

19 February 2010

Proposal to widen access to gemcitabine hydrochloride and vinorelbine

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

- Widening access to subsidised gemcitabine and vinorelbine to include funding for patients with relapsed/refractory Hodgkin's disease for a maximum of 6 cycles; and
- Widening access to subsidised gemcitabine and vinorelbine to include funding for patients with relapsed/refractory T-cell lymphoma for a maximum of 6 cycles.

Gemcitabine and vinorelbine are DHB hospital administered Pharmaceutical Cancer Treatments (PCTs). The total DHB hospital infusion service requirement of this proposal is estimated to be up to 540 x 30 minute infusions nationally per year.

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 **Friday, 5th March 2010** to:

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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

Gemcitabine

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 (additions in bold, deletions in strikethrough):

Special Authority for Subsidy

Initial application - (Hodgkin's disease or T-cell lymphoma) 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:

All of the following

1 Either

1.1 The patient has Hodgkin's disease*; or

1.1 The patient has T-cell lymphoma*; and

2 Either

2.1 Disease has failed to respond to second-line salvage chemotherapy treatment; or

2.2 Disease has relapsed following transplant; and

3 Gemcitabine to be given in combination with vinorelbine for a maximum of 6 treatment cycles.

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

4 The patient has ovarian, fallopian tube* or primary peritoneal carcinoma*; or

5 The patient has advanced transitional cell carcinoma of the urothelial tract (locally advanced or metastatic).

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.

Vinorelbine

The Special Authority criteria applying to vinorelbine (inj 10 mg per ml, 1 ml and 10 mg per ml, 5 ml and inj 1 mg for ECP) would be amended as follows (additions in bold, deletions in strikethrough):

Special Authority for Subsidy

Initial application - (Hodgkin's disease or T-cell lymphoma) 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:

All of the following

1 Either

1.1 The patient has Hodgkin's disease*; or

1.1 The patient has T-cell lymphoma*; and

2 Either

2.1 Disease has failed to respond to second-line salvage chemotherapy treatment; or

**2.2 Disease has relapsed following transplant; and
3 Vinorelbine to be given in combination with gemcitabine for a maximum of 6
treatment cycles.**

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 metastatic breast cancer; or
- 2 The patient has non-small cell lung cancer (stage IIIa, or above); or
- 3 All of the following:
 - 3.1 The patient has stage IB-IIIa non-small cell lung cancer; and
 - 3.2 Vinorelbine is to be given as adjuvant treatment in combination with cisplatin; and
 - 3.3 The patient has good performance status (WHO/ECOG grade 0-1).

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 prices of gemcitabine hydrochloride and vinorelbine would not change under this proposal.

DHB resources

If the proposal is approved an additional 45 patients per year would be expected to access funded gemcitabine and vinorelbine.

It is anticipated that in these patients vinorelbine would be administered intravenously over 6-10 minutes followed by gemcitabine hydrochloride administered intravenously over 30 minutes on days 1 and 8 every 21 days for up to 6 cycles. Therefore, the total DHB hospital infusion service requirement of this proposal is estimated to be up to 540 x 30-40 minute infusions nationally per year.

Treatment with gemcitabine and vinorelbine would be expected to displace some currently used complex salvage chemotherapy regimens and, therefore, the costs associated with administration and adverse event management of these regimens would be reduced.

Background to proposal

Gemcitabine hydrochloride and vinorelbine are DHB hospital administered PCTs.

InterPharma Pty Ltd's brand of gemcitabine hydrochloride 200 mg and 1 g injections (Gemcitabine Ebewe) is the current Hospital Supply Status brand until 30 June 2010.

New Zealand Medical and Scientific Ltd's brand of vinorelbine inj 10 mg per ml, 1 ml and inj 10 mg per ml, 2 ml (Navelbine) is the current Hospital Supply Status brand until 30 June 2011.

Gemcitabine hydrochloride and vinorelbine are currently funded for a number of cancer indications; however, neither are currently registered by Medsafe for the treatment of patients with Hodgkin's disease or T-cell lymphoma. As such, this proposal is for off-label

indications and, therefore, clinicians would need to comply Section 25 of the Medicines Act to prescribe gemcitabine hydrochloride and vinorelbine in these settings. 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.

This funding application was generated by PHARMAC staff following a review of Cancer Exceptional Circumstances (CaEC) funding applications.

Although limited, evidence indicates that gemcitabine in combination with vinorelbine has similar efficacy to other salvage chemotherapy regimens in the proposed patient groups. However, the combination of gemcitabine and vinorelbine is relatively simple to administer in an outpatient setting and has fewer toxicity issues compared with currently used salvage chemotherapy regimens.

The Cancer Treatments Subcommittee of the Pharmacology and Therapeutics Advisory Committee (CaTSoP) recommended that combination treatment with gemcitabine and vinorelbine be funded for up to 6 cycles for patients with either Hodgkins disease or T-cell lymphoma whose disease has failed to respond to second-line salvage chemotherapy or whose disease relapsed after transplantation (i.e. in the third-line setting). CaTSoP gave this recommendation a medium priority.