



Considerations guide

Telemedicine with existing BOTOX[®] OAB* patients

Overview

Telemedicine—either via video or phone—is playing an increasingly important role in OAB patient care. If you plan to use telemedicine, this guide offers some ideas and information to consider during your visits with appropriate BOTOX[®] OAB patients. It includes:

- How telemedicine can help with BOTOX[®] OAB patient care
- Things for your practice staff to do for BOTOX[®] telemedicine visits
- Sample flow for telemedicine visits with existing BOTOX[®] patients

How telemedicine can help BOTOX[®] patient care

While telemedicine does not replace in-person care, it can help both patient and providers in appropriate situations:



Can offer flexible and convenient options for the management of patients with chronic conditions, such as OAB



Allows BOTOX[®] patients who live far from the practice to visit with provider remotely for follow-ups



Allows for BOTOX[®] follow-up and maintenance to extend beyond the physician (eg, NP/PA)



May help reduce missed or canceled appointments for BOTOX[®] patients

*Overactive bladder.

Indication

Overactive Bladder

BOTOX[®] for injection is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

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 on following pages.

Things to do for BOTOX[®] telemedicine visits

Contact



Identify your BOTOX[®] patient list and reach out to let them know you offer telemedicine services

- Find current patients using EMR, as well as those who haven't returned for BOTOX[®] treatment
- Check on their current status with BOTOX[®] and see if they would like to have a telemedicine visit with their provider

Prepare



Contact BOTOX[®] patients prior to their scheduled appointment to:

- Perform medication reconciliation
- Review/update past medical/surgical history
- Remind patients to complete provider directive tasks (eg, dietary modifications and voiding diary)

Provide



Send patients educational materials either before or after the visit

- If allowed by institution, consider emailing patient educational materials
 - Most BOTOX[®] patient education materials are available to email as a PDF
 - Contact your Allergan[®] representative or visit UrologyEssentials.com to get electronic copies
- Have patients visit BOTOXforOAB.com for more information

Follow-up



Schedule a follow-up with patients immediately after the telemedicine visit

- Book an in-person or telemedicine visit as determined by the provider
- Check to see when patients are scheduled for their next BOTOX[®] treatment. If there is no re-treatment on the books, work with the provider to determine an appropriate course of action (eg, when the patient should be scheduled)
- Keep a list of BOTOX[®] OAB patients who have had a telemedicine visit and consider scheduling them for future in-person consultations

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.

BOTOX[®] is contraindicated for intradetrusor injection in patients with a urinary tract infection; or in patients with urinary retention or post-void residual (PVR) urine volume > 200 mL who are not routinely performing clean intermittent self-catheterization (CIC).

WARNINGS AND PRECAUTIONS

Spread of Toxin Effect

See Boxed Warning.

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.

Sample telemedicine follow-up for an existing BOTOX® patient

Before visit

- 1 Review patient history, prior clinical data, and status on BOTOX® treatment.
 - Consider date of last injection, timing of return of symptoms, and any barriers in the past (eg, positive urine culture)
- 2 Determine what you want to ask the patient and the concepts you wish to reinforce, especially if they have recently undergone their first BOTOX® treatment



During visit

- 1 Assess how the patient is responding to BOTOX® treatment.
 - In addition to reduction in daily leakage episodes, ask the patient about frequency and the impact on quality of life
- 2 Revisit the patient's expectations for treatment and discuss realistic outcomes.
 - Ask: "How do you feel you are doing after receiving BOTOX®? Is it what you expected?"
 - Review what the patient said they hoped to achieve during previous visits and where they are today
- 3 Reinforce the importance of BOTOX® re-treatment.
 - Remind them: "OAB is a chronic condition that often requires ongoing treatment. BOTOX® treatments may be repeated about every 6 months"^{1,2,*}
- 4 Check to see if the patient has their next BOTOX® treatment already scheduled.
 - If not, recommend that they schedule their next treatment after this visit to keep them on a regular interval



After visit

- 1 Document the visit in EMR.
 - Similar to an in-person visit, add visit reason, telemedicine consent, duration, and location conducted
- 2 Check with the office staff to see if the patient scheduled their next BOTOX® treatment at about 6 months.^{2,*}
 - If not, have them contact the patient to get something on the books
- 3 Have the office staff check the patient's insurance to determine if the patient is still approved for treatment and have them submit additional documentation if needed.

