

# 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)

Dear Dr

NHI:

Patient:

D.O.B.:

Medication: **buprenorphine/naloxone (Suboxone) 8mg (16-24mg daily sublingual)**

Application for supplies of buprenorphine/naloxone (Suboxone) 8mg (16-24mg daily sublingual) for the above patient has been approved for a period of 52 weeks, based on the information you supplied.

The Ministry of Health, Sector Support Services will notify you with the approval number. The patient will be able to obtain funded supplies from the pharmacy nominated on the application form, in this case

Please note that all renewal applications should be on the appropriate form which can be downloaded from <http://www.pharmac.govt.nz/healthpros/EC/ECForms>

The form can be either faxed to the number on the form or posted to:

PHARMAC  
PO Box 10-254  
Wellington

Yours sincerely



p.p. Jayne Watkins

Signed on behalf of:

Exceptional Circumstances Panel

*Investing in Health*

**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](mailto: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:	
Date of Birth:	
NHI No:	

**Details of Prescriber**

Last Name:	
First Name:	
Address:	
Phone:	
Facsimile:	
Email:	
Are you a General Practitioner?	

**Disease/Condition**

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

Q-T prolongation
→ Torsade de Pointes
→ cardiac arrest (VF)

**Medicine/treatment sought:**

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

Brand Name:	Suboxone
Chemical Name:	Buprenorphine / Naloxone
Manufacturer:	Reckitt Benckiser
Form and Strength:	8mg
Dosage to be used:	16-24mg
Dosage regimen: <small>(where applicable)</small>	daily, subling
Extemporaneously compound?:	Yes <input type="checkbox"/> No <input type="checkbox"/>
<small>(If Yes, attach a full list of ingredients)</small>	

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

**Nominating Pharmacist**

Name:	
Address:	
Phone:	09

Where can the medicine be obtained? This will generally NOT be a hospital pharmacy.)


**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?)
methadone.	Q-T. prolongation (490. msec)	1:500 treated patients

- (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):

(L.A.)  
 Has had oral morphine as substitute medication.  
 Has persistently diverted this and injected intravenously.  
 - Requests to go back on methadone.  
 - we, (medical officers) consider this contra-indicated



**4. OTHER ISSUES**

Is there any other relevant information that should be considered?

note of septicemia / endocarditis continues  
& habitual I.V. use.

**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.	Clinical Summary - discharged 27/02/2008.
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>3790 - 5685</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>indefinite</u>

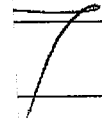
**7. RENEWAL (COMPLETE FOR RENEWALS ONLY)**

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




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Date of Request: \_\_\_\_\_

**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.

X

Date: \_\_\_\_\_

Patient Copy

**Referral Reason**  
CARDIAC ARREST

**Diagnoses**

**Primary Diagnosis**

- VF cardiac arrest w success resuscitation

**Secondary Diagnoses**

- Acute QT prolongation likely due to methadone
- Methadone program for benzodiazepine dependency

**Procedures**

**Primary Procedure**

- Diagnostic Coronary study +/- LV, 26/02/2008, Dr P Nakpathomkun

**Discharge Medications**

- Diazepam, po 7mg, mane, 2 weeks (script given)
- Diazepam, po 8mg, nocte, 2 weeks (script given)
- Paracetamol, po 1g, qid/prn, 100 tabs (script given)
- M-eslon, po 120mg, bd, 10 days (script given)
- M-eslon, po 60mg, od/prn to top up for withdrawal symptoms, 10 days (script given)
- Lactulose, po 10-20ml, bd/prn, 3 months (script given)
- Coloxyl with senna, po 2 tabs, bd/prn, 3 months (script given)
- Ibuprofen, po 400mg, tds/prn, 2 weeks (script given)
- Omeprazole, po 20mg, od, 3 months (script given)
- Aspirin EC, po 100mg, od, 3 months (script given)

**Allergies**

NKDA

**Clinical Management**

**Background:**

Benzodiazepene dependency ( known to [REDACTED] - on methadone programme )

Opioid dependency

Previous IV drug use.

Nicotine dependency

Previous hx of seizure-type activity - ?absence seizure/petit mal (not documented)

Hep B +ve

42 y.o. lady BIBA following cardiac arrest in community.

Witnessed loss of consciousness by partner. ? Had convulsion in front of parnter (became stiff and unresponsive). Ambulance called 06:28.

On ambulance arrival (06:33), was unconscious/unresponsive with agonal respirations and no palpable pulses. She was pulled off bed onto floor and CPR initiated. Initial trace showed VF.

ROSC after 2 min CPR and DC shock 360J.

Initially intubated and ventilatory effort assisted, then spontaneous resp shortly after.

On arrival at ACH,

O/E - GCS 5/15 (E1 V1 M3), T 35.4, BP 142/72, P 86, O2 sats 100%, spontaneous resp, pupils 4mm, PEARL

31/03/2010

[REDACTED]  
 CXR - RLL collapse  
 ECG - SR 94/min, no acute ischaemic changes, prolonged QT interval (QTc 490msec)  
 CT brain - NAD  
 Trop - 0.14 --> 0.19

Admitted to DCCM and was initially managed with her usual methadone (usually 115mg/day) and diazepam (7mg mane and 8mg nocte).

Case discussed with Dr [REDACTED]. Suggested that if clinical opinion is QT prolongation related to methadone, methadone can be switched to long acting morphine (initially started on 60mg, then increased to 120mg BD), with an extra PRN daily dose of 60mg if withdrawal symptoms (sweats, cramps/aches, diarrhoea) occurs.

Echo showed

- mild LV dilatation
- extensive anteroapical wall motion abnormality (involving the mid inferior septum and extends around the apex into the mid inferior and mid lateral segments)
- other regions contracts vigorously
- LV EF moderately reduced (~40%)
- no evidence of LV thrombus
- normal LV wall thickness
- abnormal LV relaxation with increased LVEDP (mild-moderate LV diastolic dysfunction)
- trivial-mild MR
- normal RV side
- some anteroapical RV hypokinesia, but overall RV systolic function normal, normal PA systolic pressure

Coronary angio (26/02/08) showed normal coronary arteries. Left ventriculography showed hypokinesia of mid-anterior wall, apex and apical inferior wall. LVEDP 10mmHg. Good LV systolic function.

ETT was a normal study with no inducible ischaemia/arrhythmia (no chest pain/ECG changes) on Bruce protocol.

Discussed with Dr [REDACTED] re: investigation findings. Decided not for ICD. QT prolongation likely secondary to methadone causing VF arrest. Therefore, she should be off methadone and will need to be seen in COPC for follow up in 2/12 with repeat echo in 1/12 to see reversibility.

Plan:

1. D/C home
2. COPC follow up with Dr W Smith in 2/12
3. Repeat Echo in 1/12 (to be done prior to clinic follow up)
4. Not for methadone
5. Continue LA Morphine
6. Ongoing CADS (under Dr A Grey) follow up in community: Ms Morgan will contact the community CADS team

#### Advice To GP

Thank you for your ongoing care.

#### Advice To Patient

We will organise a follow up appointment for you in our cardiology outpatient clinic with Dr [REDACTED] in 2 months. You will also receive a letter for an outpatient echocardiogram prior to the clinic appointment. Please attend these appointments.

Please remember that you should NOT take any more methadone, as it is most likely that methadone has caused damages to your heart causing cardiac arrest.

Please liaise with your community CADS team for ongoing management.

#### Follow Up Arrangement

Signature: \_\_\_\_\_  
Date: 27/02/2008 13:17