BEST PRACTICES
IN SEVERE SPASTICITY

PANEL RECOMMENDATIONS
SUMMARY

Medtronic
Further, Together
METHODS

The ITB Therapy Best Practices Expert Consensus Panel included 21 multidisciplinary clinicians in private practice and academic medical centers in the United States who manage pediatric and adult patients with severe spasticity. Participants represented physical medicine and rehabilitation, neurology, orthopedic surgery, neurosurgery, physical therapy, and advanced nursing practice, and collectively had over 315 years of experience managing more than 3,200 patients with ITB therapy. Four working groups within the panel each focused on a key phase of ITB therapy management: patient selection, screening test administration, post-implantation dosing and long-term management, and therapy troubleshooting. The Best Practice Expert Consensus recommendations from each working group were further developed, approved by the full panel, and served as the basis for this and three other manuscripts.

This summary presents the recommendations of the Best Practices Expert Consensus Panel on patient selection, supported by a review of the medical literature. The utility of the recommendations must always be placed within the setting of local resources and expertise. Furthermore, the opinions of the group should not be construed as an attempt to define minimum standards or medically acceptable care.

For detailed recommendations on patient selection for ITB therapy, refer to Neuromodulation August 2016, Volume 19, Number 6 to find the complete article on Best Practices for Intrathecal Baclofen therapy: Patient Selection. That issue includes the other three companion articles on key aspects of ITB therapy.

Medtronic provided administrative and editorial support, and funding support for the panel workshop.

INDICATION FOR ITB THERAPY WITH LIORESAL® INTRATHECAL (baclofen injection)

ITB Therapy (Intrathecal Baclofen Therapy) is indicated for use in the management of severe spasticity. Patients should first respond to a screening dose of intrathecal baclofen prior to consideration for long term infusion via an implantable pump. For spasticity of spinal cord origin, chronic infusion of LIoresal® INTRATHECAL via an implantable pump should be reserved for patients unresponsive to oral baclofen therapy, or those who experience intolerable CNS side effects at effective doses. Patients with spasticity due to traumatic brain injury should wait at least one year after the injury before consideration of long-term intrathecal baclofen therapy.

Abrupt discontinuation of intrathecal baclofen, regardless of the cause, has resulted in sequelae that include high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure and death.

Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g., spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional postimplant clinician and patient information (see WARNINGS).

For more information, including the BOXED WARNING, refer to the Lioresal® Intrathecal (baclofen injection) prescribing information and the SynchroMed™ II Brief Statement included in this brochure.
Severe Spasticity

- The 2005 SPASM consortium description of spasticity should be adopted as the standard operational definition.
- Severe spasticity should be defined as any spasticity condition that is unduly troublesome/problematic to patients or caregivers.
- Consideration of intrathecal baclofen (ITB) therapy should be undertaken in all patients with inadequately controlled, problematic spasticity, in all phases of disease processes.
- Patients with spasticity due to traumatic brain injury should wait at least one year after the injury before consideration of long-term intrathecal baclofen therapy.
- For spasticity of spinal cord origin, ITB therapy via an implantable infusion system should be reserved for patients unresponsive to oral baclofen or those who experience intolerable CNS side effects at effective doses.
- Patients should demonstrate a positive response to an ITB therapy screening test.

Problematic Spasticity Management Options

- Spasticity management is not a linear or hierarchical process.
  - Application of various techniques is based on advantages and disadvantages of each method.
  - ITB therapy can be considered for individuals with severe spasticity, resulting from a variety of conditions, and best applied when problematic spasticity involves several muscles or muscle groups.
  - Techniques can be applied as monotherapy or in combination.
- ITB therapy must always be considered in the context of other factors affecting patients with spasticity, with cognitive ability being of paramount significance.

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Patient Selection Considerations

- ITB therapy can be an effective tool in improving ambulatory function in certain patients. Rehabilitative therapy should be applied concomitantly in ambulatory patients.
- ITB therapy is a highly effective tool for spasticity reduction in the pediatric population. The unique characteristics of this group require specialized attention, including baseline evaluations for scoliosis, hip status, hydrocephalus, and urodynamic status.
- While not a directly disease-modifying treatment, ITB should be considered early to potentially avoid or delay musculoskeletal and functional consequences of spasticity.
- Safety and effectiveness in pediatric patients below the age of four has not been established.
- This therapy is not for everyone. Results vary. Not every individual will receive the same benefits or experience the same complications.
Therapy Education and Treatment Goals

- Patient/family/caregiver education is a crucial process in ITB therapy. Centers must create a supportive instructive environment that uses all available resources to accomplish the education goals effectively.
- Goal setting is necessary for patients and clinicians to approach the usage of ITB therapy in a meaningful and effective way.
- Clinicians must consider the absolute and relative contraindications for ITB therapy and, if needed, develop appropriate strategies for addressing these issues.
- Relative contraindications include unrealistic goals, unmanageable mental health issues, psychosocial factors affecting compliance, and financial burden.

Discuss appropriate goals for function, participation, and Activities of Daily Living (ADLs)

| Potentially Achievable Goals with ITB Therapy                          |
|----------------------------------------------------------|-----------------------------|
| **Improved Body Functions and Structure**                  | **Improved Participation**  | **Improved Activities of Daily Living** |
| Improved skin integrity                                  | Improved endurance          | Improved ease of hygiene            |
| Improved standing capacity                               | Improved standing capacity   | Improved standing capacity          |
| Improved or maintained range of motion                    | Improved ambulation speed    | Improved ambulation speed            |
| Improved orthotic tolerance                              | Improved sitting balance/   | Improved quality of ambulation      |
|                                                          | tolerance                   |                                        |
| Reduced startle response                                 | Improved orthotic tolerance  | Improved sitting balance/tolerance   |
| Reduced musculoskeletal pain                             | Improved cosmesis            | Reduced falls                        |
|                                                          | Reduced need for oral       |                                        |
|                                                          | anti-spasticity medications  |                                        |

Goals should be considered within the framework of pathology, impairment, and disability.

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**Important Safety Information for ITB Therapy with Lioresal® Intrathecal (baclofen injection)**

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This therapy is contraindicated in patients who are hypersensitive to baclofen. Implantation of the infusion system is contraindicated if the patient is of insufficient body size, requires a pump implant deeper than 2.5 cm, or in the presence of spinal anomalies or active infection. The most frequent drug adverse events vary by indication but include: hypotonia (34.7%), somnolence (20.9%), headache (10.7%), convulsion (10.0%), dizziness (8.0%), urinary retention (8.0%), nausea (7.3%), and paresthesia (6.7%). Pump system component failures leading to pump stall, or dosing/programming errors may result in clinically significant overdose or withdrawal. Acute massive overdose may result in coma and may be life-threatening.

The most frequent and serious adverse events related to device and implant procedures are catheter dislodgement from the intrathecal space, catheter break-out, and implant site infection including menigitis. Electromagnetic interference (EMI) and magnetic resonance imaging (MRI) may cause patient injury, system damage, operational changes to the pump, and changes in flow rate. Delivery of more drug volume than the programmed rate (overinfusion) can result in unexpected overdose or withdrawal, caused by early emptying of the pump reservoir. Refer to the manufacturer’s pump manual and instructions for refilling the reservoir.

For more information, including BOXED WARNING, refer to the full Lioresal® Intrathecal prescribing information at lioresal.com/prescribinginformation.