Botox® (onabotulinumtoxinA) – New indication

- On February 10, 2021, Allergan announced the FDA approval of Botox (onabotulinumtoxinA), for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication.

- Botox is also approved for the adult bladder dysfunction, chronic migraine, spasticity, cervical dystonia, primary axillary hyperhidrosis, and blepharospasm and strabismus.

- Neurogenic detrusor overactivity causes the bladder muscle to involuntarily contract, increasing the pressure in the bladder and reducing the bladder capacity, which can cause the individual to leak urine frequently and unexpectedly. Elevated bladder pressure can also lead to bladder and kidney damage over time.

    — There are several causes of neurogenic detrusor overactivity in children, such as transverse myelitis, spinal cord injury, and spina bifida, the latter of which is the most common and affects 1,500 - 2,000 babies born in the U.S. each year.

- The approval of Botox for the new indication was based on a randomized, double-blind study conducted in 133 patients 5 to 17 years of age with urinary incontinence due to detrusor overactivity who had an inadequate response to or were intolerant of at least one anticholinergic medication. Patients were randomized to 50 units, 100 units or 200 units, not to exceed 6 Uunits/kg body weight.

    — The study results demonstrated within group improvements in the primary efficacy variable of change from baseline in daytime urinary incontinence episodes (normalized to 12 hours) at the primary efficacy time point (week 6) for all 3 Botox treatment groups.
    — Additional benefits were seen with Botox 200 units for measures related to reducing maximum bladder pressure vs. 50 units.

- Botox carries a boxed warning for distant spread of toxin effect.

- The most common adverse reactions (≥ 5% and > placebo, if applicable) with Botox use in pediatric detrusor overactivity were urinary tract infection, leukocyturia, and bacteriuria.

- The recommended dose of Botox for the treatment of pediatric detrusor overactivity is 200 units of Botox per treatment administered as an intradetrusor injection if the patient's body weight is greater than or equal to 34 kg. If patient's body weight is less than 34 kg, the recommended dosage is 6 units/kg body weight administered as a bladder injection.

    — Patients should be considered for re-injection when the clinical effect of the previous injection diminishes (median time to qualification for re-treatment in the double-blind, parallel group clinical study was 207 days [30 weeks] for Botox 200 units), but no sooner than 12 weeks from the prior bladder injection.
    — Refer to the Botox drug label for additional dosing recommendations for pediatric detrusor overactivity and dosing for all its other indications.