Obesity Management with Incretin Therapies: Considerations for Patients with and without Type 2 Diabetes

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Specialty Pharmaceutical Summit

June 21, 2024

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Objectives

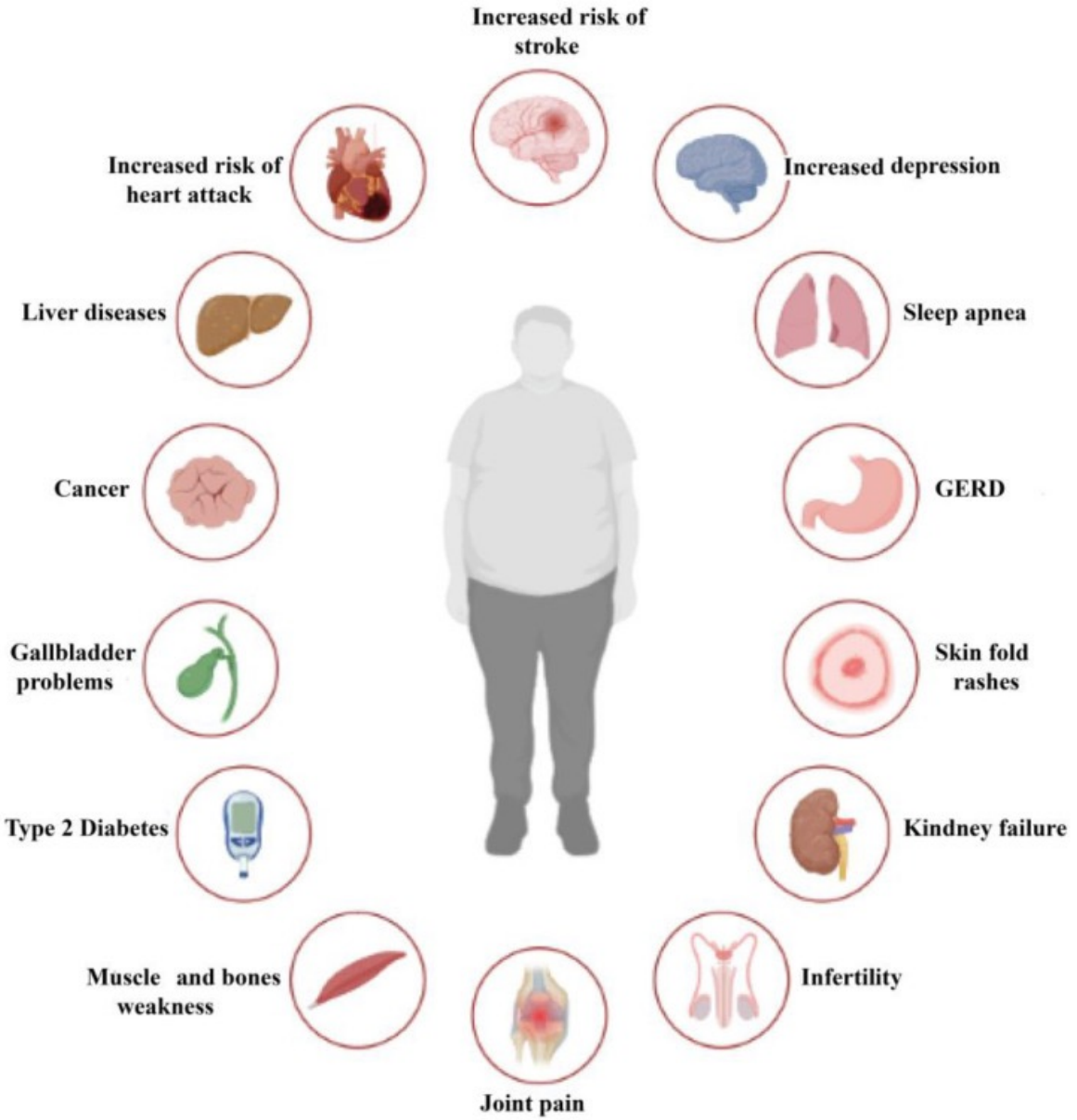
- Understand how incretin therapies benefit individuals with obesity or overweight with or without Type 2 Diabetes
- Identify benefits of treating obesity with incretin based therapies
- Discuss strategies for individualizing therapy based on patient characteristics

Background

- Obesity is a growing public health concern, with a prevalence that tripled from 1975 to 2016
- Obesity leads to an increased risk of comorbidities, including diabetes, hypertension, dyslipidemia, osteoarthritis, MASH, respiratory complications, CV diseases, cancer, and early death
- Lifestyle changes can result in modest weight loss (3-5%), but lifestyle therapies fail to achieve sustainable weight loss in most patients with obesity
- Greater weight loss yields more significant metabolic benefits and clinically meaningful improvements in patients with obesity-related comorbidities

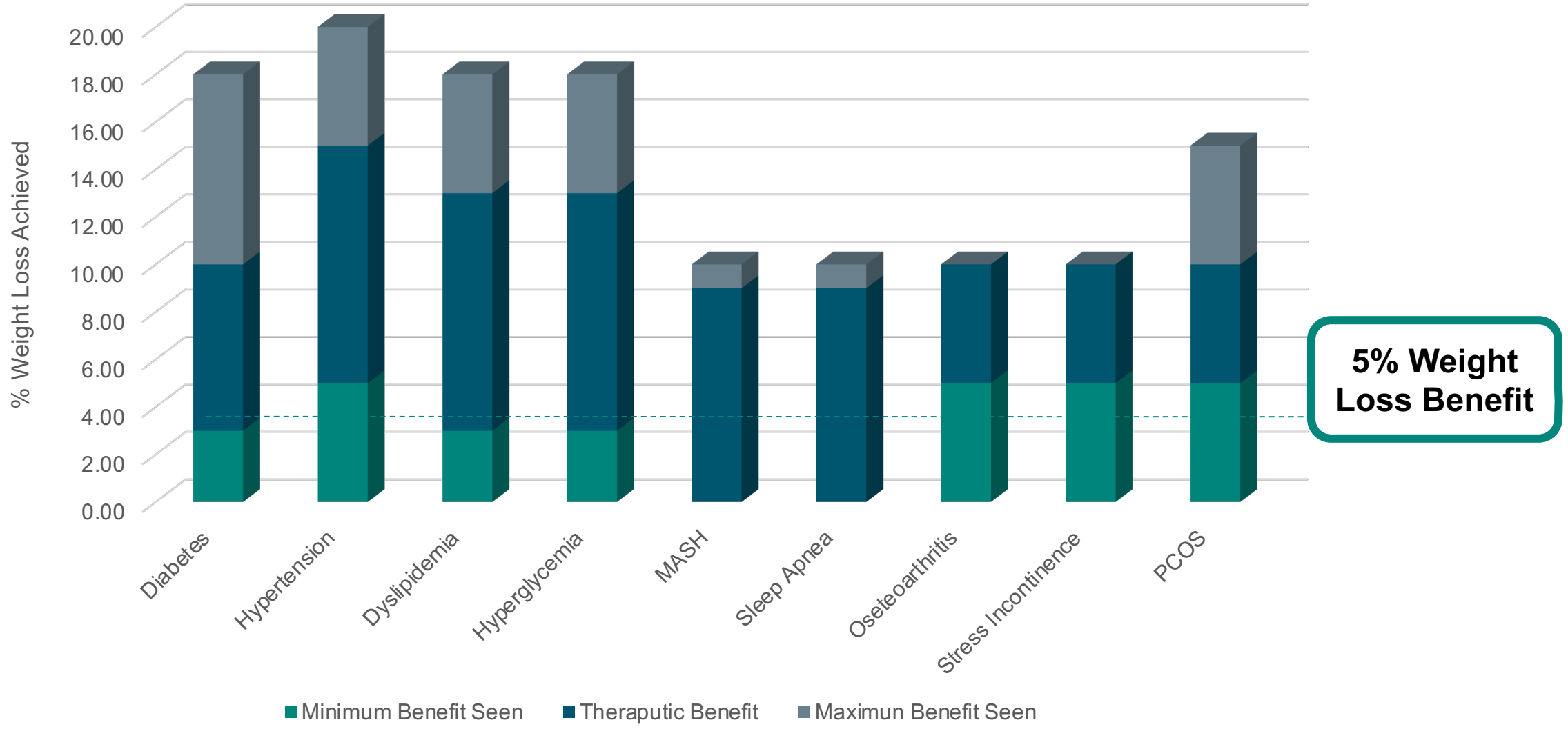
AOM = Anti-Obesity Medication; CV = Cardiovascular; FDA = The US Food and Drug Administration; NASH = Nonalcoholic Steatohepatitis. 1. https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight (Accessed April 19, 2022). 2. Salari N, et al. Diabetol Metab Syndr. 2021;13(1):110. 3. Müller TD, et al. Nat Rev Drug Discov. 2021;1-23. 4. Dombrowski SU, et al. BMJ. 2014;348:g2646. 5. Ryan DH, Yockey SR. Curr Obes Rep. 2017;6(2):187-194. 6. Ahmad NN, et al. Obesity Rev. 2021;22:e13326.

Complications and Implications of Obesity



Diabetes Care 2015;38(8):1567–1582

Weight Reduction Needed to Reduce Complications



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Diabetes Care 2015;38(8):1567–1582

Weight Reduction Needed to Reduce Complications

Weight-Related Comorbidity		Weight Loss Goal	Clinical Goals
Prediabetes		10%	• Prevention of type 2 diabetes
Type 2 diabetes		5 to ≥15%	• Reduction in HbA1c • Reduction in number and/or doses of glucose-lowering medications
Hypertension		5 to ≥15%	• Reduction in systolic and diastolic blood pressure • Reduction in number and/or doses of hypertensive medications
Obstructive sleep apnea		7 to ≥11%	• Improved symptoms • Reduction in apnea-hypopnea index
Osteoarthritis		≥10%	• Improved symptoms • Increased function
Dyslipidemia		5 to ≥15%	• Lower non-HDL-C and TGs • Higher HDL-C
Metabolic syndrome		10%	• Prevention of type 2 diabetes
Nonalcoholic fatty liver disease	Steatosis	≥5%	• Reduction in intrahepatocellular lipid
	Steatohepatitis	10-40%	• Reduction in inflammation and fibrosis

This table is adapted from Table 8 of the 2016 AACE guidelines.

