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First Script Prescription Benefit News
for Workers' Compensation

August 2018

Can Botox® be used as a pain treatment? I thought this stuff was only for wrinkles…

"Botox" is one of the brand names that represents the neurotoxin drug product, botulinum toxin, or more specifically, onabotulinumtoxinA. Other brand names for the different types of botulinum toxins include Dysport®, Myobloc®, and Xeomin®. While botulinum products are perhaps best known as popular cosmetic treatments to diminish the appearance of fine lines and wrinkles, the neuromuscular blocking agent is also FDA-approved for a number of additional indications, such as for the treatment of overactive bladder, spasticity, and for headache prevention in adults with chronic migraine. What's more, many clinicians are exploring this injectable product for off-label uses to manage various painful conditions like neuropathic pain and low back pain.

The Official Disability Guidelines (ODG) address botulinum neurotoxins (BTX-A) and outline the evidence-based studies for use in several conditions. To summarize, ODG recommends against use for most chronic pain conditions citing lack of statistical support, specifically for tension-type headache, fibromyositis, chronic neck pain, myofascial pain syndrome, and trigger point injections. When certain criteria are met, ODG recommends use in chronic migraine, spasticity following traumatic brain injury, and for urinary incontinence following spinal cord injury. While some studies have shown fair results for specific populations in treating low back pain and neuropathic pain, ODG indicates that botulinum neurotoxin is not generally recommended for these conditions; however, it may be considered as an option in certain circumstances.

While botulinum toxin may be approved in the U.S. for managing some of the conditions outlined above, many of the indications are not typically work-related. Careful consideration of the requested diagnosis to the industrial injury should be a part of requests for such products. In addition, while studies show that Botox use is generally safe, effective, and well-tolerated for approved indications, the treatments are costly and some still argue that published supporting evidence is limited. For these reasons, use of Botox is typically reserved as second-line therapy, with other medications or therapies being recommended to be tried first. To illustrate this point, a highlight of the ODG criteria and first-line therapy recommendations for use will be summarized as it relates to prevention of chronic migraine headaches. Additional information can be found within the "Head Chapter" under ODG (subscription required).

The FDA defines chronic migraine as experiencing headaches that last longer than four hours on 15 or more days per month. Botox is indicated to prevent migraine headaches through multiple injections applied to seven head and neck muscles given at approximately 12-week intervals. The total recommended dose per treatment is 155 units. ODG outlines criteria for an initial 12-week trial of Botox for migraine prevention if the injured worker has a diagnosis of chronic migraine that fits with the FDA's definition and has tried three or more first-line migraine prevention medications with no response. ODG-supported first-line oral migraine preventative medications include amitriptyline (tricyclic antidepressant); metoprolol, propranolol, or timolol (antihypertensive beta blockers); and valproic acid, divalproex, or topiramate (anticonvulsants). ODG also provides guidance for when to continue treatment with Botox, indicating that the injectable may be considered for ongoing prevention if use during the 12-week trial results in a reduction of headache days per month by at least seven days or duration of headache hours by at least 100 hours when compared to the pre-treatment average. The medication should be discontinued if the injured worker fails to meet the diagnosis of chronic migraine (i.e., if headache frequency drops below 15 days per month for three consecutive months) as Botox is not indicated for episodic migraine treatment.

Whatever the condition for which use of botulinum toxin is being requested, it is important to consider the available evidence for efficacy and safety of treatment, as well as whether or not first-line supported therapies have been tried first.

(Continued on page 2)

(Continued from page 1)

Botulinum toxin treatment can be costly and is not without side effects, including (depending on condition and injection site) neck pain, headache, pain in extremity, urinary tract issues, upper respiratory infection, flu syndrome, runny nose, increased cough, back pain, or injection site pain. In other words, while botulinum toxin treatment may be a good option for some patients, especially considering the disabling nature of some of the conditions it is indicated to treat, it is important to evaluate cost (i.e., price comparison, tolerance of adverse effects) versus benefit (i.e., therapeutic response, improved quality of life, increased function). For further insight into botulinum toxin treatments or for questions related to a specific injured worker's care, please consider contacting our team of clinical pharmacists at askthepharmacist@cvty.com.

