

Baclofen Pump Therapy for the Treatment of Spasticity

A Guide for Patients and Families

Physical Medicine & Rehabilitation



**University of Michigan
Health System**

Dear Patient and Family,

In the United States, an estimated 500,000 people have spasticity. Spasticity results in muscle spasm and stiffness that may be painful and interfere with activities of daily living. Common causes of spasticity are cerebral palsy, brain injury, spinal cord injury, stroke and multiple sclerosis. It is often possible to treat spasticity effectively with oral medications. In cases of severe spasticity that is not controlled with oral medications or when the patient has medication side effects, doctors may recommend a baclofen pump.

The FDA approved baclofen pump therapy in 1992. Since then more than 60,000 Medtronic baclofen pumps have been used worldwide to manage severe spasticity in children and adults. The University of Michigan was one of the centers that participated in the research trial that led to FDA approval. Thousands of baclofen pumps have been implanted in the United States.

At the University of Michigan Health System (UMHS) we use experts from many disciplines in the evaluation process and treatment of patients considered for baclofen pump therapy. Our experts bring years of research and clinical experience to the care of people with spasticity. Our team works together using the latest techniques to give you the best possible outcome from your baclofen pump.

This booklet will take you through the process of evaluation and treatment with a baclofen pump and inform you about what to expect during the process.

Thank you for considering UMHS for your baclofen pump therapy. We hope this information will be helpful to you and your family throughout your baclofen pump experience. We look forward to working with you.

Sincerely,

Department of Physical Medicine & Rehabilitation

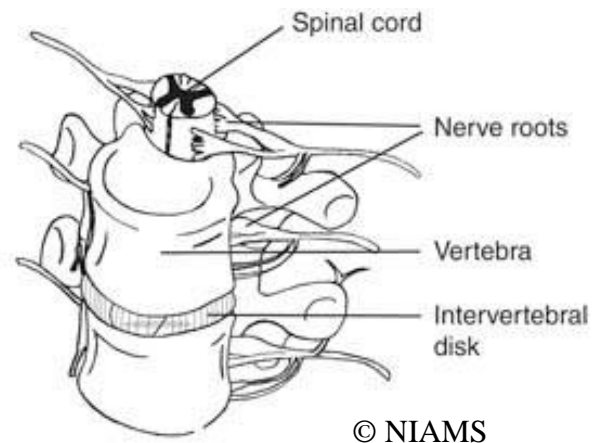
Department of Neurosurgery

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What is a baclofen Pump?

The pump is a device that delivers the drug, baclofen (brand names: Lioresal® or Gablofen®) to the spinal cord to control spasticity. Because the drug is delivered directly to the spinal cord, very small doses are just as effective at controlling spasticity as much larger doses taken by mouth (oral baclofen.) baclofen tablets are given in milligrams and baclofen by pump is given in micrograms. (1000 micrograms make one milligram.) The reason smaller dosages can be used with a pump is because the medication given in a tablet circulates in the blood stream before it reaches the spinal cord area. The pump delivers the drug into an area of the spinal cord called the intrathecal space. The intrathecal space contains the cerebrospinal fluid (CSF) the fluid that surrounds the spinal cord and nerve roots.



Section of the Spine

Some people have side effects such as drowsiness or seizures from oral baclofen. Most of the time oral medications and injections are tried before a pump is considered.

When baclofen is delivered into the intrathecal space, it inhibits or stops the spasticity messages from reaching the brain. With the implantation of a baclofen pump we hope to achieve the following:

- reduction of severe spasticity
- reduction in the need for oral anti-spasticity medications
- improved ability to perform activities of daily living
- easier caregiving
- improved comfort

Remember: the baclofen pump will not totally eliminate spasticity, and it will not cure the underlying disease.

Baclofen pump treatment can be expensive. For this reason it is important that you find out in advance what your insurance will cover, and how much you need to budget for your out-of-pocket cost. If you are considering baclofen pump therapy call your insurance company to find out exactly how much you will have to pay for your deductible and co-pays for the screening trial, the surgery to implant the pump and for the follow up care. Make this phone-call as soon as possible, before the screening trial takes place.

