



AMERICAN ACADEMY
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Re: Reconsideration Request for LCA A58423 - Botulinum Toxins

Dear Drs. Campos, Mann, McKinnon, & Sommers:

The American Academy of Ophthalmology (the Academy) is the largest association of eye physicians and surgeons in the United States. A nationwide community of nearly 20,000 medical doctors, we protect sight and empower lives by setting the standards for ophthalmic education and advocating for our patients and the public. The American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS) is the principle educational organization in oculoplastic surgery and oversees accreditation of over 60 fellowship programs in the United States and Canada with over 800 members. We innovate to advance our profession and to ensure the delivery of the highest quality eye care. We are writing to Novitas to propose an updated edition of *LCA A58423 - Botulinum Toxins*. Please find a version of *A58423* attached below, with recommended language changes highlighted in yellow.

As you review this proposed LCA, please note that the FDA label approving Onabotulinumtoxin A includes *recommended* muscle sites for the *initial* treatment, rather than a discrete list of muscles approved for

treatment of blepharospasm. There are no FDA-approved muscles or muscle areas for treatment of blepharospasm with Onabotulinumtoxin A. The FDA-approved labeling for Incobotulinumtoxin A injections for blepharospasm treatment also makes recommendations for injection sites; yet, makes clear that the number and location of injections should be based on the patient's response to treatment. It should also be noted that *L38809* itself cites literature establishing the therapeutic equivalency between Onabotulinumtoxin A, Incobotulinumtoxin A, thus it follows that either may be used in all recommended treatment sites for the management of blepharospasm at a physician's discretion.

We appreciate Novitas's consideration of these comments and would be happy to discuss this in more detail at your convenience. If you have questions or need any additional information regarding any portion of these comments, please contact AAO's Health Policy Director, Brandy Keys, MPH at bkeys@aa.org or via phone at 202-737-6662. We look forward to engaging on this important patient access issue.

Sincerely,



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