Welcome!

MCT2D Fall Regional Meetings

Lauren Oshman, MD, MPH, FAAFP

MCT2D Program Director

Liisa, PAB member

Prediabetic for many years, diagnosed with T2D in Feb 2022

I don't know if it was my doctor's approach but it was what I needed, at the right time. It made all the difference.

In our first appointment, immediately, she says enough playing around. Your numbers have been going up and up and up. And it's time to take this serious. **It was very emotional. I've never cried like that in a doctor's office before.**

She put my name in for the diabetes education and started me on a prescription of Rybelsus. But it was the perfect conversation to have at the right time when I needed to make this change. So I'm grateful to it.

MCT2D

It was the perfect conversation to have at the right time when I needed to make this change.

Rybelsus and having the chance to make the right diet choices

Such a supportive family. I feel it. I’m on the receiving end of it this time.

Year in Review

Meetings

Spring Regional Meetings (April/May 2022)

- First time convening practice clinical champions
- Introduced to the MCT2D Data Dashboards
- Discussed barriers and challenges amongst peers
- Learned about chronic kidney disease

Collaborative Wide Meeting (June 2022)

Available on YouTube!

- Convened physician organization leadership
- Shared best practices and implementation strategies from pilot/accelerated sites
- Keynote speaker (Dr. David Ludwig) presentation on low carbohydrate diets
- Demonstrated cost savings of SGLT2is/GLP-1RAs

Year in Review

What We've Been Working On

Launching the Learning Community

- Hosting educational events
- Learning Community Newsletter
- Learning from you (blog posts, patient stories, feedback)

Submitting Case Summaries

Each MCT2D physician submitted a case summary about their experience with the initiatives. **We are using these case summaries for the following:**

- Case examples
- Understanding needs (e.g. prioritized low carb resource creation based on feedback)
- Learning challenges with each initiative
- Demonstrating challenges to key stakeholders (e.g. insurers)

Today's Agenda

Time	Topic	Presenter
6:00pm - 6:15pm	**Welcome and Updates**	Lauren Oshman, MD MCT2D Program Director
6:15pm - 6:35pm	**Data Dashboard Updates**	Jake Reiss, MHSA Associate Program Manager
6:35pm - 6:55pm	**Regional Summary Statistics And Performance**	Table discussions
6:55pm - 7:05pm	**Break**	N/A
7:05pm - 7:25pm	**Updates in Diabetes Management: A Focus on SGLT-2 Inhibitors and GLP-1 Agonists**	Jamal Hammoud, MD Endocrine Consultants of MidMichigan
7:25pm - 7:50pm	**Operationalizing a Low Carb Diet In Type 2 Diabetes**	Rina Hisamatsu, RDN MCT2D Dietitian
7:50pm - 8:00pm	**Wrap Up & Closing**	Lauren Oshman, MD MCT2D Program Director

Updates

- Who is MCT2D?
- Coverage Wins
- Jumpstart Program
- New Tools

Who is MCT2D?

>300 Primary Care Practices

15 Nephrology Practices

14 Endocrinology Practices

1000+ Participating Physicians

Represented by

28 Physician Organizations

Steering Committee

12 members, representatives from each stakeholder in MCT2D (POs, PCP practices, patients, endocrinology, & nephrology)

Patient Advisory Board

Meetings bi-monthly
~12-14 regular attendees
Invited to all regional and collaborative meetings

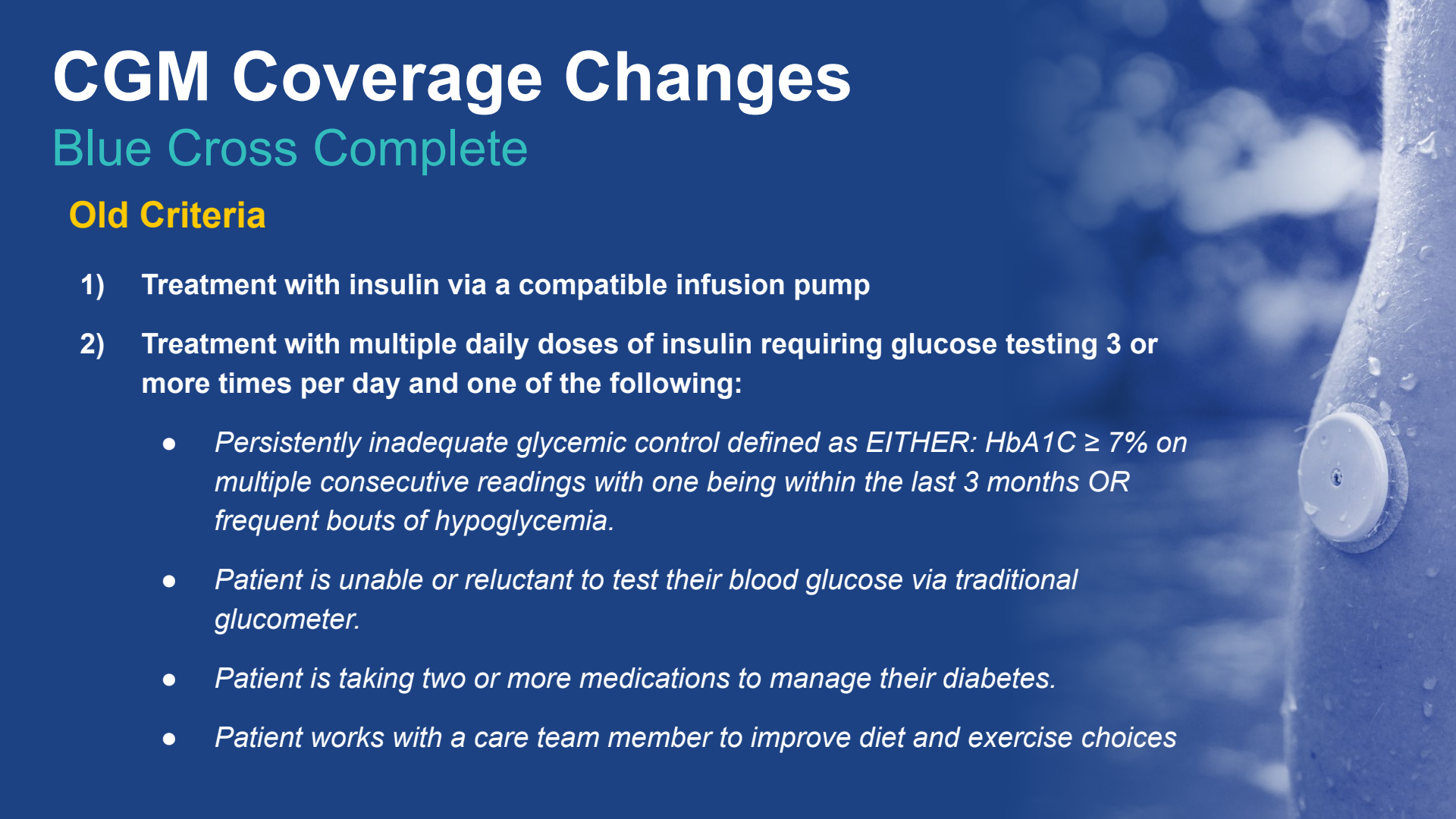
Expansions in CGM Coverage

CGM Coverage Changes

Blue Cross Complete

Old Criteria

1) **Treatment with insulin via a compatible infusion pump**
2) **Treatment with multiple daily doses of insulin requiring glucose testing 3 or more times per day and one of the following:**
    - *Persistently inadequate glycemic control defined as EITHER: HbA1C ≥ 7% on multiple consecutive readings with one being within the last 3 months OR frequent bouts of hypoglycemia.*
    - *Patient is unable or reluctant to test their blood glucose via traditional glucometer.*
    - *Patient is taking two or more medications to manage their diabetes.*
    - *Patient works with a care team member to improve diet and exercise choices*



CGM Coverage Changes

Blue Cross Complete

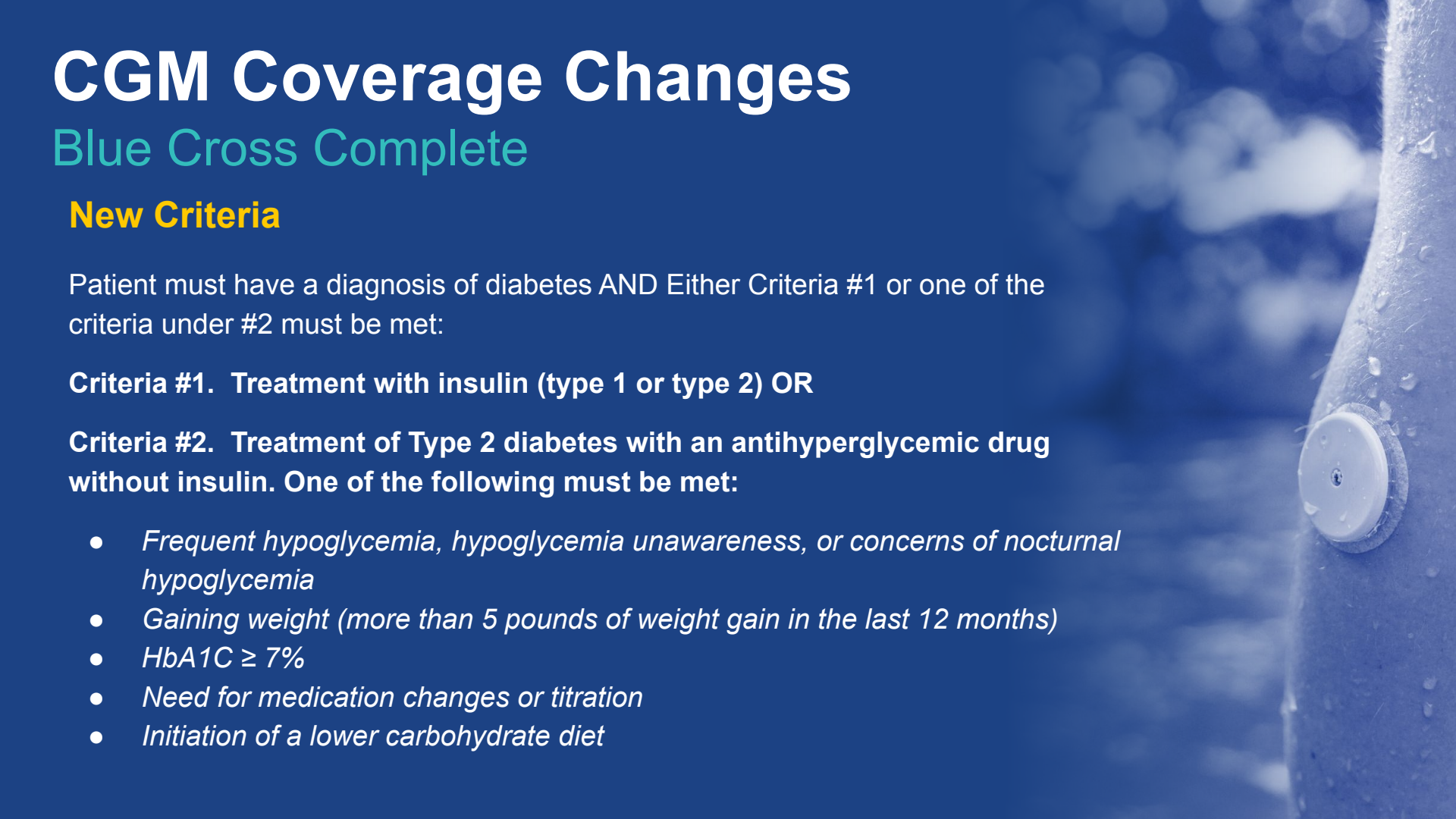
New Criteria

Patient must have a diagnosis of diabetes AND Either Criteria #1 or one of the criteria under #2 must be met:

Criteria #1. Treatment with insulin (type 1 or type 2) OR

Criteria #2. Treatment of Type 2 diabetes with an antihyperglycemic drug without insulin. One of the following must be met:

- *Frequent hypoglycemia, hypoglycemia unawareness, or concerns of nocturnal hypoglycemia*
- *Gaining weight (more than 5 pounds of weight gain in the last 12 months)*
- *HbA1C ≥ 7%*
- *Need for medication changes or titration*
- *Initiation of a lower carbohydrate diet*



CGM Coverage Changes

United Healthcare

DME Criteria and Criteria for non-MCT2D Physicians

- Diagnosis of diabetes requiring insulin
- Blood glucose testing at least 4x daily
- Insulin injections at least 3 x daily OR use of continuous insulin infusion pump
- Frequent adjustments to treatment regimen necessary based on glucose testing results
- Documented compliance to physician-directed comprehensive diabetes management program

New Criteria for MCT2D Physicians

- Ordered by an MCT2D member provider
- Patient has T2D diagnosis

Great News: United Healthcare will be adding NPs and PAs to the prior authorization removal. Stay tuned for more details!

How to use Poll Everywhere

Join by Web

1. Go to **PollEv.com**
2. Enter **MCT2D945**
3. Respond to activity

Join by Text

1. Text **MCT2D945** to **22333**
2. Text in your message

Have you submitted any CGM prescriptions for United Healthcare patients since the coverage change in mid-August?

Yes, and they went through without any issues

Yes, but there were issues with getting the CGM prescription without prior authorization

No

HEALTHY EATING JUMPSTART

GROCERY DELIVERY PROGRAM

An MCT2D + HBOM + MSHIELD Initiative

PURPOSE

To allow individuals diagnosed with **Type 2 Diabetes** who experience **food insecurity or are low-income** to have healthy, lower carb foods delivered to their home to **promote healthy eating patterns.**

OVERVIEW

3 Months of Shipt Healthy Choice Credits

$240 of total food credits ($80 per month)

Multiple Options for Ordering

Online ordering can be done on computer or mobile device

12 Weeks of Education and Support

Via website, email, and print

JUMPSTART practices in this region!

Sacred Heart Mercy Health Care Center

Alma Family Practice PC

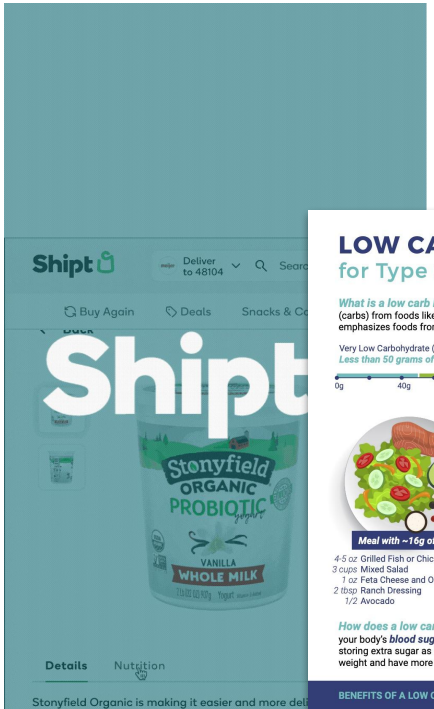
Prism Primary Care, PLLC

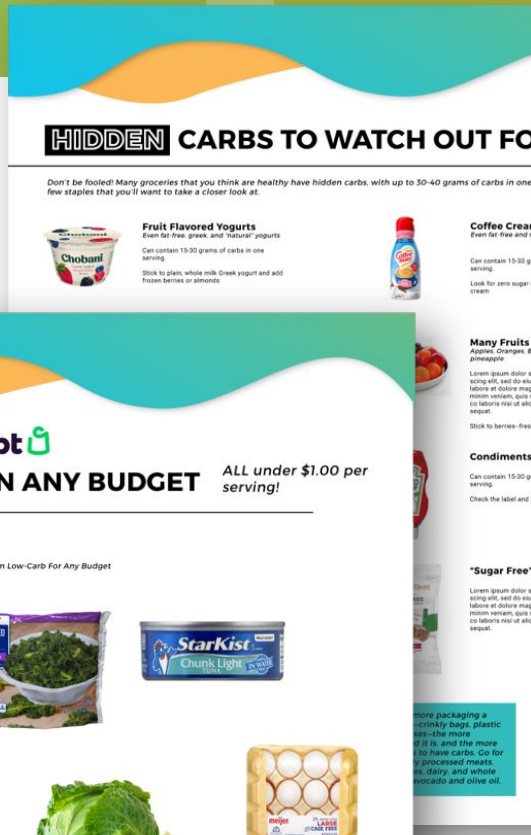
JUMPSTART practices in this region!

Practice Names

12 WEEKS of lower carb lifestyle education

Each week participants will get meal plans, recipes, tips tools, and educational materials delivered directly to them.

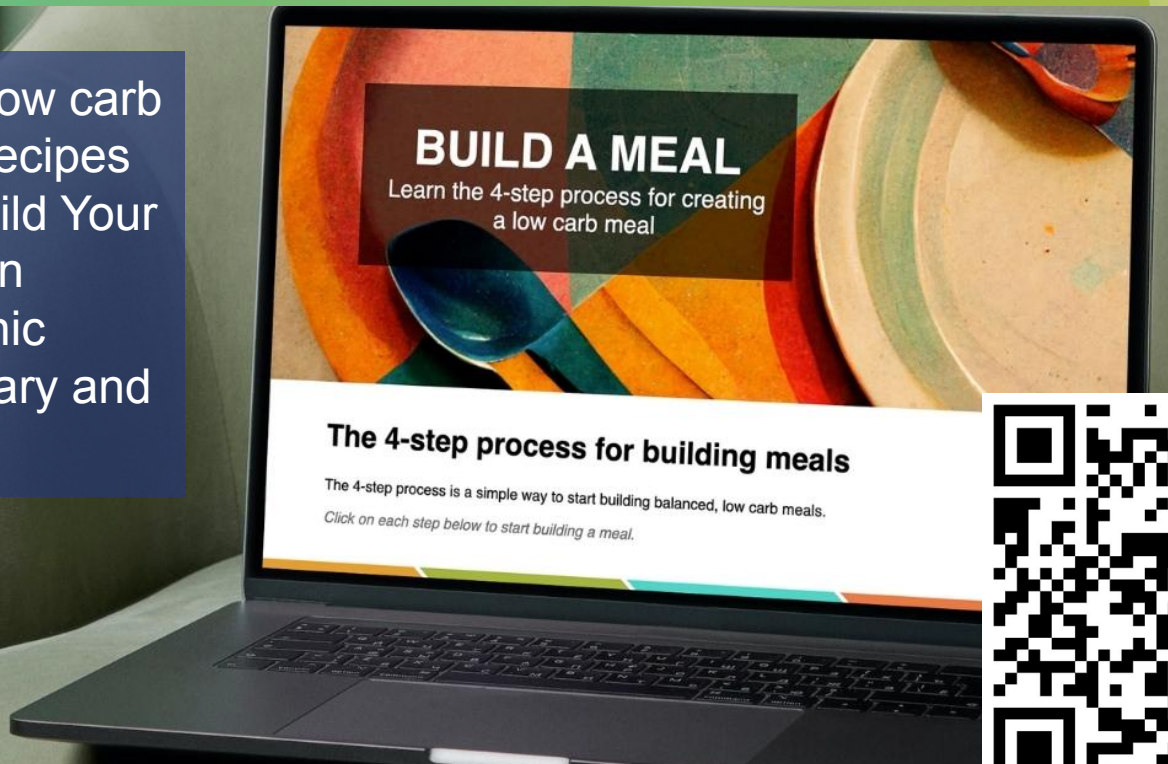




www.jumpstart.mct2d.org

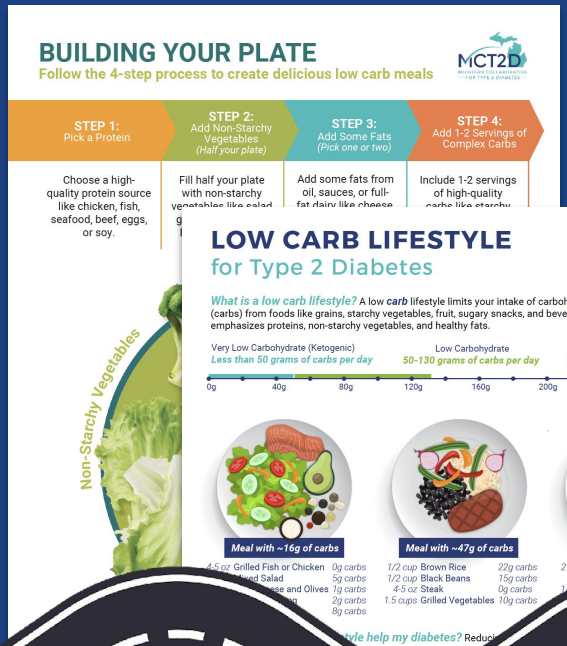
Patient-focused website open to any patient curious about starting a lower carb lifestyle

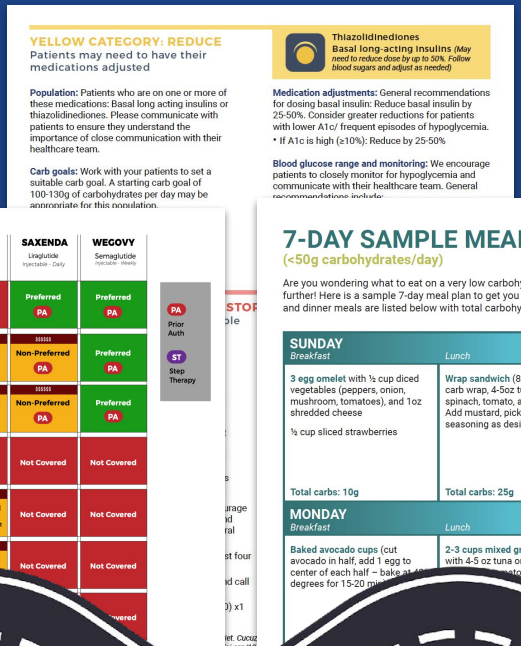
- Build a custom low carb meal plan with recipes
- Learn about “Build Your Plate” through an interactive graphic
- Set specific dietary and lifestyle goals



New MCT2D Tools

What we've been working on: new tools and resources!





