Generic Name:
Incobotulinumtoxin A
Trade Name:
Xeomin
Company:
Merz North America
Notes:

FDA approved incobotulinumtoxinA to treat chronic sialorrhea, or excessive drooling, in adult patients. It is the first and only neurotoxin with this approved indication in the United States.

Sialorrhea is a common symptom among patients who have neurological disorders such as Parkinson disease, amyotrophic lateral sclerosis, or cerebral palsy or who have had a stroke. The condition can occur from difficulty retaining saliva inside the mouth, from issues with swallowing, and from problems controlling facial muscles.

Approval for this indication was based on a Phase III, randomized, double-blind, placebo-controlled, multicenter trial involving 184 patients in which both coprimary endpoints were successfully achieved. Study participants received placebo (n = 36), incobotulinumtoxinA 75 U (n = 74), or incobotulinumtoxinA 100 U (n = 74). Overall frequency of adverse events was similar between placebo and treatment groups, with no new or unexpected adverse events reported.

This is the fourth neurological indication for the neurotoxin, which was first approved by FDA in 2010 to treat cervical dystonia and blepharospasm (in patients previously treated with onabotulinumtoxinA) in adult patients and later in 2015 for upper limb spasticity in adult patients.

Medication Monitor Categories:
Supplemental Approvals