Intrathecal Baclofen Therapy

DRAFT

Humana.

Medicaid Medical Coverage Policy

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State: LA

Table of Contents

Description
Coverage Limitations
References

Coverage Determination

Change Summary

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Summary of Changes:

10/21/2024: Annual Review, minor grammatical changes and updated references to most recent edition reviewed.

Scope:

Description

This policy applies to all Humana Healthy Horizons in Louisiana (Plan) associates who administer, review, or communicate covered physical and behavioral health benefits and services to eligible enrolled members.

Procedures:

Surgical iImplantation of a programmable intrathecal baclofen (ITB) infusion pump_for the delivery of intrathecal baclofen (ITB) therapy for individuals four years of age and older meet the medical necessity for the treatment of severe spasticity of the spinal cord or of cerebral origin—is a procedure designed to treat an individual with severe, chronic muscle spasticity related to spinal cord or brain disorders that does not respond to oral medication. Before the device is implanted, a screening trial injection of baclofen is administered to the individual to determine response to the medication. If the trial is successful and permanent therapy is indicated, a catheter is inserted into the spinal canal and connected to a small pump that is surgically positioned under the skin of the abdomen. This pump is programmed to deliver

baclofen directly into the cerebrospinal fluid surrounding the spinal cord, which helps reduce muscle stiffness, involuntary movements and related physical limitations.

Screening trial injections of baclofen do not require prior authorization (PA). PA for chronic infusion of ITB should be requested after the screening trial procedure has been completed but prior to the pump implantation.

The Plan shall cover outpatient bolus injections given to candidates for the ITB infusion treatment if medically necessary even if the member fails the screening trial procedure.

<u>Caution should be exercised when considering ITB infusion pump implantation for individuals who have a history of autonomic dysreflexia, suffer from psychotic disorders, have other implanted devices or who utilize spasticity to increase function such as posture, balance, and locomotion.</u>

The request to initiate chronic infusion shall come from the multidisciplinary team which evaluates the member. The multidisciplinary team shall be comprised of the following:

- A neurosurgeon and/or an orthopedic surgeon;
- A psychiatrist and/or a neurologist;
- A nurse;
- A social worker;
- Allied professionals (physical therapists, occupational therapist, etc.); AND
- The member's attending physician

These professionals shall have expertise in the evaluation, management, and treatment of spasticity of cerebral and spinal cord origin and shall have undergone training in infusion therapy and pump implantation by a recognized ITB product supplier with expertise in intrathecal baclofen.

The multidisciplinary team shall evaluate the candidate after the screening trial procedure has been completed but prior to the pump implantation.

The following documentation must be submitted with the request for PA:

- A recent history with documentation of assessments in the following areas:
 - Functional;
 - Medical and physical;
 - Neurological; AND
 - Psychosocial;
- Ashworth scores for pre and post administration of the ITB test dose(s); AND
- <u>Documentation of any other findings regarding the individual's condition which would assist in</u> determining medical necessity for ITB.

Coverage Determination

Humana Healthy Horizons in Louisiana members may be eligible under the Plan for surgical implantation of a programmable intrathecal baclofen (ITB) infusion pump when the following criteria are met:

The following diagnoses are considered appropriate for ITB treatment and infusion pump implantation with one or more of the following diagnosis:

- Individual is 4 years of age or older; AND
- Individual has severe spasticity due to ONE or more of the following;
 - Meningitis;
 - Encephalitis;
 - Dystonia;
 - Multiple sclerosis;
 - Spastic hemiplegia;
 - Infantile cerebral palsy;
 - Other specified paralytic syndromes;
 - Acute, but ill-defined, cerebrovascular disease;
 - Closed fracture of the base of skull;
 - Open fracture of base of skull;
 - Closed skull fracture;
 - o Fracture of vertebral column with spinal cord injury;
 - Intracranial injury of other and unspecified nature; or
 - Spinal cord injury without evidence of spinal bone injury;

AND

Muscle spasticity is related to either cerebral/brain disorder(s) OR spinal cord disorders:

Implantation of an ITB infusion pump is considered medically necessary, when the candidate is four (4) years of age or older with a body mass sufficient to support the implanted system, and one (1) or more of the following criteria is met:

Inclusive Criteria for Candidates with Spasticity of Spinal Cord Origin:

- Cerebral/brain disorders
 - Severe spasticity of cerebral origin with no more than mild athetosis; <u>AND</u>
 - The injury is older than one (1) year; AND
 - There has been a drop in Ashworth scale of one (1) or more; <u>AND</u>
 - Spasticity of cerebral origin is resistant to conservative management; or AND/OR
 - The <u>individual</u> candidate has a positive response to test dose of ITB-

OR

Inclusive Criteria for Candidates with Spasticity of Spinal Cord Origin:

Spinal cord disorders

- Spasticity of spinal cord origin that is resistant to oral antispasmodics or side effects unacceptable in effective doses: AND
- There has been a drop in Ashworth scale of two (2) or more; OR
- The <u>individual</u> candidate has a positive response to test dose of intrathecal baclofen.

