

EMR template and postprocedure notes

Sample autopopulated text to create a BOTOX[®] injection procedure report

Information gathered from market research. These considerations are for reference only and should be tailored to the unique needs of your practice.

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.

Considerations for using a BOTOX[®] procedure notes template

| EMR Field | Examples of Commonly Used Autopopulated Text* |
|--|---|
| BOTOX[®] Patient Information | [INSERT PATIENT INFORMATION] |
| History | A [INSERT AGE]-year-old [INSERT SEX] presented with urge urinary incontinence. [HE/SHE] was diagnosed with Overactive Bladder and was subsequently [INSERT NOTES RE ANTICHOLINERGIC MEDICATION USE, eg, “unable to achieve symptom control with an anticholinergic medication”]. The patient was scheduled for treatment with onabotulinumtoxinA. |
| BOTOX[®] Intraservice | [INSERT BOTOX[®] INTRASERVICE NOTES (should include description of all work associated with the BOTOX[®] procedure)] |
| Pre-procedure | Prophylactic antibiotics (excluding aminoglycosides) were administered 1 to 3 days pretreatment, on the treatment day, and continued 1 to 3 days post treatment to reduce the likelihood of procedure-related UTI. |
| Anesthesia | Today’s urinalysis showed the patient negative for infection. After informed consent was obtained, the patient was placed in the supine position. Uro-Jet[®] (Lidocaine Jelly)— <i>Uro-Jet[®]</i> was instilled using sterile technique into the urethra without difficulty. Bladder instillation —A 14 Fr red Robinson catheter was inserted into the bladder via the urethra. A bladder instillation consisting of 50 mL lidocaine 1% and 10 mL sodium bicarb 8.4% was instilled into the bladder. The bladder was then drained and irrigated with sterile saline before injection. |

*Information in this procedure report is provided for example purposes only. Your patients may be different.

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).

Please see additional Important Safety Information on following pages.

Considerations for using a BOTOX[®] procedure notes template (continued)

| EMR Field | Examples of Commonly Used Autopopulated Text* |
|---|---|
| BOTOX[®] Intraservice (continued) | [INSERT BOTOX[®] INTRASERVICE NOTES] |
| Cysto-hydrodistention | Lower urinary tract was examined. |
| BOTOX [®] 100 Units | <p>52287, J0585</p> <p>OnabotulinumtoxinA (BOTOX[®]) 100 Units was mixed gently and carefully into 10 mL of preservative-free 0.9% Sodium Chloride Injection, USP, for sterile injection into the bladder. The mixture was gently handled to ensure no breakdown of active agent within the mix. TIME ELEMENT OF 15 MINUTES.</p> <p>Procedure: The patient was re-prepped and draped. The injection needle was filled (primed) with approximately 1 mL of reconstituted BOTOX[®] prior to the injection to remove any air. A rigid cystoscope was gently inserted into the urinary bladder via the urethra. The trigone was identified and evaluated. Next, we identified 20 template injection sites within the urinary bladder. The bladder was only distended to 100-mL volume to ensure adequate muscle wall thickness to prevent needle penetration beyond the muscle wall. The bladder was instilled with enough saline to achieve adequate visualization for the injections. Careful injections were undertaken for a total of 20 injections using a [INSERT TYPE OF CYSTOSCOPE NEEDLE USED]. 0.5-mL volume was delivered at each site carefully into the muscle without excessive bleb formation submucosally. The needle was inserted approximately 2 mm into the detrusor. Injections were spaced approximately 1 cm apart. Targeted zones were injected over TIME ELEMENT OF 10 MINUTES.</p> |

*Information in this procedure report is provided for example purposes only. Your patients may be different.

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information on following pages.

Considerations for using a BOTOX[®] procedure notes template (continued)

| EMR Field | Examples of Commonly Used Autopopulated Text* |
|--|--|
| BOTOX[®] Post Service | [INSERT BOTOX[®] POSTSERVICE NOTES] |
| Postservic notes | <p>[INSERT A DESCRIPTION of the onabotulinumtoxinA administration procedure for this patient during the postservice period, including a description of all services provided on the day of the BOTOX[®] procedure prior to discharge from the office/clinic and office visits related to the service occurring within 10 days after the procedure, as in the following example.]</p> <p>The procedure was [INSERT DESCRIPTOR] tolerated without complications. Antibiotic instructions were given. Instructions were given to call the office immediately for bloody urine, difficulty urinating, urinary retention, painful or frequent urination, fever, chills, nausea, vomiting, or other illness. The patient stated that [HE/SHE] understood these instructions and would comply with them.</p> |
| BOTOX [®] patient assessment | <p>The patient remained in the treatment room for [INSERT ELAPSED TIME – MINIMUM OF 30 MINUTES] following the BOTOX[®] procedure for observation. The nurse conducted a brief examination of the patient and inquired whether the patient was experiencing any side effects from the BOTOX[®] injection and ensured that the patient was able to void. The physician returned to check on the patient and ordered the patient’s discharge with follow-up immediately by telephone should the patient experience any side effects, or via emergency room for any serious adverse reactions. A follow-up visit to assess the effect of treatment was scheduled for [INSERT TIME FRAME] days.</p> |

*Information in this procedure report is provided for example purposes only. Your patients may be different.

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

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.

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*).

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.

Please see additional Important Safety Information on following page.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Urinary Retention in Patients Treated for Bladder Dysfunction (continued)

Overactive Bladder (continued)

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](#).