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

TOBY DOUGLAS
DIRECTOR

EDMUND G. BROWN JR.
GOVERNOR

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N.L.: 05-0612
Index: Medical Benefits

TO: ALL COUNTY CALIFORNIA CHILDREN'S SERVICES (CCS) PROGRAM ADMINISTRATORS, MEDICAL CONSULTANTS, STATE CHILDREN'S MEDICAL SERVICES (CMS) STAFF, CCS HYPERTONICITY APPROVED SPECIAL CARE CENTERS, CCS APPROVED REHABILITATION CENTERS

SUBJECT: INTRATHECAL BACLOFEN (ITB) PUMPS FOR THE MANAGEMENT OF SPASTICITY AND DYSTONIA

I. PURPOSE

The purpose of this numbered letter is to provide policy guidelines for the authorization of intrathecal baclofen (ITB) pumps for management of spasticity and dystonia.

II. BACKGROUND

Baclofen is a muscle relaxant and antispasmodic approved by the Federal Food and Drug Administration for the treatment of severe spasticity and dystonia. Intrathecal administration of baclofen may be a treatment option for children and adults whose hypertonicity, spasms and/or dystonia cannot be effectively managed by other modalities, including oral medications, orthopedic surgery, physical and occupational therapy and/or injection therapy with products such as botulinum toxin or phenol. By bypassing the blood-brain barrier, intrathecal baclofen allows use of a lower does of medication, avoiding the unacceptable side-effects of higher oral or parenteral doses. Intrathecal baclofen has been associated with decreased spasticity, particularly in lower extremities, reduced pain, and greater ease of providing care.

In children and adolescents, ITB is most often used to treat severe spasticity and/or dystonia resulting from cerebral palsy, hypoxic brain injury, traumatic brain injury (TBI), or spinal cord injury. ITB may decrease spasticity and improve rehabilitation potential when used early in individuals with severe TBI and paroxysmal sympathetic hyperactivity. ITB may also be used to treat secondary generalized dystonia that impedes care or function and/or is causing discomfort. ITB is less effective, however, in treatment of primary dystonia and dystonia associated with disorders such as Wilson's Disease or Hallevorden-Spatz diseases (medications and other treatments modalities such as deep brain stimulation may be indicated for these individuals). ITB is generally used in children over four years of age, as safety and efficacy have not been established for younger children.

ITB implantation and care are generally done with a multidisciplinary team approach, involving physiatrists, orthopedic surgeons, pediatric neurologists, occupational therapists, physical therapists, orthotists, and nurse specialists with experience in use of ITB. Pre-implantation trials are often performed to assess responsiveness to ITB and are necessary when the indication is dystonia in the absence of severe spasticity (Appendix A, Baclofen Trial).

There are a significant number of complications associated with ITB use, including hypotonia, seizures (not-new onset), and infection related to implantation. There are costs related to ITB implantation and use, including cost of pump, pump replacement every five years, new catheters to accommodate growth of the child, and costs secondary to implantation. Despite the complications and the cost, use of ITB improves quality of life in most individuals with severe spasticity and in some with dystonia. When used appropriately, the use of ITB has been determined to be cost effective.[1,2,3]

III. POLICY

Effective the date of this letter, County CCS and Regional Offices shall authorize ITB when **all** of following are met:

A. Client meets program eligibility for CCS treatment services and the condition for which ITB is being requested is a CCS eligible condition that significantly impedes function and is associated with severe or moderately severe spasticity (GMFCS score 3 or greater) and/or dystonia.

B. **The CCS Medical Therapy Conference (MTC) or a CCS Hypertonicity Special Care Center (SCC)** has identified the need for comprehensive hypertonicity management.

C. A **CCS-approved physiatrist or neurologist** with experience in the care of patients with spasticity performed a comprehensive hypertonicity evaluation and has recommended ITB as the treatment of choice.

1. The team or specialist requesting the ITB has a pump management plan in place that includes the identification of a community provider/physiatrist who can perform pump refills and manage emergencies.
2. For ITB client 14 years and over, there is documentation of a plan for transitioning the client to adult care and/or is coordinating transition plan with the CCS approved SCC and primary care physician (PCP).

D. **A CCS approved Surgical Implantation Team <u>or</u> CCS approved orthopedist <u>or</u> neurosurgeon** with experience and training in ITB pump implantation located in a CCS approved tertiary hospital with a CCS approved Pediatric Intensive Care Unit (PICU) has evaluated the child and recommends ITB.

E. The County CCS Medical Director/Consultant and Supervising Therapist or designee(s) shall be responsible for the review of all requests to authorize ITB implantation to ensure proper documentation is present, justifies medical necessity, and appropriate post-operative evaluation and treatment are available.

