BOTOX® onabotulinumtoxinA injection

Chronic Migraine

Telemedicine

Guide

Applying insights from AAN, AHS, and AMA to the BOTOX® conversation

Indication

Chronic Migraine

BOTOX® for injection is indicated for the prophylaxis of headaches in adult patients with Chronic Migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).

Limitations of Use

Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in 7 placebo-controlled studies.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening, and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat Cervical Dystonia and spasticity and at lower doses.

Please see additional Important Safety Information inside.

BOTOX® onabotulinumtoxinA injection

Considerations for a Virtual **BOTOX® Chronic Migraine** Conversation

An interactive guide to help you navigate your virtual BOTOX® appointments

Telemedicine has become increasingly relevant in Chronic Migraine patient care. Healthcare visits for your BOTOX® patients may be different now. Telemedicine provides an opportunity for you to assess treatment progress and to keep your BOTOX® patients informed in between their in-office procedures.

DOT EXAMPLE

Throughout this guide, you'll notice sample EMR language for you to consider using as "dot phrases" or "smart phrases." Use them to prompt text or data to then paste into your EMR system to quickly update patient notes, write visit summary reports, communicate with patients, or create discharge papers.

IMPORTANT SAFETY INFORMATION (continued)
CONTRAINDICATIONS
BOTOX® is contraindicated in the presence of infection at the proposed injection site(s) and in patients who are hypersensitive to any botulinum toxin product or to any of the components in the formulation.

Please see additional Important Safety Information on following pages.

Table of contents

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Spread of Toxin Effect
See Boxed Warning.

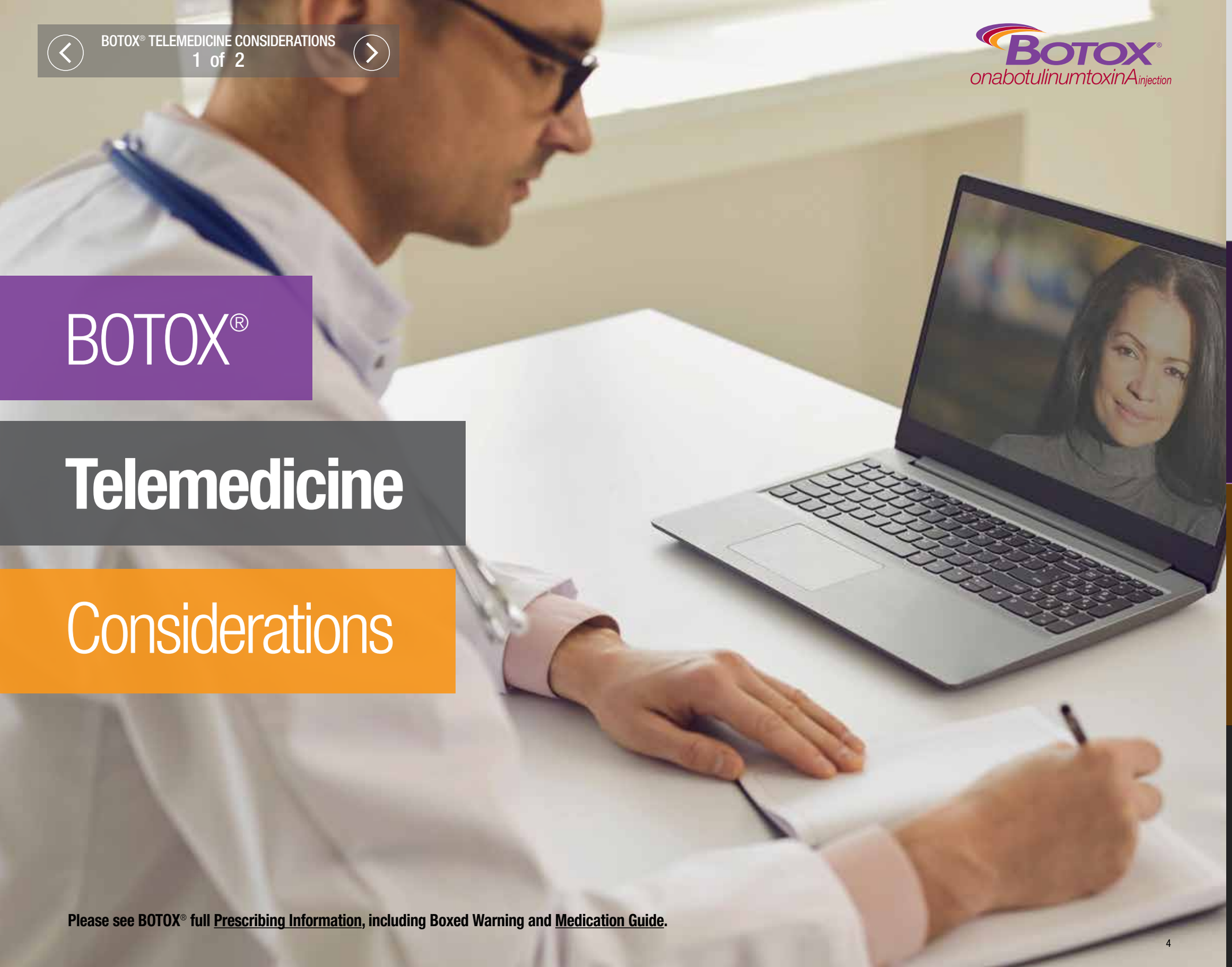
No definitive serious adverse event reports of distant spread of toxin effect associated with BOTOX® for Chronic Migraine at the labeled dose have been reported.