What is the Size of the Pump, and where is it placed?

The pump is almost 3.5 inches wide and about 3 ¾ inches long. The adult size is 1 inch thick. The pediatric pump is ¾ inch thick. The device manufacturer's booklet we provided you gives more detailed information about the pump and its size. In the clinic we have a demonstration pump that you can see and touch.

The pump and a catheter that delivers the medication will be implanted in your abdomen (belly), just below the skin layer. There will be nothing outside the skin after you heal, except for a scar.

What is the process of baclofen Pump Therapy?

Baclofen pump therapy has three phases

- 1) Screening trial
- 2) Surgery to implant the pump
- 3) Follow up, long term care

Phase One: The Screening Trial

What is the purpose of the trial?

Before considering you for implantation of the pump we need to check if your spasticity responds to baclofen delivered around your spinal cord. (This type of drug delivery is called **intrathecal** or **intraspinal** baclofen.) To find out you will receive a test dose of intrathecal baclofen. The trial will check if the spasticity responds to intrathecal baclofen and identify



potential side effects from the baclofen. Your response to baclofen will be compared to your individual goals for treatment. Examples of goals include increased comfort and/or improved positioning or walking. We will need your Informed Consent prior to the trial procedure.

If the trial reveals that the spasticity is not significantly reduced, or if you have serious side effects with the test dose, you will not be considered a candidate for a baclofen pump.

What happens during the pre-trial therapy evaluation?

Baclofen pre-trial evaluation takes approximately 2 hours and usually takes place the day before the baclofen screening trial procedure. The evaluation will include physical and occupational therapy evaluations. The evaluation will measure your level of muscle tone and function.

How is the screening trial performed?

A physiatrist and neuro-radiologist will perform the trial together. (A neuro-radiologist is a doctor with special training in imaging of the central nervous system which includes the spinal cord). The neuro-radiologist will perform a lumbar puncture (spinal tap) procedure to inject a small amount of baclofen around the spinal cord. For the lumbar puncture most patients lie on their abdomen (belly) and the doctor uses fluoroscopy in order to insert a needle between two lumbar vertebrae (spinal bones). The drug is delivered through the needle into the cerebrospinal fluid.

Fluoroscopy is a type of medical imaging that uses x-rays to obtain real-time moving images of internal structures in the patient's body.

Sedation or anesthesia are available for the lumbar puncture and injection.

If there is little or no response to the medication, you may need another screening trial with a higher dose.

What are the risks of the screening trial?

Risks from the lumbar puncture include:

- Nerve damage to legs, bowel or bladder. This is very rare.
- Infection, including meningitis
- Headache with nausea and vomiting for several days following the lumbar puncture

Risks from intrathecal baclofen include:

- Nausea and vomiting
- Too little muscle tone or floppiness
- Slow breathing rate (respiratory depression)
- Sleepiness or sedation
- Inability to empty the bladder (urinary retention)

What are the instructions for the day of the trial?

- Plan for the trial to last at least 6 hours.
- You may receive a call from anesthesia the day before the trial.
- Bring any equipment you use on a daily basis, such as braces, cane, wheelchair, and/or walker, to help in evaluating your level of muscle abilities.
- Take your usual medications, **except for the one dose of anti-spasticity medication** that you would normally take during the time of the evaluation. Bring anti-spasticity medication with you so you can take it after the testing is done.
- Check in at the front desk. The staff will direct you to the proper location. Your family will receive information as to how long they can stay at your bedside.
- Care partners or parents must remain either at your bedside or at the waiting room the entire time until you are discharged.

What can I expect at the Screening Trial?

- Care partners and parents can stay at your bedside for most of the trial, except for the time of the lumbar puncture (spinal tap) procedure. You may invite your physical therapist, occupational therapist, nurse or family member to come at the peak of the trial to observe the effects. The peak of the trial is usually 4 hours after the injection.
- We will ask you to sign a consent that lists the risks for the lumbar puncture and baclofen injection.
- One of our staff will take you into the procedure room and help you get into a comfortable position.
- Most patients will receive a numbing injection in lower back.
- The doctor will inject the baclofen into your spine. After the injection the needle will be removed.

