PHARMAC

Pharmaceutical Management Agency

Community Exceptional Circumstances
Panel Co-ordinator
PHARMAC
PO Box 10-254
Wellington 6143
Phone (04) 916 7553
Fax (09) 523 6870 (redirects to Wgtn)
Email ecpanel@pharmac.govt.nz

30th June 2010

Dear Dr

NHI:
Patient:
D.O.B.:
Medication: **n-acetyl cysteine**

The Exceptional Circumstances Panel has examined your application for the above named patient for supplies of n-acetyl cysteine. The conclusion they have reached based on the information presented is that this patient's circumstances do not meet the criteria for Community Exceptional Circumstances.

Community Exceptional Circumstances funding is available in those situations where either

1. The disease/condition is rare, or
2. The response to treatment is unusual, or
3. Some other unusual combination of clinical circumstances.

It appears that none of these situations apply. This patient's condition is not rare, and the response to alternative treatments is not unusual. (Where rare and unusual are understood to be single figures nationally). The clinical circumstances described are not sufficiently unusual for it to be appropriate to fund this patient.

If you have any additional information which would demonstrate that the above criteria are met please provide it in writing for the Panel to review. If you have any concerns about the process please contact me at the above address.

Yours sincerely

p.p. Jayne Watkins
Signed on behalf of:
Exceptional Circumstances Panel

PHARMAC
Pharmaceutical Management Agency

New Zealand Government

Application Form for Community Exceptional Circumstances Approval

Return completed form to:

Exceptional Circumstances
Panel Co-ordinator
PHARMAC
PO Box 10-254, Wellington

Phone: 04-916-7553
Facsimile: 09-523-6870
Email: ecpanel@pharmac.govt.nz

Please refer to information sheet if necessary. Complete ALL relevant details. Please type or print CLEARLY.
For *a renewal* complete this page and sections 7 and 8 only

Patient Details

Last Name:	
First Name:	
Address:	
Gender: Male / Female	Female (circled)
Date of Birth:	
NHI No:	

Details of Applying Practitioner

Last Name:	
First Name:	
Address:	
Phone:	
Facsimile:	NZMC#:
Email:	
Are you a GP [✓] or Specialist [ ] ?	

Disease/Condition

*attach further information if appropriate, a clinical report is useful, be specific

Interstitial lung disease
Leflunomide induced pneumonitis

Medicine/treatment sought:

Complete fully, attach additional information as necessary to cover all strengths required.

Brand Name:	
Chemical Name:	N-Acetyl Cysteine
Manufacturer:	
Form and Strength:	600mg
Dosage to be used:	tds
Dosage regimen: *(where applicable)*	
Extemporaneously compound?: *(If Yes, attach a full list of ingredients)*	Yes [ ] No [✓]

Note that if this is not completed an approval cannot be issued

Nominated Pharmacy (If approval given from where will supplies be obtained? This will generally NOT be a hospital pharmacy.)

Name:	
Address:	
Phone:	

or obtained cheaper by importing from Life Extension Pacific Ltd.

1. ENTRY CRITERIA

Complete the criteria to which this application applies.

☐ **(a) Rare condition** (rare is considered to be a prevalence of <10 nationally)

What is the prevalence (not incidence) of the condition in NZ?

☐ **(b) Reaction to alternative treatment unusual** (unusual is considered to be <10 nationally)

List all treatments trialled, patient response to each treatment and how often this response to this treatment occurs in NZ. (Note that failure to respond to funded treatments is not generally exceptional. In order to obtain funding through Exceptional Circumstances the nature of the response would need to be considered exceptional).

Treatment	Response of this patient	Rarity (how often would you expect this to occur?)

☑ **(c) Unusual combination of clinical circumstance applies**

Describe the unusual combination of clinical circumstances and how often this combination occurs in NZ. (Note that end of spectrum treatments are not necessarily approved; patients must be clearly distinct):

Rare side effect of leflunomide → pneumonitis
Combined with underlying (previously undiagnosed) interstitial lung disease possibly caused by previous use of methotrexate or caused by rheumatoid arthritis.

2. CLINICAL BENEFIT AND SUITABILITY

(a) **attach** evidence that it is a safe and efficacious treatment (e.g. full journal articles, **not** just references, conference proceedings or abstracts). Note that a higher degree of proof will be required for unregistered medications or registered medications for non-registered indications.

(b) Is the pharmaceutical registered for this indication in NZ? Yes ☐ No ☑

If not, has patient consent been obtained for this use as a non-registered medicine? Yes ☑ No ☐

(c) Attach specialist opinion (if available) or provide contact details of the specialist the patient has seen and who can be contacted by the EC Panel.

Name of specialist: ______________________

Address: ______________________

(Note: the Exceptional Circumstances Panel reserves the right to seek any appropriate opinion)

3. OTHER MEDICATIONS

Provide a full list of treatments for this condition that have been tried or considered.

Pharmaceutical	Unsuitable due to:
Prednisone 60mg daily	→ considerable
	side effects, not suitable
	for long term use at this
	dose & not adequate treatment
	for interstitial lung disease
	underlying this

Please list any other relevant medications that the patient is currently taking:

Prednisone, azathioprine

Metoprolol, calcium, frusemide, calciferol

4. OTHER ISSUES

Is there any other relevant information that should be considered?

5. ATTACHMENTS

Please attach any additional information which may help the Panel in assessing this application, such as relevant clinic letters, supporting references, lab results, hospital admissions record/s, management plan, and any other information which may be relevant. Please list in the table below the information which you are attaching to this application:

Additional information which is attached to this application (to be completed by applicant):

1.
2.
3.
4.
5.

(Please continue this list on an additional page if there is more information than the space provided here.)

6. COST ESTIMATE

(As this is an application for funding a cost estimate *must* be included. Failure to give a cost estimate may delay processing of the application. Note that applications in excess of $15,000 for the duration of treatment may undergo a cost utility analysis and will require PHARMAC approval).

Cost per year (quoted by nominated pharmacy, based on dosage requested. Cost must be COST BRAND SOURCE without mark-ups or dispensing fees)	* $412 for 100 tablets $ ~~100 per month~~ quoted by !
Anticipated duration of requested treatment: *(Note that approval will generally be given for only 1 year, renewal would then have to be sought)*	3 months initially.

* or by importing from Life Extension Pacific Ltd at charge of US$14.00 for 60 tablets + $7.50 postage = $21.50 US

7. RENEWAL *(COMPLETE FOR RENEWALS ONLY)*

If this is an application for renewal please attach the following:

1. **a full report** including details of the patient's clinical progress, the continuing need for the medication and the short and long term future management of this patient.
2. append any relevant and **recent specialist review.**
3. append any **relevant investigations** eg laboratory tests, radiology.

8. SIGNATURES

Signature of Medical Practitioner: ____________________

Date of Request: 27/5/10

9. PATIENT CONSENT

Patient details

Last Name	
First Name	

CONSENT BY PATIENT

For the purposes of this application form I consent to:

information concerning my medical conditions being given to the Exceptional Circumstances Panel (and if required, to PHARMAC); and

the Exceptional Circumstances Panel seeking further information from medical care providers or seeking further medical opinion as may be necessary for the consideration of my application.

Signed: ____________________ 27/5/10