BEST PRACTICES IN SEVERE SPASTICITY

PANEL RECOMMENDATIONS SUMMARY

Medtronic
Further, Together

Best Practices for Intrathecal Baclofen Therapy: Patient Selection. *Neuromodulation.* 2016;19: 607- 615.

Saulino M, Ivanhoe CB, McGuire JR, Ridley B, Shilt JS, Boster AL.

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.

SUMMARY OF PATIENT SELECTION BEST PRACTICES

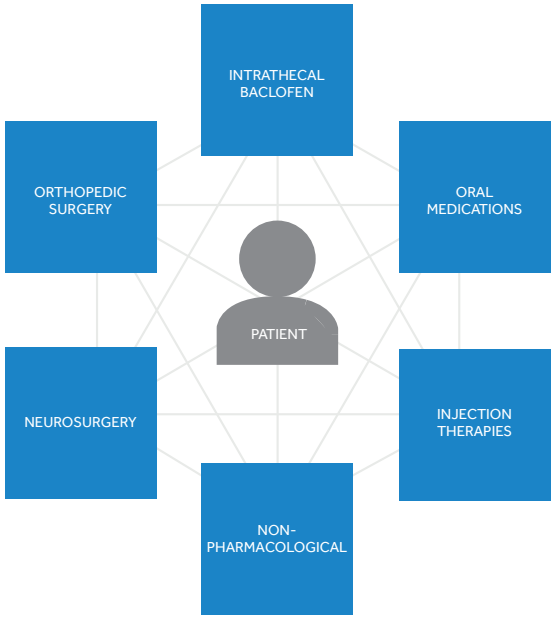
Severe Spasticity

- 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.

Severe Spasticity = Troublesome, problematic spasticity for patients and caregivers

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.

April

Receiving ITB therapy

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.

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.

Matt
Receiving ITB therapy

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/ tolerance	Improved quality of ambulation
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.

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.

SynchroMed® II Drug Infusion System Brief Statement:

Review product technical manuals, including information about EMI, and the appropriate drug labeling prior to use for detailed disclosure.

Indications: US: Chronic intrathecal infusion of Infumorph® preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, Prialt® chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of Lioresal® Intrathecal (baclofen injection) for the management of severe spasticity. Outside of US: Chronic infusion of drugs or fluids tested as compatible and listed in the product labeling.

Drug Information: Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration, screening procedures, and under-/overdose symptoms and methods of management. Patients should be informed of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions, and signs and symptoms that require medical attention.

Contraindications: System implant is contraindicated in the presence of an infection; implant depth greater than 2.5 cm below skin; insufficient body size; and spinal anomalies. Use of the system with drugs with preservatives and drug formulations with pH ≤3. Use of CAP kit for refills or of refill kit for catheter access and use of PTM to administer opioid to opioid-naïve patients.

Warnings: Non-indicated formulations may contain neurotoxic preservatives, antimicrobials, or antioxidants, or may be incompatible with and damage the system. Failure to comply with all product instructions, including use of drugs or fluids not indicated for use with system, or of questionable sterility or quality, or use of non-Medtronic components or inappropriate kits, can result in improper use, technical errors, increased risks to patient, tissue damage, damage to the system requiring revision or replacement, and/or change in therapy, and may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug under- or overdose.

An inflammatory mass that can result in serious neurological impairment, including paralysis, may occur at the tip of the implanted catheter. Clinicians should monitor patients carefully for any new neurological signs or symptoms, change in underlying symptoms, or need for rapid dose escalation. Monitor patients appropriately after refill if a pocket fill is suspected. Failure to recognize signs and symptoms of pocket fill and seek appropriate medical intervention can result in serious injury or death. Overinfusion may lead to underdose or overdose symptoms. Strong sources of electromagnetic interference (EMI) can negatively interact with the pump and cause heating of the implanted pump, system damage, or changes in pump operation or flow rate, that can result in patient injury from tissue heating, additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose. The SynchroMed II system is MR Conditional; consult the labeling for MRI information.

Precautions: Monitor patients after pump or catheter replacement for signs of underdose/overdose. Infuse preservative-free saline at minimum flow rate if therapy is discontinued for an extended period to avoid system damage. EMI may interfere with programmer telemetry during pump programming sessions.

Adverse Events: In addition to procedure-related risks, the following may occur: pocket seroma; hematoma; erosion; infection; pump inversion; post-lumbar puncture risks (spinal headache); CSF leak and rare central nervous system pressure-related problems; radiculitis; arachnoiditis; spinal cord bleeding/damage; meningitis; neurological impairment (including paralysis) due to inflammatory mass; allergic response to implant materials; surgical replacement due to end of service life or component failure; loss of therapy, drug overdose, or inability to program the pump due to component failure; catheter complications resulting in tissue damage or loss of or change in therapy; potential serious adverse effects from catheter fragments in intrathecal space.

For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com Infumorph® is a registered trademark of West-Ward Pharmaceutical. Prialt® is a registered trademark of TerSera Therapeutics LLC. Lioresal® is a registered trademark of Saol. USA Rx Only Rev 1118

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

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).

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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/cut, and implant site infection including meningitis. 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.

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Lioresal® Intrathecal (baclofen injection)
Prescribing Information

If missing, please visit
lioresal.com/prescribinginformation.

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