

## STEP THERAPY POLICY

- POLICY:** Diabetes – Thiazolidinedione Step Therapy Policy
- Actos® (pioglitazone tablets – Takeda, generics)
  - Actoplus Met® (pioglitazone/metformin tablets – Takeda, generic)
  - Actoplus Met® XR (pioglitazone/metformin extended-release tablets – Takeda [obsolete 09/30/2020])
  - Avandia® (rosiglitazone tablets – GlaxoSmithKline [obsolete 04/05/2021])
  - Duetact® (pioglitazone/glimepiride tablets – Takeda, generic)

**REVIEW DATE:** 05/11/2022

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### OVERVIEW

The thiazolidinediones (TZDs) are indicated as adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes**.<sup>1,2</sup>

Various combination products are available with other antidiabetic medications, including metformin, sulfonylureas, and dipeptidyl peptidase-4 (DPP-4) inhibitors. Of note, the combination product alogliptin/pioglitazone (Oseni™, generic) is not targeted in this policy; refer to the *Diabetes – Dipeptidyl Peptidase-4 Inhibitors Step Therapy Policy*.

### Guidelines

The American Diabetes Association Standards of Care (2022) recommend metformin as initial therapy for most patients with type 2 diabetes, unless contraindications to metformin are present.<sup>3</sup> Very high circulating levels of metformin have been associated with lactic acidosis. However, the occurrence of this complication is now known to be very rare. In patients with contraindications or intolerance to metformin, initial therapy should be based on patient factors. Any of several classes of medications, including DPP-4 inhibitors, sodium glucose co-transporter-2 inhibitors, and TZDs, may be used as add-on therapy after metformin (or as initial therapy if metformin cannot be used). Because type 2 diabetes is often a progressive disease, combination therapy may be needed for many patients over time to achieve glycemic targets. Other guidelines have similar recommendations.<sup>4</sup>

### POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

**Automation:** A patient with a of one of the following within the 130-day look-back period is excluded from Step Therapy:

- One Step 1 Product; OR
- One of the following metformin-containing products: Glucophage, Glucophage XR, Glumetza, Fortamet, metformin oral solution, Riomet, Riomet ER, metformin extended-release (generics to Fortamet and Glumetza), glyburide/metformin, glipizide/metformin, Janumet, Janumet XR, Jentadueto, Jentadueto XR, repaglinide/metformin, Kombiglyze XR, pioglitazone/metformin, pioglitazone, pioglitazone/glimeperide, Kazano, alogliptin/metformin, Invokamet, Invokamet XR, Synjardy, Synjardy XR, Xigduo XR, Segluromet.

09/30/2020

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**Step 1:** generic metformin, generic metformin extended-release (generic to Glucophage XR only)

**Step 2:** Actos, Avandia, Actoplus Met, Actoplus Met XR, Duetact

### CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

Note: A trial of one of the following metformin-containing products also satisfies the requirement: Glucophage, Glucophage XR, Glumetza, Fortamet, metformin oral solution, Riomet, Riomet ER, metformin extended-release (generics to Fortamet and Glumetza), glyburide/metformin, glipizide/metformin, Janumet, Janumet XR, Jentadueto, Jentadueto XR, repaglinide/metformin, Kombiglyze XR, pioglitazone/metformin, pioglitazone, pioglitazone/glimeperide, Kazano, alogliptin/metformin, Invokamet, Invokamet XR, Synjardy, Synjardy XR, Xigduo XR, Segluromet.

2. No other exceptions are recommended.

### REFERENCES

1. Actos<sup>®</sup> tablets [prescribing information]. Deerfield, IL: Takeda; December 2017.
2. Avandia<sup>®</sup> tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2019.
3. American Diabetes Association. Standards of medical care in diabetes – 2022. *Diabetes Care*. 2022;45(Suppl 1):S1-S258.
4. Garber AJ, Handelsman Y, Grunberger G, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm – 2020 executive summary. *Endocr Pract*. 2020;26(1):107-139.