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July 8, 2024

Part A Policy

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Palmetto GBA

**RE: Botulinum Toxin Injections [DL39836]**

To Whom It May Concern,

The American Academy of Neurology (AAN) is the world's largest association of neurologists and neuroscience professionals, with over 40,000 members. The AAN's mission is to enhance member career fulfillment and promote brain health for all. A neurologist is a doctor with specialized training in diagnosing, treating and managing disorders of the brain and nervous system. These neurological conditions affect over one in three people worldwide and include Alzheimer's disease, stroke, concussion, epilepsy, Parkinson's disease, multiple sclerosis, headache, migraine, and more.

The AAN is grateful for the opportunity to provide comments in response to this draft local coverage determination (LCD), entitled "Botulinum Toxin Injections." The AAN recognizes that this proposed LCD was released in coordination with several other Medicare Administrative Contractors (MACs) with the aim of providing consistent coverage policy related to the provision of these services. The AAN appreciates the time and effort needed to coordinate these policies and urges all MACs to undertake similar efforts when developing new coverage policies to minimize the administrative burden associated with delivering neurologic care that may span across state lines. The AAN believes these proposed policies represent several important strides to improve patient care, but also believes that further refinement is necessary to promote patient access to care and to minimize undue documentation burdens. The AAN's key concerns with the proposed coverage policy are detailed below and have been submitted to all of the MACs who issued this updated policy.

**Coverage Indications, Limitations, and/or Medical Necessity**

**General Indications and Limitations of Coverage**

The AAN is deeply concerned that in addition to the proposed draft LCDs, the MACs have issued supplementary draft local coverage articles (LCAs) that, in practice, may substantially impact access to care through the

exclusion of a large number of codes, across a variety of indications, that are commonly used when providing botulinum toxin injections. It is inappropriate for LCAs to substantively change the effect of an LCD, and the AAN is concerned that instead of clarifying policy contained in the LCD, these LCAs serve to substantively change policy contained in the proposed LCDs in a manner that harms beneficiary access. The AAN strongly urges all of the MACs to review and update the list of codes included in the proposed LCAs to ensure that access to care is not negatively impacted. In particular, the AAN believes it is critical to ensure that CPT code 76942 is included in the guidance to allow for ultrasound guided procedures.

This draft LCD proposes that botulinum toxin injections are not considered reasonable and necessary for patients with existing medical conditions which could affect neuromuscular function. Although the AAN recognizes and supports the need to ensure a patient's safety when receiving botulinum toxin, we believe that this determination should be based on a clinical decision between the patient and the provider. Just as a clinician is responsible for considering all drug-drug interactions and adverse drug effects with respect to a patient's medical illnesses, this role should continue to fall to the clinician who administers botulinum toxin, rather than being determined by the MAC. Further, botulinum toxin may sometimes be warranted in this circumstance. For instance, ocular myasthenia gravis is a neuromuscular junction disorder. Providers have used botulinum toxin very successfully to help disabled migraine patients regain the ability to engage in activities of daily living, including going back to work and caring for their families.

Further, the LCD proposes that injections are not considered reasonable and necessary for patients with severe clotting disorders. The AAN believes that the presence of a severe clotting disorder should be considered in the context of the patient's overall condition with a discussion of potential risks and benefits between the provider and patient. Not all clotting disorders preclude botulinum toxin in clinical practice.

### **Specific Indications and Limitations of Coverage by Diagnosis**

#### *Blepharospasm*

The proposed LCD states that initial injection of botulinum toxin for blepharospasm will be considered reasonable and necessary when several criteria are met. These criteria include "(m)oderate to severe chronic blepharospasm measured on objective clinical scale."<sup>1</sup> The AAN notes that while objective scales may be used by subspecialists, most clinicians (particularly general neurologists) do not use these scales. With an appropriate history and physical examination, it is commonly self-evident if the treatment is effective. Adding required scales will add paperwork, slow workflow, increase administrative burden, and increase the risk the patient could be denied treatment due to missed documentation. Further,

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<sup>1</sup> Local Coverage Determination for Botulinum Toxins, Centers for Medicare & Medicaid Services (proposed May, 30, 2024) <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39856&ver=3&keyword=botulinum%20toxin&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>.

due to the impact of additional administrative burden, clinicians may be less likely to offer a needed procedure, decreasing beneficiary access to high-quality neurologic care.