- Your family will be allowed to join you again after the spinal tap procedure is completed.
- For the first two hours after the injection you will lie flat. You will not be able to eat or drink during this time.
- After about two hours, you will be allowed to sit up and eat or drink as tolerated.
- Approximately 3 to 4 hours after the injection, you will have post-trial physical and occupational therapy evaluations.
- Before you leave the hospital the nurse will talk with you about the results of the trials and what the next steps are.
- Baclofen may relax the bladder muscles and make it difficult to urinate. We like to ensure that you have urinated before you leave.

What are the instructions after discharge from the trial:

Effects of the drug are temporary and usually go away within 8 to 24 hours of injection. Side effects may include drowsiness, nausea, vomiting, dizziness, headache, or loose muscles. You will receive detailed discharge instructions on the day of trial but here are some important points:

- After the trial, it is important to drink plenty of fluids, return to your normal foods and plan to rest for 24 hours.
- Headaches can develop, which could be related to cerebrospinal fluid leaking at the injection site (this is called a spinal headache). If you develop a headache, it is important that you keep your head down by lying flat, getting up slowly only to use restroom. Drinking plenty of fluids can help to relieve the headache.
- You may resume your usual medications the evening of the trial.
- Call PM&R if you have the following symptoms:
 - severe headache
 - redness, swelling, or drainage at the puncture site
 - fever over 101 degrees

During regular business hours call PM&R 734 936 -7175. After business hours and on weekends and holidays call 734-936-6267 and ask for the PM&R resident on call.

Phase Two: Surgery to Implant the Baclofen Pump

If the spasticity is well-controlled during the screening trial and there are no other medical concerns, the next step is to meet with the neurosurgeon. Your Physical Medicine and Rehabilitation (PM&R) provider will assist you in obtaining the appointment with the neurosurgeon.

What can I expect during the neurosurgery evaluation?

The purpose of the neurosurgery evaluation is to meet the surgeon and review your health status and candidacy for pump implantation. The neurosurgeon will discuss the benefits and risks of the procedure with you and your care partners. If there are no barriers for surgery, the neurosurgery clinic staff will schedule your surgery.

How is the surgery to implant the baclofen pump performed?

This surgery usually lasts between 2 to 3 hours. In most cases it is performed under general anesthesia. The neurosurgeon will make an incision and place the pump just under the skin of your lower abdomen (belly). The pump will be connected to a thin, flexible silicone tube called a catheter. The catheter is threaded beneath the skin into the intrathecal space around the spinal cord, into which it will deliver the medication.

What are the risks and Complications?

Baclofen pump placement has certain risks and complications, including failure to obtain relief of spasticity, need for further surgery or death. The risks and complications may result from the surgery to implant the pump, from mechanical problems of the pump or from the medication delivered through the pump.

Risks related to the surgery to implant the baclofen pump include but are not limited to:

- Infection that may require the pump to be removed.
- Bleeding that may lead to an accumulation of fluid in the pump pocket site.
- Damage to nerves. This can lead to problems such as weakness or paralysis in the legs, bladder or bowel problems or impotence.
- Cerebrospinal fluid leakage resulting in a spinal headache or accumulation of fluid in the pump pocket site.

- Pain and tenderness at the incision sites. This almost always goes away.

Mechanical complications of the pump system include, but are not limited to:

- Movement of the catheter into and out of the insertion site. This is called dislodgement.
- Leaking or kinking of the catheter.
- Programming errors or refill errors that lead to severe under dose or overdose of medication.
- Discomfort or problems in the pump pocket site.
- Mechanical problems may lead to sudden medication withdrawal. Symptoms of medication withdrawal include: itching, spastic or rigid muscles, blood pressure changes, high fever, altered mental status and/or seizures. You will receive a prescription for oral baclofen tablets to use in an emergency, if the baclofen pump fails. This will be discussed later in more detail.

