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	**Perampanel**
Brand Name	Fycompa™
Dosage Form(s)	2 mg; 4 mg; 6 mg; 8 mg; 10 mg and 12 mg tablets
Manufacturer	Eisai Limited
Submission Type	**New Submission**
Use Reviewed	As an adjunctive therapy for the management of primary generalized tonic-clonic seizures in adult patients.
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/node/88649.
Drug Benefit Council (DBC)	DBC met on June 6, 2016. DBC considered various inputs including: the final reviews completed by the Common Drug Review (CDR) on May 18, 2016, which included clinical and pharmacoeconomic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC). The DBC received no Patient Input Questionnaire responses from patients, caregivers, or Patient Groups. The DBC also considered CDR Patient Group input from two patient groups, Clinical Practice Reviews from two general physicians, and a Budget Impact Assessment
Drug Coverage Decision	**Limited Coverage Benefit** Access the perampanel criteria from **www.gov.bc.ca/pharmacarespecialauthority**
Date	September 24, 2020
Reason(s)	Drug coverage decision is consistent with the CDEC and DBC recommendations. • The drug demonstrated some advantage over placebo with respect to efficacy and quality of life. • The Ministry participated in the pan-Canadian Pharmaceutical Alliance negotiations with the manufacturer which were able to address the concerns identified by the CDEC and DBC with respect to the cost-effectiveness and value for money.

Other Information	

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 1

Drug Benefit Council (DBC) Recommendation and Reasons for Recommendation

FINAL

Perampanel (Fycompa™)

Eisai Limited

Description:

Drug review of **perampanel (Fycompa™)** for the following Health Canada approved indications:

> As adjunctive therapy in the management of primary generalized tonic-clonic (PGTC) seizures, in adult patients with epilepsy who are not satisfactorily controlled with conventional therapy.

In their review, the DBC considered the following: the final reviews completed by the Common Drug Review (CDR) on May 18, 2016, which included clinical and pharmacoeconomic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC). The DBC received no Patient Input Questionnaire responses from patients, caregivers, or Patient Groups. The DBC also considered CDR Patient Group input, Clinical Practice Reviews from two general physicians, and a Budget Impact Assessment.

Dosage Forms:

Fycompa™ is available as perampanel 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg tablets.

Recommendations:

1. The Drug Benefit Council (DBC) recommends that perampanel (Fycompa™) be listed with the following criteria and conditions:

    - Patients have tried two or more antiepileptic drugs (AEDs).
    - Less costly AEDs are ineffective or not appropriate.

    Condition:

    - Patients are under the care of a physician experienced in the treatment of epilepsy.
    - Substantial reduction in price.

Reasons for the Recommendation:

1. Summary

- One randomized, double blind, placebo-controlled trial found a statistically significantly greater median per cent reduction in seizure frequency per 28 days, and statistically significantly more patients with a ≥ 50% reduction in PGTC seizure frequency, with perampanel 8 mg compared with placebo.
- At the manufacturer's confidential submitted price, perampanel was associated with an incremental cost-utility ratio (ICUR) of $74,758 per quality-adjusted life year (QALY) when compared with background therapy alone.
- Perampanel is more costly than most other AEDs approved for treatment of PGTC seizures, or AEDs not approved but often used in clinical practice, except for lacosamide and eslicarbazepine.

2. Clinical Efficacy

- The DBC considered the CDR systematic review, which included one randomized, double blind, placebo-controlled trial (Study 332) which examined the efficacy and safety of adjunctive perampanel (up to 8 mg per day) versus placebo for the treatment of refractory PGTC seizures in patients ≥ 12 years of age with idiopathic generalized epilepsy.
- The primary outcome was the percent change in PGTC seizure frequency per 28 days relative to baseline during the double-blind treatment phase, and the key secondary outcome was the proportion of patients with ≥ 50% reduction in PGTC seizure frequency.
- In Study 332 there were statistically significantly greater median per cent reductions in seizure frequency per 28 days with perampanel 8 mg compared with placebo. Statistically significantly more patients showed a ≥ 50% reduction in PGTC seizure frequency in the perampanel versus placebo group.
- For detailed information on the systematic review of perampanel for PGTC seizures, please see the CDEC Final Recommendation at: https://www.cadth.ca/sites/default/files/cdr/complete/SR0458_complete_Fycompa_May-20-16_e.pdf.

3. Safety

- In study 332, most patients reported one or more adverse events during the trial. More patients stopped treatment due to adverse events in the perampanel group than in the placebo group, and more patients who received perampanel reported a > 7% increase in body weight and aggression or hostility-related adverse events compared with placebo. Dizziness, fatigue, somnolence and irritability were reported more frequently in those receiving perampanel than placebo.
- The frequency of serious adverse events was similar in the perampanel and placebo groups.
- For detailed information on the safety and tolerability of perampanel for PGTC seizures, please see the CDEC Final Recommendations at the links above.

4. Economic Considerations

- The DBC considered the CDR re-analyses of the manufacturer submitted cost-utility analysis, which compared perampanel added to background AED therapy to background AEDs alone in adult patients with PGTC seizures who are not satisfactorily controlled with existing therapy. At the manufacturer's confidential submitted price, perampanel was associated with an ICUR of $74,758 per QALY when compared with background therapy alone. A price reduction of over 20% would be needed for the ICUR of perampanel to fall below $50,000 per QALY.
- Perampanel is more costly than all other AEDs approved for treatment of PGTC seizures, or AEDs not approved but often used in clinical practice, except for lacosamide and eslicarbazepine.

5. Of Note

- The DBC received no Patient Input Questionnaire responses from patients, caregivers, or Patient Groups. The DBC also considered input sent to the CDR from two Patient Groups. Patients with PGTC seizures experienced a loss of independence (including the inability to drive, attain employment or attend school) and anxiety from anticipating impending seizures. Patients noted that many patients with PGTC seizures do not respond to any current medication. One patient who had taken perampanel reported their seizures had stopped but they experienced tolerable side effects, including sleepiness and dizziness.