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Incretins: Place in Therapy in T2DM

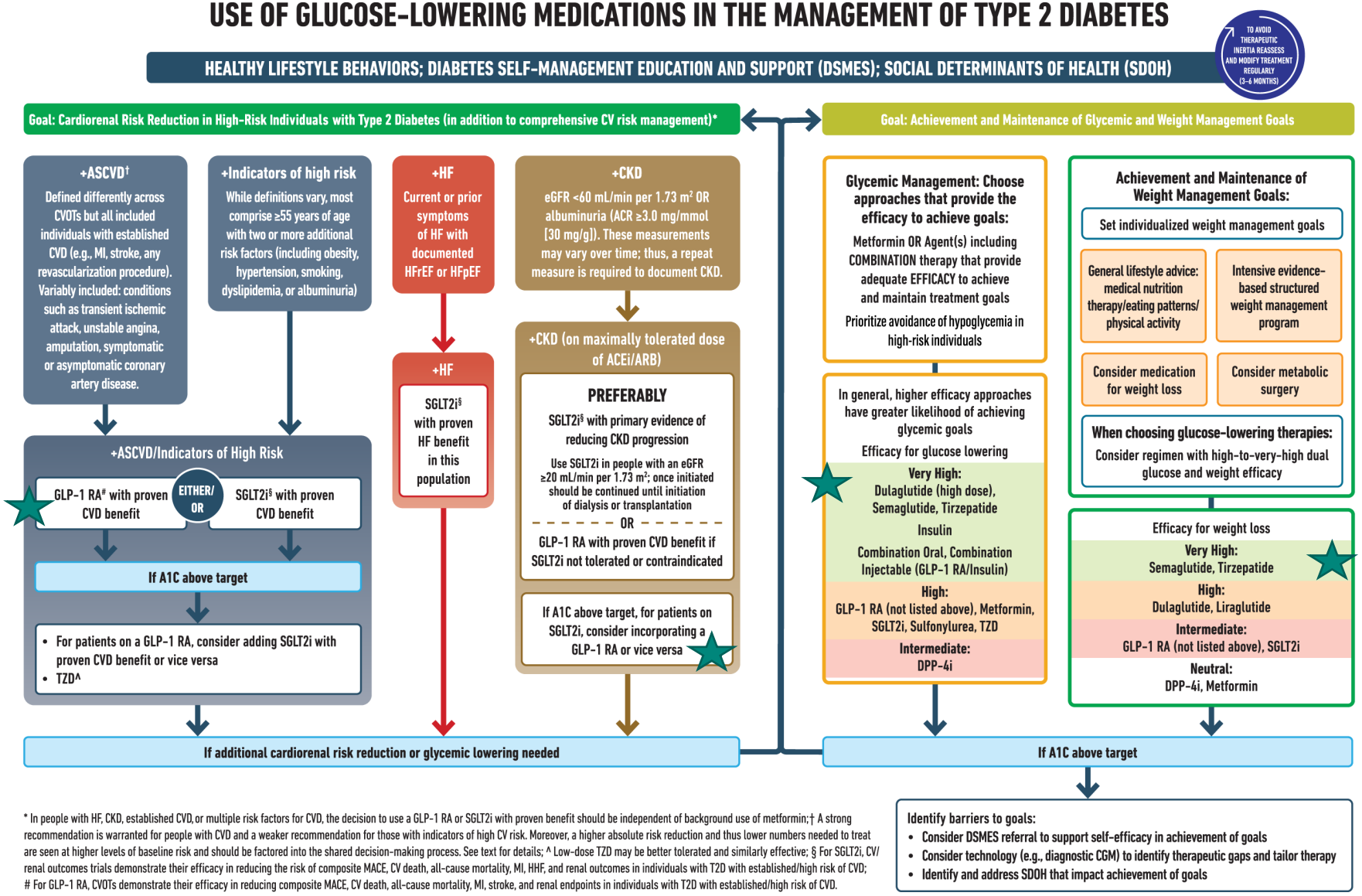
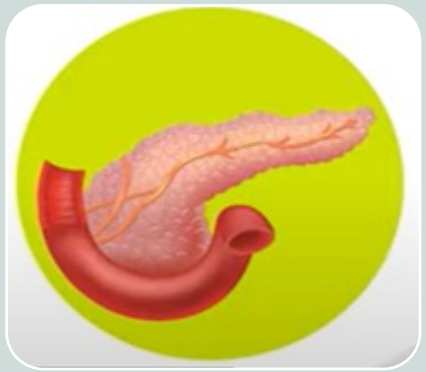


Fig 9.3: 9. Pharmacologic Approaches to Glycemic Treatment: *Standards of Care in Diabetes—2024. Diabetes Care* 1 January 2024; 47 (Supplement_1): S158–S178.

Glucagon Like Peptide 1 Receptor Agonists Mechanism of Action



Increase insulin secretion

Delayed gastric emptying

Increased satiety

Decrease hepatic glucose production

GLP1-RA Outcomes in T2DM

AWARD-6 Liraglutide vs Dulaglutide

Primary Endpoint: Mean change in A1c from baseline

- Baseline A1c: 8.1%
- 1.4% reduction in both groups

Secondary Endpoint: Mean change in weight from baseline

- Baseline weight: 206-208lb
- Liraglutide 1.8mg (n=220): -7.9lb
- Dulaglutide 1.5mg (n=299): -6.4lb

SUSTAIN-7 Semaglutide vs Dulaglutide

Baseline	Sema 0.5mg N=301	Dula 0.75mg N=299	Sema 1mg N=300	Dula 1.5mg N=299
A1c	8.3%	8.2%	8.2%	8.2%
Body Weight	96.4kg	95.6kg	95.5kg	93.4kg

Primary Endpoint: Mean change in A1c from baseline

- Semaglutide 0.5mg: -1.5% vs dulaglutide 0.75mg: -1.1%
  - Mean difference -0.4% ($p<0.0001$)
- Semaglutide 1mg: 1.8% vs dulaglutide 1.5mg: 1.4%
  - Mean difference 0.41% ($p<0.0001$)

Secondary Endpoint: Mean change in weight from baseline

- Semaglutide 0.5mg: -4.6kg vs dulaglutide 0.75mg: -2.3kg
- Semaglutide 1mg: -6.5kg vs dulaglutide 1.5mg: -3kg

Dungan KM, et al. (AWARD-6):. *Lancet.* 2014;384(9951):1349-1357.

Pratley RE, et al; (SUSTAIN 7): Lancet Diabetes Endocrinol. 2018 Apr;6(4):275-286.

GLP1-RA Dosing – T2DM with CV Risk Reduction

Liraglutide — Multi-dose pen, separate Rx for pen needles

- Start 0.6 mg SC once daily
- Increase to 1.2mg daily after 1 week
- Max: 1.8mg daily

Semaglutide — Multi-dose pen, needles come with pen

- Start 0.25mg SC once weekly
- Increase to 0.5mg weekly after 4 weeks, then increase to 1mg weekly after weeks for additional glycemic control.
- Max dose: 2mg/weekly

Dulaglutide — Single use pens, needle inside device

- Start 0.75mg SC once weekly
- Increase in 4 week increments; 1.5mg weekly, 3mg weekly
- Max dose: 4.5mg weekly

Other GLP1-RA Dosing – T2DM only

Exenatide (IR) — Multi-dose pen, separate Rx for pen needles

- Start 5 mcg SC BID; inject 60 min prior to meals
- Increase to 10 mcg BID after 1 month
- Do not use if CrCl <30 mL/min

Exenatide (ER) — Single use pen, auto-injector

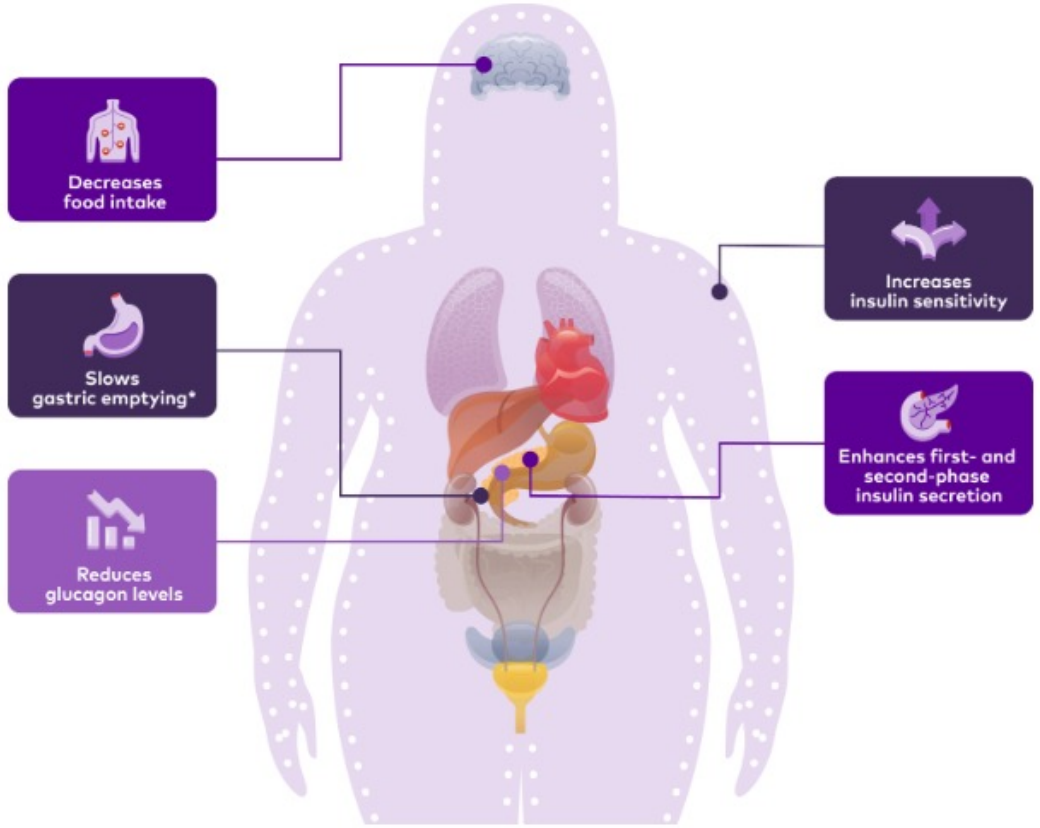
- Start 2mg SC once weekly
- Do not use if eGFR <45 mL/min

Semaglutide PO — Must be dispensed in original bottle

- Start 3mg daily, take on empty stomach with 4 oz water
- Increase to 7mg daily after 1 month
- Max dose: 14 mg daily