Lack of Interchangeability Between Botulinum Toxin Products
The potency Units of BOTOX® are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, Units of biological activity of BOTOX® cannot be compared to nor converted into Units of any other botulinum toxin products assessed with any other specific assay method.

Serious Adverse Reactions With Unapproved Use
Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX®. The safety and effectiveness of BOTOX® for unapproved uses have not been established.

Please see additional Important Safety Information on following pages.

BOTOX® onabotulinumtoxinA injection



BOTOX®

Telemedicine

Considerations

Please see BOTOX® full Prescribing Information, including Boxed Warning and Medication Guide.

BOTOX® onabotulinumtoxinA injection

Follow the **same clinical guidelines** you would with an in-person visit

BEFORE

- ☐ Contact the patient prior to scheduled appointment to:
  - Review patient history and progress on BOTOX® treatment
  - Determine what you want to ask the patient and which expectations you want to reinforce
  - Remind the patient to complete provider directive tasks
  - Clarify your practice's protocol for cancellations, schedule changes, or appointment delays
- ☐ If allowed by institution, consider emailing patient educational materials
  - Please see the Relevant Resources section for a list of some patient materials
  - Contact your Allergan® Account Specialist or visit BOTOXTodayCM.com to get electronic copies
- ☐ Have patients visit BOTOXChronicMigraine.com for more information

DURING

- ☐ Conduct a general assessment of the patient's previous injection progress
- ☐ Reinforce the importance of BOTOX® re-treatment
- ☐ Emphasize the use of a headache tracker to log headache/migraine days
- ☐ Check to see if the patient has their next BOTOX® treatment already scheduled

AFTER

- ☐ Document the visit in EMR
  - For questions and more information, please contact your Reimbursement Business Advisor (RBA)
- ☐ Instruct staff to follow up with the patient immediately after the telemedicine visit to:
  - See if the patient scheduled their next BOTOX® treatment
  - Encourage patients to check their eligibility for the BOTOX® Savings Program. Costs of both the product and procedure may be covered*,†
  - Check the patient's insurance to determine if the patient is still approved for treatment and have them submit additional documentation if needed
- ☐ Email or use the patient portal to send over any education materials you'd like the patient to review as appropriate
- ☐ Document the telemedicine appointment to align with payer policies

*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.

