

NATIONAL SPASMODIC DYSPHONIA ASSOCIATION

Guidelines for Insurance Approval and the Appeal Process in the Treatment of Spasmodic Dysphonia with Botulinum Toxin Injections



Published by

National Spasmodic Dysphonia Association

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Understanding the Process

Navigating the insurance approval and appeal process can be daunting, but with the right tools it is possible to obtain coverage of treatment.

The National Spasmodic Dysphonia Association has prepared this packet to assist with insurance approvals and appeals for the treatment of Spasmodic Dysphonia with botulinum toxin type A (Botox[®]).

Currently, Botox[®] is FDA approved to treat blepharospasm and cervical dystonia. It is used “off-label” in the treatment of Spasmodic Dysphonia. Off-label use is the practice of prescribing drugs for a purpose outside the scope of the drug's official indications. Once a drug has been approved for use for one purpose, in this case blepharospasm and cervical dystonia, physicians are free to prescribe it for any other purpose that in their professional judgment is both safe and effective. They are not limited to its official, FDA-approved indications.

This type of off-label prescribing is most commonly done with older medications that have found new uses but have not had the formal applications and studies required by the FDA to formally approve the drug for these new indications. However, there is usually extensive medical literature to support the off-label use.

The use of botulinum toxin for the treatment of Spasmodic Dysphonia is currently the treatment of choice for management of this neurological voice disorder. Over the past 20 years, botulinum toxin has been used to treat both adductor and abductor forms of the disorder, with vocal improvement noted after treatment for both. A large number of studies have documented the efficacy of botulinum toxin for improvement of vocal symptoms in individuals with Spasmodic Dysphonia.

Letter of Medical Necessity

Health insurance companies may not readily cover the use of botulinum toxin injections as a treatment for Spasmodic Dysphonia, since it is not FDA approved for this indication. They may claim the treatment is an experimental procedure and falls outside the treatment guidelines as outlined in the insurance policy.

Documentation of medical necessity may be necessary before the carrier will pay for these treatments. Included is a sample letter that a physician can adapt for his/her own use when providing documentation for a patient's need for botulinum toxin injections. With as much detail as possible, the letter should explain how this treatment would relieve the physical effects of the disorder.

Some suggestions include:

- Cite past successes with this treatment.
- Cite recent medical articles.
- Include letters from consultants.
- Review previous and failed treatments. For example, “It has been the only treatment that has been able to control my symptoms. Botox treatment is considered to be the standard of care and a first-line treatment for Spasmodic Dysphonia.
- Address the insurance’s suggested treatments.
- Be specific about psychological factors that are relevant to your chosen treatment.
- Provide information you have which a distant administrator may not know. Include that your diagnosis was confirmed by other neurologists, otolaryngologists, and/or Speech-Language-Pathologists. Include his/her name and address.

Also explain how this treatment will assist in maintaining the person’s functional capacity. Some suggestions include:

- Include letters from speech therapists.
- Cite conversations with family members.
- Discuss how it is essential in order to enable you to perform your job.

It is useful to include policy statements from professional organizations such as the American Academy of Otolaryngology.

Requesting Reimbursement and Appealing a Denied Claim

Three basic requirements must be met before any payer will accept and pay a claim for medical services:

- Services must be medically necessary as documented through coding or by materials submitted from the patient's record.
- Billing must comply with the payer's standards, rules, and regulations.
- Claim forms must be properly completed.

If one or more of these requirements is not fully met, the payer will typically identify the specific reason(s) for the claim denial, either in the denial letter itself, on the Explanation of Medical Benefits (EOMB) or on the Medicare Summary Notice (MSN) form.

The five most common reasons for denial or underpayment are:

1. Incomplete or missing information on the claim form
 2. Incorrect or inappropriate use of an ICD-9 diagnosis, CPT procedure code, or HCPCS code for BOTOX[®] treatment
 3. Incorrect or inappropriate use of modifiers
 4. Failure to observe the payer's exact requirements for coverage
 5. Failure to correctly specify the amount of drug used
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If this is the reason for the denial, be sure to check with your physician’s office. They should be able to re-submit a correct claim.

If you find that your health insurance carrier will not cover the type of treatment your doctor recommends for Spasmodic Dysphonia, question and appeal the organization’s decision. Spasmodic Dysphonia is a neurological condition that can have a significant impact on one’s functioning, employability, and quality of life. With this in mind, ask your insurance company’s decision-makers to reconsider.