Dual Incretin - Tirzepatide

- FDA Approved for treatment of T2DM in May 2022
- New class of medications, GLP1-RA/GIP
- Dosing: 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, and 15mg SC once weekly
- 2.5mg dose to minimize GI side effects
- Titrate every 4 weeks
- Same pen/injectable device as dulaglutide



https://www.mounjaro.com/hcp/how-mounjaro-works Accessed April 6 2023

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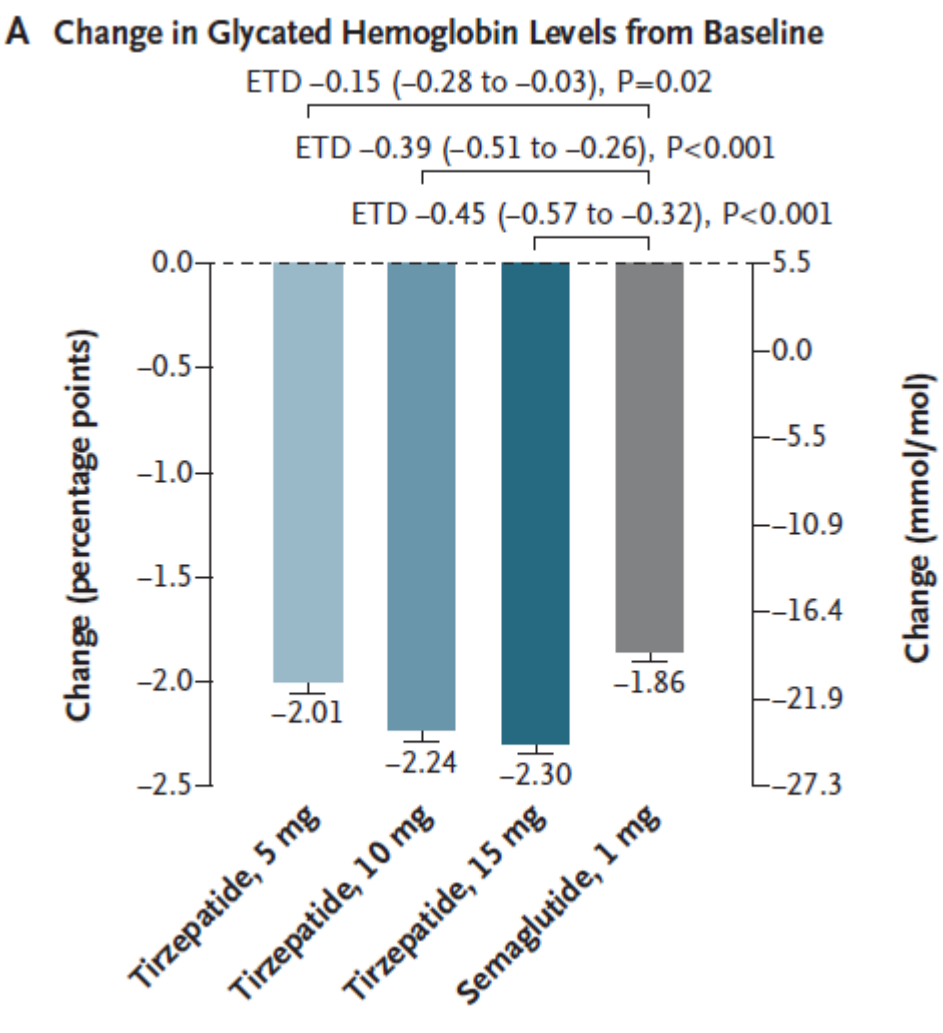
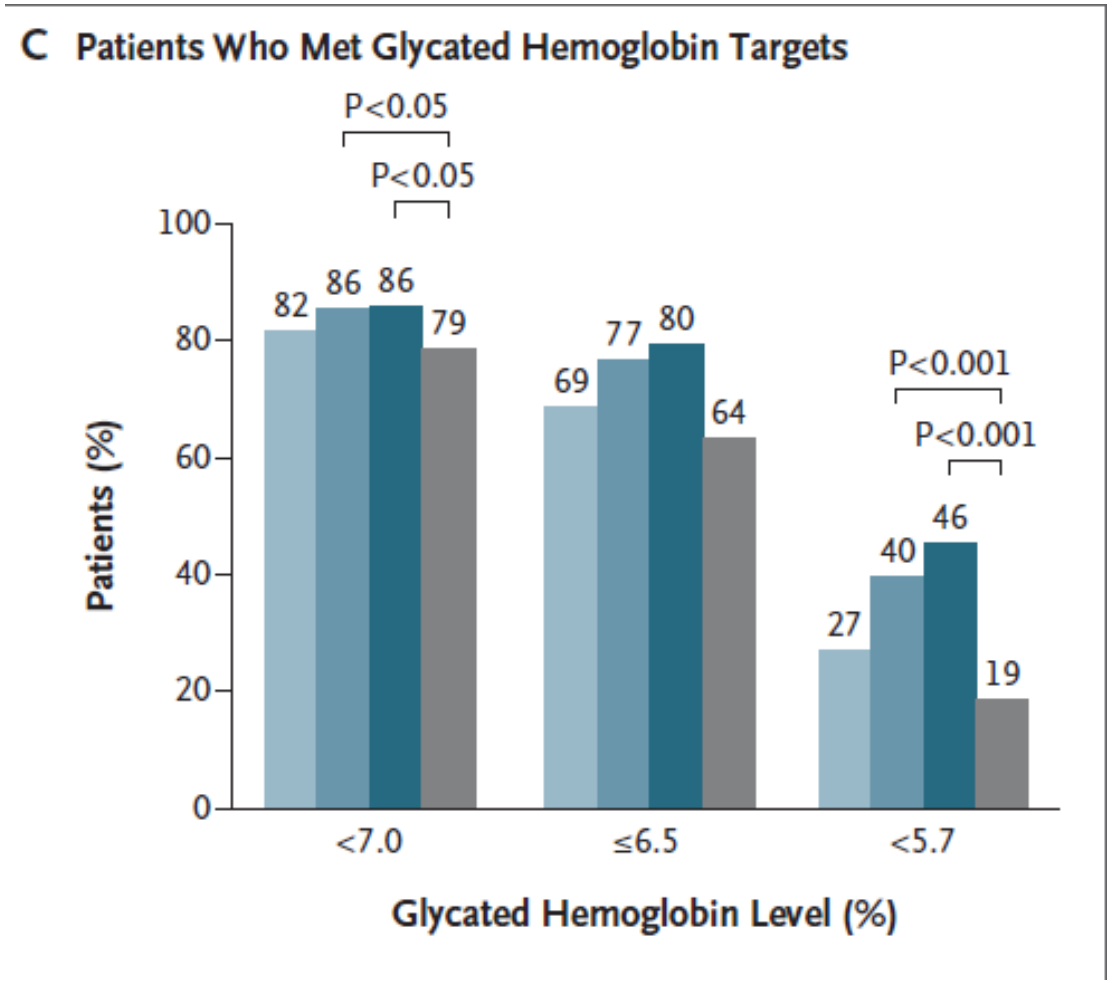
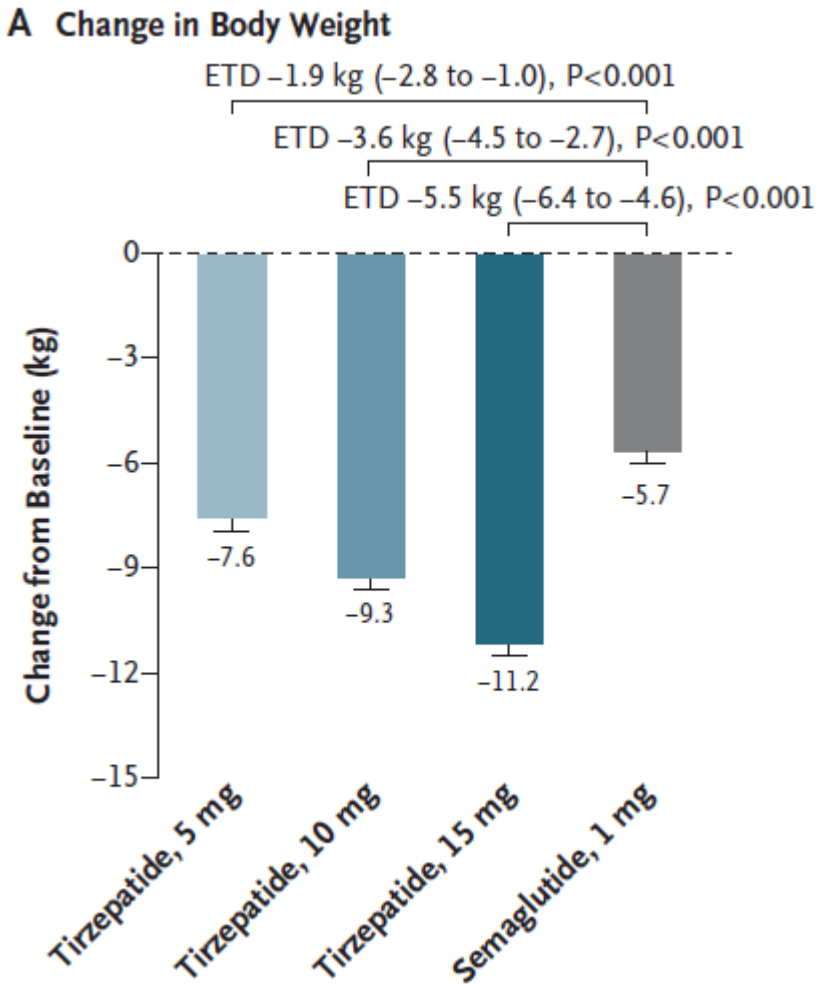
Semaglutide vs Tirzepatide in T2DM – SURPASS 2