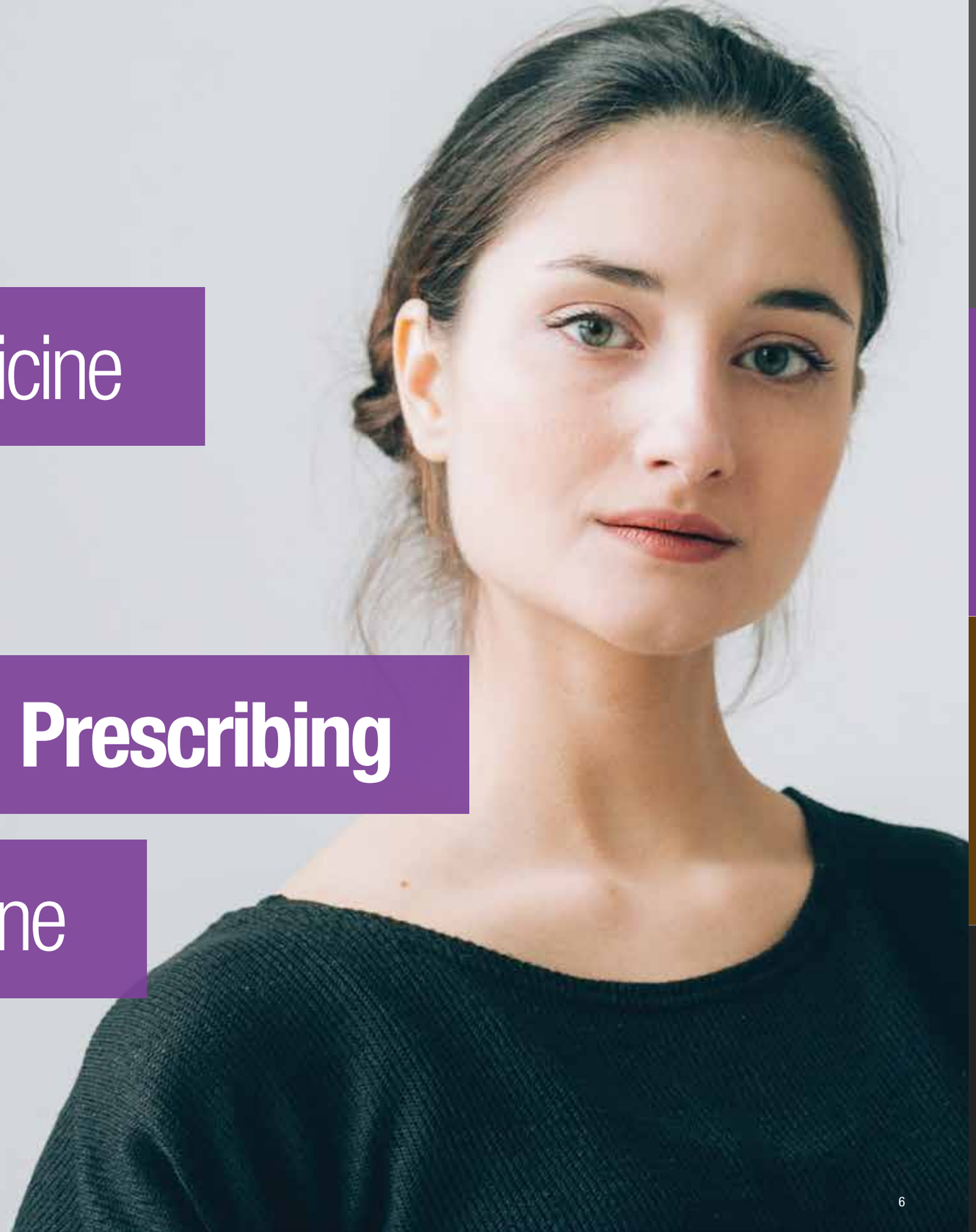
†For residents of Massachusetts and Rhode Island, offer applies only to the cost of BOTOX® and not to any related medical service(s).

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such a reaction occurs, further injection of BOTOX® should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent, and consequently the causal agent cannot be reliably determined.

