

## Drug Class Review Monograph – GPI Class 25 – Contraceptives

Review Time Frame: 05/2016 – 04/2017

*Previous Class Review: 08/2016*

### **Background:**

Hormonal contraceptives (combined estrogen-progestin or progestin-only) are indicated for routine contraception. Additionally, some contraceptive agents have non-contraceptive benefits and may be used for the treatment of conditions such as acne or menstrual cycle disorders (e.g., menorrhagia, premenstrual dysphoric disorder).

The primary mechanism for providing contraception is inhibition of the midcycle luteinizing hormone (LH) surge to prevent ovulation. Another potential mechanism of contraceptive action is suppression of gonadotropin secretion during the follicular phase of the cycle, thereby inhibiting follicular maturation. Progestin-related mechanisms include alterations in the endometrium, rendering it less suitable for implantation, and an increase in cervical mucus viscosity, which becomes less permeable to penetration by sperm. In contrast to estrogen-progestin oral contraceptive pills, ovulation is not consistently suppressed with norethindrone progestin-only contraceptive pills.

### **New treatment guideline recommendations:**

- None identified

### **Newly approved drugs:**

- None identified

### **Newly approved formulations:**

- Approved 09/16/2016: Kyleena (levonorgestrel) 19.5 mg intrauterine device; currently commercially available.

### **Newly approved generics:**

- Approved 05/06/2016: Natazia (estradiol valerate and estradiol valerate/dienogest) 1 mg and 3 mg / 2/2 mg and 2/3 mg tablets; tentatively available 05/13/2026.
- Approved 05/24/2016: Minastrin 24 Fe (norethindrone/ethinyl estradiol and ferrous fumarate) 1 mg/0.2 mg and 75 mg tablets; currently commercially available.
- Approved 10/11/2016: Beyaz (drospirenone/ethinyl estradiol/levomefolate) 3/0.02/0.451 mg tablets; currently commercially available.
- Approved 10/11/2016: Safyral (drospirenone/ethinyl estradiol/levomefolate) 3/0.03/0.451 mg tablets; tentatively available first half of 2017.
- Approved 02/13/2017: Ella (ulipristal acetate) 30 mg tablets; tentatively available 2025-2026.

### **Discontinued drugs:**

- None identified

### **FDA Safety Alerts/black box warnings:**

- None identified

**Pipeline alerts:**

Agents pending FDA approval include:

- Liletta (levonorgestrel), an intrauterine device proposed for the prevention of pregnancy for up to 4 years; PDUFA: 09/04/2017.

**References:**

1. Martin KA, Barbieri RL. Overview of the use of estrogen-progestin contraceptives. Crowley WF. (Ed), UpToDate. Waltham MA. Accessed April 2016.
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3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. URL: <http://www.clinicalpharmacology-ip.com/>. Accessed April 2016.
4. US Script Oracle PBM: Medi-Span<sup>®</sup> Master Drug Data Base. April 2016.
5. Food and Drug Administration. [WWW.FDA.GOV](http://www.fda.gov). Accessed May 2017.
6. DailyMed. Available from: <https://dailymed.nlm.nih.gov/>. Accessed April 2016.
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