

Questions and Answers

Change in Funding Status Rosiglitazone (Avandia®) and Pioglitazone (Actos® and Generics)

BACKGROUND

1. What drugs are subject to the funding status change from General Benefit to the Exceptional Access Program (EAP)?

Rosiglitazone (Avandia): 2mg, 4mg, and 8mg tablets
Pioglitazone (Actos and generics): 15mg, 30mg, and 45mg tablets

2. When are these funding changes effective?

As of June 1, 2009, both rosiglitazone and pioglitazone will only be funded through the EAP.

3. What prompted the funding change from General Benefit to the EAP for these two drugs?

This change has been prompted by product labeling changes and multiple warnings issued by the manufacturer and approved by Health Canada. Specifically, rosiglitazone and pioglitazone can cause or exacerbate congestive heart failure in certain high risk patients and both are contraindicated for use in patients with any stage of heart failure. Increased risk of fracture has also been seen in patients receiving rosiglitazone and pioglitazone, particularly women. Data on the myocardial ischemic risks of rosiglitazone and pioglitazone remain inconclusive; however, use of either agent in patients with **acute** myocardial ischemia has the possibility to potentiate heart failure and is not recommended.

4. What are the EAP criteria for rosiglitazone and pioglitazone?

For dual combination therapy of type 2 diabetes, in patients with:

- a) Inadequate glycemic control on maximal doses of metformin; OR
- b) Inadequate glycemic control, on maximal doses of sulfonylurea and demonstrated intolerance / contraindication to metformin

For triple combination therapy of type 2 diabetes, in patients with:

- a) Inadequate glycemic control on maximal doses of metformin and a sulfonylurea AND only if:
 - physician has offered insulin as alternative option first, and patient has refused or is not able to take insulin, AND
 - both physician and patient are aware that thiazolidinediones (TZDs), are not indicated for use in triple therapy.

Notes:

- Inadequate glycemic control defined as HbA1c of >7%
- Maximal doses of metformin defined as 2000mg/day
- Sulfonylureas are defined as glyburide and gliclazide, with maximal doses being 10mg/day and 160mg/day, respectively

The EAP criteria are available on the Telephone Request Service for EAP webpage at:
www.health.gov.on.ca/english/providers/program/drugs/eap_trs.html.

5. Under what conditions would EAP funding not be provided for rosiglitazone or pioglitazone?

In addition to those not meeting the criteria above, funding under the EAP for either rosiglitazone or pioglitazone **will not be provided** in the following clinical settings:

- Patients with type 1 diabetes
- Monotherapy, even if patient is intolerant or has contraindications to both metformin and sulfonylureas
- Combination use with either nitrates or insulin
- Patients with any stage of heart failure (NYHA Class I, II, III, IV)
- Patients at high risk for bone fracture (post-menopausal women with previously confirmed osteoporosis or osteopenia)
- Patients with recent history (in the past 3 months) of ischemic cardiovascular event (myocardial infarction, unstable angina)

PATIENTS CURRENTLY ON ROSIGLITAZONE OR PIOGLITAZONE

6. How is funding approval obtained for rosiglitazone and pioglitazone for EXISTING patients?

Patients who are currently receiving rosiglitazone or pioglitazone under the Ontario Drug Benefit (ODB) program will continue to have coverage in a manner that will provide no interruption in therapy. To be clear, **EAP approvals will not be required for patients who have received a claim for any of these products in the 12 months prior to the listing change date of June 1, 2009.**

7. How long is the EAP approval period for EXISTING patients who are prescribed rosiglitazone and pioglitazone?

Patients who are currently being treated with rosiglitazone or pioglitazone will be eligible for reimbursement indefinitely.

8. Should patients currently prescribed rosiglitazone and pioglitazone be switched to other therapy?

Patients should discuss with their physicians the appropriateness of ongoing use of rosiglitazone or pioglitazone as well as the appropriateness of other therapies.

9. Can patients currently on rosiglitazone or pioglitazone switch to the other product?

Patients currently being treated with rosiglitazone or pioglitazone will be eligible for reimbursement for both products after the change in funding status. EAP approvals will **not** be required for patients switching therapy.

PATIENTS NOT CURRENTLY ON ROSIGLITAZONE OR PIOGLITAZONE

10. How is funding approval obtained for rosiglitazone and pioglitazone for NEW patients?

Physicians will be required to make an application for coverage of rosiglitazone and pioglitazone for any new patient i.e. a patient that is being started on either of these products on or after June 1, 2009. Requests may be submitted by fax at 416-327-7526 or 1-866-811-9908 or through the new Telephone Request Service at 416-327-8109 or 1-866-811-9893.

11. How long is the EAP approval period for NEW patients who are prescribed rosiglitazone and pioglitazone?

For new patients meeting EAP criteria, the approval period is 5 years.

GENERAL

12. Can I continue to interchange generic pioglitazone for Actos?

The generic pioglitazone products that are currently listed as interchangeable with Actos will maintain their interchangeability designation through Part III B(Off-Formulary Interchangeable Drugs) of the Formulary.

13. What drugs for the treatment of type 2 diabetes remain listed on the ODB Formulary?

Metformin, glyburide, gliclazide, acarbose, and most insulins are listed on the ODB Formulary for the treatment of type 2 diabetes.

14. Will rosiglitazone and pioglitazone be subject to the dispensing fee policy?

Rosiglitazone and pioglitazone are not exempted medications and are subject to the dispensing fee policy. For more information on the dispensing fee policy, please refer to:
www.health.gov.on.ca/english/providers/program/drugs/odbf/odbf_conditions_for_payment.html.

15. How do I submit claims for rosiglitazone and pioglitazone under the EAP?

The usual process for submitting EAP claims via the Health Network System should be followed. Please contact the ODB Help Desk at 1-800-668-6641 if you require assistance.