*Patients should be considered for reinjection when the clinical effect of the previous injection has diminished (median time until patients qualified for the second treatment of BOTOX® in double-blind, placebo-controlled clinical studies was 169 days [~ 6 months]), but no sooner than 12 weeks from the prior bladder injection.²

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.

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. Patients with known or unrecognized neuromuscular disorders or neuromuscular junction disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from therapeutic doses of BOTOX® (see *Warnings and Precautions*).

Please see additional Important Safety Information on following page.

Other resources

The following third-party links are provided by Allergan[®] 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.

[American Medical Association \(AMA\): Quick Guide to Telemedicine in Practice](#)

[American Urological Association \(AUA\): Telemedicine](#)

[Centers for Medicare & Medicaid Services \(CMS\): COVID-19 Partner Toolkit](#)

[US Department of Health and Human Services: FAQs on Telehealth and HIPAA](#)

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*).

Urinary Tract Infections in Patients With Overactive Bladder

BOTOX[®] increases the incidence of urinary tract infection. Clinical trials for overactive bladder excluded patients with more than 2 UTIs in the past 6 months and those taking antibiotics chronically due to recurrent UTIs. Use of BOTOX[®] for the treatment of overactive bladder in such patients and in patients with multiple recurrent UTIs during treatment should only be considered when the benefit is likely to outweigh the potential risk.

Urinary Retention in Patients Treated for Bladder Dysfunction

Due to the risk of urinary retention, treat only patients who are willing and able to initiate catheterization post treatment, if required, for urinary retention.

In patients who are not catheterizing, post-void residual (PVR) urine volume should be assessed within 2 weeks post treatment and periodically as medically appropriate up to 12 weeks, particularly in patients with multiple sclerosis or diabetes mellitus. Depending on patient symptoms, institute catheterization if PVR urine volume exceeds 200 mL and continue until PVR falls below 200 mL. Instruct patients to contact their physician if they experience difficulty in voiding as catheterization may be required.

Overactive Bladder

In clinical trials, 6.5% of patients (36/552) initiated clean intermittent catheterization for urinary retention following treatment with BOTOX[®] 100 Units as compared to 0.4% of patients (2/542) treated with placebo. The median duration of catheterization for patients treated with BOTOX[®] 100 Units was 63 days (minimum 1 day to maximum 214 days) as compared to a median duration of 11 days (minimum 3 days to maximum 18 days) for patients receiving placebo.

Patients with diabetes mellitus treated with BOTOX[®] were more likely to develop urinary retention than nondiabetics. In clinical trials, 12.3% of patients (10/81) with diabetes developed urinary retention following treatment with BOTOX[®] 100 Units vs 0% of patients (0/69) treated with placebo. In patients without diabetes, 6.3% of patients (33/526) developed urinary retention following treatment with BOTOX[®] 100 Units vs 0.6% of patients (3/516) treated with placebo.

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.

ADVERSE REACTIONS

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

Overactive Bladder

The most frequently reported adverse reactions for overactive bladder occurring within 12 weeks of injection include urinary tract infection (BOTOX[®] 18%, placebo 6%), dysuria (BOTOX[®] 9%, placebo 7%), urinary retention (BOTOX[®] 6%, placebo 0%), bacteriuria (BOTOX[®] 4%, placebo 2%), and residual urine volume (BOTOX[®] 3%, placebo 0%).

A higher incidence of urinary tract infection was observed in patients with diabetes mellitus treated with BOTOX[®] 100 Units and placebo than nondiabetics.

The incidence of UTI increased in patients who experienced a maximum post-void residual (PVR) urine volume \geq 200 mL following BOTOX[®] injection compared to those with a maximum PVR < 200 mL following BOTOX[®] injection, 44% vs 23%, respectively.

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](#).

References 1. Gormley EA, Lightner DJ, Burgio KL, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline. American Urological Association Education and Research, Inc.; April 2019. 2. BOTOX[®] Prescribing Information, October 2019.