CADTH

CADTH COMMON DRUG REVIEW

CADTH Canadian Drug Expert Committee Recommendation

(Final)

ERENUMAB (AIMOVIG — NOVARTIS PHARMACEUTICALS CANADA INC.)
Indication: Prevention of migraine

RECOMMENDATION
The CADTH Canadian Drug Expert Committee recommends that erenumab be reimbursed for the prevention of chronic migraine in adults, if the following conditions are met.

Conditions for Reimbursement
Initiation criteria
1. The patient has a confirmed diagnosis of chronic migraine according to the International Headache Society criteria, which defined it as headaches that last for at least 15 days per month for more than three months of which at least eight days per month are with migraine.
2. The patient has experienced an inadequate response, intolerance, or contraindication to two or three oral prophylactic migraine medications.
3. Patients who have had a lack of therapeutic response to four or more prior oral prophylactic migraine medications are not eligible for reimbursement.
4. The physician must provide the number of headache and migraine days per month at the time of initial request for reimbursement.
5. The maximum duration of initial authorization is six months.

Renewal criteria
1. The physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as a reduction of at least 50% in the number of migraine days per month at the time of first renewal compared with baseline. At subsequent renewals the physician must provide proof that the initial 50% reduction in the number of migraine days per month has been maintained.
2. The maximum duration of subsequent authorizations following the initial authorization is six months.

Prescribing conditions
1. The patient should be under the care of a physician who has the appropriate qualifications and experience with the management of migraine headaches.

Pricing conditions
1. Reduction in price.

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Recommendation

The CADTH Canadian Drug Expert Committee (CDEC) recommends that erenumab be reimbursed for the prevention of chronic migraine in adults, if the following conditions are met.

Conditions for Reimbursement

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2. The maximum duration of subsequent authorizations following the initial authorization is six months.

Prescribing conditions

1. The patient should be under the care of a physician who has the appropriate qualifications and experience with the management of migraine headaches.

Pricing conditions

1. Reduction in price.

Reasons for the Recommendation

1. CDEC considered that erenumab could address an unmet need identified by patient groups for safe and effective medications to prevent chronic migraines in patients who have failed two or three prophylactic migraine medications. A pre-specified subgroup analysis of this patient population from Study 295 (N = 667; 12 weeks in duration) demonstrated that erenumab reduced the number of monthly migraine days compared with placebo by 2.7 days (95% confidence interval [CI], –4.2 to –1.2, P < 0.001) for the 70 mg dose and by 4.3 days (95% CI, –5.8 to –2.8, P < 0.001) with 140 mg dose. The study excluded patients who had not experienced any therapeutic response to four or more prior prophylactic medications for migraine and therefore the clinical effectiveness of erenumab in these patients could not be determined.
2. The sponsor's submitted price for erenumab is $532 per 70 mg or 140 mg autoinjector, with an annual cost of treatment of $6,384 per patient, which is higher than the annual publicly available cost for other medications commonly used to prevent migraines. The sponsor-provided pharmacoeconomic model compared the cost-effectiveness of erenumab with best supportive care (BSC), consisting of treatments used for acute migraine and onabotulinum toxin A (in chronic migraine patients only). The

cost-effectiveness of erenumab is uncertain because of the lack of high-quality data for the comparative effectiveness of erenumab and other preventive therapies for migraine.

