

Penciclovir

Product:

PENCICLOVIR (Denavir®) 1% topical cream

Class of drugs:

Antiviral agent

Indication:

Treatment of recurrent herpes labialis (cold sores)

Manufacturer:

Novartis Pharmaceuticals Canada Inc.

CED Recommendation

The CED recommended that penciclovir (Denavir) 1% topical cream not be listed on the Ontario Drug Benefit (ODB) Formulary, on the basis that this drug does not provide any appreciable benefits in the treatment of recurrent herpes labialis. Moreover, there is no evidence that it offers a therapeutic advantage over less costly treatments.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to list penciclovir (Denavir) on the ODB Formulary.

Status

No funding through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ The Committee reviewed three clinical trials that assessed the use of penciclovir (Denavir) in the treatment of recurrent herpes labialis (cold sores). These trials compared penciclovir (Denavir) to placebo.
- ◆ Findings from these studies indicated that penciclovir (Denavir) provided minor advantages over placebo in the treatment of cold sore (e.g. reducing the average healing time for lesions from 8 days to 7 days). Recurrent herpes labialis usually resolves in about a week without treatment. The Committee noted that speeding up this process by one day is not considered to be a meaningful improvement.
- ◆ There is no evidence that penciclovir (Denavir) offers a therapeutic advantage over other drugs for the treatment of recurrent herpes labialis (e.g. oral antiviral drugs).
- ◆ Penciclovir (Denavir) costs \$14.32 per gram, making it much more expensive than acyclovir cream, at \$4.23 per gram.
- ◆ **Overall, the Committee felt that penciclovir (Denavir) provides no appreciable benefits in the treatment of recurrent herpes labialis. Furthermore, there is no evidence that this product offers a therapeutic advantage over less costly treatments.**

Background:

Herpes labialis, caused by Herpes Simplex Virus, Type I (HSV-1) is one of the most common viral infections. The primary symptom of HSV-1 infection is cold sores on the gums, lips and face.

These outbreaks are often self-limiting and lesions heal spontaneously without treatment. Antiviral therapy for prevention and suppression is generally considered in those patients with six or more recurrences per year or those whose immune systems have been suppressed by disease or drug therapies.

Topical antiviral therapy is generally regarded to be less efficacious than oral systemic therapy. Medications are only efficacious when applied early during the disease course. Current antivirals do not cure the disease and only have a moderate potency when treatment is delayed.

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Detailed Discussion:

- ◆ The Committee considered data from three randomized, double-blind, placebo controlled trials in adults with recurrent herpes labialis. The three studies reported statistically significant differences in favour of penciclovir (Denavir) over placebo. Compared to patients on placebo, those using penciclovir had shorter time (one day or less) to lesion healing, loss of pain and cessation of viral shedding. The Committee noted that herpes labialis is a self-limiting condition where the average duration of an untreated cold sore is 7 days; therefore, the clinical importance of this small time difference is questionable.
- ◆ The Committee found no randomized controlled trials comparing penciclovir (Denavir) with other available treatments for recurrent herpes labialis (e.g. acyclovir, valacyclovir, famciclovir), and no evidence that penciclovir (Denavir) offers any therapeutic advantage over these agents.
- ◆ The most frequently reported side effect with penciclovir (Denavir) is local irritation at the site where the product was applied.
- ◆ The manufacturer did not submit a formal pharmacoeconomic analysis for evaluation. Penciclovir (Denavir) costs \$14.32 per gram, making it much more expensive than acyclovir cream, at \$4.23 per gram.

CEDAC Recommendation:

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

The Canadian Expert Advisory Committee recommended that penciclovir (Denavir) not be listed.



Ministry of
Health and Long-Term Care
Ontario Public Drug Programs

For more information, please contact:

Ministry of Health and Long-Term Care
Ontario Public Drug Programs
Hepburn Block, 9th Floor
80 Grosvenor Street, Queen's Park
Toronto, Ontario M7A 1R3
or click: http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html