Here are some general guidelines to follow as you work toward reimbursement for your medical treatment.

Call your insurance company. There’s usually a toll-free or “800” number you can use. You will most likely end up speaking with a customer service representative, but don’t be afraid to ask for his or her manager.

REMEMBER TO ...

-  Maintain good records
-  Write down names and contacts
-  Log on to Reimbursement website
-  Include the AAO Position Paper

Keep good records. Make a note of the dates and times you speak with customer service representatives. Write down their names and the information they give you. Keep any written correspondence regarding your treatment for Spasmodic Dysphonia and reimbursement in a file.

Submit your request in writing. Write a letter to your insurance company and include copies of receipts for treatments not reimbursed, medical test results, and statements from your physician. Always include your full name, address, and insurance policy or health plan number on all letters, e-mails, or faxes.

Appeal. If you’ve submitted a request for coverage and have been denied, write a letter appealing the decision. Following an “appeals process” is useful if your request is denied, so ask what this process requires. Appeals can take time but are a good way to get in contact with decision-makers.

If you receive your health insurance through your job, talk to your human resources (HR) or benefits manager. They may be able to help. Keep your HR department informed and give them copies of all correspondence with the insurance company.

Ask someone from your physician’s office to talk (or write) to the insurance company. A healthcare professional with an understanding of your condition and situation can explain why a particular treatment is effective and how it may affect other aspects of your health. Facilitate this process by providing a sample letter of medical necessity to your physician (see Section 3). Many practices have a billing specialist who is familiar with this process and would be able to assist.

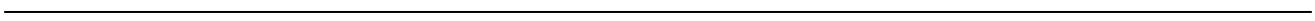
Conduct research. Do other insurance companies cover the desired treatment? If so, mention them during your dealings with your own company. Most managed care companies follow the Medicare guidelines.

Follow up. Because it’s easy for letters and calls to get lost in piles of other paperwork, contact your insurance company often. Make sure your requests are being attended to and find out when you may expect a response. Be assertive, but polite. It is important to be persistent.

If your request has been rejected, keep trying. At some insurance companies, a customer’s third request gets forwarded to a person with more responsibility and decision-making power.

As a last resort, you can contact your state's insurance commission. Many states have an insurance commission, an organization that oversees the sale and implementation of insurance, including health insurance. Your state insurance commission may be a resource for helping you with insurance coverage problems. That is, you may be required to go through the appeals process before going to the state's commission.

The NSDA has no connection or affiliation with any health insurance organizations. We do not endorse or have any influence over the organizations' policies regarding Spasmodic Dysphonia. This information is provided as a courtesy.



Botox Advantage[®] Reimbursement Program

For reimbursement support, call 800-530-6680 or log on to www.botoxreimbursement.us

As Botox[®] is an effective form of treatment of many forms of Spasmodic Dysphonia, insurance reimbursement should not stand in the way of treatment.

Allergan, the manufacturer of Botox[®] (Botulinum Toxin Type A), sponsors a comprehensive reimbursement program for patients and providers called the Botox Advantage[®] Reimbursement Program. The Botox Advantage[®] Reimbursement Program includes the Botox Advantage[®] Reimbursement Hotline and the Patient Assistance Program (PAP).

The Patient Assistance Program (PAP) is available for patients with special financial needs who are either uninsured or underinsured and/or patients who do not qualify for alternative sources of reimbursement. Verification of qualification and enrollment in PAP are additional services available through the Botox Advantage[®] Reimbursement Hotline.

The Botox Advantage[®] Reimbursement Hotline will:

- Assist with insurance verification including checking the coverage status for Botox[®] treatment, check Medical & Pharmacy benefits including co-pay and deductible (if applicable).
- Research prior authorization requirements for specific payers, assist in submitting all the appropriate paperwork and follow the case until a decision is made.
- Work directly with your physician to obtain Botox[®] reimbursement and appeal any denied claims or underpaid claims;
- Research alternate sources of reimbursement for Botox[®] if you lack insurance or cannot afford your payment responsibility;
- Help your physician determine your eligibility for the Botox[®] Patient Assistance Program if you have no Botox[®] coverage.