Implementation Considerations

- Inadequate response to oral prophylactic therapies is defined as less than a 30% reduction in frequency of headache days to an adequate dose and duration of two to three prophylactic medications, where at least two must be of a different class.
- Oral prophylactic therapies to be considered include:
  - beta blockers
  - tricyclic antidepressants
  - verapamil or flunarizine
  - sodium valproate (or divalproex sodium)
  - topiramate
  - gabapentin.
- A list of previously tried oral prophylactic medications, including doses and duration, and reasons for discontinuance, should be provided by the requesting physician.
- Contraindication or intolerable adverse effects necessitating discontinuation of oral prophylactic therapy will be considered for one of the three drugs only.
- Confirmation of specific training in the management of headache should be provided by the physician applying for reimbursement of treatment with erenumab.
- Some jurisdictions may want to include a reduction of at least 30% in the number of headache days per month and an improvement of at least five points in the Headache Impact Test (HIT-6) score, compared with baseline, as an additional criterion for renewal of reimbursement. Jurisdictions that choose to include this criterion should also request that the physician provide the score obtained on the HIT-6 at the time of initial request for reimbursement.
- The sponsor-provided pharmacoeconomic model for erenumab compared the cost-effectiveness of erenumab with onabotulinum toxin A only in the patient population with chronic migraine. Therefore:
  - If onabotulinum toxin A is reimbursed for the prevention of chronic migraine, then the cost of erenumab should not exceed the cost of onabotulinum toxin A.
  - If onabotulinum toxin A is not reimbursed for the prevention of chronic migraine, a price reduction would be required to increase the likelihood that erenumab is cost-effective.
- Erenumab should not be used in combination with onabotulinum toxin A.

Discussion Points

- Migraine is a common and debilitating headache disorder that may lead to poor quality of life, social isolation, and an inability to participate in daily activities. CDEC discussed patient and clinician input that current prophylactic medications do not benefit everyone with migraine and have adverse effects that may make them difficult to take, leading to poor adherence to regimens and non-achievement of desired outcomes.
- Patients with frequent recurrent migraines are classified by the International Headache Society as those with episodic migraine (four to 24 migraine days per month and fewer than 15 headache days per month) or those with chronic migraine (at least 15 days a month with headaches of which at least eight days are migraine days).
- CDEC reviewed data from four randomized controlled trials (RCTs) (STRIVE, ARISE, LIBERTY conducted in patients with episodic migraine, and Study 295 in patients with chronic migraine ranging from 12 to 24 weeks in duration) representing the patient population in the Health Canada–approved indication. The RCTs demonstrated that erenumab reduced the frequency of migraine days by approximately 1.0 to 2.5 days per month compared with placebo for patients with episodic or chronic migraines. CDEC noted that the minimally clinically important difference (MCID) for headache and migraine frequency has not

been definitively determined. Therefore, the therapeutic value of the approximately 1.0 to 2.5 day absolute difference in headache and migraine days between erenumab and placebo in the overall analysis population of the studies is uncertain.

- Given the uncertainty in the magnitude of the clinical benefit of erenumab in the overall analysis populations of the RCTs, CDEC examined the effects of erenumab in the subgroup of patients who had not achieved adequate response with prior preventive medications for migraine. CDEC concluded that the subgroup of patients from Study 295 with chronic migraine and who were categorized as having failed (an inadequate response due to insufficient efficacy or unacceptable tolerability) at least two prophylactic migraine medications before study enrolment was the subpopulation in which erenumab demonstrated the most benefit, relative to placebo. The subgroup was also the only pre-specified one that was similar to the sponsor's request to reimburse erenumab in patients who have at least eight migraine days per month and who have previously failed at least two migraine preventive therapies. Although CDEC noted important limitations with the analyses (such as small sample sizes per group, no adjustments made for multiple statistical comparisons, and Study 295 excluded individuals who had no therapeutic response to more than three prior therapies), the committee considered the treatment effect differences between erenumab and placebo to be large enough to suggest clinical benefit in reducing migraine days and to inform the reimbursement recommendation in this subgroup of patients.
- Data are lacking from high-quality studies to estimate the effect of erenumab on outcomes important to patients, including functionality, regaining active work and personal life roles, and reducing frequency of emergency department visits.
- CDEC could not support including patients with chronic migraine who did not have a therapeutic response to four or more oral prophylactic migraine medications in a reimbursement recommendation because of the lack of data in this subpopulation (they were excluded from the study that enrolled patients with chronic migraines, Study 295).
- CDEC discussed data from longer-term phases of Study 295 and STRIVE. Because of the limitations of these data, particularly the lack of a comparator group and the studies' high discontinuation rates, CDEC considered the results too uncertain to make conclusions regarding the longer-term efficacy and safety of erenumab.
- Comparative evidence was limited to indirect treatment comparisons of erenumab with other medications used to prevent migraines. The limitations with the indirect evidence and lack of direct active comparative evidence preclude any conclusions regarding the comparative effectiveness of erenumab with other available migraine prevention therapies.
- Patient input described their experience of receiving erenumab in combination with onabotulinum toxin A. CDEC noted the lack of evidence regarding combination use of erenumab with onabotulinum toxin A and other medications used for prevention of migraines is an important gap in evidence.
- Data are limited regarding the efficacy of erenumab in patients who have previously used onabotulinum toxin A. In a subgroup analysis of Study 295, among patients who had previously used onabotulinum toxin A, erenumab 70 mg and 140 mg were associated with approximately one fewer migraine days per month compared with placebo. [redacted]
- The cost-effectiveness of erenumab relative to onabotulinum toxin A will depend on the negotiated price of the latter drug. Given the lack of evidence to suggest that either drug is superior, the costs paid for each should be equivalent.