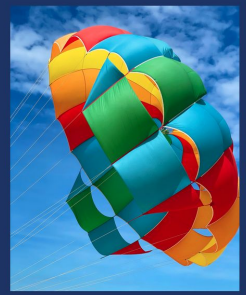
MCT2D Learning Community

The MCT2D Learning Community launched in May 2022 with opportunities to provide feedback on MCT2D developed tools, attend educational events, and contribute stories to the MCT2D blog, and the debut of the learning community newsletter.

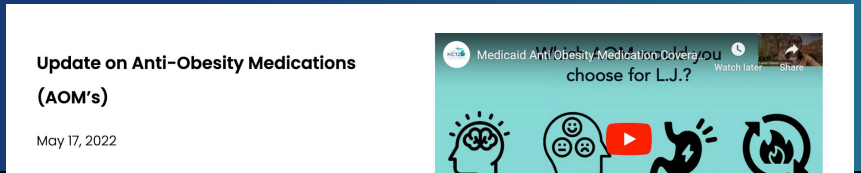
Learning Community events have included:

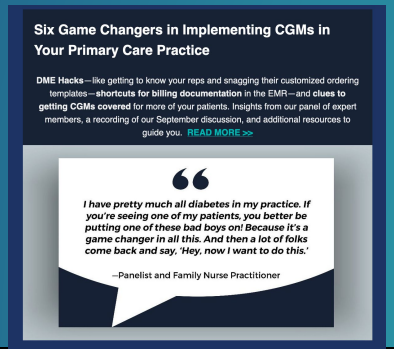
- Weight Loss Medications
  (Clinical Use and Medicaid Coverage Changes)
- Prior Authorization Panel
- CGM Implementation Panel

Prior Auth specialists have called this online tool "phenomenal" and "life changing." Are you using it?



Six key takeaways from our July 18th panel of Prior Authorization experts (including recommended tools), watch the recorded session, and browse past learning community webinars >>





What can the learning community do for you in 2023?

We want to host additional educational events and panels.

What topics are you interested in hearing about?

What topics would you like to see covered at future learning community events?

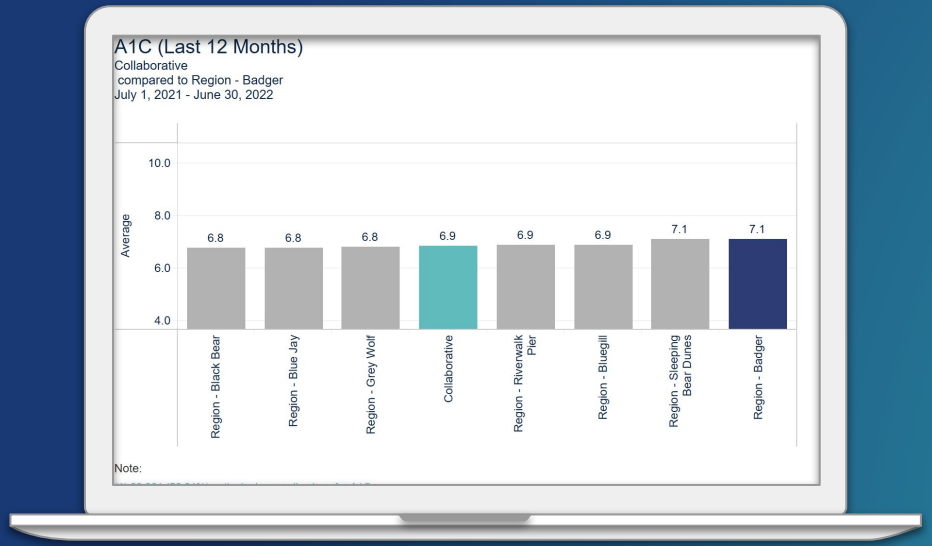
Patient Data Dashboard Updates and Demo

Jake Reiss, MHSA

MCT2D Associate Program Manager

Dashboard Enhancements

Conducted dashboard usability testing sessions



Focusing on design and user experience

Data up to date through 6/30/2022

Launched summary statistics

Later this year, addition of BCN claims data

Future Directions: Data

Rel #	MCT2D Publish date		Paid claims data through	Clinical data through
	2/15/2023	Data Refresh	11/30/2022	11/30/2022
1	4/11/2023	Release 1 Enhancement & Data Refresh	12/31/2022	12/31/2022
	5/4/2023	Data Refresh	2/28/2023	2/28/2023
2	6/19/2023	Release 2 Enhancement & Data Refresh	3/31/2023	3/31/2023
	8/4/2023	Data Refresh	5/31/2023	5/31/2023
3	9/21/2023	Release 3 Enhancement & Data Refresh	6/30/2023	6/30/2023
	11/7/2023	Data Refresh	8/31/2023	8/31/2023
4	12/14/2023	Release 4 Enhancement & Data Refresh	9/30/2023	9/30/2023

- **User experience/design changes**
- **Planned enhancements**
  - Patient exclusion tool to remove patients who should not be in the dashboard.
  - Dashboard will be limited to patients at least 18 years old.
  - Actual medication names and strengths will be listed rather than just the medication class.
  - Prepopulated reports of common and relevant filtering.
  - Adding serum creatinine
- **All payor PPQC data delayed- MDC determining an updated date this can be incorporated**

MCT2D
MICHIGAN COLLABORATIVE
FOR TYPE 2 DIABETES

Discussion: **Regional Reports**

Discussion Question Suggestions

Knowing that the insurance coverage for all of these patients are the same, why do you think we are seeing variability amongst regions?

Looking at patients who are on no therapy or patients who are on therapy that is not guideline concordant (e.g. DPP4is and sulfonylureas), what ideas do you have to improve the use of SGLT2is and GLP-1RAs?

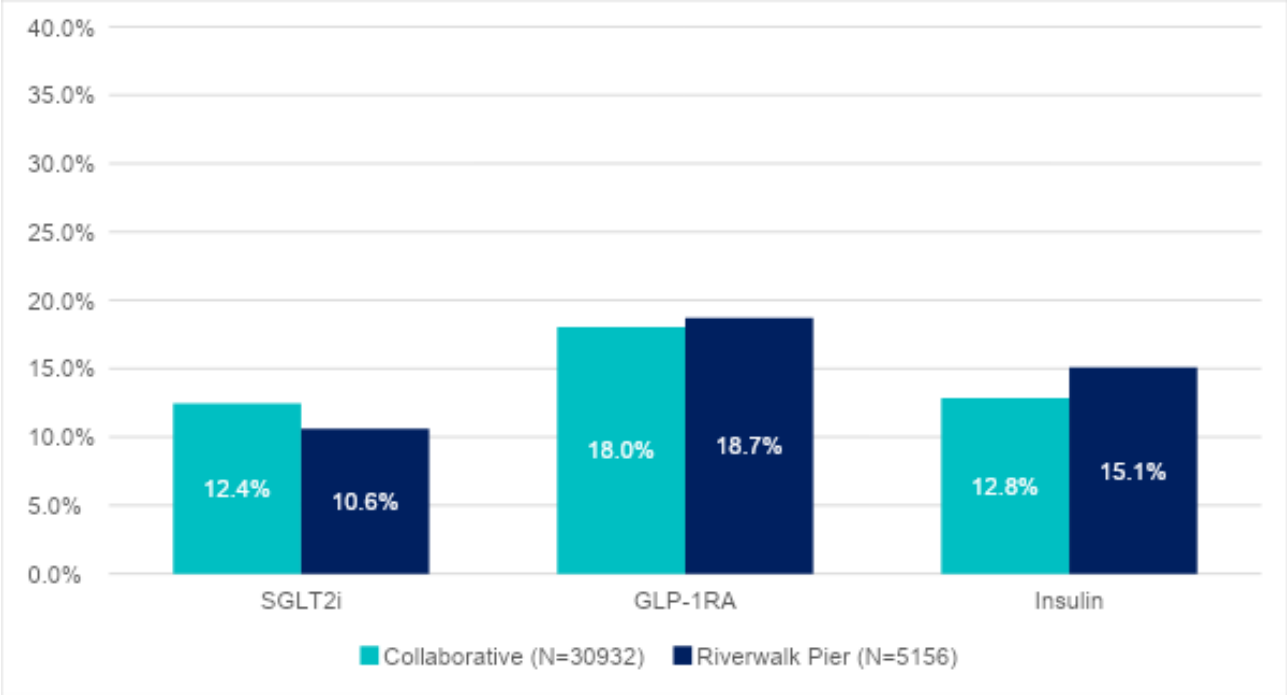
The Riverwalk Region has the 2nd highest insulin prescribing rate and highest sulfonylurea prescribing rate amongst the different regions of MCT2D. Why do you think this may be?

Michigan collaborative for type 2 Diabetes (MCT2D): Riverwalk pier

Overview

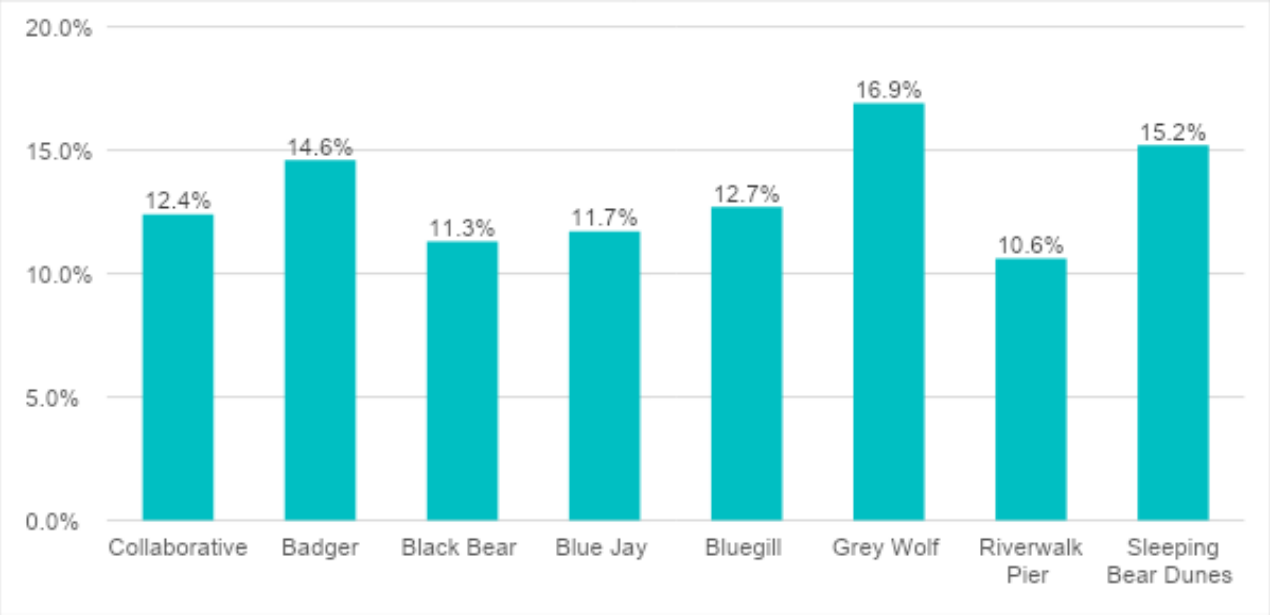
Collaborative level data includes any type 2 diabetes patient in participating practices who has been seen by a primary care physician (PCP) part of the Michigan Collaborative for Type 2 Diabetes (MCT2D). The patient population includes those who have a diagnosis code for type 2 diabetes, A1c of 6.5 or greater, and/or have been prescribed diabetes medication (ex. metformin, SGLT2i, GLP-1RA, insulin, sulfonylurea, etc.) The data is limited to just type 2 diabetes patients. Patients included must be covered by either Blue Cross Blue Shield Blue Care Network of Michigan (BCBSM) Preferred Provider Organization (PPO) or Medicare Advantage. The data in this report is preliminary and there are limitations. For instance, medication data is not available for patients with pharmacy carve outs; therefore, medication rates may be underestimated. The time frame used was from January 1, 2021 until June 30, 2022.

1. Comparison of Prescribing Rates of SGLT2i, GLP-1RA, and Insulin Between Riverwalk Pier and Collaborative (Excluding Pharmacy Carve Outs)



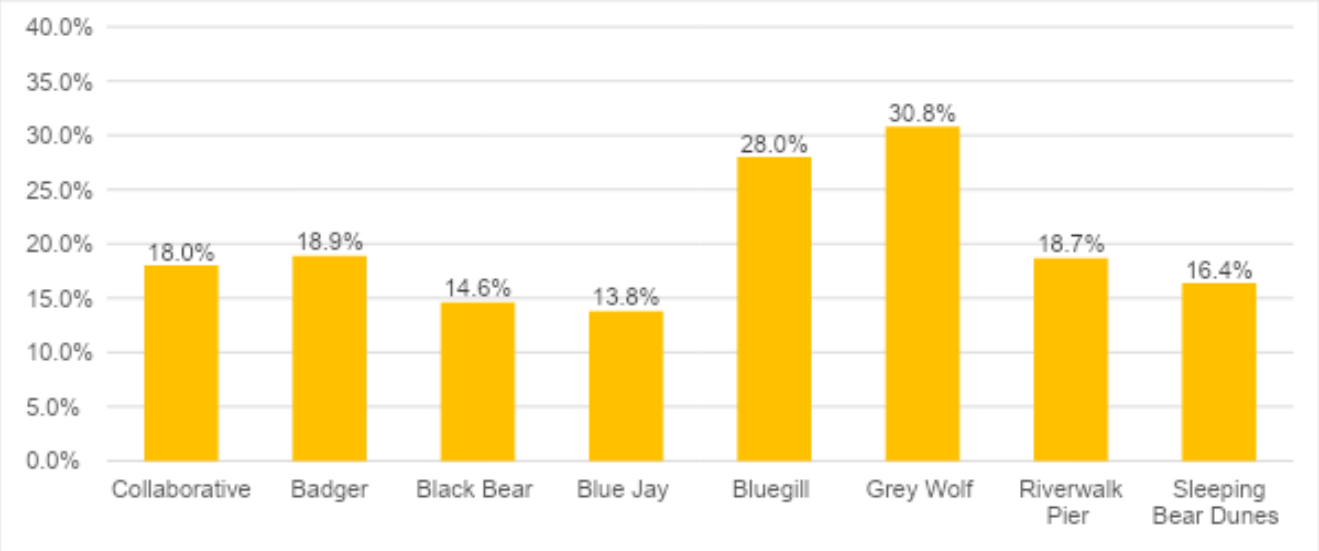
*The denominator used to calculate the medication prescribing rates was the number of unique patients (N=30,932) part of MCT2D. The patients included must be covered by either BCBSM PPO or Medicare Advantage. Data is currently unavailable for patients with other insurance coverage. The data also excludes pharmacy carve outs. For the Riverwalk bars, the denominator used to calculate the medication prescribing rates was the number of unique patients (N=5,156) part of the Riverwalk region of MCT2D.

2. Comparison of Prescribing Rates of SGLT2i Across MCT2D Regions (Excluding Pharmacy Carve Outs)



*The denominator used to calculate the medication prescribing rates was the number of unique patients (N=30,932) part of MCT2D. For each region, the denominator used to calculate the medication prescribing rates was the number of unique patients part of the region (Badger: N=3,103, Black Bear: N=9,829, Blue Jay: N=6,323, Bluegill: N=1,767, Grey Wolf: N=3,126, Riverwalk Pier: N=5,156, Sleeping Bear Dunes: N=1,628).