Continuing, the coverage requirements note that the “objective assessment must be performed and documented at baseline, after each diagnostic procedure, and at each follow-up assessment using the same scale during each assessment.”<sup>2</sup> The AAN agrees that evaluation of the success or failure of a treatment is necessary. However, placing an indefinite expectation of treatment re-evaluation during every visit will create unintended consequences. For instance, if a patient has been successfully treated and is stable on a treatment for years, and now they are seen for a recent stroke, the focus of the visit should be the stroke and not the documentation of the botulinum toxin provided a few weeks prior. As per the proposed changes, there is no flexibility to address the fact that patients will see their clinician for many different reasons over time and care should be focused on their immediate needs. Botulinum toxin injections often take several days to take effect, and as such, clinicians should use their judgment to determine when to perform a re-evaluation.

The proposed coverage policy also includes dosing guidelines for blepharospasm, noting that the “initial treatment with onabotulinumtoxinA dosing for blepharospasm associated with dystonia is 1.25 units-2.5 units into each of three sites per affected eye.”<sup>3</sup> The AAN is concerned that for many patients this will be inadequate, noting that for blepharospasm the initial starting dose is commonly higher, 20-25 units per side.<sup>4</sup> The subsequent dosing guidelines state that “doses may be increased up to two-fold if the initial response is insufficient. However, injecting more than 5 units per eye provides little additional benefit.”<sup>5</sup> Many patients will need dose increases after their initial dose, with up to 35% needing two or more dose increases.<sup>6</sup> It is not uncommon for blepharospasm patients to require up to 90 units in total.<sup>7</sup> Some blepharospasm patients need much higher doses, up to 165-340 units, for adequate treatment.<sup>8</sup>

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<sup>2</sup> Id.

<sup>3</sup> Id.

<sup>4</sup>Hassell TJW, Charles D. Treatment of Blepharospasm and Oromandibular Dystonia with Botulinum Toxins. *Toxins (Basel)*. 2020 Apr 22;12(4):269. doi: 10.3390/toxins12040269; Duarte GS, Rodrigues FB, Marques RE, Castelão M, Ferreira J, Sampaio C, Moore AP, Costa J. Botulinum toxin type A therapy for blepharospasm. *Cochrane Database Syst Rev*. 2020 Nov 19;11(11):CD004900. doi: 10.1002/14651858.CD004900.pub3.

<sup>5</sup> Local Coverage Determination for Botulinum Toxins, Centers for Medicare & Medicaid Services (proposed May, 30, 2024) <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39856&ver=3&keyword=botulinum%20toxin&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>.

<sup>6</sup> Ortisi E, Henderson HW, Bunce C, Xing W, Collin JR. Blepharospasm and hemifacial spasm: a protocol for titration of botulinum toxin dose to the individual patient and for the management of refractory cases. *Eye (Lond)*. 2006 Aug;20(8):916-22. doi: 10.1038/sj.eye.6702054. Epub 2006 Mar 10.

<sup>7</sup> Kent R, Robertson A, Quiñones Aguilar S, Tzoulis C, Maltman J. Real-World Dosing of OnabotulinumtoxinA and IncobotulinumtoxinA for Cervical Dystonia and Blepharospasm: Results from TRUDOSE and TRUDOSE II. *Toxins (Basel)*. 2021 Jul 14;13(7):488. doi: 10.3390/toxins13070488.

<sup>8</sup> Levy RL, Berman D, Parikh M, Miller NR. Supramaximal doses of botulinum toxin for refractory blepharospasm. *Ophthalmology*. 2006 Sep;113(9):1665-8. doi: 10.1016/j.ophtha.2006.03.055. Epub 2006 Jul 7. PMID: 16828511; Dashtipour K, Chen JJ, Frei K, Nahab F, Tagliati M. Systematic Literature Review of AbobotulinumtoxinA in Clinical Trials for Blepharospasm and Hemifacial Spasm. *Tremor Other Hyperkinet Mov (N Y)*. 2015 Oct 30;5:338. doi: 10.7916/D8CJ8CVR; Ortisi E, Henderson HW, Bunce C, Xing W, Collin JR. Blepharospasm and hemifacial spasm: a protocol for titration of botulinum toxin dose to

The AAN notes that the dosing guidelines contained in the LCD for blepharospasm associated with orofacial dystonia are not overly prescriptive and encourages the MACs to consider a similar approach for blepharospasm in general.

