

Drug Class Review Monograph – GPI Class 23 – Androgens, Anabolic

Review Time Frame: 05/2016 – 04/2017

Previous Class Review: N/A

Background:

Androgens and anabolic steroids are used as replacement therapy to treat delayed puberty in adolescent boys, hypogonadism and impotence in men, and breast cancer in women. They are also used to treat anemia, osteoporosis, weight loss, and other conditions with hormonal imbalance. Anabolic steroids stimulate growth in many types of tissues, especially bone and muscle. Anabolic effects also include increased production of red blood cells.

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:

- QuickShot Testosterone (testosterone), a subcutaneous injection proposed for the treatment of symptomatic testosterone deficiency in men; PDUFA: 10/20/2017.

References:

1. Snyder PJ. Testosterone treatment of male hypogonadism. Matsumoto AM. (Ed), UpToDate. Waltham MA. Accessed April 2016.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. URL: <http://www.clinicalpharmacology-ip.com/>. Accessed April 2016.
3. US Script Oracle PBM: Medi-Span[®] Master Drug Data Base. April 2016.
4. Food and Drug Administration. [WWW.FDA.GOV](http://www.fda.gov). Accessed May 2017.
5. Envolve Pharmacy Solutions internal pipeline database. Accessed May 2017.