3. Comparison of Prescribing Rates of GLP-1RA Across MCT2D Regions (Excluding Pharmacy Carve Outs)



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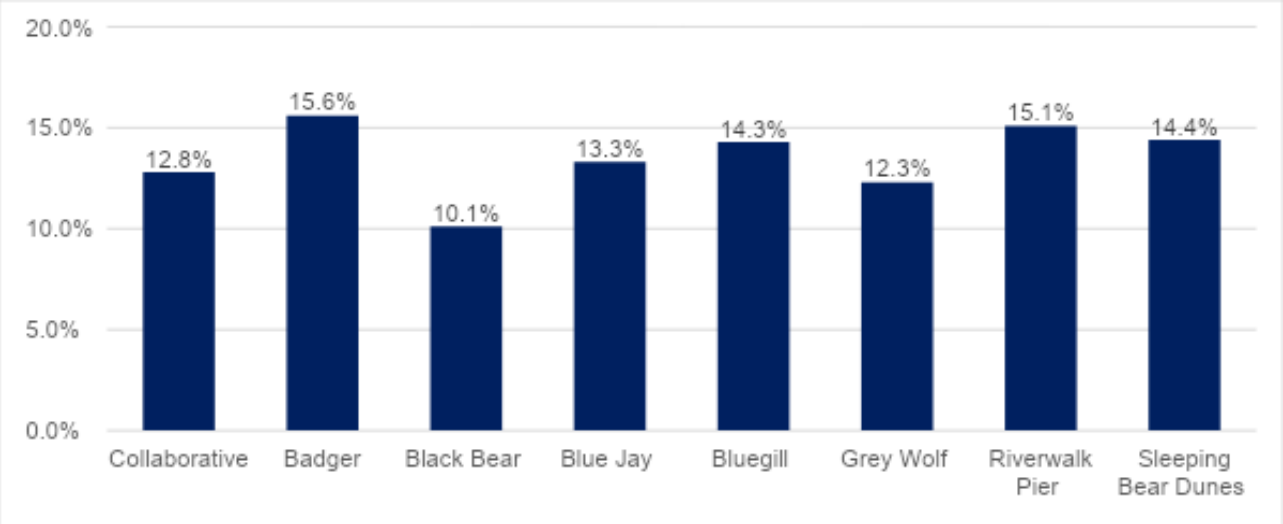
4. Comparison of Prescribing Rates of Insulin Across MCT2D Regions (Excluding Pharmacy Carve Outs)



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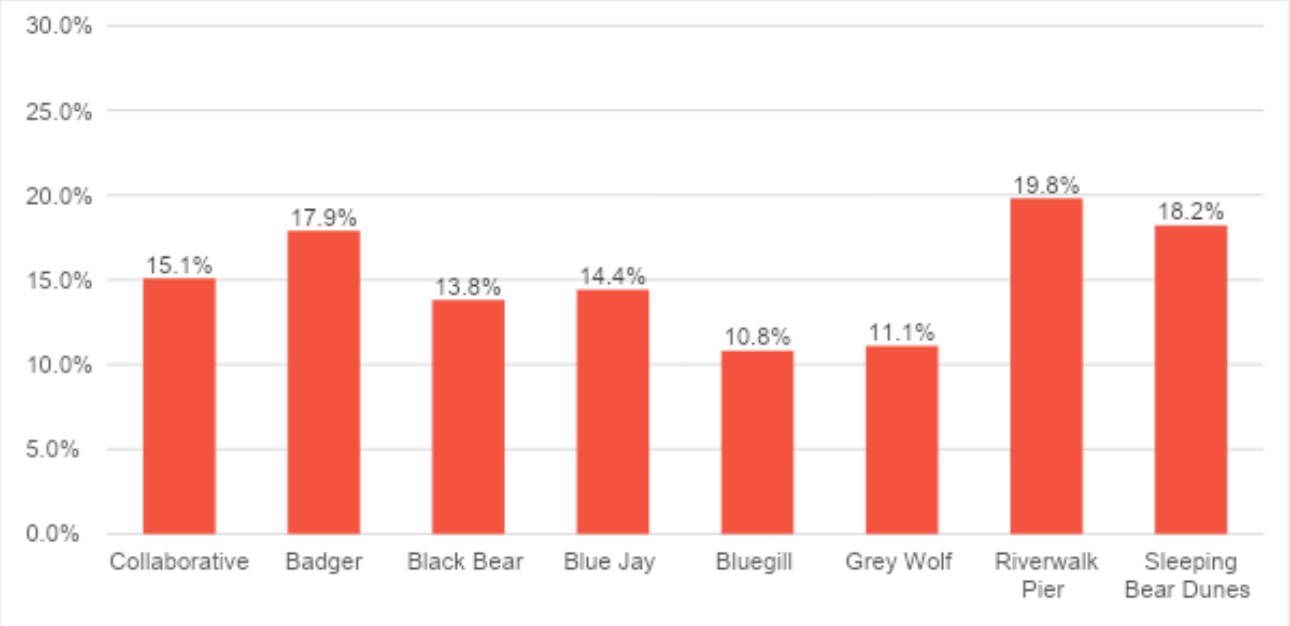
5. Comparison of Prescribing Rates of Sulfonylurea Across MCT2D Regions (Excluding Pharmacy Carve Outs)



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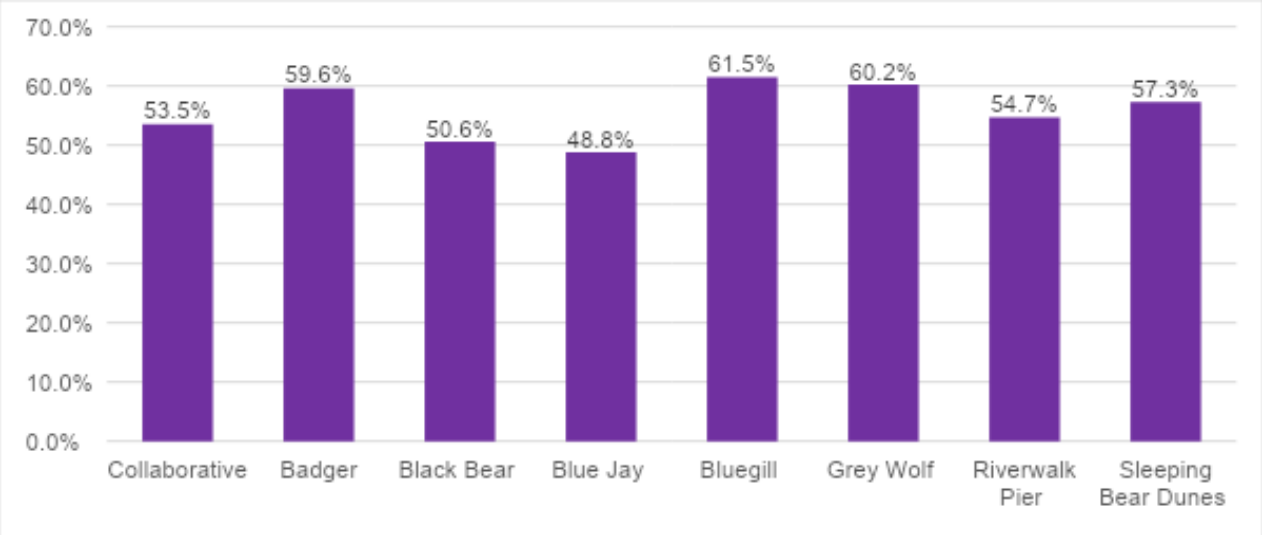
6. Comparison of Prescribing Rates of Metformin Across MCT2D Regions (Excluding Pharmacy Carve Outs)



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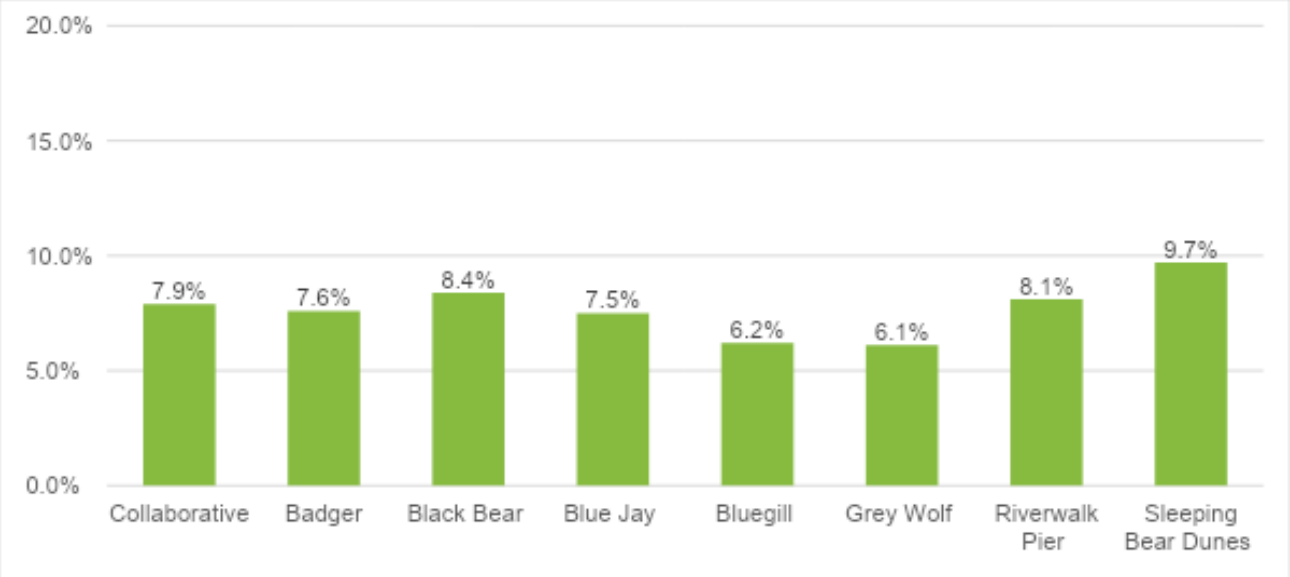
7. Comparison of Prescribing Rates of Dipeptidyl Peptidase 4 Inhibitors (DPP4i) Across MCT2D Regions (Excluding Pharmacy Carve Outs)



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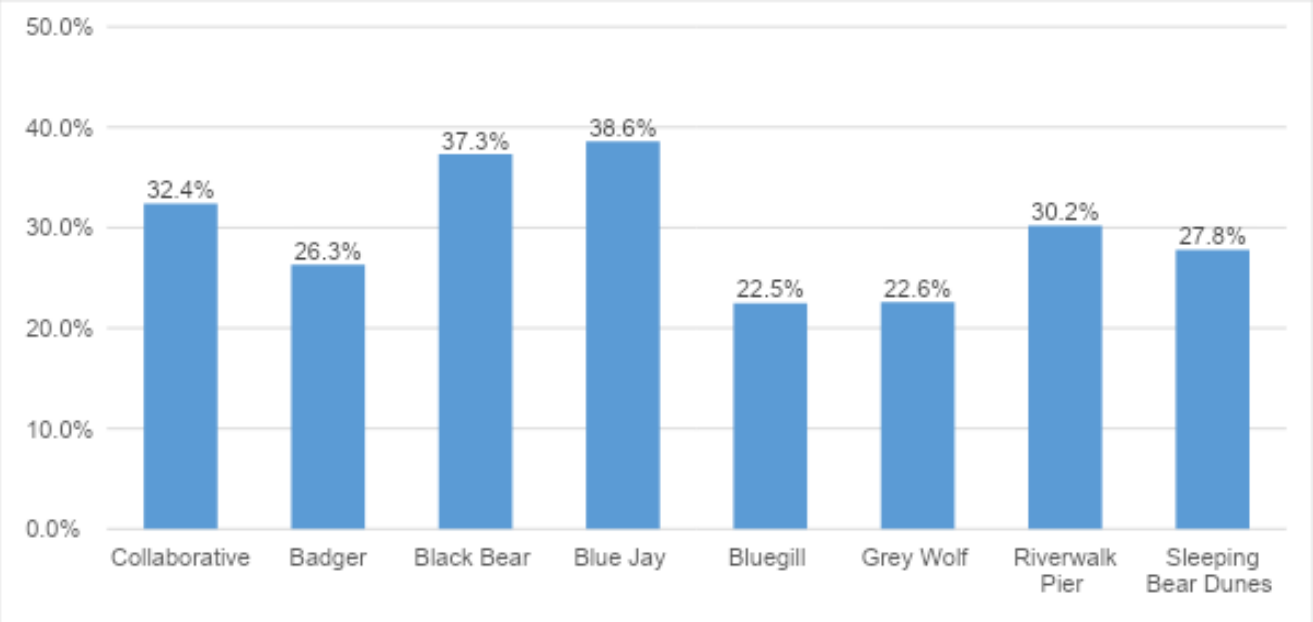
8. Percentage of Patients Not On Any Diabetes Medication Across MCT2D Regions



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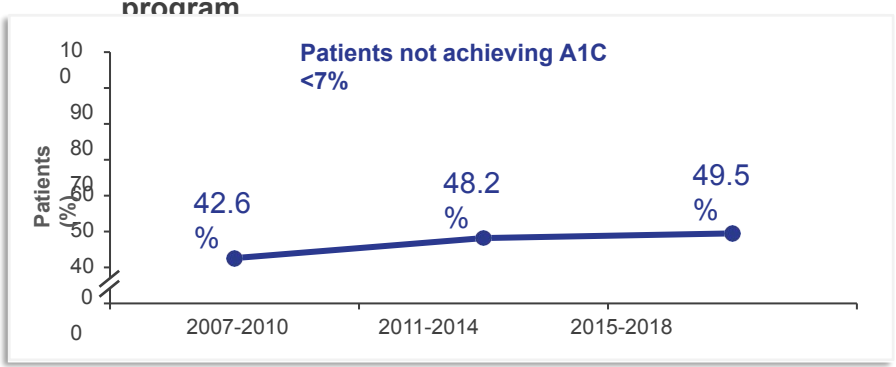
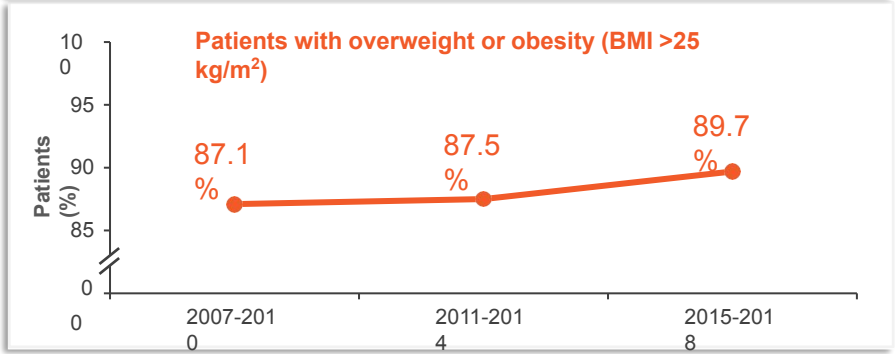
Updates in Diabetes Management: A Focus on A1C, Excess Weight and Diabetic Complications

JAMAL HAMMOUD, M.D, F.A.C.E
Clinical Professor of Medicine
Michigan State University

Despite Currently Available Treatments, A1C and BMI Are Not Improving in Patients With T2D[1,*]

US adults with diabetes in the NHANES program





*According to the latest **NHANES** data on adults with diabetes (2015-2018),†*

~50% of patients **did not** achieve an A1C <7%

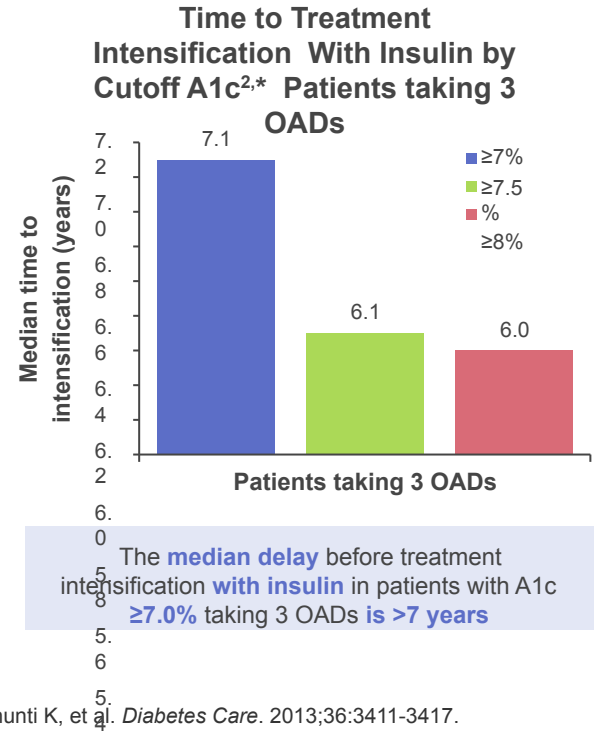
~90% of patients had **overweight or obesity**

*Over 90% of people with diabetes in the US have T2D; therefore, these data largely reflect trends in glycemic control among individuals with T2D.

†NHANES participants from 2015-2018 who were nonpregnant, ≥20 years of age, and reported having ever received a diagnosis of diabetes from a physician, aside from gestational diabetes (n=6653).[1]

A1C=glycated hemoglobin; BMI=body mass index; NHANES=National Health and Nutrition Examination Survey; T2D=type 2 diabetes; US=United States.

CLINICAL INERTIA



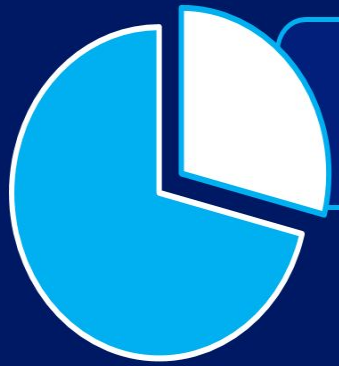
The **median delay** before treatment intensification **with insulin** in patients with A1c **≥7.0%** taking 3 OADs **is >7 years**

1. Edelman SV, Polonsky WH. *Diabetes Care*. 2017;40:1425-1432. **2**. Khunti K, et al. *Diabetes Care*. 2013;36:3411-3417.

Patients With T2D May Remain Uncontrolled Even After Starting Basal Insulin

Patients With T2D at A1C <7%
2 Years After Basal Insulin Initiation[1]

(n=14,457, average baseline A1C=8.6%)



29.2%
of patients at target
(A1C <7%)[1]

2 ...ely;

1. Curtis B, Lage MJ. *J Med Econ.* 2014;17(1):21-31. 2. Peyrot M et al. *Diabet Med*. 2012;29(5):682-689.

Language matters

- Communication between people living with type 2 diabetes and health care team members is at the core of integrated care
- Clinicians must recognise how language matters
- Language in diabetes care should be neutral, free of stigma, and based on facts; be strengths-based (focus on what is working), respectful, and inclusive; encourage collaboration; and be person-centred
- People living with diabetes should not be referred to as “diabetics,” or described as “noncompliant,” or blamed for their health condition.

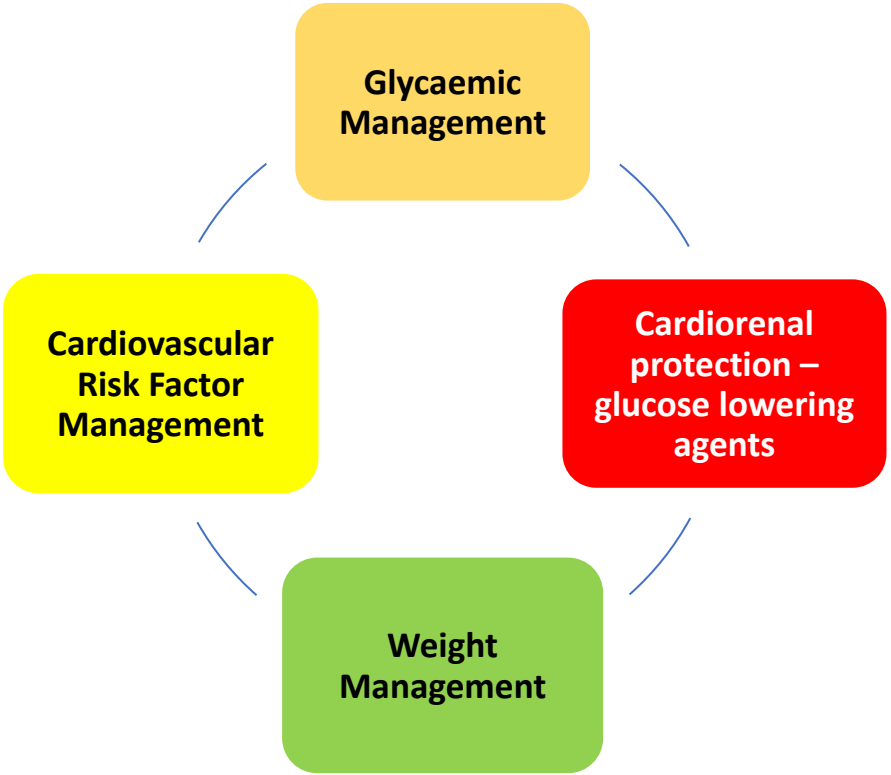
American Diabetes Association®

Davies MJ, Aroda VR, Collins BS, Gabbay RA, Green J, Maruthur NM, Rosas SE, Del Prato S, Mathieu C, Mingrone G, Rossing P, Tankova T, Tsapas A, Buse JB

Diabetes Care 2022; https://doi.org/10.2337/dci22-0034. *Diabetologia* 2022; https://doi.org/10.1007/s00125-022-05787-2.