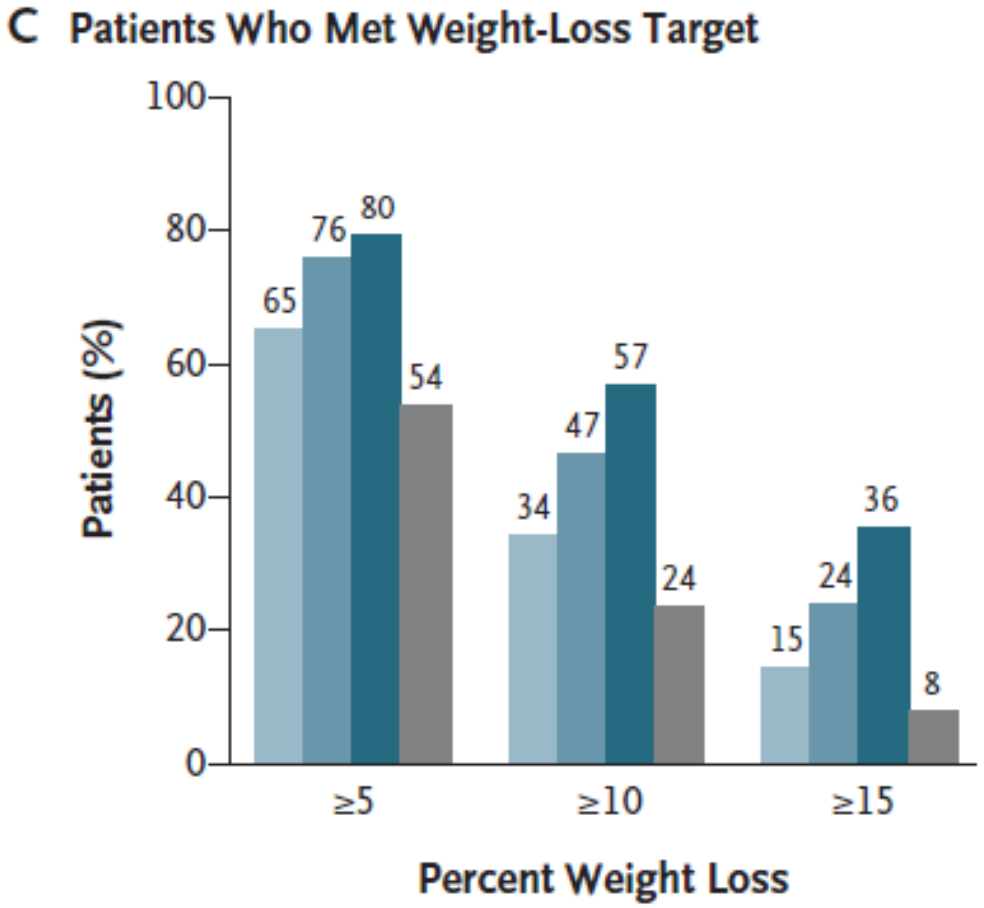




Frias JP, et al. NEJM 2021

Semaglutide vs Tirzepatide in T2DM – SURPASS 2





Frias JP, et al. NEJM 2021

Tirzepatide Trials – A1c and Weight Change

	SURPASS 1	SURPASS 2	SURPASS 3	SURPASS 4	SURPASS 5
Intervention	Placebo control	Metformin, semaglutide vs tirzepatide	Metformin +/- SGLT2i, insulin degludec vs tirzepatide	Tirzepatide vs insulin glargine	Background basal insulin +/- metformin, tirzepatide vs placebo
A1c change 5mg, 10mg, 15mg, comparator	-1.8%	-2.0%	-1.9%	-2.1%	-2.1%
	-1.7%	-2.2%	-2.0%	-2.3%	-2.4%
	-1.7%	-2.3%	-2.1%	-2.4%	-2.3%
Weight change (lb) 5mg, 10mg, 15mg, comparator	-14	-17	-15	-14	-12
	-15	-21	-21	-20	-17
	-17	-25	-25	-23	-19
	-2	-13	+4	+4	+4

Incretins in Obesity

Success of AOM on the market

Drug	Study (duration ≥1 year)	Subject (drug/placebo)	Lifestyle intervention (diet/exercise/behavior)	Weighted mean difference (kg) (95% CI) for the drug-to-placebo comparison at 1 year	% weight loss (drug/placebo)	Odds ratio (95% CrI) for achieving ≥5% weight loss	% of patients with ≥5% weight loss at 1 year (drug/placebo)	% of patients with ≥10% weight loss at 1 year (drug/placebo)
Orlistat	17 trials	5,572/5,572	Reduced fat intake or 500–800 kcal deficit/non-specific increase or 30 minutes of moderate exercise per day/yes or no	2.60 (2.16–3.04	4.6/1.7	2.70 (2.34–3.09)	48.8/22.6	17.9/8.8
Phentermine/topiramate	3 trials	1,802/1,735	500 kcal deficit/non-specific increase/yes	8.80 (7.42–10.2	8.5/1.7	9.22 (6.63–12.85)	72.0/22.8	49.7/8.6
Naltrexone/ bupropion	5 trials	6,963/5,897	500 kcal deficit/non-specific increase or 30 minutes of moderate exercise per day/yes	4.95 (3.96–5.94	6.1/2.1	3.96 (3.03–5.11)	52.4/28.3	28.3/9.7
Liraglutide	4 trials	3,096/1,649	500 kcal deficit/minimum 150 minutes of brisk walking per week/yes	5.27 (4.52–6.06	7.1/1.7	5.54 (4.16–7.78)	60.3/24.6	30.4/8.4
Lorcaserin[a]	4 trials	9,453/9,440	600 kcal deficit/30 minutes of moderate exercise per day/yes	3.22 (2.46–3.97	5.1/2.0	3.10 (2.38–4.05)	42.7/19.7	19.0/6.7

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Tak YJ, Lee SY. World J Men's Health. 2021;39(2):208-221.

Liraglutide

- FDA approved in 2014
- GLP-1RA
- BMI ≥ 30 OR BMI ≥ 27 & at least one weight-related comorbidity
- Ages 12 and older

Adjusted Weekly	
Week 1	0.6 mg daily
Week 2	1.2 mg daily
Week 3	1.8 mg daily
Week 4	2.4 mg daily
Week 5	3 mg daily

Semaglutide

- FDA approved June 2021
- GLP-1RA
- To reduce risk of major adverse cardiovascular events in adults with established CVD and either obesity or overweight
- Adults with overweight & one weight related comorbidity
- Ages 12 and older with obesity

Adjusted Monthly	
Month 1	0.25 mg weekly
Month 2	0.5 mg weekly
Month 3	1.0 mg weekly
Month 4	1.7 mg weekly
Month 5	2.4 mg weekly

Tirzepatide

- FDA Approved November 2023
- GLP-1RA/GIP
- BMI ≥ 30 OR BMI ≥ 27 & at least one weight-related comorbidity
- Ages 18 and older

Adjusted Monthly	
Month 1	2.5 mg weekly
Month 2	5.0 mg weekly
Month 3	7.5 mg weekly
Month 4	10 mg weekly
Month 5	12.5 mg weekly
Month 6	15 mg weekly

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Semaglutide – STEP Program

	STEP 1 N=1961	STEP 3 N=611	STEP 4 N=803	STEP 5 N=304	STEP 8 N=338
Study Design	Sema vs placebo	Sema vs placebo, IBT	Sustained WM	Sustained WM	Sema vs lira
Duration	68 weeks	68 weeks	68 weeks	104 weeks	68 weeks
Mean Age	46 yrs	46 yrs	46 yrs	47 yrs	49 yrs
Baseline Weight	232.1 lb	233.2 lb	211.9 lb	233.7 lb	230.4 lb
Baseline BMI	37.9	38.0	38.4	38.5	37.5
Primary Outcome	12.4% Δ ≥ 5% weight reductions 86.4% v 31.5%	10.3% Δ ≥ 5% weight reductions 86.6% v 47.6%	12.4% Δ ≥ 5% weight reductions 88.7% v 47.6%	12.6% Δ ≥ 5% weight reductions 77.1% v 34.4%	15.8% vs 6.4% (-9.4% P<.001) ≥ 10% weight Reductions 70.9% v 25.6%
Impact on SBP/DBP mmHg	-1.8/-2.41	-3.9/-2.2	-3.9/-0.6	-4.2/-3.7	-2.8/-4.5

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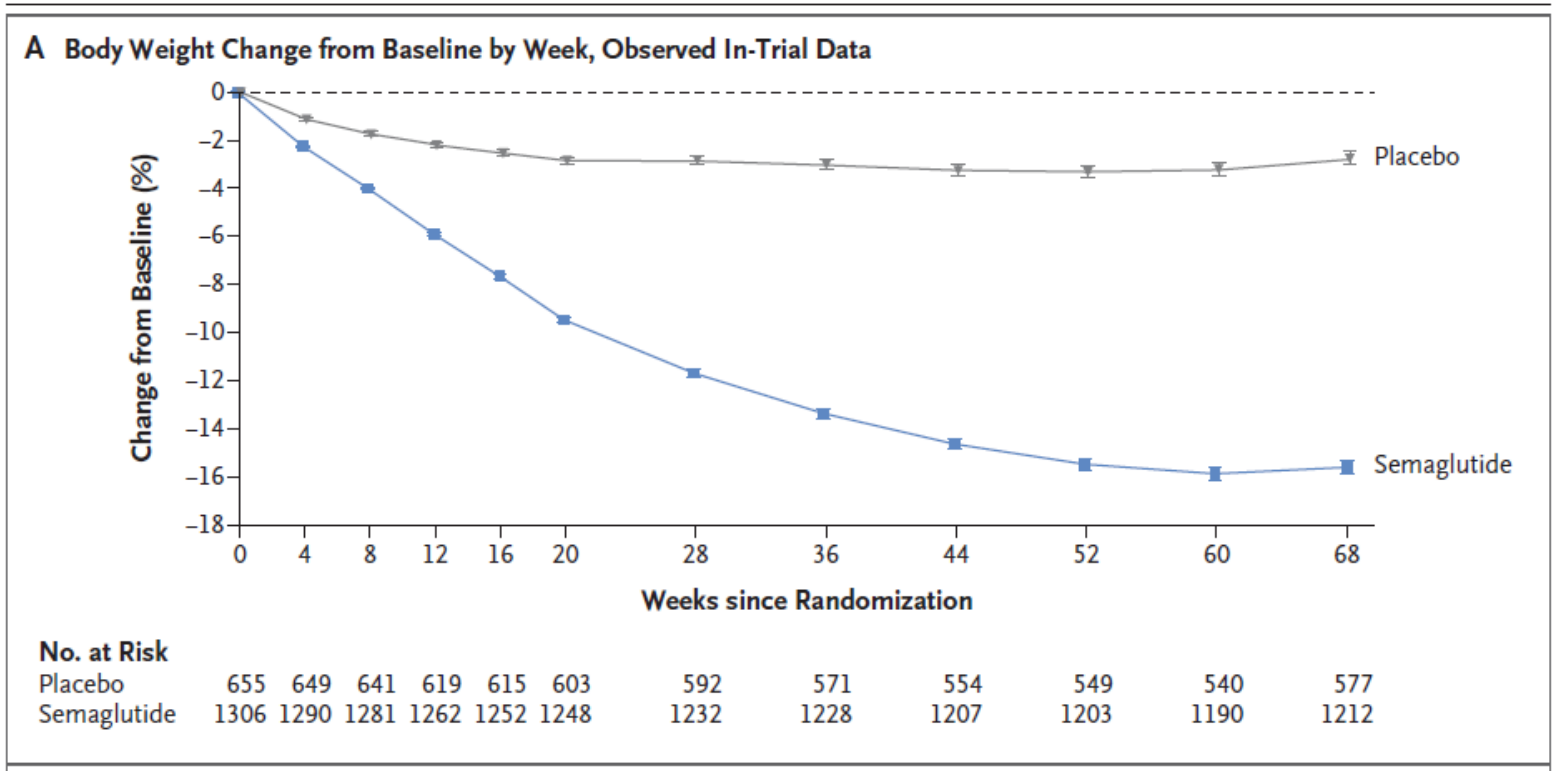
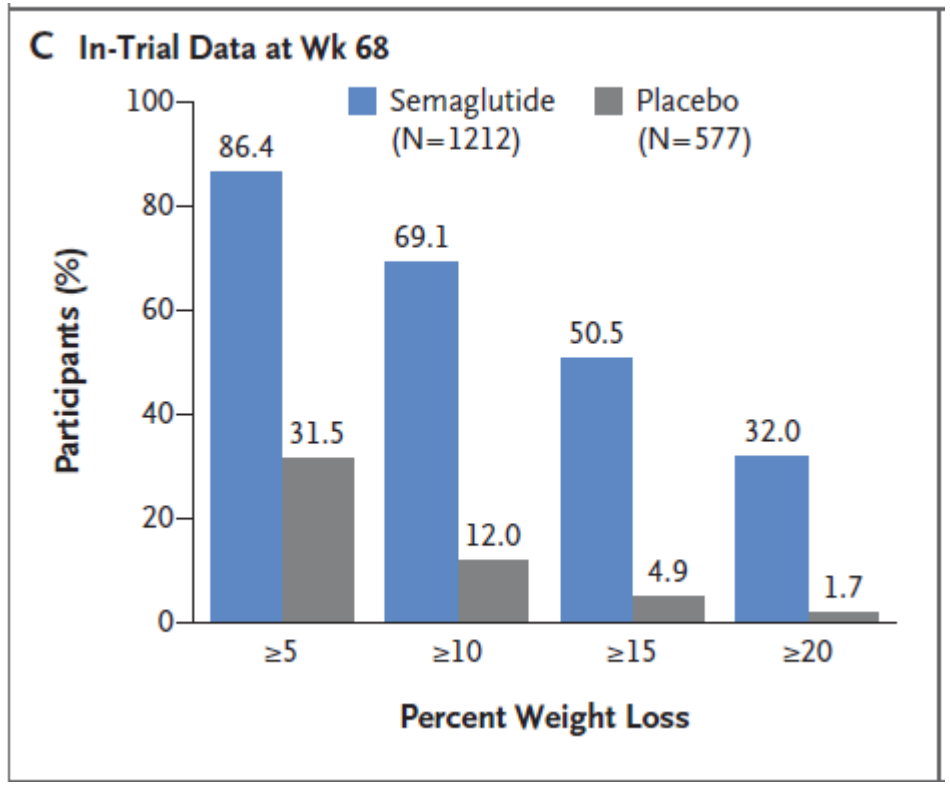
Wilding JPH et al. N Engl J Med. 2021 Wadden TA et al. JAMA 2021 Rubino D et al. JAMA 2021 Garvey WT et al.Nat Med. 2022 Rubino DM et al.JAMA. 2022 Weghuber D et al. N Engl J Med 2022

