Medtronic

Control Workflow™

An approach to help eliminate systemic opioids and provide effective pain relief



Purpose of workflow

The Control Workflow™ approach provides a treatment option for chronic pain, using low-dose targeted drug delivery (TDD). Patients should receive appropriate pain treatment based on careful consideration of the benefits and risks of treatment options.

TDD has demonstrated a substantial reduction in the amount of drug required to effectively manage chronic pain.[1,2] By having an outlined workflow, we are hoping to reduce perceived barriers to this therapy.



Help eliminate systemic opioids

Titrate to the lowest effective dose for the patient

Treat an underserved patient population

Patient selection

Although TDD can be used for many different types of pain, consider this selection criteria for the workflow:

- **Minimum visual analogue scale (VAS) score of five**
- **Intolerable side effects with systemic medication or not meeting CDC systemic dose recommendation[3]**

Potential patient profile

- **Failing systemic opioids**
  - intolerable side effects
  - inadequate pain relief
- **Elderly, opioid-naive patients**

Pain etiology examples:

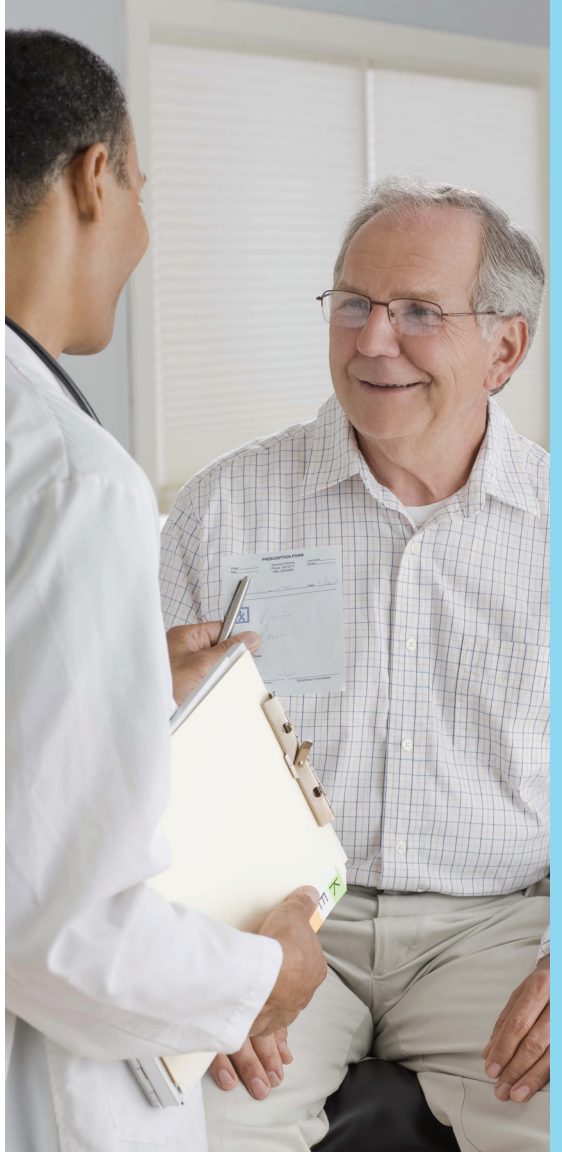
- **Chronic compression fractures, diffuse degenerative disc disease (DDD), spinal stenosis**
- **Failed back surgery syndrome (FBSS), chronic low back pain (CLBP), primary nociceptive pain**
- **Abdominal pain (e.g. chronic pancreatitis[4])**

Weaning conversation[1]

The Grider study suggests that an opioid taper and an opioid-free period:

- **May improve long-term analgesia versus a combination of oral/intrathecal drug delivery**
- **May help to maintain analgesia at microgram doses**
- **May enable a reversal of opioid tolerance in six weeks**

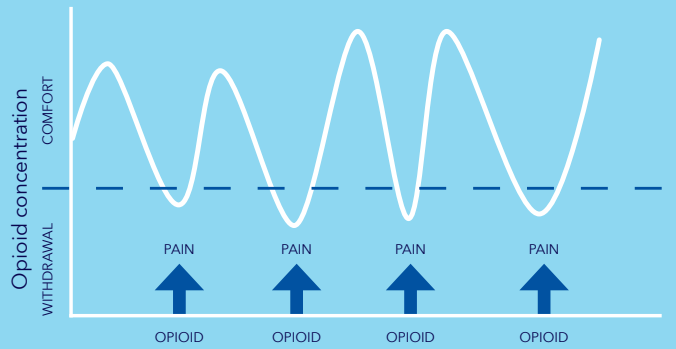
Patients who are already opioid naive do not require a wean.



There is evidence to suggest that in chronic pain patients using long-term opioid therapy (LTOT=long-term opioid therapy, generally in reference to oral opioids) vs. nonopioid medication, there was no meaningful long-term improvement in chronic pain symptoms or quality of life between patients on LTOT vs. nonopioid medications.[5]

In fact, the available evidence is insufficient to determine the efficacy of LTOT for improving chronic pain and function.[6]

Opioid withdrawal-mediated pain



Visual interpretation of pain-opioid withdrawal process, as described in Grider et. al., 2011[1]

Weaning protocol

A 100% taper of systemic opioid medication and a drug "holiday" will allow you to titrate to the lowest effective dose and manage dose escalation.[2,7] The opioid holiday has been shown to drive lower initial doses compared to similar studies without a holiday.[7,8,9]

100% taper

Tailor the duration and steps of taper to the individual patient.

