

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

17th June 2010

Dear Dr

NHI:

Patient:

D.O.B.:

Medication: **hypromellose dextran 70 (Bion Tears) eye drops (1-2 drops PRN QID)**

Application for supplies of hypromellose dextran 70 (Bion Tears) eye drops (1-2 drops PRN QID) 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



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

28 MAY 2010

022791

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
Date of Birth:	
NHI No:	

Details of Applying Practitioner

Last Name:	
First Name:	
Address:	
Phone:	
Facsimil:	
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

Facial Nerve Palsy 2° to Acoustic Neuroma & Secondary Dry Eyes.
ALLERGY/REACTION TO STANDARD LUBRICANTS. → REQUIRE BLON DROPS → WITHOUT PRESERVATIVE.

Medicine/treatment sought:

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

Brand Name:	BLON TEARS
Chemical Name:	HYDROXYMELLOZE DESPREAN 70
Manufacturer:	ALCON
Form and Strength:	EYE DROPS
Dosage to be used:	12 PROPS PER QID
Dosage regimen: (where applicable)	
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

Nominator

Name:	
Address:	
Phone:	

Supplies 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?

FACIAL Palsy POST Acoustic Neuroma SURGERY

- (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)

see Attached letters

Treatment	Response of this patient	Rarity 'how often would you expect this to occur'
TEARS PLUS	CORNEAL ULCERATION	?
WAS THE 4 TEARS "	"	?

- (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):

AS ABOVE - Acoustic Neuroma SURGERY →
→ FACIAL NERVE Palsy - SEVERE - REQUIRING GOLD IMPLANT TO
R EYE UPPER LID - TO ASSIST CLOSURE. - STILL THIS IS NOT ENOUGH
SO NEEDS CONSTANT ARTIFICIAL LUBRICATION BUT HE HAS DEVELOPED
A CHRONIC IRRITATION & CORNEAL ULCERATION AS A RESPONSE TO
THE PRESERVATIVES IN STANDARD LUBRICANTS. → FINE WITH
BION . PRESERVATIVE FREE.

2. CLINICAL BENEFIT AND SUITABILITY

7. SPECIALIST ADVISED IN LETTER.

(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

PRV
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:
VISTIL	REACTION - CORNEAL OPACIFICATION
W/OUT FILM TABLETS	→ REACTION - " "
PANASC.	→ REACTION " "
POLY TABLETS	→ REACTION " "

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

4. OTHER ISSUES

Is there any other relevant information that should be considered?

He can't afford the cost of Treatment himself.

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.	Hospital Discharge
2.	Ophthalmologist Report.
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>546.00</u>
Anticipated duration of requested treatment: (Note that approval will generally be given for only 1 year, renewal would then have to be sought)	-LIFELONG

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, ra

8. SIGNATURES

Signature of Medical Practitioner: _____

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.

Signed:

: 20/5/10

295

20 January 2010

cc

Dear

Ocular Summary:

- 1 Right seventh nerve palsy following acoustic neuroma surgery 1994
- 2 Past right ectropion repair/right medial and lateral canthoplasty/right subperiosteal mid face lift/
Gold implant right upper lid
- 3 Arcus senilis
- 4 Cortical lens opacity

Visual Acuity: Right 6/9 corrected and left 6/6

- Treatment:**
- 1 Bandage soft contact lens insitu
 - 2 Bion Tears up to one hourly
 - 3 Chloramphenicol ointment at night
 - 4 Taping the eyelid closed at night

- Follow Up:**
- 1 Six months in the Eye Clinic
 - 2 Removal of contact lens at Opticians in three weeks

Comment:

I saw N on 6 January 2010 when he was referred by the Emergency Department with a very red rough cornea and reduced vision. He was only managing counting fingers.

Affectively the cornea was very dry and exposed. I managed this with the above treatment and he is now seeing 6/9 with a pinhole and the eye is a lot more comfortable and not red.

.../2



I have advised him to continue with the above treatment and I will see him on an urgent basis if necessary otherwise for review in six month's time.

; can remove the contact lens in three week's time and if in the days or weeks following removal the eye is exacerbated then I would be very happy for them to insert a new Bandage contact lens.

Yours sincerely

[Redacted signature area]

[Redacted box]

Inbox Report

Person preparing referral:

Referring Physician:

Primary Care Provider:

NHI:

Diagnosis Details:

multiple corneal abrasions

Diagnosis Details:

scleritis

Procedure Details:

chloro-sig ointment 6x a day eye patch in PM

Consulting Doctor:

Admission Time:

29 Dec 2009 12:59 pm

Discharge Time:

29 Dec 2009 3:15 pm

Clinic Name:

Hospital Emergency Dept

Allergies

MULTIPLE

Presenting Medication

aspirin, furosemide,
bleph-10 1 drop QID most recent antibiotic

Past Medical History

AF

GORD

gout

CHF

HTN

IHD

CN VII palsy post acoustic neuroma surgery

multiple plastic surgeries to help eye close

Discharge Medications

chlorsig ointment 6 times a day with eye patch at night

Presenting Complaint

R red eye

Vital Signs

HR: 58

BP: 176/86

Temperature: 36.7

SaO2%: 99

Outpatient Details:

Patient to see GP as necessary

Clinical Notes

83 yo male with symptoms of 'gritty' RIGHT eye for 5 days, redness for 3-4 days, worsening 'filmy' vision x 1 day. denies trauma to eye

patient patched eye at night last night that seemed to help him

Inbox Report

denies headache/ eye pain with movement/ ear pain/ nausea/ vomiting/ fever/ cough/ sore throat

has seen GP regarding this condition for the past 4-5 days and dx with corneal ulcers, at first visit given chlorsig drops both eyes QID. this patient reports resulted in stinging and more redness after this dose. went back to GP and changed to Bleph 10 1 drop QID with again stinging and redness that seemed to worsen pain but improved the gritty

referred for evaluation in ED

reviewed past medical records and appears to have had a similar episode July/Aug of 2007. Patient now recalls it as similar to previous

according to history has a CN VII palsy after acoustic neurmoa surgery and requires eyes drops all day to help with moisture. He has had abrasions in the past treated by his GP. Saw Dr. august 2007 and offered Polyvisc ointment rather than eye drops 6 times a day but had new corneal involvement at time of eye clinic visit

right eye figners at 2 meters

left eye 6/7

exam: pleasant gentleman hard of hearing

patient with muslce atrophy of face with with drawn face and lips

right eye bottom lid droops, top lid can cover 85% of eye with slow blink

EOMI

pupils equal round and reactive

gross inspection sclera inflammed and red

cloudy appearing cornea as compared to left

without staining: corneal defects center at 6 oclock and 2 oclock

slit lamp: no cells or flares appreciated but difficult to assess due to hazy refraction of light

with fluorescein staining: uptake at iris limbus 1 oclock and 7 oclock, over center punctate uptake filming over cornea and field of vision

concern for corneal abrasion most likely due to coarse dryness due to anatomic defect of eye closing

discussed case with ophtho oncall

no need for transport

to change to chlorsig OINTMENT for moisture and antibiotic

Inbox Report

effect increase to 6 times a day

to try patch at night

for review at 8 am in ED

if possible to have have review by Dr. if available

Notes for GP

reviewed patient to see ED tomorrow, referral to ophtho if available

Instructions to Patient

None Provided

Observation date:
