B.C. Ministry of Health Services Drug Coverage Decisions

About PharmaCare

B.C. PharmaCare helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

PharmaCare Coverage

The Ministry of Health Services (Ministry) makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs and resources and the evidence-based recommendations of an independent advisory body called the Drug Benefit Council (DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including available clinical and pharmacoeconomic evidence, clinical practice and ethical considerations, and the recommendations of the national Common Drug Review, when applicable.

Inside

Page 1 includes the Ministry decision and reasons in wording that is easier for readers without a medical background to understand. **Page 2** summarizes the DBC recommendation, the Ministry's decision and the reasons for the Ministry's decision.

Clopidogrel (Plavix®) after drug-eluting stent insertion

Understanding the DBC Recommendation and PharmaCare Coverage Decision

Background

- When fat builds up inside blood vessels, the vessels become narrow. Less blood and oxygen flow to the heart. This may cause symptoms such as chest pain.
- A stent is a wire-mesh tube that a surgeon inserts at the narrow site of the vessel to hold it open. Scar tissue can form over the stent and cause the vessel to close. Drug-eluting stents (DES) are coated with a drug that helps stop the scar tissue from forming.
  - There may be a higher chance of blood clots forming at the site of the stent, causing a blockage.
- **Clopidogrel** has the brand name **Plavix®.** This drug stops platelets from clumping together to form a clot. It is called an antiplatelet agent or a platelet aggregation inhibitor. It is used together with ASA (acetylsalicylic acid or Aspirin®) to stop blood clots from forming after DES insertion.

Why was this drug reviewed?

- Before this review, clopidogrel was only covered for 6 months after DES insertion. A request was made to increase this to 12 months.

What did the review find?

- There are not enough studies to prove how long a patient should have this treatment: 6 months or 12 months.
- The safety of this treatment is yet to be confirmed. Guidelines and the U.S. Food and Drug Administration (FDA) recommend using this treatment. This is based on initial studies and the opinions of experts. The FDA continues to assess new information.
- The DBC notes that research on this treatment is weak.

What decision was made?

- Clopidogrel will have **limited coverage** for up to 12 months after DES insertion.
- ASA will not be covered because it can be obtained without a prescription and its use with clopidogrel after DES insertion was not reviewed.
- The Ministry in collaboration with Cardiac Services BC will evaluate the potential benefits of using clopidogrel for 12 months after DES insertion. The results of this evaluation will inform a reassessment of this coverage decision.

Key Term

- **Limited Coverage** drugs are not normally considered the first choice in treatment, or other drugs may offer better value. To receive coverage, the patient's physician must submit a Special Authority request to PharmaCare. If the request is approved, the drug is covered up to the usual PharmaCare coverage limits. Actual reimbursement depends on the rules of a patient's PharmaCare plan including any annual deductible requirement.

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

Please visit us online to find out more about the Pharmaceutical Services Division and the PharmaCare program at www.health.gov.bc.ca/pharme. To find out more about how drugs are considered for PharmaCare coverage, visit www.health.gov.bc.ca/pharme/formulary.

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Clopidogrel (Plavix®) after drug-eluting stent insertion

Drug Class

- Platelet aggregation inhibitor

Available Dosage Forms

- 75 mg tablets

Sponsor/Requestor

- Pharmaceutical Services Division

Submission (Request) to PharmaCare

- Request to modify Special Authority coverage for clopidogrel bisulfate (Plavix®) following the insertion of coronary drug eluting stents (DES) from 6 months to 12 months.

Drug Benefit Council (DBC) Recommendations

- Current clopidogrel limited coverage criteria be modified as follows:
  - In combination with acetylsalicylic acid (ASA or Aspirin®) post coronary DES insertion for up to 12 months in patients at low risk of bleeding.
- Use of coronary DES to be reviewed by the Ministry.

Decision and Status

- **Limited coverage**. No coverage for ASA. Clopidogrel is available through the Special Authority program for up to 12 months in patients with a documented stent procedure with a DES.
- The Ministry in collaboration with Cardiac Services BC will be evaluating the clinical impact of 12-month coverage.
- Effective February 18, 2008

Reasons for the Ministry of Health Services Decision

- A literature search was performed to identify randomized controlled trials (RCTs) evaluating the optimal duration of treatment with the combination of clopidogrel plus ASA in patients post coronary DES insertion. There is insufficient evidence from RCTs regarding the optimal length of treatment with clopidogrel post coronary DES insertion.
- There is insufficient evidence from RCTs regarding the safety of the combination of clopidogrel and ASA for 12 months post coronary DES insertion.
- Clinical guidelines and the U.S. Food and Drug Administration (FDA) recommendations advocating the combination of clopidogrel and ASA use post coronary DES insertion for 12 months in patients at a low risk of bleeding are largely based on observational studies and expert opinion.
- The DBC recognizes the limitations in the current evidence regarding the optimal length of treatment with clopidogrel post coronary DES insertion.

Decision Summary

- The clinical evidence supporting the use of clopidogrel for 12 months post coronary DES insertion is based on limited clinical data, consisting primarily of observational data and expert opinion rather than RCT data. For this reason, the Ministry in collaboration with Cardiac Services BC will be evaluating the clinical impact of extending coverage of clopidogrel to 12 months for this indication. The results of this evaluation will inform a reassessment of this coverage decision.
- The final decision did not include coverage of ASA since this product is non-prescription, making it difficult to apply Special Authority procedures. Also, the review did not include a comparison of clopidogrel alone and in combination therapy with ASA.

Key Term

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