BACKGROUND
The prevalence of diagnosed diabetes mellitus is 7% in the US population (all ages). Type 2 diabetes mellitus (T2DM) accounts for 95% to 95% of all diagnosed cases of diabetes.1

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

• A biguanide, such as pioglitazone HCl or metformin maleate.
• A sulfonylurea, which includes products such as glyburide or glipizide.

Poor compliance and persistence with OADs have been documented,• due to the lack of an oral route for insulin and the difficulty of developing a long-lasting action. Because of these, patients require the constant supply of more than 30 days.

In the United States, approximately 62 million people have diabetes mellitus (DM), and 34% of these people have T2DM.2 Of these 34%, 26.4% are T2DM patients who are managed with oral anti-diabetic drugs (OADs).2

A thiazolidinedione (TZD), such as pioglitazone HCl or rosiglitazone maleate,

• improves glycemic control,
• improves beta cell function,
• increases insulin sensitivity, and
• reduces progression of microvascular complications in T2DM.3

TZDs are available as fixed-dose combination (FDC) and loose-dose (LDC) components.

In the TZD cohort, patients either used a TZD with an OAD, or they used rosiglitazone alone.

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

• Medication persistence.
• Point-of-service costs, which include medical and pharmacy costs.

METHODS
A retrospective analysis was performed on data (2001 to 2005) from the Human Capital Management Services (HCMS) Research Reference Database consisting of approximately 510,000 enrollees representing the retail, service, manufacturing, and financial industries.

• Patients with T2DM were identified based on the presence of International Classification of Diseases, 9th Revision (ICD-9) diagnostic codes for T2DM (250.90, diabetes mellitus, not stated as uncontrolled), or 250.X2 (type 2 diabetes mellitus, T2DM).

• The FDC cohort was based on the presence of additional research is needed with newer data in these cohorts to further inform us on long-term impact on compliance and cost.

SUMMARY AND CONCLUSIONS
Adherence as measured by persistence with FDC combination therapy was significantly better than with LDC.

• FDC TZD therapies provide an advantage for patients with T2DM. T2DM is associated with substantial direct cost (bundled) of illnesses, which can be a large financial liability to employers.

• Management of T2DM with TZD combination therapies that foster compliance and persistence may result in reduced costs from an employer's perspective.

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

• This study suggests that:
  • Patients achieve compliance benefits from reduced medication burden by using FDC.
  • Additional research is needed to review these data in cohorts to further inform us on long-term impact on compliance and cost.

Medication Adherence and Direct Medical and Prescription Cost Impact of Fixed-Dose vs Loose-Dose Thiazolidinedione Combination Products Between Type 2 Diabetes Mellitus Patients
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RESULTS
• Index Date was assigned by the first FDC T2D Rx or the first occurrence of T2D within 45 days of metformin or sulfonylurea in the LDC component.

• Index Dates before 31 May 2004 were required to avoid the FDC component plus metformin supply shortage between June 2005 and July 2006.

• Employment was included in the analyses 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 metformin plus only, as was the FDC with sufficient data during the study period.

• It is assumed that the FDC cohort is representative of the T2D class and polytherapy/metformin.

• 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 T2D and either metformin or a sulfonylurea without a gap in supply of more than 30 days.

• Employment outcomes for the two groups were compared over the 12 months following the Index Date and included:

  • Medication persistence decay curves.
  • Differences in the length of time the patient had a supply of both the T2D and either metformin or a sulfonylurea without a gap in supply of more than 30 days.

• Patients were required to be continuously employed and eligible for health benefits for at least 12 months after the Index Date.

• Point-of-service costs, which include medical and pharmacy costs.

• Direct medical costs: doctor’s office; inpatient hospital; outpatient hospital; emergency department; laboratory; pharmacy; and “other.”

• The composition of the FDC cohort serves as a surrogate for the overall population of T2DM patients.

• Patients in the FDC cohort used rosiglitazone as TZD component.

• Within the LDC cohort, the medication persistence curves were similar to the pioglitazone and rosiglitazone subcohorts.

• Differences were considered significant if P<0.05.

• All point-of-service costs (Table 2) were similar between the cohorts.

• Overall costs as well as the individual direct medical costs and Rx costs all trended lower for the FDC cohort.

REFERENCES