Canadian Agency for Drugs and Technologies in Health

Agence canadienne des médicaments et des technologies de la santé

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

ETONOGESTREL/ETHINYL ESTRADIOL (NuvaRing™ - Organon Canada Ltd.)

Description:

NuvaRing™ is a contraceptive vaginal ring containing two active components, etonogestrel and ethinyl estradiol.

Dosage Forms:

NuvaRing™ contains 11.4 mg etonogestrel and 2.6 mg ethinyl estradiol and releases, on average, 120 µg/day of etonogestrel and 15 µg/day of ethinyl estradiol over a three week period of use.

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that NuvaRing™ be listed on the condition that the amount paid by drug plans for NuvaRing™ per cycle not exceed the current maximum paid for oral contraceptives.

Reasons for the Recommendation:

1. The Committee considered a systematic review of randomized controlled trials (RCTs) of at least six months duration which compared NuvaRing™ with any contraceptive containing a combination of estrogen and progestin that is approved for use in Canada. Two RCTs comparing NuvaRing™ with oral contraceptives (one versus levonorgestrel 150 µg/day plus ethinyl estradiol 30 µg/day and another versus drospirenone 3 mg/day plus ethinyl estradiol 30 µg/day) met the inclusion criteria for the systematic review. There were no significant differences in pregnancy rates between study groups in either RCT.

2. There is no evidence that NuvaRing™ is associated with improved compliance with therapy in comparison to oral contraceptives.

3. NuvaRing™ costs $14.01 per cycle, which is more expensive than most oral contraceptive agents. Although NuvaRing™ offers a contraceptive option for women who are unable to successfully adhere to oral contraceptive therapy, the Committee felt that the increased cost of NuvaRing™ over oral contraceptives was not justified.

Summary of Committee Considerations:

There were no statistically significant differences in the rates of total adverse events, withdrawals due to adverse events or serious adverse events in the one RCT which reported on these outcomes. The RCT comparing NuvaRing™ with drospirenone/ethinyl estradiol reported less nausea (2.8% vs 5.8%) and

vomiting (0.4% vs 2.5%) in patients in the NuvaRing™ arm. Both RCTs reported higher rates of vaginitis (pooled results 11.3% vs 5.3%) and leucorrhea (pooled results 4.9% vs 2.0%) in patients in the NuvaRing™ arm. Accidental expulsion of the NuvaRing™ device occurred in 5.4% of women in one RCT.

Of Note:

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.

2. Drug plans that do not have the capacity to implement a maximum allowable cost program for contraceptives should only consider listing NuvaRing™ if the amount paid for NuvaRing™ per cycle does not exceed the current maximum paid for oral contraceptives.

Background:

CEDAC provides formulary listing recommendations to publicly funded drug plans. Recommendations are based on an evidence-based review of the medication's effectiveness and safety and an assessment of its cost-effectiveness in comparison to other available treatment options. For example, if a new medication is more expensive than other treatments, the Committee considers whether any advantages of the new medication justify the higher price. If the recommendation is not to list a drug, the Committee has concerns regarding the balance between benefit and harm for the medication, and/or concerns about whether the medication provides good value for public drug plans.