

29 July 2009

Proposal to widen access to gemcitabine hydrochloride

PHARMAC is seeking feedback on a proposal to widen funded access to gemcitabine hydrochloride. In summary, the proposal involves:

- Widening access to subsidised gemcitabine to include funding for adjuvant treatment of patients with macroscopically resected pancreatic cancer for a maximum of 6 cycles; and
- Amending the current funding restrictions on gemcitabine for advanced pancreatic cancer such that re-treatment with gemcitabine would only be funded where disease progression occurs more than 12 months after previous adjuvant gemcitabine treatment.

Gemcitabine is a DHB hospital administered Pharmaceutical Cancer Treatment. The estimated total additional infusion service requirement for this proposal is estimated to be up to 1,350 x 30 minute infusions nationally per year.

Gemcitabine is not approved by Medsafe for the adjuvant treatment of pancreatic cancer; therefore, clinicians would need to comply with Section 25 of the Medicines Act to prescribe it in this setting.

More details of the proposal, including the proposed changes to the Special Authority criteria, can be found on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback please submit it in writing by 4 pm on **Thursday, 13 August 2009** to:

Jackie Evans
Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: jackie.evans@pharmac.govt.nz

Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

The Special Authority criteria applying to gemcitabine hydrochloride (Inj 200 mg and Inj 1 g and Inj 1 mg for ECP) would be amended as follows from 1 October 2009 (additions in bold, deletions in strikethrough):

Special Authority for Subsidy

Initial application - (Pancreatic Cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Either:

1 Both

- 1.1 The patient has macroscopically resected (R0 or R1) pancreatic carcinoma*;**
- and**
- 1.2 To be used for a maximum of 6 treatment cycles; or**

2 Both

- 2.1 The patient has advanced pancreatic carcinoma; and**
- 2.2 Either**
 - 2.2.1 The patient is gemcitabine naïve; or**
 - 2.2.2 The patient has had a gemcitabine treatment-free interval of 12 months or more.**

Initial application - **(Other indications)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

- 1 The patient has non small cell lung carcinoma (stage IIIa, or above); or
- 2 The patient has advanced malignant mesothelioma*; or
- ~~3 The patient has advanced pancreatic carcinoma; or~~
- 43** The patient has ovarian, fallopian tube* or primary peritoneal carcinoma*; or
- ~~54~~ The patient has advanced transitional cell carcinoma of the urothelial tract (locally advanced or metastatic).

Renewal - (Pancreatic Cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Either:

1 Both

- 1.1 The tumour has relapsed and requires re-treatment; and**
- 1.2 The patient has had a gemcitabine treatment-free interval of 12 months or more; or**

2 The patient has advanced Pancreatic Cancer and requires continued therapy.

Renewal - **(Other Indications)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 The patient requires continued therapy; or
- 2 The tumour has relapsed and requires re-treatment.

Note: Indications marked with a * are Unapproved Indications.

The listed price of gemcitabine hydrochloride would not change under this proposal.

Background to proposal

Gemcitabine hydrochloride is a DHB hospital administered Pharmaceutical Cancer Treatment (PCT). The InterPharma Pty Ltd brand of gemcitabine hydrochloride 200 mg and 1 g injections (Gemcitabine Ebewe) is the current Hospital Supply Status brand until 30 June 2010.

Gemcitabine hydrochloride is currently funded for a number of cancer indications including advanced pancreatic cancer. In relation to pancreatic cancer, gemcitabine is currently registered by Medsafe for:

- treatment of patients with locally advanced or metastatic adenocarcinoma of the pancreas; and
- treatment of patients with 5-FU refractory pancreatic cancer.

As such, this proposal (for adjuvant treatment) is for an off-label indication and therefore clinicians would need to comply Section 25 of the Medicines Act to prescribe it in this setting. Section 25 prescribing is not an unusual situation for cancer treatments; it requires that clinicians obtain informed consent from their patients for 'off-indication' use.

Infusional 5-fluorouracil (5FU) treatment is the current standard adjuvant treatment for resectable pancreatic cancer, however, evidence for 5FU is poor.

PHARMAC received an application from the Gastrointestinal Cancer Special Interest Group of the New Zealand Association of Cancer Specialists to widen funded access to gemcitabine. The Cancer treatments subcommittee of PTAC (CaTSoP) recommended that the Special Authority restriction applying to gemcitabine be amended to allow for the adjuvant treatment of macroscopically resected pancreatic cancer.

CaTSoP also recommended that the Special Authority restriction applying to metastatic [advanced] pancreatic cancer be amended to prevent re-treatment with gemcitabine if disease progression occurs within 12 months of adjuvant treatment.

It is anticipated that this proposal would result in approximately 75 additional patients accessing funded gemcitabine treatment annually. Each patient would require 6 cycles of treatment, with each cycle consisting of one 30 minute infusion each week for 3 weeks, a total of 18 x 30 minute infusions per patient. Therefore, the total additional DHB hospital service requirement nationally is expected to be up to 1,350 x 30 minute infusions per year. It should be noted that some of this additional service requirement would be offset by a reduction in current services associated with current treatment options and the retreatment of patients with relapsed disease.