

Committee to Evaluate Drugs (CED)

Recommendations and Reasons

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Isotretinoin

Product: Isotretinoin (Epuris®)

Class of Drugs: retinoid

Reason for Use: severe acne

Manufacturer: Cipher Pharmaceuticals Ltd.

Date of Review: September 11, 2013

CED Recommendation

The CED recommended that isotretinoin (Epuris®) not be funded. The CED noted that two other isotretinoin products are already listed on the Formulary at a lower price and the higher price for Epuris® is not justified.

Executive Officer Decision*

Based on the CED's recommendation and an agreement with the manufacturer to help address the CED's concerns, the Executive Officer decided to fund isotretinoin (Epuris®) on the Ontario Drug Benefit Formulary as a General Benefit.

Funding Status*

Funded on the Ontario Drug Benefit Formulary as a General Benefit.

* 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:

- Epuris® is a new isotretinoin product used for the treatment of severe acne. Two other isotretinoin agents are currently listed on the Ontario Drug Benefit Formulary.
- The CED reviewed one phase III, double-blind, multicentre, non-inferiority randomized controlled trial — ISOCT.08.01 — evaluating the efficacy and safety of Epuris® compared to standard isotretinoin in patients with severe, retinoid-naïve, recalcitrant nodular acne. The study demonstrated comparable efficacy and safety of Epuris® in relation to standard isotretinoin.
- The CED also reviewed the results of twelve biopharmaceutical studies demonstrating that under fed conditions, Epuris® and standard isotretinoin are equivalent, but that in the fasted state, the absorption of Epuris® is approximately 83% greater than that of standard isotretinoin. There is a lack of clinical evidence to demonstrate that this greater bioavailability in the fasted state represents a therapeutic advantage.
- Epuris® costs approximately \$1 - \$8 per day depending on the dose. Epuris® 10mg and 40mg capsules are more expensive than the alternative isotretinoin products in the same capsule strengths.
- Overall, Epuris® has been shown to be equivalent and comparable in efficacy and safety to standard isotretinoin under fed conditions. Although the absorption of Epuris® is greater than standard isotretinoin in the fasted state, the product monograph recommends that Epuris® be taken with food and the clinical relevance of the increased absorption under fasting conditions is unknown. Two isotretinoin products are listed on the Formulary at a lower price, there are no treatment gaps, and the higher price for Epuris® is not justified.

Background:

Acne is a dermatological disorder that results from the action of hormones and other substances on the skin's oil glands and hair follicles. Acne causes the skin's pores to become plugged and to break out into lesions commonly called pimples. Acne lesions usually occur on the face, neck, back, chest, and shoulders. Although acne is not usually a serious health condition, it can be a source of significant emotional distress, especially during puberty, and when severe, acne can result in permanent scarring.

Isotretinoin is a systemic retinoid that is used in the treatment of severe, recalcitrant acne.

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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