

8 June 2009

Pioglitazone sole supply arrangement and widening of access

PHARMAC is pleased to announce the widening of access to pioglitazone via a sole supply agreement with Douglas Pharmaceuticals.

Pioglitazone belongs to a group of medicines called thiazolidinediones and is used in the treatment of diabetes.

Summary of the decision

From 1 July 2009, the Special Authority for pioglitazone will be amended to allow wider access for patients and to remove the need for renewal of Special Authority applications. The new Special Authority criteria have changed extensively from those that we consulted on in our letter dated 17 March 2009.

Douglas Pharmaceutical's brand of the 15 mg, 30 mg and 45 mg tablets (Pizaccord) will be fully funded in Section B and listed in Part II of Section H of the Pharmaceutical Schedule from 1 July 2009. Pizaccord was approved for sale in New Zealand in March 2009 by Medsafe.

There will be a 6 month transition before the Actos brand of pioglitazone is delisted, and Pizaccord becomes the sole subsidised brand from 1 December 2009. During the first 3 months of the transition Actos and Pizaccord will both be fully subsidised.

If you have any queries about this funding decision you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.

Details of the decision

Access widening

- The current Special Authority form SA0859 will be deleted and replaced with the following Special Authority restrictions from 1 July 2009 (changes are indicated by bold text and strikethrough):

Initial application – (Patients with type 2 diabetes) from any relevant practitioner. Approvals valid for ~~4-year~~ **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.**

~~Any of the following:~~

~~Monotherapy~~

- ~~1. All of the following:~~

~~1.1 To be used as monotherapy for patients who after six months of diet and lifestyle changes have inadequate poor glycaemic control (defined as HbA1c > 7.0% in tests carried out at least two months apart); and~~

~~1.2 Metformin is contraindicated or not tolerated after a minimum of a four-week trial period; and~~

~~1.3 Sulphonylurea is contraindicated or not tolerated or the patient is obese; or~~

~~In combination with a sulphonylurea~~

~~2. Both:~~

~~2.1 For use in combination with a sulphonylurea for patients who after diet and lifestyle changes and a six-month trial of a sulphonylurea have poor glycaemic control (defined as HbA1c > 7.5% measured within the last month of the six-month period); and~~

~~2.2 Metformin is contraindicated or not tolerated after a minimum of a four-week trial period; or~~

~~In combination with metformin~~

~~3. Both:~~

~~3.1 For use in combination with metformin for patients who after diet and lifestyle changes and a six-month trial of the maximum tolerated dose of metformin have poor glycaemic control (defined as HbA1c > 7.5% measured within the last month of the six-month period); and~~

~~3.2 Sulphonylurea is contraindicated or not tolerated, or the patient is obese; or~~

~~In combination with a metformin after a trial of metformin and sulphonylurea and metformin~~

~~4. For use in combination with a sulphonylurea and metformin for patients who after diet and lifestyle changes and a six-month trial of a combination of metformin and a sulphonylurea at maximum tolerated doses have poor glycaemic control (defined as HbA1c > 7.5% measured within the last month of the six-month period); or~~

~~In combination with insulin~~

~~5. For use in combination with insulin in patients requiring more than 1.5 units per kilogram of insulin a day for at least 6 months in conjunction with metformin if tolerated.~~

~~Renewal — (Patients with type 2 diabetes) from any relevant practitioner. Approvals valid for 1 year where patient is continuing to derive benefit from treatment.~~

~~Notes: Pioglitazone is not to be used in triple oral combination (defined as a combination of metformin, sulphonylurea and pioglitazone).~~

~~Pioglitazone should not be used in patients with heart failure.~~

~~Liver function tests should be performed at baseline.~~

~~Gastrointestinal side effects are relatively common when initiating metformin therapy. Upward titration of metformin dose over several weeks and taking metformin with food will help to minimize these side effects.~~

~~Poor glycaemic control is defined as HbA1c > 7.0% measured within the last month of the six-month period.~~

~~Intolerance and contraindications for metformin include: serum creatinine \geq 0.15 or creatinine clearance $<$ 60 ml/min; significant liver impairment; severe left ventricular dysfunction (this would normally be a contraindication to the use of pioglitazone also); and intolerable gastrointestinal side effects that persist beyond 4 weeks duration.~~

~~Intolerance for sulphonylurea includes: nausea; diarrhoea; rash; blood disorders (thrombocytopenia, agranulocytosis, aplastic anaemia); erythema multiforme, exfoliative~~

~~dermatitis, hepatitis; and syndrome of inappropriate antidiuretic hormone secretion (SIADH) with water retention and hyponatraemia.~~

~~Maximum tolerated dose of metformin is defined as: a A dose up to a maximum of 3 g daily.~~

~~Maximum tolerated dose of a sulphonylurea is defined as: a A dose up to a maximum of glibenclamide 20 mg daily or glipizide 20 mg daily or gliclazide 320 mg daily.~~

~~For the purposes of these criteria "obese" is defined as body mass index (BMI) greater than 33 kg/m².~~

~~However, as ethnic differences between patients may vary BMI scores, practitioners may use discretion as to whether the patient meets this criterion.~~

~~It is considered that when applying, that the patient may have initiated "six months diet and lifestyle changes" from the date of diagnosis of type 2 diabetes.~~

Sole supply of pioglitazone

- Pizaccord will be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 July 2009, at the following prices and subsidies (ex-manufacturer, excluding GST):

Form and Strength	Pack Size	Price and subsidy
Tab 15 mg	28	\$2.61
Tab 30 mg	28	\$5.23
Tab 45 mg	28	\$7.80

- The subsidy and price for Actos will be reduced in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 July 2009 as follows (ex-manufacturer, excluding GST):

Form and Strength	Pack Size	Price and subsidy
Tab 15 mg	28	\$45.78
Tab 30 mg	28	\$70.43
Tab 45 mg	28	\$89.39

- The subsidy for Actos will be reduced to the same level as Pizaccord from 1 October 2009 as follows:

Form and Strength	Pack Size	Subsidy
Tab 15 mg	28	\$2.61
Tab 30 mg	28	\$5.23
Tab 45 mg	28	\$7.80

- Pizaccord will be the Sole Subsidised Supply brand of pioglitazone, and Pizaccord will have Hospital Supply Status, from 1 December 2009 until 30 June 2012.

What feedback was received?

We appreciate the feedback we received and acknowledge the time people took to respond. All consultation responses were considered in the decision on the proposed changes. All responses were generally supportive of the proposal.

The changes to the Special Authority that were consulted on were made as a result of various comments expressing concern that it was very prescriptive and confusing for prescribers to read and understand. After further consultation with the Diabetes Subcommittee of PTAC, changes were made to simplify the criteria while retaining the intent. The Special Authority has been maintained to encourage appropriate sequential prescribing given that there are safety concerns associated with pioglitazone.