

9 August 2010

Approval of proposals for various pharmaceuticals

PHARMAC is pleased to announce the approval of proposals for pharmaceuticals in several therapeutic groups which aim to address some issues relating to funded access. The decision will result in, for some pharmaceuticals, increasing the subsidies, amending access criteria and listing new presentations; while reducing the subsidies and ceasing funding for some other pharmaceuticals.

These decisions were the subject of a consultation letter dated 2 July 2010.

All decisions will take effect from 1 September 2010 unless otherwise stated. If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.

Summary of the decisions

Diabetes

- *Pioglitazone* – the Special Authority criteria will be amended whilst maintaining the current intent of the criteria.
- *Acarbose* – the Special Authority will be removed.

Hormones

- *Buserelin acetate* – this medicine will be delisted, and funding will cease from 1 December 2010.

Infections

- *Azithromycin* – the Practitioner Supply Order (PSO) limit will be increased from 4 tablets (2 packs) to 8 tablets (4 packs).

Musculoskeletal System

- *Long-acting ibuprofen* – the subsidy for the ibuprofen 800 mg long-acting tablet will be increased to match the current manufacturer's price so that it is fully funded without the need for the current Special Authority.
- *Amended Special Authority access for patients managed long-term on various non-steroidal anti-inflammatory drugs (NSAIDs)* – all Special Authority for Manufacturers' Price approvals will be converted to an indefinite duration (i.e. removing the need for further renewal applications to be made) and no new approvals will be granted.
- *Naproxen Sodium tablets* – the subsidy for naproxen sodium 275 mg and 550 mg tablets will be reduced to the level of the subsidy for the equivalent strengths of naproxen (250 mg and 500 mg tablets, respectively) through the application of reference pricing from 1 December 2010.
- *Tenoxicam powder for injection* – tenoxicam 20 mg powder for injection will be listed, fully funded, in the NSAIDs section of Section B of the Pharmaceutical Schedule.

Nervous System

- *Anaesthetics* – lignocaine 2% injections and lignocaine 2% viscous solution will be listed fully funded; the prescribing restrictions will be removed from lignocaine hydrochloride injections; all lignocaine injection presentations will be available on PSO and bupivacaine injections will be delisted from Section B of the Pharmaceutical Schedule.
- *Anxiolytics, Sedatives and Hypnotics* – the “month restriction” will be removed from all pharmaceuticals within these subgroups of Section B of the Pharmaceutical Schedule, meaning that repeat dispensings will be funded. There will be no change to the quantity that clinicians can prescribe (which was, and still is, up to three months’ worth on a prescription) and monthly dispensing will still apply.
- *Ondansetron and tropisetron* – the “Retail pharmacy-Specialist” restrictions will be removed.

Oncology

- *Capecitabine* – the Special Authority will be amended to allow a medical practitioner, on the recommendation of a relevant specialist, to make applications for subsidies.

Respiratory

- *Nedocromil, sodium cromoglycate, theophylline oral liquid* – the subsidies for nedocromil (aerosol inhaler, 2 mg per dose CFC-free), sodium cromoglycate (powder for inhalation, 20 mg per dose and aerosol inhaler, 5 mg per dose CFC-free) and theophylline (oral liq 80 mg per 15 ml) will be increased to match the current manufacturers’ surcharges so that they are fully funded for patients.

Details of the decisions

Diabetes

Pioglitazone (Pizaccord)

The Special Authority criteria (SA0959) for pioglitazone will be amended as follows (changes in strikethrough):

Initial application - (Patients with type 2 diabetes) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

1. Patient has not achieved glycaemic control on maximum doses of metformin ~~and~~/or a sulfonylurea or where either or both are contraindicated or not tolerated.
2. Patient is on insulin

Acarbose (Glucobay)

The Special Authority (SA0925) for acarbose will be removed, which will allow any practitioner to prescribe acarbose (tab 50 mg and tab 100 mg) without the need for a Special Authority application.

Hormones

Buserelin acetate (Suprefact)

Buserelin acetate (inj 1 mg per ml, 5.5 ml) will be delisted from Section B of the Pharmaceutical Schedule from 1 December 2010.

Infections

Azithromycin (Arrow-Azithromycin)

The 4 tablet (2 pack) limit of azithromycin tablets available on a PSO will be increased to 8 tablets (4 packs).

Musculoskeletal System

Long-acting ibuprofen (Brufen Retard)

The subsidy for ibuprofen 800 mg long-acting ibuprofen tablets will be increased from \$1.50 to \$9.12 per pack of 30 to match the current manufacturer's price, resulting in this presentation becoming fully funded.

