

# Health Quality Ontario

## Intrathecal Drug Delivery Systems for Cancer Pain and Noncancer Pain: OHTAC Recommendation

### ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE RECOMMENDATIONS

- OHTAC recommends against the expansion of public funding for intrathecal drug delivery systems for patients with chronic pain due to advanced cancer
- OHTAC recommends against the expansion of public funding for intrathecal drug delivery systems for patients with chronic non-malignant back pain

### BACKGROUND

Cancer is the leading cause of death in Canada: it was associated with an estimated 76,600 deaths in 2014.<sup>1</sup> About two thirds of patients with incurable cancer experience pain.<sup>2</sup> At the end of life, about 10% to 30% of cancer patients receiving conventional pain therapies have pain that is refractory (difficult to manage) or persistent.<sup>2</sup> Currently available options include opioid rotation, parenteral infusions, neuraxial analgesia, nerve blocks, and surgery. Refractory pain and concerns about side effects drive the search for alternative pain management options in cancer patients.

Reliable estimates of the prevalence of refractory noncancer chronic pain are difficult to find. Options available to treat refractory pain include non-opioid analgesic medications, opioid analgesics, neuraxial analgesia, nerve blocks, and surgery, as well as multidisciplinary rehabilitation programs.<sup>3</sup>

Intrathecal drug delivery systems provide pain relief by direct infusion of medication into the cerebrospinal fluid. To see how effective intrathecal drug delivery systems are, we looked at studies comparing them with routine pain management, or with routine pain management plus a rehabilitation program.

[ABOUT OHTAS](#)

Contact us: [Evidence@hqontario.ca](mailto:Evidence@hqontario.ca)

## SUMMARY OF FINDINGS

The health technology assessment completed by Health Quality Ontario and its research partners is available in two separate reports.<sup>4,5</sup> Completed decision determinants frameworks are included in this report.

These were the key findings of the health technology assessment:

- Very low quality evidence suggests that intrathecal drug delivery systems results in fewer drug-related side effects, with no difference in cancer pain, compared with comprehensive pain management
- Very low quality evidence suggests that intrathecal drug delivery systems improve noncancer pain, but not quality of life, compared with conventional medical management
- Cost-effectiveness could not be established owing to the poor quality of evidence
- The estimated budget impact for implementation in Ontario is \$100,000 in the first year to \$500,000 in fifth year for cancer pain, and \$1.5 million in the first year to \$5.0 million in fifth year for noncancer pain

## OHTAC DELIBERATIONS

The Ontario Health Technology Advisory Committee (OHTAC) accepted the findings of the health technology assessment.

OHTAC members acknowledged that some patients may benefit from intrathecal drug delivery systems. However, given the very low quality of evidence, OHTAC members felt that they could not support widespread adoption of the technology beyond the current status in Ontario. OHTAC members also felt that the evidence was not sufficiently conclusive to definitively recommend against public funding.

## Decision Determinants for Intrathecal Drug Delivery Systems for Cancer Pain

Decision Criteria	Subcriteria	Decision Determinants Considerations
<b>Overall clinical benefit</b> How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	<b>Effectiveness</b> How effective is the health technology/intervention likely to be (taking into account any variability)?	We found very low quality evidence that intrathecal drug delivery systems added to comprehensive pain management reduce overall drug toxicity; no significant reduction in pain scores was observed
	<b>Safety</b> How safe is the health technology/intervention likely to be?	The risk of serious procedure- or equipment-related harms over a 4-week period may be as low as 14% or as high as 38%
	<b>Burden of illness</b> What is the likely size of the burden of illness pertaining to this health technology/intervention?	According to expert opinion, the number of surgeries that can be performed per year is 5 and could increase to 30 in 5 years (Dr. Catherine Smyth, personal communication, September 2, 2015)
	<b>Need</b> How large is the need for this health technology/intervention?	There is an unmet need for this technology for a subgroup of cancer patients with persistent severe pain or serious drug toxicity (about 1,600 <sup>a</sup> patients annually)
<b>Consistency with expected societal and ethical values<sup>b</sup></b> How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	<b>Societal values</b> How likely is the adoption of the health technology/intervention to be congruent with expected societal values?	Very likely
	<b>Ethical values</b> How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	Very likely
<b>Value for money</b> How efficient is the health technology likely to be?	<b>Economic evaluation</b> How efficient is the health technology/intervention likely to be?	Unclear: evidence is insufficient and of inadequate quality to address this question
<b>Feasibility of adoption into health system</b> How feasible is it to adopt the health technology/intervention into the Ontario health care system?	<b>Economic feasibility</b> How economically feasible is the health technology/intervention?	Adoption of technology appears to be feasible, resulting in a budget impact of between \$100,000 and \$500,000 per year for the first 5 years
	<b>Organizational feasibility</b> How organizationally feasible is it to implement the health technology/intervention?	Neuraxial analgesia requires ongoing monitoring and committed resources. Intrathecal drug delivery care teams should consist of interventional pain physicians, nurses, palliative care physicians, pharmacists, and primary care providers

<sup>a</sup>Derived from the closest available statistics: 26,076 people died of cancer in Ontario in 2009; 64% of advanced cancer patients experience some pain, of which 10% may be refractory;  $26,076 \times 0.64 \times 0.1 = 1,669$ .<sup>2,6,7</sup>