### *Blepharospasm Associated with Orofacial Dystonia*

The proposed LCD states that, among other requirements, botulinum toxin injections for blepharospasm associated with orofacial dystonia will be considered reasonable and necessary with “moderate to severe chronic blepharospasm associated with orofacial dystonia measured on objective clinical scale.”<sup>9</sup> The LCD further states that “the objective assessment must be performed and documented at baseline, after each diagnostic procedure, and at each follow-up assessment using the same scale during each assessment.”<sup>10</sup>

As noted above, the AAN appreciates that the dosing guidelines contained in this section are not overly prescriptive but maintains our above stated concern that while objective scales may be used by subspecialists, most clinicians (particularly general neurologists) do not use these scales. Additionally, we again have concerns associated with requiring repeat assessments. The AAN agrees that evaluation of the success or failure of a treatment is necessary. However, placing an open-ended expectation of treatment re-evaluations during every encounter will create unintended consequences. The AAN urges the MACs to consider modifying requirements mandating use of an objective clinical scale and reassessment using that tool after every diagnostic procedure and at every follow up assessment.

### *Cervical Dystonia*

The proposed LCD states that, among other requirements, botulinum toxin injections for cervical dystonia will be considered reasonable and necessary with “moderate to severe cervical dystonia assessed by an objective scale.”<sup>11</sup> Further, the “objective assessment must be performed and documented at baseline, after each diagnostic procedure, and at each follow-up assessment using the same scale during each assessment.”<sup>12</sup>

The AAN wishes to reiterate our above stated concern that while objective scales may be used by subspecialists, most clinicians (particularly general neurologists) do not use these scales. Additionally, to reiterate the above, the AAN agrees that evaluation of the success or failure of a treatment is necessary. However, placing an indefinite expectation of treatment re-evaluation during every visit will create unintended consequences. The AAN urges the MACs to consider modifying requirements mandating use of an objective clinical scale and

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the individual patient and for the management of refractory cases. Eye (Lond). 2006 Aug;20(8):916-22. doi: 10.1038/sj.eye.6702054.

<sup>9</sup> Local Coverage Determination for Botulinum Toxins, Centers for Medicare & Medicaid Services (proposed May, 30, 2024) <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39856&ver=3&keyword=botulinum%20toxin&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>.

<sup>10</sup> Id.

<sup>11</sup> Id.

<sup>12</sup> Id.

reassessment using that tool after each diagnostic procedure and at each follow up assessment.

### *Chronic Migraine*

The proposed LCD requires that for chronic migraine the “objective assessment must be performed and documented at baseline, after each diagnostic procedure, and at each follow-up assessment using the same scale during each assessment.”<sup>13</sup> Again, the AAN agrees that evaluation of the success or failure of a treatment is necessary. However, placing an indefinite expectation of treatment re-evaluation during every visit will create unintended consequences. The AAN urges the MACs to consider modifying requirements mandating reassessment after each diagnostic procedure and at each follow up assessment.

Under the Indications for Coverage, the proposed LCD requires that the headaches be “moderate to severe in intensity with typical migraine headache characteristics.”<sup>14</sup> However, migraine attacks can occur with mild or no headache present, but with other incapacitating symptoms, such as dizziness, cognitive impairment, nausea or vomiting, aura, phonophobia, or photophobia. In this circumstance, a botulinum toxin injection could benefit the patient and lessen the symptoms. As such, the AAN recommends that the MACs characterize the migraine attack by both the presence and severity of the headache and accompanying symptoms.

Under Initial Botulinum Injections, the proposed LCD requires the beneficiary to have a trial of and inadequate response to a two-month trial of at least one agent in any two of the antidepressant, beta blocker, calcium channel blocker, or antiepileptic classes, or to have contraindication to any of these medications in the aforementioned classes. We emphasize that none of the agents listed are FDA-approved for chronic migraine. While onabotulinumtoxinA is FDA approved for chronic migraine, many agents within the calcitonin gene-related peptide (CGRP) class are also FDA-approved for chronic migraine but not listed within this proposal. According to the American Headache Society’s recent position statement, a trial of onabotulinumtoxinA could be an alternative to a trial of two classes of medications.<sup>15</sup> The AAN recommends the addition of the CGRP class and requests consideration to fail one agent instead of two agents.

