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Reimbursement Recommendation

Lemborexant (Dayvigo)

Indication: For the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Sponsor: Eisai Limited

Final recommendation: Do not reimburse

Summary

What Is the Reimbursement Recommendation for Dayvigo?

Canada's Drug Agency (CDA-AMC) recommends that Dayvigo should not be reimbursed by public drug plans for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Why Did CDA-AMC Make This Recommendation?

- In the initial submission in 2023, 2 randomized controlled trials (RCTs) (the SUNRISE 1 and SUNRISE 2 studies) were reviewed. The clinical benefit of Dayvigo was uncertain due to limitations or concerns, including an enriched population, inconsistent results, missing data, lack of control for multiplicity, absence of or failure to meet minimum important differences, not assessing patient-centred outcomes (e.g., anxiety, productivity, or relationships), and uncertainty in the safety profile of Dayvigo (i.e., somnolence, falls, dependence). Evidence from an indirect treatment comparison (ITC) was also assessed. It is uncertain whether Dayvigo offers a meaningful clinical benefit compared to other treatments used for insomnia due to several limitations.
- In the present resubmission, 2 real-world observational studies (i.e., Juday et al. and Hirata et al.) investigating the association between risk of falls and Dayvigo were submitted as additional evidence. The evidence from Juday et al. and Hirata et al. was uncertain to determine whether Dayvigo was associated with a lower risk of falls, compared to other medications, due to several limitations such as possible selection bias due to inclusion of current users only, bias due to misclassification of exposures and outcomes, and residual confounding. No other evidence was submitted to address gaps identified in 2023.
- Based on the evidence reviewed, it is uncertain whether Dayvigo offers a meaningful clinical benefit compared to other treatments used for insomnia.

Additional Information

What Is Insomnia?

Insomnia is a sleep disorder characterized by difficulty falling asleep, staying asleep, and/or getting good quality sleep. Chronic insomnia disorder (CID) is a persistent form of insomnia in which patients have difficulties falling asleep or staying asleep for 3 nights or more per week for at least 3 months, even when the sleeping conditions are good.
A 2023 RAND Europe report estimated that the prevalence of CID in

Summary

the general adult population in Canada was 8.8%, while another study reported a 16.3% prevalence of CID based on interviews of 4,037 adults in Canada in 2023.

Unmet Needs in Insomnia

There are currently no publicly funded pharmacological treatments approved in Canada for long-term use in adults with CID. There is a need for pharmacological treatment options for CID which are effective in terms of improving sleep quality and continuity as well as improving daytime functioning and health-related quality of life. There is also a need for the pharmacological treatments to be nonaddictive, well-tolerated, and safe for long-term use.

How Much Does Dayvigo Cost?

Treatment with Dayvigo is expected to cost approximately $641 per patient per year.

Recommendation

The Canadian Drug Expert Committee (CDEC) recommends that lemborexant not be reimbursed for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Rationale for the Recommendation

Lemborexant was previously reviewed by CDEC on the basis of 2 double-blind, phase III, RCTs in adults with insomnia (SUNRISE 1 [N = 1,006] and SUNRISE 2 [N = 971]) as well as evidence from an ITC. Lemborexant received “Do not reimburse” from CDEC on January 10, 2023, due to several evidence gaps and concerns. The clinical significance of the effects of lemborexant was uncertain due to an enriched population, inconsistent results, missing data, lack of control for multiplicity, and absence or failure to meet minimum important differences. Additionally, the trials did not assess patient-centred outcomes such as anxiety, productivity, or relationships, and further evidence was needed to address concerns like somnolence, fall risk, and dependence. The indirect evidence comparing lemborexant to other treatments was uncertain due to numerous limitations, precluding definitive conclusions. In the present resubmission, CDEC reviewed additional evidence submitted by the sponsor on the risk of falls while taking lemborexant, consisting of 2 real-world observational studies (i.e., Juday et al. and Hirata et al.). Results from Juday et al. showed that compared to lemborexant, the risk ratio (RR) of falls in outpatients aged 18 years and older was 1.179 (95% confidence interval [CI], 0.838 to 1.657) for trazodone, 1.268 (95% CI, 0.907 to 1.772) for zolpidem, and 1.768 (95% CI, 1.295 to 2.413) for benzodiazepines as a class, all favouring lemborexant. The study by Hirata et al. did not provide direct comparative results. Findings from Hirata et al. showed that between in-hospital patients who used the medication versus those who did not use the medication, the odds ratio for in-hospital falls was 1.188 (95% CI, 0.774 to 1.825; P = 0.431) for lemborexant, 1.255 (95% CI, 1.118 to 1.409; P < 0.001) for benzodiazepine hypnotic drugs, and 1.293 (95% CI, 1.118 to 1.496, P = 0.001) for Z-drugs. CDEC acknowledged the potential value of the 2 real-world studies in terms of addressing 1 of the key concerns identified by the initial CDEC deliberation — risk of falls associated with lemborexant. However, CDEC could not draw definitive conclusions on whether lemborexant was associated with a lower risk of falls, compared to other medications, due to several major limitations in the 2 observational studies, such as possible selection bias due to inclusion of prevalent users only, bias due to misclassification of exposures and outcomes, and residual confounding.

CDEC deliberated on the input received from 4 patient groups and 8 clinician groups. Patients and clinicians expressed a strong and urgent need for new pharmacological treatment options for CID which are effective in improving sleep quality and continuity, nonaddictive, well-tolerated, and safe for long-term use, as well as able to improve daytime functioning and health-related quality of life. During the reconsideration meeting, CDEC upheld that the additional real-world safety evidence related to risk of falls was inconclusive. Additionally, CDEC noted that the real-world evidence did not address other gaps (e.g., clinical significance, effect on patient-centred outcomes, comparative effects, somnolence, and dependence) that were important to patients. Consequently, the additional real-world evidence was inadequate to warrant a change in CDEC’s

previous conclusion, which is that no definitive conclusion could be reached regarding whether lemborexant would address unmet needs identified by patients and clinicians.

