

NOTICE FROM THE EXECUTIVE OFFICER

April 1, 2011

EAP criteria change for rosiglitazone (Avandia)

Exceptional Access Program (EAP)

The EAP criteria have been revised for the drug product(s) listed below:

Rosiglitazone (Avandia) 2mg, 4mg, 8mg tablet

These changes have been prompted by additional product labeling changes and multiple warnings issued by the manufacturer and approved by Health Canada. There are new restrictions on the use of rosiglitazone based on an assessment of recent trial data suggesting an elevated risk of cardiovascular events in patients treated with rosiglitazone. Patients are urged to discuss the updated labeling and warnings with their physicians to determine appropriateness for ongoing use.

There are no changes being made at this time to the EAP funding criteria for pioglitazone (Actos and generics).

New requests for patients not currently on rosiglitazone under EAP:

Requests will be considered for the treatment of type 2 diabetes mellitus in patients for whom all other oral antidiabetic agents that are funded under the ODB program, in monotherapy or in combination, do not result in adequate glycemic control or are inappropriate due to contraindications or intolerance; AND the patient has refused or is not able to take insulin; AND, there is no reference in the request to a known contraindication to rosiglitazone. Inadequate glycemic control is defined as HbA1C >7.0.

In addition, references to the new restrictions on the use of rosiglitazone including the requirement for patient's written informed consent will be provided in the response to all EAP requests for rosiglitazone.

Full details of the revised criteria are posted on the EAP website at:

http://www.health.gov.on.ca/english/providers/program/drugs/eap_criteria.html

Patients currently on rosiglitazone under EAP:

Patients currently being treated with rosiglitazone will continue to have coverage with no interruption in therapy. Patients are urged to discuss the updated labeling and warnings with their physicians to determine appropriateness for ongoing use.

Physicians who wish to switch therapy for their patients from rosiglitazone to pioglitazone should submit a request by fax to 416-327-7526 (toll-free 1-866-811-9908), or through the Telephone Request Service (TRS) by calling 416-327-8109 (toll-free 1-866-811-9893).

We will continue to monitor utilization of rosiglitazone and make further changes if necessary.