Drug Monograph

Drug/Drug Class: **Tanzeum™ (albiglutide) injection/ GLP-1 receptor agonists**

Prepared for: MO HealthNet
Prepared by: Xerox Heritage, LLC

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose:	The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, require a clinical edit or require prior authorization for use.
Dosage Forms & Manufacturer:	Tanzeum™ is available in a 30 mg single-dose prefilled pen and a 50 mg single-dose prefilled pen that contain 30 mg and 50 mg of albiglutide respectively. GlaxoSmithKline LLC Wilmington, DE 19808
Summary of Findings:	Tanzeum™ is a subcutaneous GLP-1 receptor agonist approved for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise. Tanzeum™ demonstrated efficacy in the treatment of type 2 diabetes when used as monotherapy and in combination with various other antidiabetic agents, and a decrease in HbA1c of 0.6% to 0.9% can be expected. Tanzeum™ failed to achieve noninferiority to once daily liraglutide, but may be a reasonable option for patients requiring a GLP-1 agonist who are unable or unwilling to use a daily subQ injection. The most common adverse effects are upper respiratory tract infections, diarrhea, nausea, and injection site reactions.
Status Recommendation:	☐ Prior Authorization (PA) Required ☐ Open Access ☐ Clinical Edit ☒ PDL
Type of PA Criteria:	☐ Increased Risk of ADE ☐ Preferred Agent ☐ Appropriate Indications ☒ Non Preferred Agent

Purpose

The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug, a clinical edit drug or an open access drug. While prescription expenditures are increasing at double-digit rates, payors are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

Introduction[2]

Type 2 diabetes, once called non-insulin-dependent diabetes, is the most common form of diabetes, affecting 90% to 95% of the 26 million Americans with diabetes.

Dosage Form(s) [1]

Tanzeum™ is available in a 30 mg single-dose prefilled pen and a 50 mg single-dose prefilled pen that contain 30 mg and 50 mg of albiglutide respectively.

Manufacturer [1]

GlaxoSmithKline LLC, Wilmington, DE 19808

Indication(s) [1]

Tanzeum™ is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Clinical Efficacy [1] (mechanism of action/pharmacology, comparative efficacy)

Tanzeum™ is a recombinant fusion protein genetically fused to human albumin. It functions as a GLP-1 receptor agonist which augments glucose-dependent insulin secretion, thereby lowering fasting glucose and reducing postprandial glucose excursions. Tanzeum™ also delays gastric emptying.

Pharmacokinetics

	Tanzeum
Volume of distribution	11 L
Metabolism	Vascular endothelium via catabolism by proteolytic enzymes
Half-life	5 days

Tanzeum ™ monotherapy significantly improved HbA1c and FPG compared with placebo among patients with inadequately controlled type 2 diabetes.

Tanzeum™ Monotherapy

STUDY DESIGN	Randomized, double-blind, placebo-controlled, 52-week, multicenter trial (n=296).
INCLUSION CRITERIA	Patients with type 2 diabetes inadequately controlled with diet and exercise.
EXCLUSION CRITERIA	Not specified.
TREATMENT REGIMEN	Patients (mean age, 53 years) were randomized to receive Tanzeum™ 30 mg subQ once weekly (n=100), Tanzeum™ 50 mg subQ once weekly (titrated at week 12 from 30 mg once weekly; n=97) or placebo (n=99).
RESULTS	After 52 weeks of treatment, mean HbA1c values changed by -0.7% and -0.9% from baseline in the Tanzeum™ 30 mg and 50 mg groups, respectively, compared with 0.2% in the placebo group ($p < 0.0001$ for each group). Only 21% of placebo patients achieved an HbA1c value of < 7% compared with 49% and 40% of patients who received Tanzeum™ 30 mg and 50 mg, respectively. By week 52, the adjusted mean FPG decreased by 16 mg/dL and 25 mg/dL from baseline among patients who received Tanzeum™ 30 mg and 50 mg, respectively, compared with an increase of 18 mg/dL in the placebo group ($p < 0.0001$ for each group). The adjusted mean change in weight from baseline was similar between the Tanzeum (-0.4 to -0.9 kg) and placebo (-0.7 kg) groups.
SAFETY	Not specified.

Tanzeum™ resulted in significant reductions in HbA1c compared with placebo, sitagliptin, or glimepiride when added to metformin therapy.

