BACKGROUND
The prevalence of diagnosed diabetes mellitus is 7% in the US population (all ages). Type 2 diabetes mellitus (T2DM) accounts for 90% to 95% of all diagnosed cases of diabetes.

Persistence with prescription (Rx) therapy is often suboptimal among patients with T2DM, who are managed with oral anti-diabetic drugs (OADs) to control glycemic levels, poor health outcomes, and increased resource utilization. Many patients with T2DM who are managed with one anti-diabetic drug (OAD) require polytherapy that may include combinations of:

• A thiazolidinedione (TZD), such as pioglitazone H2O or rosiglitazone H2O
• Metformin, a biguanide

• Sulfonylureas, which include products such as glyburide or glipizide.

Poor compliance and persistence with OADs have been documented; and when multiple OADs are needed to maintain glycemic control, non-persistence may be exacerbated.

The OAD market now includes T2DM combination products for pioglitazone/metformin and rosiglitazone/metformin and pioglitazone/glimepiride and rosiglitazone/glimepiride (immediate).

It is important to understand the impact that OAD therapies have on compliance and cost.

OBJECTIVE
The goals of the current study were to assess the impact of fixed-dose (FDC) and loose-dose (LDC) combination thiazolidinedione (TZD) on the following:

• Index Date was assigned by the first FDC TZD Rx for the first occurrence of T2DM within 45 days of metformin or sulfonylurea in the LDC component.
• Index Dates before 31 May 2004 were required to avoid the FDC patients’ supply shortage between June 2005 and July 2006.
• Employees included in the analysis were required to be continuously employed and eligible for health benefits for at least 12 months after the Index Date.
• Because of the 12-month eligibility requirement and the timeframe of the study, the FDC cohort is represented by pioglitazone plus metformin only, as it was the FDC with sufficient data during the study period.
• It is assumed that the FDC cohort is representative of the TZD class and pioglitazone/metformin combination.
• Comparisons were made between 2 groups (FDCs and LDCs).
• Persistence was defined as the length of time the patient had a supply of both the TZD and either metformin or a sulfonylurea without a gap in supply of more than 30 days.

■ Outcomes

• Employee outcomes for both groups were compared over the 12 months following the Index Date and included:
  - Medication persistence decay curves.
  - Number of months of therapy defined as the months of supply purchased during the 12 months following the Index Date.
  - Point-of-care direct costs.
  - Total medical costs: doctor’s office; inpatient hospital; outpatient hospital; office visits; emergency department; laboratory; pharmacy; and “other.”

Statistical Analysis
• Employees in the LDC and FDC cohorts were matched 1:1 using logistic regression and propensity scores for age, tenure (years with the Index Date), sex, marital status, race, employment status (except employees not paid on an hourly basis and are not paid for overtime work), full-time/permanent status, salaried (defined by first digit of employee’s postal zip code), employer, and average copay.

• These results indicate an opportunity for improved management of patients with T2DM, which may result in reduced costs from an employer’s perspective.

• Patients achieve compliance benefits from reduced medication supply interruptions.

• Additional research is needed with newer data in these cohorts to further inform us on long-term impact on compliance and cost.

SUGGESTED REFERENCES
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