For subsequent botulinum injections, the proposed LCD requires that the patient, among other requirements, have demonstrated  $\geq 50\%$  reduction in migraine headache days per month,  $\geq 50\%$  reduction in migraine headache episodes per month, and a reduction in headache-related disability and objective improvement in functioning. Typically, an initial injection and two subsequent botulinum toxin injections (*i.e.*, a nine-month course) are necessary to determine whether the treatment is effective. Additionally, this requirement

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<sup>13</sup> Id.

<sup>14</sup> Id.

<sup>15</sup> Charles, Andrew, et al., “Calcitonin Gene-related Peptide-targeting Therapies Are a First-line Option for the Prevention of Migraine: An American Headache Society Position Statement Update,” *Journal of Head and Face Pain*, (Mar. 11, 2024) <https://headachejournal.onlinelibrary.wiley.com/doi/full/10.1111/head.14692>.

would be difficult to operationalize if the provider is required to evaluate a patient and document effectiveness after the initial injection but before any subsequent injections.

According to the proposed LCD, when the provider deems it appropriate to assess whether the injections are effective, the provider will determine if the patient had either a  $\geq 50\%$  reduction in migraine headache days per month,  $\geq 50\%$  reduction in migraine headache episodes per month, or a reduction in headache-related disability and objective improvement in functioning. Requiring all three conditions to be present will potentially cause barriers for patients who benefit from the injections but do not experience all three benefits. We believe a lower threshold of reduced headache frequency over the course of three months is reasonable and allows the clinician to find the appropriate dose for a particular patient. The AAN encourages the MACs to revise the reasonable and necessary conditions for subsequent botulinum toxin injections to reflect the number of doses needed prior to evaluating effectiveness and the conditions providers use to determine effectiveness. Furthermore, we disagree that a  $\geq 50\%$  reduction in migraines is necessary to judge the success of the treatment due to the number of patients who benefit and have a higher quality of life, though may not achieve that level of effectiveness. However, we understand the need to affirm the treatment has demonstrated value and recommend this value be changed to  $\geq 30\%$  reduction in migraine headache days per month and  $\geq 30\%$  reduction in migraine episodes per month.

Further, the proposed LCD requires the provider to assess and implement biobehavioral therapy as appropriate for preventative headache treatment. The AAN is concerned that there are social factors that cause biobehavioral therapy to be unfeasible for or inaccessible to many patients and requiring biobehavioral therapy as a condition for subsequent injections will further exacerbate existing health disparities and health equity issues. The AAN urges the MACs to revise this requirement in the proposed LCD to ensure that a provider's evaluation and determination that biobehavioral therapy is not appropriate for a particular patient does not preclude the patient from receiving subsequent injections.

The proposed LCD defines chronic migraine as “a recurrent chronic headache disorder with two major types described as either episodic migraines or chronic migraines based on the frequency of the headaches.”<sup>16</sup> The AAN notes that migraine, not chronic migraine, is a recurrent headache disorder with two major types described as either episodic migraine or chronic migraine based on the frequency of the headaches. Neurologists typically consider chronic and episodic migraine to be different conditions based on the frequency of the headaches. Chronic migraine is a recurrent chronic headache disorder in which headaches occur on fifteen or more days per month for more than three months with at least eight days per month with symptoms consistent with migraine ICHD-3 diagnostic criteria. Episodic migraine is also a headache disorder, based partially on less frequent headaches. Episodic

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<sup>16</sup> Local Coverage Determination for Botulinum Toxins, Centers for Medicare & Medicaid Services (proposed May, 30, 2024) <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39856&ver=3&keyword=botulinum%20toxin&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>.

migraine is not a subtype of chronic migraine, although it may evolve to chronic migraine.<sup>17</sup> The AAN recommends revising the definition of chronic migraine to reflect this distinction.

