

INFORMATION SHEET FOR HOSPITAL, COMMUNITY AND CANCER EXCEPTIONAL CIRCUMSTANCES

Q: *What are the requirements for funding for my patients under Exceptional Circumstances?*

A: There are three ways to obtain Exceptional Circumstances approval:

- Community Exceptional Circumstances
- Hospital Exceptional Circumstances
- Cancer Exceptional Circumstances.

Community Exceptional Circumstances (CEC)

1. Entry Criteria

CEC allows for the funding of community-based treatments that are not covered under the provisions of the Pharmaceutical Schedule. A fixed budget has been set aside from the pharmaceutical budget to cover the funding of treatments for CEC. There are three entry criteria that allow for CEC funding, one of which must be met:

*The condition is rare.
The reaction to alternative treatment is unusual.
An unusual combination of clinical circumstances applies.
(Where rare and unusual are defined as single figures nationally)*

As a guideline to assist with filling out the form there are three points that need to be considered.

- Whilst a patient may be suffering from a rare disease/condition, the symptom requiring treatment may not be rare. For example the patient may have a rare disease. The most common manifestation of this disease is severe pain. Pain management is not a rare condition. Therefore, an application to CEC for funding of a treatment for pain management is unlikely to be successful.
- The general reference point for determining an “unusual reaction” is the published documentation from Medsafe (www.medsafe.govt.nz). Common reactions would generally be excluded from CEC.
- The criterion of “an unusual combination of clinical circumstances” allows a degree of discretion for the panel. The test applied is one of fairness to fund the pharmaceutical for one individual in one specific clinical circumstance while declining all others. The focus is on clinical, not social or economic, circumstances. The clinical circumstance must be directly related to the use of the requested medication for the particular patient.

Once the entry criteria have been met, supplementary criteria are examined as follows:

2. *Clinical Benefit and Suitability:*

- a) evidence must be included to show that the requested treatment has already shown a demonstrated and significant clinical benefit to this patient. CEC funding is not available to fund trials. OR
- b) evidence must be attached to show that the requested treatment is a safe and efficacious treatment for this condition. AND
- c) all applications should clearly show which alternative treatments have been trialled and the reasons why they were unsuitable. Additionally which alternative treatments were considered but deemed unsuitable for trial and why.

3. *Cost Benefit:*

The cost of the treatment should be acceptable when assessed on cost benefit grounds and evaluated against other health funding priorities. An application with total cost in excess of \$30,000 will be sent for a Cost Utility Analysis. Should the Cost per Quality Adjusted Life Year be in excess of \$15,000 the final decision on funding will be made by PHARMAC.

4. *Health Services Budget:*

CEC funding is not available where the proposed treatment is part of a DHB or other provider contract or the responsibility of another Government funded agency. CEC funding is not available for inpatients in DHBs or persons living in residential care facilities with drug inclusive MOH contracts. For example CEC funding is not available to fund medications administered by infusion; as these are administered under medical supervision the funding is the responsibility of the DHB.

5. *Patient Income Criteria:*

CEC funding is not available for financial reasons alone. Where all other criteria are met CEC funding will be granted to patients who:

- a) EITHER have a community services card and are already receiving the maximum WINZ benefit available to them,
- b) OR provide a declaration stating that it is otherwise unreasonable to expect them to pay. CEC is not available to fund part charges.

Hospital Exceptional Circumstances (HEC)

HEC allows for the funding of community-based treatments for patients currently in DHB hospitals who are awaiting discharge, where there is no other provision for funding the treatment in the Pharmaceutical Schedule. Funding for HEC is from the DHB Hospital's budget. The sole criterion for accessing HEC funding is cost-effectiveness.

Evidence must be provided to demonstrate that funding the pharmaceutical for a specific patient is more cost-effective for the hospital than the most likely alternative intervention or outcome.

Cancer Exceptional Circumstances (CaEC)

1. Criteria

CaEC allows for the funding of pharmaceuticals for the treatment of cancer in the in-patient, outpatient or day patient setting that are not covered under the provisions of the Pharmaceutical Schedule, in some circumstances.

The intention of the policy is to assess the extent of usage of pharmaceutical cancer treatments outside of the “oncology basket” and establish a funding pool for cancer treatment exceptions. Until this time funding for CaEC is from the DHB hospital’s budget.

The following criteria for approval are based on the concepts of peer-review within the DHB hospital, and ensuring equity of access to pharmaceutical cancer treatments across DHBs:

- i. Confirmation that the proposed use was evaluated and approved using established DHB review mechanisms involving experienced clinicians;
- ii. Confirmation that the DHB hospital providing treatment has agreed to fund the treatment;
- iii. Confirmation that the condition is considered unusual (and therefore a decision to treat is unlikely to result in access inequities across DHBs);
- iv. The proposed use has not been considered or is not currently under consideration by PHARMAC for funding (note a list of active applications for funding and PTAC recommendations is available on PHARMAC’s website);
- v. Specification of the;
 - a. Product to be used
 - b. Dose and treatment schedule
 - c. Duration of treatment
 - d. Indication
 - e. Total cost
- vi. The total cost is <\$30,000 over a 5-year period (NPV). If the application is for a treatment of \$30,000 or over it will be referred for a CUA followed by a decision from PHARMAC.