When calling the Hotline and inquiring about your situation, be prepared to provide the details of your insurance, including your name, address, phone number, birth date and social security number and the insurance company's name, address, phone, and policy identification numbers. In addition, you will be asked for your physician's name, phone number, and information about your Botox[®] treatment, including diagnosis/diagnosis code.

Resources and References

Provided in this section are useful resources including sample letters, position papers, and an explanation of Spasmodic Dysphonia.

Sample Letter of Medical Necessity: Prior to treatment with Botox®

On Physician letterhead

Date

Payer name and address

Re: *insert patient's name*

Date of Birth: *insert patient's date of birth*

Policy ID/Group Number: *insert patient's policy ID/group number*

Policy Holder: *insert name of patient's policy holder*

Dear *insert name of payer*:

I am writing on behalf of [*patient name*] to document the medical necessity of [*insert treatment option here*] for the treatment of Spasmodic Dysphonia [*insert primary and secondary ICD-9 codes*]. This letter provides information about the patient's medical history and diagnosis and a statement summarizing my treatment rationale.

Spasmodic Dysphonia is a neurological voice disorder that can have a devastating effect on a patient's quality of life, causing physical discomfort, social embarrassment, and disruption of occupational and daily activities. This has certainly been true for [*patient name*], who has endured the symptoms of Spasmodic Dysphonia for [*insert duration of symptoms here*].

Specifically, [*he or she*] has had difficulties with [*insert quality-of-life and job problems here*].

[Discuss patient's diagnosis, treatment history, and degree of illness]

More conservative therapies have not controlled [*patient name*]'s symptoms. The use of Botox® in this manner is well-documented in literature including the enclosed position paper by the American Academy of Otolaryngology as the only treatment that has been able to effectively control patients' symptoms.

In light of this clinical information, and this patient's condition, [*insert treatment option here*] is medically necessary and warrants coverage. Please contact me at [(000) 000-0000] if you require additional information.

Sincerely,

[Physician's name]

Sample Letter of Medical Necessity: Post-treatment with Botox®

On Physician letterhead

Date

Payer name and address

Re: *insert patient's name*

Date of Birth: *insert patient's date of birth*

Policy ID/Group Number: *insert patient's policy ID/group number*

Policy Holder: *insert name of patient's policy holder*

Dear *[insert name of payer]*:

On *[insert date]*, I examined *[insert patient's name]* and determined a diagnosis of *[insert name of condition(s) and primary and secondary ICD-9 codes.]* Specifically, the results of my examination were *[include details such as physical exam results and clinical impressions.]*

Spasmodic Dysphonia is a neurological voice disorder which can have a devastating effect on a patient's quality of life, causing physical discomfort, social embarrassment, and disruption of occupational and daily activities. This has certainly been true for *[patient name]*, who has endured the symptoms of Spasmodic Dysphonia for *[insert duration of symptoms here]*.

This patient was initially treated by *[describe treatment and supply procedure codes]* but this did not result in significant improvement. I then treated *[insert patient's surname]* by *[describe procedure and supply procedure code]* with Botox® (Botulinum Toxin Type A) Purified Neurotoxin Complex, billing code J0585 for *[insert "right," "left," or "both" side(s) for insert name of diagnosis and corresponding ICD-9 code.]*

I have prescribed Botox® because *[provide explanation.]* This treatment was medically necessary because *[insert medical rationale.]*

This patient's response to the initial dose of Botox® has been *[indicate the status, if applicable]*. Based on this outcome, I plan to treat *[insert patient's name and indicate the planned course of treatment and duration]*. My clinical expectations for this treatment are *[indicate expectations]*. Follow-up is expected to involve *[include expected additional evaluations and treatments]*.

The use of Botox® in this manner is well documented in literature including the position paper by the American Academy of Otolaryngology. A copy of the paper is enclosed for your review.

This treatment will assist *[insert patient's name]* to (or: is crucial for person X to) achieve and maintain maximum functional capacity by restoring the ability to speak and perform daily activities. Please contact me at *[(000) 000-0000]* if you require additional information.

Sincerely,
[Physician's name]

Sample Letter of Medical Necessity: From the Patient to the Insurance Carrier

Patient's Name
Address

Date

Medical Director
Insurance Company
Address

Re: Authorization for Botulinum Toxin Type A treatment for Spasmodic Dysphonia for patient X (health insurance certification number)

Dear *[insert name of payer]*:

I am writing to request prompt approval and expedition of the authorization for treatment of my neurological voice disorder, Spasmodic Dysphonia, with injections of Botulinum toxin. The diagnosis and procedure codes are as follows: *[insert procedure codes]*: I have been treated since *[insert year]*: by *[insert name of doctor]*: for Spasmodic Dysphonia, Adductor Type (AD/SD) with Botulinum toxin injections.