Background

Erenumab has a Health Canada indication for the prevention of migraines in patients who have at least four migraine days monthly. It is a monoclonal antibody that binds to and inhibits calcitonin gene–related peptide and is administered by subcutaneous injection at a dosage of either 70 mg or 140 mg once monthly. Erenumab is available as an autoinjector in 70 mg and 140 mg strengths.

Summary of Evidence Considered by CDEC

CDEC considered the following information prepared by the CADTH Common Drug Review: a systematic review of RCTs of erenumab, critiques of indirect comparisons and non-randomized studies, and a critique of the manufacturer's pharmacoeconomic evaluation. The committee also considered input from a clinical expert with experience in treating patients with migraines, and patient group–submitted information about outcomes and issues important to patients.

Summary of Patient Input

One patient group submission (in two parts), from Migraine Canada and Migraine Quebec (supported by several other patient organizations), provided input for this review. Patient perspectives were obtained primarily through two surveys. The following is a summary of key input from the perspective of the patient group:

- Migraines are common and can have a significant impact on patients' lives and the lives of those around them. During attacks, the ability to accomplish tasks, work, and interact with others is compromised. Cognition is affected, with slowed thinking, lack of focus, and difficulty in reading and speaking. Patients report having been disabled as a result of migraines, unable to work, and dependent on others for many activities of daily living.
- Patients often try multiple medications with no success, or experience side effects and seek alternative therapies.
- Patients often experience side effects from therapies. These include sleepiness, fatigue, weight gain, gastrointestinal upset, depression, anxiety or mood difficulties, dizziness, cognitive problems, low blood pressure, fainting, and exercise intolerance. These are frequently problematic enough to lead to the discontinuation of medication.
- For patients, the most important aspect of a treatment is efficacy (reducing the frequency, severity and duration of migraines), followed by reduced side effects and improved quality of life.

Clinical Trials

The systematic review included four sponsor-provided, multinational, placebo-controlled, double-blind RCTs. STRIVE (N = 955), LIBERTY (N = 246), and ARISE (N = 577) were conducted in patients with episodic migraines, defined as an average of four or more and fewer than 15 migraine days per month, and fewer than 15 headache days per month, for the three months before screening. Study 295 studied patients with chronic migraine, defined as headaches for at least 15 days per month for more than three months, of which at least eight days per month are with migraine. In Study 295 (N = 667) patients received either erenumab 70 mg subcutaneous once monthly or erenumab 140 mg subcutaneous once monthly, or matching placebo. STRIVE had a 24-week double-blind treatment period while the other trials included a 12-week double-blind phase. The double-blind treatment phase in Study 295 was followed by a 28-week treatment period where all patients received erenumab, re-randomized to either the 70 mg or 140 mg dose. After the end of all treatment phases there were 12 weeks of follow up for safety. In STRIVE, 9% to 10% of patients from the erenumab groups withdrew, versus 12% of placebo patients. In Study 295, 4% of erenumab patients and 7% of placebo patients withdrew. In LIBERTY, 2% to 3% of patients withdrew. In ARISE, 5% to 6% of patients withdrew. There were no clear differences between groups.

