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Comments and Responses Regarding Draft Local Coverage Determination Botulinum Toxins Type A and Type B

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Botulinum Toxins Type A and Type B LCD. The official notice period for the final LCD begins on May 15, 2008, and the final determination will become effective on July 1, 2008.

Comment: A commenter supported the consistency of the policy with many other Medicare local coverage determinations (LCDs) in regards to coverage of the type A and type B toxins allowing the physician to determine which toxin to use for the individual patient. A bibliography with 151 listings regarding Botulinum toxins was provided.

Response: We appreciate the comment and receipt of the bibliography.

Comment: Two commenters registered concerns regarding the nearly equivalent coverage for the type A and B toxins. One suggested there be equivalent coverage for cervical dystonia and allowance of the type B toxin for other conditions for those who are not candidates for treatment with Botulinum type A. One applauded the draft policy language stating the two toxin preparations were not interchangeable. Submitted documentation included the *American Hospital Formulary System (AHFS)* and *DrugDex Drug Evaluations* information regarding on- and off-label uses for each toxin; the Cahaba Government Benefit Administrators, LLC "Botulinum Toxins" LCD (L24817); and references addressing the safety of the A toxin, trials comparing the A and B toxins, and papers describing the toxin side effects.

Response: The comments, submitted material, additional *DrugPoints* formulary information and other contractor LCDs were reviewed or re-reviewed. The following two statements were removed from the LCD:

- Botulinum toxin type B (Myobloc™) will be covered for the same indications as Botulinum toxin type A (Botox®) unless noted below.
- Physicians must make the decision as to which agent to use in beneficiary care.

The following statements were substituted:

- It is expected that physicians will be familiar with and experienced in the use of these agents and use evidence-based medicine to select the appropriate drug and dose regimen for each patient condition and use. Physicians may decide which agent to use in beneficiary care except as noted below.

Use of Botulinum toxin type B was already restricted in the draft policy to those patients who had demonstrated resistance to the type A toxin for primary focal hyperhidrosis. A similar restriction was clarified for patients with urinary incontinence due to neurogenic detrusor overactivity (NDO).

Comment: Allowance of coverage was requested for Dysport, containing Clostridium Botulinum type A toxin-haemagglutinin complex and currently used in Europe. Peer-reviewed literature was provided. Evidently, the FDA is reviewing approval for cervical dystonia.

Response: The United States Food and Drug Administration (FDA) has not yet approved this drug. Therefore, we cannot allow Medicare payment.

Comment: A commenter wrote concerning the allowance of Botulinum toxin for the treatment of headache. He noted most of the initial reports on Botulinum toxin in tension-type headache and in migraine were positive and that most of the open-label studies were positive. However, randomized, double-blind, placebo-controlled studies present contradictory results regarding efficacy. He thus felt that widespread use of Botulinum toxin therapy in headache could not currently be recommended.

Response: We agree that the recent literature regarding the use of Botulinum toxin in the treatment of headache has been more negative than positive. Therefore, the policy restricts the allowance to “those patients with intractable headaches (chronic daily headaches) who had significant disability due to the headaches, were refractory to standard and usual conventional therapy, and for whom Medicare has previously allowed coverage on a case-by-case basis. In addition, the patients must have demonstrated a significant decrease in the number and frequency of headaches and an improvement in function upon receiving Botulinum toxin.”

Comment: An attendee at an Open LCD Meeting asked for clarification regarding coverage for headache and whether coverage would be extended to myofascial pain syndrome.

Response: As stated above, only those patients with headache meeting all of the criteria in the policy, who have previously had Botulinum toxin approved on a case-by-case basis, and who have responded well, will be considered by coverage. It was also noted that the current literature does not support coverage of Botulinum toxin use for myofascial pain syndrome. The ICD-9-CM code, 729.1, was incorrectly placed in the draft LCD and has been removed in the final LCD.

Comment: Two individuals noted that the description of CPT code 64613 had been revised in 2006 and was now the appropriate code for Botulinum toxin laryngeal injections. The code description now reads, “Chemodenervation of muscles(s); neck muscles(s) (eg, for spasmodic torticollis, spasmodic dysphonia).”

Response: We appreciate the information and have changed the policy. The other procedure codes (31513, 31570, 31571, and 31599) listed for spasmodic dysphonia injections were deleted. The ICD-9-CM code 428.75 (Laryngeal spasm) was moved to procedure code 64613 as one supporting the medical necessity of the procedure.

Comment: It was noted that the Medicare Physician Fee Schedule Database bilateral indicator for CPT code 64613 had been changed to “1” which allows payment of 150% of the fee schedule for injections to each side of the neck.

Response: We agree and will remove “the neck” from the statement in the “Limitations” portion of the draft policy that stated the neck was one site. The statement now reads, “A site is defined as one eye (including all muscles surrounding the eye including both upper and lower lids); one side of the face; or all muscles of one limb and their associated girdle muscles.”

Comment: The CPT code 64653 [Chemodenervation of eccrine glands; other area(s) (eg, scalp, face, neck), per day] was included on the policy but the ICD-9-CM code for Frey’s syndrome was not listed as a diagnosis that supports medical necessity.

Response: Primary, but not secondary focal hyperhidrosis, was purposely listed as the ICD-9 code that supported medical necessity. The CPT code 64653 was included for treatment of palmar or plantar hyperhidrosis.

Comment: The CPT code 92265 (Needle oculoelectromyography, one or more extraocular muscles, one or both eyes, with interpretation and report) was not listed as a procedure that can be used for guidance of chemodenervation for strabismus.

Response: We have added the information to the Supplemental Instructions Article “General Guidelines for claims submitted to Carriers or Intermediaries.”

Comment: A commenter noted that the “Utilization Guidelines” contained dosage information for the A toxin but not the B.

Response: The information specific to the A toxin was removed.

Comment: A neurologist attending one of the Open LCD meetings voiced concern about the amount of Medicare reimbursement for treatment of patients requiring Botulinum toxins.

Response: The physician was directed to his specialty society and its representation on the Relative Value Update Committee.