GUIDELINE STATEMENT

This guideline outlines the management of members with spasticity using Botulinum Toxin as required by the Children’s Rehabilitative Services Program, Arizona Health Care Cost Containment System, State of Arizona. Clinical Guidelines are used to create best practices for the multispecialty and interdisciplinary.

PURPOSE

Clinical Practice Guidelines represent the minimum requirements for providing care for members with spasticity/dystonia where Botulinum Toxin is being considered for treatment. Care and treatment using Botulinum Toxin for spasticity/dystonia should be provided in a manner that includes adherence to and consistency with the following Guideline. The purpose of this guideline is to promote a uniform level of care at CRS MSIC sites for members with spasticity/dystonia due to a CRS condition such as cerebral palsy or other neurological conditions. The relevance to specific situations will depend on individual variations in clinical course and professional judgment. In addition, this document should serve as a tool to assess programs, secure resources needed to enhance patient care and education, and guide the future development and treatment spasticity or dystonic movements responsive to Botulinum Toxin.

A. Goals:

1. To maintain maximum individual functioning using a multispecialty, interdisciplinary team approach including consideration of member and family expressed preferences for treatment of spasticity or dystonia.
2. To improve quality of life for members with spasticity or dystonia due to CRS related conditions.

B. Objectives:

1. To maintain a network with specialists able to coordinate care for and treat spasticity/dystonia related to CRS conditions for effective management and outcomes.
2. This implies easy accessibility to the appropriate specialists and interdisciplinary team members experienced with the treatment of spasticity not responding to treatments tried prior to consideration of Botulinimum Toxin.

3. Specialists must be able to provide accurate and timely diagnosis as well as be knowledgeable of appropriate treatments for these conditions.

4. Nurses at the MSIC must also be experienced or have additional training to be competent in supporting the members treatment and educational needs.

5. Services will be provided in a multispecialty, interdisciplinary clinic in a member centric, family friendly, culturally sensitive manner.

DEFINITIONS:

**Children’s Rehabilitative Services (CRS):** An AHCCCS program for children with certain diagnoses which provides services using an integrated family-centered, culturally competent, multi-specialty, interdisciplinary approach.

**Botulinum Toxin:** is a neurotoxin produced by the bacterium Clostridium botulinum which is used for paralyzing muscles to help with muscle spasms for a variety of medical conditions.

**Multi Specialty Interdisciplinary Clinic (MSIC):** The Specialty Medical Home for the members with diagnoses as designated by the Arizona Administrative Code (AAC) R9-7-202 (R9-22-1303, 10-1-2013).

I. PROCEDURAL GUIDELINES for POLICY COMPLIANCE

A. **CRS Enrollment:**

   CRS members diagnosed with spasticity or dystonia due to cerebral palsy, nervous system trauma, and inflammatory or degenerative conditions will be seen at the CRS Multispecialty Interdisciplinary Clinics. Specialty Clinics may include Orthopedic, Neurology, Spasticity or Neurosurgery Clinics.

B. **Interdisciplinary Team Membership:**

   The following Team Members are present during MSIC specialty clinics providing services for CRS members with spasticity or dystonia. The specialists and interdisciplinary team members provide recommendations to the family and member prior to treatment decisions regarding treatment with Botulinum Toxin or other alternative treatments.

<table>
<thead>
<tr>
<th>Clinics</th>
<th>Interdisciplinary Team Members</th>
<th>Interdisciplinary Team Members Available During Specialty Clinics As Needed</th>
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<tbody>
<tr>
<td>Neurosurgery</td>
<td>Neurosurgeon</td>
<td>Educator</td>
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<td></td>
<td>Registered Nurse</td>
<td>Social Worker</td>
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<td>Child Life Specialist</td>
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<td>Translator</td>
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<td>Advocate</td>
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<tr>
<td>Neurology</td>
<td>Pediatric Neurologist Registered Nurse</td>
<td>Child Life Specialist Educator Social Worker Translator Advocate</td>
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<tr>
<td>Orthopedic- Cerebral Palsy</td>
<td>Orthopedic Surgeon Occupational Therapist Physical Therapist Registered Nurse/LPN Social Worker</td>
<td>Child Life Specialist Educator Nutritionist Translator Orthotist Cast Room Tech Wheelchair Tech Advocate</td>
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<tr>
<td>Spasticity Clinic</td>
<td>Physical Rehabilitation Medicine Specialist (Physiatrist), Orthopedist or Neurologist Occupational Therapist Physical Therapist Registered Nurse/LPN Social Worker</td>
<td>Translator Orthotist Advocate Child Life Specialist</td>
</tr>
</tbody>
</table>

C. **Patient Selection Criteria/Prerequisites:**

1. Systematic reviews for treatment of spasticity in children with cerebral palsy found evidence to support use of botulinum toxin A for the management of spasticity when it is administered with concomitant rehabilitation therapy. The Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society also published an evidence-based review of the pharmacologic treatment of spasticity in children and adolescents with cerebral palsy in 2010. For localized/segmental spasticity that warrants treatment in children and adolescents with cerebral palsy, botulinum toxin type A should be offered as an effective and generally safe treatment (Level A) and there is insufficient data to support or refute the use of botulinum toxin type B (Level U).

2. Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology published evidence-based (studies classified as Class I to IV and recommendations classified as levels A to U) assessments on the use of botulinum neurotoxin in the treatment of autonomic disorders and pain,138 movement disorders,147 and spasticity. Botulinum Toxin should be offered as an option for the treatment of spasticity in adults (Level A). Spasticity in adults may result from a variety of causes such as stroke, trauma, multiple sclerosis, and neoplasm involving the central nervous system.