<sup>b</sup>The anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

## Decision Determinants for Intrathecal Drug Delivery Systems for Noncancer Pain

Decision Criteria	Subcriteria	Decision Determinants Considerations
<b>Overall clinical benefit</b> How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	<b>Effectiveness</b> How effective is the health technology/intervention likely to be (taking into account any variability)?	Very low quality of comparative observational evidence showed internally inconsistent results. Reduction in pain with intrathecal drug delivery systems did not translate into global treatment satisfaction or improved quality of life and well-being
	<b>Safety</b> How safe is the health technology/intervention likely to be?	The incidence of serious adverse events requiring surgical treatment owing to device-related issues (e.g., catheter migration, catheter obstruction, pump failure) varied from 10% to 33% (across six case series) <sup>8</sup>
	<b>Burden of illness</b> What is the likely size of the burden of illness pertaining to this health technology/intervention?	According to expert opinion, the number of surgeries that can be performed per year is 30–50 (Dr. Anuj Bhatia, personal communication, September 3, 2015) and could increase to 100–200 in 5–10 years
	<b>Need</b> How large is the need for this health technology/intervention?	Reliable estimates of the prevalence of refractory noncancer chronic pain were unclear
<b>Consistency with expected societal and ethical values<sup>a</sup></b> How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	<b>Societal values</b> How likely is the adoption of the health technology/intervention to be congruent with expected societal values?	Unclear
	<b>Ethical values</b> How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	No major concerns; quite likely
<b>Value for money</b> How efficient is the health technology likely to be?	<b>Economic evaluation</b> How efficient is the health technology/intervention likely to be?	The cost-effectiveness evidence was of insufficient quality to allow any assessment of the appropriateness of funding the procedure in this population
<b>Feasibility of adoption into health system</b> How feasible is it to adopt the health technology/intervention into the Ontario health care system?	<b>Economic feasibility</b> How economically feasible is the health technology/intervention?	Unclear. The budget impact is estimated to be \$1.5 million in the first year and to increase to \$5.0 million per year in the fifth year
	<b>Organizational feasibility</b> How organizationally feasible is it to implement the health technology/intervention?	Neuraxial analgesia requires ongoing monitoring and committed resources. Intrathecal drug delivery care teams should consist of interventional pain physicians, nurses, palliative care physicians, pharmacists, and primary care providers

<sup>a</sup>The anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

## REFERENCES

- (1) Canadian Cancer Society. Canadian cancer statistics 2014. Special topic: skin cancers [Internet]. Toronto (ON): The Society; 2014 [cited 2014 Jul 10]. Available from: <http://www.cancer.ca/~media/cancer.ca/CW/cancer%20information/cancer%20101/Canadian%20cancer%20statistics/Canadian-Cancer-Statistics-2014-EN.pdf>
- (2) Smyth CE, Jarvis V, Poulin P. Brief review: Neuraxial analgesia in refractory malignant pain. *Can J Anaesth*. 2014;61(2):141-53.
- (3) Guzman J, Esmail R, Karjalainen K, Malmivaara A, Irvin E, Bombardier C. Multidisciplinary rehabilitation for chronic low back pain: systematic review. *BMJ*. 2001;322(7301):1511-6.
- (4) Ottawa Hospital Research Institute, University of Ottawa, and Health Quality Ontario. Intrathecal drug delivery systems for cancer pain: a health technology assessment. *Ont Health Technol Assess Ser* [Internet]. 2016 January;16(1):1-51. Available from: <http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/hta-cancer-pain>.
- (5) Ottawa Hospital Research Institute, University of Ottawa, and Health Quality Ontario. Intrathecal drug delivery systems for noncancer pain: a health technology assessment *Ont Health Technol Assess Ser* [Internet]. 2016 January;16(2):1-77. Available from: <http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/hta-noncancer-pain>.
- (6) Cancer Care Ontario. Incidence and mortality in Ontario. Deaths for cancers by sex, Ontario, 2009 [Internet]. Toronto (ON): Cancer Care Ontario; 2014 [cited 2014 Jun 10]. Available from: <https://www.cancercare.on.ca/cms/One.aspx?portalId=1377&pageId=121950#two-tab>
- (7) Ripamonti CI, Bandieri E, Roila F. Management of cancer pain: ESMO Clinical Practice Guidelines. *Ann Oncol*. 2011;22 Suppl 6:vi69-77.
- (8) Intrathecal fentanyl for chronic nonmalignant pain [structured abstract]. *Health Technol Assess*. 2005;1:19.

**Permission Requests:** All inquiries regarding permission to reproduce any content in Health Quality Ontario reports should be directed to [EvidenceInfo@hqontario.ca](mailto:EvidenceInfo@hqontario.ca).

**About Health Quality Ontario**

**About OHTAC**

**How to Obtain OHTAC Recommendation Reports From Health Quality Ontario**

Health Quality Ontario  
130 Bloor Street West, 10<sup>th</sup> Floor  
Toronto, Ontario  
M5S 1N5  
Tel: 416-323-6868  
Toll Free: 1-866-623-6868  
Fax: 416-323-9261  
Email: [EvidenceInfo@hqontario.ca](mailto:EvidenceInfo@hqontario.ca)  
[www.hqontario.ca](http://www.hqontario.ca)

**Citation**

Health Quality Ontario. Intrathecal drug delivery systems for cancer pain and noncancer pain: OHTAC recommendation [Internet]. Toronto (ON): Queen's Printer for Ontario; 2016 January. Available from: <http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/cancer-noncancer-pain>.