MINISTRY OF HEALTH
DECISION BRIEFING DOCUMENT

Cliff # 631968

PREPARED FOR: Heather Davidson, A/Executive Director, PharmaCare - **FOR DECISION**

TITLE: PharmaCare Recommendation to not amend current Special Authority criteria for Proscar® (finasteride) 5 mg tablets

BACKGROUND:

Brand Name:
Proscar®
Generic Name:
Finasteride
Manufacturer:
Merck Frosst Inc.
Manufacturer's Listing Request:
Manufacturer is requesting Restricted Benefit status for patients with benign prostatic hyperplasia (BPH) and based on the clinical and economic rationale presented in their submission amend the listing criteria to include the following: 1. Treatment of patients with BPH who have a prostate specific antigen (PSA) level greater than 1.3 ng/ml (a marker for an enlarged prostate gland), in combination with an alpha blocker. 2. Second line therapy in patients with BPH following treatment failure or intolerance to an alpha blocker.
PharmaCare Current Coverage
PharmaCare coverage is now provided under the Limited Coverage program with the following SA criteria; For patients with Benign Prostatic Hyperplasia (BPH): • *Diagnosis of benign prostatic hyperplasia* ***PLUS*** *treatment failure or intolerance to alpha-blocking agents.*
Dosage Forms:
5 mg tablets
Date Submission Received by PharmaCare:
January 30, 2004
Approved Indications:
Treatment and control of benign prostatic hyperplasia (BHP) and the prevention of urologic events; specifically, reducing the risk of acute urinary retention (AUR) and the risk of BPH-related surgery.

TI Summary:

- There is insufficient evidence to suggest that finasteride in combination with an alpha blocker provides a therapeutic advantage over an alpha blocker alone or finasteride alone in patients with symptomatic BPH. In addition, there is no evidence to suggest that finasteride provides a therapeutic advantage over placebo in patients who have failed or are intolerant to alpha blocker therapy.
- The official Health Canada indication for finasteride as stated in the product monograph is "For the treatment and control of BPH and for the prevention of urologic events to: reduce the risk of acute urinary retention and to reduce the risk of surgery including transurethral prostate resection (TUPR) and prostatectomy." The current request for Pharmacare funding by the manufacturer is for the additional indication of "Treatment of patients with BPH who have a prostate specific antigen (PSA) level greater than 1.3 ng/ml (a marker for an enlarged prostate gland), in combination with an alpha blocker" and "Second line therapy in patients with BPH following treatment failure or intolerance to an alpha blocker."
- With regards to the current request, there is insufficient evidence from double blind, randomized controlled trials to support either indication. Of note (with reference to the first newly requested indication), the threshold of PSA > 1.3 ng/ml as a criteria for patients who would be candidates for or would benefit from finasteride and alpha blocker combination therapy have not been studied in double-blind, randomized controlled trials. More generally, specific level of PSA that identifies patients who may benefit from any therapy for symptomatic BPH has not been determined.
- The reviewers found no RCT evidence to justify the manufacturer's recommendation that patients with a PSA > 1.3 ng/ml, or any other defined threshold, acts as a necessary or sufficient condition for finasteride therapy.
- There is insufficient evidence to conclude that finasteride, in combination with an alpha blocker, provides a therapeutic advantage over an alpha blocker alone or finasteride alone in patients with symptomatic BPH.
- The reviewers found no RCTs that studied patients with symptomatic BPH who had failed or were intolerant to alpha blocker therapy. As a result, the manufacturers request to fund these patients in not supported by valid scientific evidence.

DBC RECOMMENDATION:

- At its meeting on March 4, 2005, the DBC recommended no change to the Special Authority criteria for finasteride.
  For patients with Benign Prostatic Hyperplasia (BPH):
  - *Diagnosis of benign prostatic hyperplasia*
    PLUS
    treatment failure or intolerance to alpha-blocking agents.

PHARMACARE RECOMMENDATION:

- PharmaCare is recommending status quo - no change to Special Authority criteria for Proscar® (finasteride) 5 mg tablets.
  For patients with Benign Prostatic Hyperplasia (BPH):
  - *Diagnosis of benign prostatic hyperplasia*
    PLUS
    treatment failure or intolerance to alpha-blocking agents.

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Approved/Not Approved — Date Signed
Heather Davidson
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PharmaCare

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