

5 July 2006

To All Pharmaceutical Suppliers, Medical Groups and Interested Parties

Proposal to amend or remove the Special Authority criteria for various pharmaceuticals, and to delist oxypentifylline from Part IV of Section H of the Pharmaceutical Schedule

PHARMAC is proposing to remove or amend the Special Authority criteria for various pharmaceuticals listed in Section B of the Pharmaceutical Schedule, and to delist oxypentifylline from Part IV of Section H of the Pharmaceutical Schedule (since removal of the Special Authority for oxypentifylline would remove the need for this listing), with effect from 1 September 2006. We are now seeking feedback on this proposal. A summary of this proposal is provided in the following table:

Pharmaceutical	Special Authority	Other restriction
Ursodeoxycholic acid	Would be amended to remove the requirement for gastroenterologists to write prescriptions, and to allow general physicians to make Special Authority applications	Special Authority – Retail pharmacy – specialist prescription (no change from present)
Oxyentifylline	Would be removed	Hospital pharmacy [HP3] (no change from present)
Acetylcysteine eye drops	Would be removed	Would be amended to: Hospital pharmacy [HP1] – specialist
Total parental nutrition	Would be removed	Would be amended to: Hospital pharmacy [HP1] – specialist
Apomorphine hydrochloride	Would be removed	Would be amended to: Hospital pharmacy [HP3] – specialist
Animal insulins	Would be removed	There would be no restriction
Rapid-acting insulins	Would be removed	Would be removed
Bupivacaine hydrochloride	Would be removed	Would be amended to: Hospital pharmacy [HP3] – specialist
Interferon alpha-2a	Would be removed	Would be amended to: Hospital pharmacy [HP3] – PCT – specialist
Interferon alpha-2b	Would be removed	Would be amended to: Hospital pharmacy [HP3] – PCT – specialist

Details of the proposal are as follows:

- the Special Authority applying to ursodeoxycholic acid cap 300 mg would be amended as follows (changes in bold and strikethrough):

~~Prescriptions must be written by a gastroenterologist.~~

Special Authority for Subsidy - form: SA0458**xxx**

Initial application only from a gastroenterologist or **general physician**. Approvals valid for 6 months for applications meeting the following criteria:

both:

1 Primary biliary cirrhosis confirmed by antimitochondrial antibody titre (AMA) > 1:80, and raised cholestatic liver enzymes with or without raised serum igM or, if AMA is negative, by liver biopsy; and

2 Patient not requiring a liver transplant (bilirubin > 170umol/l; decompensated cirrhosis).

Note: liver biopsy is not usually required for diagnosis but is helpful to stage the disease

Renewal only from a gastroenterologist or **general physician**. Approvals valid for 2 years for applications meeting the following criteria: the treatment remains appropriate and the patient is benefiting from treatment.

Note Actigall is not an appropriate therapy for patients requiring a liver transplant (bilirubin > 170 micromol/l; decompensated cirrhosis). these patients should be referred to an appropriate transplant centre. treatment failure - doubling of serum bilirubin levels, absence of a significant decrease in AIP or Alt and ASt, development of varices, ascites or encephalopathy, marked worsening of pruritus or fatigue, histological progression by two stages, or to cirrhosis, need for transplantation.

- the Special Authority applying to oxyptentifylline tablet 400 mg would be removed, while maintaining the "Hospital Pharmacy [HP3]" restriction, with effect from 1 September 2006 as follows (changes in strikethrough):

~~Special Authority for Subsidy—Form SA0125~~

~~Initial application—(Chronic post-thrombotic venous stasis ulcers) from any medical practitioner. Approvals valid for 2 years for applications meeting the following criteria:~~

~~Both:~~

~~1 Chronic post-thrombotic venous stasis ulcers of more than 4 months duration; and~~

~~2 Other interventions have failed.~~

~~Initial application—(Sudden hearing loss) only from an otolaryngologist. Approvals~~

~~valid for 2 years for applications meeting the following criteria:~~

~~Sudden hearing loss.~~

~~Renewal from any medical practitioner. Approvals valid for 2 years for applications meeting the following criteria:~~

~~The treatment remains appropriate and the patient is benefiting from treatment.~~

- oxyptentifylline tablet 400 mg would be delisted from Part IV of Section H of the Pharmaceutical Schedule, with effect from 1 September 2006.
- the Special Authority applying to extemporaneously compounded acetylcysteine eye drops would be removed, with effect from 1 September 2006, as follows (changes in strikethrough):

~~Special Authority for Subsidy—Form: SA0122~~

~~Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~Filamentary keratitis.~~

~~Renewal only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~The treatment remains appropriate and the patient is benefiting from treatment.~~

- the restriction for acetylcysteine eye drops would be amended from 1 September 2006 as follows (changes in bold and strikethrough):