Key critical appraisal issues included the relatively short-term follow up (12 or 24 weeks of double-blind treatment phase) given that this is a first-in-class drug with a novel mechanism of action used to treat a chronic condition. The lack of an active comparator and that the HIT-6 (an established measure of headache symptoms and function domains) and health-related quality of life (HRQoL) were only assessed as exploratory outcomes in the included trials are additional limitations in the study design. The sponsor did not perform an intention-to-treat analysis as part of its primary analysis of continuous outcomes, and instead used imputation on sensitivity analyses, which were consistent with the results of the primary analysis.

Outcomes

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

- Reduction frequency of monthly migraine days: Data were collected via patient-completed electronic diaries to record the onset and severity of migraine and headache episodes. In LIBERTY, this was reported as the percentage of patients with a 50% reduction in monthly migraine days at week 12 and in the other studies it was reported as the change from baseline in monthly migraine days to the end of the double-blind treatment period. The MCID for reduction in monthly migraine days is unclear.
- The migraine physical function impact diary (MPFID): MPFID was a secondary outcome in all of the included studies except Study 295, where it was exploratory. MPFID was developed by the sponsor and asks patients about the physical, functional, and global impact of their migraines. It is scored on a five-point scale, with higher scores indicating more negative impact on function. Domain scores were transformed and scaled to a 100 point score, and the daily MPFID was averaged over a 28-day period. [redacted]

- Migraine-Specific Quality of Life Questionnaire (MSQ): The MSQ is a self-reported, disease-specific instrument that assesses the impact of migraines on a patient's HRQoL. The questionnaire comprises three domains: role function restrictive, role function preventive, and emotional function. For each domain, scores range from 0 to 100. A higher score indicates a better HRQoL. MSQ can also be scored in the reverse fashion, with a lower score indicating higher function. For the role function restrictive domain, the group level MCID was 3.2 and 10.9 in episodic and chronic migraine, respectively; for the role function preventive domain, MCIDs were 4.6 and 8.3 for episodic and chronic migraine, respectively; and for the emotional function domain the MCIDs were 7.5 and 12.2, respectively. MSQ was an exploratory outcome in the studies.
- HIT-6 questionnaire: The HIT-6 comprises six items that measure pain, social functioning, role functioning, vitality, cognitive functioning, and psychological distress. The total HIT-6 score range is from 36 to 78. The higher the score the more significant the impact of the disease is on the daily life of the respondent. HIT-6 was an exploratory outcome in the studies. For patients with episodic migraine, the within-group MCID was –2.5 and the between-group MCID was –1.5, and for chronic daily headaches it was –2.3 points.
- The Work Productivity and Activity Impairment Instrument (WPAI): The WPAI is a self-administered questionnaire that measures impairments in work and activities during the past seven days due to general health or a specific health problem. The questionnaire elicits information on the number of days or hours missed from work, days or hours worked, days during which the performing of work was challenging, and the extent to which the patient was limited at work (work impairment). No migraine-specific MCID was found for this instrument. WPAI was an exploratory outcome in LIBERTY and was performed weekly via an electronic diary.
- Acute headache or migraine pain medication use: This was defined as intake of medication(s) (per month) to treat headache pain.
- Serious adverse events (SAEs), total adverse events (AEs), withdrawal due to AEs, and notable harms.

