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.

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.

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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**

   - 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.”
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.
   - 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.
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.

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

ADVERSE REACTIONS
Adverse reactions to BOTOX® for injection are depicted 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%).

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).

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