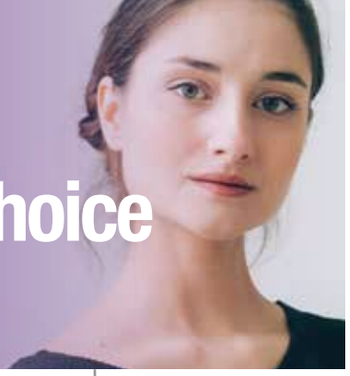
Please see additional Important Safety Information on following pages.



Example Telemedicine Appointment: **Diagnosing and Prescribing** for Chronic Migraine

Please see BOTOX® full Prescribing Information, including Boxed Warning and Medication Guide.

Patient discussion point: BOTOX® is a **first-choice treatment option** in Chronic Migraine



BOTOX® onabotulinumtoxinA injection

BEFORE

1. **REVIEW:** Go over patient medical history and determine the considerations for a balanced, comprehensive discussion about Chronic Migraine and BOTOX® treatment.
2. **PREPARE:** Gather the materials you want to share on screen and/or send via email/portal.
   - Please contact your Allergan® Account Specialist or download materials from BOTOXTodayCM.com
3. **DETERMINE:** Decide on an approach to assess the patient using open-ended questions to engage in dialogue.

DURING

1. **ASSESS:** Conduct a Chronic Migraine assessment:
   - Uncover headache frequency
   - Ask about "crystal clear" days to determine how many days each month patients have no headache/migraine whatsoever
   - Determine extent of disability
   - Identify migraine features
2. **EDUCATE:** Clearly communicate a diagnosis and educate patients on Chronic Migraine prevention, including available treatments such as BOTOX®.
   - Discuss efficacy and review possible side effects
   - Explain your personal experience with BOTOX®
   - Outline the specifics of the in-office procedure
   - Consider whether the patient is appropriate for BOTOX® and for a sample to evaluate efficacy and safety
3. **RECOMMEND:** Consider providing a clear BOTOX® recommendation and then set specific, realistic treatment goals.
   - State: "There is no cure for Chronic Migraine, but as we discussed, there are treatments that may reduce your number of headache days. Based on my personal experience, I think BOTOX® could be a good option for you. BOTOX® for Chronic Migraine injections are done in-office, every 12 weeks."
4. **REASSURE:** Address cost concerns by encouraging the patient to check their eligibility and enroll in the BOTOX® Savings Program before receiving their first BOTOX® treatment, as eligible, commercially insured patients may pay as little as $0 for BOTOX® treatment.

AFTER

1. **SEND:** Provide patient resources and encourage them to log headache/migraine days on their phone by texting TRACK to 50334.* Patients keep track of their headache/migraine days by texting to log them and, at the end of the month, receive a free customized report. This may help to inform future discussions and assessments with your patients.
2. **SCHEDULE:** Instruct staff to schedule the appropriate patient to receive a BOTOX® sample to evaluate efficacy and safety.
3. **DOCUMENT:** Record the visit in EMR similar to an in-person visit by adding visit reason, consent, and duration. For questions or more information, please contact your RBA.

DOT EXAMPLE

We have elected to proceed with BOTOX® injections for the prevention of Chronic Migraine. I recommend BOTOX® starting with 2 treatments, 12 weeks apart. Patient previously tried at least 2 oral preventive treatments as documented. Patient experiences XX (15 or more) headache days per month for at least the past 3 months. Of these, XX (at least 8) headaches have consistent migraine features. Headaches last XX (at least 4) hours or more per day.

