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Referral guidelines for intrathecal drug delivery

Intractable cancer pain management

Patients with cancer are often reluctant to report the extent of their pain and, therefore, are at a particularly high risk for undertreatment of pain. Unfortunately, unrecognized pain is untreated pain; as a result, among outpatients with metastatic disease, 1 in 3 will have pain that interferes with the way they live.[1] The cost of inadequate pain control and related side effects (of pain medications) is high, both in terms of impaired function and quality of life.[2-4] For many patients, oral analgesics may be adequate; however, those cancer patients with intractable pain who meet any of the criteria listed to the right may be appropriate for more advanced pain management techniques. Consider referring those patients to a pain management specialist for an evaluation and to learn about options for chronic pain control using intrathecal opioids. Pending a successful intrathecal opioid trial, a permanent intrathecal catheter and Medtronic SynchroMed™ programmable pump could be implanted for chronic pain control.

Continued SynchroMed™ pump and pain management can then be conducted at:

Referrals for intrathecal analgesia, or pain management evaluations, should be directed to:

Criteria:

1. Symptoms of pain due to advanced stage cancer at presentation
2. Refractory to conventional pain management because of intractable drug adverse effects or unsatisfactory analgesia[3-6]
3. Visual analog scale (VAS) of ≥ 5
4. Consider early evaluation of intrathecal drug delivery

Note: It is important to consider increased assessment and referral vigilance for women, minorities, and the elderly, who have been shown to be at increased risk for inadequate analgesia.[1,2,7-9]

References:

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4. Stearns L, Boortz-Marx R, Du Pen S, Friehs G, et al. Intrathecal drug delivery for the management of cancer pain: a multidisciplinary consensus of best clinical practices. *J Support Oncol.* 2005;3(6):399-408.

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7. Carr D, Goudas L, Lawrence D, et al. Management of cancer symptoms: pain, depression, and fatigue. Evidence Report/Technology Assessment No. 61 (Prepared by the New England Medical Center Evidence-based Practice Center under Contract No 290-97-0019). AHRQ Publication No. 02-E032. Rockville, MD: Agency for Healthcare Research and Quality. July 2002. Downloaded at http://www.ahrq.gov/clinic/epcsums/csympsum.htm on 04/22/2009.

8. Bernabei R, Gambassi G, Lapane K, Landi F, et al. Management of pain in elderly patients with cancer. *JAMA.* 1998;279(23):1877-1882.

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SynchroMed™ 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 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; pump migration; 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

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