BOTOX® onabotulinumtoxinA injection

CHRONIC MIGRAINE

BOTOX® for Chronic Migraine?

is it time to get started?

BOTOX® prevents headaches in adults with Chronic Migraine: 15 or more headache days a month, each lasting 4 hours or more. BOTOX® is not approved for 14 or fewer headache days a month.

BOTOX® prevents, on average, 8 to 9 headache days and migraine/probable migraine days a month (vs 6 to 7 for placebo).

It's time to think differently about how you treat your Chronic Migraine.

It's time to talk to your doctor about BOTOX® and ask if samples are available.†

in a survey,

92%

of current BOTOX® users wish they'd talked to their doctor and started treatment sooner!*

and

97%

of current BOTOX® users plan to keep using it!*

By participating in the BOTOX® Savings Program, you acknowledge and agree to the full Terms & Conditions set out at BOTOXSavingsProgram.com/TermsandConditions. Patients enrolled in Medicare, Medicaid, TRICARE, or any other government-reimbursed healthcare program are not eligible. Other restrictions and maximum limits apply.

text SAVE to 27747‡

you may pay

$0

BOTOXChronicMigraine.com

*2020 BOTOX® Chronic Migraine Patient Market Research BOTOX® Current Users (n=71).
†Only a doctor can determine if BOTOX® is right for you. Sample availability may vary by provider or location.

‡See Privacy & Terms: http://bit.ly/2RvxiWr. Message & data rates may apply. Message frequency may vary. Text HELP for help or STOP to end.

Indication

BOTOX® is a prescription medicine that is injected to prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years or older.

It is not known whether BOTOX® is safe and effective to prevent headaches in patients with migraine who have 14 or fewer headache days each month (episodic migraine).

IMPORTANT SAFETY INFORMATION

BOTOX® may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX®:

- **Problems swallowing, speaking, or breathing,** due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, and trouble swallowing

Please see additional Important Safety Information about BOTOX® on the adjacent page.

Allergan
an AbbVie company

Summary of Information about BOTOX® (onabotulinumtoxinA)

What is the most important information I should know about BOTOX®?

BOTOX® may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX®:

- **Problems swallowing, speaking, or breathing,** due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, and trouble swallowing

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX® has been used at the recommended dose to treat Chronic Migraine.

BOTOX® may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX®. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

BOTOX® dosing units are not the same as, or comparable to, any other botulinum toxin product.

What is BOTOX®?

BOTOX® is prescription medicine a medical professional injects into muscles to prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years and older.

It is not known whether BOTOX® is safe or effective to prevent headaches in people with migraine who have 14 or fewer headache days each month (episodic migraine).

Who should not receive BOTOX®?

Do not receive BOTOX® if you are: allergic to any of the ingredients in BOTOX® such as botulinum toxin type A and human serum albumin; had an allergic reaction to another botulinum toxin product such as Myobloc® (rimabotulinumtoxinB), Dysport® (abobotulinumtoxinA), or Xeomin® (incobotulinumtoxinA); or have a skin infection at the planned injection site.

What should I tell my doctor before treatment?

Tell your doctor about all your muscle or nerve conditions, such as amyotrophic lateral sclerosis (Lou Gehrig's disease), myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects.

Tell your doctor if you have or have had breathing problems such as asthma or emphysema; swallowing problems; bleeding issues; plan to or have had surgery; have forehead muscle weakness such as trouble raising your eyebrows; drooping eyelids; or any changes to your face.

Tell your doctor if you are pregnant, plan to become pregnant, are breastfeeding or plan to breast feed. It is not known if BOTOX® (onabotulinumtoxinA) can harm your unborn baby or if BOTOX® passes into breast milk.

What Are Common Side Effects?

The most common side effects include neck pain; headache; migraine; slight or partial facial paralysis; drooping eyebrows; eyelid drooping; bronchitis; musculoskeletal stiffness; muscular weakness; pain in 1 or more muscles, ligaments, tendons, or bones; muscle spasms; injection site pain; and high blood pressure. Other side effects have been reported including allergic reactions e.g. itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint.

