

## Drug Class Review Monograph – GPI Class 26 – Progestins

Review Time Frame: 05/2016 – 04/2017

*Previous Class Review: 08/2016*

### **Background:**

Progestin is a synthetic form of progesterone, a natural steroid hormone, which can be used for contraception or as hormonal therapy to treat such conditions as secondary amenorrhea, abnormal uterine bleeding, and endometriosis. The topic of contraception is reviewed separately.

Progestin can be used to achieve normalized progesterone levels in pre-menopausal women with secondary amenorrhea or dysfunctional uterine bleeding and thus help re-establish normal menstrual patterns. When used in the menopausal woman with an intact uterus, progestin reduces endometrial growth which serves as a protective effect that decreases the risk of endometrial hyperplasia when used with estrogen.

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

- None identified

### **Newly approved drugs:**

- None identified

### **Newly approved formulations:**

- None identified

### **Newly approved generics:**

- None identified

### **Discontinued drugs:**

- None identified

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

- None identified

### **Pipeline alerts:**

Agents pending FDA approval include:

- Makena (hydroxyprogesterone), a new auto-injector formulation proposed for the reduction of risk of preterm birth in women who are pregnant with one baby and who have spontaneously delivered one preterm baby in the past; PDUFA: 10/17/2017.

### **References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. URL: <http://www.clinicalpharmacology-ip.com/>. Accessed April 2016.
2. US Script Oracle PBM: Medi-Span<sup>®</sup> Master Drug Data Base. April 2016.
3. Food and Drug Administration. [WWW.FDA.GOV](http://WWW.FDA.GOV). Accessed May 2017.
4. DailyMed. <https://dailymed.nlm.nih.gov/>.

5. Envolve Pharmacy Solutions internal pipeline database. Accessed May 2017.