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

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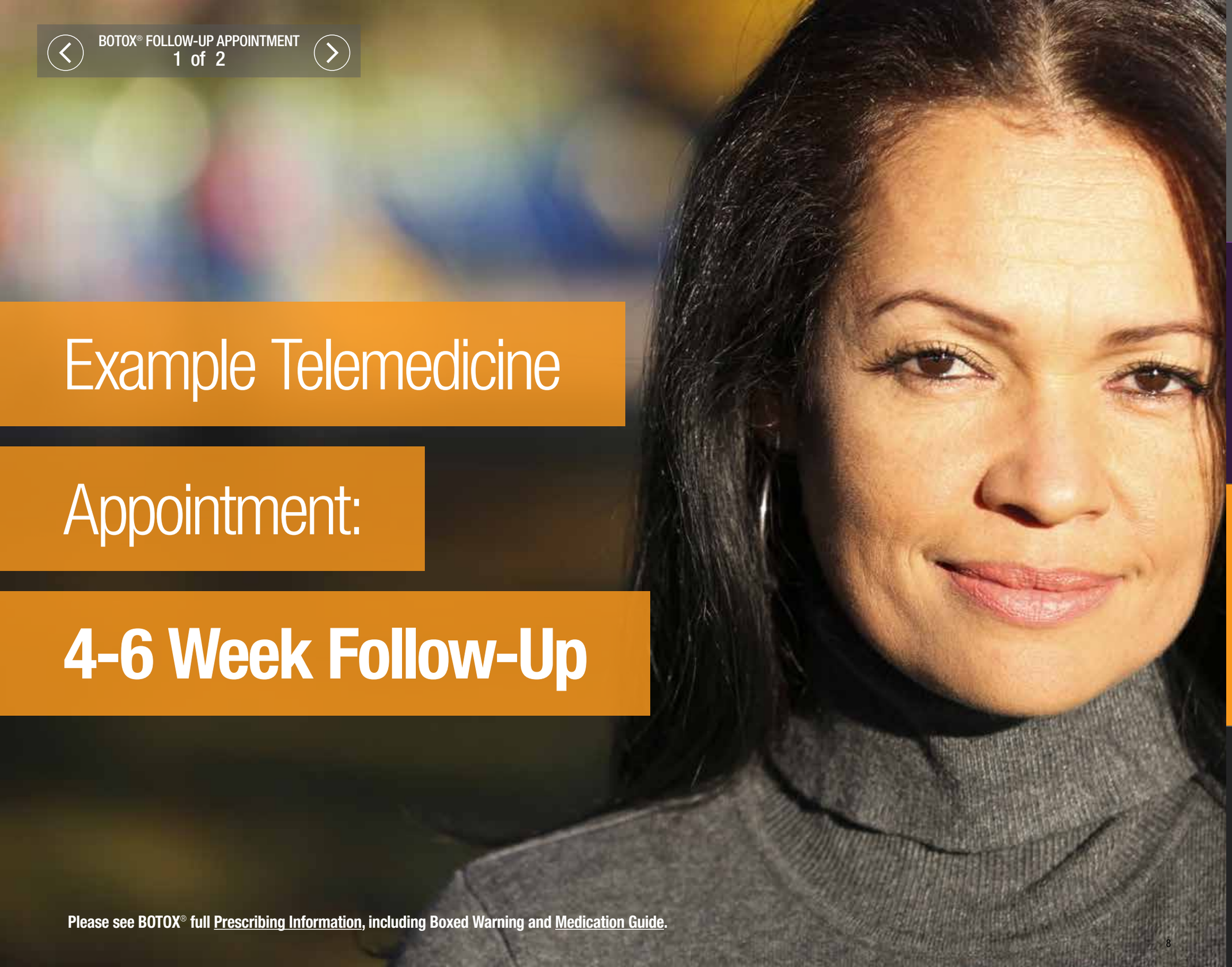
IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Increased Risk of Clinically Significant Effects With Pre-existing Neuromuscular Disorders
Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis (ALS), or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin.

Please see additional Important Safety Information on following pages.



Example Telemedicine Appointment:

4-6 Week Follow-Up

Patient discussion point: BOTOX® **retreatment is critical** to help patients stay on track

BOTOX® onabotulinumtoxinA injection

BEFORE

1. **REVIEW:** Determine what you want to ask the patient and review which expectations to reinforce, especially if it's after their first BOTOX® treatment.
2. **PREPARE:** Gather the approved and appropriate materials you want to share on screen and/or via email/portal.
   - Please contact your Allergan® Account Specialist or download materials from BOTOXTodayCM.com
3. **DETERMINE:** Decide on an approach to assess the patient using open-ended questions to engage in dialogue.