EASD European Association for the Study of Diabetes

Preventing Complications



Davies MJ, Aroda VR, Collins BS, Gabbay RA, Green J, Maruthur NM, Rosas SE, Del Prato S, Mathieu C, Mingrone G, Rossing P, Tankova T, Tsapas A, Buse JB

Diabetes Care 2022; https://doi.org/10.2337/dci22-0034. *Diabetologia* 2022; https://doi.org/10.1007/s00125-022-05787-2.

SGLT2 Inhibitors

	Efficacy[1]	Hypoglycaemia	Weight change[2]	CV effects		Renal effects		Oral/SQ	Cost
				Effect on MACE	HF	Progression of DKD	Dosing/use considerations*		
SGLT2 Inhibitors	Intermediate to high	No	Loss (intermediate)	Benefit: canagliflozin, empagliflozin	Benefit: canagliflozin, dapagliflozin, empagliflozin, ertugliflozin	Benefit: canagliflozin, dapagliflozin, empagliflozin	• See labels for renal dose considerations of individual agents • Glucose-lowering effect is lower for SGLT2 inhibitors at lower eGFR	Oral	High

- *Glucose-lowering mechanism of action:* Reduce renal tubular glucose reabsorption
- *Clinical Efficacy Profile:* Intermediate to high glucose-lowering efficacy, lower at lower eGFR; low inherent risk of hypoglycaemia; intermediate weight loss
- *Cardiorenal Effects:* Demonstrated protective effects in studied trial populations:
  - Reduction in major adverse cardiovascular events
  - Reduction in overall CV death (with heterogeneity across the class)
  - Reduction in risk of hospitalisation for heart failure
  - Reduction in risk of kidney outcomes
- Increased confidence surrounding safety issues of interest

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Davies MJ, Aroda VR, Collins BS, Gabbay RA, Green J, Maruthur NM, Rosas SE, Del Prato S, Mathieu C, Mingrone G, Rossing P, Tankova T, Tsapas A, Buse JB

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GLP-1 Receptor Agonists

	Efficacy[1]	Hypoglycaemia	Weight change[2]	CV effects		Renal effects		Oral/SQ	Cost
				Effect on MACE	HF	Progression of DKD	Dosing/use considerations*		
GLP-1 RAs	High to very high	No	Loss (intermediate to very high)	Benefit: dulaglutide, liraglutide, semaglutide (SQ) Neutral: exenatide once weekly, lixisenatide	Neutral	Benefit for renal endpoints in CVOTs, driven by albuminuria outcomes: dulaglutide, liraglutide, semaglutide (SQ)	• See labels for renal dose considerations of individual agents • No dose adjustment for dulaglutide, liraglutide, semaglutide • Monitor renal function when initiating or escalating doses in patients with renal impairment reporting severe adverse GI reactions	SQ; oral (semaglutide)	High

- *Glucose-lowering mechanism of action:* Augment glucose-dependent insulin secretion & glucagon suppression, decelerate gastric emptying, curb post-meal glycaemic increments, reduce appetite, calorie intake and body weight
- *Clinical Efficacy Profile:* High to Very High glucose-lowering efficacy, low inherent risk of hypoglycaemia; intermediate to high weight loss
- *Cardiorenal Effects:* cardioprotective, with evidence of reduction in major adverse cardiovascular events, CV death, fatal or non-fatal MI, fatal or non-fatal stroke, all-cause mortality, composite kidney outcome driven by macroalbuminuria
- Increased confidence surrounding safety areas of interest

American Diabetes Association.

Davies MJ, Aroda VR, Collins BS, Gabbay RA, Green J, Maruthur NM, Rosas SE, Del Prato S, Mathieu C, Mingrone G, Rossing P, Tankova T, Tsapas A, Buse JB

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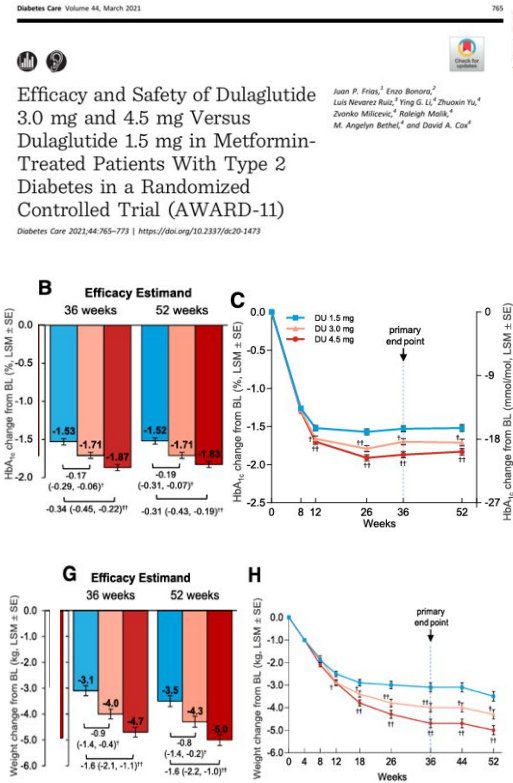
GLP-1 RA Therapeutic Updates

- First oral GLP-1 RA (oral semaglutide) developed and available
- Higher dose GLP-1 RAs (dulaglutide, semaglutide) with incremental benefits in glucose weight efficacy
- Greater clinical expertise in anticipating and addressing GI effects



Diabetes Care Volume 44, March 2021 765

Efficacy and Safety of Dulaglutide 3.0 mg and 4.5 mg Versus Dulaglutide 1.5 mg in Metformin-Treated Patients With Type 2 Diabetes in a Randomized Controlled Trial (AWARD-11)

Juan P. Frías,[1] Enzo Bonora,[2] Luis Nevarez Ruiz,[3] Ying G. Li,[4] Zhuoxin Yu,[4] Zvonko Milicevic,[4] Raleigh Malik,[4] M. Angelyn Bethel,[4] and David A. Cox[4]

Diabetes Care 2021;44:765–773 | https://doi.org/10.2337/dc20-1473

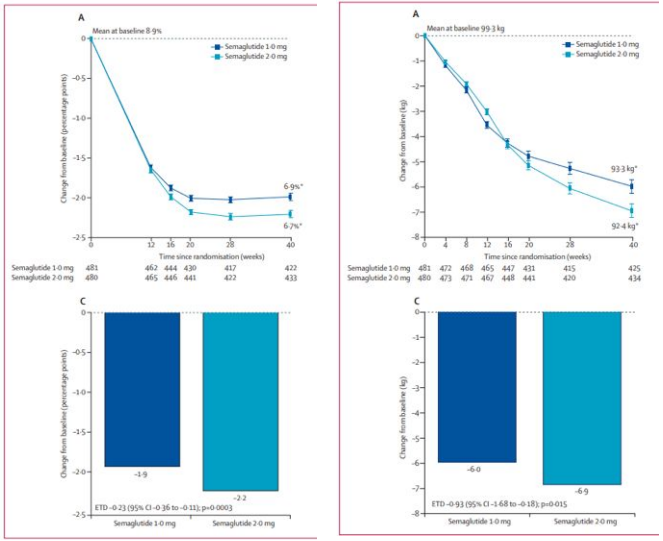
Efficacy and safety of once-weekly semaglutide 2·0 mg versus 1·0 mg in patients with type 2 diabetes (SUSTAIN FORTE): a double-blind, randomised, phase 3B trial

Juan P Frías, Pernille Auerbach, Harpreet S Bajaj, Yasushi Fukushima, Ildiko Lingvay, Stanislava Macura, Anette L Søndergaard, Tsvetalina I Tankova, Nikolaos Tentolouris, John B Buse

Summary

Background Semaglutide is an effective treatment for type 2 diabetes; however, 20–30% of patients given semaglutide 1·0 mg do not reach glycaemic treatment goals. We aimed to investigate the efficacy and safety of once-weekly semaglutide 2·0 mg versus 1·0 mg in adults with inadequately controlled type 2 diabetes on a stable dose of metformin with or without a sulfonylurea.

Lancet Diabetes Endocrinol 2021; 9: 563–74
Published Online July 19, 2021 https://doi.org/10.1016/S2213-8587(21)00174-1



Glucose-dependent insulinotropic polypeptide (GIP) receptor and GLP-1 receptor agonist (tirzepatide)

	Efficacy[1]	Hypoglycaemia	Weight change[2]	CV effects		Renal effects		Oral/SQ	Cost
				Effect on MACE	HF	Progression of DKD	Dosing/use considerations*		
GIP and GLP-1 RA	Very high	No	Loss (very high)	Under investigation	Under investigation	Under investigation	• See label for renal dose considerations • No dose adjustment • Monitor renal function when initiating or escalating doses in patients with renal impairment reporting severe adverse GI reactions	SQ	High

- *Glucose-lowering mechanism of action:* GIP receptor and GLP-1 receptor agonist; enhances first and second-phase insulin secretion, and reduces glucagon levels, both in a glucose-dependent manner
- *Clinical Efficacy profile:* Very high glycaemic efficacy; low inherent risk of hypoglycaemia; weight loss (high); cardiorenal effects unknown (trials in progress)

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Davies MJ, Aroda VR, Collins BS, Gabbay RA, Green J, Maruthur NM, Rosas SE, Del Prato S, Mathieu C, Mingrone G, Rossing P, Tankova T, Tsapas A, Buse JB

Diabetes Care 2022; https://doi.org/10.2337/dci22-0034. *Diabetologia* 2022; https://doi.org/10.1007/s00125-022-05787-2.

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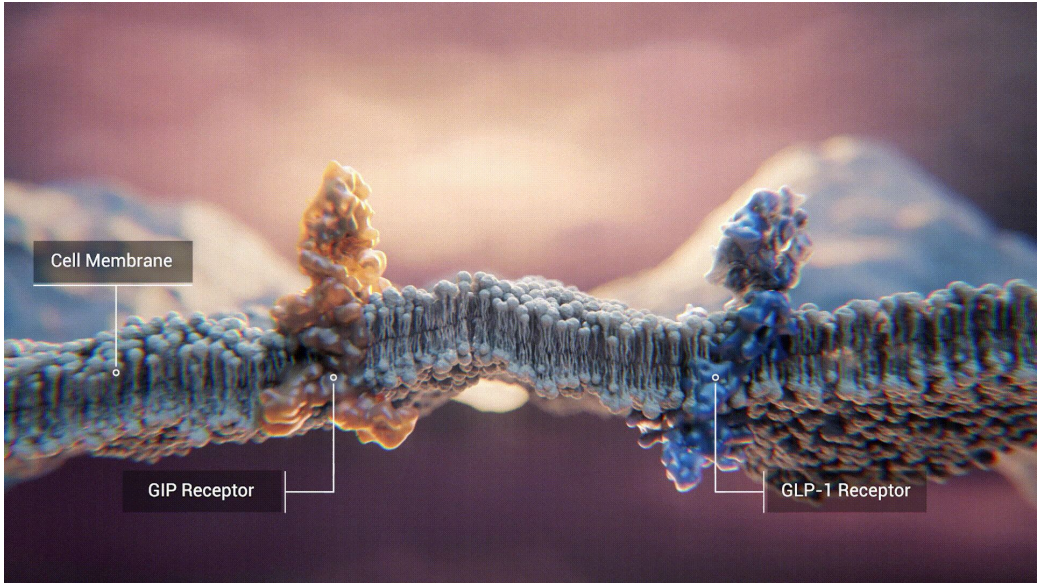
Tirzepatide Is the First and Only Approved GIP and GLP-1 Receptor Agonist[1]

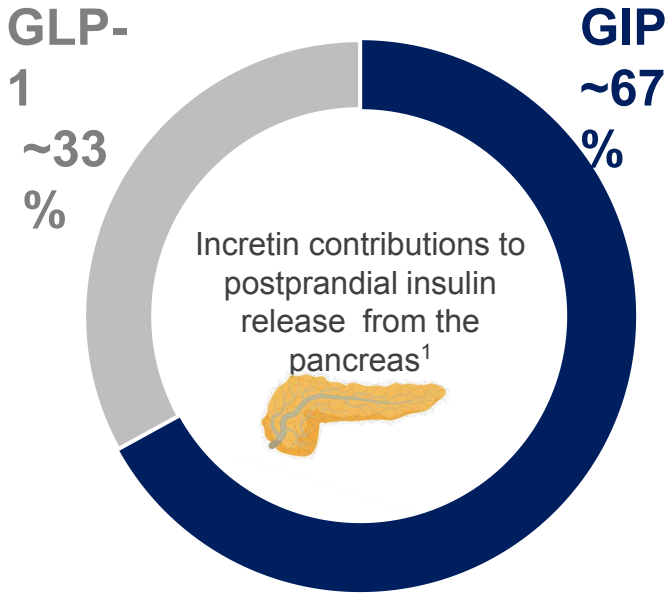
Tirzepatide is a single molecule that activates GIP and GLP-1 receptors in the body

Structure	Based on the backbone of native GIP[1,2]
Mean half-life	Approximately 5 days, enabling once-weekly dosing[1,2]
Dose adjustment	No dose adjustment of Tirzepatide is recommended for patients with renal or hepatic impairment[1]



GIP=glucose-dependent insulinotropic polypeptide; GLP-1=glucagon-like peptide-Coskun T, et al. *Mol Metab*. 2018;18:3-14.

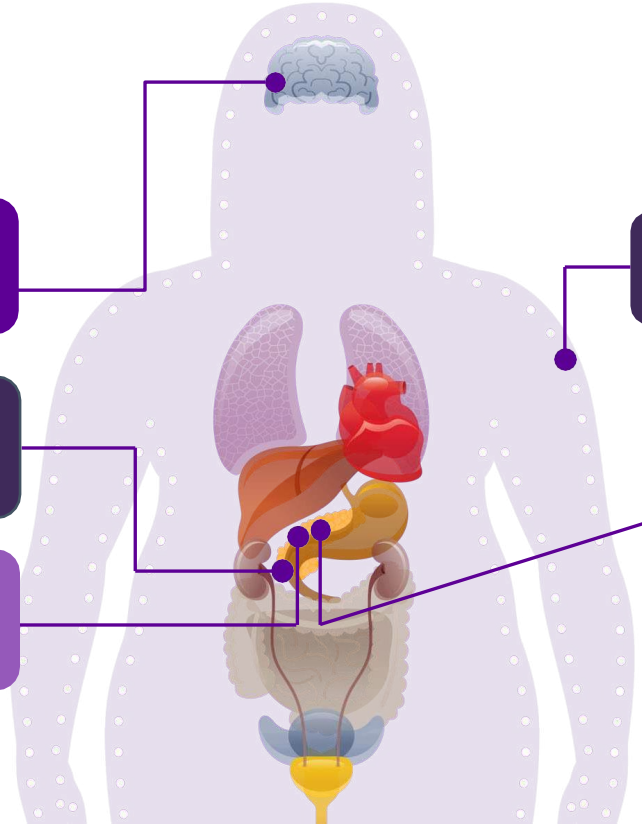
GIP and GLP-1 Are Incretin Hormones Released From the Gut in Response to Food Intake[1,2]



- **GIP** is responsible for **two-thirds** of the incretin effect in healthy people, generating a more significant impact on insulin secretion than GLP-1[1]
- The incretin effect of GIP and GLP-1 is diminished in people with T2D[3]

1. Nauck MA, et al. *Diabetes*. 2019;68(5):897-900.
2. Holst JJ. *Metabolism*. 2019;96:46-55.
3. Nauck MA, et al. *Diabetes Obes Metab*. 2018;20(suppl 1):5-21.

Tirzepatide Works in the Following Ways[1]

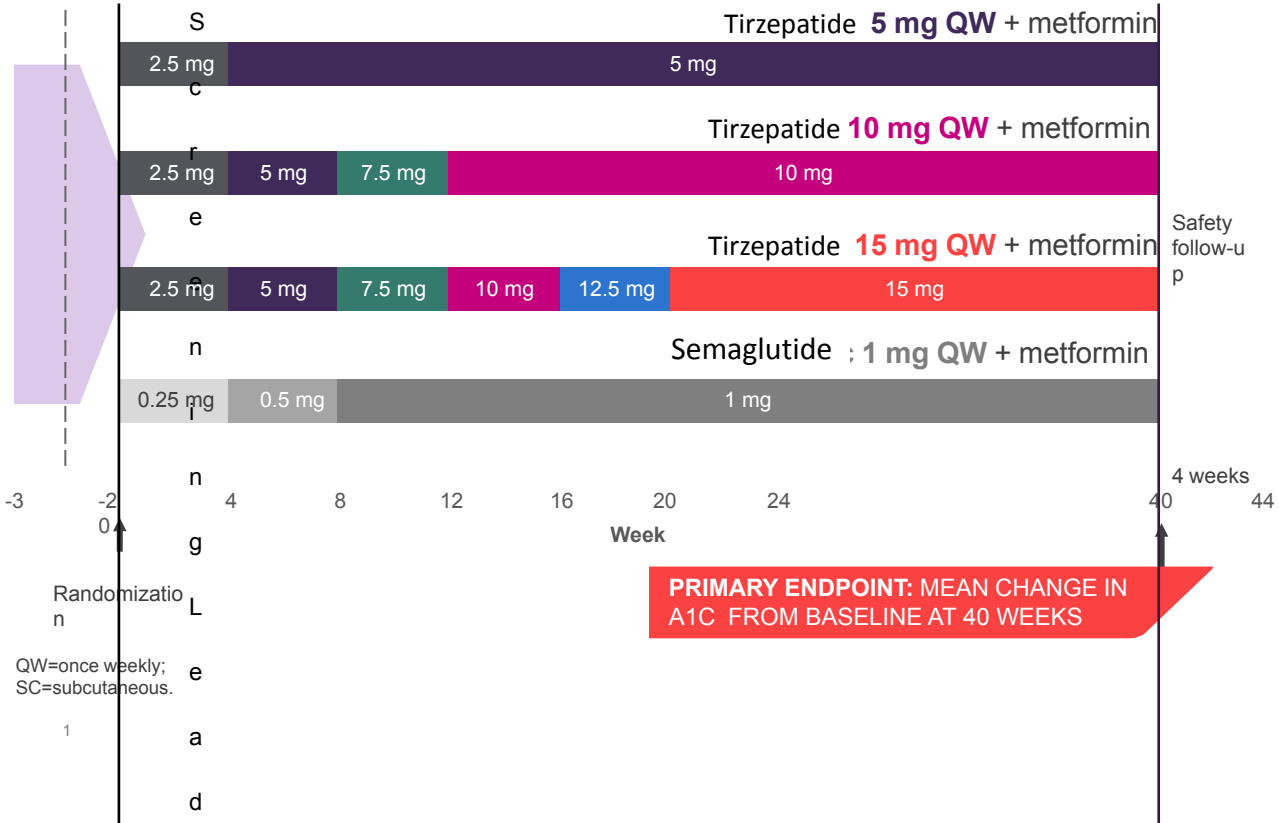


- Decreases food intake
- Slows gastric emptying*
- Reduces glucagon levels
- Increases insulin
- Enhances first- and second-phase

*This effect diminishes over time.