IV. POLICY IMPLEMENTATION

Authorization:

A. Requests for initial comprehensive hypertonicity evaluation:

1. The Service Authorization Request (SAR) shall be submitted to the local CCS program by one of the following:
   a. CCS approved Hypertonicity/Rehabilitation SCC; or
   b. Designated physician with experience and training in comprehensive care of patients with hypertonicity including ITB;
   c. Designated physician with ITB experience associated with Rehabilitation SCC at CCS approved tertiary hospital with CCS approved PICU.

Note: Hypertonicity evaluation/ management physicians who are not associated with CCS approved Hypertonicity/Rehabilitation SCC must be associated with a CCS approved tertiary hospital with a CCS approved PICU.

Requests received to authorize physicians not associated with CCS approved Hypertonicity/Rehabilitation SCC or a CCS approved tertiary hospital with a CCS approved PICU must be accompanied by documentation from the SCC/facility that the physician has full privileges in his/her department for ITB implantation. Such requests and documentation should be reviewed with Children's Medical Services designated Medical Consultant.

2. The SAR must be accompanied by a comprehensive hypertonicity evaluation report which shall include the following:
   Identification of client's medical home provider/primary care physician (PCP), and other specialists involved in care including, if applicable, the CCS Medical Therapy Unit.
   a. Relevant medical history of the condition leading to spasticity, including medical and surgical interventions previously attempted and their outcomes.
   b. Indications for pump implantation including justification of ITB over other treatment modalities.

c. Assessment of client's general health, nutritional status, medical and/or surgical problems, and/or medications that may impact ITB implantation and/or management.
d. For patients with history of hydrocephalus and/or ventricular shunt, documentation that the shunt is functional.
e. Physical examination that includes current weight, cognitive level, physical findings supporting the findings of severe spasticity and/or dystonia. Include current level of motor function (GMFCS) and/or Ashworth score.
f. Documentation that family/caregivers understand the nature of the ITB pump intervention (including risks, potential complications, and alternative treatments); are able to give long-term commitment to care; have adequate supports including ability to keep appointments and to contact Hypertonicity SCC or hypertonicity physician/designee in an emergency.
g. Results of the ITB trial if completed (Appendix A, ITB Trial).
h. Documentation of functional goals
i. Baclofen Pump Request Questionnaire, Appendix B, submitted by referring center is recommended but not required; it may be used to facilitate initial ITB request completion.

3. Documentation by neurosurgeon/orthopedist including:
   a. Report of ITB education provided to patient/family and/or legal caregiver.
   b. Post-operative recommendations for positioning, bracing, surgery and/or therapy.
4. Documentation of communication and coordination with PCP, MTU staff, and other medical and/or surgical consultants, including surgical clearance for ITB when medical or surgical condition may interfere with or be impacted by ITB implantation.

5. If the documentation requirements in IV.A.1-4 are met, the SAR for initial evaluation may be authorized for a time period of up to one year from the date of CCS program eligibility.

B. Authorization for ITB Trials: See Appendix A, ITB Trial

C. Authorization for initial pre-operative surgical evaluation: The client's existing authorization to the Hypertonicity SCC or the hypertonicity management physician may be used for the pre-operative evaluation.

D. Authorization for ITB pump implantation:

1. Authorization for ITB pump implantation shall be issued to a neurosurgeon or an orthopedic surgeon who is a member of the Hypertonicity/Rehabilitation SCC surgical implantation team or who works with the Hypertonicity/Rehabilitation SCC at a CCS approved tertiary hospital with a CCS approved PICU.
2. Authorize SCG01, not SCG51, to surgeon, with separate surgery codes according to D4 (See Table 1)
3. Authorize hospital inpatient stay up to seven days.
4. Codes for catheter implantation- See Table 1
5. A separate authorization for the pump shall be issued only if:
   a. The hospital has a Medi-Cal contract in a closed area and provides documentation that reimbursement for the pump is carved out of its per diem rate; or
   b. The hospital has a Medi-Cal contract in an open area or
   c. The hospital does not have a Medi-Cal contract.

E. Authorization for post-operative ITB pump management:

1. Authorize the following to approved SCC/ physician following implantation:
   a. Prescriptions for medications related to hypertonicity management.
   b. Prescriptions for medically necessary physical and occupational therapy; durable medical equipment; and orthotics (unless these services will be managed by staff at the MTU post-ITB implantation),

c. Pump reservoir refills and maintenance including pump analysis/reprogramming are typically done every 3 months, with units adequate to reflect number of anticipated future visits until date of next CCS financial eligibility period or next SCC visit.

d. Pump refills may be provided by a nurse or nurse practitioner working under the direct supervision of the Hypertonicity SCC or hypertonicity management.