The primary efficacy outcome in three of the trials was the reduction from baseline in monthly migraine days. In the other study it was reported as a 50% reduction in monthly migraine days.

Efficacy

In general, there were one- to two-day reductions in monthly migraine days out of eight to nine monthly migraine days at baseline, compared with placebo during a three- to six-month treatment period among those patients with episodic migraine (STRIVE, LIBERTY, and ARISE). The reduction was approximately 2.5 days out of 18 monthly migraine days at baseline in patients with chronic migraine (Study 295). There was no difference in the mean reduction of monthly migraine days between erenumab 70 mg and 140 mg across the studies. The studies also assessed the percentage of patients who experienced a 50% reduction in monthly migraine days, and there were consistently more erenumab-treated patients than placebo patients who achieved this threshold.

Subgroups of interest in the systematic review were patients who have failed (i.e., lack of efficacy, intolerance, or clinical contraindication) prior oral prophylactic medications, number of migraine days per month at baseline, and patients who exhibit signs of medication-overuse headaches versus those who do not. The specific subgroup identified in the sponsor's reimbursement request (adults with at least eight migraine days monthly and who have failed, are intolerant to, or have a contraindication to at least two migraine prevention therapies) was not analyzed in any of the studies. A subgroup analysis of patients who had failed at least two prior preventive medications in Study 295 (patients with chronic migraines) was the only pre-specified subgroup analysis that was similar to the sponsor's reimbursement request. In this analysis, erenumab 70 mg was associated with a –2.7 (95% CI, –4.2 to –1.2, $P < 0.001$) reduction in monthly migraine days, and erenumab 140 mg was associated with a –4.3 (95% CI, –5.8 to –2.8, $P < 0.001$) reduction in monthly migraine days compared with placebo at 12 weeks. Study 295 excluded patients from enrolment who had failed four or more prior preventive medications for chronic migraines. A post hoc analysis of patients from STRIVE (episodic migraine population) who had failed at least two prior prophylactic medications suggested that treatment with both doses of erenumab resulted in greater reductions in monthly migraine days at months four to six versus placebo (–1.3 [95% CI, –2.6 to 0.0] for 70 mg and –2.7 [95% CI, –4.0 to 1.4] for 140 mg). Other subgroup analyses supported the statistical superiority of erenumab versus placebo for reduction in migraine frequency across subgroups; however, all of the subgroup analyses were limited by small sample sizes, potential imbalances between patient characteristics, and not being controlled for multiple comparisons.

Erenumab reduced the use of acute medication for migraines by 0.6 to 1.5 days from a baseline of three to five days over three to six months in episodic migraine, and by 2.0 to 2.5 days from a baseline of nine days over three months in chronic migraine.

Functional ability was assessed using the physical and everyday activities domains of the MPFID. Erenumab statistically significantly improved both domains across the studies, and most of these differences were clinically significant, although there was a wide range of possible MCIDs, introducing some uncertainty into the analysis.

Other patient function and HRQoL were exploratory outcomes in each of the studies. Although the results were generally supportive of the primary analyses, the limitations associated with the study designs and statistical analyses for these outcomes precludes drawing strong conclusions regarding the effects of erenumab on functioning and HRQoL.

Harms (Safety)

There were no deaths in any of the included studies.

AEs occurred in STRIVE in 57% and 56% of patients in the erenumab groups and 63% in the placebo group. In Study 295, AEs occurred in 44% and 47% of patients receiving erenumab and in 39% of patients receiving placebo. In LIBERTY, AEs occurred in 55% of erenumab patients and 54% of placebo patients, and in ARISE in 48% of erenumab patients and 55% of placebo patients.

