Botox® (onabotulinumtoxinA) – Expanded indication

- On July 9, 2020, AbbVie and Allergan announced the FDA approval of Botox (onabotulinumtoxinA), for the treatment of spasticity in patients 2 years of age and older.
    - This approval expands and streamlines the previous indication which was for the treatment of lower/upper limb spasticity in adult patients; treatment of upper limb spasticity in pediatric patients 2 to 17 years of age; and treatment of lower limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy.
    - Botox has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.

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

- This label expansion is based on Allergan and another manufacturer (Ipsen Biopharmaceuticals) selectively waiving orphan exclusivity marketing rights each company held for the use of their respective neurotoxins in the treatment of pediatric patients with spasticity caused by cerebral palsy.

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

- The recommended total dose of Botox for pediatric lower limb spasticity is 4 units/kg to 8 units/kg (maximum 300 units) divided among affected muscles.
    - Refer to the Botox drug label for additional administration recommendations and for dosing for all of Botox's other indications.