Side effects of baclofen medication:

Those include loose muscles, drowsiness, nausea or vomiting, headache, dizziness or lightheadedness. Serious side effects such as slow breathing rate (respiratory depression), seizures, and loss of consciousness are rare.

See page 16 for a quick guide for identifying side-effects, and information about when and who to call if you have side effects.

Phase Three: Long Term Care for Baclofen Pump Therapy

What can I expect after baclofen pump placement?

You will return to the neurosurgery or PM&R clinic about two weeks after surgery for a check of your wound and condition.

Baclofen Pump Dose Adjustments

After the pump is implanted there will be a transition phase to determine the exact dosage you need to relieve spasticity. During this phase we will gradually reduce other medications so we can determine the appropriate pump dose you need. You may not have maximum

spasticity or rigidity relief during this transition. We may need to see you frequently at the clinic during this time of medication adjustment so we can monitor your health and address any issues that may occur.

Medtronic Patient Identification Card:

The Medtronic Company will mail you a card with the model and serial number of your pump. Keep this card with you at all times. It shows that you have an implanted medical device, and will be useful in case of an emergency. You will also need it when going through security at airports.

If you do not receive a card in the mail contact Medtronic: 1-800-510-6735.

More information about the Medtronic Patient Identification card is available at:

<http://www.medtronic.com/patients/severe-spasticity/living-with/product-support/index.htm>

Some people like to have medical alert jewelry in addition to the card. Many commercial companies offer medical bracelets and jewelry. The MedicAlert Foundation is a non-profit organization that offers medical ID's and bracelets to its members. More is available at <http://www.medicalert.org/> or phone number 1-888-633-4298.

What are the instructions while I am receiving baclofen pump therapy?

The PM&R team will manage your long term care while you receive baclofen through the pump. We will refer to this team as “your pump management provider” in the remainder of the booklet.

- Avoid alcohol or mood-altering drugs while you are receiving baclofen pump therapy.
- Carry your Pump I.D. Emergency Notification card with you at all times. Inform family and friends about the emergency cards and procedures. Program the Medtronic phone number into your phone, tablet or other electronic device.
- Use caution when operating a motor vehicle. It is your responsibility not to drive if you are having drowsiness, sleepiness or other side effects that may impact your driving.

- For many, follow-up may include participating in physical and/or occupational therapy. This is an important part of your treatment to optimize your function. Therapy usually begins 6 to 8 weeks after your pump has been implanted.
- X-rays or CT scans will not damage your pump. However, certain tests or procedures, such as **MRI**, may damage your pump or result in drug overdose or underdose. Your pump management doctor needs to clear all medical procedures such as diathermy, radiation therapy, hyperbaric treatment or lithotripsy. Consult with your pump management doctor before undergoing any medical tests or procedures.
- **Avoid** the following activities:
 - Scuba diving below 30 feet
 - hot tub warmer than 102 degrees
 - tanning booths
 - sky jumping or diving

Consult with your surgeon before participating in extreme sports.

Special precautions before you have Magnetic Resonance Imaging (MRI)

MRI **will temporarily** stop the pump motor and you will not receive any medication. Once the person is removed from the MRI machine, the pump should resume normal operation, but there is a slight chance there may be a delay in the return of proper pump motor function after an MRI. For this reason you must make sure that your pump management provider checks your pump within two hours after the MRI. Call the PM&R office if you are going to have an MRI.

Oral baclofen supply for urgent use

You will receive a prescription for oral baclofen tablets to use in an emergency, if the baclofen pump fails. There will be directions on the bottle, so you will be safe taking the correct dose. Keep the bottle available at home and take it with you when you leave home for more than a day.

Battery Replacement

The pump has a lithium battery with a service life of six (6) years. The battery must to be replaced before it reaches the end of the six year service-life period.

Pump Refills

Pump refills are completed according to protocol under the supervision of your pump management doctor at the PM&R clinic. Timing of refills can be every few months, but no more than 6 months apart, depending on your medication dose. Expect to spend about 60 minutes at your refill appointment.