~~Special Authority—Hospital pharmacy [HP1]-specialist~~

- the Special Authority applying to total parenteral nutrition would be removed, with effect from 1 September 2006, as follows:

~~Special Authority for Subsidy—Form SA0610~~

~~Initial application from any specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:~~

~~All of the following:~~

- ~~1 Quantity used by patient on a weekly volume intravenously (Details to be attached to application); and~~
- ~~2 Amount of nutrition patient is able to receive orally (Details to be attached to application); and~~
- ~~3 Exact formula of TPN (Details to be attached to application); and~~
- ~~4 Who has paid for TPN so far (Details to be attached to application); and~~
- ~~5 Place of manufacture (Details to be attached to application); and~~
- ~~6 Complete medical history of patient including details of previous therapies. (Details to be attached to application).~~

~~Renewal (Previous approval has expired) from any specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:~~

~~The treatment remains appropriate and the patient is benefiting from treatment.~~

- the restriction for total parenteral nutrition would be amended from 1 September 2006 as follows (changes in bold and strikethrough):

~~Special Authority—Hospital pharmacy [HP1]-specialist~~

- the Special Authority applying to apomorphine hydrochloride injection 10 mg per mL, 1 mL, would be removed, with effect from 1 September 2006, as follows (changes in strikethrough):

~~Special Authority for Subsidy—Form SA0309~~

~~Initial application only from a neurologist or physician for the elderly (FRACP).~~

~~Approvals valid for 2 years for applications meeting the following criteria:~~

~~All of the following:~~

- ~~1 Idiopathic Parkinson's disease; and~~
- ~~2 The patient does not have dementia and/or neuropsychiatric disorders; and~~
- ~~3 Has responded to L-dopa; and~~
- ~~4 Any of the following:~~
 - ~~4.1 Has resistance to conventional treatment of severe motor fluctuations; or~~
 - ~~4.2 Has severe "off" period disability; or~~
 - ~~4.3 Has severe "off" period dystonic cramps.~~

~~Renewal only from a neurologist or physician for the elderly (FRACP). Approvals valid for 2 years for applications meeting the following criteria:~~

~~The treatment remains appropriate and the patient is benefiting from treatment.~~

- the restriction for apomorphine hydrochloride injection 10 mg per mL, 1 mL would be amended from 1 September 2006 as follows (changes in bold and strikethrough):

~~Special Authority—Hospital pharmacy [HP3]-specialist~~

- the Special Authority applying to insulin animal injection 100 u per mL, 10 mL (insulin neutral and insulin isophane) would be removed, with effect from 1 September 2006, as follows (changes in strikethrough):

~~Special Authority for Subsidy – Form SA0750~~

~~Initial application only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:~~

~~Continuation of previous therapy.~~

- the Restriction on subsidy for rapid-acting insulin analogues (insulin aspart inj 100 u per mL, 3mL; insulin aspart inj 100 u per mL, 10 mL; insulin lispro inj 100 u per mL, 3 mL; insulin lispro inj 100 u per mL, 10 mL) would be removed, with effect from 1 September 2006, as follows (changes in strikethrough):

~~1) prescribed with insulin isophane, or insulin glargine, but are on a different prescription and the prescription is endorsed accordingly; or prescribed on the same prescription as insulin isophane, or insulin glargine, in which case the prescription is deemed to be endorsed; or~~

~~2) a Special Authority has been approved.~~

~~For 1) and 2) first prescription to be written by a Specialist (diabetologist, general physician or paediatrician). Any medical practitioner can write subsequent prescriptions.~~

- the Special Authority (waiver of restriction) applying to rapid-acting insulin analogues (insulin aspart inj 100 u per mL, 3mL; insulin aspart inj 100 u per mL, 10 mL; insulin lispro inj 100 u per mL, 3 mL; insulin lispro inj 100 u per mL, 10 mL) would be removed, with effect from 1 September 2006, as follows (changes in strikethrough):

~~Special Authority available to waive restriction – Form: SA0641~~

~~Initial application only from a diabetologist, general physician or paediatrician.~~

~~Approvals valid without further renewal unless notified for applications meeting the following criteria:~~

~~Either:~~

~~-1 Both:~~

~~-1.1 Use alone (monotherapy); and~~

~~-1.2 The patient is unable to use any other insulins including those on insulin pump treatment; or~~

~~-2 Both:~~

~~-2.1 Use with insulin other than insulin isophane (including ready mixed preparations); and~~

~~-2.2 A reasonable trial of insulin isophane has been undertaken and it is not effective or not well tolerated.~~

~~Note~~

~~"Reasonable trial", "unable to use", "not effective", "not well tolerated", and "not well tolerated" are not defined and we ask clinicians to use their clinical judgement in interpreting these terms.~~

