BASTIAN VOICE INSTITUTE
for voice, swallowing & airway disorders

Dear Sir or Madam:

Thank you for the opportunity to provide public comment on the proposed changes to the coverage of botulinum neurotoxin (BoNT) injections. I am a laryngologist with a lifetime caseload of an estimated 1,400 persons with spasmodic dysphonia (SD) caused by laryngeal dystonia. I continue to treat nearly 100 patients per month for this condition. In addition, I serve as medical director for Dysphonia International (formerly the National Spasmodic Dysphonia Association).

I oppose the proposed changes as they will effectively remove access to treatment for a significant subset of my patients.

Some background: Spasmodic dysphonia is a neurological voice condition that diminishes voice/speech intelligibility in both personal life and the workplace. It also markedly increases the effort required to communicate to the point of exhaustion. Untreated patients may lose their jobs, and the negative social impact is major.

There are two primary variants (adductory SD (~90%) and abductory SD (~10%)). For the former, the voice cuts out, squeezes down so that syllables or words are lost. For the latter, the voice abruptly drops out to a whisper, again losing syllables or words.

Within the entire population, variable features necessitate *individualization*. For example, there is also variation of severity, presence or absence of tremor, dose needed, target muscles, and, crucially, *the rate at which their bodies "metabolize" the botulinum toxin*. The dose for one patient may easily be 10 times that used for another, based in individual sensitivity/dose requirement. While the average duration of benefit might be 14 to 16 weeks, there are a fortunate few who can obtain very good results for 20 weeks. And there are *the unfortunate few who metabolize so quickly that they are injected as often as every 8 weeks*. Furthermore, patients occasionally choose a partial dose because of an upcoming event (reunion, speech, work presentation) and they know that the next injection will be needed sooner than usual.

The problem with the proposed guidelines: The proposed guidelines limit drastically flexibility available to both physician and patient, in providing quality care. Two big examples: they effectively remove access from a subset of

patients who are rapid metabolizers… and from time to time, a patient who needs an earlier injection than usual would be denied access, too. And so, with your guidelines as many as 10 or 20% of patients will spend part of each year treated *untreated, and suffering*.

This is not to mention that the muscle mentioned in your proposed guidelines for the initial injection is only appropriate for the ~10% of patients who have the AB-ductory variant. The muscles that are injected for the ~90% of patients with AD-ductory spasmodic dysphonia are not mentioned anywhere in the guidelines.

Consider actual patient scenarios…

1. A first-grade teacher with adductory SD receives botulinum toxin injections that allow her to continue her profession. Her longstanding pattern, however, is as follows: The voice is breathy but functional for a couple of weeks; voice is very much improved for 5 weeks. And then spasms return with a vengeance, beginning just 7 weeks after the injection. Despite taking this patient to the maximum dose she can tolerate (due to initial breathiness side effect), her spasms routinely return nearly completely after only 8 or 9 weeks. Accordingly, for the six years since her diagnosis, she has been coming for re-treatment every 8 weeks. This patient would spend 3 months a year suffering with her disorder essentially untreated, making teaching extremely difficult to impossible during those months, while she waits for the final four of the 12-week stipulation to pass.
2. A young woman with SD is to be married. As the date approaches, she realizes that spasms will be noticeable for the festivities. She comes per her routine at 14 weeks, but since the wedding is only 2 weeks away, she requests a half-dose, so that she will go directly to good voice and skip the usual initial breathiness side effect. This works very well for the wedding, but just 7 weeks later she is, as expected, ready for another injection. She is forced to wait 5 weeks with a terrible voice until the 12-week requirement is met.
3. A patient has been receiving very successful injections every 16 weeks for 20 years. She has been extremely happy with the results. But after her most recent injection with her usual dose, she says she had very little breathiness and went straight to the “golden period” of voice. (Targeting is a challenge, and despite a good EMG signal, the placement must have been suboptimal. This happens every 20 injections or so, even when done by skilled and experienced physicians.) But now, at ten weeks, spasms are very evident and she has an important Zoom call that she must lead with international customers of her business. She is distraught when learning she cannot have another injection until after the crucial sales event.

4. A longstanding patient, treated successfully for 25 years, has moved to another state. She received an injection there just 3 weeks ago, but nothing happened. She got no benefit at all. She has returned to the area to visit her sister and requests an injection, since her spasms are fully back. She learns that she cannot have another injection and must suffer vocally for another 9 weeks, waiting for the full 12-week interval to elapse, even though there was no response to the out-of-state injection.

This proposal, if finalized, will devastate patients who fall into one of the scenarios above. Imagine being told "you can't wear your glasses for the next month," or "Sorry, you must take your hearing aids out for the next five weeks," or "Sorry, you can't use your wheelchair (or cane, or insulin or blood pressure medicine) for the next few weeks." This proposed change would leave a subset of people with SD sidelined socially and vocationally purely due to refusing them medically necessary care.

And so, I respectfully request that you reject these proposed changes. Quality patient care requires the freedom to *individualize for patient benefit*. The proposed guidelines will significantly limit the physician-patient decision making process and reduce access to care for the community of patients with SD. Thank you again for this opportunity to comment.

Sincerely,

Robert W. Bastian, MD

BASTIAN VOICE INSTITUTE
3010 Highland Parkway – Suite. 550
Downers Grove, IL 60515