

Desogestrel/Ethinyl Estradiol

Product:

DESOGESTREL/ETHINYL ESTRADIOL
(Linessa® 21,28)

Class of drugs:

Oral contraceptive (birth control pill)

Indication:

Prevention of pregnancy

Manufacturer:

Organon Canada Ltd.

CED Recommendation

The CED recommended that desogestrel/ethinyl estradiol (Linessa) not be listed on the Ontario Drug Benefit (ODB) Formulary, on the basis that compared with existing listed alternatives, this product provides no additional treatment, safety, or quality of life benefits.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer has decided not to list desogestrel/ethinyl estradiol (Linessa).

Status

No funding through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Desogestrel/ethinyl estradiol (Linessa) is a birth control pill that combines estrogen and desogestrel, a synthetic form of progesterone (a naturally occurring female sex hormone).
- ◆ Desogestrel/ethinyl estradiol (Linessa) has similar efficacy for preventing pregnancy compared to other birth control pills, with an annual pregnancy rate among users of 1-2%.
- ◆ Several types of oral birth control pills are available as General Benefits on the ODB Formulary. Prices range from \$10-\$13 a month. The price of desogestrel/ethinyl estradiol (Linessa) is in the higher range when compared to other oral contraceptives listed on the Formulary.
- ◆ In addition, the product provided no proven safety advantages over similar oral contraceptives.
- ◆ Some concern has been expressed, particularly in the United States, that desogestrel, a so-called Third Generation progestogen, might be associated with higher rates of blood clots compared with earlier forms of this hormone.
- ◆ **Overall, the Committee noted that desogestrel/ethinyl estradiol (Linessa) provides no added value in terms of efficacy, safety, or quality of life over existing alternatives available on the Formulary.**
- ◆ As such, the CED recommended not to fund desogestrel/ethinyl estradiol (Linessa).

Background:

Desogestrel/ethinyl estradiol (Linessa) is a "combination pill", the most common type of oral birth control. It contains two female sex hormones, an estrogen and a synthetic version of progesterone.

The birth control pills works by preventing the monthly release of an egg by the ovaries and by thickening the mucus the cervix produces, which slows the movement of the sperms that enter the uterus.

Not all women should take oral contraceptives, and it is important for women to share a complete medical history with the doctor prescribing this medication. Some pre-existing conditions such as cancer, jaundice, or blood clots could lead to serious complications.

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Detailed Discussion:

- ◆ The manufacturer, Organon Canada Ltd., asked the Ministry of Health and Long-Term Care to consider listing desogestrel/ethinyl estradiol (Linessa) on the ODB Formulary. The Committee considered the request twice, in December 2006, and again in February 2007.
- ◆ The Committee considered two studies the manufacturer submitted comparing desogestrel/ethinyl estradiol (Linessa) to ethinyl estradiol/norethindrone (Ortho 7/7/7). Desogestrel/ethinyl estradiol (Linessa) appears to offer no therapeutic or safety advantage over ethinyl estradiol/norethindrone (Ortho 7/7/7).
- ◆ Pregnancy rates with desogestrel/ethinyl estradiol (Linessa) were low, although slightly higher than with ethinyl estradiol/norethindrone (Ortho 7/7/7).
- ◆ There is some controversy surrounding increased rates of thromboembolism in patients taking combination oral contraceptives containing third generation progestogens like desogestrel. The overall risk for this adverse event is small, making it difficult to detect in studies comparing alternatives.
- ◆ Side effects of desogestrel/ethinyl estradiol (Linessa) may include headaches, belly pain, weight gain, nausea or vomiting, break-through bleeding or spotting, swelling, breast enlargement and tenderness, and yeast infections.
- ◆ The price submitted for desogestrel/ethinyl estradiol (Linessa) is in the higher range of the prices for other oral contraceptives listed on the Formulary.
- ◆ Overall, the Committee noted that desogestrel/ethinyl estradiol (Linessa) does not appear to provide a therapeutic advantage, improved safety profile, or improved tolerability compared to other combination oral contraceptives currently listed on the Formulary. Therefore, the Committee concluded that desogestrel/ethinyl estradiol (Linessa) does not provide any additional value over existing alternatives.

CEDAC Recommendation:

The Canadian Expert Advisory Drug Committee did not review desogestrel/ethinyl estradiol (Linessa).



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