

## Botox<sup>®</sup> (onabotulinumtoxinA) – Expanded indication

- On October 18, 2019, the [FDA approved](#) Allergan's [Botox \(onabotulinumtoxinA\)](#), for the treatment of lower limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy.
  - Previously, Botox was approved for adult patients for lower limb spasticity.
- Botox is also approved for the treatment of overactive bladder, urinary incontinence due to detrusor overactivity, prophylaxis of headaches in adult patients with chronic migraine, treatment of upper limb spasticity in adult and pediatric patients 2 to 17 years of age, treatment of cervical dystonia in adult patients, treatment of severe axillary hyperhidrosis, treatment of blepharospasm, and treatment of strabismus.
- The expanded indication was approved based on a double-blind, placebo-controlled study of 381 pediatric patients with lower limb spasticity. The co-primary endpoints were the average of the change from baseline in modified Ashworth Scale (MAS) ankle score, and the average of the Clinical Global Impression of Overall Change by Physician (CGI) at week 4 and week 6.
  - The week 4 and 6 average MAS score was -1.01 and -1.06 for the Botox 4 units/kg dose and 8 units/kg dose, respectively vs. -0.80 for the placebo dose ( $p < 0.05$  for the 8 units/kg dose vs. placebo).
  - The week 4 and 6 average CGI score was 1.49 and 1.65 for the Botox 4 units/kg dose and 8 units/kg dose, respectively vs. 1.36 for the placebo dose ( $p < 0.05$  for the 8 units/kg dose vs. placebo).
- Botox carries a boxed warning for distant spread of toxin effect.
- The most common adverse effect ( $\geq 5\%$  and  $>$  placebo) with Botox use in pediatric spasticity was upper respiratory tract infection.
- The recommended dose for treating pediatric lower limb spasticity is 4 units/kg to 8 units/kg divided among the affected muscles. The total dose of Botox administered per treatment session in the lower limb should not exceed 8 units/kg or 300 units, whichever is lower.
  - When treating both lower limbs or the upper and lower limbs in combination, the total dose should not exceed the lower of 10 units/kg body weight or 340 units, in a 3-month interval.
- Consult the Botox drug label for dosing recommendations for all additional indications.