Austedo® (deutetrabenazine) – New indication

- On August 30, 2017, Teva announced the FDA approval of Austedo (deutetrabenazine) for the treatment of tardive dyskinesia (TD) in adults.
    - Austedo is also approved for the treatment of chorea associated with Huntington's disease (HD).
- TD is a neurological disorder characterized by repetitive involuntary movements, usually of the jaw, lips, and tongue. Some affected individuals may also experience involuntary movement of the extremities or difficulty breathing.
    - TD is estimated to affect at least 500,000 Americans.
    - TD is sometimes seen in patients who have been treated with antipsychotic medications for long periods of time.
    - The symptoms of TD can be severe and are often persistent and irreversible.
- The new indication for Austedo was approved based on two placebo-controlled trials involving 335 adult patients with TD. The primary endpoint was the Abnormal Involuntary Movement Scale (AIMS) for the assessment of TD severity.
    - In both trials, Austedo demonstrated greater statistically significant improvements in mean AIMS scores vs. placebo.
- Austedo carries a boxed warning regarding the risk of depression and suicidality in patients with HD.
- The recommended dosage of Austedo for TD is determined individually for each patient based on reduction of TD and tolerability. When first prescribed to patients who are not being switched from tetrabenazine, the recommended starting dose of Austedo is 6 mg orally twice daily.
    - The maximum recommended daily dose is 48 mg.
    - Doses ≥ 12 mg per day should be administered in two divided doses.
    - Austedo should be swallowed whole. Do not chew, crush, or break tablets.
    - For patients at risk of QT prolongation, the QT interval should be assessed before and after increasing total Austedo dosage above 24 mg per day.
    - Refer to the Austedo drug label for dosing in HD and when switching from tetrabenazine.