

Calcipotriol/Betamethasone Dipropionate

Product:

CALCIPOTRIOL/BETAMETHASONE
DIPROPIONATE (Dovobet®)
50mcg/g & 0.5mg/g ointment

Class of drugs:

Vitamin D analogue/corticosteroid

Indication:

Treatment of psoriasis

Manufacturer:

Leo Pharma Inc.

CED Recommendation

The CED recommended that calcipotriol/betamethasone (Dovobet) be listed on the Ontario Drug Benefit (ODB) Formulary for use in patients with psoriasis who have failed topical steroids and calcipotriol therapy. The CED's recommendation was made on the condition that the manufacturer adequately addresses the Committee's concerns relating to the cost and appropriate use of this product.

Executive Officer Decision

Based on the CED's recommendation and a subsequent listing agreement that addressed both price and utilization, the Executive Officer decided to list calcipotriol/betamethasone dipropionate (Dovobet) on the ODB Formulary for use in patients with psoriasis who have failed topical steroids and calcipotriol therapy.

Status

Funding available through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Calcipotriol/betamethasone (Dovobet) is an ointment containing two drugs used in the treatment of psoriasis.
- ◆ The individual components of Dovobet, calcipotriol and betamethasone, are both available as standalone agents and are both listed on the Formulary.
- ◆ Clinical evidence supports that calcipotriol/betamethasone (Dovobet) is more efficacious than either calcipotriol alone or betamethasone alone in the treatment of psoriasis.
- ◆ Although calcipotriol/betamethasone (Dovobet) has been demonstrated to work better than each of its individual components alone, there is no evidence that it is more efficacious than the concurrent use of standalone calcipotriol and betamethasone.
- ◆ In the absence of evidence to support therapeutic superiority of the combination product, the Committee indicated that the cost of calcipotriol/betamethasone (Dovobet) should not exceed the combined costs of the individual components—calcipotriol and betamethasone.
- ◆ Calcipotriol/ betamethasone (Dovobet) is recommended to be used once daily for a maximum duration of four weeks. Because calcipotriol and betamethasone, as standalone treatments, are usually applied twice daily, the Committee was concerned that prescribers and patients would also use the combination product twice daily. This would significantly increase the cost of treatment. The Committee indicated that these concerns relating to drug cost and usage patterns must be addressed by the manufacturer to ensure that the drug program does not incur extra costs if this combination product is to be listed on the Formulary.
- ◆ **Overall, the Committee acknowledged that calcipotriol/betamethasone (Dovobet) is a reasonable alternative for psoriasis patients who have failed first-line treatment with topical steroids and calcipotriol therapy. However, the Committee recommended that concerns relating to drug cost and appropriate utilization be addressed if Formulary listing is to be considered.**

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 ointment. Calcipotriol, a derivative of vitamin D, works by reducing the production of skin cells. Betamethasone, a corticosteroid, helps reduce inflammation.

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Detailed Discussion:

- ◆ The Committee considered the funding of calcipotriol/betamethasone (Dovobet) on numerous occasions, initially in July 2002 and most recently in April 2007.
- ◆ Calcipotriol and betamethasone are both available as individual agents and are both listed on the Formulary.
- ◆ Calcipotriol/betamethasone (Dovobet), applied once daily, was demonstrated to be superior in efficacy (measured by mean percent changes in the Psoriasis Area Severity Index scores) to either calcipotriol once or twice daily, or betamethasone dipropionate once daily.
- ◆ There are no direct head-to-head studies comparing calcipotriol/betamethasone (Dovobet) against the concurrent use of the two individual component medications.
- ◆ Calcipotriol and betamethasone, when used individually, are usually applied twice daily. Given that the single ingredient products are used twice daily by most psoriasis patients, the Committee was concerned that twice daily use of calcipotriol/betamethasone dipropionate (Dovobet) would also be likely. This would double the cost per treatment course.
- ◆ Overall, the Committee acknowledged that calcipotriol/betamethasone (Dovobet) is a reasonable alternative for the treatment of psoriasis for patients who have failed first-line treatment with topical steroids and calcipotriol therapy. Therefore, the Committee recommended that calcipotriol/betamethasone (Dovobet) be funded on the condition that the manufacturer addresses concerns relating to the cost and appropriate utilization of this product.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) did not review calcipotriol/betamethasone (Dovobet).



Ministry of
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