ZEPBOUND (AUTOINJECTOR) - (2.5 mg/0.5 mL, 5 mg/0.5 mL ; Subcutaneous Solution)

Generic Name	TIRZEPATIDE	**Innovator**	Eli Lilly
Dosage	2.5 mg/0.5 mL, 5 mg/0.5 mL ; Subcutaneous Solution	**Branded US Sales**	More Than $1000 mn
Probable FTF	More Than 5	**Known Para IV Filers**	More Than 5
Other ANDA developers	None	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	ZEPBOUND™ is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obesity) or • 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease)		
Complexities	Yes		

Chronology Of Events

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Executive Summary

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Chronology Of Events

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ZEPBOUND (AUTOINJECTOR) - (7.5 mg/0.5 mL ; Subcutaneous Solution)

Generic Name	TIRZEPATIDE	**Innovator**	Eli Lilly
Dosage	7.5 mg/0.5 mL ; Subcutaneous Solution	**Branded US Sales**	More Than $1000 mn
Probable FTF	More Than 5	**Known Para IV Filers**	More Than 5
Other ANDA developers	None	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	ZEPBOUND™ is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obesity) or • 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease)		
Complexities	Yes		

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ZEPBOUND (AUTOINJECTOR) - (10 mg/0.5 mL, 12.5 mg/0.5 mL, 15 mg/0.5 mL ; Subcutaneous Solution)

Generic Name	TIRZEPATIDE	**Innovator**	Eli Lilly
Dosage	10 mg/0.5 mL, 12.5 mg/0.5 mL, 15 mg/0.5 mL ; Subcutaneous Solution	**Branded US Sales**	More Than $1000 mn
Probable FTF	More Than 5	**Known Para IV Filers**	More Than 5
Other ANDA developers	None	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	ZEPBOUND™ is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • 30 kg/m2 or greater (obesity) or • 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease)		
Complexities	Yes		

Chronology Of Events

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