

Committee to Evaluate Drugs (CED)

Recommendations and Reasons

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Testosterone transdermal patch

Product: testosterone (Androderm®) 24.3 mg transdermal patch (line extension)

Class of Drugs: androgen

Reason for Use: testosterone deficiency (hypogonadism)

Manufacturer: Actavis Specialty Pharmaceuticals Co.

Date of Review: November 13, 2013

CED Recommendation

The CED recommended that the Androderm® 24.3 mg transdermal patch be funded in the same manner as Androderm® 12.2mg transdermal patch, which is listed on the Ontario Drug Benefit Formulary as a Limited Use Benefit. The CED noted that Androderm® 24.3mg is equivalent to two 12.2 mg patches and the two product strengths are proportionately priced.

Executive Officer Decision*

Based on the CED's recommendation and an agreement with the manufacturer, the Executive Officer decided to fund Androderm® 24.3 mg transdermal patch on the Ontario Drug Benefit Formulary as a Limited Use Benefit according to specific criteria.

Funding Status*

Funded on the Ontario Drug Benefit Formulary as a Limited Use Benefit according to specific criteria.

* This information is current as of the posting date of the document. For the most up-to-date information on Executive Officer decision and funding status, see: www.health.gov.on.ca/en/pro/programs/drugs/status_single_source_subm.aspx

Highlights of Recommendation:

- Androderm® is available in two product strengths. The 12.2mg transdermal patch delivers 2.5mg of testosterone per day, and the 24.3mg transdermal patch delivers 5mg of testosterone per day. The 12.2mg patch is already funded on the Ontario Drug Benefit Formulary as a Limited Use Benefit.
- The CED had previously reviewed Androderm® 24.3 mg transdermal patch but had made a negative recommendation due to concerns over the manufacturer's bioequivalence data.
- The manufacturer has now provided revised pharmacokinetic analyses and the newly submitted data support that Androderm® 24.3mg patch is equivalent to two Androderm® 12.2 mg patches.
- Androderm® 24.3 mg is available at the same cost per mg as Androderm® 12.2 mg.
- Overall, Androderm® 24.3 mg patch has been shown to be equivalent to two Androderm® 12.2 mg patches. The two product strengths are proportionately priced and the funding of the 24.3 mg patch will likely be cost-neutral or slightly cost-savings to the program.

Background:

Male hypogonadism is a condition in which testosterone production is low. Hypogonadism may be due to primary testicular failure caused by post-infectious testicular damage, bilateral orchidectomy, or testicular injury. Hypogonadism may also be caused by testicular failure secondary to gonadotropin deficiency (e.g. due to a pituitary tumor or irradiation) or due to an inherited or acquired hypothalamic defect (e.g. Kallmann's syndrome or hypothalamic tumors).

Low testosterone is associated with impotence and decreased sexual desire, fatigue and loss of energy, depression, and regression of secondary sexual characteristics.

Androderm® is a testosterone transdermal patch indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone (hypogonadism).

Detailed Discussions:

There are no additional relevant details.

Committee to Evaluate Drugs (CED)

The Committee to Evaluate Drugs (CED) is comprised of practicing physicians, pharmacists, health economists, and patient representatives. In conducting its review, the CED considers data contained in the drug manufacturer's submission, input provided by patient groups, findings from the national Common Drug Review and the pan-Canadian Oncology Drug Review, and other scientific information as necessary.

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