STEP 1 Outcomes



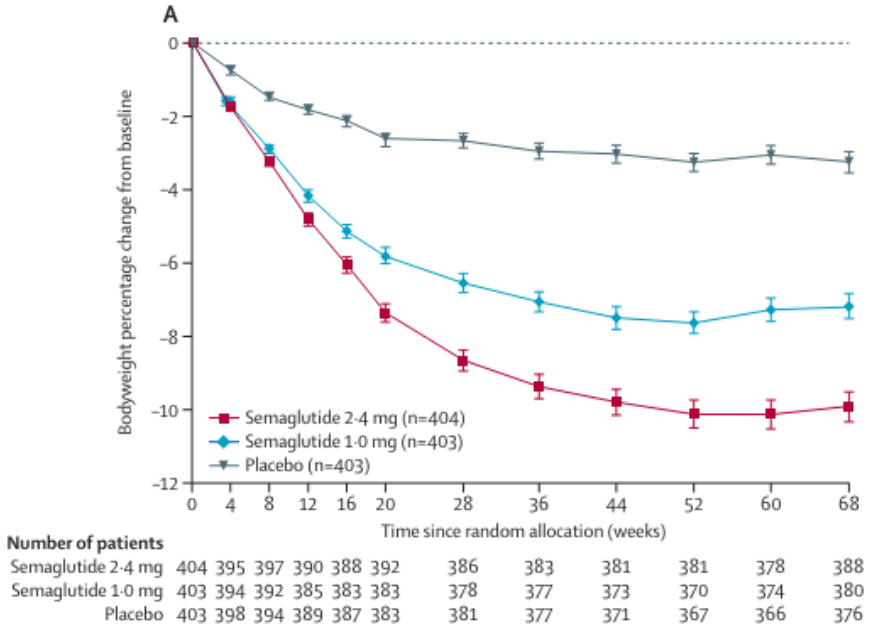


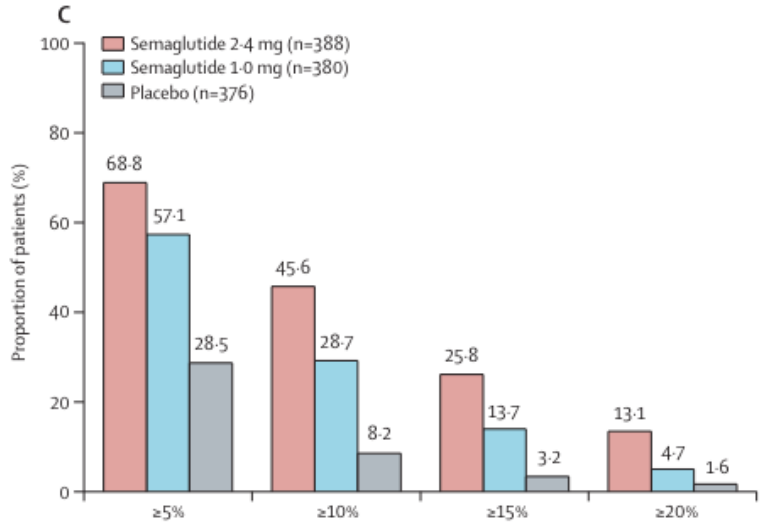
. Wilding JPH et al. N Engl J Med. 2021

STEP 2 – Semaglutide 2.4mg vs Semaglutide 1mg vs Placebo in T2DM

- 68 week, phase 3a trial
- 1210 patients with T2DM and overweight or obesity were randomized 1:1:1 to receive semaglutide 2.4mg, semaglutide 1mg, or placebo once weekly

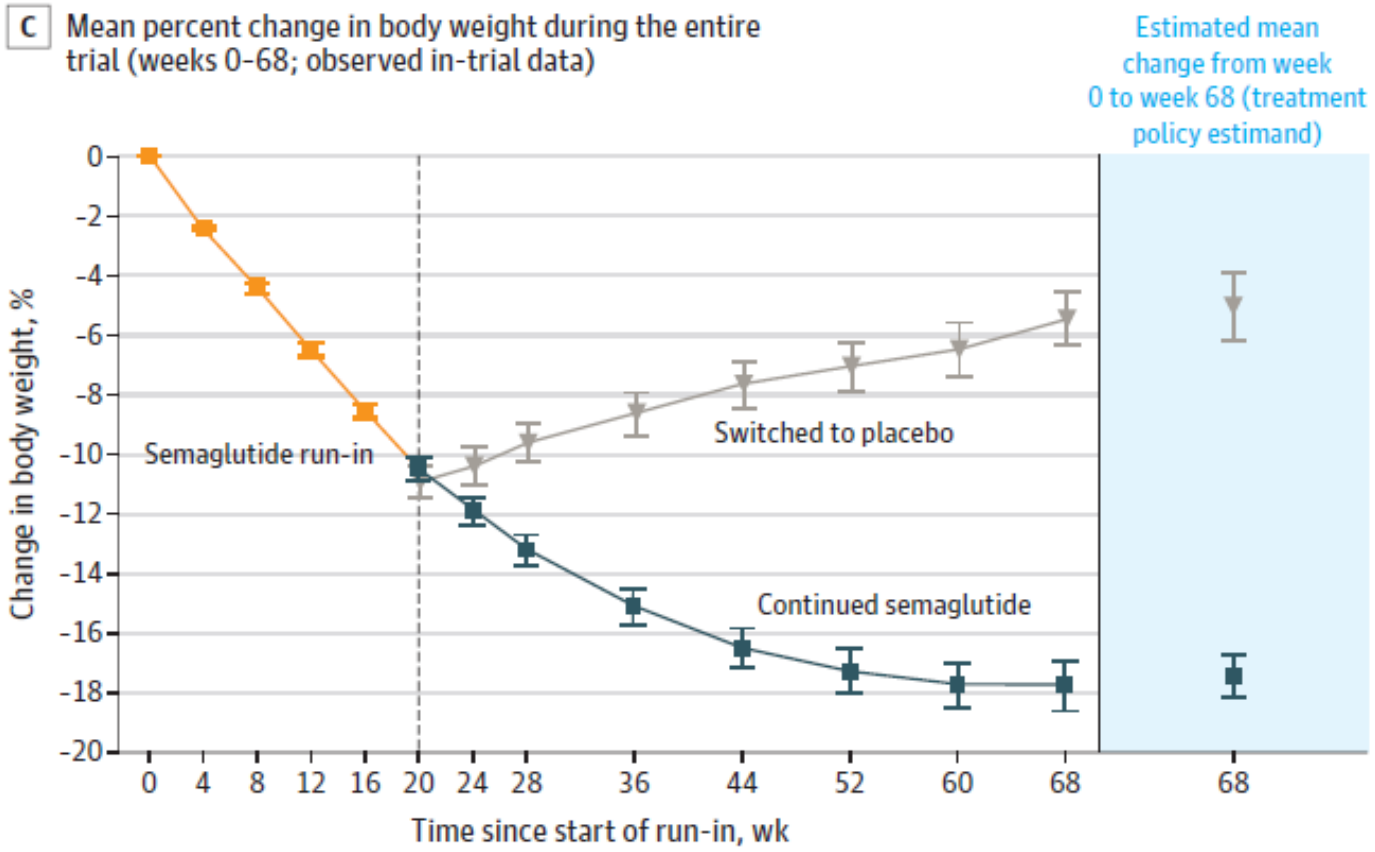
- Primary Outcome
- Mean change in body weight (%)
  - –9.6% vs –7.0% vs –3.4%
  - Sema 2.4 mg vs Placebo:
    - –6.2% (–7.3 to –5.2); P<.0001
  - Sema 2.4 mg vs Sema 1 mg
    - –2.7% (–3.7 to –1.6); P<.0001