These are not all of the possible side effects. Call your doctor for medical advice if you experience any side effects after treatment with BOTOX®.

What Should I Tell My Doctor About Medicines and Vitamins I Take?

Using BOTOX® with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received BOTOX® in the past.** Tell your doctor if you have received an injection with another botulinum toxin product in the last 4 months, such as Myobloc®, Dysport®, or Xeomin®. Be sure your doctor knows which product you received.

Tell your doctor about all prescription and over-the-counter medicines, vitamins and herbal supplements you take; recent antibiotic injections; anticholinergics; muscle relaxants; allergy or cold medicine; sleep medicine; aspirin-like products; and blood thinners. **Ask your doctor if you are not sure whether your medicine is listed above.**

To Learn More

If you would like more information, talk to your doctor and/or go to BotoxChronicMigraine.com for full Product Information.

You may report side effects to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

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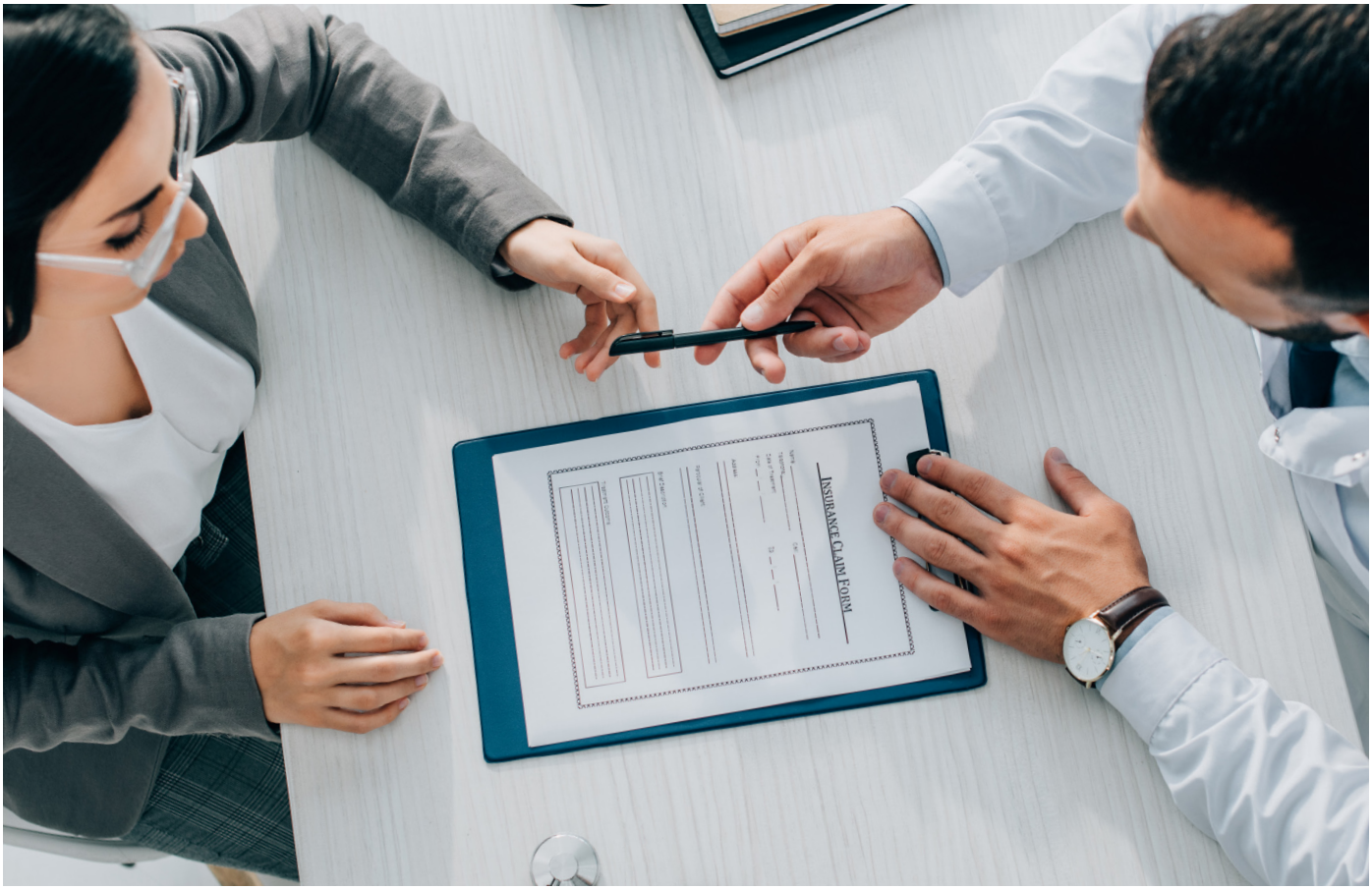
Dancing With the Devil