Amended Special Authority access for patients managed long-term on various NSAIDs

All valid approvals for the Special Authority for Manufacturers Price (SA0291) applying to NSAIDs will be converted to lifetime approvals so that no further renewal applications will need to be made. No new approvals will be granted. The Special Authority will be amended as follows (deletions in strikethrough, additions in bold):

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

~~Both:~~

- ~~1 Inflammatory arthritis (including osteoarthritis with an inflammatory component); and~~
- ~~2 Stabilised and are well controlled on the particular NSAID medication.~~

~~Renewal from any medical practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.~~

Notes: Subsidy for patients with existing approvals prior to 1 September 2010. Approvals valid without further renewal unless notified. No new approvals will be granted from 1 September 2010.

Naproxen Sodium tablets (Sonaflam and Synflex)

The subsidy for naproxen sodium 275 mg and 550 mg tablets will be reduced to the level of the subsidy for the equivalent tablet strengths of naproxen 250 mg and 500 mg (Noflam 250 and Noflam 500, respectively) through the application of reference pricing from 1 December 2010 as follows:

| Chemical | Presentation | Brand | Pack size | Current subsidy and price | New subsidy |
|-----------------|---------------|----------|-----------|---------------------------|-------------|
| Naproxen sodium | 275 mg tablet | Sonaflam | 120 | \$6.00 | \$5.69 |
| Naproxen sodium | 550 mg tablet | Synflex | 100 | \$12.80 | \$9.95 |

Prices and subsidies are expressed ex-manufacturer, excluding GST

Tenoxicam powder for injection (AFT)

Tenoxicam 20 mg powder for injection (AFT) will be listed, without restrictions, in the NSAIDs section of Section B of the Pharmaceutical Schedule at a price and subsidy of \$9.95 per vial (ex-manufacturer, excluding GST).

Nervous System

Anaesthetics

The following lignocaine presentations will be listed, fully funded, in Section B of the Pharmaceutical Schedule:

| Chemical | Presentation | Brand | Pack size | Subsidy and price |
|--------------------------|---------------------|-------------------|------------------|--------------------------|
| Lignocaine hydrochloride | Viscous solution 2% | Xylocaine Viscous | 200 ml | \$55.00 |
| Lignocaine hydrochloride | Inj 2%, 5 ml | Xylocaine | 50 | \$23.00 |
| Lignocaine hydrochloride | Inj 2%, 20 ml | Xylocaine | 5 | \$15.00 |

Prices and subsidies are expressed ex-manufacturer, excluding GST

We note that there were errors in the consultation letter for the proposed subsidies and prices for new lignocaine presentations to be in Section B of the Pharmaceutical Schedule. The above table includes the correct subsidies and prices.

Lignocaine viscous solution 2% will be removed from the Discretionary Community Supply (DCS) list.

The “only if prescribed on prescription for a dialysis patient or child with rheumatic fever or on a PSO for emergency use” restriction will be removed from the listings of lignocaine hydrochloride injection 0.5%, 5 ml, 1%, 5 ml and 1%, 20 ml in Section B of the Pharmaceutical Schedule.

All lignocaine hydrochloride injection presentations listed in Section B of the Pharmaceutical Schedule will be subject to the “Up to 5 inj available on a PSO” rule.

Lignocaine gel 2%, 10 ml urethral syringe (Pfizer) and lignocaine gel 2% with chlorhexidine 0.05%, 10 ml urethral syringe (Pfizer) listed in Section B of the Pharmaceutical Schedule will be subject to a “Up to 5 syringes available on a PSO” rule.

Bupivacaine hydrochloride injection 0.5%, 4 ml (Marcain Isobaric) and injection 0.5% with 8% glucose, 4 ml (Marcain Heavy) will be delisted from Section B of the Pharmaceutical Schedule.

Ondansetron (Zofran and Zofran Zydis) and tropisetron (Navoban)

The “Retail pharmacy-Specialist” restrictions will be removed from ondansetron and tropisetron.