Under Indications of Coverage for chronic migraine, the proposed LCD states, “the headaches are causing an objective significant functional disability.”<sup>18</sup> The AAN reiterates our above stated concern that while objective scales may be used by subspecialists, most clinicians (particularly general neurologists) do not use these scales. Additionally, to reiterate the above, the AAN agrees that evaluation of the success or failure of a treatment is necessary. The AAN urges the MACs to consider modifying requirements mandating use of an objective clinical scale and reassessment using that tool after each diagnostic procedure and at each follow up assessment.

The proposed LCD permits providers to use a CGRP agent and botulinum toxin for chronic migraine. The AAN is supportive of this update, but clarification is needed to ensure that patients will not be penalized if they receive a CGRP agent and have their headache profile improve, for example, from twenty-five headache days per month to fourteen headache days per month yet are still debilitated on those fourteen days. We encourage the MACs to provide additional language that will recognize patients may still have an underlying diagnosis of chronic migraine and allow patients who are still struggling—although less than previously—to have access to additional medications such as onabotulinumtoxinA.

Under Limitations of Coverage, the proposed LCD lists the conditions that botulinum toxin injections are not medically necessary as treatment, including chronic daily headaches. The AAN is supportive of this limitation. However, to ensure that chronic migraine is not considered exclusionary as a form of chronic headaches, the AAN recommends clarifying this limitation by specifying that botulinum toxin injections are not necessary for unspecified chronic daily headache.

As per the proposed LCD, botulinum toxin injections must not be given more frequently than every twelve weeks, regardless of diagnosis, unless specifically addressed in the policy. While we agree that twelve weeks is a reasonable period for many patients, we believe it is necessary to allow a request for duration change for patients who demonstrate on repeat visits the need for earlier dosing. Some patients find their treatments only lasts ten weeks. Universal application of a 12-week frequency limit can cause undue disability in migraine or spasticity, depending on the disease of concern. While we expect most patients would continue their twelve-week schedule, we recommend revising the proposed LCD to allow an opportunity to appeal the dosing schedule for patients who require more frequent dosing.

### *Focal Hand Dystonia*

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<sup>17</sup> Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. *Headache*. 2015 Mar;55 Suppl 2:103-22; quiz 123-6. doi: 10.1111/head.12505\_2. PMID: 25662743.

<sup>18</sup> Local Coverage Determination for Botulinum Toxins, Centers for Medicare & Medicaid Services (proposed May, 30, 2024) <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39856&ver=3&keyword=botulinum%20toxin&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>.

The proposed LCD states that, among other requirements, botulinum toxin injections for focal hand dystonia will be considered reasonable and necessary with “moderate to severe chronic focal hand dystonias measured on objective clinical scale.”<sup>19</sup> The LCD further states that “the objective assessment must be performed and documented at baseline, after each diagnostic procedure, and at each follow-up assessment using the same scale during each assessment.”<sup>20</sup>

The AAN wishes to reiterate our above stated concern that while objective scales may be used by subspecialists, most clinicians (particularly general neurologists) do not use these scales. Additionally, to reiterate the above, the AAN agrees that evaluation of the success or failure of a treatment is necessary. However, placing an indefinite expectation of treatment re-evaluation per every visit will create unintended consequences. The AAN urges the MACs to consider modifying requirements mandating use of an objective clinical scale and reassessment using that tool after each diagnostic procedure and at each follow up assessment.

### *Hemifacial Spasm/Facial Dystonia*

The proposed LCD states that, among other requirements, botulinum toxin injections for hemifacial spasm/facial dystonia will be considered reasonable and necessary with “moderate to severe primary or secondary hemifacial spasm measured on objective clinical scale.”<sup>21</sup> The LCD further states that “the objective assessment must be performed and documented at baseline, after each diagnostic procedure, and at each follow-up assessment using the same scale during each assessment.”<sup>22</sup>

The AAN wishes to reiterate our above stated concern that while objective scales may be used by subspecialists, most clinicians (particularly general neurologists) do not use these scales. Additionally, to reiterate the above, the AAN agrees that evaluation of the success or failure of a treatment is necessary. However, placing an indefinite expectation of treatment re-evaluation per every visit will create unintended consequences. The AAN urges the MACs to consider modifying requirements mandating use of an objective clinical scale and reassessment using that tool after each diagnostic procedure and at each follow up assessment.