Opioid holiday

Appropriate for your patient up to six weeks.



Trialing

The goal of the trial is to establish the patient's response to intrathecal opioids. Once the pump is in place, it may take several months to optimize drug delivery.

There are multiple trialing options. If you are considering this workflow, use this option:

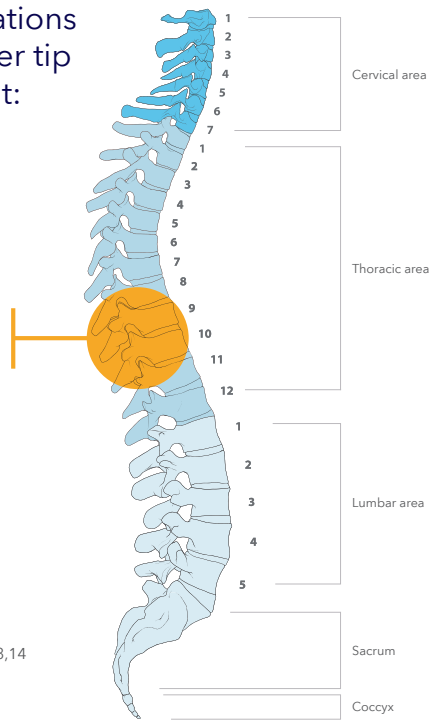
- **Single bolus of up to 250 mcg morphine,[2,10] consider using 1 cc of solution by barbotage. (1–2 cc of CSF aspirated, repeated 2–4 times)**
- **If catheter is used, consider posterior catheter tip placement**

Considerations for a successful trial[2,11]:

- **50% pain relief**
- **Documented functional improvement**
- **Confirmation of improvement from family member or significant other**

Implant

Considerations for catheter tip placement:



Expected location of receptors for back pain[2,7,12]: T9–T12

Consider posterior catheter tip placement[13,14]

Initiating therapy:

- **Start at trial dose.**
- **When considering drug concentration, think about pump size and refill date.**

Infusion protocols

Simple continuous dosing

- **Start at trial dose**
- **10% daily dose per myPTM™ bolus once patient is no longer opioid naive**
- **Two-hour lockout**
- **Adjust boluses as needed to cover pain**

Flex dosing

- **Use trial dose as dose constant**
- **Program to minimum basal rate**
- **50% of remaining daily dose delivered one hour prior to patient's normal wake-up time over the most rapid programmable duration**
- **Remaining 50% of daily dose delivered 12 hours later over the most rapid programmable duration**
- **Adjust boluses as needed to cover pain**

Titration is based on overall assessment

Patient follow-up suggestions

Follow-up is key to therapy success:

- **Meet with the patient every three months, or more often if needed.**
- **Schedule four-week follow-up after every dose adjustment.**
- **Complete a neuro exam at every three-month visit to check for possible inflammatory mass.**
- **Avoid routine dose escalation.**
- **Titrate as needed to achieve optimal therapy efficacy.**



Safe access to MRI scans

The SynchroMed™ III pump was designed to be safe for patients who may require an MRI scan.

- **1.5T and 3.0T MR-conditional†**
- **Designed to resume therapy after MRI scan**
- **Must interrogate the pump post MRI to ensure normal operation has resumed‡**
- **Pump does not need to be emptied prior to scan.**

MR †Under specific conditions for 1.5T and 3.0T MRI scans. Consult the labeling for MRI information.
‡Requires interrogation to confirm pump status.



TDD safety

Enhanced design, Increased reliability

At Medtronic, we are dedicated to continuously enhancing our pump's performance and reliability through ongoing product improvements. The SynchroMed™ III Pump was equipped with the following durable design updates.

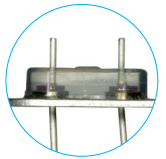
Equipped with durable design updates



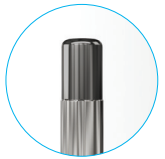
2011
Battery coating added



2015
Gear wheel 3 material change



2015
Feedthroughs encapsulated



2017
Diamond-like carbon (DLC) coating added

Safety protocols enable you and your team to react quickly and effectively to potential concerns.

Whenever initiating a bolus or dose adjustment, make sure to monitor the patient for adverse reactions.

Control Workflow™ potential safety benefits:

- **The severity of a pocket fill may be lower due to the reduced drug concentration.**
- **The severity of adverse events may be reduced due to the decreased drug concentration.**

Education and patient support

Our tailored and varied medical education offerings help you stay current and learn about new technologies and techniques. Cutting-edge clinicians help their practices stay competitive and improve patient care.

Medtronic supports patients by offering opportunities to connect with people, either by telephone or at our Therapy Awareness Partnership Programs (TAPs). For patients, live conversations and a mobile phone app provide the opportunity to ask focused questions and to gain information so they can be confident in their therapy decision.



Notes

Notes

References

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Simple, safe and effective intrathecal therapy made possible by the SynchroMed™ III implantable infusion system

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For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

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