PDL NEW DRUG REVIEW

Proprietary Name: Tanzeum®
Common Name: albiglutide
PDL Category: Diabetic-Non-Insulin Injectables

Comparable Products	Preferred Drug List Status
Bydureon	Non-Preferred with Conditions
Byetta	Preferred with Conditions
Victoza	Non-Preferred with Conditions

Summary

Indications and Usage: Adjunct to diet and exercise to improve glycemic control in adults with type 2 DM. Tanzeum® is not recommended as first-line therapy for those inadequately controlled on diet and exercise. It has not been studied in the following: patients with a history of pancreatitis; patients with severe GI disease including gastroparesis; or in combination with insulin. Therefore, other antidiabetic therapies should be considered in patients with a history of pancreatitis and the use in those with pre-existing severe GI disease is not recommended. Last, Tanzeum® is not indicated for treatment of type 1 DM or for the treatment of patients with diabetic ketoacidosis; it is not a substitute for insulin in these patients.

This is a pregnancy category C medication. The safety and efficacy of use in children have not been established.

Dosage Forms: Injection, lyophilized powder in single-dose pen (pen injector): 30mg, 50mg

Recommended Dosage: 30mg QW SC in abdomen, thigh, or upper arm region; the dose may be increased to 50mg QW if inadequate glycemic control. While dose adjustments are not required with renal impairment, renal function should be monitored in this population reporting severe GI reactions. If starting Tanzeum® and will be used concomitantly with an insulin secretagogue or insulin, consider reducing the dose of the later agents.

Common Adverse Drug Reactions: *Listed % incidence for adverse drug reactions= reported % incidence for drug (Tanzeum®) minus reported % incidence for placebo. Please note that an incidence of 0% means the incidence was the same or that the active drug was less than placebo.* The most frequently reported adverse events included upper respiratory tract infection (1.2%), diarrhea (2.6%), nausea (1.5%), injection site reaction (8.4%), cough (0.7%), back pain (0.9%), arthralgia (0.2%), sinusitis (0.4%), documented symptomatic hypoglycemia (0%), and influenza (2%). In 7 placebo- and active-controlled trials, pneumonia was reported more with Tanzeum® vs all comparator groups (1.8% vs 0.8%), as well as pancreatitis (0.3% vs 0% placebo or 0.1% active comparator).

Contraindications: In patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); with a prior serious hypersensitivity to albiglutide or any component of the compound

Manufacturer: GlaxoSmithKline

Analysis: Albiglutide, the active ingredient of Tanzeum®, is an agonist of the glucagon-like peptide-1 (GLP-1) receptor, augmenting glucose-dependent insulin secretion and slowing gastric emptying. Albiglutide does have a box warning regarding the increased risk of thyroid C-cell tumors. These tumors have been seen in rodent studies with GLP-1 receptor agonists; however, it is not known if Tanzeum® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans. It is contraindicated in patients with a personal or family history of MTC or with MEN 2. In addition, the value of routine serum calcitonin or thyroid ultrasound monitoring is not known with Tanzeum® use. The risks and symptoms of thyroid tumors should be discussed with patients.

A 52-week double-blind, placebo-controlled trial was performed to assess the safety and efficacy of albiglutide in inadequately controlled type 2 DM patients. Compared with placebo, there were significant reductions in HbA1c with albiglutide (-0.7% with the 30mg dose and -0.9% with the 50mg dose vs +0.2 with placebo; $p<0.0001$ vs placebo). Changes in weight from baseline were not significantly different. There were several trials in which Tanzeum® was compared to placebo when used adjunctively to metformin, pioglitazone, or metformin plus a sulfonylurea. In these trials, Tanzeum® plus the background antidiabetic resulted in significantly greater HbA1c reductions when compared to placebo plus the background antidiabetic agent. In addition, one trial compared Tanzeum® plus metformin with sitagliptin plus metformin and glimepiride plus metformin. The reduction in HbA1c was significantly greater with Tanzeum® vs the active comparators.

One open-label, 32-week, non-inferiority trial compared albiglutide with liraglutide in a population with type 2 DM inadequately controlled on monotherapy or combination diabetic therapy. The change in HbA1c from baseline at week 32 was -0.8% with albiglutide vs -1% with liraglutide, with a difference from liraglutide of 0.2%. This did not meet the pre-specified non-inferiority margin of 0.3%. The proportion achieving HbA1c <7% was 42% with albiglutide vs 52% with liraglutide. The change from baseline in fasting plasma glucose was -22mg/dl with albiglutide vs -30mg/dl with liraglutide ($p<0.005$ in favor of liraglutide), and the change in body weight was -0.6kg vs -2.2kg, respectively ($p<0.005$ in favor of liraglutide). In the open-label study that compared Tanzeum® with insulin lispro, the between-treatment difference of -0.2% met the pre-specified non-inferiority margin of 0.4%. In addition, there was a statistically greater decrease in body weight with Tanzeum® vs insulin (-0.7kg vs +0.8kg; $p<0.0001$).

It is recommended that Tanzeum® remain non-preferred and be available to the few who are unable to tolerate preferred alternatives.

PDL Placement:

- ☐ **Preferred**
- ☒ **Non-Preferred with Conditions**
- ☐ **Preferred with Conditions**

References

[1] Tanzeum [package insert]. Wilmington, DE: GlaxoSmithKline; 2014.