1.

Tirzepatide 5 mg, 10 mg, and 15 mg vs Semaglutide 1 mg as the Only Add-on to Metformin



Study description[1,2]

- SURPASS-2 was a 40-week, open-label (double- blind with respect to Tirzepatide dose assignment), active-controlled, phase 3 trial that randomized 1879 adult patients with T2D who had inadequate glycemic control on stable doses of metformin alone to receive once-weekly SC Tirzepatide 5 mg, 10 mg, or 15 mg or once-weekly SC Ozempic 1 mg (1:1:1:1 ratio), all in combination with metformin ≥1500 mg per day
- The primary objective was to demonstrate noninferiority of Tirzepatide 10 mg and/or 15 mg to Ozempic in mean change from baseline in A1C at 40 weeks
- The key secondary objectives were assessed at 40 weeks: noninferiority of Tirzepatide 5 mg to Ozempic in mean change from baseline in A1C; superiority of Tirzepatide to Ozempic in mean change from baseline in A1C; superiority of proportion of patients with A1C <7%; superiority in mean change from baseline in weight; superiority of Tirzepatide 10 mg and/or 15 mg to Ozempic in proportion

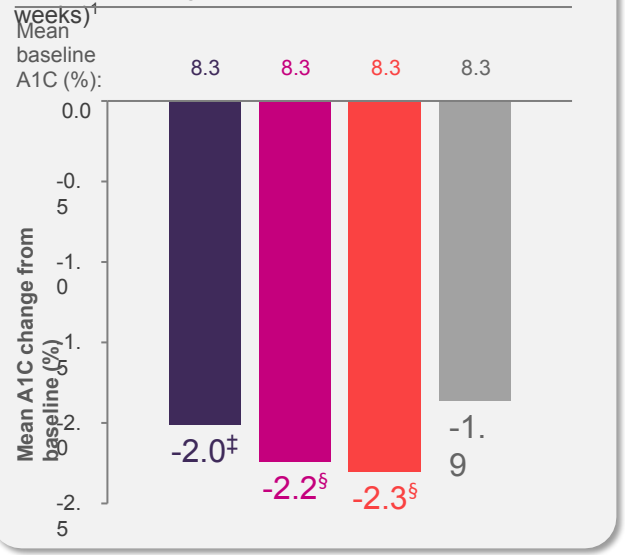
Select overall baseline demographics[1,2]

- Mean A1C: 8.3%
- Mean BMI: 34.2 kg/m^2
- Mean duration of T2D: 8.6 years

Tirzepatide Demonstrated Superior A1C Reductions Across Doses, and as a Key Secondary Endpoint, Weight Change vs Semaglutide 1 mg Was Evaluated

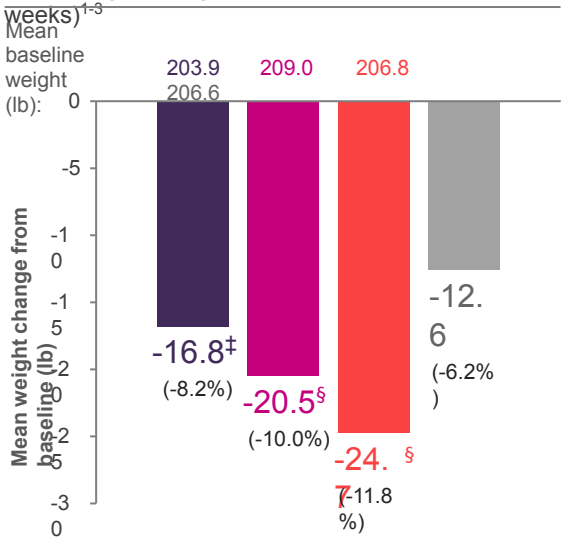
Primary endpoint

Mean A1C change from baseline (40 weeks)[1]



Key secondary endpoint

Mean weight change from baseline (40 weeks)[1-3]



Tirzepatide 5 mg (n=470) | Tirzepatide 10 mg (n=469) | Tirzepatide mg (n=469) | Semaglutide 1 mg (n=468)

Tirzepatide is not indicated for weight loss.

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

Limitations of Use: Tirzepatide has not been studied in patients with a history of pancreatitis. Tirzepatide is not indicated for use in patients with type 1 diabetes mellitus.

*In other studies of glycemic control with a primary endpoint at 40 or 52 weeks, mean reductions in A1C with Tirzepatide ranged from 1.8% to 2.1% for the 5 mg dose, 1.7% to 2.4% for the 0 mg dose, and 1.7% to 2.4% for the 15 mg dose.[1]

†In clinical studies with Tirzepatide , weight change from baseline was a secondary endpoint. In other studies of glycemic control with a primary endpoint at 40 or 52 weeks, mean reductions in body weight ranged from 12 lb to 15 lb for the 5 mg dose, 15 lb to 21 lb for the 10 mg dose, and 17 lb to 25 lb for the 15 mg dose.[1,2]

‡*P*<0.05 for superiority vs Ozempic 1 mg, adjusted for multiplicity.

§*P*<0.001 for superiority vs Ozempic 1 mg, adjusted for multiplicity.

1. Frías JP, et al. *N Engl J Med.* 2021;385(6):503-515.

Adverse Reactions in Pool of Placebo-Controlled Trials Reported in ≥5% of Patients Taking Tirzepatide

	Tirzepatide 5 mg (n=237) (%)	Tirzepatide 10 mg (n=240) (%)	Tirzepatide 15 mg (n=241) (%)	Placebo (n=235) (%)
Nausea	12	15	18	4
Diarrhea	12	13	17	9
Decreased appetite	5	10	11	1
Vomiting	5	5	9	2
Constipation	6	6	7	1
Dyspepsia	8	8	5	3
Abdominal pain	6	5	5	4
Discontinuation due to GI-related AEs	3.0	5.4	6.6	0.4

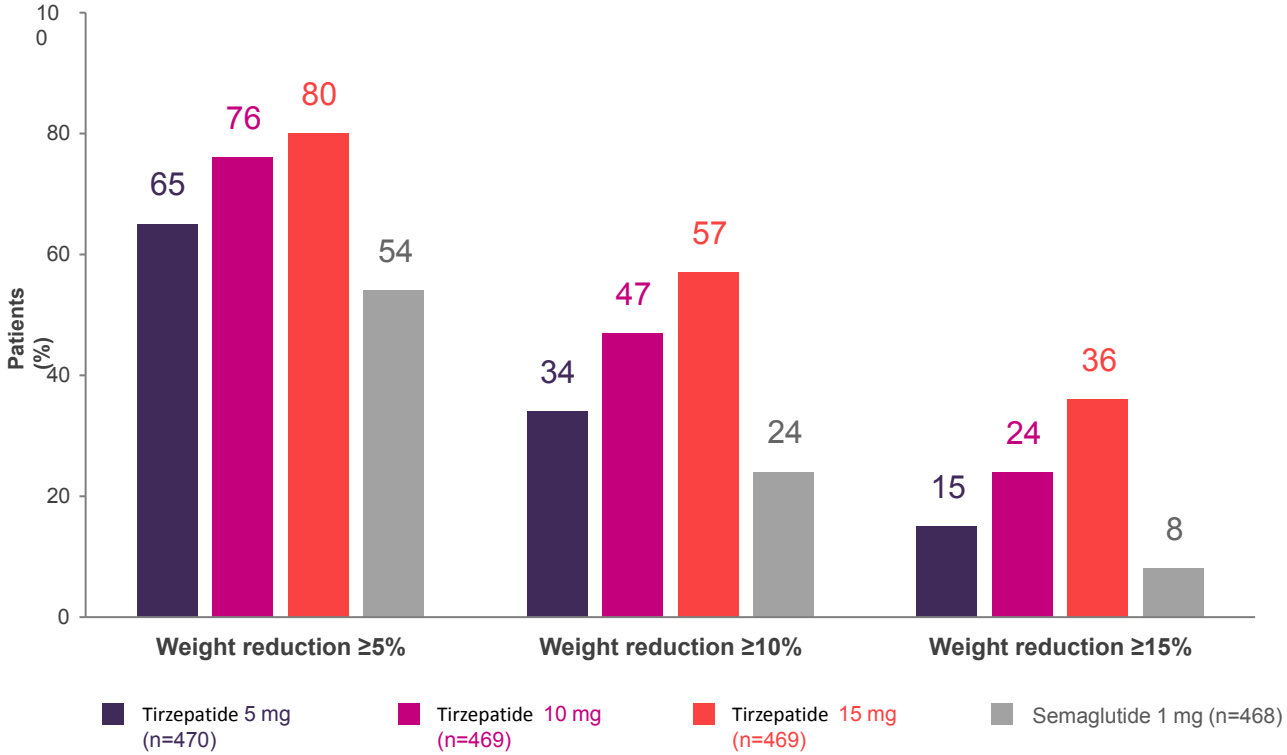
This table shows common adverse reactions, excluding hypoglycemia, associated with the use of Tirzepatide in the pool of phase 3 placebo-controlled trials. These adverse reactions occurred more commonly with Tirzepatide than placebo and in at least 5% of patients treated with Tirzepatide . Percentages reflect the number of patients who reported at least 1 treatment-emergent occurrence of the adverse reaction. In the pool of placebo-controlled trials, gastrointestinal adverse reactions occurred more frequently among patients receiving Tirzepatide than placebo (placebo 20.4%, Tirzepatide 5 mg 37.1%, Tirzepatide 10 mg 39.6%, Tirzepatide 15 mg 43.6%).[1]

Select Important Safety Information

Acute Kidney Injury: Tirzepatide has been associated with gastrointestinal adverse reactions, which include nausea, vomiting, and diarrhea. These events may lead to dehydration, which if severe could cause acute kidney injury. In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, sometimes requiring hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Tirzepatide in patients with renal impairment reporting severe adverse gastrointestinal reactions.

Severe Gastrointestinal Disease: Use of Tirzepatide has been associated with gastrointestinal adverse reactions, sometimes severe. Tirzepatide has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Percentage of Patients at Weight Reduction Thresholds at 40 Weeks



Tirzepatide **is not indicated for weight loss.**

In clinical studies, the proportion of patients with weight reductions of ≥5%, ≥10%, and ≥15% was an additional secondary endpoint not controlled for type I error.

Proportions were determined using logistic regression with multiple imputation using retrieved dropout for missing value at 40 weeks.

Jastreboff AM, le Roux CW, Stefanski A, et al. *N Engl J Med.* 2021;385(6):503-515.

#

Composite Endpoint Results

(A1C ≤6.5% + weight reduction ≥10%* + no clinically significant or severe hypoglycemia‡)

Tirzepatide 5 mg (n=470)

32 %

Tirzepatide 10 mg (n=469)

51 %

Tirzepatide 15 mg (n=469)

60 %

Ozempic 1 mg (n=468)

22 %

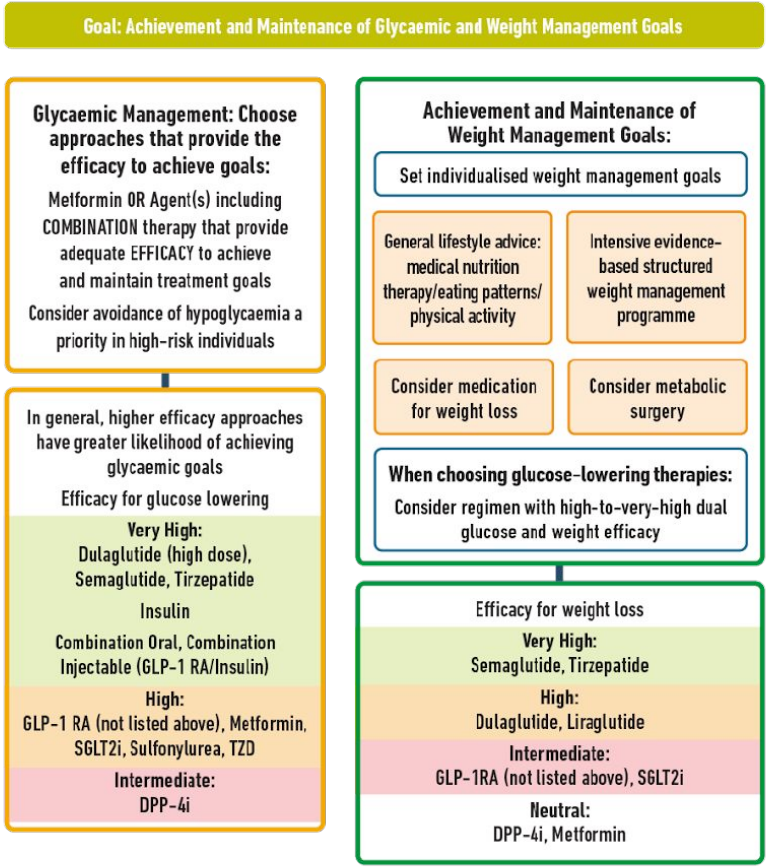
Select Important Safety Information

Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin: Concomitant use with an insulin secretagogue (e.g., sulfonylurea) or insulin may increase the risk of hypoglycemia, including severe hypoglycemia. The risk of hypoglycemia may be lowered by reducing the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.

* **Tirzepatide is not indicated for weight loss.**

†In SURPASS-2, composite outcome was a prespecified secondary endpoint not controlled for type I error. Analysis based on efficacy estimand data (on-treatment efficacy without the influence of rescue therapy).

‡Clinically significant hypoglycemia defined as plasma glucose <54 mg/dL. Severe hypoglycemia defined as episodes requiring the assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions.



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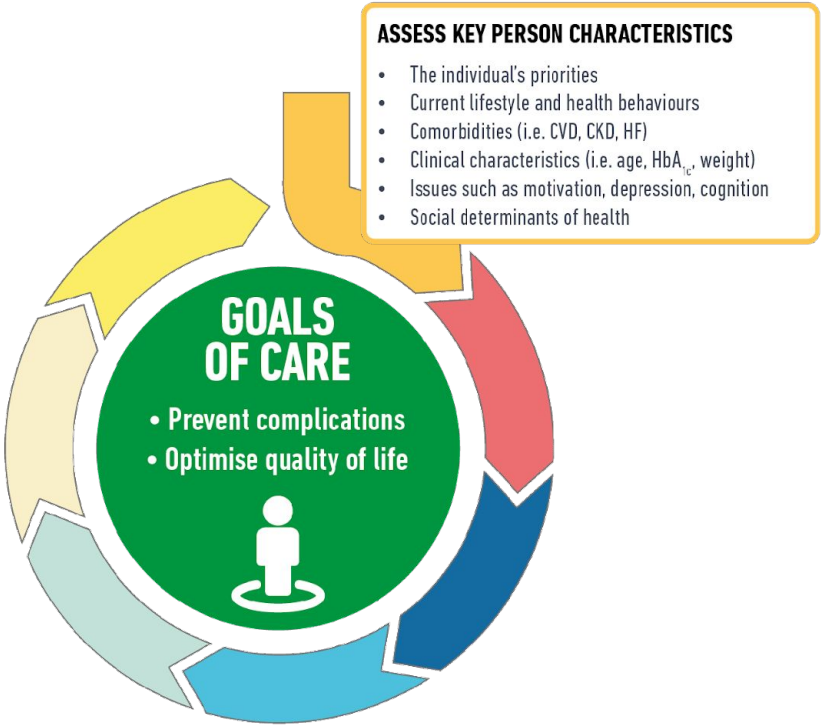
Diabetes Care 2022; https://doi.org/10.2337/dci22-0034. *Diabetologia* 2022; https://doi.org/10.1007/s00125-022-05787-2.

FIGURE 1: DECISION CYCLE FOR PERSON-CENTRED GLYCAEMIC MANAGEMENT IN TYPE 2 DIABETES



BGM, Blood Glucose Monitoring; BP, Blood Pressure; CGM, Continuous Glucose Monitoring; CKD, Chronic Kidney Disease; CVD, Atherosclerotic Cardiovascular Disease; DSMES, Diabetes Self-Management Education and Support; HF, Heart Failure.

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Davies MJ, Aroda VR, Collins BS, Gabbay RA, Green J, Maruthur NM, Rosas SE, Del Prato S, Mathieu C, Mingrone G, Rossing P, Tankova T, Tsapas A, Buse JB

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ASCVD trials for GLP-1's

3P MACE: composite endpoint of non-fatal myocardial infarction, non-fatal stroke, or death from cardiovascular causes

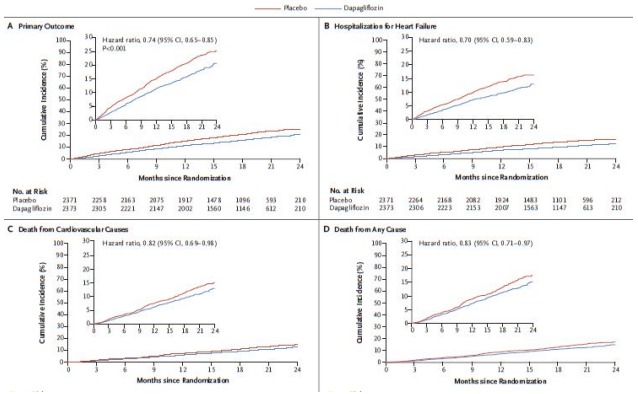
	LEADER (2016) Victoza® (liraglutide)	SUSTAIN-6 (2016) Semaglutide (Ozempic®)	REWIND (2019) Trulicity® (dulaglutide)
Inclusion	• DM2, ≥ 50 yo ASCVD, CKD 3 or greater, or CHF NYHA II-III • Or ≥ 60 years + ≥ 2 CV risk factors	• DM2, ≥50yo + ASCVD, chronic heart failure (NYHA class II-III), or CKD stage 3 or higher • Age ≥60 years with ≥ 1 risk factor	DM2, Age ≥ 50 yo w/ASCVD or ≥ 55 yo + subclinical vascular disease or ≥ 60 yo + ≥2 more CV risk factors
Sample Size	N = 9340 (3.8 yrs), 81% ASCVD Victoza 1.8 mG	N = 3297 (2.1 yrs), 83% ASCVD Ozempic 0.5 and 1 mG	N = 9901 (5.4 yrs), 31% ASCVD Trulicity 1.5 mG dose
Primary endpoint	**3P MACE: ↓13%**	**3P MACE: ↓26%**	**3P MACE: ↓12%**
Notable Secondary endpoints	There is no significant difference in HF hospitalization **↓16% composite renal (& retinal) outcomes**	There is no significant difference in HF hospitalization **↓36% new or worsening nephropathy** ↑Retinopathy complications (hazard ratio, 1.76; 95% CI, 1.11 to 2.78; P=0.02)	There is no significant difference in HF hospitalization **↓15% composite renal outcomes**

Long Island Jewish Medical Center
Northwell Health

Gerstein et al, The Lancet, olume 394, Issue 10193, 121 – 130
V Marso SP et al. New Journal of Medicine. 2016; **375**(4): 311-22
England Marso SP et al., N d 2016; 375:1834-1844

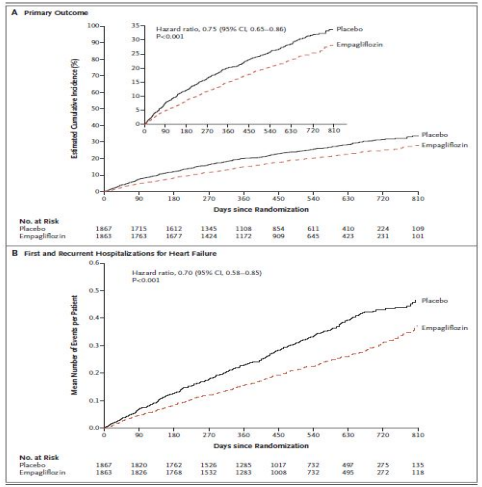
Effect of SGLT2i in people with heart failure

DAPA-HF



N Engl J Med 2019;381:1995-2008

EMPEROR-REDUCED



N Engl J Med 2020;383:1413-1424

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EMPEROR-PRESERVED

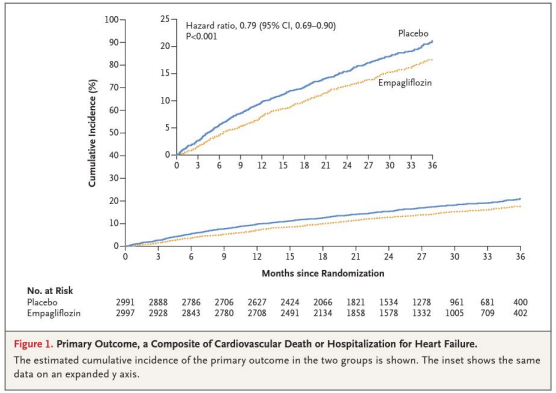

Figure 1. Primary Outcome, a Composite of Cardiovascular Death or Hospitalization for Heart Failure.
The estimated cumulative incidence of the primary outcome in the two groups is shown. The inset shows the same data on an expanded y axis.