The CaEC policy is administered directly by PHARMAC staff. Where applications clearly meet the criteria, approval will be communicated by PHARMAC staff to the applicant and the pharmacy. Where PHARMAC staff do not consider an application meets the criteria the application will be referred to the HEC panel for review. Every reasonable effort will be made to respond to CaEC applications within 72 hours (not including weekends and statutory holidays).

Applicants under CaEC have the right of appeal. All correspondence with the Panel must be in writing and made through the Exceptional Circumstances office. An appeal will be examined by the HEC panel. Should the Panel still decline the application, then the applicant may request a review. Contact should be made with the Medical Director, PHARMAC who will arrange for a review to be undertaken.

Q: *Who can apply for Exceptional Circumstances?*

A: Any medical practitioner can apply for CEC funding. The panel recommends that all applicants provide additional specialist endorsement in support of their application.

Applications for HEC and CaEC approval will only be considered from hospital physicians.

Q: *Who makes the decisions on Exceptional Circumstances?*

A: For HEC and CEC a panel of clinicians considers all applications against the specified criteria and makes recommendations regarding whether funding should be approved or not.

The clinicians on the panel are:

Dr Howard Wilson – GP, Pharmacologist (Chairperson)
Dr Mel Brieseman – Medical Officer of Health, Christchurch
Dr Paul Tomlinson – Paediatrician, Southland DHB
Dr David Waite – Physician, Capital and Coast DHB
Dr Sharon Kletchko – GM, Planning and Funding Nelson Marlborough DHB
Dr Andrew Herbert – Consultant Gastroenterologist, MidCentral DHB

The Panel meets by teleconference every two weeks to consider all CEC applications. Urgent CEC applications may be considered outside of this meeting timetable via e-mail or teleconference as required.

Every reasonable effort will be made to process HEC applications within 48 hours (not including weekends and statutory holidays).

The CaEC policy is administered directly by PHARMAC staff. Where applications clearly meet the criteria, approval will be communicated directly by PHARMAC staff. Where PHARMAC staff do not consider an application meets the criteria the application will be referred to the HEC panel for review. Every reasonable effort will be made to respond to CaEC applications within 72 hours (not including weekends and statutory holidays).

Q: *What do I have to do to get funding?*

A: Exceptional Circumstances staff provide a form that needs to be completed before the panel can consider your application.

The CEC and HEC form has three sections:

- Section 1: Patient, applicant and treatment details – please complete for all applications
- Section 2: HEC funding only
- Section 3: CEC funding only

CaEC has a separate form.

Please note it is possible that an application made for HEC funding will be declined but then considered under the provisions for CEC and vice versa. If you believe that

your application may be considered under alternative provisions please fill out the alternative section of the form. Doing so will mean that the panel will be able to deal with your application without delay rather than waiting for you to provide the additional information.

Q: *What is the panel able to decide?*

A: The recommendations for HEC, CaEC and CEC funding differ.

For HEC and CaEC funding the panel may recommend that:

- funding not be made available for the treatment. In this case, the DHB hospital cannot fund the treatment for the individual. The EC recommendation is binding.
- funding be made available for the treatment. The DHB Hospital may at its discretion fund the treatment from its own budget.
- defer the decision on CaEC funding to PHARMAC, where the treatment for the patient is greater than \$30,000 (5 year NPV).

For CEC applications the panel may:

- approve funding
- decline funding
- defer the decision to PHARMAC, where the treatment for the patient is greater than \$30,000.

Q: *What if I wish to appeal the Panel's decision?*

A: Applicants under HEC, CaEC and CEC have the right of appeal. All correspondence with the Panel must be in writing and made through the Exceptional Circumstances office. An appeal will be examined by the same panel. Should the Panel still decline the application, then the applicant may request a review. Contact should be made with the Medical Director, PHARMAC who will arrange for a review to be undertaken.

Q: *Whom should I contact to discuss progress with my application?*

A: EC applications are managed by co-ordinators who are contactable by phone or e-mail.

CEC – Jayne Watkins 04-916-7553 ecpanel@pharmac.govt.nz
HEC – Rachel Pratt 04-916-7521 ecpanel@pharmac.govt.nz
CaEC – Rachel Pratt 04-916-7521 ecpanel@pharmac.govt.nz

You may also fax information to them. The fax number is 09-523-6870 for all applications (redirects to Wellington).

Postal address: Exceptional Circumstances
 PHARMAC
 PO Box 10-254
 Wellington

If your application is incomplete a co-ordinator will contact you to request additional information. The panel is only able to consider applications that are complete.

Guidelines:

Examples of the sorts of applications which are often made to CEC but which do not meet the criteria are:

- Vioxx or Celebrex in the treatment of arthritis; this is not a rare condition, and a gastric reaction to NSIADs is not unusual.
- Applications made to fulfil WINZ requirements. Exceptional Circumstances no longer provides 'decline' letters, as WINZ policy no longer requires such letters.