Pump Alarms

The pump will alarm if it needs to be refilled, if it malfunctions or if the battery reaches end-of-service. There are two types of alarms:

- a non-critical alarm with a single tone sound
- a critical alarm with multi-tone sound

You can hear the alarms at the Medtronic website:

<http://www.medtronic.com/patients/severe-spasticity/living-with/product-support/index.htm>

Call your PM&R pump management doctor **immediately** whenever you hear the pump alarm.

Who will I contact if I have problems or questions?

Contact information for Physical Medicine and Rehabilitation:

Rita Ayyangar MD

Liza Green MD

Virginia Nelson MD

Joseph Hornyak MD

Edward Hurvitz MD

Margy Fox MS, RN

During regular business hours call 734-936-7175

After hours and for urgent matters call: 734-936-6267 and ask for the Physical Medicine and Rehabilitation doctor on call.

Physical Medicine and Rehabilitation Website: <http://www.med.umich.edu/pmr/>

Location: Burlington Office Center, 325 East Eisenhower, Suite 100, Ann Arbor, MI 48109

Contact information for Neurosurgery:

Pediatric Neurosurgery

During regular business hours call

734-615-0536

Hugh Garton MD

Bela Seltzer RN, PNP

Tara Egnor RN NP

Jennifer Nordin RN, NP

Adult Neurosurgery:

During regular business hours call:

734-936-9593

Oren Sagher, MD

Parag Patil, MD

Donna Rossini, RN, NP 734-936-7010

Susan Grube RN MSN 734-936-7010

To reach pediatric or adult neurosurgery after hours and for urgent matters call: 734-936-6267 and ask for the Neurosurgery doctor on call

Website: <http://www.med.umich.edu/neurosurgery/>

Additional helpful tips

Privacy Laws

If you would like a friend or family member to be involved in verbal discussions regarding your health care, you or your guardian can complete a “Family and Friends List” form.

<http://www.med.umich.edu/i/policies/umh/01-04-312.htm>

Local Accommodations

- The Patient and Visitor Hotel Accommodations Program can locate and reserve hotel accommodations near the University Hospital for patients and families. Hotels offer preferred rates when reservations are made through the program.
- Some funding for lodging may be available through your insurance plan. Please check with your insurance plan to see what is covered.
- For reservations or for more information, contact the Patient and Visitor Hotel Accommodations Program at 800-544-8684 or 734-936-0135 or visit their Website at <http://www.med.umich.edu/hotels>.

Additional information from Medtronic

Medtronic has a website with information for people on baclofen pump therapy:

<http://www.medtronic.com/patients/severe-spasticity/>

Disclaimer: This document contains information and/or instructional materials developed by the University of Michigan Health System (UMHS) for the typical patient with your condition. It may include links to online content that was not created by UMHS and for which UMHS does not assume responsibility. It does not replace medical advice from your health care provider because your experience may differ from that of the typical patient. Talk to your health care provider if you have any questions about this document, your condition or your treatment plan.

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Quick guide to identify side effects, overdose or withdrawal of baclofen

(copy this page for care providers, school personnel, others)

Following is a list of side-effects that may affect people on baclofen pump therapy. If you have mild side-effects call your pump management doctor as soon as possible. **If you have severe symptoms of overdose or withdrawal** go to your nearest emergency room as soon as possible.

Baclofen Side Effects

- Loose muscles
- Drowsiness
- Nausea, vomiting
- Headache
- Dizziness/lightheadedness

Baclofen Overdose

- Severe drowsiness
- Dizziness/lightheadedness
- Slow and shallow breaths
- Loss of consciousness
- Seizures

Baclofen Withdrawal

- Itching
- High fever
- Low blood pressure
- Tingling sensations
- Altered mental status
- Severe spasticity or muscle rigidity

If you are having withdrawal symptoms locate your oral baclofen back up supply and follow the instructions on the bottle.

Contact Information for Physical Medicine and Rehabilitation:

Rita Ayyangar MD

Liza Green MD

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Joseph Hornyak MD

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