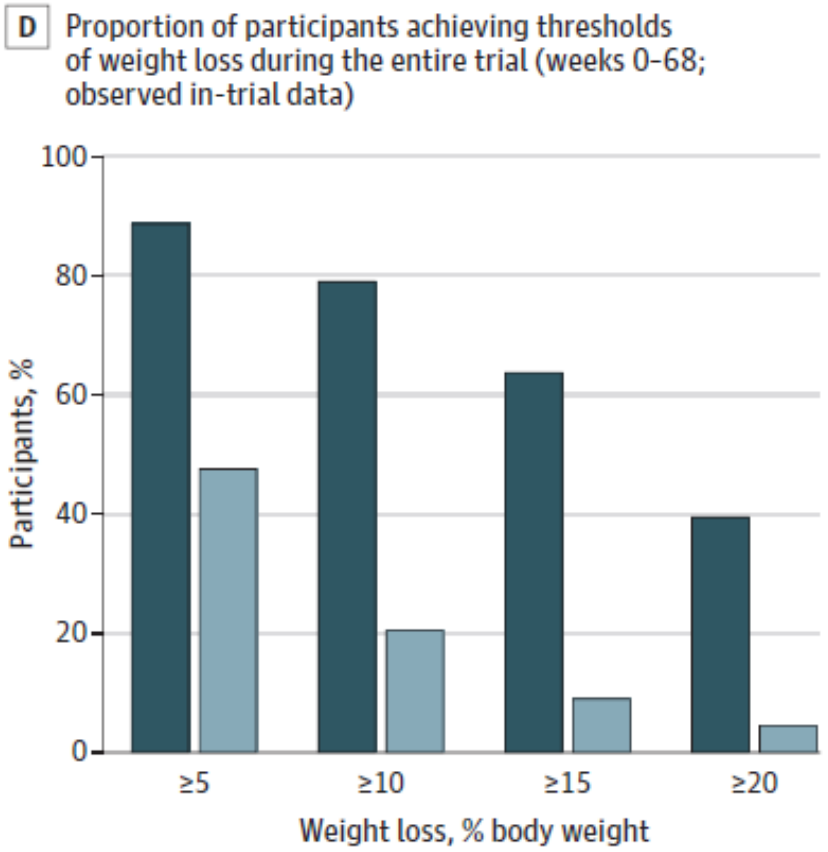




Davies et al. Lancet 2021

STEP 4


C
Mean percent change in body weight during the entire trial (weeks 0-68; observed in-trial data)
Estimated mean change from week 0 to week 68 (treatment policy estimand)
Change in body weight, %
0
-2
-4
-6
-8
-10
-12
-14
-16
-18
-20
Semaglutide run-in
Switched to placebo
Continued semaglutide
0 4 8 12 16 20 24 28 36 44 52 60 68 68
Time since start of run-in, wk


D
Proportion of participants achieving thresholds of weight loss during the entire trial (weeks 0-68; observed in-trial data)
Participants, %
100
80
60
40
20
0
≥5
≥10
≥15
≥20
Weight loss, % body weight

Tirzepatide - SURMOUNT

	SURMOUNT 1 N=1961	SURMOUNT 3 N=611	SURMOUNT 4 N=803
Study Design	Tirzep vs placebo	Tirzep vs placebo, ILM	Tirzep Sustained WM
Duration	72 weeks	72weeks	36-88 weeks
Mean Age	45 yrs	45 yrs	48 yrs
Baseline Weight	230.6 lb	225.5 lb	236.1 lb
Baseline BMI	38.0	36.1	38.4
Primary Outcome	22.5% Δ ≥ 5% weight reductions 96.3% v 27.9%	21.1% Δ ≥ 5% weight reductions 94.4% v 10.7%	5.5% Δ Maintaining ≥ 80% weight reductions 89.5% v 16.6%
Impact on SBP/DBP mmHg	-6.2/-4.0	-4.5/-2.6	-11.8/-5.4

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Jastreboff AM, et al. N Engl J Med. 2022;387(3):205-216. SURMOUNT-3 phase 3 trial. *Nat Med* **29**, 2909–2918 (2023). SURMOUNT-4 Randomized Clinical Trial. *JAMA*. 2024;331(1):38–48

SURMOUNT 2 – Obesity and T2DM

- Phase 3, double blind, randomized, placebo-controlled trial
- Adults with BMI ≥27 and A1c 7-10%
- Mean age: 54 and mean body weight: 100.7 kg; BMI 36.1
- Doses studied: 10mg and 15mg/week vs placebo
- Primary Outcome:
  - Mean change in bodyweight at week 72 with tirzepatide 10 mg and 15 mg was -12·8% and -14·7% respectively, and -3·2% with placebo
    - Estimated treatment differences versus placebo:
    - -9·6% percentage points (95% CI -11·1 to -8·1) with tirzepatide 10 mg
    - -11·6% percentage points (-13·0 to -10·1) with tirzepatide 15 mg (all p<0·0001).
  - More participants treated with tirzepatide versus placebo met bodyweight reduction thresholds of 5% or higher (79-83% vs 32%).

Lancet. 2023 Aug 19;402(10402):613-626

SELECT Trial

- Semaglutide has proven CV benefit in T2DM (SUSTAIN 7)
- SELECT enrolled individuals age 45 and older with pre-existing CVD and a BMI of ≥ 27
  - 17,604 patients enrolled and were randomized in a 1:1 ratio to once weekly semaglutide or placebo
  - Primary Outcome: death from CV causes, nonfatal MI or non-fatal stroke
    - A primary cardiovascular end-point event occurred in 569 of the 8803 patients (6.5%) in the semaglutide group and 701 of the 8801 patients (8.0%) in the placebo group
      - Hazard ratio, 0.80; 95% confidence interval [CI], 0.72 to 0.90; P<0.001

Patient Demographics	Semaglutide (n=8803)	Placebo (n=8801)
Age	61.6 years	61.6 years
Male sex %	72.2	72.5
Body Weight, Kg	96.5	96.8
BMI	33.3	33.4
CV inclusion Criteria MI only Stoke only PAD only Two of the above	 67.7% 17.9% 4.3% 8.2%	 67.5% 17.7% 4.6% 8.2%

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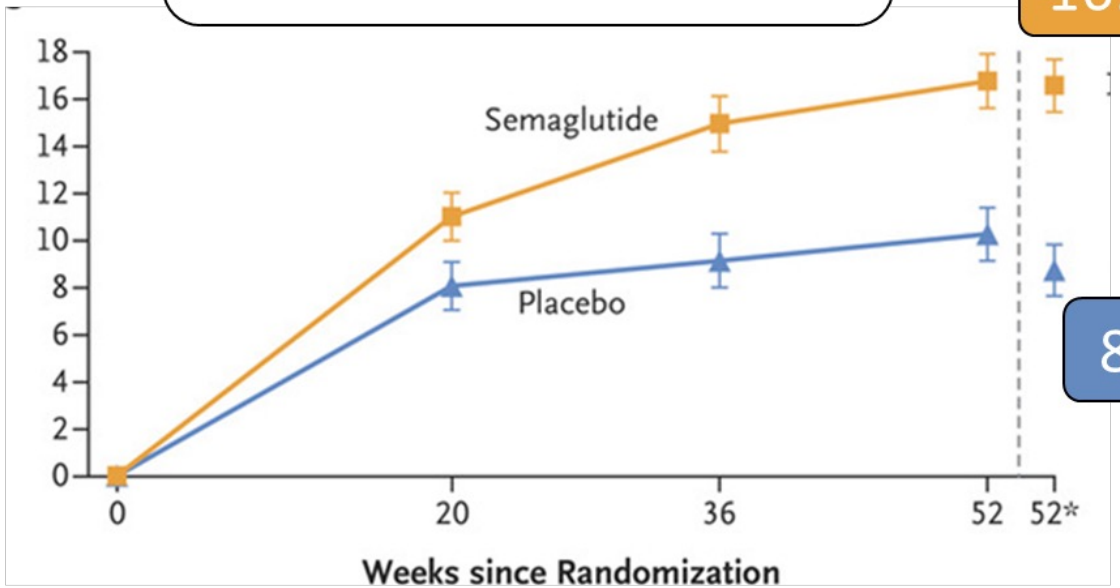
N Engl J Med 2023; 389:2221-2232

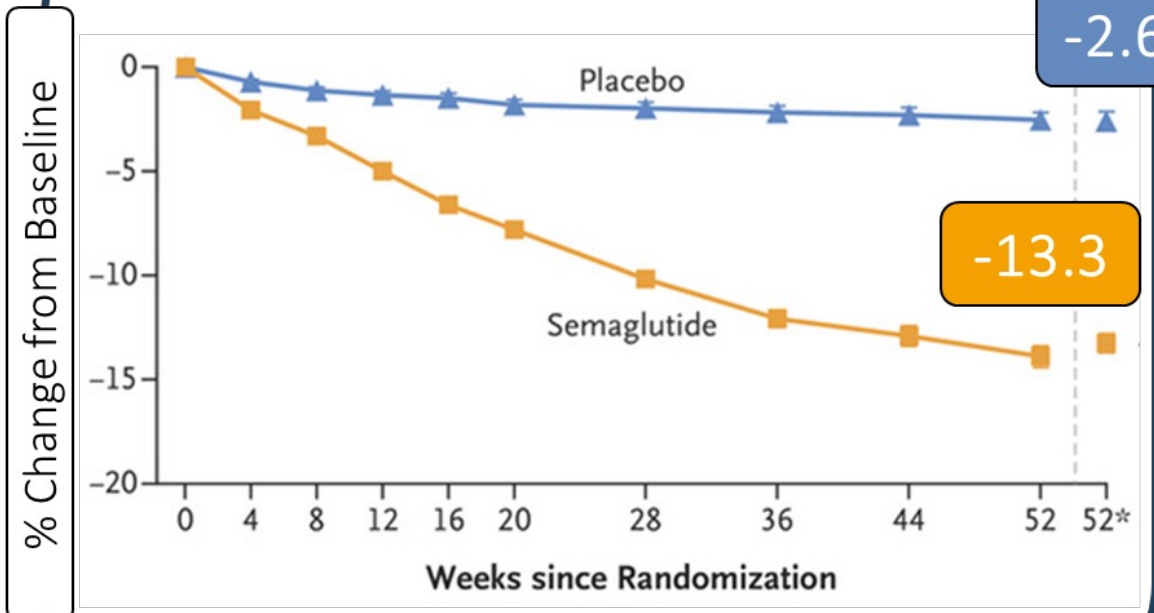
STEP HFpEF – Semaglutide in Patients with Heart Failure Preserved Ejection Fraction and Obesity

