Toviaz® (fesoterodine fumarate) – New indication

- On June 17, 2021, the FDA approved Pfizer's Toviaz (fesoterodine fumarate), for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 6 years of age and older with a body weight greater than 25 kg.

- Toviaz is also approved for the treatment of overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency.

- The approval of Toviaz for the new indication was based on a randomized, open-label study consisting of a 12-week efficacy phase followed by a 12-week safety extension phase in pediatric patients from 6 years to 17 years of age. During the 12-week efficacy phase, 124 patients were randomized to receive Toviaz 4 mg, Toviaz 8 mg, or active comparator orally once daily. The primary efficacy endpoint was the mean change from baseline in maximum cystometric bladder capacity (MCBC) at week 12.

    — Treatment with Toviaz 4 mg or 8 mg daily resulted in improvements from baseline to week 12 in the primary efficacy endpoint, MCBC, for pediatric patients, with numerically higher changes from baseline for Toviaz 8 mg daily than for Toviaz 4 mg daily. The change from baseline with Toviaz 4 mg was 58.1 (95% CI: 28.8, 87.4) and with Toviaz 8 mg the change from baseline was 83.4 (95% CI: 54.2, 112.5).

- The most common adverse reactions (≥ 2%) with Toviaz use in pediatric patients with NDO were diarrhea, urinary tract infection, dry mouth, constipation, abdominal pain, nausea, increased weight, and headache.

- In pediatric patients weighing greater than 25 kg and up to 35 kg, the recommended dose of Toviaz is 4 mg orally once daily. If needed, dosage may be increased to Toviaz 8 mg orally once daily.

- In pediatric patients weighing greater than 35 kg, the recommended starting dosage of Toviaz is 4 mg orally once daily. After one week, the dose should be increased to 8 mg orally once daily.

- Refer to the Toviaz drug label for dosing for OAB.