Discussion Points

- **Reconsideration request:** The sponsor requested a reconsideration of the initial draft recommendation to not reimburse lemborexant for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. There were 3 major issues outlined by the sponsor in the request for reconsideration that were discussed by CDEC, including recognizing the inherent limitations of observational studies and administrative data which affect all research on insomnia treatments and considering the evidence demonstrating the association between reduced risk of falls and lemborexant use as conclusive; adequately reflecting the urgency, consistency, and relevance of the inputs received from patients and clinicians; as well as acknowledging the limitations faced by lemborexant to fulfill comparator requirements (i.e., including benzodiazepines as a relevant comparator to lemborexant) and re-examining the ITC evidence.
- **Unmet needs:** During the initial meeting and the reconsideration meeting, CDEC examined the input received from 4 patient groups and 8 clinician groups. CDEC discussed multiple unmet needs identified by patients and clinicians including the need for effective and safe pharmacological treatment options that can improve sleep quality and continuity, daytime functioning, and patients' quality of life. CDEC also revisited the evidence gaps and concerns raised from the previous CDEC deliberation of lemborexant. CDEC noted that the 2 real-world studies (Juday et al. and Hirata et al.) could only provide insights on 1 of the safety concerns about lemborexant — risk of falls, and there was no new evidence to address other patients' unmet needs or evidence gaps previously identified by CDEC.
- **Patient and clinician group feedback on the draft recommendation:** During the reconsideration meeting, CDEC reviewed feedback on the draft recommendation from 2 patient groups and 8 clinician groups. In general, the feedback from patient and clinician groups expressed deep concerns about the initial "Do not reimburse" recommendation and its associated implications. Patient groups emphasized that CID is "a serious condition with no effective treatments publicly funded for long-term use." Patient groups also noted that the patients' unmet need for an effective and safe long-term pharmacological treatment for CID was undervalued, and the decision not to reimburse lemborexant would deny patients the access to a pharmacological treatment that could address their unmet need. Clinician groups and individual clinicians who treat insomnia emphasized that lemborexant at least offers a safer alternative to benzodiazepines and Z-drugs which are still reimbursed despite well-documented risks such as cognitive impairment, falls, dependence, and withdrawal. Based on their clinical experience of using lemborexant and their knowledge of patients' testimonials, lemborexant is considered an effective and safe treatment option. During the reconsideration meeting, CDEC discussed the implications in depth, acknowledged the urgent need from patients, and recognized the perspectives and experiences of the clinician groups and individual clinicians who treat insomnia.

However, CDEC members did not find the patient, clinical experts, and clinician groups input sufficient to conclude that lemborexant would address the identified unmet needs.

- **New reimbursement request:** CDEC noted that for the resubmission the sponsor submitted a new reimbursement request, which narrowed the target population from patients with insomnia to patients with CID diagnosed according to the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (*DSM-5*), characterized by persistent difficulty initiating or maintaining sleep or experiencing early morning awakenings for at least 3 nights per week for 3 months or longer. CDEC noted that the population in the new reimbursement request is aligned with the inclusion criteria of the SUNRISE trials. CDEC acknowledged that the unmet needs for CID are similar to broader insomnia and that long-term use of pharmacotherapies remains an issue. However, CDEC determined that the new reimbursement request did not warrant changes to any conclusion the committee had made during the previous deliberation on lemborexant.
- **Internal validity of the real-world evidence:** During the initial meeting, CDEC discussed the findings from Juday et al. and Hirata et al. Results from Juday et al. suggested that the risk of falls associated with lemborexant among adults with insomnia over a 6-month follow-up was lower with statistical significance, compared to benzodiazepines as a class. Point estimates of risk of falls for comparisons between lemborexant and trazodone, and between lemborexant and zolpidem were in favour of lemborexant but without statistical significance due to imprecision (i.e., CIs crossed the null). The point estimate from the Hirata et al. study indicated increased odds of in-hospital falls for those taking lemborexant compared with those not taking lemborexant, but the CI was wide and crossed the null. CDEC was not able to draw any definitive conclusion on the association between lemborexant and risk of falls in patients with chronic insomnia due to several major limitations identified in Juday et al. and Hirata et al., which reduced the internal validity of the real-world evidence. For instance, both Juday et al. and Hirata et al. were subject to possible selection bias due to inclusion of prevalent users only which might miss early adverse events and bias the estimate of effect toward a lower risk, bias due to misclassification of exposures and outcomes, and residual confounding. Additionally, studies lacked a prespecified protocol, which increases the risk of bias and undermines the credibility of the findings. During the reconsideration meeting, CDEC emphasized that during the deliberation process for lemborexant, CDEC evaluated the evidence within its proper context to ensure the interpretation of the findings is not overemphasized or minimized. CDEC determined that the sponsor's arguments that misclassification bias is common to many observational studies and that the feasibility of reducing confounding factors is limited by the structure and granularity of real-world data sources do not mitigate any of the limitations or justify an increase in the level of certainty in evidence.
- **Challenges associated with study designs on insomnia pharmacological treatment research:** During the initial and reconsideration meetings, CDEC recognized that the limitations identified in Juday et al. and Hirata et al. (i.e., misclassification of exposures and outcomes, residual confounding) are inherent limitations of observational studies. These limitations largely stem from the absence of randomization, which makes it difficult to ensure comparability between groups. However, CDEC

emphasized that the presence of common limitations associated with a particular study design does not justify accepting greater uncertainty in the evidence. The committee values observational studies and recognizes the importance of a well-designed, rigorously conducted real-world study. The key consideration is whether the evidence submitted, regardless of study design, is sufficiently valid. For insomnia, which is not a rare condition, RCTs are feasible. In fact, the sponsor provided 2 RCTs (SUNRISE 1 and SUNRISE 2) in the initial 2022 submission, comparing lemborexant with placebo and with zolpidem tartrate extended release. While challenges exist in insomnia research, CDEC expects sponsors to submit robust evidence from RCTs or observational studies. CDEC deliberations are an independent process considering available clinical evidence and economic evidence, patients,' caregivers,' and providers' experiences; impacts on health systems; and broader social and ethical issues. CDEC noted that every disease condition is different and has its own methodological challenges or limitations (e.g., study design, data collection). These challenges and limitations are often mentioned in various documents published by CDA-AMC or other organizations. CDEC emphasized that discussing study limitations or potential limitations in these documents is a health technology assessment process to facilitate proper interpretation of findings and an essential process to promote consistency and transparency. However, the standard process of acknowledging potential limitations in the documents published by CDA-AMC or other organizations does not eliminate the need to evaluate the validity of the evidence under review.