Estimated Difference, 7.8 points
(95%CI, 4.8 to 10.9) P<0.001



Change in KCCQ-CSS

Estimated Difference, 10.7 % points
(95%CI, -11.9 to -9.4) P<0.001

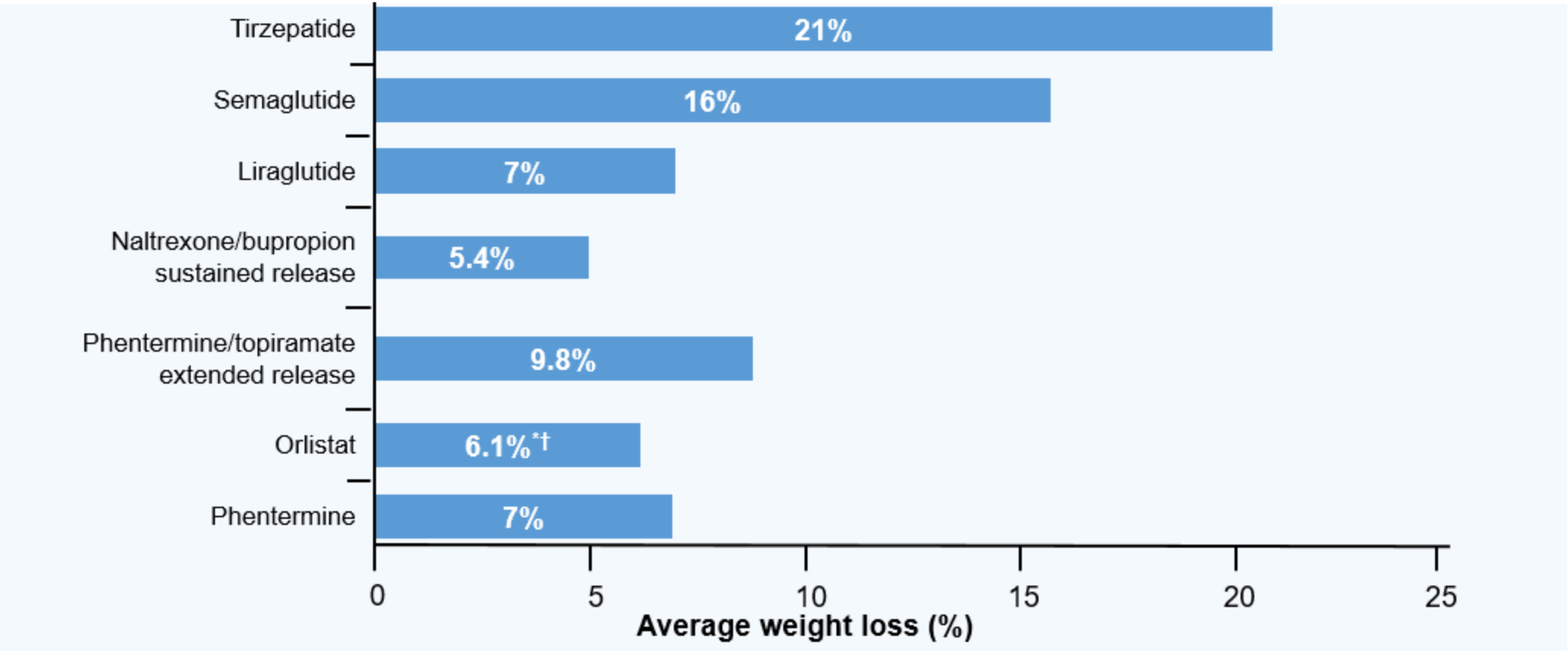


Change in Body Weight

KCCQ-CSS Kansas City Cardiomyopathy Questionnaire clinical summary score

MN Kosiborod et al. N Engl J Med 2023;389:1069-1084

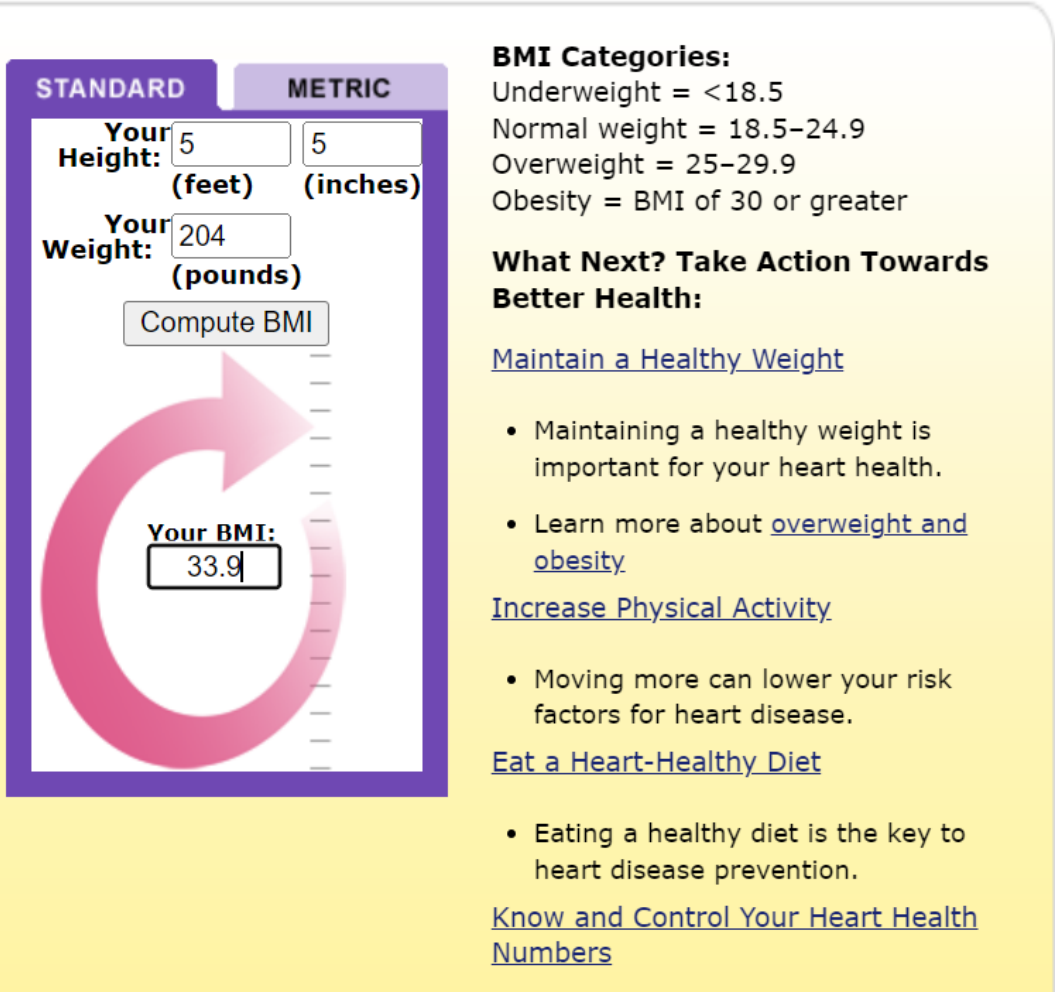
Current Pharmacotherapy: Efficacy



Bray GA et al. Lancet 2016;387:1947–56

Case 1

- A 32 year old female presents to primary care for her annual physical.
  - BP: 122/67
  - HR: 68
  - A1c 5.4%
  - Scr: 1.0
  - LDL 127
  - Weight: 204 lb
  - Height: 5 ft 5 inches

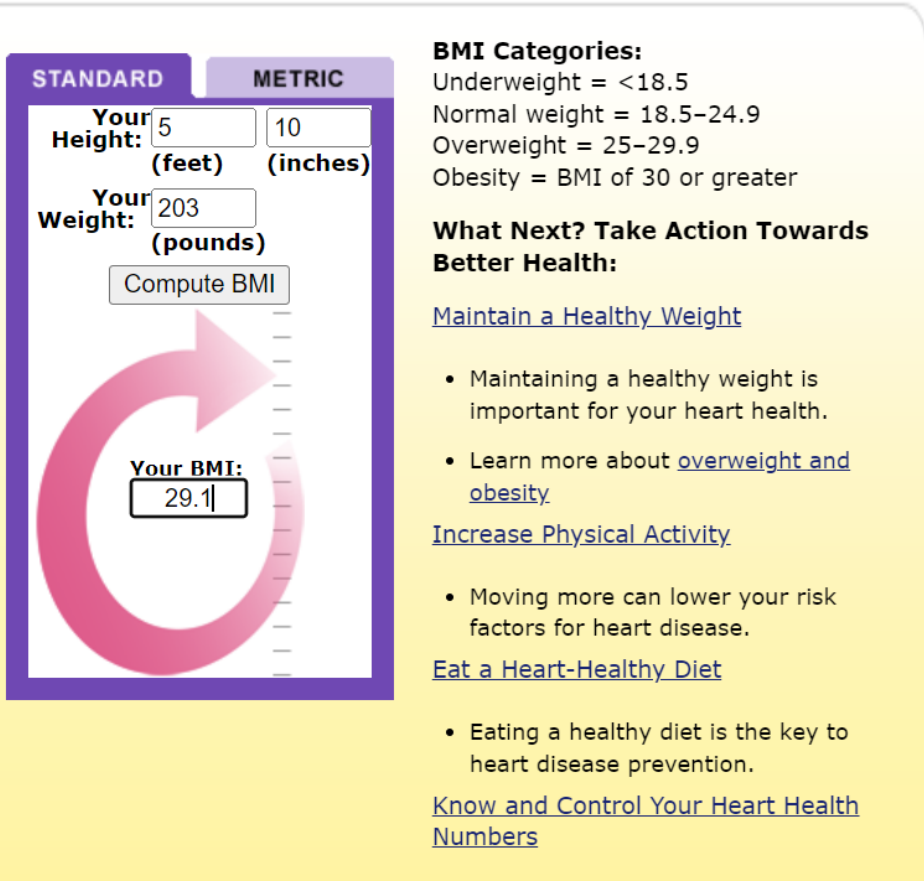


https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm

Case 2

- 48 year old male with T2DM, HTN, NSTEMI, HFpEF and CKD is referred to your pharmacy clinic for chronic disease state management
  - BP: 144/92
  - HR: 78
  - A1c 9.4%
  - Scr: 1.9, eGFR 50
  - UACR 321
  - LDL 115
  - Weight: 203 lb
  - Height: 5 ft 10 inches

Metformin 500mg once daily
Glipizide 5mg with dinner
Lisinopril 5mg daily
Atorvastatin 80mg daily
ASA 81mg daily
Metoprolol ER 50mg daily



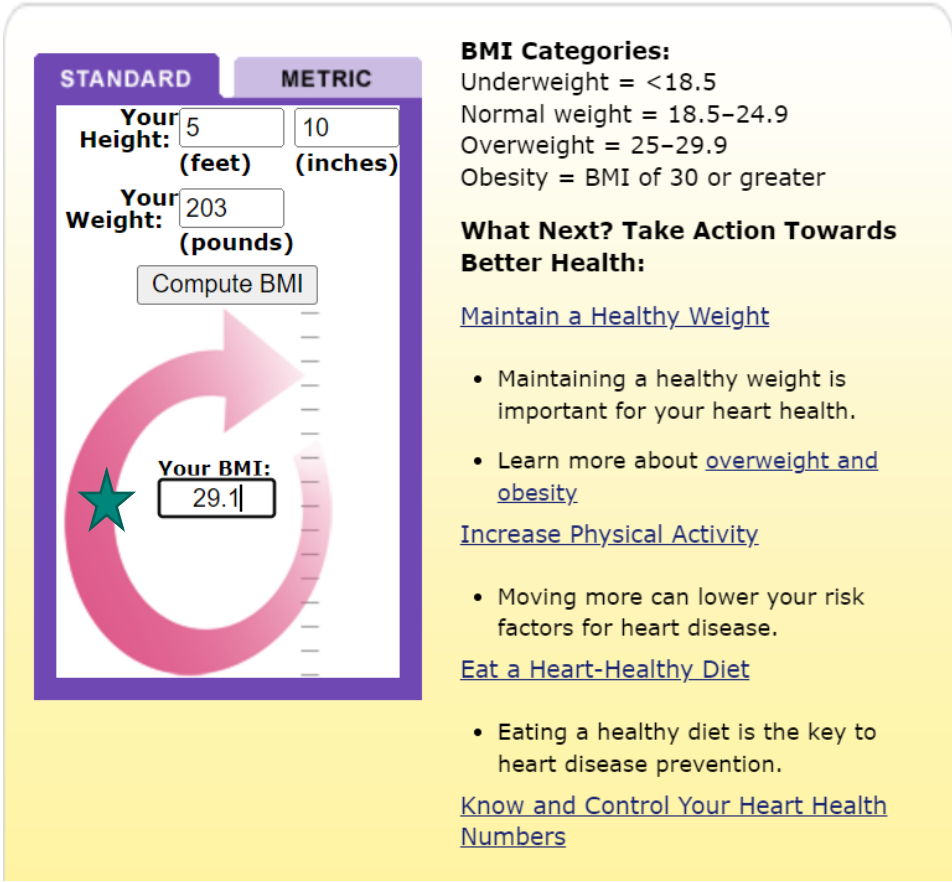
https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm

Therapy Selection Considerations

Case 2

- 48 year old male with T2DM, HTN, NSTEMI, HFpEF and CKD is referred to your pharmacy clinic for chronic disease state management
  - BP: 144/92
  - HR: 78
  - A1c 9.4%
  - Scr: 1.9, eGFR 50
  - UACR 321
  - LDL 115
  - Weight: 203 lb
  - Height: 5 ft 10 inches

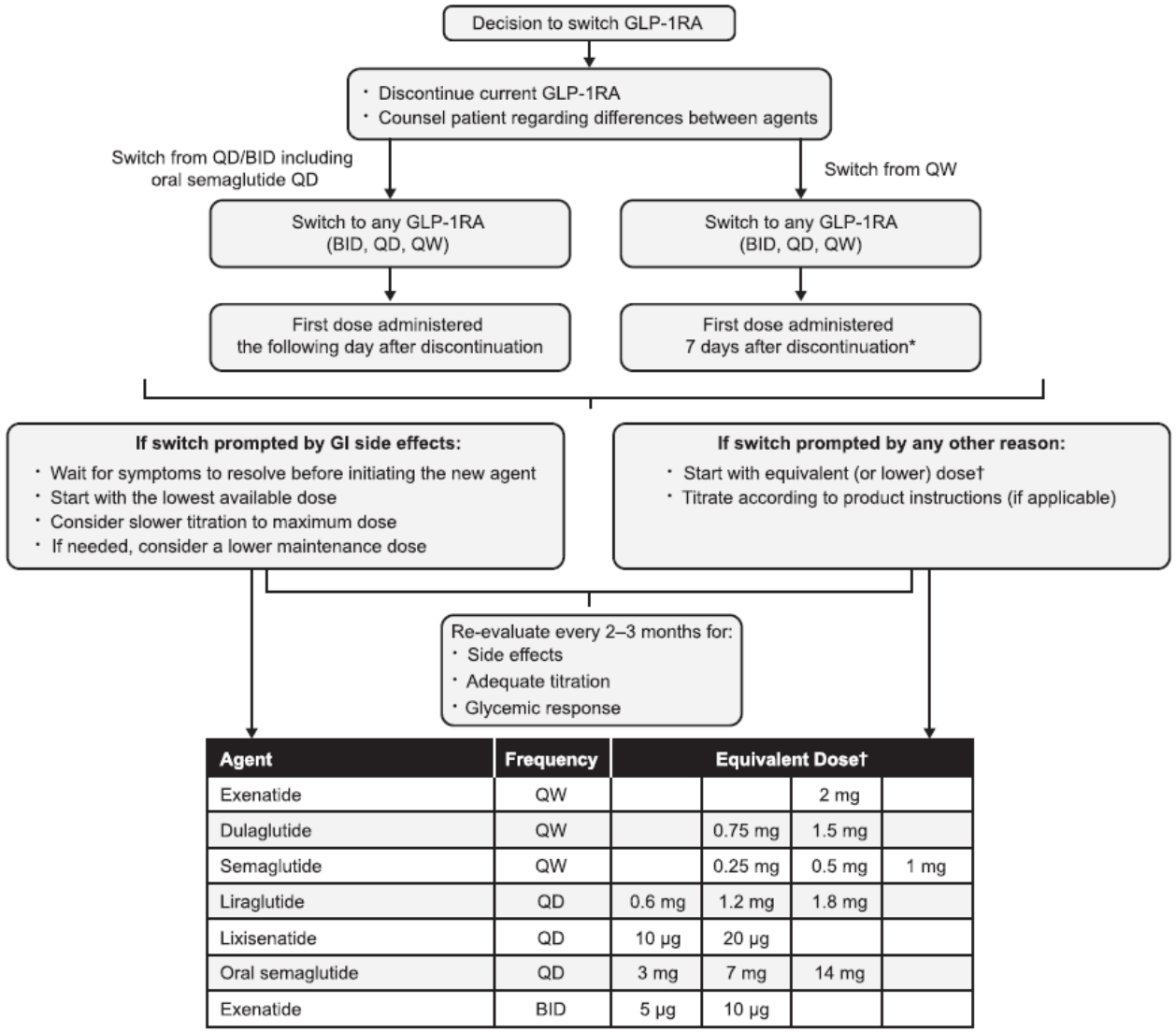
Metformin 500mg once daily
Glipizide 5mg with dinner
Lisinopril 5mg daily
Atorvastatin 80mg daily
ASA 81mg daily
Metoprolol ER 50mg daily



https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm

Switching Between Incretin Therapies

ALMANDOZ ET AL.



Agent	Frequency	Equivalent Dose†			
Exenatide	QW			2 mg	
Dulaglutide	QW		0.75 mg	1.5 mg	
Semaglutide	QW		0.25 mg	0.5 mg	1 mg
Liraglutide	QD	0.6 mg	1.2 mg	1.8 mg	
Lixisenatide	QD	10 µg	20 µg		
Oral semaglutide	QD	3 mg	7 mg	14 mg	
Exenatide	BID	5 µg	10 µg		

Almandoz et al. *Clin Diabetes* 1 October 2020; 38 (4): 390–402.

Switching Between Incretin Therapies

TABLE 4 GLP-1 Receptor Agonist Drug Shortages and Suggested Comparative Doses for Treating Type 2 Diabetes

Agent	Dosing Route and Interval	Comparative Doses									
Exenatide	SC twice daily	5 μg*	10 μg								
Lixisenatide	SC daily	10 μg*	20 μg								
Liraglutide	SC weekly	0.6 mg*	1.2 mg	1.8 mg							
Exenatide XR	SC weekly			2 mg							
Dulaglutide	SC weekly		0.75 mg[a]*	1.5 mg[a]	3 mg[b]†	4.5 mg[b]†					
Semaglutide	SC weekly		0.25 mg[b]*	0.5 mg[b]		1 mg[a]	2 mg[a]‡				
Semaglutide	PO daily	3 mg*	7 mg	14 mg							
Tirzepatide	SC weekly			2.5 mg[a]*			5 mg[a]‡	7.5 mg[a]	10 mg[a]	12.5 mg[a]	15 mg[a]

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Clin Diabetes 1 July 2023; 41 (3): 467–473

Guidance on Managing Missed Doses

TABLE 1 Manufacturer Recommendations for Missed Doses of GLP-1 Receptor Agonists

Agent	Recommended Dosing Interval	Manufacturer Recommendations for Missed Doses
Short-acting agents		
Exenatide	Twice daily	• Skip missed dose and resume at the next scheduled dose.
Lixisenatide	Once daily	• If a dose is missed, administer within 1 hour prior to next meal.
Long-acting agents		
Dulaglutide	Once weekly	• Administer as soon as possible if there are ≥3 days (72 hours) until next scheduled dose. • If <3 days before next scheduled dose, skip the missed dose and administer on the next scheduled day.
Exenatide XR	Once weekly	• Administer as soon as possible if there are ≥3 days (72 hours) until the next scheduled dose. • If <3 days before next scheduled dose, skip the missed dose and administer on the next scheduled day.
Liraglutide	Once daily	• If dose is missed, resume with the next scheduled dose.
Semaglutide (injectable)	Once weekly	• Administer as soon as possible within 5 days after the missed dose. • If >5 days have passed, skip the dose and administer on the next scheduled day.
Semaglutide (oral)	Once daily	• If dose is missed, resume with the next scheduled dose.
Tirzepatide	Once weekly	• Administer as soon as possible within 4 days (96 hours) after the missed dose. • If >4 days have passed, skip the dose and administer on the next scheduled day.

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Clin Diabetes 1 July 2023; 41 (3): 467–473

Guidance on Managing Missed Doses

TABLE 2 Considerations for Resuming a GLP-1 Receptor Agonist After a Prolonged Lapse in Therapy

Agent	Last Dose Administered	Recommendation(s) for Resuming Therapy
Dulaglutide*	1.5 mg once weekly	• Resume at 1.5 mg once-weekly dose. • Expect comparable tolerability to that experienced prior to dose interruption.
	3 or 4.5 mg once weekly	• Use best judgment if ≥3 doses are missed. ◦ It is unknown whether tolerance to the GI adverse events will remain if reinitiated at the higher dose after ≥3 missed doses. ◦ Decision can be informed by patient's prior GI tolerability. ◦ In consideration of the above, clinicians may consider reinitiating at 1.5 mg once weekly.
Injectable semaglutide†	1 mg once weekly	• If ≤2 doses are missed, reinitiate at 1 mg once weekly. • If 3–4 doses are missed, reinitiate at 0.5 mg weekly. • If ≥5 doses are missed, reinitiate at 0.25 mg once weekly.
Tirzepatide‡	≥5 mg once weekly	• If ≤2 doses are missed, reinitiate at the same dose (provided the dose was adequately tolerated). • If ≥3 doses are missed, reinitiate at 5 mg once weekly.

Clin Diabetes 1 July 2023; 41 (3): 467–473

Summary

- In people with T2DM, ADA guidelines suggests 3-7% weight reduction, >10% reduction may lead to remission
- Incretin hormones are a group of metabolic hormones that are released after eating and enhance the secretion of insulin from the pancreas. The two primary incretin hormones are GLP-1 and GIP.
- These classes of medications are beneficial in T2DM and obesity as they enhances insulin secretion, inhibits glucagon release, slows gastric emptying, and promotes a feeling of fullness
- Various trial outcomes demonstrate ≥2% reduction in A1c in T2DM and potential for up to 20% reduction in body weight in obesity studies with dual incretin
- Treatment selection should be based on diagnosis, insurance coverage, and consideration of cardiovascular risk factors
- Individuals with T2DM tend to have less weight reduction with incretins than people without diabetes
- Pharmacists can play a role in therapy selection, device education, and dose escalations in T2DM and obesity

Obesity Management with Incretin Therapies: Considerations for Patients with and without Type 2 Diabetes

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Specialty Pharmaceutical Summit

June 21, 2024

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