N Engl J Med 2021;385:1451-1461

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Effects of SGLT2i in people with chronic kidney disease

	CREDENCE[a-c]	DAPA-CKD[d-f]	EMPA-KIDNEY[g-h]
Population	**DIABETIC KIDNEY DISEASE** ✓ T2D x Non-DM x Non-Albuminuric	**PROTEINURIC CHRONIC KIDNEY DISEASE** ✓ T2D ✓ Non-DM x Non-Albuminuric	**CHRONIC KIDNEY DISEASE** ✓ T2D ✓ Non-DM ✓ Non-Albuminuric
No. of patients	4401[b,c]	4304	~6000
Key inclusion criteria	eGFR ≥30 to <90 **and** UACR >300 mg/g	eGFR ≥25 to ≤75 **and** UACR ≥200 mg/g	eGFR ≥20 to <45 **or** eGFR ≥45 to <90 and UACR ≥200 mg/g
Primary composite outcome	ESKD, doubling of creatinine, or renal/CV death	ESKD, ≥50% sustained eGFR decline, or renal/CV death	ESKD, or ≥40% sustained eGFR decline, or renal/CV death
Study start and stop date (announced or planned)	February 2014 [b] July 2018	February 2017 [d] March 2020	November 2018 [g] ~June 2022
Results	+ [c]	+ [f]	+ [g-i] *

DM, diabetes mellitus; eGFR, estimated glomerular filtration rate; ESKD, end-stage kidney disease; TBD, to be determined; UACR, urinary albumin:creatinine ratio. a. Jardine MJ, et al. Am J Nephrol. 2017;46:462-472; b. ClinicalTrials.gov. Accessed November 09, 2021. https://clinicaltrials.gov/ct2/show/NCT02065791; c. Perkovic V, et al. N Engl J Med. 2019;380:2295-2306; d. ClinicalTrials.gov. Accessed November 09, 2021. https://clinicaltrials.gov/ct2/show/NCT03036150; e. Heerspink HJL, et al. Nephrol Dial Transplant. 2020;35:274-282; f. Heerspink HJL, et al. N Engl J Med. 2020;383:1436-1446; g. ClinicalTrials.gov. Accessed November 09, 2021. https://clinicaltrials.gov/ct2/show/ NCT03594110; h. Herrington WG, et al. Clin Kidney J. 2018;11:749-761. i. https://www.boehringer-ingelheim.com/human-health/metabolic-diseases/early-stop-chronic-kidney-disease-trial-efficacy

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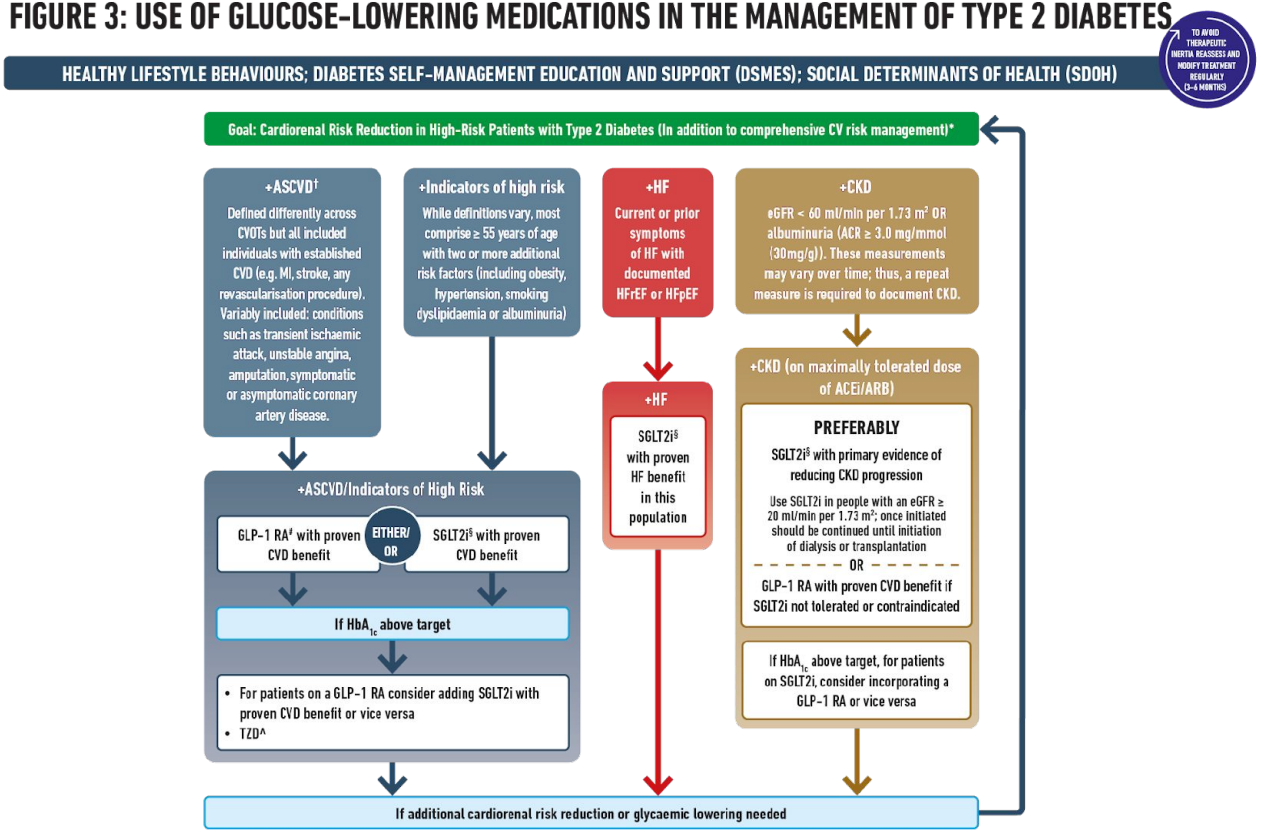
Diabetes Care 2022; https://doi.org/10.2337/dci22-0034. *Diabetologia* 2022; https://doi.org/10.1007/s00125-022-05787-2.

FIGURE 3: USE OF GLUCOSE-LOWERING MEDICATIONS IN THE MANAGEMENT OF TYPE 2 DIABETES



ACEi, Angiotensin-Converting Enzyme Inhibitor; ACR, Albumin/Creatinine Ratio; ARB, Angiotensin Receptor Blocker; ASCVD, Atherosclerotic Cardiovascular Disease; CGM, Continuous Glucose Monitoring; CKD, Chronic Kidney Disease; CV, Cardiovascular; CVD, Cardiovascular Disease; CVOT, Cardiovascular Outcomes Trial; DPP-4i, Dipeptidyl Peptidase-4 Inhibitor; eGFR, Estimated Glomerular Filtration Rate; GLP-1 RA, Glucagon-Like Peptide-1 Receptor Agonist; HF, Heart Failure; HFpEF, Heart Failure with preserved Ejection Fraction; HFrEF, Heart Failure with reduced Ejection Fraction; HHF, Hospitalisation for Heart Failure; MACE, Major Adverse Cardiovascular Events; MI, Myocardial Infarction; SDOH, Social Determinants of Health; SGLT2i, Sodium-Glucose Cotransporter-2 Inhibitor; T2D, Type 2 Diabetes; TZD, Thiazolidinedione.

* In people with HF, CKD, established CVD or multiple risk factors for CVD, the decision to use a GLP-1 RA or SGLT2i with proven benefit should be independent of background use of metformin; † A strong recommendation is warranted for people with CVD and a weaker recommendation for those with indicators of high CV risk. Moreover, a higher absolute risk reduction and thus lower numbers needed to treat are seen at higher levels of baseline risk and should be factored into the shared decision-making process. See text for details. ^ Low-dose TZD may be better tolerated and similarly effective; § For SGLT2i, CV/renal outcomes trials demonstrate their efficacy in reducing the risk of composite MACE, CV death, all-cause mortality, MI, HHF and renal outcomes in individuals with T2D with established/high risk of CVD; # For GLP-1 RA, CVOTs demonstrate their efficacy in reducing composite MACE, CV death, all-cause mortality, MI, stroke and renal endpoints in individuals with T2D with established/high risk of CVD.

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EASD European Association for the Study of Diabetes

Consensus recommendations

- In people with established CVD, a GLP-1RA with proven benefit should be used to reduce MACE or an SGLT2i with proven benefit should be used to reduce MACE and HF and improve kidney outcomes.

MACE = major adverse cardiovascular events

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Consensus recommendations

- In people with established CVD, a GLP-1RA with proven benefit should be used to reduce MACE or an SGLT2i with proven benefit should be used to reduce MACE and HF and improve kidney outcomes.
- In people without established CVD but with multiple cardiovascular risk factors (such as age ≥55, obesity, hypertension, smoking, dyslipidaemia, or albuminuria), a GLP-1RA with proven benefit could be used to reduce MACE or an SGLT2i with proven benefit could be used to reduce MACE and heart failure and improve kidney outcomes.

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Conclusions and recommendations

- In people with CKD, SGLT-2 inhibitors and GLP-1RA reduce risk of MACE independent of eGFR.
- In people with CKD, SGLT2i also reduce risks of HF and kidney outcomes (including end-stage kidney disease).
- In people with CKD and eGFR≥ 20 ml/min per 1.73 m^2, an SGLT2i with proven benefit should be initiated to reduce risks of MACE, HF and kidney outcomes.
- If such treatment is not tolerated or is contraindicated, a GLP-1RA with proven CV outcomes benefit could be considered

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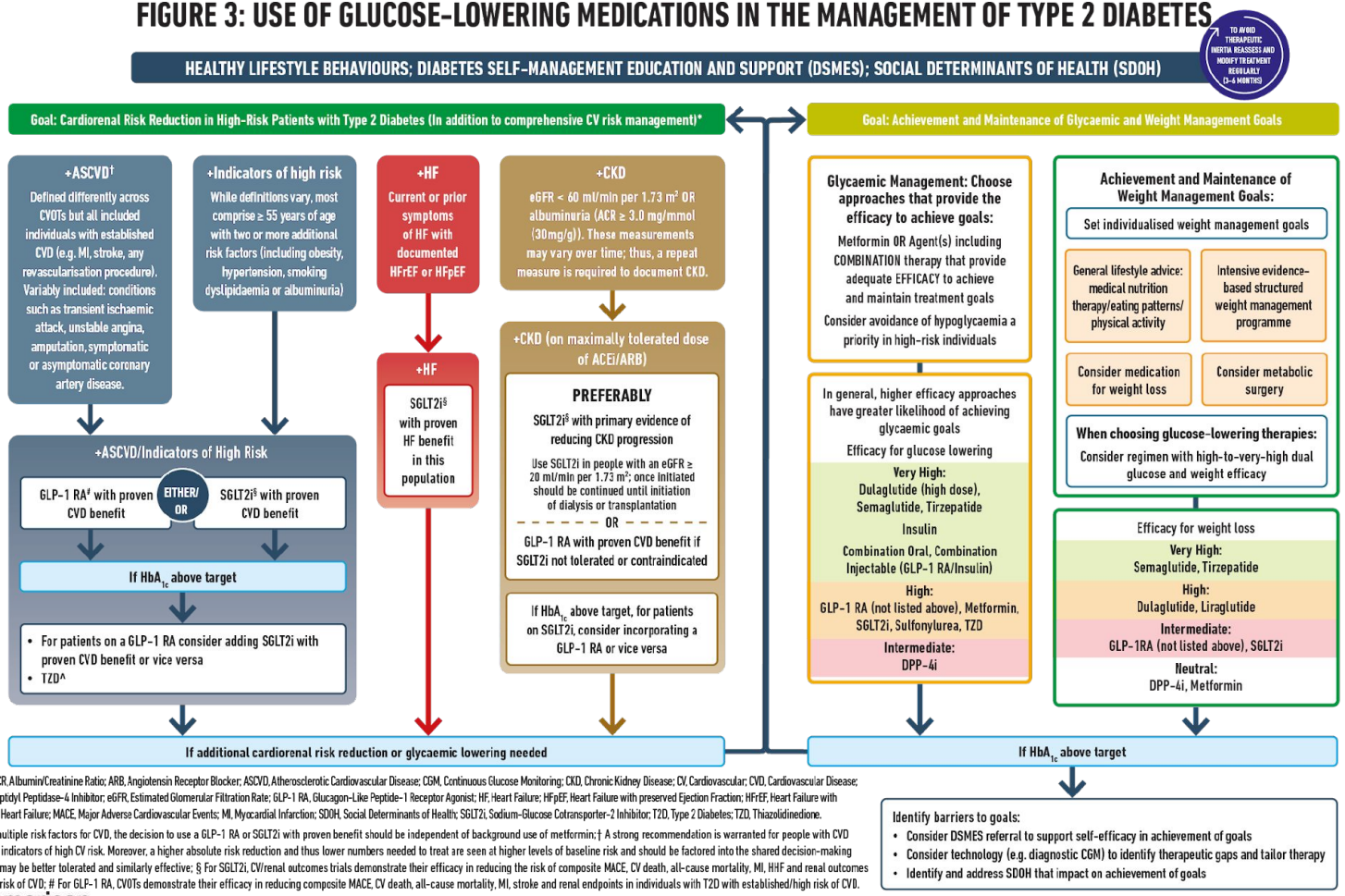

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IMPORTANCE OF INTEGRATED CARE

Acknowledge the lifelong and evolving nature of type 2 diabetes.

Identify and coordinate with the team.

Know your local resources.

Language matters in diabetes care.

Davies MJ, Aroda VR, Collins BS, Gabbay RA, Green J, Maruthur NM, Rosas SE, Del Prato S, Mathieu C, Mingrone G, Rossing P, Tankova T, Tsapas A, Buse JB

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INDIVIDUALISATION OF CARE

Consider each person living with diabetes as an individual with specific context, risks and preferences.

Healthcare systems should monitor and address inequity in the delivery of evidence-based interventions for type 2 diabetes.

Assess and address social determinants of health for each individual living with diabetes, particularly in those not achieving goals.

Incorporate comorbidities when developing and implementing the management plan.

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DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT

Embrace DSMES as being as important as other aspects of diabetes care such as pharmacotherapy.

Identify and know how to access your local DSMES resources.

Impress upon the person and the healthcare team the importance of DSMES in the ongoing holistic approach to the management of type 2 diabetes.

Initiate or refer for DSMES at diagnosis, annually, with changes in social or health status and with transitions of care or life situation.

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Davies MJ, Aroda VR, Collins BS, Gabbay RA, Green J, Maruthur NM, Rosas SE, Del Prato S, Mathieu C, Mingrone G, Rossing P, Tankova T, Tsapas A, Buse JB

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FACILITATING HEALTHY BEHAVIOURS AND WEIGHT MANAGEMENT

Specific health behaviour and weight management goals should be agreed upon between the person with type 2 diabetes and the care team; shared decision making is an important component of this discussion.

Emphasise self-monitoring behaviours and review data collected (e.g. glucose monitoring, weight, tracking physical activity) in clinical visits to convey their importance in achieving the desired health behaviour goals.

People taking insulin or a sulfonylurea should be educated about the risk of hypoglycaemia when undertaking physical activity or adopting a specific nutritional plan. Prescribe glucagon in people at high risk of severe hypoglycaemia.

DSMES and MNT can help the person living with diabetes to identify and address barriers to implementing healthier behaviours.

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PLACE OF INSULIN IN TYPE 2 DIABETES

The use of a GLP-1 RA should be considered prior to initiation of insulin.

When initiating insulin, start with a basal insulin and intensify the dose in a timely fashion, titrating to achieve the individualised fasting glycaemia target set for every person.

When insulin is initiated, continue organ-protective glucose-lowering medications and metformin.

Refer for DSMES when initiating insulin or advancing to basal-bolus therapy.

