RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

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.