

# 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](mailto:ecpanel@pharmac.govt.nz)

5th May 2010

Dear ,

NHI:

Patient:

D.O.B.:

Medication: **montelukast (Singulair)**

The Exceptional Circumstances Panel has examined your application for the above named patient for supplies of montelukast (Singulair). 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 (severe asthma) 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 whilst declining all others applying for the same medication.

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*

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

# Application Form for Community Exceptional Circumstances Approval

26 APR 2010

022675

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: <input checked="" type="radio"/> Male <input type="radio"/> Female
Date of Birth:
NHI No:

### Details of Applying Practitioner

Last Name:
First Name:
Address:
Phone:
Facsimile:
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

Severe asthma
Not able to work

### Medicine/treatment sought:

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

Brand Name:	SINGULAR
Chemical Name:	montelukast sodium
Manufacturer:	MSD
Form and Strength:	tablet 10mg
Dosage to be used:	10mg x 1
Dosage regimen: (where applicable)	10mg x 1
Extemporaneously compound?:	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
(If Yes, attach a full list of ingredients)	

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?

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- (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 (how often would you expect this to occur?)
Theophylline <sup>250mg</sup>	still wheezing	1/1000
Flixotide <sup>250µg</sup>	-  -	1/1000
Serevent <sup>250µg</sup>	-  -	1/1000
Ventoline <sup>100µg</sup>	-  -	1/1000
doxataadine <sup>10mg</sup>	-  -	1/1000

- (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):

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## 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:
Prednisolone 20mg tab	side-effects

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

Roxithromycin 300mg for pneumonia

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**4. OTHER ISSUES**

Is there any other relevant information that should be considered?

young patient. Would be better to avoid repetitive treatments with prednisolone. Needs to be able to work again

**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):

	Discharge summary from Gisborne Hospital
2.	Consultation GP notes 16.11.2009
3.	Consultation notes 20.4.2010
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)	\$ 834
Anticipated duration of requested treatment: <i>(Note that approval will generally be given for only 1 year, renewal would then have to be sought)</i>	life long

**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: 20.4.2010

**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: 22.4.2010

**MEDICAL SERVICES**

Typed: 15 February 2010

Dear

Mr [redacted] returns for follow up of his asthma. This 25 year old gentleman has improved recently and he is unsure whether this is due to being away from the concrete facility where he was working or changes in his medications. He has also lost about 5kg in weight. His peak flows have increased to 460 today.

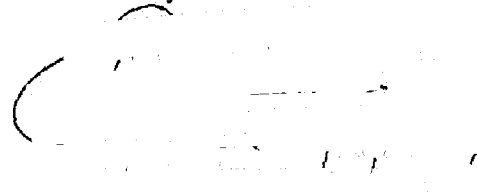
He had a chest x-ray and alpha one antitrypsin levels done after the last visit which were within normal limits. He has been back on theophylline without any complications. He has been trying to take his Loratadine daily though has been out of it for the last week. I have given him a renewal on his Loratadine and instructed him to keep on with his Flixotide, Serevent and Ventolin as needed as well as continue the theophylline.

It does not appear that there are any other significant underlying problems apart from allergic asthma. He is able to continue training for rugby four times weekly. We have discussed his return to work and while he seems to be doing well at the present time working as a concrete block maker it may be unreasonable for him given the significant dust exposure can potentially flare up his asthma so I have encouraged him to consider finding an alternative line of work at this point.

NOT WORKING PRESENTLY

With kind regards.

Yours sincerely

  
CONSULTANT PHYSICIAN

## Consultation

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Patient:

Address:

DOB:

Provider:

Date:

Type: Consult In Surgery

### Subjective

Still major problems with asthma.

Can not work

Feels a bit like the flu. No fever, no phlegm

### Objective

Obj : normal colours and resp

Temp 37.7

Cavum o : normal

St p : monophonic ronchi, maybe just a little crepitation basal dxt.

St c : normal

Conc : exacerbation of asthma, maybe even pneumonia.

To use Rx for Roxithromycin if fever or phlegm.

Hard to help this patient. He is taking all the inhalation he can. Can not afford

Singulair. Maybe SA for that?

Rx: 1 - Ipratropium Bromide 20mcg/1dose Inhaler 200doses - 2-4 puffs a day

Rx: 90 - Loratadine 10mg Tab - 1 tabs, Once Daily

Rx: 3 - Ventolin Cfc Free 100mcg/1dose Inhaler 2 - 2, As Required

Rx: 3 - Serevent Cfc-Free 25mcg/1dose Inhaler 12 - 2, Twice Daily

Rx: 3 - Flixotide Cfc Free 250mcg/1dose Inhaler - 2, Twice Daily

Rx: 30 - Theophylline 250mg Sustained Release Tab - 1 tabs, Twice Daily

Rx: 7 - Roxithromycin 300mg Tab - 1 tabs, Once Daily



## Consultation

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Patient: [faded]  
Address: [faded]  
DOB: [faded]

Provider: [faded]  
Date: 16 Nov 2009  
Type: Consult In Surgery

### Subjective

presents again c severe breathlessness.

### Objective

o/e T 36.1, throat nad., lungs in/expirational wheezing some scattered rales. SaO2 98%.  
px prednisone  
dx asthma attack, ?alveolitis?

Rx: 20 - Prednisone 20mg Tab - 3 tabs, Once Daily  
Out Box: Off Work Certificate

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