- **Periodic Safety Update Report:** At the reconsideration stage, the sponsor submitted the safety data in the latest Periodic Safety Update Report (PSUR) (reporting period: December 20, 2024, to June 19, 2025) to support the association between reduced risk of falls and lemborexant use. [redacted]. CDEC recognized that the PSUR provided important and valuable insights for the safety of lemborexant; however, there is uncertainty associated with the findings. First, the data in the PSUR were aggregated based on various individual data sources (e.g., clinical trials, individual case safety reports). The internal validity of the aggregated data in the PSUR is dependent on the validity of the individual data sources. The sponsor has confirmed that "there is no protocol for the PSUR as the PSUR is not a clinical study." Without more information, CDEC could not further evaluate the internal validity of the aggregate data reported in the PSUR. Moreover, the aggregate data in the PSUR were from people with insomnia disorder, irregular sleep-wake rhythm disorder, and volunteers in good health and covered all formulations, doses, and routes of lemborexant, which makes it difficult to attribute the safety signals to only patients with CID and to the formulations, doses, and routes indicated in the Health Canada indication. The PSUR does not provide information on fall risk compared to other relevant treatments used to treat CID in clinical practice in Canada, where the data were collected in a similar manner. As a result, the PSUR does not enable conclusions about comparative fall risk in the population relevant to the reimbursement request.
- **Indirect treatment comparison:** During the reconsideration meeting, CDEC discussed issues surrounding whether benzodiazepines should be a relevant comparator to lemborexant and issues

related to ITC evidence. CDEC noted that in the initial submission of lemborexant, the reimbursement request was for patients with insomnia (including short-term insomnia). CDEC determined that it was appropriate to consider benzodiazepines as a relevant comparator to lemborexant in the initial submission in 2022. CDEC recognized that in the current resubmission, the reimbursement request has been updated to CID. CDEC noted that in the Clinical Review report conducted by the CDA-AMC review team, it specified that benzodiazepines are for short-term use and that "benzodiazepines were grouped for analysis, however clinical experts consulted by the review team noted that the fall risk might not be similar for those with longer vs. shorter mechanisms of action." CDEC noted that for the current resubmission, including ITC data for lemborexant against benzodiazepines was not a mandatory requirement for resubmission eligibility, and the sponsor did not submit any updated ITC evidence or new ITC evidence to CDA-AMC for evaluation. The ITC evidence remains unchanged from the ITC evidence submitted to CDEC for deliberation in the 2022 lemborexant submission. CDEC determined that the ITC evidence had been adequately assessed in the previous recommendation and was unable to draw any new conclusion due to lack of new or updated ITC evidence.

- **Generalizability of the real-world evidence:** During the initial meeting, CDEC noted some generalizability issues in the Juday et al. and Hirata et al. studies. For instance, in Juday et al., the focus on data from patients in 50 large US health care organizations underrepresented patients without health coverage or smaller practices, the insomnia definition was broader than the CID *DSM-5* criteria (i.e., includes acute insomnia), and recurrent falls were not captured which did not allow for the full impact on fall risk to be assessed. Hirata et al. focused on inpatients who were not required to be affected by insomnia, the setting was predominantly rural hospitals in Japan and lacked description of the dose of lemborexant used or direct comparative estimates versus other relevant treatments. During the reconsideration meeting, CDEC discussed the sponsor's argument that generalizability issues as previously described are commonly seen or may not be avoided in other studies in the field of insomnia. CDEC determined that the argument does not mitigate any of the generalizability issues identified in the Juday et al. and Hirata et al. studies.
- **Ethics and equity consideration:** During the reconsideration meeting, clinicians noted that cognitive behavioural therapy for insomnia (CBT-I), considered as the first-line treatment for chronic insomnia, is not widely accessible in Canada, due to limited access and out-of-pocket cost. CDEC acknowledged the ethics and equity concerns regarding access from patients, clinical experts, and clinician groups; however, based on evidence reviewed, CDEC could not draw definitive conclusions on whether lemborexant was associated with a lower risk of falls, compared to other medications.

Background

CID, referred to as insomnia disorder in the *DSM-5*, is defined as difficulties with sleep onset and/or sleep maintenance, with symptoms lasting for 3 nights or more per week for at least 3 months and present despite adequate conditions for sleep. Several factors have been shown to be associated with an increased risk of

insomnia, including older age, female sex, family history of insomnia, previous episode of insomnia, tendency to wake up more easily from sleep, tendency for increased sleep disturbances when faced with stressful events, as well as psychiatric and psychological factors (e.g., anxiety, depression, increased daytime stress reactivity). Many comorbidities, such as depression, anxiety, hypertension, chronic pain, pulmonary disease, obstructive sleep apnea, and substance use disorders, can coexist with CID and be worsened by CID. CID has a negative impact on patients' health, stress levels, daytime functioning, productivity at work, academic performance, social interactions and romantic relationships, safety, and quality of life. The global prevalence of insomnia varies, ranging from 79% in Brazil to 23.2% in Western Europe. In Canada, the estimated prevalence of chronic insomnia based on the *DSM-5* diagnostic criteria was 16.3% (95% CI, 15.1% to 17.6%), obtained via phone interviews conducted from April to October 2023 among 4,037 adults.

The clinical experts consulted by the review team noted that the goals of treatment for CID include improved sleep initiation and maintenance, improvement of terminal insomnia and overall leading to restorative sleep, improved quality of sleep, as well as improved subjective wakefulness or function during the day. CBT-I is considered as the first-line treatment for chronic insomnia by expert consensus in Canada (i.e., the 2024 consensus for the management of CID in Canada), international clinical practice guidelines (e.g., the European Sleep Research Society 2023 update), and the clinical experts consulted by the review team. However, patients do not always undergo CBT-I either because it is not readily available or there are barriers to accessing it (e.g., cost, lack of sleep behavioural specialists). CBT-I alone may also not be successful in some patients. Thus, pharmacological therapy may be considered as an alternative. According to the clinical experts consulted by the review team, CBT-I and pharmacotherapy can be used concurrently or sequentially. There are currently no approved or recommended pharmacological treatments indicated for CID available on public drug plans in Canada. According to the clinical experts consulted by the CDA-AMC review team, some of the currently used pharmacotherapeutic options in Canada include trazodone (an atypical antidepressant drug, commonly used off label), Z-drugs (e.g., zopiclone), antipsychotic drugs (off label), and benzodiazepines (either indicated for short-term insomnia or off label), and so forth. The 2024 consensus for the management of chronic insomnia in Canada pointed out that dual orexin receptor antagonists (DORAs) might have benefits which outweigh the risks for long-term use; however, no DORAs are publicly reimbursed in Canada at the time of this review.