Tanzeum™ and Metformin

STUDY DESIGN	Randomized, double-blind, 104-week, multicenter trial (n=999).
INCLUSION CRITERIA	Patients with type 2 diabetes inadequately controlled on metformin.
EXCLUSION CRITERIA	Not specified.
TREATMENT REGIMEN	Patients (mean age, 55 years) were randomized to add-on Tanzeum™ 30 mg subQ weekly with optional titration to 50 mg weekly after a minimum of 4 weeks (n=297), sitagliptin 100 mg daily (n=300), glimepiride 2 mg daily

	with optional titration to 4 mg daily (n=302), or placebo (n=100).
RESULTS	After 104 weeks of treatment, significant differences ($p < 0.0137$) were found in the mean HbA1c change from baseline between the Tanzeum™ (-0.6%) group and the sitagliptin (-0.3%), glimepiride (-0.4%), and placebo (0.3%) groups. The proportion of patients achieving an HbA1c of < 7% was 39%, 32%, 31%, and 16% in the Tanzeum™, sitagliptin, glimepiride, and placebo groups, respectively. Treatment with Tanzeum™ also significantly reduced the adjusted mean FPG (-18 mg/dL; $p < 0.0137$) from baseline compared with sitagliptin (-2 mg/dL), glimepiride (-8 mg/dL), or placebo (10 mg/dL). A significant difference in the adjusted mean change in body weight was found between patients treated with Tanzeum™ (-1.2 kg) and glimepiride (1.2 kg) at week 104.
SAFETY	Not specified.

Contraindications [(1)]

- Hypersensitivity to Tanzeum™ or any component of the product
- Medullary thyroid carcinoma, personal or family history
- Multiple endocrine neoplasia syndrome type 2

Warnings and Precautions [(1)]

- Thyroid C-cell tumors, increased risk possible; patients with thyroid nodules and/or elevated calcitonin levels should be referred to an endocrinologist; the value of routine monitoring has not been established.
- Gastrointestinal disease, preexisting and severe; use not recommended.
- Hypersensitivity reactions, severe, with pruritus, rash and dyspnea have been reported; discontinue use immediately.
- Hypoglycemia, increased risk with concomitant use of insulin or insulin secretagogues (eg, sulfonylureas); consider reducing dose of insulin or insulin secretagogue when initiating albiglutide.
- Pancreatitis, acute, has been reported; consider alternative therapy in patients with history of pancreatitis; monitoring recommended; if pancreatitis is suspected, suspend therapy immediately; if confirmed, permanently discontinue therapy.
- Renal failure, acute, or worsening of chronic renal failure has been reported; has occurred in patients with or without underlying renal disease.
- Renal impairment, use caution with initiating therapy, when increasing dosage, and in patients experiencing severe gastrointestinal reactions.

Adverse Effects [1]

Most common, ≥ 5%	Tanzeum™ (n=923)	Placebo (n=468)
Upper respiratory tract infection	14.2%	13%
Diarrhea	13.1%	10.5%
Nausea	11.1%	9.6%
Injection site reaction	10.5%	2.1%
Cough	6.9%	6.2%
Back pain	6.7%	5.8%
Arthralgia	6.6%	6.4%
Sinusitis	6.2%	5.8%
Influenza	5.2%	3.2%

Drug Interactions [1]

- Simvastatin

Dosage and Administration [1]

The recommended dose is 30 mg subQ once weekly; increase to 50 mg subQ once weekly if necessary for additional efficacy.

Cost

GENERIC NAME	BRAND NAME	MANUFACTURER	STRENGTH	COST/ PACKAGE	COST*/ MONTH
Albiglutide	Tanzeum	GlaxoSmithKline	30 mg/single-dose prefilled pen	$81.49	$325.96
			50 mg/single-dose prefilled pen	$81.49	$325.96
Exenatide	Bydureon	Bristol Myers Squibb	2 mg/single-dose vial	$105.85	$423.40
Exenatide	Byetta	Bristol Myers Squibb	5 mcg/dose, 1.2 mL prefilled pen, 60 doses	$410.95	$410.95
			10 mcg/dose, 2.4 mL Prefilled pen, 60 doses	$410.94	$410.95
Liraglutide	Victoza	Novo Nordisk	6 mg/ml, 3 mL multi-dose prefilled pen, 15 doses**	$188.79	$377.58

*WholesaleAcquisitionCost
** Dose = 1.2 mg/day

Conclusion

Tanzeum™ is a subcutaneous GLP-1 receptor agonist approved for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise. Albiglutide demonstrated efficacy in the treatment of type 2 diabetes when used as monotherapy and in combination with various other antidiabetic agents, and a decrease in HbA1c of 0.6% to 0.9% can be expected. Albiglutide failed to achieve noninferiority to once daily liraglutide, but may be a reasonable option for patients requiring a GLP-1 agonist who are unable or unwilling to use a daily subQ injection. The most common adverse effects are upper respiratory tract infections, diarrhea, nausea, and injection site reactions.

Recommendation

This drug is being considered for inclusion in the state specific Preferred Drug List and is a non-preferred agent.

References

1. Product Information: Tanzeum™, albiglutide. GlaxoSmithKline LLC, Research Triangle Park, NC, 4/2014.
2. Type 2 Diabetes Overview (2014). Retrieved September 5, 2014 from http://www.webmd.com/diabetes/guide/type-2-diabetes

Prepared by: Luke Boehmer, PharmD

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