2. The following must be included in requests for ITB refill or annual renewal

a. Codes for ITB refill and electronic analysis: (Table 1)

b. Written documentation to family and community-based medical providers for handling ITB related emergencies

c. Annual assessment and documentation of ongoing coordination of client's transition planning beginning at age 14.

3. The functions E. 1.a – d above may be delegated by the Hypertonicity/Rehabilitation SCC or CCS authorized hypertonicity management physician to a CCS paneled community physician with training and experience in assessing ITB pump function, programming and refilling. The Hypertonicity/Rehabilitation SCC or authorized hypertonicity management physician is responsible for assuring the following:

a. Qualifications of the delegated physician;

b. Ongoing two-way communication; and

c. Protocols are established for client's referral back to the Hypertonicity/Rehabilitation SCC or hypertonicity physician for ITB pump function maintenance and management.

4. Authorization of the codes for ITB refill and maintenance found in Table 1 shall be to ITB approved center or designee.

F. Pharmacy requests and CCS authorizations.

1. ITB dispensed as an outpatient medication is claimed by the pharmacy using the NDC number with the physician's authorization. The baclofen

for infusion shall be authorized according to the hypertonicity management physician's prescription.

NOTE: Only FDA approved concentrations provided by the manufacturer may be approved. This drug should not be compounded.

2. ITB may be authorized using HCPCS code X7108 intrathecal baclofen 10 mg only if billed with E0783 for the pump at the time of implantation.
3. Baclofen billing
   a. If dispensed as an outpatient medication, is claimed by the pharmacy using the NDC number with the physician's authorization, according to the Hypertonicity/Rehabilitation SCC prescription.
   b. May be separately authorized to the pharmacy if there is no physician authorization for those facilities which do not bill for physician services.
   c. If dispensed with pump, ITB is billed with E0783 at the time of implantation; may be authorized using HCPCS code X7108, intrathecal baclofen 10 mg.
   d. Only FDA approved concentrations provided by the manufacturer may be approved. This drug should not be compounded.

G. Medical and/or surgical care related to pump and/or catheter malfunction and/or intrathecal baclofen withdrawal or overdose are benefits of the CCS program except as noted below:

1. For those facilities billing directly for the pump hardware and there is pump failure, information must be submitted demonstrating that the pump warranty has expired.
2. If there has been a manufacturer recall for defective equipment for which the manufacturer is financially responsible.

Any exception to policies outlined in this numbered letter will only be made after justification to the Children's Medical Services Medical Director or designee.

Please direct any comments or questions about the contents of this numbered letter to Dr. Jill Abramson, Chief, Medical Policy and Consultation Section, at Jill.Abramson@dhcs.ca.gov

Sincerely,

Robert Dimand, MD
Chief Medical Officer
Children's Medical Services

Enclosures

[1] Miller F. The effects of continuous intrathecal baclofen infusion in non-ambulant children with cerebral palsy. Dev Med Child Neurol. 2011 Jun 27

[2] Krach, LE, Kriel, RL, Day, SM and DJ Strauss. Survival of individuals with cerebral palsy receiving continuous intrathecal baclofen treatment: a matched-cohort study. Dev Med Child Neurol. 2010 Jul;52(7):672-6

[3] Dan B, Motta F, Vles JS, Vloeberghs M, Becher JG, Eunson P, Gautheron V, Lütjen S, Mall V, Pascual-Pascual SI, Pauwels P, Røste Consensus on the appropriate use of intrathecal baclofen (ITB) therapy in paediatric spasticity. GK Eur J Paediatr Neurol. 2010 Jan;14(1):19-28

Table 1: Codes related to Intrathecal Baclofen Pumps

Section	Code/Service Code Grouping	Description/Notes
	SCG 01	
	SCG 02	
	SCG 51	
IV D	**Pump Implantation**	
	62350 (CPT)	Implantation, revision or repositioning of tunneled intrathecal catheter for long-term medication administration via external or implantable infusion pump, without laminectomy
	62351	Implantation, revision or repositioning of tunneled intrathecal catheter for long-term medication administration via external or implantable infusion pump, with laminectomy (patients with spinal fusion)
	62362	Implantation of intrathecal baclofen pump
	77003 (CPT)	Fluoroscopy procedure code for catheter placement
IV D4	When authorizing a pump, authorize only one of the following codes	
	E0783	Catheter and programmable pump
	E0786	Programmable pump (replacement only)
	E0785	Intraspinal catheter only (replacement)
IV E2	**Authorization of the codes for ITB refill and maintenance**	
	95990	Refill and maintenance of pump by a non-physician
	95991	Refill and maintenance of pump by a physician
	62367	Electronic analysis of programmable pump without reprogramming
	62368	Electronic analysis of programmable pump with reprogramming
IV F2	X7108 (HCPCS)	Intrathecal baclofen 10 mg only if billed with E0783 for the pump at the time of implantation
	X3920	Physical therapy assessment for the trial
	X3922	Maximum of 3 units for subsequent assessments
	J0476 (HCPCS)	Intrathecal trial kit is not a Medi-Cal benefit or CCS benefit and *should not be authorized*.
	62311	Baclofen Screening Trial

