase III Clinical Development Program (Study 001/002 and Study 004) conducted subsequent to conditional marketing authorization to confirm the preliminary findings from the Early Stage Clinical Development Program.

Summary of CDEC Considerations:

The Committee considered the following information prepared by the CADTH CDR: a systematic review of efficacy and safety studies of LCIG for patients with PD and a review of published economic studies and Health Technology Assessment (HTA) agency assessments. The Committee also considered input from a clinical expert with experience in treating patients with PD, and patient group–submitted information about outcomes and issues important to patients.

Patient Input Information:

Three patient groups — Parkinson Association of Alberta, Parkinson Society British Columbia, and Parkinson Canada — responded in a joint submission to the CDR call for patient input. Patient perspectives were obtained through surveys (online or otherwise) and telephone or in-person interviews. The following is a summary of key input from the perspective of the patient groups:

- According to the patient groups, PD negatively affects patients' overall QoL as well as their confidence and independence, socialization, relationships, recreational and everyday activities, and ability to work.
- Slowness, stiffness, impaired balance, cognitive changes, memory problems, mood changes, difficulty sleeping, difficulty swallowing, speech problems, cognitive impairments, bladder/bowel issues, and muscle rigidity were identified by patients as the most important PD symptoms to control and manage.
- As the disease progresses, patients become more dependent on medications to maintain their ability to function, and finding the ideal balance between the side effects of the medications and their benefit often becomes more difficult. Patients expect PD treatments to minimize "off" time while maximizing functional "on" time (without troublesome dyskinesia), resulting in a durable response and improving PD symptoms while minimizing treatment-associated side effects such as dyskinesia, constipation, hallucination, sleep disturbances, and dystonia.

- According to the patient groups, LCIG eliminated the need to take frequent oral medications entirely, or partially reduced the dosage. This resulted in more time for the patients to travel, socialize, perform chores, and engage in pastimes, thereby improving their overall QoL. LCIG also eliminated the significant dietary challenges associated with eating protein while on OLC.
- Patients highlighted a few discomfort-causing issues related to the device or procedure, such as the size and weight of the pump, difficulty when dressing, special consideration when showering or swimming, the need to clean the tube daily, regular change of battery, and infections and itchiness at the stoma. In addition, travelling was inconvenient, as cassettes need to be refrigerated. However, patients unanimously stated that the clinical benefits outweigh the side effects and complications related to the device or procedure.

Clinical Trials

Study 001/002 (N = 71) was designed to evaluate the efficacy and safety of LCIG for the treatment of patients with advanced levodopa-responsive PD who do not have satisfactory control of severe, debilitating motor fluctuations and hyper-/dyskinesia despite optimized treatment with available combinations of PD medicinal products, and for whom the benefits of this treatment may outweigh the risks associated with the insertion and long-term use of the PEG-J tube required for administration. Patients were randomized to a 1:1 ratio of optimally titrated LCIG (20 mg/mL levodopa and 5 mg/mL carbidopa monohydrate solution) in addition to placebo IR OLC capsules or optimally titrated IR OLC 100 mg/25 mg capsules in addition to placebo LCIG for 12 weeks.

Study 004 (N = 354) was a non-comparative, multinational, multi-centre, open-label, long-term safety study. Patients included in this study were not previously treated with LCIG in Study 001/002. The study objective was to evaluate the safety of LCIG for the treatment of patients with advanced levodopa-responsive PD over a 54-week period. LCIG was delivered as an aqueous solution containing 20 mg/mL levodopa and 5 mg/mL carbidopa monohydrate packaged in 100 mL cassettes administered as a morning bolus dose followed by continuous infusion at a constant rate for the remainder of each patient's waking day (approximately 16 hours). Key limitations of Study 004 include its open-label and non-comparative study design as well as the lack of adjustments for multiple statistical testing.

Patients who completed Study 001/002 had the option to enrol in an optional 12-month open-label, non-comparative safety extension study (Study 003, N = 62). Furthermore, patients who completed either Study 003 or Study 004 were able to enrol in Study 005, which was also an open-label, non-comparative safety extension study (N = 262), for up to 6.9 years of follow-up.

