CADTH REIMBURSEMENT REVIEW

Patient and Clinician Group Input

Nab-paclitaxel

Non-Sponsored

Indication: In combination with gemcitabine for the adjuvant treatment of pancreatic cancer.

April 22, 2024

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CADTH in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings.

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CADTH Reimbursement Review

April 24, 2024

Name of Drug: Nab-Paclitaxel

Indication: In combination with gemcitabine for the adjuvant treatment of pancreatic cancer.

Name of Patient Group: Canadian Cancer Society & Craig's Cause Pancreatic Cancer Society

Author of Submission: Stephen Piazza, Director of Advocacy (Canadian Cancer Society)

1. About Your Patient Group

The Canadian Cancer Society (CCS) works tirelessly to save and improve lives. CCS is the only national charity that supports Canadians with all cancers in communities across the country. We fund the brightest minds in cancer research. We provide a compassionate support system for all those affected by cancer, from coast to coast and for all types of cancer. As the voice for Canadians who care about cancer, we work with governments to establish health policies to prevent cancer and better support those living with the disease. More information about CCS can be found here. CCS used Hill and Knowlton Strategies to support coordination of this submission.

Craig's Cause Pancreatic Cancer Society is a national charity dedicated to both increasing survival and improving the quality of life for every Canadian diagnosed with pancreatic cancer through awareness raising, education, support and research. Craig's Cause collaborated with CCS to draft this submission.

2. Information Gathering

CCS reached out to Craig's Cause Pancreatic Cancer Society requesting their collaboration to reach out to people living with pancreatic cancer with a call-out for patients to provide patient input for this submission.

3. Disease Experience

Patient 1 is 45 years old male with stage 4 pancreatic cancer. He was motivated to participate in the CCS/Craig's Cause join patient submission to improve the pancreatic cancer journey for

other patients in Canada. From May 2022 to January 2023, Patient 1 underwent 18 rounds of chemotherapy. There has been a lack of continuity in his care as he has been assigned to 7 different oncologists during his journey. He was prescribed chemotherapy and radiation. Both the patient and his oncologist identified that the radiation therapy machine that would best suit his cancer, could not be found in Canada. The patient paid out of pocket to receive radiation therapy in California and has since seen hopeful results. He has applied for reimbursement through the Alberta Health Care Insurance Plan Out-of-Country unit, however is yet to receive a response.

Patient 2 is 58 years old and was diagnosed with stage 2 pancreatic cancer in May of 2021. She expressed that she has had a great experience navigating the health care system, apart from long wait times during her chemo appointments. She noted that she began treatment 2 weeks following her diagnosis. She is currently undergoing her final round of chemotherapy after which she will undergo tests to assess the state of the cancer.

4. Experiences with Currently Available Treatments Improved Outcomes

Patient 1 has currently found and enrolled himself in a clinical trial in Vancouver, however has been informed that the trial may close and is hopeful that he will get coverage to continue receiving this therapy through Canada's Special Access Programme. The patient underwent 18 rounds of FOLFIRINOX chemotherapy, during which he experienced neuropathy in his fingers and toes. He reported being unable to pick up pills or button his shirt. Despite most of his dexterity returning in his hands gradually after the cessation of the chemotherapy, he believes he has permanent neuropathy in his feet. They are always very cold and what he described as a "constant reminder of the cancer".

Patient 2 is currently undergoing chemotherapy and takes hydromorphone for chronic pain caused by cancer. She experienced nausea and a burning sensation in her fingers, however, her most debilitating symptom is her lethargy. She noted that she doesn't have the energy to do her daily activities.

5. Experience with Drug Under Review

Neither patient has received Nab-Paclitaxel in combination with gemcitabine.

6. Companion Diagnostic Test

Patient 1 presented to his general practitioner with abdominal pain throughout 2021 and was misdiagnosed with pancreatitis. Following a series of further diagnostic procedures including an upper endoscopy, the clinicians discovered that his pancreas had begun to atrophy and he was misdiagnosed with chronic pancreatitis. An MRI was scheduled with regards to this misdiagnosis. A biopsy was also done on the patient which came back with pre-cancerous cells, and a surgery was scheduled for April 2022 to remove the pre-cancerous cells. Given that the MRI for his previous misdiagnosis was already scheduled, the patient decided to undergo the imaging test. It was only then, in late February 2022, that they discovered a spot on his liver and cancelled the surgery. In the following month, 7 pathology reports were done, one of which was

sent to the Mayo Clinic, but was misplaced, which concluded that he had two other spots on his liver, and the patient was diagnosed with stage 4 pancreatic cancer.

Patient 2 was experiencing abnormal tiredness and dark urine. She visited the emergency room due to her symptoms and the doctors immediately inserted a stent, and a biopsy was ordered. Patient 2 was diagnosed with stage 2 pancreatic cancer one week later.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

   Hill and Knowlton provided support to complete the patient submission, including completing the patient interview.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

   Hill and Knowlton provided support to complete the patient submission, including completing the patient interview.

3. List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review

   N/A.