Brand Name	Active Ingredient	FDA-Approved Indications	ODG Status	Cost*
Botox	onabotulinumtoxinA	Treatment of OAB, urinary incontinence associated with neurologic condition, spasticity, cervical dystonia, severe axillary hyperhidrosis, blepharospasm, strabismus; Prevention of headaches in adults with chronic migraine	N	$1,442.40
Botox Cosmetic	onabotulinumtoxinA	Temporary improvement in the appearance of lines/wrinkles	N	$397.20
Dysport	abobotulinumtoxinA	Treatment of cervical dystonia; Temporary improvement in the appearance of lines/wrinkles	N	$982.20
Myobloc	botulinum toxin type B	Treatment of cervical dystonia	N	$697.20
Xeomin	incobotulinumtoxinA	Treatment of cervical dystonia, blepharospasm	N	$882.00

**Cost based on MediSpan AWP for units needed to complete one treatment at FDA-approved starting dose for cervical dystonia (Botox dosing is for chronic migraine; Botox Cosmetic dosing is for listed indication)*

References:
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/
www.odg-twc.com

Drug of the Month

Aimovig®

Aimovig (erenumab-aooe), developed by Amgen, is a first of its kind once-monthly injection product for migraine prevention. Recently approved by the FDA (May 16, 2018), this novel agent works by blocking the activity of calcitonin gene-related peptide (CGRP), one of the molecules involved in migraine attacks.

Aimovig is available as 70 mg of erenumab-aooe in a 1 mL single-dose, pre-filled auto-injector for subcutaneous use, and comes in a package of one or two doses. The approved recommended dosing for Aimovig is 70 mg once monthly, with some patients benefiting from 140 mg once monthly administered as two consecutive injections of 70 mg each. The product is intended for self-injection into the abdomen, thigh, or upper arm.

Clinical studies showed that Aimovig is generally well-tolerated with the most commonly reported adverse effects being injection site reactions and constipation. Aimovig is not yet addressed in the Official Disability Guidelines; however, it is comparable in pricing to another injectable migraine product supported as a second-line treatment option for chronic migraine sufferers: Botox (onabotuinumtoxinA). According to Medispan, the cost (based on AWP) of the two available Aimovig products is $690. First-line oral preventative migraine medications including select antidepressants, anticonvulsants, or antihypertensive agents are recommended to be tried before consideration for Aimovig.

Furthermore, biologic medications like Aimovig fall in the "specialty" drug category, and additional oversight is recommended due to the complex or costly nature of these types of drugs. The appropriateness for use of Aimovig in relation to the work injury, as well as prior treatment history, should be determined prior to coverage consideration.

Reference: https://www.accessdata.fda.gov/scripts/cder/daf/

Regulatory Update

Hawaii

Senate Bill 2646 requires prescribers of certain controlled substances to consult the State's Electronic Prescription Accountability System before issuing a prescription for a controlled substance, under certain circumstances. This bill has a retroactive effective date of July 1, 2018.

Hawaii has also adopted Senate Bill 2244, which requires health care providers in the workers' compensation system who are authorized to prescribe opioids to adopt and maintain policies for informed consent to opioid therapy in circumstances that carry elevated risk of dependency, and establishes limits for concurrent opioid and benzodiazepine prescriptions. This bill became effective on July 9, 2018.

Mississippi

Mississippi has adopted changes to its requirements for the Mississippi Prescription Monitoring Program (MS PMP). Effective July 29, 2018, a pharmacist is required to review the PMP under certain circumstances prior to dispensing a prescription for a Schedule II opiate.

Oregon

Oregon has amended Rules OAR 333-023-0805, -0810 and -0820 and adopted rule OAR 333-023-0825 regarding changes to the Prescription Drug Monitoring Program (PDMP). This rule was published on June 28, 2018 and became effective July 2, 2018.

Rhode Island

Amended House Bill 7416 allows a pharmacist to dispense a partial fill of a Schedule II controlled substance at the request of the patient or the prescriber. The bill was signed by the governor and became effective July 2, 2018.

Virginia

Virginia has adopted Regulations 18 VAC 85-21-10 through -170, relating to opioid prescribing limitations and requirements for acute and chronic pain management applicable to doctors of medicine, osteopathic medicine, and podiatry and to physician assistants. These changes are effective as of August 8, 2018.

Coventry's Regulatory and Legislative Affairs (RLA) group will continue to monitor further discussion on these topics. If you have questions regarding these changes, please contact your First Script Account Manager.