A Physician's Perspective



When you dance with the devil, you don't get to pick the tune.

— Sherrilyn Kenyon

In the practice of medicine generally and headache medicine specifically, insurers often require "prior authorization" (PA) before they will reimburse the patient or provider for a test (e.g., brain MRI scan) or therapy (e.g., Botox injections). If PA is denied, the client/patient typically has the right to appeal that decision, and that process often requires direct involvement on the part of the provider.

The general public may have limited insight into various aspects of the PA and appeals process. They perhaps would be surprised to learn a) how much time providers spend engaged in that process, b) that providers receive no direct financial compensation for the time devoted and, c) correspondingly, how much it costs providers to support the process.

For example, prescription of the new and exciting therapies for acute migraine treatment and migraine prevention almost invariably require a PA. If providers prescribe these therapies to a high volume of patients, they must hire staff to handle the PA and appeal process. If the given provider already is at full capacity in terms of his/her patient volume, there is no way to recover the cost of the new staff members' salaries and benefits. Put another way, as there is no compensation to the physician for the effort he/she makes in prescribing these therapies and no "spare time" magically appears to devote to that effort, prescribing these therapies can be a losing proposition for the physician…financially, professionally and emotionally.

At the headache center where I previously worked, there were two full-time staff members whose only responsibility was to handle PAs and appeals for onbotulinumtoxinA (BotoxA) and the newer therapies for migraine. The dismal truth was that because my colleagues and I prescribed the newer migraine therapies (which in many cases we had helped to

> **These [pharma-ceutical companies] are businesses not charities.**

develop), our department lost money.

If a PA is denied and an appeal is then launched, the provider typically is asked to write a letter supporting the appeal or, more onerous, to engage in what is called a "peer to peer" interview (more on this travesty to come). Again, there is no compensation to the provider or, in the case of an academic institution, to his/her department for the time and effort the provider expends.

In a study whose results were presented at the annual scientific meeting of the American Headache Society, we found that an academically-based headache sub-specialist spends an average of 28 hours per month performing "electronic tasks" related to the PA and appeal process. There is no direct financial compensation for the work done during those 28 hours. Instead of conducting research that might assist in raising the existing standard of care, doing clinical work that both benefits patients and generates revenue for the department or training the students, residents, fellows and junior faculty who eventually will replace us, senior faculty are spending the equivalent of at least 1/2 work-day per week on the keyboard, dancing to the tune chosen by the relevant insurer.

Some of those tunes involve some very sour notes. We have one insurer in the metropolitan DC area who requires that patients with chronic migraine (CM) fail three oral therapies - none of which possesses an FDA indication for treatment of CM and only one of which can be said to have any reasonable evidence base for treating CM – in order to receive BotoxA, a therapy which earned its FDA indication for treatment of chronic migraine 12 years ago and which possesses a solid evidence base for that indication.

Given this sad circumstance and evidence that the longer a patient remains "stuck" in chronic migraine the more difficult it may be to treat that patient successfully, this insurer is, in effect, asking providers to become complicit in practicing suboptimal medicine. Such inferior patient management borders on malpractice.