For your information, I was first diagnosed with Spasmodic Dysphonia *[insert year]*: years ago by *[insert name of doctor]*: Several other physicians have confirmed my diagnosis of Spasmodic Dysphonia. Among them are: *[insert name of doctor]*: (neurologist/movement disorder specialist), *[insert name of doctor]*: (otolaryngologist) and *[insert name of healthcare professional]*, (Speech-Language-Pathologist).

I have found that Botulinum toxin injections have made it possible for me to function at work and in my home life, relieving the significant strain and breaking in my voice. It has been the only treatment that has been able to control my symptoms. I hope that you can work to expedite authorization and approve my treatment as soon as possible as my symptoms are returning and it is becoming very difficult for me to function and communicate with *[insert type of person you work with]*:

Thank you for your time and consideration. I trust that you now have all the information necessary to expedite this request.

Sincerely,
[Patient's name]

POLICY STATEMENT

American Academy of Otolaryngology Head and Neck Surgery

Section I. Treatment of Spasmodic Dysphonia

The American Academy of Otolaryngology-Head and Neck Surgery, Inc. ("AAO-HNS") considers Botulinum toxin (Botox®) a safe and effective modality of treatment for Spasmodic Dysphonia (laryngeal dystonia) and it may be offered as primary therapy for this disorder.

Section II. Botox® Treatment for Other Head And Neck Dystonia

A. Blepharospasm

The AAO-HNS considers Botox® a safe and effective modality for the treatment of blepharospasm and it may be offered as a primary form of therapy. Botox® has been approved as a safe and effective treatment of blepharospasm by the FDA.

B. Cervical Dystonia (Spasmodic Torticollis)

The AAO-HNS considers Botox® a safe and effective modality for the treatment of cervical dystonia. There is some controversy as to whether Botox® or pharmacotherapy should be offered as primary therapy. The benefit from Botox® outweighs that of pharmacotherapy in many cases, certainly for the treatment of rotational cervical dystonia, or cervical dystonia associated with severe pain. In cases where there is inadequate response with pharmacotherapy, or there are intervening side effects, treatment with Botox® may be offered.

C. Orolinguomandibular Dystonia

1. The AAO-HNS states that local injections of Botox® into the masseter and temporalis muscles for jaw-closing, and external (lateral) pterygoid and digastric muscles for jaw-opening dystonia is established as a safe and effective modality for managing this disorder.

2. Considering the difficulty of the procedure in treating complicated jaw deviations and jaw opening, this form of treatment is limited to patients who have failed more conservative therapies. However, the benefit has been dramatic for some in this select group. Use of Botox® for jaw-opening and deviation dystonia, injecting toxin into the external pterygoid and digastric muscles is promising, but additional experience is needed.

3. Lingual dystonia may be effectively treated with Botox®, but there is a significant risk of dysphagia. Botox® therapy is investigational for this indication.

D. Hemifacial Spasm (HFS) and/or Synkinesis

The AAO-HNS considers local injections of Botox® into facial muscles a safe and effective modality in treating hemifacial spasm and/or synkinesis. This modality of therapy may be offered as primary therapy in managing the condition.

E. The AAO-HNS considers local injections of Botox® into laryngeal muscles a safe and effective modality in treating neurogenic laryngeal stridor. This modality of therapy may be offered as primary therapy in managing the condition.

F. Botox® can be applied to patients for treatment of Frye Syndrome.

G. Botox® can be applied to patients for facial cosmetic indications.

Important Notice: The American Academy of Otolaryngology-Head and Neck Surgery, Inc. and Foundation (AAO-HNS/F) Policy Statements are guidelines only. In no sense do they represent a standard of care. The applicability of an indicator for a procedure, and/or of the process or outcome criteria, must be determined by the responsible physician in light of all the circumstances presented by the individual patient. Adherence to these guidelines will not ensure successful treatment in every situation. The AAO-HNS emphasizes that these policies should not be deemed inclusive of all proper treatment decisions or methods of care, nor exclusive of other treatment decisions or methods of care reasonably directed to obtaining the same results. Guidelines are not a substitute for the experience and judgment of a physician and are developed to enhance the physicians' ability to practice evidence-based medicine.

