

Drospirenone/Ethinyl Estradiol

Product:

DROSPIRENONE/ETHINYL ESTRADIOL (Yasmin 21, 28[®], 3 mg drospirenone and 0.03 mg ethinyl estradiol)

Class of drugs:

Monophasic combination oral contraceptive

Indication:

Prevention of pregnancy

Manufacturer:

Berlex Canada Inc.

CED Recommendation

The CED recommended that drospirenone/ethinyl estradiol (Yasmin 21, 28) not be listed on the Ontario Drug Benefit (ODB) Formulary, on the basis that it does not provide added value in efficacy, safety, or quality of life when compared with existing alternatives already available on the Formulary.

Executive Officer Decision

Based on the CED's recommendation and a subsequent pricing agreement, the Executive Officer has decided to list drospirenone/ethinyl estradiol (Yasmin) on the ODB Formulary.

Status

Funding available through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Drospirenone/ethinyl estradiol (Yasmin) is an oral contraceptive containing two synthetic hormones: progesterone (drospirenone) and estrogen (ethinyl estradiol), used to prevent pregnancy. Its manufacturer, Berlex Canada Inc., also suggests it may reduce acne and premenstrual symptoms.
- ◆ The drug appears to work similarly to other oral contraceptives on the market.
- ◆ After reviewing a study of drospirenone/ethinyl estradiol (Yasmin) for treating acne, the Committee noted there was no significant difference in how well drospirenone/ethinyl estradiol (Yasmin) worked, compared with another oral contraceptive, norgestimate/ethinyl estradiol (Tri-Cyclen).
- ◆ Drospirenone/ethinyl estradiol (Yasmin) is less expensive than some similar contraceptives on the Formulary, but is more expensive than ethinyl estradiol/levonorgestrel (Alesse) and norgestimate/ethinyl estradiol (Tri-Cyclen), the two most frequently prescribed oral contraceptives on the Formulary.
- ◆ **Overall, the Committee noted that drospirenone/ethinyl estradiol (Yasmin) did not provide added value in efficacy, safety, or quality of life when compared with existing alternatives already available on Formulary.**
- ◆ As such, the CED recommended not to fund drospirenone/ethinyl estradiol (Yasmin).

Background:

Drospirenone/ethinyl estradiol (Yasmin) 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 pill 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.

Drospirenone/ethinyl estradiol (Yasmin) can also be used to reduce acne and premenstrual symptoms.

continued...

Detailed Discussion:

- ◆ The manufacturer of drospirenone/ethinyl estradiol (Yasmin) asked the Ontario Ministry of Health and Long-Term Care to reconsider listing the oral contraceptive on the Ontario Drug Benefit Formulary, citing its potential to reduce acne and premenstrual symptoms.
 - ◆ This was the fourth time that the Committee had reviewed the submission.
 - ◆ After reviewing a randomized-controlled trial concerning the treatment of acne vulgaris, the Committee noted that drospirenone/ethinyl estradiol did not significantly improve the acne when compared with norgestimate/ethinyl estradiol (Tri-Cyclen). The CED also noted that any differences in outcome were very small, and insufficient to warrant a price premium over currently listed alternatives on the Formulary.
 - ◆ After examining the evidence of an improvement in premenstrual symptoms, the Committee noted that in five of the six categories cited, there was no difference in the efficacy between drospirenone/ethinyl estradiol (Yasmin) and ethinyl estradiol/levonorgestrel (Alesse). The Committee did not believe a small difference in one category justified the price premium.
 - ◆ Similar to other oral contraceptives, side effects of drospirenone/ethinyl estradiol (Yasmin) may include abdominal cramping or bloating, acne, back pain, breast pain, tenderness or swelling, diarrhea, dizziness, nausea and vomiting, breakthrough bleeding, nervousness, swelling of ankles and feet, unusual tiredness or weakness.
 - ◆ The manufacturer suggested that patients would switch to drospirenone/ethinyl estradiol (Yasmin) from the two most commonly prescribed oral contraceptives. An analysis suggested any overall impact of switches would have little effect on the Formulary budget, since switches from higher-cost alternative oral contraceptives to drospirenone/ethinyl estradiol (Yasmin) would likely offset any switches from lower-cost alternatives.
- ◆ Overall, the Committee noted that drospirenone/ethinyl estradiol (Yasmin) does not demonstrate a therapeutic advantage or improved tolerability over other oral contraceptives listed on the Formulary. In order for the CED to reconsider a recommendation for funding, drospirenone/ethinyl estradiol (Yasmin) should be priced at or below the lowest-cost alternative oral contraceptive currently listed on the Formulary.

CEDAC Recommendation:

The Canadian Expert Advisory Drug Committee recommended that the combination of 3 mg drospirenone and 0.03 mg ethinyl estradiol (Yasmin) 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
415 Yonge Street, Suite 1601
Toronto, Ontario M5B 2E7
or click: www.moh.on.gov.ca/dss/ced