Lemborexant has been approved by Health Canada for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Lemborexant is a competitive DORA. It is available as oral tablets and the dosage recommended in the product monograph is 5 mg, taken no more than once per night and within a few minutes before going to bed, with at least 7 hours remaining before the planned time of awakening. The dose may be increased to the maximum recommended dose of 10 mg based on clinical response and tolerability.

Submission History

Lemborexant was previously reviewed by CDA-AMC and received a recommendation to not reimburse for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance from CDEC on January 10, 2023. The original review of lemborexant included 2 double-blind, phase III, RCTs in adults with insomnia, SUNRISE 1 (N = 1,006) and SUNRISE 2 (N = 971), as well as 1 sponsor-submitted ITC and a published network meta-analysis.

The rationale of the 2023 CDEC recommendation against reimbursement of lemborexant included:

- It was unclear whether lemborexant would address the needs identified as important to patients, including uninterrupted and restorative sleep, more effective treatment options, fewer side effects, and long-term treatment effectiveness.
- Although 2 randomized, controlled, double-blind, phase III RCTs (SUNRISE 1 [N = 1,006] and SUNRISE 2 [N = 971]) in adults with insomnia showed that treatment with lemborexant resulted in statistically significant improvements in measures of sleep onset, sleep maintenance, and sleep efficiency compared with placebo, it remained uncertain whether the magnitude of the treatment effect was clinically meaningful for multiple outcomes due to variability in results, missing data, lack of control for multiplicity, lack of an estimated minimal important difference (MID), or the MID was not met.
- It is unknown whether lemborexant had a beneficial effect on outcomes that were important to patients, including stress, anxiety, productivity, or relationships as this was not assessed in the SUNRISE 1 and SUNRISE 2 trials.
- Further evidence was needed to address key concerns associated with pharmacological treatment of insomnia, including somnolence, risk of falls, and dependence (i.e., rebound insomnia). In the pivotal SUNRISE 1 and SUNRISE 2 trials, rates of somnolence were higher among patients receiving lemborexant than comparators. The numbers of events for falls were small in the SUNRISE 1 and SUNRISE 2 trials. The rates of rebound insomnia and withdrawal symptoms or dependence were lower for lemborexant, compared to zolpidem in the SUNRISE 1 trial; however, the results had limitations such as missing data and the differences between groups were not statistically tested.
- Extended-release zolpidem was the active comparator used in the SUNRISE 1 trial, while placebo served as control in the SUNRISE 2 trial. CDEC determined that extended-release zolpidem was not a comparator relevant to clinical practice in Canada as it was not used in Canada at the time of the CDEC consideration (i.e., January 2023). There was no direct evidence comparing the efficacy and safety of lemborexant relative to other drugs commonly used to treat insomnia in clinical practice in Canada. The indirect evidence comparing lemborexant to other treatments was uncertain due to numerous limitations, precluding definitive conclusions. Based on the direct and indirect evidence available at the time, CDEC was not able to draw a conclusion on how the efficacy or safety profile of lemborexant would compare to other drugs.
- CDEC noted that the pivotal SUNRISE 1 and SUNRISE 2 trials included an enriched study population, with which the treatment effects observed could be larger than what would be observed in

clinical practice. In addition, the generalizability of the results from the trials to patients excluded from the studies was considered uncertain.

- CDEC noted that duration of treatment with lemborexant was 30 days in the SUNRISE 1 trial and up to 12 months in the SUNRISE 2 trial; therefore, data on long-term effectiveness and safety are limited to this time frame. Furthermore, CDEC noted that safety demonstrated in the clinical trials may not always be generalizable to real-world practice.

To address some of the limitations and gaps in evidence identified by CDEC, in the present resubmission the sponsor submitted additional data obtained from real-world settings.

Sources of Information Used by the Committee

To make its recommendation, the committee considered the following information:

- a review of 2 real-world studies (Juday et al. and Hirata et al.)
- patients' perspectives gathered by 4 patient groups: Migraine Canada, the Alzheimer Society of Ontario (ASO), the Mood Disorders Society of Canada (MDSC), and the Gastrointestinal (GI) Society
- input from public drug plans that participate in the reimbursement review process
- 2 clinical specialists with expertise diagnosing and treating patients with insomnia
- input from 8 clinician groups: Addiction Medicine Specialists, the Cardiometabolic Patient Clinician Group, the Depression and Anxiety Clinician Group, the Primary Care Clinician Group, the Alberta Psychiatrists, the Chronic Insomnia Clinician Group, the Aging Patients Clinician Group, and the Women's Health Clinician Group
- a review of the pharmacoeconomic model and report submitted by the sponsor
- information submitted as part of the sponsor's request for reconsideration (described subsequently)
- feedback on the draft recommendation.

Perspectives of Patients, Clinicians, and Drug Programs

The information in this section is a summary of input provided by the patient and clinician groups who responded to our call for input and from clinical expert(s) consulted for the purpose of this review.

Patient Input

Input for this review was submitted by 4 patient groups: Migraine Canada, the ASO, the MDSC, and the GI Society. Migraine Canada gathered information through 3 surveys for adults in Canada with migraine and sleep challenges or insomnia: a 2021 Quality of Life survey (N = 1,165), a 2022 national online survey for those with experience taking lemborexant (N = 220), and a 2024 national survey (N = 177). ASO gathered information through a review of published literature as well as semistructured interviews with patients with insomnia and clinicians. MDSC gathered information through a 2021 survey for individuals in Canada

experiencing sleep and mental health challenges (N = 1,200), a 2024 survey of patients with migraine and insomnia prepared by Migraine Canada (N = 142), and interviews with patients with insomnia (N = 8) and clinicians (N = 2). The GI Society gathered information through focused discussions with health care providers and researchers, and 1 interview with an individual currently taking lemborexant.

Patient groups emphasized that chronic insomnia is a debilitating condition, arising from a wide range of factors, that impacts nearly all aspects of life, and results in substantial societal cost. Patient groups highlighted that sleep deprivation compromises physical, mental, and emotional health; impairs daily functioning and productivity; and strains personal relationships. According to patient groups, insomnia is often associated with feelings of hopelessness, emotional instability, and chronic fatigue, diminishing patients' ability to engage in work, relationships, and self-care.

Patient groups reported limited access to CBT-I, lack of awareness or referrals, and variable effectiveness. Pharmacological options often include benzodiazepines, nonbenzodiazepine hypnotic drugs, barbiturates, and off-label use of antidepressant drugs and antipsychotic drugs. In the Migraine Canada survey, commonly used medications included zopiclone (27%), trazodone (27%), gabapentin (24%), and benzodiazepines (17%). However, adverse effects such as grogginess, withdrawal symptoms, weight gain, and mood disturbances associated with the use of these medications, were frequently reported. Additionally, the potential for dependency with currently available treatments was reported by the patient groups as highly concerning for patients and physicians.