There's no question that in the short run there is money to be saved from requiring a client to treat his/her migraine with a less effective but cheaper alternative, but ethical issues aside, the long-term direct and indirect costs associated with inferior, suboptimal management of migraine - or of any medical disorder - may exceed what it would have cost simply to authorize the requested test or therapy in the first place. Don't kid yourself - any pious declarations issuing forth from representatives of the health insurance industry about the need to reduce unnecessary medical costs are largely a cover for their desire to improve the company's short-term bottom line.

And why should we expect otherwise? These are businesses… not charities. Businesses cannot thrive unless they earn money and will vanish if they fail to turn a profit. The same goes for the higher-level executives in those companies, whose investment in the company is limited to the short-term (i.e., the period of time they occupy their posts before moving on to another, more attractive position with another company).

Back to that "peer to peer" interview… Before it was approved for use in prevention/suppression of chronic migraine in 2010, I'd worked with BotoxA in headache research for the better part of a decade. Since 2010 I have treated thousands of chronic migraine patients with BotoxA. I have continued to do research involving BotoxA for the

treatment of chronic migraine and other headache disorders, and my colleagues and I specifically have demonstrated that the cost of BotoxA may be offset by the associated reduction in the use of healthcare resources such as the emergency room and urgent care centers. Finally, I have authored or co-authored roughly 20 BotoxA-related manuscripts published in the peer-reviewed medical literature, and I have lectured to audiences of providers in Europe, South America and across the U.S. on the topic of BotoxA and chronic migraine.

In a so-called "peer to peer" interview I am required to humbly request authorization to administer BotoxA from an individual who has never seen the relevant patient and who may have little or no direct clinical experience with BotoxA… let alone experience with research involving that treatment. I have found myself in that position many dozens of times, and I can assure you that it is a frustrating experience.

Very frustrating. *As it is meant to be.* What stake do insurers have in making the PA and appeals process simple or in any way efficient? Just the opposite, there is the implicit expectation that in many cases the patient, provider or both simply will give up…and you can be sure that they do. Quite often. *Who wins?* is reflected in the insurer's bottom line.

Rather than becoming frustrated and angry, and rather than treating patients at a level below what we believe they require and deserve, what are providers to do? Well, a provider could say: *if your insurer will not allow me to treat you as I believe you should be treated, I will not beg your insurer to allow me to practice good medicine. If you don't like my policy, you are free to find another provider.* If other providers followed suit, then perhaps patients might be motivated to do battle themselves with their insurers and stop expecting providers to compromise their professional integrity or, worse, blaming the provider for the denials and delays imposed by insurers.

That's great, but where does it leave the patient? It's hard enough to find providers with the knowledge, experience and inclination required to diagnose and treat headache effectively. If a high proportion of those providers opt out of the PA and appeal process, the quality of care for headache will suffer.

Who wins? is reflected in the insurer's bottom line.

This is no small matter. The president-elect of the American Medical Association considers the PA and appeal process to be the #1 problem existing in American healthcare delivery. By passively participating in this "dance with the devil", medical providers make unappealing compromises in the care they provide to their patients and, ironically, assist in the erosion of their own morale and professional quality of life.

It's high time this dance stopped. Again, what if providers refused to participate in any PA and appeals process which was based on financial considerations rather than evidence-based medicine and clinical outcome? Who would feel the pain if this dance ended? You, the patient, will. If your insurer will not allow your provider to manage you in a manner that he/she believes to be in your best interest, and if your provider therefore advises you that under the circumstances you will need to seek

It's high time this dance stopped.

care elsewhere, you may left out in the cold.

Who else will feel the pain? The pharmaceutical industry…whose dollars we so badly need to develop the new and revolutionary therapies that progressively raise the standard of care. If insurers refuse to authorize those therapies and providers consequently refuse to participate in an appeals process game that is rigged against them, the prescribing of those therapies necessarily will decrease.

It's time for this repulsive system to stop riding on the backs of medical providers. The system is broken, and it needs to be fixed. No fix will occur until patients unite with providers to say: *No more*. To the readership of this magazine: disabuse yourself of any notion that healthcare insurers are grinding down medical providers because it is somehow in your best interest. Join those providers who are awakening to the fact that reform is needed, and help in the effort to bring us to a better place.