SAEs occurred in 1% to 3% of the study populations and there were no clear and consistent differences between groups in any of the included studies. In STRIVE, 2.5% of erenumab 70 mg patients and 1.9% of erenumab 140 mg patients versus 2.2% of placebo patients had an SAE during the 24-week double-blind treatment phase. In Study 295, 3.2% of erenumab 70 mg and 1.6% of erenumab 140 mg versus 2.5% of placebo patients had an SAE during the 12-week double-blind treatment phase. In LIBERTY, 1.7% of erenumab 140 mg patients versus 0.8% of placebo patients had an SAE, while in ARISE, 1.1% of erenumab 70 mg patients and 1.7% of placebo patients had an SAE during the 12-week, double-blind treatment phases of these studies.

In STRIVE, 2.2% of patients in each of the erenumab groups withdrew due to an AE versus 2.5% of patients in the placebo group. In the other studies, withdrawals due to AEs occurred in between 0% and 2% of patients with no clear differences between groups within studies.

Hypersensitivity and other injection site reactions were a notable harm in this review, and these events were infrequent across the included studies, with no clear and consistent differences between groups within studies. Vascular-related AEs were also a notable harm, based on the vascular effects of calcitonin gene–related peptide; however, there were no clear or consistent differences in hot flushes, hypertension, or hypotension between groups in any of the studies.

Indirect Treatment Comparisons

The sponsor-submitted indirect treatment comparison found no statistically significant difference between erenumab 140 mg and botulinum toxin A regarding patients with chronic migraine who had failed three prior therapies achieving a 50% reduction in monthly migraine days. There were numerous methodological limitations of this analysis. A published network meta-analysis in chronic migraine found that erenumab was not favoured over topiramate or botulinum toxin A with respect to monthly migraine days, use of acute medications, and for all-cause discontinuation. In episodic migraine, erenumab was only favoured over topiramate, but not over propranolol or amitriptyline for reducing monthly migraine days. For reducing acute medication, only the higher dose of erenumab (140 mg) was favoured over the low dose of topiramate (50 mg). For all-cause discontinuations, both doses of erenumab (70 mg and 140 mg) were favoured over the higher dose of topiramate (200 mg), but not over any other comparator.

Cost and Cost-Effectiveness

At the sponsor's submitted price of $532 per 70 mg or 140 mg autoinjector, the average annual drug cost is approximately $6,384 per patient.

The sponsor submitted a cost-utility analysis from the perspective of a Canadian publicly funded health care payer comparing erenumab with BSC for the prevention of migraines in adults who have at least four migraine days per month (indication, base case) and for the prevention of migraines in adults who have at least eight migraine days per month and who have previously failed, are intolerant to, or have a contraindication to at least two migraine preventive therapies (sponsor's reimbursement request). Both the base-case and reimbursement-request populations consisted of patients with episodic migraines and chronic migraines, with episodic migraine being defined as patients having fewer than 15 monthly headache days, of which four to 14 are monthly migraine

days; and chronic migraine being defined as patients having 15 or more monthly headache days, of which eight or more are monthly migraine days. Erenumab was compared with onabotulinum toxin A in a scenario analysis in patients with chronic migraine. The sponsor's submitted model consisted of a decision tree to determine patient response to treatment during a 12-week assessment period, and a Markov model to assess long-term treatment costs and benefits based on patients' response to treatment during the assessment period over a five-year time horizon. Response was defined as a 50% reduction in monthly migraine days from baseline to the end of the assessment period. Efficacy data for BSC and erenumab were derived using data from the Study 295 trial in patients with chronic migraine and the pooled results of the STRIVE and LIBERTY trials in patients with episodic migraine. Efficacy data for the comparison with onabotulinum toxin A was derived from an indirect treatment comparison comparing erenumab 140 mg with onabotulinum toxin A in chronic migraine patients who had failed to respond to at least three prior treatments. Health state utility values were derived by mapping MSQ data from Study 295 and STRIVE to EuroQol 5-Dimensions utility values. Health state costs were dependent on monthly migraine day frequency and were estimated using responses from Canadian patients to a global online survey and the Canadian results of the International Burden of Migraine Study of patients with migraines.