Generally, patients having experience with lemborexant noted improved daily alertness, work performance, and relationship stability, with minimal grogginess or concerns about dependency. The most common adverse effect reported by these patients were vivid dreams or nightmares, which were described by some as milder than with other medications.

Patients strongly value nonaddictive, well-tolerated treatments that support both sleep initiation and maintenance, without residual sedation, to improve daytime functioning and quality of life. For patients with migraines, reducing the frequency and severity of attacks, along with improving sleep are key treatment goals.

In general, the patient group input submitted for the resubmission of lemborexant is aligned with the patient group input for the initial submission of lemborexant, despite their different areas of focus and interest. For the initial submission, CDA-AMC received input from the MDSC, Migraine Canada, and Menopause Chicks. Patient group input of the initial submission highlighted that patients need treatment to address several important outcomes, including uninterrupted and restorative sleep, greater access to treatment, more effective treatment options, long-term treatment effectiveness, fewer side effects, less stress and anxiety, improved productivity, and improved relationships with family members and colleagues.

Clinician Input

Input From Clinical Experts Consulted for This Review

The clinical experts consulted by the CDA-AMC review team noted that the goals of treatment are improved sleep initiation and maintenance, and improvement of terminal insomnia, overall leading to restorative sleep, improved quality of sleep, as well as improved subjective wakefulness or function during the day. The clinical experts noted that the major unmet need is lacking effective pharmacological treatments with minimal side effects, including long-term side effects, particularly development of tolerance, and low potential for addiction.

According to the clinical experts consulted by the CDA-AMC review team, the mechanism of action of DORAs (i.e., counteracting inappropriate wakefulness at night) is considered fundamentally different from any other pharmacological drug on the market for treatment of insomnia or CID. The clinical experts noted that DORAs will likely shift the treatment paradigm and become a first-line drug for the treatment of CID in the absence of other comorbidities and in patients with comorbid insomnia and sleep apnea, given its lack of effect on breathing patterns. Experts noted that DORAs may take up to 8 weeks to be fully effective. They highlighted that based on their mechanism of action, DORAs such as lemborexant have the potential to address the root cause of CID, unlike other drugs used for insomnia.

The clinical experts consulted by the CDA-AMC review team noted that in general most patients with insomnia may be candidates for lemborexant except for pediatric patients (younger than 18 years) and patients who are pregnant, nursing, or with severe hepatic impairment, narcolepsy, or idiopathic hypersomnia. According to the clinical experts, patients that might be more suitable for treatment with lemborexant include those with insomnia and a history of anxiety or trauma (frequently troubled by inappropriate wakefulness at night due to hyperarousal), older adults with insomnia disorder, and those with a history of addiction and insomnia disorder. The clinical experts noted that patients who would not be suitable include those with narcolepsy or intolerance to the drug. The clinical experts noted that diagnosis of CID is primarily clinical. A polysomnography study can be done in certain cases (e.g., clinical suspicion for comorbid obstructive sleep apnea or other sleep disorder) and brief questionnaires can be used (e.g., Insomnia Severity Index, Sleep Condition Indicator), but they are not used routinely in clinical care.

According to the clinical experts consulted by the CDA-AMC review team, to assess the response to treatment, patients are asked generally if their symptoms have been improved (e.g., whether they are sleeping better, longer, and feeling refreshed) and if they feel better about their daytime functioning. The clinical experts noted that objective tests or sleep diaries are not generally used, and beyond patients' subjective descriptions, the following outcomes can be used to determine an adequate treatment response: sleep latency of less than 30 minutes, sleep efficiency of greater than 90%, improved functional outcome in the day (e.g., less groggy, more energy), improved mood and/or anxiety, improved performance at work or school, decreased irritability or emotionality, improvement in other symptoms (e.g., pain, overall improvement in subjective well-being, improved continuity of sleep at night, and less wake after sleep onset). The clinical experts noted that treatment response is most frequently assessed 1 to 3 months after treatment initiation, but there is a wide variability in the frequency of assessment.

According to the clinical experts consulted by the review team, lemborexant should be discontinued due to allergy to lemborexant, when there is lack of treatment response (may need to use 3 or more months to adequately assess the treatment effects on total sleep time and sleep efficiency), or side effects that are intolerable or unacceptable for patients (e.g., rapid eye movement [REM] intrusion phenomena, daytime sedation, or nocturnal parasomnia behaviours).

The clinical experts consulted by the review team noted that clinicians in several fields (e.g., family physicians, psychiatrists, internal medicine specialists, and neurologists) may use lemborexant to treat patients. According to the clinical experts, sleep specialists are usually not required to diagnose, treat, or monitor patients who might receive lemborexant unless a comorbid sleep condition (comorbid insomnia and sleep apnea) is suspected. Clinical experts highlighted equity issues such as limited access to CBT-I, which disproportionately affects patients with lower socioeconomic status, comorbidities, or those in rural areas. Additionally, the lack of public reimbursement for lemborexant may exacerbate disparities, as patients unable to afford out-of-pocket costs are left with less effective or riskier alternatives.

The input from the clinical experts for the resubmission of lemborexant is aligned overall with the input from the clinical experts for the initial submission of lemborexant.

Clinician Group Input

Input for this review was submitted by 8 clinician groups: Addiction Medicine Specialists (8 health care providers), the Cardiometabolic Patient Clinician Group (12 health care providers), the Depression and Anxiety Clinician Group (5 health care providers), the Primary Care Clinician Group (24 health care providers), the Alberta Psychiatrists (11 health care providers), the Chronic Insomnia Clinician Group (17 health care providers), the Aging Patients Clinician Group (13 health care providers), and the Women's Health Clinician Group (4 health care providers). These groups represent a broad range of health care providers across Canada, including psychiatrists, family physicians, internists, and specialists in addiction, mental health, women's health, and care for older adults. Information included in the input was informed by clinical experience, and gathered through advisory board meetings, focused discussions, and email correspondence.

