

## Drug Class Review Monograph – GPI Class 28 – Thyroid Agents

Review Time Frame: 05/2016 – 04/2017

*Previous Class Review: 11/2016*

### **Background:**

Thyroid agents are thyroid hormones used to supplement the natural thyroid hormones in the body. Thyroid drugs are used for treating low thyroid activity (hypothyroidism), treating or suppressing different types of goiters, and diagnosing certain thyroid conditions.

Antithyroid agents prevent or suppress the biosynthesis of thyroid hormones. Antithyroid agents are used to treat hyperthyroidism by inhibiting the excessive production of thyroid hormones or by decreasing thyroid hormone activity.

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

- In the 2016 update of the medical guidelines for clinical practice for the diagnosis and management of thyroid nodules, the American Association of Clinical Endocrinologists (AACE), American College of Endocrinology (ACE), and Associazione Medici Endocrinologi (AME) recommend against the use of levothyroxine (LT4) for suppressive therapy of thyroid nodules. Surgery remains the treatment of choice for malignant or suspicious nodules.

### **Newly approved drugs:**

- None identified

### **Newly approved formulations:**

- Approved 12/15/2016: Tirosint-SOL (levothyroxine sodium) 13 mcg/mL, 25 mcg/mL, 50 mcg/mL, 75 mcg/mL, 88 mcg/mL, 100 mcg/mL, 112 mcg/mL, 125 mcg/mL, 137 mcg/mL, 150 mcg/mL, 175 mcg/mL, and 200 mcg/mL oral solution; tentatively available by August 15, 2017.

### **Newly approved generics:**

- Approved 6/29/2016: levothyroxine sodium for injection 100 mcg and 500 mcg vials; anticipated commercial availability unknown.

### **Discontinued drugs:**

- None identified

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

- None identified

### **Pipeline alerts:**

Agents pending FDA approval include:

- None identified

### **References:**

1. Brent GA. Thyroid hormone action. Ross DS. (Ed), UpToDate. Waltham MA. Accessed April 2016.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. URL: <http://www.clinicalpharmacology-ip.com/>. Accessed May 2017.
3. US Script Oracle PBM: Medi-Span<sup>®</sup> Master Drug Data Base. April 2016.
4. Food and Drug Administration. [WWW.FDA.GOV](http://www.fda.gov). Accessed May 2017.
5. Gharib H, Papini E, Garber JR, et al. American Association of Clinical Endocrinologists, American College of Endocrinology, and Associazione Medici Endocrinologi medical guidelines for clinical practice for the diagnosis and management of thyroid nodules—2016 update. *Endocr Pract.* 2016; 22(5): 622-639.
6. Envolve Pharmacy Solutions internal pipeline database. Accessed May 2017.