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Stephen Piazza
Position: Director of Advocacy
Patient Group: Canadian Cancer Society

Date: **2024-04-26**

CADTH

CADTH Reimbursement Review

Clinician Group Input

CADTH Project Number: PX0360
Generic Drug Name (Brand Name): Nab-paclitaxel
Indication: In combination with gemcitabine for the adjuvant treatment of pancreatic cancer.
Name of Clinician Group: Ontario Health (Cancer Care Ontario) Gastrointestinal Cancer Drug Advisory Committee
Author of Submission: Dr. Erin Kennedy, Dr. Suneil Khanna, Dr. Michael Raphael, Dr. Rachel Goodwin

1. About Your Clinician Group

OH-CCO's Drug Advisory Committees provide timely evidence-based clinical and health system guidance on drug-related issues in support of CCO's mandate, including the Provincial Drug Reimbursement Programs (PDRP) and the Systemic Treatment Program.

2. Information Gathering

Information was gathered by email.

3. Current Treatments and Treatment Goals

The current treatments include FOLFIRINOX, capecitabine with gemcitabine, and single agent gemcitabine. In the APACT study, gemcitabine/nab-paclitaxel showed only marginal OS benefit over gemcitabine alone (and it hasn't been compared to FOLFIRINOX or Cape/Gem, which are preferred options)

4. Treatment Gaps (unmet needs)

4.1. Considering the treatment goals in Section 3, please describe goals (needs) that are not being met by currently available treatments.

Patients with 5-FU intolerance or DYPD deficiency have only gemcitabine as an option, so gemcitabine/nab-paclitaxel might be a good option for these patients. This treatment is also an option for patients with other relative/absolute contraindication to the use of mFOLFIRINOX.

5. Place in Therapy

5.1. How would the drug under review fit into the current treatment paradigm?

Gemcitabine/nab-paclitaxel is currently standard of care in the first-line, metastatic setting (along with mFOLFIRINOX). This combination could be used in the adjuvant setting but would only recommend for select cases (see above).

5.2. Which patients would be best suited for treatment with the drug under review? Which patients would be least suitable for treatment with the drug under review?

See above.

The patients best suited for treatment with adjuvant gemcitabine and nab-paclitaxel would be those who have undergone pancreas cancer surgery, who have a relative/absolute contraindication to the use of mFOLFIRINOX, and who, in the opinion of the treating clinician, have a sufficient performance status and suitable labs to safely proceed with adjuvant chemotherapy.

5.3 What outcomes are used to determine whether a patient is responding to treatment in clinical practice? How often should treatment response be assessed?

Patients should undergo blood work prior to each dose of gemcitabine and nab-paclitaxel.

Patients should be assessed by an oncology practitioner or appropriate delegate at least every 2-3 cycles with history, directed physical examination.

There is no standard or uniformly followed surveillance imaging protocol for patients after curative intent surgery for pancreas cancer. Consideration should be given to completing surveillance CT scans every 6-12 months for up to 5 years depending in the individual patient's clinical circumstances.

5.4 What factors should be considered when deciding to discontinue treatment with the drug under review?

Patients should discontinue therapy after 6, 28 day cycles of gemcitabine and nab-paclitaxel, or if unacceptable toxicity or intolerance, judged jointly by patient and clinician, is experienced, or if disease recurrence/progression occurs while on treatment.

5.5 What settings are appropriate for treatment with [drug under review]? Is a specialist required to diagnose, treat, and monitor patients who might receive [drug under review]?

The decision to proceed with adjuvant gemcitabine and nab-paclitaxel following curative intent pancreas cancer should be made in an informed, joint-decision making process between the individual patient and their oncology practitioner. This therapy should be administered under the supervision of a medical oncologist. This therapy can safely be delivered in a hospital outpatient clinic or an out-of-hospital chemotherapy infusion clinic. A nurse with training in oncology is necessary to safely infuse this medication.

6. Additional Information

N/A

7. Conflict of Interest Declarations

To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the clinician group input. CADTH may contact your group with further questions, as needed. Please see the *Procedures for CADTH Drug Reimbursement Reviews* (section 6.3) for further details.

1. Did you receive help from outside your clinician group to complete this submission? If yes, please detail the help and who provided it.

   OH-CCO provided a secretariat function to the group.

2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission? If yes, please detail the help and who provided it.

   No.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review. **Please note that this is required for each clinician who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.**

Declaration for Clinician 1

Name: Dr. Erin Kennedy
Position: Lead, Ontario Health (Cancer Care Ontario) Gastrointestinal Cancer Drug Advisory Committee
Date: 29-03-2024

☒ **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for Clinician 1

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 2

Name: Dr. Suneil Khanna
Position: Member, Ontario Health (Cancer Care Ontario) Gastrointestinal Cancer Drug Advisory Committee
Date: 29-03-2024

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 2: Conflict of Interest Declaration for Clinician 2

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
BMS	X			

Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 3

Name: Dr. Michael Raphael
Position: Member, Ontario Health (Cancer Care Ontario) Gastrointestinal Cancer Drug Advisory Committee
Date: 11-04-2024

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 3: Conflict of Interest Declaration for Clinician 3

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 4

Name: Dr. Rachel Goodwin
Position: Member, Ontario Health (Cancer Care Ontario) Gastrointestinal Cancer Drug Advisory Committee
Date: 12-04-2024

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 4: Conflict of Interest Declaration for Clinician 4

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
BMS	X			
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.