State of California—Health and Human Services Agency
Department of Health Care Services

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Director

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N.L.: 01-0510
Index: Benefits
(Supercedes N.L.: 07-0407)

TO: ALL COUNTY CALIFORNIA CHILDREN SERVICES (CCS) PROGRAM ADMINISTRATORS, MEDICAL CONSULTANTS, STATE CHILDREN'S MEDICAL SERVICES (CMS) STAFF, REGIONAL OFFICE STAFF, INDEPENDENT COUNTY CHIEF/SUPERVISING THERAPISTS, DEPENDENT COUNTY LEAD THERAPISTS, AND MEDICAL THERAPY UNIT STAFF

SUBJECT: BOTULINUM TOXIN

I. PURPOSE

The purpose of this revised numbered letter is to update N.L.: 07-0407 which transferred responsibility for review and authorization of Botulinum Toxin requests from the State CMS Branch Office to CCS County and CMS Branch Regional offices, and provided guidance on authorizing Botulinum Toxin requests for CCS County and Regional Offices. N.L.: 07-0407 is revised to include information concerning the addition of a second Botulinum Toxin Type A product, which is a Medi-Cal benefit effective June 1, 2010.

II. BACKGROUND

N.L.: 09-0899 provided policy guidance on new medical treatment modalities which required authorization by the CMS Branch Office. Botulinum Toxin was included in N.L.: 09-0899 as one of these new medical treatment modalities/interventions. The current widespread use of Botulinum Toxin in children and adolescents makes continued control authorization unwieldy. This numbered letter provides policy and policy implementation for the authorization of Botulinum Toxin by CCS County and CMS Branch Regional Offices.

Botulinum Toxin is a neurotoxin produced by the bacteria *Clostridium botulinum* that inhibits the release of acetylcholine at the neuromuscular junction thus producing temporary focal or localized paralysis and alleviating overactive neural activity in target organs (e.g., muscle or sweat gland). Seven distinct serotypes of Botulinum Toxin exist: type A, B, C-1, D, E, F, and G. Each serotype Is produced by a specific strain of *Clostridium Botulinum.* The clinical effects of Botulinum Toxin are generally seen in one to three days and usually last three to six months.

There are two distinct serotype A Botulinum Toxin therapeutic products (Botox® and Dysport®) and one serotype B Botulinum Toxin product (Myobloc®) that have been approved by the U.S. Food and Drug Administration (FDA):

- Botox® (Onabotulinumtoxin A) was first approved by the FDA in 1989 for the treatment of blepharospasm and strabismus. Subsequently it has been FDA approved for treatment of cervical dystonia, severe primary axillary hyperhidrosis, upper limb spasticity, and for temporary improvement of glabellar lines (cosmetic). Botox® has become an important treatment modality for spasticity (increased muscle tone) and dystonia (sustained muscle spasms causing abnormal movements and/or posture) management in children with cerebral palsy. Botox® has been effective for minimizing impairment and improving function for children with spasticity secondary to encephalopathy, traumatic brain injury, stroke, genetic syndromes, spinal cord injuries, human immunodeficiency virus (HIV), and neurodegenerative disorders. These “off label” uses for the treatment of spasticity and dystonia have been supported in the medical literature and in accepted drug compendia, such as the DrugDex, Clinical Pharmacology, and the American Hospital Formulary Service Drug Information.

- Dysport® (Abobotulinumtoxin A) was FDA approved in April 2009 for the treatment of cervical dystonia and glabellar lines. It has been used in Europe for many years for treating children and adolescents with spasticity. It is a Medi-Cal benefit effective June 1, 2010.

- Myobloc® (Rimabotulinumtoxin B), approved by the FDA in 2000 for cervical dystonia, is used infrequently, and generally only if there is resistance to Botulinum Toxin Type A.

Although similar in certain aspects, it is important to understand that Botulinum Toxin products are not interchangeable. They differ from one another in dose units, names, and dosing. They are chemically, pharmacologically, and clinically distinct. The units of biological activity of one Botulinum Toxin product cannot be compared to or converted into units of any other Botulinum Toxin product. The dosing of any Botulinum Toxin product must be individualized to each patient based upon many factors including but not limited to the size of the muscles to be injected; the number of muscles to be injected; body weight; the condition being treated; the expected patient response; and the general health of the patient. Standard doses do not exist.

Prior to any treatment for spasticity with Botulinum Toxins, conservative treatments such as physical/occupational therapy interventions (e.g., stretching, strengthening, and positioning) or support bracing should be tried. If conservative treatment is not satisfactory, then Botulinum Toxin injections can be tried. Botulinum Toxin can provide graded focal relief in muscles selected for treatment. Spasticity is important to treat, as it can lead to incoordination, loss of function, pain, and permanent muscle shortening, or contracture. Goals of Botulinum Toxin injections for spasticity management in children may include:

- decreasing or preventing contractures or deformities,
- promoting/improving function (especially upper extremity),
- alleviating pain,
- increasing the ease of caregiving and self-care,
- improving hygiene
- improving mobility,
- improving flexibility (range of motion),
- improving positioning,
- improving tolerance to wearing braces/splints (orthoses),
- improving fit of orthoses,
- maintaining/improving postural alignment
- improving standing posture and/or gait, or
- postponing or delaying surgery for tendon lengthening (particularly until the child is older and at less risk of possible complications; and possibly decreasing the need for repeated surgical interventions).

