Department: Utilization Management	Policy and Procedure No:		
Policy and Procedure Title: Intrathecal Baclofen Therapy Clinical Coverage Policy			
Process Cycle: Annually	Responsible Departments: Clinical		
Approved By: Patricia Jones, RN	Issue Date: 1/1/23	Revised:	

<u>PURPOSE</u>: The purpose of this policy is to define Intrathecal Baclofen Therapy services and the criteria for medical necessity for Humana Healthy Horizons in Louisiana.

POLICY AND PROCEDURE:

Policy: Intrathecal Baclofen Therapy Clinical Coverage Policy

Procedure:

Intrathecal Baclofen Therapy

Surgical implantation of a programmable infusion pump for the delivery of intrathecal baclofen (ITB) therapy for individuals four years of age and older meet medical necessity for the treatment of severe spasticity of the spinal cord or of cerebral origin. The following diagnoses are considered appropriate for ITB treatment and infusion pump implantation with **one or more** of the following diagnosis:

- 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;
- 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

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

Inclusive Criteria for Candidates with Spasticity of Cerebral Origin

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- o There is severe spasticity of cerebral origin with no more than mild athetosis;
- The injury is older than one year;
- There has been a drop in Ashworth scale of 1 or more;
- Spasticity of cerebral origin is resistant to conservative management; or
- The candidate has a positive response to test dose of ITB.
- Inclusive Criteria for Candidates with Spasticity of Spinal Cord Origin
 - Spasticity of spinal cord origin that is resistant to oral antispasmodics or side effects unacceptable in effective doses;
 - o There has been a drop in Ashworth scale of 2 or more; or
 - The 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;
- 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 MCO 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 recipient. The multidisciplinary team shall be comprised of the following:

- o A neurosurgeon and/or an orthopedic surgeon,
- A physiatrist and/or a neurologist,

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- o The recipient's attending physician,
- o A nurse,
- A social worker,
- o 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 nationally 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 to the MCO:

- 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).
- Documentation of any other findings regarding the recipient's condition which would assist in determining medical necessity for ITB, i.e., a videotape of the trial dosage

ADDITIONAL RESOURCES:

Louisiana Department of Health, Louisiana Medicaid Managed Care Organization (MCO) Manual; Updated June 30, 2022. MCO Manual 2022-06-30.pdf (la.gov). Accessed August 16, 2022. Louisiana Department of Health, Louisiana Medicaid Managed Professional Services Manual, Chapter 5; Issued 02-01-2012. PS.pdf (lamedicaid.com). Accessed August 17, 2022.

VERSION CONTROL:

Version.Review.Approval History				
Department:	• • • • • • • • • • • • • • • • • • • •	Reviewed and Approved By:	Date:	Additional Comments:
Clinical	Policy Development	Tiffany LeBlanc	8/18/2022	

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Clinical	Policy Review	Patricia Jones/Cali	8/22/2022	
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Clinical	Policy Review	Dr. Ian Nathanson, VP	8/22/2022	
		Medicaid Clinical		
Clinical	Adoption Review	Medicaid Quality	8/25/2022	Committee approved. Ben
		Governance		Thompson, Committee Chair
		Committee		

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