

Committee to Evaluate Drugs (CED)

Recommendations and Reasons

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Calcipotriol / Betamethasone Dipropionate gel

Product: Calcipotriol / Betamethasone (Dovobet®) 50mcg/g & 0.5mg/g gel

Class of Drugs: vitamin D analogue / corticosteroid

Reason for Use: plaque psoriasis vulgaris on the body

Manufacturer: LEO Pharma Inc.

Date of Review: September 11, 2013

CED Recommendation

The CED recommended that calcipotriol/betamethasone (Dovobet®) gel not be funded for the treatment of plaque psoriasis on the body, on the basis that the potential added convenience of this combination product does not justify its higher cost.

Executive Officer Decision*

Based on the CED's recommendation and an agreement with the manufacturer to help address concerns raised by the CED, the Executive Officer decided to fund calcipotriol/betamethasone (Dovobet®) gel on the Ontario Drug Benefit Formulary for the treatment of plaque psoriasis on the body.

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:

- Calcipotriol and betamethasone (Dovobet®) gel contains two active ingredients used in the treatment of psoriasis. This funding review evaluated the use of Dovobet® gel in the treatment of plaque psoriasis on the body. Dovobet® gel is already funded on the Ontario Drug Benefit Formulary for psoriasis on the scalp. Dovobet® ointment is also available on the Formulary.
- Two clinical studies showed that Dovobet® gel is more effective than either calcipotriol alone or betamethasone alone in the treatment of mild to moderate plaque psoriasis on the body.
- There is no evidence that Dovobet® gel is more effective than the concurrent use of calcipotriol and betamethasone or Dovobet® ointment for the treatment of psoriasis on the body.
- Dovobet® gel may have several potential advantages over Dovobet® ointment. In general, topical gel preparations may be less messy, more cosmetically elegant, and sometimes better absorbed. Dovobet® gel may also provide added patient convenience because the product can be applied to both scalp and body.
- Dovobet® gel costs \$1.47 per gram. This is more expensive than the combined cost of the individual calcipotriol and betamethasone products.
- Overall, the CED noted that Dovobet® gel has been shown to be effective in the treatment of mild to moderate plaque psoriasis on the body. In addition, Dovobet® gel may offer added patient convenience over the ointment form or the combination use of the individual component products. The CED was concerned with the added costs associated with this product.

Background:

Psoriasis is a chronic inflammatory skin condition. It usually affects the elbows, knees, scalp, back, face, palms and feet; but it can occur anywhere on the body. Patients typically have patches of raised, reddish skin covered by silvery-white scales. Patients with psoriasis often cycle through flare-ups and remissions.

There is currently no cure. Common treatments include the use of corticosteroids, ultraviolet light therapy, coal tar topical treatment, vitamin D derivatives and, in severe cases, oral medications that modify the body's immune response.

Calcipotriol/betamethasone (Dovobet®) is a combination topical product. Calcipotriol, a derivative of vitamin D, works by reducing the production of skin cells. Betamethasone, a corticosteroid, helps reduce inflammation.

Detailed Discussions:

- Two randomized controlled studies – LEO 80185-G23 and MBL 0202INT – demonstrated that Dovobet® gel was overall more efficacious than calcipotriol alone or betamethasone alone in the treatment of mild to moderate plaque psoriasis on the body. In addition, the

overall incidence of adverse events and severe adverse events was not statistically significantly different between Dovobet® gel and the comparators in either study.

- Dovobet® gel has not been compared in clinical studies to the combination use of individual products of calcipotriol and betamethasone, nor to Dovobet® ointment for the treatment of psoriasis vulgaris on the body.
- Dovobet® gel may have several potential advantages over Dovobet® ointment. The gel form may be considered to be less messy and more cosmetically elegant. Although there is a lack of clinical trial evidence to support the following benefits observed in clinical practice, topical gels have been suggested to be effective and functionally preferable on palmar surfaces (absorb quickly and avoid need for gloves, etc.). Gel preparations may be more effective for the treatment of nail disease as they may be absorbed more readily at the nail fold and nail plate.
- Dovobet® gel may provide added patient convenience because the product can be applied to both scalp and body.
- Overall, the CED noted that Dovobet® gel has been shown to be effective in the treatment of mild to moderate plaque psoriasis on the body. In addition, Dovobet® gel may offer added patient convenience over the ointment form or the combination use of the individual component products. The CED was concerned with the added costs associated with this product.

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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