Clinician groups highlighted the current treatment paradigm for chronic insomnia in Canada, which mainly includes nonpharmacological therapies (e.g., CBT-I), pharmacological treatments (e.g., benzodiazepines, Z-drugs, DORAs, antidepressant drugs, atypical antipsychotic drugs), and other nonprescriptive or over-the-counter treatments (e.g., melatonin, alcohol or cannabis, antihistamines, natural health products). Based on clinician groups, in general, currently available pharmacotherapies primarily promote sedation and alleviate symptoms of chronic insomnia without addressing the underlying disease mechanism and are associated with notable side effects, such as next-day impairment, memory and motor issues, weight gain, dependence, and cardiac arrhythmias.

Aligned with the clinical experts consulted by the review team, clinician groups agreed that treatment goals for chronic insomnia should include improving sleep quality and continuity, enhancing daytime functioning, and minimizing adverse and sedative effects, and supporting the use of lemborexant as a first-line

pharmacological treatment for chronic insomnia. Clinician groups noted that if reimbursed, lemborexant would lead to a shift in current treatment paradigm.

Clinician groups noted that generally most patients aged 18 years or older with insomnia are suitable for lemborexant. The Chronic Insomnia Clinician Group and the Primary Care Clinician Group noted that patients aged younger than 18 years or older adolescents may be eligible to receive lemborexant. The Primary Care Clinician Group also noted that patients with insomnia who are pregnant may receive lemborexant, whereas the clinical experts consulted by the review team considered these patients ineligible. Based on the input from clinician groups, less suitable candidates for lemborexant included those with narcolepsy or those who respond well to short-term use of existing therapies. Lemborexant may also be less effective in individuals with low treatment adherence or those who have been refractory to many previous treatments, as clinician groups noted that evidence has shown possible reduced efficacy in these patients.

Clinician groups emphasized that patient-reported outcomes are key to evaluating treatment response, including perceived sleep quality (e.g., restful sleep, reduced nighttime awakenings), next-day functioning (e.g., alertness, reduced brain fog), and overall quality of life. Some clinician groups noted that standardized tools like the Insomnia Severity Index or Epworth Sleepiness Scale might be used to evaluate changes in sleep to determine treatment response and that objective markers, such as reduced time to sleep onset, fewer awakenings, improved sleep consolidation, and reduced need to nap, were useful in evaluating response.

Clinician groups noted that in general, discontinuation of lemborexant should be based on joint patient-physician decisions, weighing the benefit with the potential risks. Discontinuation of lemborexant may be considered in cases of lacking efficacy, patient preference, unacceptable adverse effects, or initiation of a sedating medication for another condition (e.g., antidepressant drug to treat depression). While lemborexant is expected to produce rapid sleep benefits, the clinician groups noted that it may take 2 to 4 weeks for lemborexant to show full effects, a shorter estimated time than that provided by the clinical experts consulted by the CDA-AMC review team (i.e., 4 to 8 weeks). The clinician groups noted that ongoing consistent use of lemborexant is required until patients achieve several weeks to months of stable remission to reduce relapse risk.

The clinician groups noted that lemborexant could be administered in inpatient and outpatient settings, including emergency departments, long-term care facilities, clinics, hospitals, and at home. The clinician groups noted that lemborexant does not require a specialized setting or specialist to initiate and monitor response, as it is easy and safe to prescribe, with no titration needed and minimal risk of adverse effects, overdose, or dependency. The groups noted that family physicians and specialists could prescribe and monitor lemborexant treatment, and in some jurisdictions, pharmacists would also be authorized to prescribe lemborexant to patients.

Clinician groups with first-hand experience prescribing lemborexant reported that it has significantly improved the treatment of chronic insomnia, allowing for earlier, more effective intervention, especially in patients with complex medical and psychiatric comorbidities. However, clinician groups noted cost remains a major barrier

for patients on public drug plans, who often struggle to afford lemborexant without sacrificing other essentials or relying on family support.

While all clinician groups expressed a favourable position regarding lemborexant, the Chronic Insomnia Clinician Group provided further input on the 2023 CDEC recommendation against reimbursement of lemborexant for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance, which was summarized in the main body of the Clinical Review report.

The inputs from the clinician groups for the resubmission of lemborexant are aligned overall with inputs from the clinician groups for the initial submission of lemborexant.

Drug Program Input

Input was obtained from the drug programs that participate in the reimbursement review process. The following were identified as key factors that could potentially impact the implementation of a recommendation for lemborexant:

- relevant comparators
- considerations for initiation of therapy
- considerations for continuation or renewal of therapy
- considerations for discontinuation of therapy
- generalizability
- systemic and economic issues.

The clinical experts consulted for the review provided advice on the potential implementation issues raised by the drug programs.

Clinical Evidence

Two retrospective observational studies (Juday et al. and Hirata et al.) from the real-world setting are included in the review and appraised by the review team.

Study by Juday et al.

In Juday et al., eligible patients were adults who were diagnosed with insomnia, had at least 1 pharmacy claim for an insomnia medication of interest, visited the health care system during the 6 months postindex date, and had no evidence of falls, hip fractures, or traumatic brain injuries for 6 months before the index date. Patients were required to be exposed to 1 of the following insomnia medications: lemborexant, trazodone, zolpidem, or benzodiazepines (as a class). The primary outcome was the proportion of patients with at least 1 fall during the 6-month follow-up period. After propensity score matching, there were 716 patients in each group with a mean age of 54 years. About 62% and 38% of the patients were female and male, respectively. The most common comorbidities were anxiety disorders (35%), hypertension (34%), and mood disorders (24%). The subanalysis of patients aged 65 years and older had 164 patients in each group.

Results

Risk of Falls in Patients Aged 18 Years and Older

In the 6-month follow-up period, 7.82% of patients in the lemborexant group, 9.92% in the zolpidem group, 9.22% in the trazodone group, and 13.83% in the benzodiazepine group had at least 1 fall recorded. Absolute between-group differences with 95% CI were not provided. Compared to lemborexant, the RR of falls was 1.179 (95% CI, 0.838 to 1.657) for trazodone, 1.268 (95% CI, 0.907 to 1.772) for zolpidem, and 1.768 (95% CI, 1.295 to 2.413) for benzodiazepines as a class.

Risk of Falls in Patients Aged 65 Years and Older

In the 6-month follow-up period, 8.54% of patients in the lemborexant group, 10.98% in the zolpidem group, 10.37% in the trazodone group, and 16.46% in the benzodiazepine group had at least 1 fall recorded. Absolute between-group differences with 95% CI were not provided. Compared to lemborexant, the RR of falls was 1.214 (95% CI, 0.619 to 2.381) for trazodone, 1.286 (95% CI, 0.662 to 2.498) for zolpidem, and 1.929 (95% CI, 1.050 to 3.543) for benzodiazepines as a class.

