

### Guideline 2-33 Version 2

## A Quality Initiative of the Program in Evidence-Based Care (PEBC), Ontario Health (Cancer Care Ontario)

# Role of Adjuvant Treatment in Resected Pancreatic Ductal Adenocarcinoma

Members of the Gastrointestinal Disease Site Group

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Guideline 2-33 was reviewed in 2025 and ENDORSED by members of the Gastrointestinal Disease Site Group. (See Section 6: Document Assessment and Review for details)

Guideline 2-33 Version 2 is comprised of 6 sections. You can access the summary and full report here: <u>https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/71976</u>

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## Role of Adjuvant Treatment in Resected Pancreatic Ductal Adenocarcinoma

## Section 1: Recommendations

This section is a quick reference guide and provides the guideline recommendations only. For key evidence associated with each recommendation, the systematic review, and the guideline development process, see the Full Report.

#### **GUIDELINE OBJECTIVES**

To make recommendations regarding the adjuvant treatment (adjuvant chemotherapy, adjuvant chemoradiation therapy [CRT] and adjuvant stereotactic body radiation therapy [SBRT]) of patients with resected pancreatic ductal adenocarcinoma (PDAC) with respect to overall survival (OS), progression-free survival (PFS), toxicity/safety, and quality of life.

#### TARGET POPULATION

These recommendations apply to adults with resected PDAC with R0 or R1 margins who are eligible for adjuvant treatment. This guideline does not apply to patients being considered for neoadjuvant therapy of PDAC.

#### **INTENDED USERS**

The intended users of this guideline are clinicians involved in the delivery of care to patients with resected PDAC.

#### RECOMMENDATIONS

#### Recommendation 1

Adjuvant chemotherapy is recommended for patients with R0 or R1 resected pancreatic ductal adenocarcinoma. Modified FOLFIRNOX (mFOLFIRINOX) is recommended for appropriately fit patients. If a patient is not suitable for mFOLFIRINOX, alternative options include gemcitabine plus capecitabine or gemcitabine alone.

#### Qualifying Statements for Recommendation 1

- All patients who have had a R0 or R1 PDAC resection should be assessed for adjuvant chemotherapy by a medical oncologist.
- All adjuvant chemotherapy options should be discussed with each patient.
- Adjuvant treatment can be delayed to allow patients adequate time to recover from surgery. Data from ESPAC-3 demonstrate that there is no difference in survival outcomes if adjuvant chemotherapy is delayed by up to 12 weeks (2).
- Data from ESPAC-4 demonstrate that R status was not significantly associated with local recurrence, distant recurrence, or death without recurrence (3).
- The JASPAC-01 trial was limited to a Japanese population. Results of trial using the agent S-1 are not considered applicable to Western populations.

### Added in June 2025:

 Nab-paclitaxel plus gemcitabine may be considered if mFOLFIRINOX is not suitable. Updated results from the APACT Trial (Tempero MA, Pelzer U, O'Reilly EM, et al. J Clin Oncol. 2023;41(11):2007-19) demonstrates that although there is no advantage for nab-paclitaxel plus gemcitabine compared to gemcitabine alone with respect to independently assessed DFS (which was the primary end point of the trial), there was an OS advantage (41.8 vs. 37.7 months, HR, 0.80; 95% CI, 0.678 to 0.947; p=0.0091). OS was a secondary endpoint in the APACT trial. (See Section 6 for details).

#### **Recommendation 2**

There is insufficient evidence to support the routine use of adjuvant chemoradiation for patients with R0 or R1 resected PDAC. The role for adjuvant CRT remains uncertain.

#### **Qualifying Statements for Recommendation 2**

• Whether there is a role for adjuvant CRT in the presence of positive margins and/or node-positive disease may be discussed on a case-by-case basis in the setting of a multidisciplinary case conference and a discussion with the patient outlining the risk and benefits of treatment.

#### Recommendation 3

Following surgical resection of pancreatic cancer, adjuvant SBRT is only recommended on a clinical trial or multi-institutional registry. (Endorsed from the American Society for Radiation Oncology [ASTRO] guideline by Palta et al. 2019) (1).