Understanding Spasmodic Dysphonia

Definition: Spasmodic Dysphonia (SD), a focal form of dystonia, is a neurological voice disorder that involves involuntary “spasms” of the muscles in the vocal cords causing interruptions of speech and affecting the voice quality. SD causes the voice to break up while the person is speaking and sometimes the voice will also have a tight, strained, or strangled quality. It can also be termed as “laryngeal dystonia” as it is a form of dystonia.

Symptoms: Spasmodic Dysphonia causes a person’s voice to break during vowel sounds. Some persons with adductor SD also have a harsh strangled voice while others with abductor SD sound breathy and have voice breaks on certain consonants. The voice breaks can make the person sound like they are upset. The control problems of the vocal cords result in different speech symptoms in the two types of disorder - *adductor SD* and *abductor SD*. Symptoms vary during the day, become aggravated by certain speaking situations, such as talking on the phone, or increase during stressful situations. It usually is not painful, but exerted efforts to vocalize can leave one feeling exhausted. Voice samples of SD appear on the NSDA Web site (www.dysphonia.org) and also on the DVD called “Understanding Spasmodic Dysphonia.”

Causes: The cause of Spasmodic Dysphonia is unknown. Dystonias are generally characterized by excessive contraction of muscles with associated abnormal movements and postures possibly due to abnormalities in the basal ganglia – the area of the brain that helps coordinate movements of the muscles throughout the body. While anecdotal evidence may suggest that symptom onset follows illnesses such as viral infection, bronchitis or surgery, or following a stressful event, such as job stress, death of a loved one, or divorce, it has not been scientifically proven and has not been wholly agreed upon by the medical community.

Prevalence: Spasmodic Dysphonia is estimated to affect more than 50,000 people in North America, but this number may be higher due to ongoing misdiagnosis or undiagnosed cases of the disorder. Spasmodic Dysphonia is one of thirty movement disorders – chronic and debilitating neurological conditions that affect more than 40 million Americans – nearly one in seven people – twice the number of people living with diabetes and four times the number of those surviving cancer.

Treatment: Local injections of botulinum toxin, such as Botox® (Botulinum toxin type A), into the vocal cord muscles have proven to be the most effective treatment for persons with adductor SD. The treatment relaxes the vocal muscles so that spasms are greatly diminished and speech is improved. The treatment can also reduce the harsh strangled quality and help decrease the effort required to speak. Speech therapy and other treatments (e.g., breathing/relaxation exercises) may also help in some persons. No medications are helpful in everyone. Surgery is an option if other treatments are unsuccessful.

Age of Onset: Although it can start any time during a life, Spasmodic Dysphonia seems to begin frequently in the 40- to 50-year-old group and more often in women than men. Recent evidence is showing that symptoms may begin earlier in persons with a family history of dystonia.

Diagnosis: An interdisciplinary team of professionals evaluate and provide accurate differential diagnosis. This team usually includes a *speech-language pathologist* who evaluates voice production and voice quality; a *neurologist* who carefully searches for other signs of dystonia or other neurological conditions; and an *otolaryngologist* (or Ear, Nose and Throat (ENT)) who examines the vocal cords and their movements.

Misdiagnoses: SD is often misdiagnosed as laryngitis, anxiety/psychological issues, acid reflux, or other disorders. The majority of patients go undiagnosed or misdiagnosed for years, some as many as ten years or more. However, some patients with other voice disorders can be misdiagnosed as spasmodic dysphonia.

Changes in symptoms: It is not common for symptoms of Spasmodic Dysphonia to disappear but there are occasions when the symptoms will fluctuate. People with Spasmodic Dysphonia often try to improve their speech by changing the tenor or pitch of the voice or find effective way to modulate their voice to get around the spasms. Typically, Spasmodic Dysphonia affects only the speaking voice so laughing, crying, and shouting are normal. In some persons singing can be less affected than speaking.

This fact sheet was reviewed by Christy Ludlow, Ph.D., Medical Chairperson, National Spasmodic Dysphonia Association, Chief, Laryngeal and Speech Section, Medical Neurology Branch, National Institute on Neurological Disorders and Stroke (NINDS), National Institutes of Health



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