

DIABETES

Class	Medication	Form	Dose	Paediatric Trial HbA1c and BMI SDS/weight change [#]	TGA approval	PBS listed	Non-PBS cost per month
Biguanide	Metformin	Tablet: 500mg 850mg 1000mg	250 – 2000mg daily divided in 2 doses	Metformin vs rosiglitazone. TODAY Study¹ Metformin youth T2D 10-16y² Metformin monotherapy in T2D³	T2D ≥ 10 years	T2D (general schedule)	
	Metformin XR	Tablet: 500mg 750mg 1000mg	500 - 2000mg daily. <u>Cannot</u> be crushed	Off-label use. APEG T2D Guidelines, MJA, 2020⁴	T2D > 18 years	T2D (general schedule)	
GLP-1RA	Semaglutide* (Ozempic)	Pen: 0.25/0.5mg 1mg	0.25 – 1mg weekly	Nil clinical trial data	T2D > 18 years	T2D (criteria based, authority required)	~\$130- 260
	Dulaglutide (Trulicity)	1.5mg	1.5mg weekly	Dulaglutide youth T2D 10-18y. AWARD-PEDS⁵ Outcomes HbA1c: -0.6% (0.75mg), -0.9% (1.5 mg) vs +0.6% (26w) BMI: NS	T2D > 18 years	T2D (criteria based, authority required)	~\$135
	Liraglutide (Victoza)	3ml pen cartridge: 0.6mg, 1.2mg, 1.8mg	0.6 – 1.8mg daily	Liraglutide youth T2D 10-17y. Ellipse Trial⁶ Outcomes HbA1c: -0.64% vs +0.42% (26w) HbA1c: -0.5% vs +0.8% (52w) BMI SDS: NS (26w) (BMI SDS: -0.34 vs -0.16 (52w)	T2D > 18 years	No	~\$300
SGLT2 inhibitor	Dapagliflozin (Forxiga)	5mg 10mg	5 – 10mg daily	Dapagliflozin youth T2D RCT⁷ Outcomes HbA1c: -0.26% vs +0.5% (24w NS)	T2D > 18 years. Chronic Kidney Disease. Heart failure.	T2D (criteria based, streamlined authority)	
	Dapagliflozin (Xigduo XR)	5/1000mg 10/500mg 10/1000mg	5 - 10mg/500		T2D > 18 years. Chronic Kidney Disease. Heart failure.	T2D (criteria based, streamlined authority)	

Pharmacotherapy for youth living with T2D and obesity

	Combined with metformin XR		-2000mg daily				
	Empagliflozin (Jardiance)	10mg 25mg	10mg – 25mg daily	Empagliflozin vs linagliptin vs placebo youth T2D 10-17y. DINAMO Trial⁸ Outcomes HbA1c: -0.17% vs +0.68% (26w) Weight: NS	T2D > 10 years. In those >18 years, Chronic Kidney Disease. Heart failure.	T2D (criteria based, streamlined authority)	
	Empagliflozin (Jardiamet XR) Combined with metformin XR	5/500- 1000mg 12.5/500- 1000mg	5/500- 1000mg to 12.5/500- 1000mg daily		T2D > 18 years. Chronic Kidney Disease. Heart failure.	T2D (criteria based, streamlined authority)	
GIP and GLP-1RA	Tirzepatide (Mounjaro)	2.5mg 5mg 7.5mg 10mg 12.5mg 15mg	2.5 - 15mg weekly	SURPASS-PEDS Completed Feb 2025 no results available yet https://clinicaltrials.gov/study/NCT05260021?cond=Type%20%20Diabetes%20Mellitus%5C(T2DM%5C)&intr=tirzepatide&rank=9	T2D ≥18 years	No	~\$600
DPP4 inhibitors	Linagliptin (Trajenta)	5mg	5mg daily	Empagliflozin vs linagliptin vs placebo youth T2D 10-17y. DINAMO Trial⁸ <i>This did not demonstrate efficacy in paediatric patients 10-17 years</i> Outcomes HbA1c: +0.33 vs +0.68% (26w; NS) Weight: NS	T2D ≥18 years	T2D (criteria based, streamlined authority)	
	Sitagliptin (Januvia)	50mg, 100mg	100mg daily	Sitagliptin for youth with T2D 10-17y⁹ <i>This did not demonstrate efficacy in paediatric patients 10-17 years</i> Outcomes HbA1c: -0.58 vs -0.09% (20w) HbA1c: +0.35 vs +0.73% (54w; NS) Weight: NS	T2D ≥18 years	T2D (criteria based, streamlined authority)	