Outcomes

Outcomes were defined a priori in the CDR systematic review protocol. Of these, the Committee discussed the following:

- Mean difference in the change from baseline in the daily normalized "off" time.
- Mean difference in the change from baseline "on" time, including:
  - "On" time without troublesome dyskinesia ("on" time without dyskinesia and "on" time with non-troublesome dyskinesia)
  - "On" time without dyskinesia
  - "On" time with non-troublesome dyskinesia
  - "On" time with dyskinesia
- Mean difference in the change from baseline in PDQ-39.
- Mean difference in the change from baseline in Clinician Global Impression – Improvement (CGI-I).
- Mean difference in the change from baseline in UPDRS.
- Mean difference in the change from baseline in EuroQol 5-Dimensions 3-Level (EQ-5D-3L) Summary Index Score.
- Mean difference in the change from baseline in Zarit Burden Interview (ZBI) score.

The primary outcome in one RCT (Study 001/002) was the mean difference in the change from baseline in the daily normalized "off" time, while the primary outcome in all 19 open-label, non-comparative studies (including Study 004 and both long-term safety extensions, Study 003 and Study 005) was the frequency of adverse events (AEs).

Efficacy

Compared with IR OLC, LCIG was associated with a statistically significant reduction in daily normalized "off" time at week 12 in Study 001/002 (the primary outcome) completed via PD diary. The adjusted least squares mean difference (LSMD) in change from baseline was –1.91 hours (95% CI, –3.05 to –0.76; *P* = 0.0015) in favour of LCIG. Furthermore, results of the sensitivity analyses (using mixed-model repeated measures to impute data and sensitivity analyses with varying covariates requested by the FDA) were mostly consistent with the primary analysis for this outcome. The minimal clinically important difference (MCID) is approximately −1.00 hour.

The evaluation of "off" time as the primary end point in Study 001/002 was supported by the evaluation of a key secondary end point (adjusted for multiple statistical testing), normalized "on" time without troublesome dyskinesia (a composite of "on" time without dyskinesia and "on" time with non-troublesome dyskinesia). Overall, LCIG was also associated with a statistically significant improvement in daily normalized "on" time without troublesome dyskinesia at week 12. The adjusted LSMD in change from baseline was 1.86 hours (95% CI, 0.56 to 3.17; *P* = 0.0059) in favour of the LCIG. When looking at the two components of the composite separately, it appeared that the results were primarily driven by the increase in "on" time without dyskinesia (adjusted LSMD in change from baseline were 2.28 hours [95% CI, 0.47 to 4.09; *P* = 0.0142]) since the change in "on" time with non-troublesome dyskinesia was not statistically significant (–0.73 [95% CI, –2.22 to 0.76; *P* = 0.3294]). Overall, the result of the key secondary outcome was also consistent with the primary analysis; however, no MCID was identified for the change in "on" time. No adjustments for multiple statistical testing were made for the individual components of this end point.

Other secondary outcome measures (adjusted for multiple statistical testing) included change from baseline in the PDQ-39 Summary Index Score, CGI-I Score, UPDRS Part II (activities of daily living subscore), UPDRS Part III (motor subscore), EQ-5D-3L Summary Index Score, and the ZBI score. Compared with IR OLC, LCIG was associated with a statistically significant and clinically meaningful reduction in favour of the study drug for both the PDQ-39 Summary Index Score (adjusted LSMD in change from baseline were –7.0 [95% CI, –12.6 to –1.4; *P* = 0.0155] compared with an MCID of –1.6) and the UPDRS Part II score (adjusted LSMD in change from baseline –3.0 [95% CI, –5.3 to –0.8; *P* = 0.0086] compared with an MCID of –2.3). The results for the CGI-I score were also statistically significantly in favour of the LCIG (adjusted LSMD in change from baseline was –0.7 [95% CI, –1.4 to –0.1; *P* = 0.0258]); however, no MCID was identified. Therefore, the clinical meaningfulness of the change in CGI-I remains unclear. No statistically significant differences between treatments were reported for the UPDRS Part III (adjusted LSMD in change from baseline was 1.4 [95% CI, –2.8 to 5.6; *P* = 0.5020]).