Caution should be exercised when considering ITB infusion pump implantation for candidates who

- Have a history of autonomic dysreflexia; or
- Suffer from psychotic disorders;
- Have other implanted devices; or
- Utilize spasticity to increase function such as posture, balance, and locomotion

Consideration shall not be made if the candidate:

- Fails to meet any of the inclusion criteria;
- Is pregnant, or refuses or fails to use adequate methods of birth control;
- Has a severely impaired renal or hepatic function;
- Has a traumatic brain injury of less than one year pre-existent to the date of the screening dose:
- Has history of hypersensitivity to oral baclofen;
- Has a systematic or localized infection which could infect the implanted pump; or
- Does not respond positively to a 50, 75, or 100 mcg intrathecal bolus of baclofen during the screening trial procedure.

NOTE: The Plan shall cover outpatient bolus injections given to candidates for the ITB infusion treatment if medically necessary even if the member fails the screening trial procedure.

Prior authorization (PA) for chronic infusion of ITB shall be requested after the screening trial procedure has been completed but prior to the pump implantation. The request to initiate chronic infusion shall come from the multidisciplinary team which evaluates the member. The multidisciplinary team shall be comprised of the following:

- A neurosurgeon and/or an orthopedic surgeon;
- A psychiatrist and/or a neurologist;
- The member's attending physician;
- A nurse;
- A social worker; and
- Allied professionals (physical therapists, occupational therapist, etc.)

These professionals shall have expertise in the evaluation, management, and treatment of spasticity of cerebral and spinal cord origin and shall have undergone training in infusion therapy and pump implantation by a recognized ITB product supplier with expertise in intrathecal baclofen.

The multidisciplinary team shall evaluate the candidate after the screening trial procedure has been completed but prior to the pump implantation.

The following documentation must be submitted with the request for PA:

- A recent history with documentation of assessments in the following areas:
- Medical and physical;
- Neurological;
- Functional; and
- Psychosocial;
- Ashworth scores for pre and post administration of the ITB test dose(s); and
- Documentation of any other findings regarding the member's condition which would assist in determining medical necessity for ITB, i.e., a videotape of the trial dosage.

Coverage Limitations

<u>Humana Healthy Horizons in Louisiana members may NOT be eligible under the Plan for ITB infusion pump implantation for any of the following:</u>

- Does not respond positively to a 50, 75, or 100 mcg intrathecal bolus of baclofen during the screening trial procedure; OR
- Fails to meet any of the inclusion criteria; OR
- Has a severely impaired renal or hepatic function; OR
- Has a systematic or localized infection which could infect the implanted pump; OR
- Has a traumatic brain injury of less than one year pre-existent to the date of the screening dose; OR
- Has history of hypersensitivity to oral baclofen; OR
- Is pregnant, or refuses or fails to use adequate methods of birth control

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment when any of the above contraindications are present. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Page: 6 of 6

Definitions:

N/A

References

1. Louisiana Department of Health. Medicaid Services Manual. Chapter 5: Professional Services. https://ldh.la.gov/medicaid. Published February 1, 2012. Updated August 4, 2025.

Louisiana Department of Health Bureau Financing. 5.1 Intrathecal Baclofen Therapy (8/13/2024). Professional Services Chapter Five of the Medicaid Services Manual (2/1/2012). Accessed 10/22/2024.

Version Control:

Change Summary

08/22/2022: Policy creation-Approved by LDH for Readiness

05/15/2023: Approved by LA UM Committee

09/06/2023: Changed to new template for Annual Review Due by 5.15.24.

01/12/2024: Minor changes made.

10/1/2024: Annual Review

10/07/2025 Annual Review, No Coverage Change. New Clinical Coverage Policy Template

Non-Compliance:

Failure to comply with any part of Humana's policies, procedures, and guidelines may result in disciplinary actions up to and including termination of employment, services, or relationship with Humana. In addition, state and/or federal agencies may take action in accordance with applicable laws, rules, and regulations.

Any unlawful act involving Humana systems or information may result in Humana turning over all evidence of unlawful activity to appropriate authorities. Information on handling sanctions related to noncompliance with this policy may be found in the Expectations for Performance, and Critical Offenses policies, both of which may be found in the Associate Support Center via Humana's secure intranet on Hi! (Workday & Apps/Associate Support Center)