3. Botulinum Toxin may be considered for hemifacial spasm, focal lower limb dystonia, and motor tics (Level C).

4. For other conditions outside of this policy and reference to the specific brands of Botulinum Toxin which have FDA approval for use, see:
II. GUIDELINES FOR MANAGEMENT AND TREATMENT OF SPASTICITY

A. Initial Botulinum Toxin Treatment

1. Functional Improvement Criteria for Referral: A member must have documented increased muscle tone or spasticity which clearly puts him/her at risk for joint deformity or which causes one or more of the following:
   a. Pain
   b. Interference with one or more of the following functions:
      c. Proper positioning
      d. Standing
      e. Gait
      f. Patient ability to perform activities of daily living
      g. Caregiver ability to maintain hygiene, care, or positioning

2. Member/Family Education:
   a. Provider must provide diagnostic information regarding probable outcome of Botox
   b. Planned treatment of targeted muscle group(s).
   c. Balanced information on the mechanisms of Botox treatment as well as potential for discomfort and side effects of the treatment.

3. Previous Treatment: There must be documentation that trials of less invasive approaches to spasticity management appropriate for the clinical situation of the member (i.e. serial casting, night splinting, a reasonable course of physical or occupational therapy, OR oral medication). Approaches should have not adequately reduced the influence of spasticity on function during the previous months of treatment and that the relative merits and risks of Botulinum Toxin treatment have been considered.

4. Current Treatment: Member must be receiving ongoing medical or rehabilitative/habilitative management through CRS and have been evaluated in a related MSIC clinic within the previous three months.

5. Team Recommendations: Documentation that the member’s candidacy for Botulinum Toxin treatment has been discussed in a staffing which includes all relevant team members. This team will include at the minimum, the managing MSIC specialist, therapist, and member/family.

6. Therapy Documentation: Documentation of physical and/or occupational therapy evaluation within the previous three months to record pre-treatment status and function, as related to the goals of Botox injection. This evaluation will have included:
a. Classification of deformity, established measures of ROM, spasticity and, if appropriate, pain.
b. Measures of functional ability.

7. **Treatment Plan** which includes:
   a. Functional and physical treatment goals, how and when they will be measured, and by whom.
   b. Target muscle (group) and planned dosage
   c. Post-injection therapy treatment recommendations, including frequency of sessions.
   d. Time at which post-injection physical and functional evaluations will take place and when child will return to appropriate neurology, orthopedic, physiatry/physical medicine and/or multi-disciplinary clinics

8. **Member/Family Acceptance of Plan:** It must be clear that there are no psycho-social contraindications (i.e. poor attendance to medical or therapy appointments or home exercise program in the recent member/family history) that would interfere with effectiveness of the treatment

**B. Continued Treatment**
The administering provider should make a determination for all subsequent Botox therapy Recommendations after consideration of other therapy and specialists input. There should be the following supportive documentation:

1. **Evidence that the member meets patient selection criteria as listed above.**

2. **Documentation if there have been any new surgeries or condition changes which may affect the member’s need for additional Botulinum Toxin or concern that Botulinum Toxin is no longer appropriate.**

3. **Documentation of the continued goals and outcome measures as follows:**
   a. Classification of deformity, established measures of ROM, spasticity and, if appropriate, pain.
   b. Measures of functional ability

4. **Documentation that the family is participating in therapy or home exercise program with compliance.**

5. **Information regarding previous Botulinum Toxin treatment and where, any adverse reactions and outcomes of treatment.**

6. **Any changes to the treatment plan which might include:**
   a. Functional and physical treatment goals, how and when they will be measured, and by whom.
   b. Target muscle (group) and planned dosage
   c. Post-injection therapy treatment recommendations, including frequency of sessions
   d. New time at which post-injection physical and functional evaluations will take place and when child will return to appropriate neurology, neurosurgeon, orthopedic, physiatry/physical medicine and/or multi-disciplinary clinic
C. **Treatment Outcome Assessment:**

Evaluation of treatment outcomes will differ somewhat depending upon the individual outcome goals established as part of the member’s treatment plan. In all cases, however, outcomes will be assessed in each of the following areas

1. **Technical/Musculoskeletal Outcomes.** Assessed by physicians and therapists (Note: documentation is usually made by physical or occupational therapist). Examples:
   a. Increased ROM
   b. Tone reduction
   c. Pain reduction, if appropriate
   d. Increased tolerance for bracing or splinting
   e. Objective Evaluation, i.e.
      i. Upper Extremity- Quality of Upper extremity Skill test (QUEST)
      ii. Lower Extremity- Goal Attainment Scale (GAS) or
      iii. Gross Motor Function Measure (GMFM)

2. **Functional Outcomes.** Assessed by therapists. Examples:
   a. Improved speed or quality of gait
   b. Improved positioning for healthy posture and function
   c. Improved ability to transfer
   d. Increased ability to perform activities of daily living, such as feeding, grooming, hygiene
   e. Post-treatment should be evaluated at both the expected apex and nadir, if practical
   f. Objective Evaluation:

3. **Member/Family Satisfaction.** Assessed by therapist and/or social worker. Examples:
   a. Member/family perception of disability change
   b. Increased ease of care
   c. Member commitment to treatment plan

D. **Botulinum Toxin Prior Authorization Form.**

Must be filled out and submitted with PSR. Can be found at the UnitedHealthcare Community Plan website location:


**Bibliography:**