Study 001/002 also evaluated health-related QoL using the EQ-5D-3L Summary Index Score (adjusted LSMD in change from baseline was 0.07 [95% CI, –0.01 to 0.15; *P* = 0.0670]) and caregiver burden using the ZBI score (adjusted LSMD in change from baseline was –4.5 [95% CI, –10.7 to 1.7; *P* = 0.1501]). These end points should be considered exploratory despite being part of the testing hierarchy, given that they were evaluated subsequent to failure of a prior end point in the hierarchy (UPDRS Part III); therefore, the clinical importance of these changes also remains unclear.

Changes in the mean daily normalized "off" time and "on" time without troublesome dyskinesia at week 54 compared with baseline were –4.4 hours (2.9, *P* < 0.001) and 4.8 hours (3.4, *P* < 0.001) in Study 004, respectively. The mean change in "on" time with troublesome dyskinesia was –0.4 (2.8, *P* = 0.023). Changes in the mean UPDRS Part II score, PDQ-39 Summary Index Score, EQ-5D Summary Index Score and the EQ-5D visual analogue scale were -4.4 (6.5, P<0.001), –6.9 (14.1, *P* < 0.001), 0.064 (0.203, *P* < 0.001) and 14.0 (24.8, *P* < 0.001), respectively. Efficacy outcomes in Study 004 were not adjusted for multiple statistical comparisons.

Harms (Safety and Tolerability)

Overall, 95% and 100% of patients experienced AEs in the LCIG + placebo (PBO) IR OLC capsules group and PBO LCIG + IR OLC capsules group in Study 001/002, respectively. The frequencies of AEs were relatively similar across treatment groups. The most common AEs were falls (11% versus 12%), atelectasis (8% versus 0%), anxiety (8% versus 3%), confusional state (8% versus 3%), oedema peripheral (8% versus 0%), oropharyngeal pain (8% versus 0%), and upper respiratory tract infection (8% versus 0%) in the LCIG + PBO IR OLC capsules and PBO LCIG + IR OLC capsules groups, respectively. Fewer patients experienced serious adverse events (SAEs) in the LCIG + PBO IR OLC capsules group compared with the PBO LCIG + IR OLC capsules group in Study 001/002 (14% versus 21%, respectively). The most common SAEs were confusional state (5% versus 0%) and pneumonia (0% versus 6%) in the LCIG + PBO IR OLC capsules and PBO LCIG + IR OLC capsules groups, respectively.

Overall, one patient (3%) and two patients (6%) withdrew due to AEs in the LCIG + PBO IR OLC capsules and PBO LCIG + IR OLC capsules groups in Study 001/002, respectively. The most common reasons were hallucination and psychotic disorder (3% versus 0% each) and peritonitis, post-procedural complication, and post-procedural discharge (0% versus 3% each) in the LCIG + PBO IR OLC capsules and PBO LCIG + IR OLC capsules groups, respectively. No deaths were reported in Study 001/002.

Most patients experienced device-related complications across both treatment groups in Study 001/002 (92% and 85% in the LCIG + PBO IR OLC capsules and PBO LCIG + IR OLC capsules groups, respectively.) Overall, 76% compared with 79% and 57% compared with 56% of patients experienced long-term complications of PEG-J and risks of PEG-J insertion in the LCIG + PBO IR OLC capsules group and PBO LCIG + IR OLC capsules group, respectively. The most common long-term complications of PEG-J were complication of device insertion (57% versus 44%), procedural pain (30% versus 35%), and incision-site erythema (19% versus 12%), while the most common risks of PEG-J insertion were abdominal pain (51% versus 32%) and pneumoperitoneum (11% versus 3%) in the LCIG + PBO IR OLC capsules and PBO LCIG + IR OLC capsules groups, respectively.

