RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Dysport (abobotulinum toxin A) is an acetylcholine release inhibitor and a neuromuscular blocking agent. Dysport acts as a neuromuscular blocking agent that works by preventing the release of neurotransmitters. This produces a paralyzing effect of the surrounding area of injection. Dysport, like Botox and Myobloc, is a botulinum toxin. Although Botox and Dysport are both botulinum type-A toxins, they are not interchangeable. The two drugs have distinct dosing differences.

Regulatory Status
FDA-approved indication: Dysport is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:

1. The treatment of adults with cervical dystonia
2. The 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
3. The treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors, wrist flexors and finger flexors.
4. The treatment of lower limb spasticity in pediatric patients 2 years of age and older

Dysport has a boxed warning regarding the distant spread of toxin effect. The effects of Dysport and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties that can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in patients who have underlying conditions that would predispose them to these symptoms.

Off Label Uses:
Dysport is recommended for additional compendial indications for spasticity (upper and lower limbs) due to multiple causes (i.e. cerebral palsy, stroke, multiple sclerosis and post-traumatic brain and spinal cord injury) in both adults and children as well as benign essential blepharospasm.

Safety and effectiveness have not been established in patients under the age of 18 years of age for cervical dystonia and blepharospasm.

Dysport FEP Clinical Rationale
Summary
Dysport (abobotulinum toxin A) is an acetylcholine release inhibitor and a neuromuscular blocking agent. Dysport, like Botox and Myobloc, is a botulinum toxin. Although Botox and Dysport are both botulinum type-A toxins, they are not interchangeable. Dysport has a boxed warning regarding the distant spread of toxin effect after injection (2).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Dysport while maintaining optimal therapeutic outcomes.

References