NS: not significant, SDS: standard deviation score, BMI: body mass index #weight regain is observed once medication are ceased. *semaglutide is marketed under two brand names with two different indications: Ozempic indicated for the management of type 2 diabetes, Wegovy indicated for chronic weight management.

OBESITY

Class	Medication	Form	Dose	Paediatric data (HbA1c / weight) [#]	TGA approval	PBS listed	Non-PBS cost per month
GLP-1RA	Liraglutide (Saxenda)	0.6 – 3mg doses	3ml pen cartridge: 0.6, 1.2mg, 1.8mg, 2.4mg, 3mg daily	Liraglutide. Adolescents with Obesity¹⁰ Kelly A, <i>NEJM</i> , 2020 SCALE Kids. Liraglutide for Children 6 to <12 Years with Obesity¹¹ Fox CK, <i>NEJM</i> , 2024	Obesity (BMI $\geq 30\text{kg/m}^2$) ≥ 18 years	No	~\$400
	Semaglutide* (Wegovy)	0.25 - 2.4mg	0.25mg, 0.5mg, 1mg, 1.7mg, 2.4mg weekly	STEP-TEENS. Semaglutide in adolescents with obesity¹² Weghuber D, <i>NEJM</i> , 2022 Outcomes BMI: -16% vs +0.6% (68w) Study including 6-12 years currently recruiting. https://clinicaltrials.gov/study/NCT05726227?cond=Obesity&term=children&intr=semaglutide&rank=1#study-overview	Obesity (BMI $\geq 95^{\text{th}}$ centile) adolescents ≥ 12 years	No	~\$250-450
GIP and GLP-1RA	Tirzepatide (Mounjaro)	2.5 – 15mg Kwikpen (pre-filled) or vial	2.5, 5mg, 7.5mg, 10mg, 12.5mg, 15mg weekly	This trial was completed in early this year no results available yet https://clinicaltrials.gov/study/NCT05696847?cond=Obesity&intr=tirzepatide&rank=6	T2D and obesity ≥ 18 years	No	~\$600

NS: not significant, SDS: standard deviation score, BMI: body mass index [#]weight regain is observed once medication are ceased. *semaglutide is marketed under two brand names with two different indications: Ozempic indicated for the management of type 2 diabetes, Wegovy indicated for chronic weight management.

Pharmacotherapy for youth living with T2D and obesity

Current paediatric clinical trials, expected completion and comparative adult outcomes

Trial name, number	Medication	Status	Estimated completion	Adult trial	Adult trial outcome	Adult trial reference
PIONEER TEENS <i>NCT04596631</i>	Oral semaglutide vs placebo	Actively recruiting	March 2026	PIONEER 1	14mg dose resulted in: HbA1c -1.5% Weight -4.1kg	Aroda et al <i>Diabetes Care</i> 2019
<i>NCT05067621</i>	Semaglutide , sc weekly – assess effects in obese youth with IGT/T2D and NAFLD	Actively recruiting	January 2027	Sema-MiDiab01 (retrospective, observational study)	Positive impact on Beta-cell preservation	Berra CC et al <i>Front Endocrinol</i> 2023
SURPASS PEDS <i>NCT05260021</i>	Tirzepatide sc weekly	Closed, awaiting results	February 2025	SURPASS 1	10mg dose resulted in: HbA1c -1.89%. Weight -8kg	Rosenstock J et al <i>The Lancet</i> 2021
<i>NCT04029480</i>	Ertugliflozin vs placebo	Active, not recruiting	April 2025	VERTIS MET Trial	15mg Ertugliflozin resulted in: HbA1c -0.9%. Weight -3.6 kg	Gallo S <i>Diabetes Obes Met</i> 2019

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