Drug Coverage Decision for B.C. PharmaCare

About PharmaCare B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

Details of Drug Reviewed

Drug	**Erenumab**
Brand Name	**Aimovig®**
Dosage Form(s)	70 mg/mL and 140 mg/mL autoinjectors
Manufacturer	Novartis Pharmaceuticals Canada Inc.
Submission Type	**New Submission**
Use Reviewed	Prevention of chronic migraine in adults
Common Drug Review (CDR)	Yes, CDR recommended: **to Reimburse with clinical criteria and/or conditions**. Visit the CDR website for more details: www.cadth.ca/sites/default/files/cdr/complete/SR0578%20Aimovig%20-%20CDEC%20Final%20Recommendation%20July%2024%2C%202020%20%28redacted%29_For%20Posting.pdf
Drug Benefit Council (DBC)	The DBC met on September 14, 2020, and DBC considered various inputs including: final reviews completed by the CDR on July 22, 2020, which included clinical and pharmacoeconomic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC). The DBC also considered Patient Input Questionnaire responses from 58 patients, 2 caregivers, and 2 patient groups; patient input provided to the CDR; a Clinical Practice Review from one specialist; and a Budget Impact Assessment.
Drug Coverage Decision	**Non-Benefit**
Date	March 29, 2022.
Reason(s)	**Drug coverage decision is consistent with the DBC recommendation.** • Erenumab demonstrated advantages over placebo in the number of monthly migraine days in one randomized controlled trial (RCT) in patients with chronic migraine who had failed at least two prophylactic migraine medications. • The trials compared erenumab to placebo only, and consequently there is a lack of direct active comparative evidence to show the comparative effectiveness of erenumab with the many other available migraine prevention therapies.

	• At the submitted price erenumab was not considered cost-effective for this indication. The Ministry participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer and a deal was not reached. Therefore, the Ministry was not able to address the concerns identified by the CDEC and DBC with respect to the cost-effectiveness and value for money.
Other Information	The DBC Recommendations & Reasons for Recommendations is attached

The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the Drug Benefit Council (DBC) gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called the Common Drug Review (CDR)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

Visit The Drug Review Process in B.C. - Overview and Ministry of Health - PharmaCare for more information.

This document is intended for information only.
It does not take the place of advice from a physician or other qualified health care provider.

Appendix

Drug Benefit Council (DBC) Recommendation and Reasons for Recommendation

FINAL

Erenumab (Aimovig®)

Novartis Pharmaceuticals Canada Inc.

Description:

Drug review of **erenumab (Aimovig®)** for the following Health Canada approved indications:

For the prevention of migraine.

In their review, the DBC considered the following: the final reviews completed by the Common Drug Review (CDR) on July 22, 2020, which included clinical and pharmacoeconomic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC). The DBC also considered Patient Input Questionnaire responses from 58 patients, 2 caregivers, and 2 patient groups; patient input provided to the CDR; a Clinical Practice Review from one specialist; and a Budget Impact Assessment.

Dosage Forms:

Aimovig® is available as erenumab 70 mg/mL and 140 mg/mL solution for subcutaneous injection in a pre-filled single dose autoinjector.

Recommendations:

1. The Drug Benefit Council (DBC) recommends that erenumab not be listed.

Reasons for the Recommendation:

1. Summary

- One randomized controlled trial (RCT) in patients with chronic migraine who had failed (an inadequate response due to insufficient efficacy or unacceptable tolerability) at least two prophylactic migraine medications demonstrated

that erenumab reduced the number of monthly migraine days compared with placebo by 2.7 days for the 70 mg dose and by 4.3 days with 140 mg dose.
- The trials compared erenumab to placebo only, and consequently there is a lack of direct active comparative evidence to show the comparative effectiveness of erenumab with the many other available migraine prevention therapies.
- At the manufacturer submitted price, the annual cost of erenumab is higher than the annual publicly available cost for other medications commonly used to prevent migraines.

2. Clinical Efficacy

- The DBC considered the CDR clinical review of erenumab, which included four RCTs (STRIVE, ARISE, and LIBERTY, conducted in patients with episodic migraine, and Study 295, conducted in patients with chronic migraine ranging from 12 to 24 weeks in duration) representing the patient population in the Health Canada approved indication.
- CDEC focused its review on Study 295, which examined the effects of erenumab in the subgroup of patients with chronic migraine 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.
- Study 295 included 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 manufacturer 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.
- 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 for the 70 mg dose and by 4.3 days with 140 mg dose.
- Study 295 excluded patients who had not experienced any therapeutic response to four or more prior prophylactic medications for migraine; therefore, the clinical effectiveness of erenumab in these patients could not be determined.
- The only comparative evidence available was limited to indirect treatment comparisons of erenumab with other medications used to prevent migraines. There is a lack of direct active comparative evidence to show the comparative effectiveness of erenumab with other available migraine prevention therapies.
- 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 four studies is uncertain.
- For detailed information on the systematic review of erenumab please see the CDEC Final Recommendation at: https://www.cadth.ca/erenumab.

3. Safety

- There were no clear safety issues emerging from the included studies, and no clear and consistent tolerability issues, though the studies were not powered to assess harms.
- Given the novel mechanism of erenumab, longer term comparative studies are warranted.
- For detailed information on the safety and tolerability of erenumab, please see the CDEC Final Recommendations at the link above.

4. Economic Considerations

- The DBC considered the CDR reanalysis of the manufacturer's economic submission, which compared the cost-effectiveness of erenumab with best supportive care (BSC), consisting of treatments used for acute migraine and onabotulinumtoxinA (in chronic migraine patients only).
- At the manufacturer's submitted price, the annual cost of erenumab is higher than the annual publicly available cost for other medications commonly used to prevent migraines.
- 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.

5. Of Note

- Patient input responses indicated that migraines are a neurological disease that is present in about 1 in 7 people worldwide, and which can affect people of all ages including children but are most prevalent in women. Migraines often present with severe, throbbing, recurring pain, and nausea, vomiting, dizziness, extreme sensitivity to sound, light, touch and smell, visual disturbances, and tingling or numbness in the extremities or face are also common symptoms.
- Patients with episodic migraine have attacks occurring 14 days or less and is now further separated in low-frequency (1-6 days) and high frequency (7-14 days). Chronic migraine is diagnosed when patients have 15 or more headache days per month and is associated with more disability and comorbidities.
- Migraines usually last between 4 and 72 hours and, as a result, can have severe impacts on a patient's ability to work or attend school, their social life, their ability to care for dependents, and may lead to medication overuse.
- Most patients reported trying numerous other medications, but that these medications were either of limited effectiveness in relieving migraines or that they tended to lose effectiveness over time. Patients who tried erenumab reported a variety of responses, from limited effectiveness for a short time to a "life-changing" reduction in the number of migraine days experienced per month.
- Patients noted that, as no one medication is effective for every person with migraines, a variety of medications should be available.