While the AAN appreciates the inclusion of subsequent dosing guidelines noting that a gradual increase in the number of units after one year may be required, we note that some hemifacial spasm patients need higher doses (up to 90 units), and in one study some patients needed doses up to 140 units.<sup>23</sup> In addition, increasing the dose in patients who have only a

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<sup>19</sup> Id.

<sup>20</sup> Id.

<sup>21</sup> Id.

<sup>22</sup> Id.

<sup>23</sup> Dashtipour K, Chen JJ, Frei K, Nahab F, Tagliati M. Systematic Literature Review of AbobotulinumtoxinA in Clinical Trials for Blepharospasm and Hemifacial Spasm. *Tremor Other Hyperkinet Mov (N Y)*. 2015 Oct 30;5:338. doi: 10.7916/D8CJ8CVR; Costa J, Espírito-Santo C, Borges A, Ferreira JJ, Coelho M, Moore P, Sampaio C. Botulinum toxin type A therapy for hemifacial spasm. *Cochrane Database Syst Rev*. 2005 Jan 25;2005(1):CD004899. doi: 10.1002/14651858.CD004899.pub2. Update in: *Cochrane Database Syst Rev*. 2020



short duration of response can increase their interval of control and interval between needing re-treatment by 5-30 days per unit increase of dose.<sup>24</sup>

### *Upper and Lower Spasticity*

The proposed LCD requires that for upper and lower spasticity the “objective assessment must be performed and documented at baseline, after each diagnostic procedure, and at each follow-up assessment using the same scale during each assessment.”<sup>25</sup> Again, the AAN agrees that evaluation of the success or failure of a treatment is necessary. However, placing an indefinite expectation of treatment re-evaluation per every visit will create unintended consequences. The AAN urges the MACs to consider modifying requirements mandating reassessment after each diagnostic procedure and at each follow up assessment.

### **Conclusion**

The AAN greatly appreciates the opportunity to provide our input on this proposed coverage policy. Injection of botulinum toxin is considered the first line therapy for a variety of neurologic conditions, and the AAN believes it is critical that coverage policies allow neurologists to determine the most appropriate course of treatment for their patients, rather than having care limited by overly burdensome coverage requirements. The AAN appreciates the efforts taken to ensure consistency across the various LCDs but urges all Medicare Administrative Contractors to heed the AAN’s feedback to avoid undue restrictions on necessary neurologic care. The AAN appreciates that our guidelines are cited heavily throughout this draft coverage policy and stands ready to serve as a resource for the MACs in determining the most appropriate coverage policies associated with delivering this service. For any additional information or questions, please contact Matt Kerschner, the AAN’s Director, Regulatory Affairs and Policy, at [mkerschner@aan.com](mailto:mkerschner@aan.com) or Cale Coppage, the AAN’s Senior Government Relations Manager, at [ccoppage@aan.com](mailto:ccoppage@aan.com).

Sincerely,



Carlayne E. Jackson, MD, FAAN

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Nov 19;11:CD004899; Ortisi E, Henderson HW, Bunce C, Xing W, Collin JR. Blepharospasm and hemifacial spasm: a protocol for titration of botulinum toxin dose to the individual patient and for the management of refractory cases. *Eye (Lond)*. 2006 Aug;20(8):916-22. doi: 10.1038/sj.eye.6702054. Ortisi, E., Henderson, H., Bunce, C. et al. Blepharospasm and hemifacial spasm: a protocol for titration of botulinum toxin dose to the individual patient and for the management of refractory cases. *Eye* 20, 916–922 (2006). <https://doi.org/10.1038/sj.eye.6702054>

<sup>24</sup> Maneksha V, Chakrabarty S, Tanwar M, Pillai MR. Outcomes of a regional variant of botulinum toxin type A in the treatment of essential blepharospasm and hemifacial spasms: A retrospective study. *Indian J Ophthalmol*. 2021 Oct;69(10):2777-2781. doi: 10.4103/ij.o.IJO\_3656\_20.

<sup>25</sup> Local Coverage Determination for Botulinum Toxins, Centers for Medicare & Medicaid Services (proposed May, 30, 2024) <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39856&ver=3&keyword=botulinum%20toxin&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>.

President, American Academy of Neurology