Critical Appraisal

Reporting of the study did not adhere fully to the *Guidance for Reporting Real-World Evidence*. Risk of bias due to exposure misclassification is possible because this relied on the first pharmacy claim in the identification period, which does not consider adherence, discontinuation, switch of treatments, nor concomitant use of other insomnia drugs during follow-up. There is a risk of bias in selection of patients into the study due to the inclusion of prevalent users, which means that patients may have been using insomnia medications for some time before entering the study. Falls that occur early in treatment that might have caused patients to stop taking the drug would be missed. The issue is compounded by excluding patients with prior falls (in the past 6 months), resulting in patients at higher risk of falls being underrepresented in the sample. The inclusion requirement of at least 1 encounter with the health care system during follow-up may have excluded multiple patients who experienced the outcome of falls and did not report it or were not hospitalized for it, patients who died, and an unknown proportion of patients without the outcome of falls. These patients may differ systematically across groups. Risk of bias due to outcome misclassification is possible due to substantial variation among clinicians in the level of detail recorded in their medical notes. The outcome definition included *International Statistical Classification of Diseases and Related Health Problems, 10th Revision* codes for various injuries, which obscured the true relationship between the treatment exposures and fall risk. Propensity score matching was used to balance potential confounding variables between the lemborexant cohort and comparator cohorts. Although the propensity score matching was successful, residual confounding likely remains because relevant confounders such as treatment history, duration, intensity (dose), and time since diagnosis were not considered. Missing data were not imputed; missing data from race and ethnicity were classified as unknown. The authors did not describe how other categories of missing data were handled which precluded full meaningful adjustment for some variables. There were no explicit exclusions, which is a strength of real-world studies compared to RCTs. Limitations to generalizability included the focus on data from patients in 50 large US health care organizations which underrepresents patients without health coverage or smaller practices; the insomnia definition being broader

than the CID *DSM-5* criteria (includes acute insomnia); the lack of description of the doses of lemborexant and comparator insomnia medications used; and that recurrent falls were not captured, which does not allow for the full impact on fall risk to be assessed.

Study by Hirata et al.

In Hirata et al., eligible patients were those aged 20 years or older and admitted to 1 of 8 hospitals in Japan during the study period. Patients were exposed to 1 of the following hypnotic medication groups: benzodiazepines, Z-drugs, suvorexant, lemborexant, ramelteon, and other hypnotic drugs, at the time of admission. The outcome of interest was the occurrence of inpatient falls. Of the 150,278 patients, 390 (0.3%) were exposed to lemborexant. In the full population, the median age was 70 years (range, 58 to 79 years), and 46.9% and 53.1% were female and male, respectively. The patients were classified into the fall group (n = 3,458) and nonfall group (n = 146,820).

Results

Odds of In-Hospital Falls

Between patients who used the medication versus those who did not use the medication, the odds ratio for falls was 1.188 (95% CI, 0.774 to 1.825) for lemborexant, 1.255 (95% CI, 1.118 to 1.409) for benzodiazepines, and 1.293 (95% CI, 1.118 to 1.496) for Z-drugs.

Critical Appraisal

Reporting of the study did not adhere fully to the *Guidance for Reporting Real-World Evidence*, and the aim of this pilot study was not to draw causal inferences. Instead, the study examined the association between hypnotic medication use and inpatient falls. Exposure was ascertained using pharmacy records, but the time period during which exposure was ascertained and actual exposure time period before admission was not described in the study. Risk of bias due to misclassification of exposed or unexposed status is possible because it occurred without consideration of adherence, discontinuation, or switch of treatments occurring before hospitalization or during follow-up. There is a risk of bias in selection of patients into the study because the limited reporting does not suggest that inclusion was limited to new users of the relevant drugs. This means that patients may have been using insomnia medications for some time before entering the study. Falls that occur early in treatment that might have caused patients to stop taking the drug would be missed, and those remaining on the treatments are likely to be patients at lower risk of falls. Although there is a lack of clarity in the publication, it appears that exposure status was collected up to the day following admission. The time before the index date should have been classified as unexposed, but it is unclear whether this occurred. Some risk of immortal time bias is possible but could be small as this represents a single day of potentially misclassified exposure time. The potential for bias due to outcome misclassification could not be fully ascertained due to lack of reporting of the fall outcome description and its validation. A multivariable logistic regression model was used to adjust for several potentially confounding variables; empirical evaluation of the model performance (balance of confounders) was not possible. Residual confounding is likely to remain given that some relevant confounding variables were not considered, such as the presence of insomnia, insomnia treatment history, treatment duration and intensity (dose), and length of hospital stay (follow up). Missing data were not imputed, which precluded full meaningful adjustment for

some variables. There were no explicit exclusions, which is a strength of real-world studies compared to RCTs. Limitations to generalizability included the focus on inpatients who were not required to be affected by insomnia, the setting being predominantly rural hospitals in Japan, the lack of description of the dose of lemborexant used, and the lack of direct comparative estimates versus other relevant treatments.

Additional Supportive Evidence for the Reconsideration

PSUR (Reporting Period: December 20, 2024, to June 19, 2025)

In their reconsideration request, the sponsor provided a PSUR. The safety data in the PSUR were collected from various sources, including completed and ongoing clinical trials and postmarketing data sources which included spontaneous individual case safety reports (ICSRs) from health care professionals, consumers, scientific literature, worldwide competent authorities, as well as solicited noninterventional ICSRs.

[redacted]

Although information on various adverse events was available in the PSUR, only fall events were considered relevant to the reconsideration request. Overall, although the PSUR provides important and valuable insights for the safety of lemborexant, there was some uncertainty associated with the findings from the PSUR report. The data in the PSUR were aggregated based on various individual data sources (e.g., clinical trials, ICSRs). The internal validity of the aggregated data in the PSUR is dependent on the validity of the individual data sources. The sponsor has confirmed that “there is no protocol for the PSUR as the PSUR is not a clinical study.” Without more information, the CDA-AMC review team could not evaluate further on the internal

validity of the aggregate data reported in the PSUR. Moreover, the aggregate data in the PSUR were from people with insomnia disorder, irregular sleep-wake rhythm disorder, and volunteers in good health and covered all formulations, doses, and routes of lemborexant, which makes it difficult to attribute the safety signals to patients with insomnia and to the formulations, doses, and routes indicated in the Health Canada indication. The PSUR does not provide information on fall risk compared to other relevant treatments used to treat CID in clinical practice in Canada, where the data were collected in a similar manner. As a result, the PSUR does not enable conclusions about comparative fall risk.

