Dysport® (abobotulinumtoxinA) – New Indication

- On August 1, 2016, Ispen Biopharmaceuticals announced the FDA approval of Dysport (abobotulinumtoxinA) for injection for the treatment of lower limb spasticity in pediatric patients two years of age and older.

- Dysport is also FDA approved for the following:

    - Treatment of adults with cervical dystonia.
    - Temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients < 65 years of age.
    - Treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors, wrist flexors and finger flexors.

- Dysport is the first and only FDA-approved botulinum toxin for the treatment of pediatric lower limb spasticity.

- Spasticity is a condition in which there is an abnormal increase in muscle tone or stiffness in one or more muscles, which might interfere with movement. Spasticity is usually caused by damage to nerve pathways in the brain or spinal cord that control muscle movement, and may occur in association with cerebral palsy, spinal cord injury, multiple sclerosis, stroke, and brain or head trauma.

- The new indication is based on data from a clinical study of 235 pediatric patients (2 – 17 years old) with lower limb spasticity due to cerebral palsy causing dynamic equinus foot deformity. Patients were randomized to Dysport or placebo. Those treated with Dysport showed statistically significant improvements in lower limb spasticity symptoms at week 4 and week 12 ($p < 0.05$ for all measures vs. placebo).

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

- The most frequently reported adverse reactions (≥ 10%) with Dypsort for the treatment of lower limb spasticity in pediatric patients include upper respiratory tract infection, nasopharyngitis, influenza, pharyngitis, cough and pyrexia.

- For pediatric lower limb spasticity, the dose of Dysport in initial and sequential treatment sessions should be tailored to the individual patient based on the size, number and location of muscles involved, severity of spasticity, the presence of local muscle weakness, the patient's response to previous treatment, and/or adverse event history with botulinum toxins.

    - The recommended dose of Dysport for the treatment of pediatric lower limb spasticity is 10 to 15 units/kg per limb. The total dose per treatment session must not exceed 15 units/kg for unilateral lower limb injections, 30 units/kg for bilateral injections, or 1,000 units, whichever is lower. Re-treatment, based on return of clinical symptoms, should not occur in intervals of less than 12 weeks.
    - Dysport is not interchangeable with other preparations of botulinum toxin products and therefore, units of biological activity of Dysport cannot be compared to or converted into units of any other botulinum toxin products.

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- For use of Dysport in cervical dystonia, glabellar lines, and upper limb spasticity in adults, refer to the prescribing information for the recommended doses.