Anxiolytics, Sedatives and Hypnotics

The current “Month Restriction” will be removed from all the pharmaceuticals within the subgroups of Section B of the Pharmaceutical Schedule that currently have a “Month

Restriction”, so that repeat prescriptions will be funded (although month dispensing by pharmacies will still be required). The relevant pharmaceuticals are:

| Sedatives & Hypnotics | | |
|----------------------------------|--------------------------|-------------------|
| <i>Pharmaceutical</i> | <i>Presentation</i> | <i>Brand</i> |
| Lormetazepam | Tab 1 mg | Noctamid |
| Midazolam | Tab 7.5 mg | Hypnovel |
| Nitrazepam | Tab 5 mg | Nitrados |
| Temazepam | Tab 10 mg | Normison |
| Triazolam | Tab 125 µg, 250 µg | Hypam |
| Zopiclone | Tab 7.5 mg | Apo-Zopiclone |
| Anxiolytics | | |
| <i>Pharmaceutical</i> | <i>Presentation</i> | <i>Brand</i> |
| Alprazolam | Tab 250 µg, 500 µg, 1 mg | Arrow-Alprazolam |
| Buspirone | Tab 5 mg, 10 mg | Pacific Buspirone |
| Diazepam | Tab 2 mg, 5 mg | Arrow-Diazepam |
| Lorazepam | Tab 1 mg, 2.5 mg | Ativan |
| Oxazepam | Tab 10 mg, 15 mg | Ox-Pam |

Oncology

Capecitabine (Xeloda)

The Special Authority for capecitabine (tab 150 mg and 500 mg) will be amended to allow a medical practitioner on the recommendation of a relevant specialist to make applications for subsidies as follows (changes in bold):

Initial application only from a relevant specialist **or medical practitioner on the recommendation of a relevant specialist**. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

- 1 The patient has advanced gastrointestinal malignancy; or
- 2 The patient has metastatic breast cancer*; or
- 3 The patient has stage III (Dukes' stage C) colorectal*# cancer and has undergone surgery; or
- 4 Both:
 - 4.1 The patient has poor venous access or needle phobia*; and
 - 4.2 The patient requires a substitute for single agent fluoropyrimidine*.

Renewal only from a relevant specialist **or medical practitioner on the recommendation of a relevant specialist**. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 The patient requires continued therapy; or
- 2 The tumour has relapsed and requires re-treatment.

Note indications marked with * are Unapproved Indications, # capecitabine is approved for stage III (Dukes' stage C) colon cancer.

Respiratory

Nedocromil (Tilade), Sodium Cromoglycate (Intal Spincaps and Vicrom) and, Theophylline (Nuelin)

The subsidies for nedocromil (aerosol inhaler, 2 mg per dose CFC-free), sodium cromoglycate (powder for inhalation, 20 mg per dose and aerosol inhaler, 5 mg per dose CFC-free) and theophylline (oral liq 80 mg per 15 ml) will be increased to match the current manufacturers' prices, resulting in these presentations becoming fully funded as follows:

| Chemical | Presentation | Brand | Pack size | Current subsidy and price | New subsidy and price |
|---------------------|---|----------------|--------------|---------------------------|-----------------------|
| Nedocromil | Aerosol inhaler, 2 mg per dose CFC-free | Tilade | 112 doses OP | \$23.20 (\$28.07) | \$28.07 |
| Sodium cromoglycate | Powder for inhalation, 20 mg per dose | Intal Spincaps | 50 doses | \$16.31 (\$17.94) | \$17.94 |
| | Aerosol inhaler, 5 mg per dose CFC-free | Vicrom | 112 doses OP | \$23.20 (\$28.07) | \$28.07 |
| Theophylline | Oral liq 80 mg per 15 ml | Nuelin | 500 ml | \$4.06 (\$15.50) | \$15.50 |

Prices and subsidies are expressed ex-manufacturer, excluding GST

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposals.

The most commonly raised issue related to the proposed removal of the "Month Restriction" from pharmaceuticals in the Anxiolytics and Sedatives & Hypnotics therapeutic groups, with several responders concerned that a "three month funding provision" would increase the potential for abuse and dependency of these pharmaceuticals.

We would like to highlight that the decision to remove the "month restriction" does not alter the amount able to be prescribed (which has always been up to three months' worth of treatment) nor does it allow 3-monthly dispensing – with the exception of patients meeting the Access Exemption criteria, patients will not be able to be dispensed more than one month's worth of funded medication at a time. However, the decision will provide funding for these treatments in situations where the clinician considers that more than one month of treatment is clinically appropriate. We note that many patients have already been accessing more than one month's worth of funding because their clinicians have been giving them three prescriptions (each for one month's worth of treatment) instead of one prescription for three months' worth.

Finally, we note that we consulted on a proposal to apply a "Retail pharmacy-Specialist" restriction to enoxaparin sodium to allow various anti-coagulation indications to be prescribed for patients discharged from hospital while retaining the Special Authority criteria for applications from any relevant practitioner. As a result of a consultation response we are deferring a decision on this proposal because we have been informed that the change would not be able to be implemented by community pharmacies. We intend to work further on this proposal, before making a decision.