Appendix A: Baclofen Trial

Pre-implantation trials are often performed to assess responsiveness to intrathecal baclofen. For children with spasticity, the trial often includes injection of a bolus dose via lumbar puncture, with monitoring of Ashworth scores at baseline and periodically. Because almost all of these children respond to ITB, some centers have discontinued trials for this group. Medi-Cal and many other payers, however, continue to require a trial before (authorization of) pump implantation. For children with dystonia, on the other hand, a pre-implantation trial usually consists of a continuous infusion done over several days through an implanted catheter attached to an external pump. Some physicians feel the risk of infection in this situation outweighs the benefits of the trial.
A screening test is not required, but if an intrathecal bolus injection or continuous infusion screening test has been done,

1. A positive response must be documented as measured by an improvement in Ashworth score and/or decrease in dystonia.
2. There must be evidence that the test dose has been tolerated without significant adverse effects

Screening test scoring

a. If a bolus trial is done, there should be objective scoring using the *Ashworth or modified Ashworth score* at baseline and every two hours up to 6 hours
b. If a continuous infusion trial is done, there should be an objective dystonia scoring tool (F-M dystonia rating scale, Unified Dystonia Rating Scale, Global Dystonia Rating Scale)
c. The results of the test dose must include Ashworth scores of affected muscles, improvement, and concluding comments or results of Dystonia Rating Scale, which must be included in a written report to justify proceeding to pump implantation.

Requests to authorize baclofen trial

1. Intrathecal bolus trial done is usually done as a short stay procedure.
2. Hospital must be CCS approved and appropriate level for the service.
3. The approved surgeon may be authorized with SCG 01.

4. Physical therapy assessment for the trial using X3920 for the initial assessment and X3922 for a maximum of 3 units for subsequent assessments
5. Codes for authorization:
    a. 62350 - Surgical procedure code for catheter implantation. Note: CPT 62350 is included in SCG 51.
    b. 77003 - Fluoroscopy procedure code for catheter placement. This code is included in SCG 01/02.
    c. Non-surgical physician services are included in SCG 01/02.
6. For intrathecal bolus trial done as a short stay procedure:
    a. Physician codes are included in SCG 01 or SCG 02
    b. Medication for the trial is supplied in 50 mcg/ml syringe as either Lioresal or Gablofen. The drug may be authorized using the NDC code or billed directly by the pharmacy using the NDC code for the product with the physician's authorization. If there is no physician authorization at facilities which do not bill for physician services, then the medication may be separately authorized.
    c. Physical therapy – see 4 above
    d. J0476 HCPCS code for intrathecal trial kit is not a Medi-Cal or CCS benefit and *should not be authorized*.
7. For an intrathecal trial done with continuous infusion,
    a. Surgical services shall be authorized for catheter implantation , CPT code 62350
    b. CPT Code for fluoroscopy for catheter placement - see above
    c. Non-surgical physician services are included in SCG 01 or 02.
    d. Physical therapy assessment shall be authorized as in as 4 above.

California Children's Services
Department of Health Care Services

Appendix B:

Baclofen Pump Questionnaire (to be completed by physician)

DATE:
CLIENT:
DOB:
DIAGNOSIS RELATED TO THIS REQUEST:

GMFCS and/or Ashworth SCORE:

REQUESTING PHYSICIAN/SPECIALTY:

FACILITY:

IS MTU AWARE? ☐ Y ☐ N MTU NAME:

IS PCP AWARE? ☐ Y ☐ N PCP NAME:

LIST ORTHOPEDICS/NEUROLOGIST INVOLVED IN CARE OF CHILD PROVIDING LETTER OF SUPPORT:

PLAN FOR MEDICAL MANAGEMENT OF ITB INCLUDING REFILLS:

PLAN FOR CARE IN EMERGENCY, PHYSICIANS WHO WILL BE INVOLVED:

FUNCTIONAL GOALS:

FAMILY AWARENESS OF ITB RESPONSIBILITIES/IN AGREEMENT WITH PLAN?:

PRIOR TREATMENT:

WHY BACLOFEN PUMP IS BEST CHOICE:

TRANSITION PLAN (IF >= 14):