- the Special Authority applying to bupivocaine hydrochloride inj 0.5%, 4 mL (Marcain Isobaric) and bupivacaine hydrochloride inj 0.5%, 8% glucose, 4 mL (Marcain Heavy), would be removed, with effect from 1 September 2006, as follows (changes in strikethrough):

~~Special Authority for Subsidy – Form SA0140~~

~~Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~Both:~~

~~-1 Pain management in the terminally ill; and~~

~~2 Standard therapy has failed.~~

~~Renewal only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~The treatment remains appropriate and the patient is benefiting from treatment.~~

- the restriction for bupivacaine hydrochloride would be amended from 1 September 2006 as follows (changes in bold and strikethrough):

~~Special Authority—Hospital pharmacy [HP3]-**specialist**~~

- the Special Authority applying to interferon alpha-2a (inj 3 m iu prefilled syringe; inj 4.5 m iu prefilled syringe; inj 6 m iu prefilled syringe; inj 9 m iu prefilled syringe; inj 18 m iu multidose cartridge; inj 18 m iu multidose cartridge x 2 starter pack) would be removed, with effect from 1 September 2006, as follows (changes in strikethrough):

~~Special Authority for Subsidy—Form SA0404~~

~~Initial application—(Basal cell carcinoma) only from a dermatologist, plastic surgeon or radiation oncologist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~Both:~~

~~1 Basal cell carcinoma unable to be treated surgically or by radiotherapy; and~~

~~2 Unsuitability for surgery confirmed by a Plastic Surgeon or Oncologist.~~

~~Note~~

~~Maximum reimbursable dosage 15 million iu/week~~

~~Initial application—(Chronic hepatitis C) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:~~

~~Chronic hepatitis C.~~

~~Initial application—(Indications other than Basal cell carcinoma and Chronic hepatitis C) only from a relevant specialist, plastic surgeon or radiation oncologist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~Any of the following:~~

~~3 Chronic myelogenous leukaemia; or~~

~~4 Hairy cell leukaemia; or~~

~~5 Cutaneous T cell lymphoma; or~~

~~6 Essential thrombocythaemia; or~~

~~7 Multiple myeloma; or~~

~~8 Chronic active hepatitis B.~~

~~Renewal—(Basal cell carcinoma) only from a dermatologist, plastic surgeon or radiation oncologist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~Unsuitability for surgery confirmed by a Plastic Surgeon or Oncologist.~~

~~Renewal—(Indications other than Basal cell carcinoma and Chronic hepatitis C) only from a relevant specialist, plastic surgeon or radiation oncologist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~the treatment remains appropriate and the patient is benefiting from treatment.~~

- the restriction for interferon alpha-2A would be amended from 1 September 2006 as follows (changes in bold and strikethrough):

~~Special Authority—Hospital pharmacy [HP3] – PCT – **specialist**~~

- the Special Authority for interferon alpha-2b (inj 18 m iu, 1.2 ml multidose pen; inj 30 m iu, 1.2 ml multidose pen; inj 60 m iu, 1.2 multidose pen) would be removed, with effect from 1 September 2006, as follows (changes in strikethrough):

~~Special Authority for Subsidy Form SA0464~~

~~Initial application—(Basal cell carcinoma) only from a dermatologist, plastic surgeon or radiation oncologist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~Both:~~

- ~~1 Basal cell carcinoma unable to be treated surgically or by radiotherapy; and~~
- ~~2 Unsuitability for surgery confirmed by a Plastic Surgeon or Radiation Oncologist.~~

~~Note~~

~~The maximum reimbursable dosage is 15 million iu per week~~

~~Initial application—(Chronic hepatitis C) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:~~

~~Chronic hepatitis C:~~

~~Initial application—(Indications other than Basal cell carcinoma and Chronic hepatitis C) only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~Any of the following:~~

- ~~3 Chronic myelogenous leukaemia; or~~
- ~~4 Hairy cell leukaemia; or~~
- ~~5 Multiple myeloma; or~~
- ~~6 Chronic active hepatitis B.~~

~~Renewal—(Basal cell carcinoma) only from a dermatologist, plastic surgeon or radiation oncologist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~Unsuitability for surgery confirmed by a Plastic Surgeon or Oncologist.~~

~~Renewal—(Indications other than Basal cell carcinoma and Chronic hepatitis C) only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~The treatment remains appropriate and the patient is benefiting from treatment.~~

- the restriction for interferon alpha-2b would be amended from 1 September 2006 as follows (changes in bold and strikethrough):

~~Special Authority—Hospital pharmacy [HP3] – PCT – specialist~~

It is anticipated that the proposed changes, if approved by PHARMAC's Board, or Chief Executive under delegated authority, would take effect from 1 September 2006. If you wish to make comments for the PHARMAC Board to consider when making its decision on whether to accept this proposal, please forward them to PHARMAC by **5:00 pm, 19 July 2006**. All comments submitted by this date will be considered.

Yours sincerely



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Therapeutic Group Manager