The sponsor reported incremental cost-utility ratios (ICURs) of $89,773 and $84,204 per quality-adjusted life-year (QALY) for erenumab 70 mg and 140 mg, respectively, in the base case. The sponsor reported ICURs of $63,152 and $46,704 per QALY for erenumab 70 mg and 140 mg, respectively, in the reimbursement request.

CADTH identified several key limitations with the sponsor's economic submission:

- The sponsor only included onabotulinum toxin A as part of a scenario analysis in patients with chronic migraine. Additionally, relevant comparators such as topiramate, pizotifen, and flunarizine were excluded from the analysis. Therefore, the cost-effectiveness of erenumab relative to these treatments is unknown.
- Limitations with the indirect treatment comparison restricted the validity of the results.
- The long-term treatment efficacy of erenumab is uncertain.
- The health states in the model did not fully capture the migraine condition, as the impact of erenumab on migraine severity was not incorporated in the model.
- Data from non-homogenous trials was pooled to inform model inputs without adjusting for sample sizes or baseline characteristics.
- As no natural change in migraine severity or frequency was incorporated in the analysis, the natural history of migraines has not been accounted for.
- There were discrepancies between the sponsor's frequency estimates for health care resource use and those provided by the clinical expert consulted by CADTH for this review.
- Parameter uncertainty was inadequately explored in the probabilistic analysis.
- Health state utility values were informed by treatment-dependent monthly migraine day distributions. Additionally, mapping is not recommended by CADTH, and the approach to mapping had limitations. A utility decrement for the mode of administration of onabotulinum toxin A was also deemed to be inappropriate by clinical experts.
- Long-term treatment discontinuation was not informed by the most recent data from the ongoing open-label extension study (Study 178) of erenumab.
- Results were not reported in a stratified manner by subgroup (i.e., episodic migraine and chronic migraine).

In the CADTH base case, resource use frequency estimates and all-cause long-term negative discontinuation rates were revised; treatment-specific monthly migraine day distributions were removed when calculating health state utilities; the discontinuation parameter for onabotulinum toxin A was removed from the probabilistic analysis to be consistent with erenumab; and, the mode of administration utility decrement for onabotulinum toxin A was removed. All CADTH analyses were presented as a stratified analysis (i.e., in separate episodic migraine and chronic migraine populations).

For the base case, erenumab 70 mg was extendedly dominated for both episodic migraine and chronic migraine. Erenumab 140 mg compared with BSC was associated with an ICUR of:

- $153,635 per QALY for episodic migraine
- $66,359 per QALY for chronic migraine.

For the reimbursement request, erenumab 70 mg was extendedly dominated. Erenumab 140 mg compared with BSC was associated with an ICUR of:

- $105,695 per QALY for episodic migraine
- $39,840 per QALY for chronic migraine.

CADTH could not address the limitations associated with the lack of consideration of key comparators, migraine severity, natural history of migraines, inappropriate pooling of trial data, uncertain long-term efficacy, and limitations in the indirect treatment comparison. The limitations with the indirect treatment comparison result in cost-effectiveness findings that are highly uncertain.

CDEC Members

Dr. James Silvius (Chair), Dr. Ahmed Bayoumi, Dr. Bruce Carleton, Dr. Alun Edwards, Mr. Bob Gagne, Dr. Ran Goldman, Dr. Allan Grill, Mr. Allen Lefebvre, Ms. Heather Neville, Dr. Rakesh Patel, Dr. Danyaal Raza, Dr. Emily Reynen, Dr. Yvonne Shevchuk, and Dr. Adil Virani.

October 16, 2019 Meeting (Initial)

Regrets

Two CDEC members did not attend.

Conflicts of Interest

None

March 18, 2020 Meeting (First Reconsideration)

Regrets

None

Conflicts of Interest

None

July 15, 2020 Meeting (Second Reconsideration)

Regrets

One CDEC member did not attend.

Conflicts of Interest

None