DURING

1. **ASSESS:** Evaluate the patient's response to BOTOX® treatment.
   - **Ask:** *"What has been your experience so far with BOTOX® treatment?"*
   - Probing for details can help you to better assess the patient's progress and help keep them on track with their overall treatment plan
2. **REMIND:** Revisit the patient's treatment expectations and discuss realistic outcomes.
   - Review what the patient said they hoped to achieve during previous conversations and where they are today
3. **EDUCATE:** Reinforce the importance of BOTOX® retreatment.
   - **State:** *"Chronic Migraine is a disease that often requires ongoing treatment. BOTOX® treatments need to be repeated every 12 weeks."*[1]
   - **Remind** patients that response to treatment could take time
4. **REASSURE:** Address procedure concerns and share any safety precautions you have taken for in-office visits.

AFTER

1. **SCHEDULE:** Check with staff if the patient has scheduled their next BOTOX® treatment within 12 weeks of their last. If not, have them get something on the books.
2. **VERIFY:** Instruct office staff to check the patient's insurance to determine if the patient is still approved for treatment and submit additional documentation if needed.
3. **DOCUMENT:** Record the visit in EMR similar to an in-person visit by adding visit reason, consent, and duration. For questions or more information, please contact your RBA.

DOT EXAMPLE

During virtual appointment, treatment progress with BOTOX® for Chronic Migraine was assessed. Will continue to monitor for adverse reactions accordingly.

Relevant Resources

Helpful telemedicine resources

BOTOX® onabotulinumtoxinA injection

Helpful links

The following third-party links are provided by Allergan, an AbbVie company, as a courtesy and do not constitute an endorsement of the products or services offered by these websites. Allergan® is not responsible for the content of any of these third-party websites.

- Centers for Medicare & Medicaid Services (CMS): Telemedicine Information
- American Medical Association (AMA): AMA Quick Guide to Telemedicine in Practice
- American Academy of Neurology (AAN): Telemedicine and Remote Care

Questions about BOTOX® prior authorizations, reimbursement, or operational matters?

Your Allergan® Reimbursement Business Advisor is available upon request for these matters.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Dysphagia and Breathing Difficulties

Treatment with BOTOX® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Please see additional Important Safety Information on following pages.

Relevant BOTOX® patient resources

BOTOX® onabotulinumtoxinA injection

Resources to provide patients BEFORE appointment

1. BOTOX® Patient Brochure*
2. BOTOX® Patient Videos

Resources to discuss with patients DURING appointment

3. Physician/Patient Flip chart
4. Chronic Migraine Preventive Treatments Guide

Resources to provide patients AFTER appointment

5. Setting Expectations Brochure*
6. BOTOX® Savings Program Patient Brochure

1.

2.

3.

4.

5.

6.

*Also available in Spanish.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Human Albumin and Transmission of Viral Diseases

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

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For more information and resources, visit **BOTOXTodayCM.com**

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IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

Adverse reactions to BOTOX® for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

Chronic Migraine

The most frequently reported adverse reactions following injection of BOTOX® for Chronic Migraine include neck pain (9%), headache (5%), eyelid ptosis (4%), migraine (4%), muscular weakness (4%), musculoskeletal stiffness (4%), bronchitis (3%), injection-site pain (3%), musculoskeletal pain (3%), myalgia (3%), facial paresis (2%), hypertension (2%), and muscle spasms (2%).

Postmarketing Experience

Adverse reactions that have been identified during postapproval use of BOTOX® are discussed in greater detail in Postmarketing Experience (Section 6.3 of the Prescribing Information).

There have been spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility or anaphylaxis, after treatment with botulinum toxin. There have also been reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including cardiovascular disease. The exact relationship of these events to the botulinum toxin injection has not been established.

DRUG INTERACTIONS

Co-administration of BOTOX® and other agents interfering with neuromuscular transmission (eg, aminoglycosides, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX® may potentiate systemic anticholinergic effects. The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX®.

Please see BOTOX® full Prescribing Information including Boxed Warning and Medication Guide.

Reference: 1. BOTOX® Prescribing Information, February 2021.

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MIND Migraine: Innovation Navigation Discovery ™