Complementary therapies, such as physical and occupational therapy, are used to maximize anticipated outcomes. An effective treatment is almost always associated with an ongoing therapy program that builds upon the relaxation in tone, decreased pain, improved tolerance of orthoses, improved hygiene, and decreased burden of care. Intensive physical or occupational therapy, daily home stretching, serial casting and night splints may maximize and prolong the effects of the Botulinum Toxin injections. Coordination with the Medical Therapy Unit and/or outpatient therapy clinic needs to occur to assure availability of physical and occupational therapy services following Botulinum Toxin injections. Botulinum Toxin can be used in conjunction with other therapies, e.g., oral medications or intrathecal baclofen, to allow optimal tailoring of therapy for the clinical situation.

Some children may require electromyography (EMG) guidance in order to determine the proper injection site(s). Because of the multiple injections that are required, children may require a topical anesthetic to numb the skin over the muscles to be injected, a general anesthetic, or sedation.

Botox® injections have been used as therapy for other conditions, including but not limited to the following (with the usual requesting specialist in parentheses): strabismus and blepharospasm (ophthalmologist); torticollis/cervical dystonia (physiatrist, neurologist, orthopedist); achalasia (gastroenterologist or surgeon); internal anal sphincter hypertonicity in Hirschsprung's Disease when medical treatment has failed and the surgeon is trying to avoid anal myectomy (surgeon); neurogenic bladder dysfunction (urologist); drooling for children with CP after failure with medical treatment (ENT physician, neurologist, physiatrist); and debilitating hyperhidrosis (surgeon, dermatologist, physiatrist). In these conditions, Botox® injections are often administered to avoid surgery or as an alternative when medication treatments have failed or have had unacceptable adverse effects.

III. POLICY

Effective the date of this letter, County CCS and CMS Branch Regional Offices shall authorize Botulinum Toxin when the following are met:

A. Child meets program eligibility for CCS treatment services and the condition for which Botulinum Toxin is being requested is a CCS eligible condition or has resulted from or impacts the management of a CCS eligible condition; and

B. There is a medical report (including physical exam and goal(s) of Botulinum Toxin (therapy) recommending Botulinum Toxin for treatment of spasticity or dystonia from a CCS approved physician who is either a physiatrist, orthopedist, or neurologist; or

C. There is a medical report recommending Botulinum Toxin for the treatment of another condition for which there are supporting citations in the established drug compendia or peer reviewed medical literature provided by the requesting physician, and the requesting physician is an appropriate CCS approved pediatric specialist.

IV. POLICY IMPLEMENTATION

Authorization:

A. Botulinum Toxin Type A (Botox®), Abobotulinum Toxin Type A (Dysport®), and Botulinum Toxin Type B (Myobloc®) are on the CCS table (Medi-Cal Manual) of "Drugs Requiring Separate Authorization", and thus require separate authorization. Abobotulinum Toxin Type A (Dysport®) is added to the table effective June 1, 2010.

B. The physician billing code for Botox® is J0585 (per unit), for Dysport® is J0586 (per 5 units), and for Myobloc® is J0587 (per 100 units).

- The usual request for Botox® for spasticity for children is 200 to 400 units, but as much as 600 units may be requested for an adolescent. There should be at least three months between doses.

- The usual request for Myobloc® for spasticity for children is 10,000 to 20,000 units. There should be at least three months between doses.

- The dosing for Dysport® for spasticity for adults is 250 to 1000 units. There should be at least three months between doses.

C. If a pharmacy requests authorization for the Botulinum Toxin medication, then the pharmacy is authorized by National Drug Code (NDC) number for the Botulinum Toxin. If a pharmacy is requesting authorization for Botulinum Toxin, there should be no authorization to a physician for the Botulinum Toxin, only for the codes as identified in IV.F.

D. For requests from physicians administering Botulinum Toxin at Shriners Hospitals, the Service Authorization Request (SAR) must be issued to the pharmacy identified by Shriners using the NDC number for the Botulinum Toxin medication. Neither the physician nor Shriners Hospital receives an authorization.

E. The medical report from a CCS approved specialist (see III.B), recommending Botulinum Toxin injections for spasticity or dystonia does not have to come from the CCS approved specialist who is requesting authorization and will be administering the injections. For example, some CCS approved physiatrists may evaluate the child with spasticity or dystonia in their Physical Medicine and Rehabilitation (PM&R) clinic and will refer to another CCS approved physiatrist, orthopedist, or neurologist for the actual injections.

F. Other codes for authorization:

- The physician administering Botulinum Toxin will need Service Code Grouping (SCG) 01. Even if the physician already has an SCG 01, you should still add SCG 01 to the SAR for Botulinum Toxin as this is the SAR that will be used for all the services related to the administration of Botulinum Toxin. SCG 01 will cover, for example, the visit, room charges, supplies, medications (e.g., EMLA cream), anesthesia, and/or sedation.

- EMG codes 95873 and 95874 (for chemodenervation guidance) are not in SCG 01, so will require a separate authorization. If EMG codes 95860-64 are requested, these are contained in SCG 01, so these do not require separate authorization.

- Chemodenervation codes, for example 64612, 64613, 64614, and 64650, are not contained in any SCG and need to be authorized as requested. Chemodenervation codes are authorized per functional muscle group and the "K" procedure type must be selected. The number of functional muscle groups to be injected is the number of units entered on the SAR. The provider should include the number of functional muscle groups or the units in the request.

G. Although most children with spastic cerebral palsy will be open to the Medical Therapy Program, this is not a requirement in order for the child to be authorized for Botox®, Dysport®, or Myobloc®.

If you have any questions regarding this numbered letter, please contact your state regional office medical consultant.

Original signed by Harvey Fry for Luis R. Rico

Luis R. Rico, Acting Chief
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