CADTH REIMBURSEMENT REVIEW

Clinical Review Report

GENERIC DRUG NAME (BRAND NAME)
(Sponsor)
Indication:
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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada’s health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada’s federal, provincial, and territorial governments, with the exception of Quebec.
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Executive Summary

Table 1: Submitted for Review

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
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<tbody>
<tr>
<td>Drug product</td>
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<tr>
<td>Indication</td>
<td></td>
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<tr>
<td>Reimbursement request</td>
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<td>Health Canada Approval Status</td>
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<td>Health Canada Review Pathway</td>
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Introduction

Stakeholder Perspectives

Patient Input

Clinician input

Drug program input

Clinical Evidence

Pivotal Studies and Protocol Selected Studies

Description of studies

Efficacy Results

Harms Results

Critical Appraisal

Indirect Comparisons

Description of studies
Efficacy Results

Harms Results

Critical Appraisal

Other Relevant Evidence

Description of studies

Efficacy Results

Harms Results

Critical Appraisal

Conclusions
Introduction

Disease Background

Standards of Therapy

Drug

Table 2: Key characteristics

<table>
<thead>
<tr>
<th>Mechanism of Action</th>
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<tr>
<td>Indication</td>
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<tr>
<td>Route of Administration</td>
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<tr>
<td>Recommended Dose</td>
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<tr>
<td>Serious Adverse Effects or Safety Issues</td>
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<tr>
<td>Other</td>
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</table>
Stakeholder Perspectives

Patient Group Input

Clinician Input
Clinician group input

Input from clinical experts consulted by CADTH

Unmet Needs

Place in therapy

Patient population

Assessing response to treatment

Discontinuing treatment

Prescribing conditions

Additional considerations

Drug Program Input
Clinical Evidence

Systematic Review (Pivotal and Protocol Selected Studies)

Objectives

Methods

Table 3: Inclusion criteria for the systematic review

<table>
<thead>
<tr>
<th>Patient Population</th>
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<tbody>
<tr>
<td>Intervention</td>
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<tr>
<td>Comparators</td>
<td></td>
<td></td>
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<tr>
<td>Outcomes</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Study Design</td>
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</tbody>
</table>

Findings from the Literature

Figure 1: Flow Diagram for Inclusion and Exclusion of Studies
### Table 4: Details of Included Studies

<table>
<thead>
<tr>
<th>DESIGNS &amp; POPULATIONS</th>
<th>Study Name</th>
<th>Study Name</th>
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<tbody>
<tr>
<td>Study Design</td>
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<tr>
<td>Locations</td>
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<td>Patient Enrollment Dates</td>
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<td>Randomized (N)</td>
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<td>DRUGS</td>
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<tr>
<td></td>
<td>Comparator(s)</td>
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<tr>
<td>DURATION</td>
<td>Phase</td>
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<tr>
<td></td>
<td>Run-in</td>
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<td>Double-blind</td>
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<td></td>
<td>Follow-up</td>
<td></td>
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<td>OUTCOMES</td>
<td>Primary End Point</td>
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<tr>
<td></td>
<td>Secondary and Exploratory End Points</td>
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<tr>
<td>NOTES</td>
<td>Publications</td>
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Description of studies

Populations

Inclusion and exclusion criteria

Baseline characteristics

**Table 5: Summary of Baseline Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Study</th>
<th>Study</th>
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</table>

Interventions

Outcomes

**Table 6: Summary of Outcomes of Interest Identified in the CADTH Review Protocol**

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Study</th>
<th>Study</th>
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Statistical analysis

Primary Outcome(s) of the Studies

Secondary Outcomes of the Studies
Results

Patient Disposition

Exposure to study treatments

Efficacy

*Efficacy outcome 1*

*Efficacy outcome 2*

Harms

*Adverse events*

*Serious adverse events*

*Withdrawals due to adverse events*

Mortality

*Notable harms*

Critical Appraisal

*Internal validity*

*External validity*
Indirect Evidence

Objectives and Methods for the Summary of Indirect Evidence

Description of Indirect Comparison(s)

Methods

Objectives

Study Selection Methods

ITC analysis methods

Results

Summary of included studies

Results

Critical Appraisal

Summary
Other Relevant Evidence

This section includes submitted long-term extension studies and additional relevant studies included in the sponsor’s submission to CADTH that were considered to address important gaps in the evidence included in the systematic review.

Long-term extension studies

Methods

Populations

Interventions

Outcomes
Statistical analysis

Patient Disposition

Exposure to study treatments

Efficacy

Harms

Critical Appraisal
Discussion

Summary of Available Evidence

Interpretation of Results

Efficacy

Harms

Other Considerations

Conclusions
Appendix 1: Literature Search Strategy
Appendix 2: Excluded Studies

Table 7: Excluded Studies

<table>
<thead>
<tr>
<th>Reference</th>
<th>Reason for Exclusion</th>
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</tbody>
</table>
Appendix 3: Detailed Outcome Data
Appendix 4: Description and Appraisal of Outcome Measures

Aim
To describe the following outcome measures and review their measurement properties (validity, reliability, responsiveness to change, and minimal important difference):

Findings
Appendix 5: Companion Diagnostic Testing
References