



## RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

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### NORELGESTROMIN/ETHINYL ESTRADIOL transdermal patch (Evra—Janssen-Ortho Inc.)

**Description:**

Norelgestromin/ethinyl estradiol is a transdermal combination estrogen/progestin patch indicated for contraception.

**Recommendation on Reconsideration:**

CEDAC recommends that the norelgestromin/ethinyl estradiol transdermal patch not be listed.

**Reasons for the recommendation:**

1. In the two randomized controlled trials comparing the norelgestromin/ethinyl estradiol transdermal patch with oral contraceptives that evaluated pregnancy rates, the pregnancy rates were similar (pregnancy rate 0.6% vs 1.2%; 0.5% vs 0.3%).
2. In all 3 randomized trials that reported withdrawals, the withdrawal rate was higher in the patients receiving the transdermal patch. These differences were statistically significant in two trials.
3. In all 3 randomized controlled trials that reported withdrawals because of adverse effects, rates of withdrawal in the norelgestromin/ethinyl estradiol transdermal patch-treated patients were higher than in women on oral contraceptive agents. More frequent patient withdrawals on the norelgestromin/ethinyl estradiol transdermal patch were due, primarily, to complaints of skin irritation at the site of the patch and breast discomfort, pain and engorgement.
4. The norelgestromin/ethinyl estradiol transdermal patch is more than twice as expensive as oral contraceptive agents.
5. In summary, the norelgestromin/ethinyl estradiol transdermal patch is more expensive, of similar efficacy, and associated with more patient withdrawals in the clinical trials than oral contraceptive agents.

**Of Note:**

1. No evidence was provided that the norelgestromin/ethinyl estradiol patch has an advantage over oral contraceptive agents in patients with clinically significant malabsorption syndromes.