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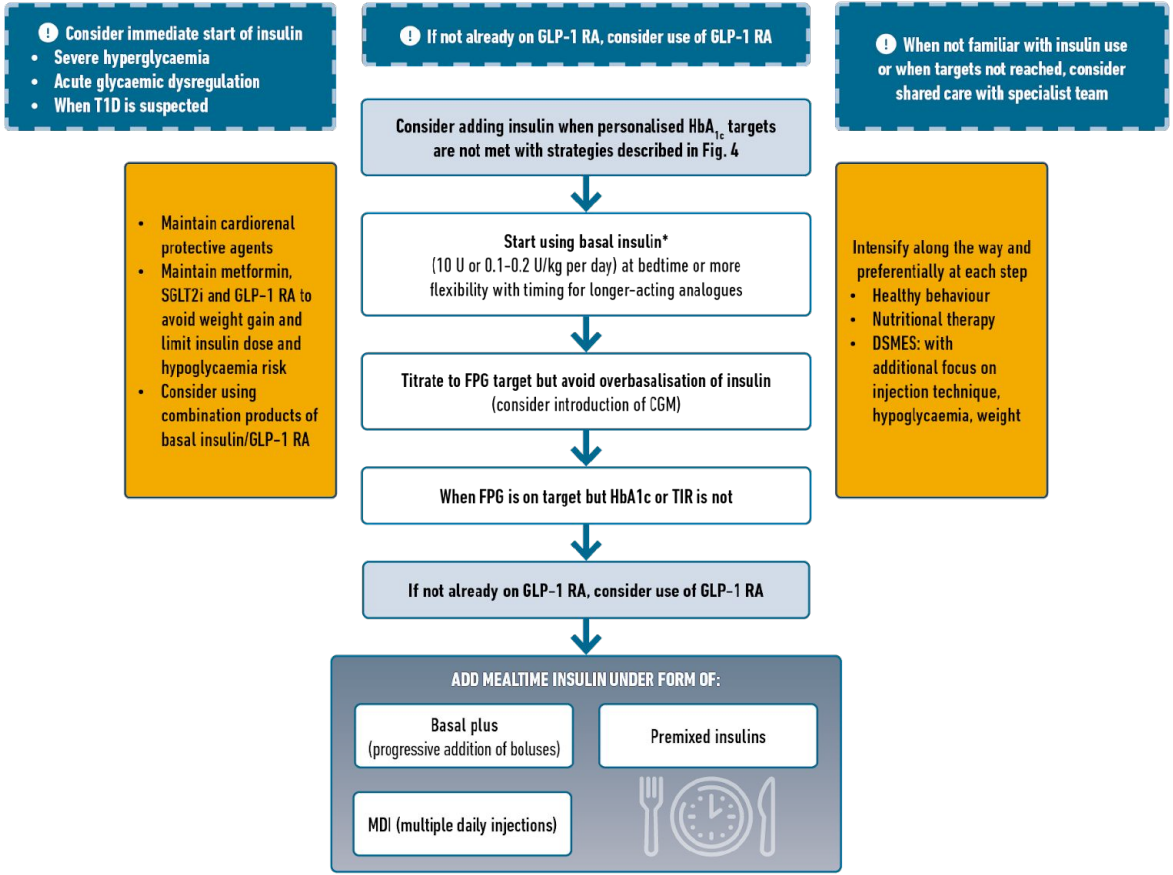
FIGURE 5: PLACE OF INSULIN[1]



*NPH Insulin or preferably analogue to reduce nocturnal hypoglycaemia risk

CGM, Continuous Glucose Monitoring; DSMES, Diabetes Self-Management Education and Support; FPG, Fasting Plasma Glucose; GLP-1 RA, Glucagon-Like Peptide-1 Receptor Agonist; SGLT2i, Sodium-Glucose Cotransporter-2 Inhibitor; T1D, Type 1 Diabetes; TIR, Time in Range.

1, More details can be found in Davies M, D'Alessio DA, Fradkin J et al. Management of Hyperglycaemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetologia 2018 61(12):2461–2498, and American Diabetes Association Professional Practice Committee, Draznin B, Aroda VR et al. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes-2022. Diabetes Care. 2022 Jan 1;45(Suppl 1):S125–43.

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PLACE OF TECHNOLOGY

Technology can be useful in people with type 2 diabetes but needs to be part of an holistic plan of care and supported by DSMES.

Consider CGM in people with type 2 diabetes on insulin.

Adapt the clinic/system to optimise effective use of technology among people with type 2 diabetes, particularly to support behaviour change through self-monitoring.

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WORKING WITHIN THE SYSTEM TO DELIVER IMPROVED CARE

Identify and incorporate continuing education activities on the management of type 2 diabetes for all members of the healthcare team.

Team-based care is required for integrated care of diabetes; this includes coordination between multiple disciplines (diabetes care and education specialists, dietitians, psychologists, etc.) and often other medical specialties (primary care, endocrinology, ophthalmology, nephrology, etc.)

Management of type 2 diabetes requires continuous quality improvement interventions tailored to the local setting.

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Any Questions?

Diving Deeper

Operationalizing a Low Carb Diet in Type 2 Diabetes

Rina Hisamatsu, MPH RDN
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Health Educator, MCT2D
rinhis@med.umich.edu

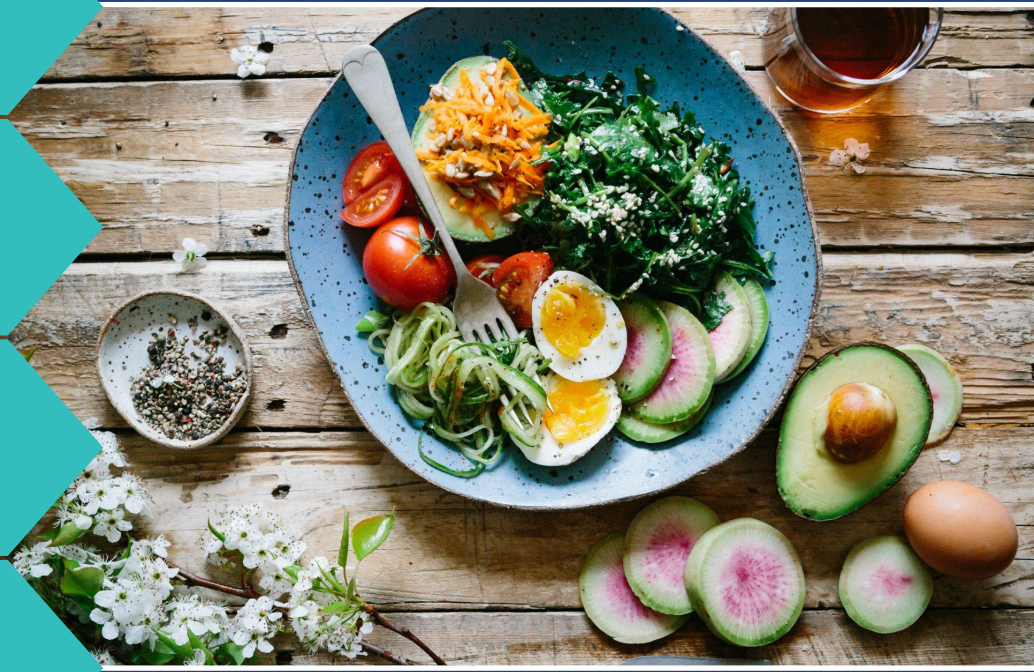
Overview

01 MCT2D core goals and the low-carb initiative

02 Fundamentals of the low-carbohydrate lifestyle

03 Identifying Suitable Patients

04 Case examples



The Michigan Collaborative for

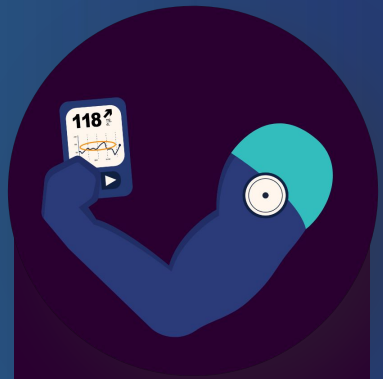
TYPE 2 DIABETES

MCT2D

MCT2D Quality Improvement Goals

Prescribing of GLP1 Receptor Agonists & SGLT2 inhibitors

Supporting Lower Carbohydrate Diets



Expanding use of Continuous Glucose Monitoring (CGM)

Focus for Today

How to integrate low-carbohydrate meal plans as an effective means of blood sugar control

Variations Of The Low-Carbohydrate Meal Plan

Very Low Carbohydrate (Keto) Diet	Low Carbohydrate Diet	Moderate Carbohydrate Diet	High Carbohydrate Diet
• ≤10% • 20-50g carbs/day	• >10-26% • 50-130g carbs/day	• 26-45% • 130-225g carbs/day	• >45% • >225g carbs/day

Based on 2000 kcal/day

Sainsbury et al. Diabetes Research and Clinical Practice, 2018

Fundamentals of The Low-Carbohydrate Lifestyle

A Well-Formulated Low-Carbohydrate Meal Plan…

Prioritizes protein intake

Includes an abundance of non-starchy vegetables

Includes some fats for satiety

A Well-Formulated Low-Carbohydrate Meal Plan

Low Carbohydrate Foods

High Carbohydrate Foods

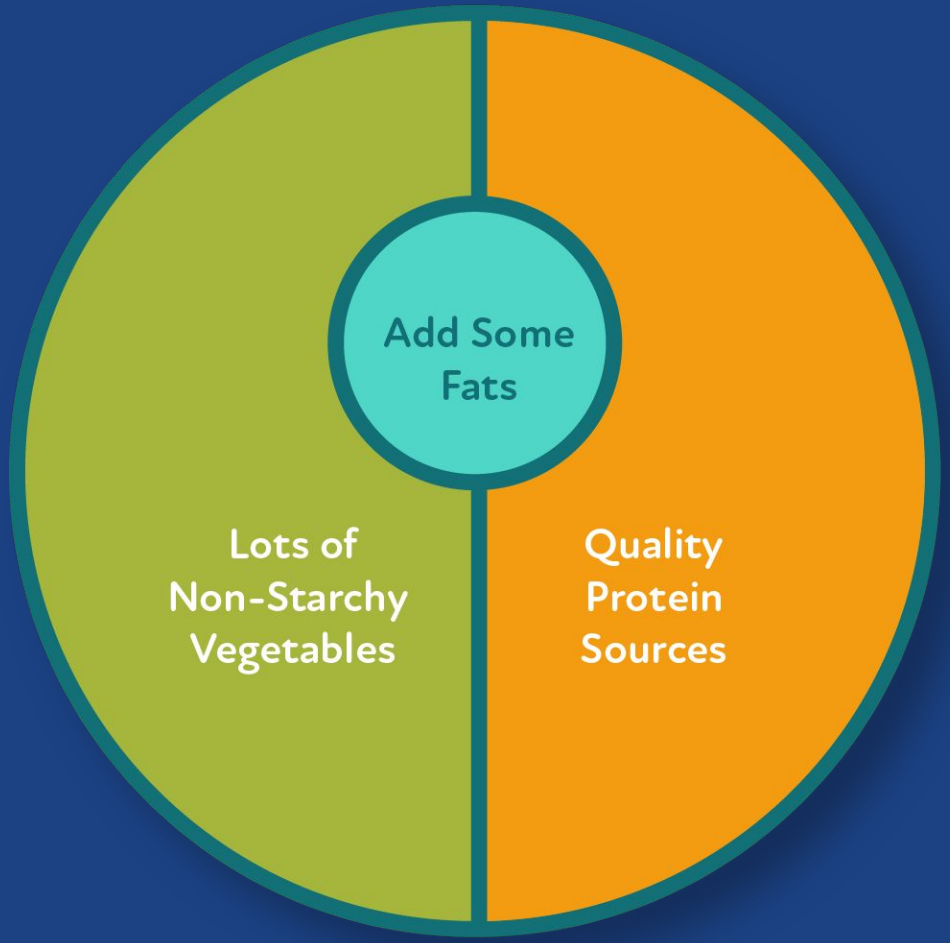
The Step Process
(3 step)

- Very low-carbohydrate meal plan
- <50g total carbohydrates/day

1) Pick a protein source

2) Add non-starchy vegetables

3) Add some fats



The Step Process
(4 step)

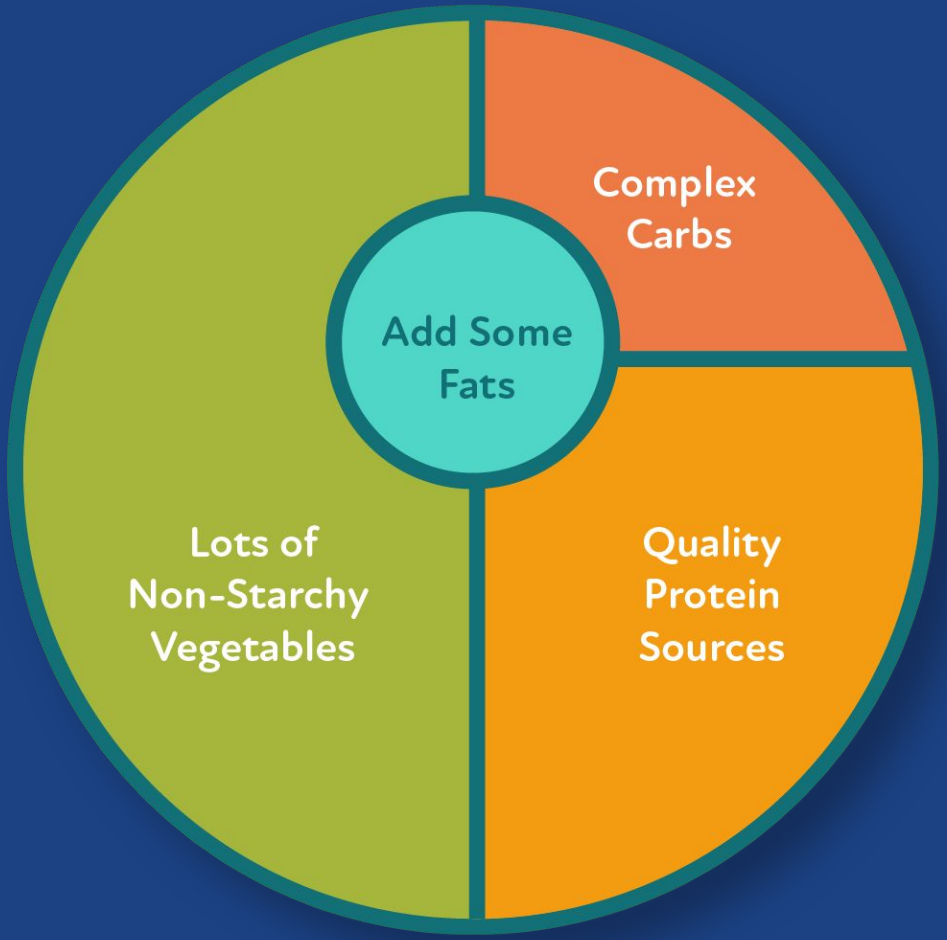
- Low carbohydrate meal plans
- 50-130g total carbohydrates/day

1) Pick a protein

2) Add non-starchy vegetables

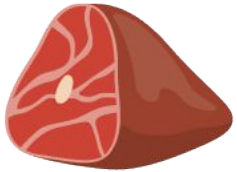
3) Add some fats

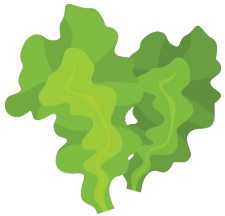
4) Add some complex carbs



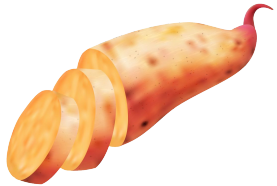
Summary

STEP 1: Pick a Protein	STEP 2: Add Non-Starchy Vegetables *(Half your plate)*	STEP 3: Add Some Fats	STEP 4: Add 1-2 Servings of Complex Carbs
Choose a high-quality protein source like chicken, fish, seafood, beef, eggs, or soy.	Fill half your plate with non-starchy vegetables like salad greens, broccoli, or Brussels sprouts.	Add some fats from oil, sauces, or full-fat dairy like cheese, butter or sour cream.	Include 1-2 servings of high-quality carbs like starchy vegetables, fruits, legumes/lentils or whole grains.

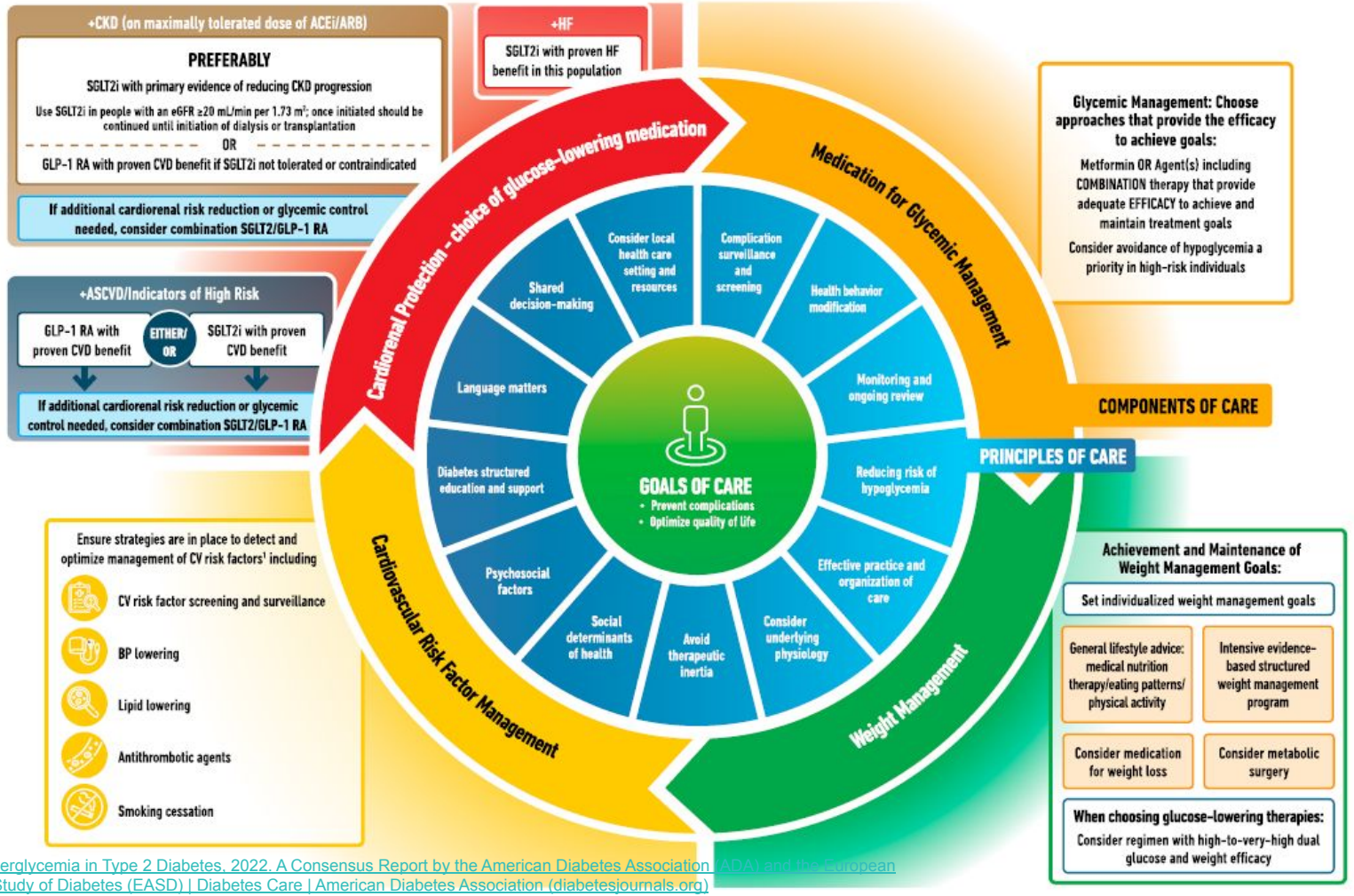








HOLISTIC PERSON-CENTERED APPROACH TO T2DM MANAGEMENT



Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) | Diabetes Care | American Diabetes Association (diabetesjournals.org)

Modifying Meal Plans to Fit Dietary Restrictions And Cultural Preferences

Pescatarian

- Includes fish and shellfish
- Includes soy, nuts and seeds, legumes/lentils*

Vegetarian/Vegan

- Includes soy, nuts and seeds, legumes/lentils*
- +/- eggs and dairy products

***Legumes/lentils can be added based on individual carb goals**

Adapting to cultural food preferences including:

Hispanic cuisine

South Asian cuisine

East Asian cuisine

Case Example A

Working together with care team to reach individualized carbohydrate goal

Case Example A: Ted

40 y.o. M, with PMH of T2D, obesity, HTN, TIA (2019)

Established care 1 year ago at Diabetes Clinic with following baseline:

- Starting weight: 342 lbs, BMI 47.7
- Hemoglobin A1c: 6.6%
- FBGs: 120s range

Medications: Victoza (d/c prior to initial eval at clinic), Januvia, Lisinopril, Metformin, Aspirin

Intervention

1. **Initiated GLP1-RA (Ozempic, escalated dose from 0.25mg to 1mg over 4-5 mo)**
2. **Education on low-carbohydrate meal plan**
    a. Recommended ≤100g carbs/day
    b. 5 Ps to avoid (Pastas, regular Pop, Pastries, Potatoes, b(B)read)
    c. Focus on: lean meats, non starchy vegetables 50/50 plate method
3. **Physical activity goals discussed**
    a. Weight lifting to preserve muscle mass

Within 1 year…

- ★ **Medication Reduction:**
  - D/C metformin, Januvia, Lisinopril
- ★ **Weight Reduction:**
  - 104 lbs total: 342 → 238 lbs (BMI 47.7 → 33.2)
  - Lost 7 lbs in 1 mo, 18 lbs in 2 mos, 59 lbs in 5 mos
- ★ **A1c Reduction:**
  - 6.6% → 5.4% (at most recent visit)
- ★ **FBGs Improvement: <90 mg/dL**

Patient Quotes

“[I’m] eating smaller, more frequent meals, and increasing lean proteins and vegetables.”