In general, a similar number of patients (70% compared with 71%) experienced gastrointestinal AEs in Study 001/002, the most common being nausea (30% versus 21%), constipation (22% versus 21%), and flatulence (16% versus 12%) in the LCIG + PBO IR OLC capsules and PBO LCIG + IR OLC capsules groups, respectively. More patients experienced psychiatric disorders in the LCIG + PBO IR OLC capsules group compared with the PBO LCIG + IR OLC capsules group (46% compared with 29%). The most common were depression (11% versus 3%), insomnia (11% versus 12%), anxiety (8% versus 3%), and confusional state (8% versus 3%) in the LCIG + PBO IR OLC capsules and PBO LCIG + IR OLC capsules groups, respectively. A total of 3% and 9% of patients experienced polyneuropathy and associated signs and symptoms, the most common reason being balance disorder (3% compared with 6%) in the LCIG + PBO IR OLC capsules and PBO LCIG + IR OLC capsules groups, respectively. Fewer patients experienced nervous system disorders in the LCIG + PBO IR OLC capsules group compared with the PBO LCIG + IR OLC capsules group (30% compared with 47%). The most common were dyskinesia (14% versus 12%), dizziness (8% versus 6%), and headache (8% versus 12%) in the LCIG + PBO IR OLC capsules and PBO LCIG + IR OLC capsules groups, respectively. In general, a similar number of patients (22% compared with 27%) experienced vascular disorders, the most common being orthostatic hypotension (14% versus 24%) and hypertension (8% versus 0%) in the LCIG + PBO IR OLC capsules and PBO LCIG + IR OLC capsules groups, respectively.

Generally, AEs (including serious and non-serious) reported in Study 001/002 were consistent with the known AE profile of levodopa/carbidopa (e.g., depression, anxiety, confusion) and PD patients who have undergone the PEG-J procedure. Overall, the safety profile of Duodopa in Study 003, 004, and 005 was generally consistent with that identified in Study 001/002, with no new safety signals identified after up to 60 months of treatment.

Cost and Cost-Effectiveness

LCIG is available as a hard plastic cassette containing 100 mL of gel with 2,000 mg of levodopa and 500 mg carbidopa, with the total dose being administered over approximately 16 hours. At the manufacturer's marketed price of $166 per cassette, the annual cost per patient is $60,590 based on a dose of one cassette per day.

The manufacturer was invited to submit pharmacoeconomic information for this submission, but chose not to provide a pharmacoeconomic report or model.

CDR clinical reviewers identified several new studies since the 2009 submission (including Study 001/002, Study 003, and Study 004), suggesting that LCIG had statistically significant and clinically meaningful reductions in patients “off” time when compared with IR OLC. No new signals regarding harms have emerged.

In the absence of an economic evaluation or model, CDR performed a literature search to identify published economic studies of LCIG for the treatment of advanced PD, and reviewed HTA agency recommendations.

No studies were identified that assessed the cost-effectiveness of LCIG for advanced PD in the Canadian setting. The studies that were identified were not deemed generalizable to the Canadian context and may be of limited value in informing the cost-effectiveness of LCIG in Canada.

No studies were identified assessing the cost-effectiveness of LCIG compared with DBS, which was deemed a relevant comparator by CDR-participating drug plans and the clinical expert consulted for this review. CDR identified two reports outlining surgical assessments, consultations, procedures, and device-related costs associated with DBS treatment in Ontario. Health Quality Ontario (HQO, 2005) reported costs of approximately $30,000 to $35,000 (inflated to 2018 Canadian dollars) while Ng (2013) stated costs of DBS to be approximately $27,000 (inflated to 2018 Canadian dollars). Both reports indicated that battery replacement would need to occur at approximately five years, but did not consider this cost in their calculations.

In the absence of an economic evaluation conducted for the Canadian setting, CDR was unable to assess the cost-effectiveness of LCIG in light of the new clinical information.

CDEC Members:

Dr. James Silvius (Chair), Dr. Silvia Alessi-Severini, Dr. Ahmed Bayoumi, Dr. Bruce Carleton, Dr. Alun Edwards, Mr. Bob Gagne, Dr. Ran Goldman, Dr. Allan Grill, Dr. Peter Jamieson, Mr. Allen Lefebvre, Dr. Kerry Mansell, Dr. Yvonne Shevchuk, and Dr. Adil Virani.

July 18, 2018 Meeting

Regrets:

One CDEC member did not attend.

Conflicts of Interest:

None