

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

4th June 2010

Dear

NHI:

Patient:

D.O.B.:

Medication: **omeprazole (Losec)**

The Exceptional Circumstances Panel has examined your application for the above named patient for supplies of omeprazole (Losec). The conclusion they have reached 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



Jayne Watkins

Signed on behalf of:

Exceptional Circumstances Panel

Investing in Health

Application Form for Community Exceptional Circumstances Approval

25 MAY 2010
022779

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:	
Gender:	Male / <u>Female</u>
Date of Birth:	
NHI No:	

Details of Applying Practitioner

Last Name:	
First Name:	
Address:	
Phone:	
Facsimile:	6. 9 NZMC#:
Email:	
Are you a GP <input checked="" type="checkbox"/> or Specialist <input type="checkbox"/> ?	

Disease/Condition

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

<u>Gastro-oesophageal Reflux</u>
<u>Disease</u>
<u>Barrett's Oesophagus.</u>

Medicine/treatment sought:

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

Brand Name:	<u>Losec</u>
Chemical Name:	<u>Omeprazole</u>
Manufacturer:	<u>AstraZeneca</u>
Form and Strength:	<u>40mg Caps</u>
Dosage to be used:	<u>1 bd</u>
Dosage regimen: (where applicable)	<u>"</u>
Extemporaneously compounded?:	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
<small>(If Yes, attach a full list of ingredients)</small>	

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:

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 trialed, 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 <small>how often would you expect this to occur?</small>
Dr. Reddy's Omeprazole	Diarrhoea, abdominal discomfort.	? Rarity factor (unknown)
Pan topazole 40mg	Much less effective than OSEC brand	"
Ranitidine + famotidine	Much less effective in Symptom Control	"

- (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):

Unknown.

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:
Pantoprazole	Ineffective in Maximum dosage
Ranitidine	" " " "
Famotidine	" " " "

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

Calciferol 50,000 in tab $\dot{\bar{r}}$ monthly.

4. OTHER ISSUES

Is there any other relevant information that should be considered?

N/A

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.	Oesophago-Gastro duodenoscopy Report 7/8/2007 -
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)	\$ <u>169-20</u>
Anticipated duration of requested treatment: (Note that approval will generally be given for only 1 year, renewal would then have to be sought)	<u>1 year.</u>

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: _____

2189

*** 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: _____

Date: 5th May 2010

011 05 023 0123 FAX: 05

179 4813

- 9 AUG 2007

Centre

OESOPHAGO-GASTRO DUODENOSCOPY REPORT

Dear

re:

Obj: [faint handwritten text]

I have seen or gastroscopy today.

INDICATION

She has continuing intermittent reflux symptoms, generally controlled on her Losec. She has had previously documented Barrett's intestinal metaplasia (short segment). There has been no dysplasia.

PROCEDURE

A Pentax video gastroscope was used with 2.5mg, Midazolam and 75µg Fentanyl.

FINDINGS

The instrument passed from the mouth through to the second part of the duodenum. The duodenum appeared normal. The stomach appeared normal. At the distal end of the oesophagus there was some minor oedema and erythema along the squamocolumnar margin with some very minor endoscopic Barrett's change. Biopsies were taken. There are no alarm features.

OPINION

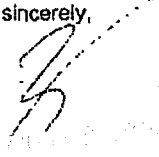
- 1. Gastro-oesophageal reflux disease.
- 2. Short segment Barrett's (stable).

I will review the histology and comment if there is anything of concern. She could remain on Omeprazole 20mg daily. If she wished to take a cautious approach with respect to her risk of developing oesophageal cancer it would not be unreasonable to re-check her oesophagus again in three to five years, or earlier, if there were concerning symptoms.

Kind regards.

Recall 2012

Yours sincerely,



GASTRO