Economic Evidence

- Lemborexant is available as 5 mg and 10 mg oral tablets. At the submitted price of $1.76 per 5 mg or 10 mg tablet, the annual cost of lemborexant is expected to be $641 per patient, based on the Health Canada–recommended dosage.
- The economic analysis was informed by clinical evidence previously submitted to CDA-AMC. Evidence generated from the RCTs and ITCs remains unchanged from the initial submission. The clinical efficacy of lemborexant was informed by the SUNRISE 1 and SUNRISE 2 clinical trials. The efficacy of modelled treatments was derived from a sponsor-submitted ITC which compared the efficacy and safety of lemborexant to placebo, triazolam, and temazepam. The indirect evidence submitted by the sponsor suggests that lemborexant may improve subjective sleep onset latency compared to triazolam; however, substantial imprecision, unresolved heterogeneity, and uncertainty in the plausibility of the transitivity assumption was identified by CDA-AMC, which precludes the use of the ITC to inform decision-making.
- The results of the CDA-AMC base case suggest that over 180 days:
  - Lemborexant is predicted to be associated with higher costs to health care systems than lorazepam, quetiapine, flurazepam, temazepam, trazodone, triazolam, zopiclone, nitrazepam, and no treatment (incremental costs = $276 to $321), primarily driven by increased costs associated with drug acquisition.
  - Lemborexant is not predicted to extend life compared to all modelled treatments but may slightly improve the quality of life due to increasing the likelihood a patient has improved sleep quality. This results in a gain of 0.003 quality-adjusted life-years compared to quetiapine.
  - The incremental cost-effectiveness ratio of lemborexant compared to quetiapine was $103,511 per quality-adjusted life-years gained in the CDA-AMC base case. The estimated incremental cost-effectiveness ratio was sensitive to efficacy parameters (i.e., subjective sleep onset latency), and the relative risk of falls, motor vehicle accidents, and workplace accidents. As no comparative evidence was presented for lorazepam, quetiapine, flurazepam, zopiclone, and nitrazepam, there is uncertainty associated with the cost-effectiveness of lemborexant when compared to these treatments. Given the level of clinical uncertainty in the submitted ITC, it is unclear whether lemborexant provides incremental benefit relative to currently reimbursed treatments.

- CDA-AMC estimates that the budget impact of reimbursing for the treatment of CID (i.e., the reimbursement requested population) will be approximately $165 million over the first 3 years of reimbursement compared to the amount currently spent on comparators, with an estimated expenditure of $189 million for lemborexant over this period. When considering the Health Canada indication (i.e., acute and chronic insomnia), the budget impact is estimated to be $257 million for the first 3 years of reimbursement. The actual budget impact of reimbursing lemborexant will depend on the market uptake of lemborexant and the number of people eligible for treatment. At the submitted price, the incremental budget impact of lemborexant is predicted to be greater than $40 million in year 2 and year 3 of reimbursement, and the economic feasibility of adoption must be addressed. Additionally, the magnitude of uncertainty in the budget impact must be addressed to ensure the feasibility of adoption, given the difference between the sponsor's estimate and the estimate by CDA-AMC.

Request for Reconsideration

The sponsor filed a request for reconsideration of the draft recommendation for lemborexant for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. In their reconsideration request:

- The sponsor expressed concerns regarding the data standard adopted by CDEC. The sponsor is of the view that the limitations of the Juday et al. and Hirata et al. studies (i.e., misclassification bias, bias due to residual confounding, generalizability issues) should be contextualized within the broader challenges of insomnia research. The inherent limitations of observational studies and administrative data which affect all insomnia treatments should be recognized. The evidence demonstrating the association between reduced risk of falls and lemborexant use should be considered conclusive. The sponsor provided data from a PSUR.
- The sponsor expressed concern that the draft recommendation did not adequately reflect the urgency, consistency, and relevance of the input from patient and clinician groups.
- The sponsor is of the view that benzodiazepines should not be considered as a relevant comparator to lemborexant and the ITC evidence should be re-examined accordingly.

In the meeting to discuss the sponsor's request for reconsideration, CDEC considered the following information:

- information from the initial submission related to the issues identified by the sponsor
- feedback from 2 clinical specialists with expertise in diagnosing and treating patients with insomnia
- feedback on the draft recommendation from 2 patient groups: the GI Society and the MDSC
- feedback on the draft recommendation from 8 clinicians or clinician groups: the Addiction Medicine Specialists, the Cardiometabolic Patient Clinician Group, the Depression and Anxiety Clinician Group, the Primary Care Clinician Group, the Alberta Psychiatrists, the Chronic Insomnia Clinician Group, the Aging Patients Clinician Group, and the Women's Health Clinician Group

- feedback on the draft recommendation from the public drug plans that participate in the reimbursement review process.

All feedback received in response to the draft recommendation is available on the CDA-AMC website.

CDEC Information

Meeting date: August 27, 2025

Members of the Committee

Dr. Peter Jamieson (Chair), Dr. Kerry Mansell (Vice-Chair), Dr. Sally Bean, Daryl Bell, Dan Dunsky, Dr. Ran Goldman, Dr. Trudy Huyghebaert, Morris Joseph, Dr. Dennis Ko, Dr. Christine Leong, Dr. Alicia McCallum, Dr. Srinivas Murthy, Dr. Nicholas Myers, Dr. Krishnan Ramanathan, Dr. Marco Solmi, Dr. Edward Xie, and Dr. Peter Zed.

Regrets: Two expert committee members did not attend.

Conflicts of interest: None

Reconsideration Meeting Date: December 17, 2025

Members of the Committee

Dr. Peter Jamieson (Chair), Dr. Kerry Mansell (Vice-Chair), Dr. Sally Bean, Daryl Bell, Dan Dunsky, Dr. Ran Goldman, Dr. Trudy Huyghebaert, Dr. Dennis Ko, Dr. Christine Leong, Dr. Alicia McCallum, Dr. Srinivas Murthy, Dr. Nicholas Myers, Dr. Krishnan Ramanathan, Dr. Marco Solmi, Carla Velastegui, Dr. Edward Xie, and Dr. Peter Zed.

Regrets: Two expert committee members did not attend.

Conflicts of interest: None

Canada's Drug Agency
L'Agence des médicaments du Canada
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Questions or requests for information about this report can be directed to Requests@cda-amc.ca.