

## INFORMATION SHEET FOR COMMUNITY, HOSPITAL 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.

a) 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.

b) The general reference point for determining if a reaction is likely to be considered to be an “unusual reaction” is the medicine data sheet published by MedSafe ([www.medsafe.govt.nz](http://www.medsafe.govt.nz)). If the reaction is documented on the medicine data sheet, it would generally not be considered “unusual” and therefore an application on the grounds of such a reaction would not be likely to meet the CEC criteria.

c) 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:**

- a) evidence must be attached to show that the requested treatment is a safe and efficacious treatment for this condition. Full journal articles not just references should be provided. OR
- b) 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.

**3. Other Medications:**

All applications should clearly show which alternative treatments have been trialled and the reasons why they were considered to be unsuitable and the alternative treatments that were considered but deemed unsuitable for trial and why.

A list of other medications that the patient is currently taking should be provided.

**4. Other Issues:**

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 of treatment in excess of \$15,000 may be sent for a Cost Utility Analysis. The final decision on funding will then be made by PHARMAC.

**5. Attachments:**

Additional information may be provided. This can include relevant clinic letters, lab results, hospital admission records, or any other information the applicant considers is relevant.

**6. Cost Estimate**

- A cost estimate must be provided with the application. Applications where the total cost of treatment exceeds \$15,000 may require further analysis and approval from PHARMAC.
- 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.
- 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.
- CEC funding is not available on financial grounds alone; the entry criteria must be met.

## 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-saving to the DHB Hospital.

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

Under this scheme, all funded alternative treatments must be considered, and where appropriate tried, before consideration of an unfunded medicine will be given.

An application for ongoing approval (renewal) should provide an update on the patient's clinical progress and any information that was requested by the Panel at previous approval. It should include any additional information which may help the Panel in assessing ongoing approval under the criterion eg clinic letters, lab results, hospital admission records, management plan.

Applicants under Hospital EC 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.

## Cancer Exceptional Circumstances (CaEC)

### 1. Criteria

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

The intention of the policy was to assess the extent of usage of pharmaceutical cancer treatments outside of the "oncology basket" and a funding pool for cancer treatment exceptions was established 1 July 2009. From 1 July 2011, funding for cancer treatments, including CaEC treatments, was combined with that for community pharmaceutical treatments and is managed by PHARMAC.

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 condition is considered unusual (and therefore a decision to treat is unlikely to result in access inequities across DHBs);
- iii. 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);
- iv. Specification of the;
  - a. Product to be used

- b. Dose and treatment schedule
  - c. Duration of treatment
  - d. Indication
  - e. Total cost
- v. 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 may 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 to the pharmacy. Where PHARMAC staff do not consider an application meets the criteria the application will be referred to the EC 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 EC 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 authorised prescriber 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), PTAC (Deputy Chair)
- 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
- Dr George Laking – Oncologist, PTAC, Auckland 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 EC 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 can provide the form that needs to be completed before the panel can consider your application. Forms may also be downloaded from [www.pharmac.govt.nz](http://www.pharmac.govt.nz)

- There is a separate application form for each scheme ie CEC, HEC, and CaEC.

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 both CEC and HEC forms. 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 (for HEC) or the DHB (for CaEC) may at its discretion fund the treatment from its own budget.

For CEC applications, the panel may:

- approve funding
- decline funding
- defer the decision to PHARMAC, where the total cost of treatment for the patient is greater than \$15,000.

**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	Katie Appleby	Ph: 04 916 7553	ecpanel@pharmac.govt.nz
Cancer EC	Katie Appleby	Ph: 04 916 7553	ecpanel@pharmac.govt.nz
Hospital EC	Anne Glennie	Ph :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.