“[I’m] feeling great - receiving compliments from family and friends has been motivating.”

Delicious Ways to Enjoy Low-Carb Meals

Sample Meal Plan
(Low Carb 50-130g)

SUNDAY

Breakfast	*Lunch*	*Dinner*
3 egg omelet with ½ cup diced vegetables (peppers, onion, mushroom, tomatoes), and 1oz shredded cheese 1 slice whole wheat bread or 1 cup mixed berries **Total carbs: 20-25g**	**Wrap sandwich** (8 inch low carb wrap, 4-5oz turkey, cheese, spinach, tomato, and onion). Add mustard, pickles, mayo, and seasoning as desired *Optional: add 1oz nuts for crunch or avocado* **Total carbs: 25-30g**	**2 cups spaghetti squash*** topped with ½ cup low carb tomato sauce, 4-5oz ground beef, and 1 cup sautéed non-starchy vegetables *Optional: add grated Parmesan* **Note: Can also use high-protein, low carbohydrate pasta* **Total carbs: 40g**

MONDAY

Breakfast	*Lunch*	*Dinner*
¾ cup plain Greek yogurt topped with 1oz mixed nuts, 1 cup berries or 1 piece fruit (1 small apple, plum, kiwi, 1 cup cantaloupe) **Total carbs: 25g**	**2-3 cups mixed greens** topped with 4-5oz tuna or other canned fish, ½ cup chickpeas, diced cucumber, tomato, onion, pickles, olives, avocado, and feta or shredded cheese Serve with 2 tbsp ranch dressing or lemon and olive oil vinaigrette **Total carbs: 25g**	**Chicken Alfredo** (whole grain fettuccine with 4-5oz chicken grilled, ½ cup Alfredo sauce, and 2oz (dried) whole grain fettuccine) Serve with side salad (dressing full-fat or olive oil and vinegar) **Total carbs: 50g**

TUESDAY

Breakfast	*Lunch*	*Dinner*
Baked avocado cups (cut avocado in half, add 1 egg to center of each half, then bake at 425 degrees for 15-20 min) 1 piece of fruit (1 small apple, plum, kiwi, 1 cup cantaloupe, 1 cup berries) **Total carbs: 30g**	**Lettuce wraps** (2-3 large lettuce leaves topped with 4-5 oz turkey or chicken, 2 tbsp hummus, diced tomato, onion, and 1oz pumpkin seeds) **Total carbs: 20g**	**2 cups lentil soup** (brown lentils, onions, garlic, diced carrots, zucchini, celery, mushrooms) Chia pudding (mix 1 tbsp chia seeds, ½ cup coconut cream, and a dash of stevia. Let sit overnight) *You can make these in batches!* **Total carbs: 43g**

WEDNESDAY

Breakfast	*Lunch*	*Dinner*
Farmer's breakfast made with 2 slices bacon or other breakfast meats 1-2 eggs, cooked in any style ½ cup sautéed spinach or other greens 1 slice whole grain toast **Total carbs: 20g**	**Burrito bowl** made with 1 cup cauliflower rice, 4-5oz taco meat, 1 cup sautéed vegetables, ½ cup black beans, 2 tbsp salsa, and 1 tbsp sour cream 1 small fruit **Total carbs: 42g**	**4-5oz Grilled/baked fish** 2 cups baked/grilled non-starchy vegetables sprinkled with 1oz mixed nuts ½ cup sautéed corn or 1 small baked sweet potato *Optional: add 1 tbsp sour cream or butter* **Total carbs: 32g**

Sample Meal Plan
(Very-Low Carb <50g)

SATURDAY

Breakfast	*Lunch*	*Dinner*
Egg bites (whisk together 2-3 eggs, with chopped onion, peppers, tomato, spinach, mushrooms, herbs and spices, 1-2 oz cheese of choice. Pour mixture into muffin tin and bake at 350 degrees for 15-20 min or until set)	**1 cup tuna salad/chicken salad/ egg salad** Serve over 2 cups of mixed leafy greens or make into a wrap or sandwich using low carbohydrate bread. *Optional: 1 oz cheese or nuts*	**4-5 oz steak** Roasted brussel sprouts with crushed bacon 1 cup mashed cauliflower with garlic and parsley
Total carbs: 5g	**Total carbs: 10g (26g with wrap)**	**Total carbs: 15g**

SUNDAY

Breakfast	*Lunch*	*Dinner*
3 egg omelet with ½ cup diced vegetables (peppers, onion, mushroom, tomatoes), and 1oz shredded cheese ½ cup sliced strawberries	**Wrap sandwich** (8 inch low carb wrap, 4-5oz turkey, cheese, spinach, tomato, and onion). Add mustard, pickles, mayo, and seasoning as desired	**2 cups zucchini noodles** topped with ½ cup low carbohydrate tomato sauce, 4-5oz ground beef, and 1 cup sauteed non-starchy vegetables *Optional: add grated Parmesan*
Total carbs: 10g	**Total carbs: 25g**	**Total carbs: 15g**

TUESDAY

Breakfast	*Lunch*	*Dinner*
¾ cup plain Greek yogurt topped with 1 oz chopped almonds, ½ cup mixed berries	**Lettuce wraps** (2-3 large lettuce leaves topped with 4-5oz ground turkey or chicken, diced tomato, and ½ diced avocado, ¼ cup shredded cheese, 2 tbsp ranch dressing)	**Meatloaf** made with sugar-free BBQ glaze, 1 cup sauteed green beans, 1 cup cauliflower mash
Total carbs: 18g	**Total carbs: 10g**	**Total carbs: 18g**

WEDNESDAY

Breakfast	*Lunch*	*Dinner*
Farmer's breakfast made with 2 slices bacon or other breakfast meats 2 eggs, cooked in any style ½-1 cup spinach or other greens sauteed with garlic ½ cup berries	**Burrito bowl** made with 1.5 cups cauliflower rice, 4-5 oz taco meat, 1 cup sauteed vegetables, 2 tbsp salsa, 1 tbsp sour cream, 1 tbsp guacamole	**4-5 oz grilled fish** 2 cups sauteed non-starchy vegetables sprinkled with 1 oz walnuts
Total carbs: 12g	**Total carbs: 17g**	**Total carbs: 10g**

Identifying Your Patients

Taking The First Step

1. Identify “low-risk” patients: not on insulins, sulfonylureas, SGLT2i’s
2. Patients with high engagement/interest in pursuing a low carb lifestyle

Griauzde et al. Front Nutr. (2021)

Avoiding Potential Risks

1) Hypoglycemia

Monitor and adjust blood sugar lowering medications (insulin/combination insulins, sulfonylureas, SGLT2is etc.)

SGLT2-inhibitors

- DO NOT USE: If daily carb intake <50 grams due to risk of euglycemic DKA
- Safe in patients consuming >100 grams of carbs daily

2) Hypotension

Monitor BP for all patients

TREAT hypotension: adjust medications as needed

MONITOR for hyponatremia: consider medication adjustment, comorbidities, hydration status

Cucuzzella M, Riley K, Isaccs D, International Working Group on Remission of T2D
https://doi.org/10.3389/fnut.2021.688540
http://eguideline.guidelinecentral.com/i/1180534-low-carb-nutritional-approaches-guidelines-advisory/13?

Adapting Medications for Type 2 Diabetes to a Low Carb Diet

GUIDE FOR STARTING PATIENTS
on a Low Carb Lifestyle

A low carbohydrate (carb) lifestyle consists of reducing one's carbohydrate intake to 50-130g of total carbohydrates per day. Patients with type 2 diabetes (T2DM) who are interested in adopting a low carbohydrate lifestyle should monitor their blood glucose carefully and work closely with their primary care team to adjust medications as needed. **Risk of hypoglycemia is greatest among patients who are on insulin or sulfonylureas, particularly if they significantly reduce carbohydrate intake without adjusting their medications.**

Patients with T2DM who are on these medications may need to have their medications proactively reduced (i.e., when their diet is initiated) to prevent hypoglycemia. View a detailed review on medication management for patients with T2DM who follow a low carbohydrate lifestyle by visiting **michmed.org/Jyng5** or scanning the QR code.

Low carbohydrate lifestyles are not 'one-size-fits-all.' Success may require fine-tuning and adjustments along the way to find a suitable carbohydrate range for a patient. Considerations such as patient desire/interest, experience, cultural background, and commitment to work closely with their care team and be proactive in self-management skills are necessary tools for success.

MONITORING BLOOD PRESSURE

- Monitor BP for all patients
- For patients with controlled BP or edema:
  - Consider stopping/decreasing diuretics during the first 2-4 weeks of dietary change
  - If BP/edema increase: return to prior dose
- TREAT hypotension: advise patient to monitor for fatigue and dizziness, can give patient permission to stop a medication in this setting (HOLD medication and call office).
- Monitor for hyponatremia
- Hydration!

SETTING CARB GOALS & ADJUSTING MEDICATIONS

GREEN CATEGORY: CONTINUE
Patients will need minimal medication adjustment

Biguanides
GLP-1 RAs
DPP-4 Inhibitors

Population: These patients are considered low risk for hypoglycemia/hypotension: Patients with T2D who are NOT on insulin or sulfonylureas (Biguanides/Metformin, GLP-1 receptor agonists, DPP-4 inhibitors are OKAY).

Carb goal: Work with your patients to set a suitable carb goal. A starting carb goal of 50-130g of carbohydrates per day may be appropriate for this population.

Medication adjustments: If patients are on BP-lowering medications, close monitoring and adjustments may be necessary to prevent hypotension.

Blood glucose range and monitoring: Most patients should achieve a fasting glucose level of 70-130 mg/dL and a two-hour post-prandial meal of <180 mg/dL. Work with your patient to determine blood sugar monitoring goals.

Look for this handout!

SAFE

- Biguanides
- GLP1 Agonists
- DPP4 Inhibitors

REDUCE

- Basal long acting insulins— may need to reduce dose by up to 50%. Follow blood sugars and adjust as needed
- Thiazolidinediones

STOP

- Sulfonylureas
- Meglitinides
- SGLT2 inhibitors
- Bolus meal time insulin. *Might need small amounts to correct high blood sugar.*
- Combination insulins (70/30) — switch to basal long acting
- Alpha-glucosidase inhibitors

Cucuzzella M, Riley K, Isaccs D, International Working Group on Remission of T2D
https://doi.org/10.3389/fnut.2021.688540

Recognizing Challenges

- ★ **Time** constraints
- ★ **Availability** for clinicians to cover in routine visits
- ★ **Access** to clinic resources (MAs, RNs, RDs, Pharmacists, Care Navigators etc.)

Resources and Teaching Tools

- MCT2D Resource Library
- Diet Doctor Free CME course
- Low-Carbohydrate and Very Low-Carbohydrate Eating Patterns in Adults with Diabetes: A Guide for Health Care Providers (ADA)
- The Art and Science of Low Carbohydrate Eating
- Low Carb For Any Budget - Cooking Keto With Kristie
- Always Hungry? by Dr. David Ludwig
- Diet Doctor

Case Example B

Strategies to mitigate potential risk from medications

Team-based care

Case Example B: Fred

69 y.o. M with hx of T2D, dx in 2007 (or possibly earlier)

Started low-carb + CGM program in 7/2022 with following baseline:

- Starting weight: 235 lbs, BMI 35
- Hemoglobin A1c: 7.7%

Medications: Insulin glargine: 30 units twice daily, Insulin aspart: 5 units B/L/D, Dulaglutide: 3mg weekly

Patient counseled to keep total carbs ≤100g per day

MEDICATIONS:

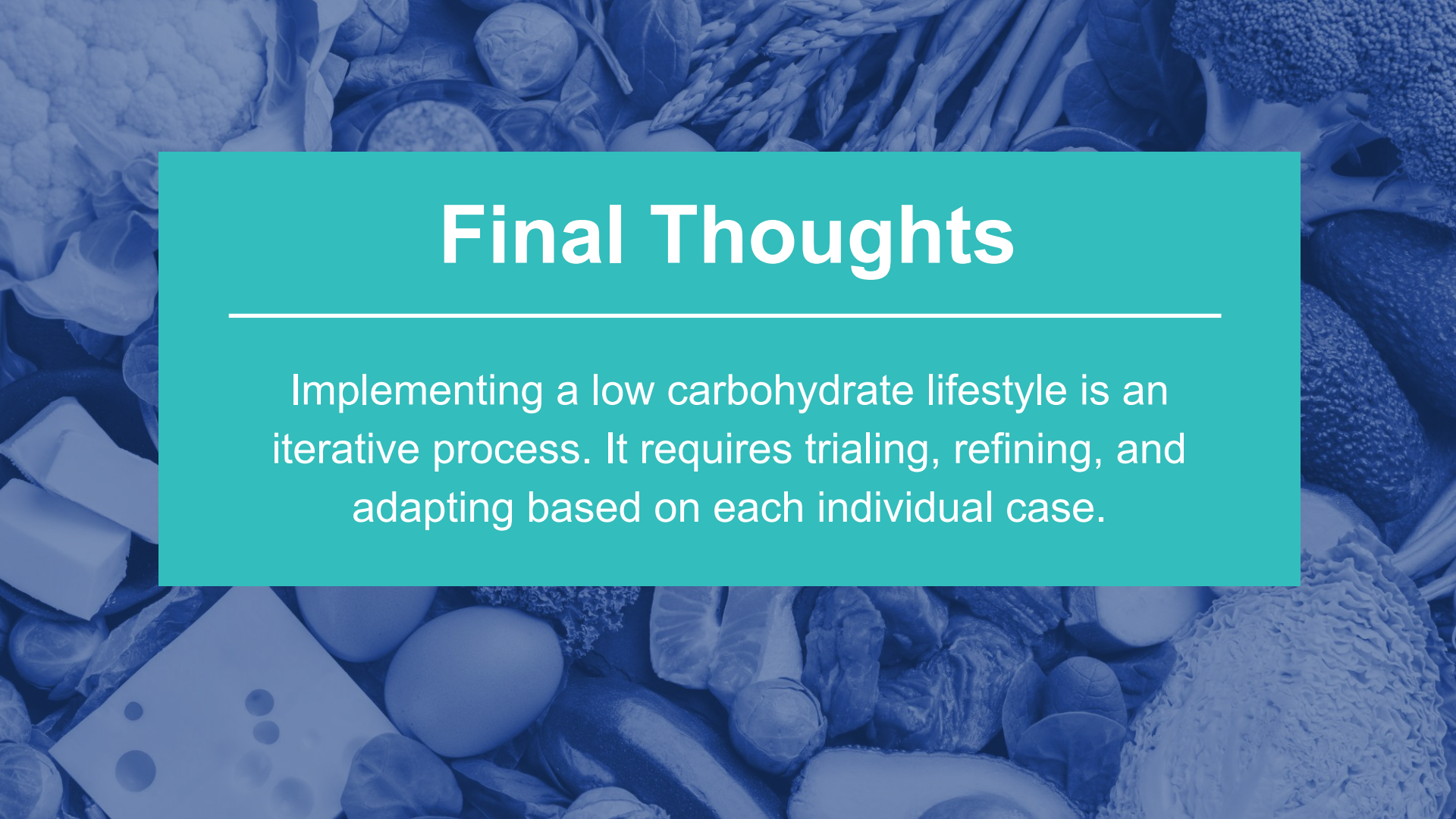
Insulin glargine: 30 units **twice** daily
Insulin aspart: 5 units B/L/D
Dulaglutide 3mg weekly

Within 1 Month of Program…

- ★ Discontinued insulin aspart
- ★ Insulin glargine: 30U bid → 20U qd
- ★ 10 lb weight loss (235 → 225)
- ★ Reduced BP meds
- ★ CGM time in range ~85%
- ★ Patient reports “feeling great”

Key Takeaways

1) Using CGM data, pt able to make real-time connections between food and its effect on blood glucose.
2) Pt felt empowered by results from low-carb lifestyle: weight loss, de-escalation of meds, improved blood glucose control.



Final Thoughts

Implementing a low carbohydrate lifestyle is an iterative process. It requires trialing, refining, and adapting based on each individual case.

Thank you!

Questions/
Concerns?

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Closing

Jackie Rau, MHSA

MCT2D Program Manager

Next Steps for MCT2D

- Value Based Reimbursement requirements for Year 2
- MCT2D Learning Community

First Official Year Coming to a Close

In that time we:

- Trained 601 MCT2D clinical champions and physicians on SGLT2i/GLP1RAs, low carbohydrate diets, and continuous glucose monitors
- Hosted 7 regional meetings and 1 collaborative wide meeting totaling over 247 attendees
- Began deploying the MCT2D interventions with patients in the practices, identifying barriers and challenges
- Shared best practices amongst collaborative members through the panels on prior authorization and CGMs.

We will be distributing a progress survey as one of the program requirements in December (due 2/1/23) to learn more about how the first year went for your practice

Year 2 VBR

Requirement	Responsibility
Ongoing Learning Community Requirement: Participate in one learning community activity for each of the two engagement levels. Details below. Due 7/15/2023	Level 1: Each physician Level 2: Each PO/Each Practice
Complete Progress Survey (due 2/1/2023)	Practice
Work with your physician organization to maintain a log of practice interventions and changes related to implementation of the quality initiatives	Practice
Identify and submit one best practice related to continuous glucose monitoring, low carbohydrate diet, prescribing SGLT2s or GLP1s, or urine albumin testing (Due 5/1/2023).	Practice
Distribute patient reported outcomes survey flyers and encourage patient participation.	Practice
Learn about coverage for your primary payor via MCT2D developed videos and materials and take a short post-test to confirm understanding.	Practice
Attend Fall 2022 and Spring 2023 regional meetings	Practice clinical champion
Present on your site's implementation of the quality improvement initiatives at a collaborative meeting, regional meeting, or conference call, if requested	Practice

Learning Community Newsletter

- Began distributing learning community newsletter in May
- Five editions out now, will continue sending these monthly to all clinical champions and all who subscribe
- Encourage subscriptions from your other providers in the clinic
- Will distribute tools through this, announce learning opportunities, etc.
- Where blogs will be posted, etc.

Link to subscribe: michmed.org/e8X8N

Thank you!

We appreciate you joining us today and for your work improving care for patients with T2D!