

**UNIVERSITY PHYSICIANS HEALTH PLANS**  
(University Family Care)

**PHARMACY REFERRAL GUIDELINE**

**THIAZOLIDINEDIONES**  
**(PIOGLITAZONE - ACTOS®, ROSIGLITAZONE - AVANDIA®)**

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Indications:

- Management of type 2 diabetes alone or in combination with sulfonylureas, metformin, or insulin

Dosage:

- Pioglitazone: 15–45 mg po qd
- Rosiglitazone 4–8 mg daily divided qd- bid

Contraindications/Precautions:

- Hepatic dysfunction
- Congestive heart failure (NYHA class III and IV)
- Fluid retention can occur which may lead to, or exacerbate, congestive heart failure when either drug is used as monotherapy or in combination with insulin.

Monitoring:

- LFT's before initiating therapy and every 2 months for the first 12 months of therapy then periodically thereafter. If ALT increases 1-2.5 times the upper limit of normal, close clinical and laboratory monitoring is indicated. If ALT increases to 3 times the upper limit of normal, reevaluate and discontinue therapy if the ALT remains elevated.
- A1C every 3-6 months

Criteria for Use:

- Baseline A1C  $\geq 7\%$  obtained within the previous 2 months prior to request
- Failure to achieve an A1C  $< 7\%$  on maximal doses of combination therapy including a sulfonylurea (e.g., glyburide  $\geq 10$  mg daily) and metformin ( $\geq 2000$  mg daily) for at least 4 months. If there is a contraindication to the use of either a sulfonylurea or metformin, the patient must be on a maximal dose of the alternative agent.

**OR**

Failure to achieve an A1C  $< 7\%$  on an insulin dose of  $> 50$  units daily. In addition, must have failed a combination of insulin with a maximal dose of

metformin ( $\geq 2000$  mg daily) . Initial approval will be for 4 months. Patient must have an A1C  $< 7\%$  for continued approval.

- Only once daily dosing will be approved
- Initial authorization will be given for four months. Must achieve and maintain an A1C  $< 7\%$  for continued authorization.
- Only one third-line agent will be approved. Third-line agents include sitagliptin (Januvia®), TZDs (Actos®, Avandia®), exenatide (Byetta®), and pramlintide (Symlin®).

*Approved by the Pharmacy and Therapeutics Committee 11/12/02; Revised and approved by the Pharmacy and Therapeutics Committee 5/03; Reviewed 12/05, 6/06, 1/08, 5/09*