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 Subject: Intrathecal Pump for the Infusion of Baclofen  
 Effective Date: April 6, 2009

Clinical Documentation and Prior Authorization Required	√	Type of Review - Case Management	
Not Covered		Type of Review – Precertification Department	√
		Administrative Process (Internal Use Only)	MD

**Note:** Background, product, and disclaimer information is located at the end of this document.

### Overview

Baclofen (Lioresal) is a skeletal muscle relaxant used to relieve severe spasticity of spinal or cerebral origin. The drug is provided intrathecally via an infusion pump to patients who have not responded to or cannot tolerate maximal doses of oral baclofen therapy. Intrathecal infusion of baclofen is used for patients with a diagnosis of multiple sclerosis and spasticity manifested by spasms, pain, clonus, and muscular rigidity. Baclofen infusion therapy is also used for severe spinal cord spasticity resulting from spinal cord injury, stroke, traumatic brain injury and cerebral palsy. The drug is not effective for the treatment of Parkinsonism or rheumatic disorders.

### Coverage Guidelines

Tufts Health Plan may authorize coverage for intrathecal infusion pumps, for the infusion of baclofen, for Members meeting the one of the following clinical criteria:

- The Member has severe spasticity of spinal or cerebral origin which has proven unresponsive to conventional treatments (e.g. maximal doses of oral medications, nerve blocks, botox injections and physical therapy),
- The Member has had unacceptable side effects from or intolerance to oral baclofen at the maximal effective dose
- The Member must have a positive response to a single, intrathecal bolus dose of baclofen. ( A positive response is defined as an average two-point drop on an objective muscle tone or spasm screening system (e.g., the Ashworth and spasm scale))

### Spasticity and Spasm Scales

**Ashworth Scale<sup>1</sup>** (score degree of muscle tone):

1. No increase in tone
2. Slight increase in tone, giving a “catch” when affected part is moved in flexion or extension
3. More marked increase in tone, but affected part easily flexed
4. Considerable increase in tone, passive movement difficult
5. Affected part rigid in flexion or extension

<sup>1</sup> Hayes, Inc. Intrathecal baclofen for spasticity of spinal origin or due to multiple sclerosis. Hayes Directory. December 14, 2005. Data provided by Gilmartin et al. (2000).

**Spasm Frequency Scale<sup>2</sup>** (score spasm frequency):

- 0 No spasms
- 1 Spasms with vigorous stimulation
- 2 Occasional spontaneous or easily induced spasms
- 3 Spontaneous spasms, 1-10 per hour
- 4 Spontaneous spasms, >10 per hour

**Penn Spasm Scale<sup>3</sup>** (score spasm frequency):

- 0 No spasms
- 1 Mild spasms induced by stimulation
- 2 Infrequent full spasms occurring <1 per hour
- 3 Spasms occurring >1 per hour
- 4 Spasms occurring >10 per hour

Limitations

Tufts Health Plan will not authorize the coverage of intrathecal baclofen for the treatment of dystonia.

Codes

The following HCPCS/CPT code(s) require prior authorization:

Code	Description
E0782	Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0783	Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)

References

1. Albright L.A., Baclofen in the treatment of cerebral palsy. *Journal of Child Neurology*. 1996, 11 (Supp 1): S29-34.
2. Albright, L.A, Barry, M, et. al. Infusion of intrathecal baclofen for generalized dystonia in cerebral palsy. *Journal of Neurosurgery*. 1998;88(1):73-76.
3. Azouvi, P, Mane, M, et. al. Intrathecal baclofen administration for control of severe spinal spasticity: functional improvement and long-term follow-up. *Archives of Physical Medicine & Rehabilitation*. January 1996; 77(1):35-9..
4. Hayes, Inc. Intrathecal baclofen for cerebral palsy. Hayes Directory. November 10, 2005.
5. Hayes, Inc. Intrathecal baclofen for cerebral palsy. Hayes Directory. Update Search. December 18, 2007.
6. Hayes, Inc. Intrathecal baclofen for dystonia. Hayes Directory. November 28, 2005.
7. Hayes, Inc. Intrathecal baclofen for dystonia. Hayes Directory. Update Search. January 3, 2008.
8. Hayes, Inc. Intrathecal baclofen for spasticity of spinal origin or due to multiple sclerosis. Hayes Directory. December 14, 2005.
9. Hayes, Inc. Intrathecal baclofen for spasticity of spinal origin or due to multiple sclerosis. Hayes Directory. Update Search. January 3, 2008.

<sup>2</sup> Hayes, Inc. Intrathecal baclofen for spasticity of spinal origin or due to multiple sclerosis. Hayes Directory. December 14, 2005. Data provided by Coffey et al. (1993).

<sup>3</sup> Hayes, Inc. Intrathecal baclofen for spasticity of spinal origin or due to multiple sclerosis. Hayes Directory. December 14, 2005. Data provided by Meythaler et al. (2001).

10. Middel, B, Kuipers-Umpeijer, H, et. al. Effect of intrathecal baclofen delivered by an implanted programmable pump on health related quality of life in patients with severe spasticity. *Journal of Neurology, Neurosurgery & Psychiatry*. August 1997; 63(2):204-9.
11. Ordia J, Fischer E, et. al. Chronic intrathecal delivery of baclofen by a programmable pump for the treatment of severe spasticity. *Journal of Neurosurgery*. 1996, 85: 452-57.

## Approval History

Reviewed by the Medical Technology Assessment Committee in September 1998.

Subsequent Endorsement Date(s) and Changes Made:

- November 2000: Renewed without changes
- October 2001: Renewed without changes
- May 2002: Removed evaluation by multidisciplinary team, added 'positive response to initial intrathecal bolus' to criteria #3
- May 27, 2003: Renewed, updated to new format
- June 11, 2004: Guideline title changed from 'Baclofen Intrathecal Infusion Pump', format updated.
- August 19, 2005: Reviewed and renewed without changes
- October 2, 2006: Reviewed and renewed without changes
- April 25, 2007: Reviewed, additional limitation added for the treatment of dystonia, Spasticity and Spasm scales added for reference.
- March 26, 2008: Reviewed and renewed without changes
- April 6, 2009: Reviewed and renewed without changes

## Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for Tufts Health Plan benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. Tufts Health Plan makes coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Medical Necessity Guidelines apply to all fully insured Tufts Health Plan products unless otherwise noted in this guideline or the Member's benefit document. This guideline does not apply to Tufts Health Plan Medicare Preferred or to certain delegated service arrangements. For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. Providers in the New Hampshire service area are subject to CIGNA HealthCare's provider arrangement for the purpose of CareLink<sup>SM</sup>.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of

benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.