August 2021

CCHCS Care Guide: Type 2 Diabetes

SUMMARY | **DECISION SUPPORT** | **PATIENT EDUCATION/SELF MANAGEMENT**

GOALS[1]

[1]2021 American Diabetes Association (ADA) Standards of Care, Diabetes Care, Vol 44, Supplement

- **A1C Goal: < 7% - personalize based on patient factors (See pg 4 & Attachment 1)**
- **Blood Sugar: Fix the fasting first (goal glucose 80-130 mg/dl)**
  Then fix pre-prandial (goal glucose 80-130 mg/dl)
  Then fix post-prandial (goal glucose ≤ 180 mg/dl)
- **Blood Pressure (BP) < 140/90 *Lower target for some patients* (See page 6)**
- **Statin treatment goal based on age and presence of known Atherosclerotic Cardiovascular Disease (ASCVD). (See page 7)**

ALERTS

- **Blood sugar < 70 mg/dl**
- **Blood sugar > 400 mg/dl**
- **Altered level of consciousness**
- **Consider Latent Autoimmune Diabetes in adults (LADA) in patients with notable drop in response to oral medications**

SCREENING

Screening Indications if asymptomatic (repeat minimally Q 3 years if normal):
BMI ≥ 25 kg/m^2 or ≥ 23 kg/m^2 in Asian Americans with risk factors ^ and all persons beginning at age 45, & in human immunodeficiency virus (HIV) on antiretroviral treatment, and women with a history of Gestational Diabetes Mellitus (GDM). Annual screening also recommended for Pre-diabetes and > 1 year post-solid organ transplant (more frequently in first year post-transplant). The US Preventative Services Task Force 3.2021 update recommends screening all adults age 35-70 with overweight or obesity and consider lower age/BMI if risk factors and urges interventions for pre-diabetes. American Society of Endocrinology recommends screening when ≥ 65 years if will act on results with shared decision making.

Risk Factors Include – *Diabetes Mellitus (DM) first degree relative, African/Native/Asian American, Latino or Pacific Islander, hypertension (HTN), CVD, dyslipidemia, polycystic ovary, physically inactive, severe obesity, acanthosis nigricans, on steroids, thiazides and atypical antipsychotics, obese planning pregnancy, when starting or switching antiretroviral therapy and 3-6 months after start or switch. (Annually thereafter if normal).*

DIAGNOSTIC CRITERIA[2]

[2]Adapted from ADA Standards of Medical Care in Diabetes 2021, Abridged for Primary Care Providers, Page 3, Table 2.2/2.5

Test	Pre-Diabetes	Diabetes (DM)	Gestational Diabetes
A1C	5.7 - 6.4%	≥ 6.5%	-
Fasting Plasma Glucose*	100 - 125 mg/dl	≥ 126 mg/dl	≥ 92 mg/dl 1 hr ≥ 180 mg/dl 2 hr ≥ 153 mg/dl
Random Plasma Glucose	-	≥ 200 mg/dl	-

*In absence of unequivocal hyperglycemia, confirm results by repeat testing. Only diagnostic if classic symptoms of hyperglycemia.

INITIAL EVALUATION

History
- Complete clinical history including Cardiovascular (CV) Risk Factors and 10 year CV risk calculation (See page 9)
- End organ sequelae: Retinopathy, nephropathy, neuropathy, Coronary Artery disease (CAD), Peripheral Vascular Disease (PVD), Cerebrovascular Disease, Chronic Kidney Disease (CKD)
- Patient self-management capacity
  Four critical times for self-care evaluations: at diagnosis, when not meeting targets, development of complications, and life transitions
- Fingerstick blood sugar (FSBS) logs
- Symptoms/signs of hypoglycemia
- Medications
- Patient concerns/compliance with meds
- Patient well-being/need for depression screen
- Check status of screenings

Physical Exam
- Vitals, BP, Body Mass Index (BMI), fundoscopic (every 1-2 years until retinopathy), CV exam, PVD exam: pulses, Foot Exam (quick check for wound risk, comprehensive monofilament test annually (See Attachment 3)

Laboratory
- A1C, Fasting lipid panel, Spot urine Albumin to Creatinine ratio, Creatinine (Cr), thyroid stimulating hormone (TSH), Antibody studies if needed

TREATMENT OPTIONS

Therapeutic Lifestyle Changes: All patients (See page 4)
Aggressive control of CVD risk factors
Diabetes Medications: See Algorithms pages 2-3
Step 1: Metformin
Step 2: Sulfonylurea, Pioglitazone, Glucagon-like peptide receptor agonist (GLP-1) for ASCVD/Sodium glucose Cotransporter Inhibitor (SGLT-2) for ASCVD, CKD and Heart Failure with reduced Ejection Fraction (HFrEF) or Basal Insulin (GLP-1 preferred before insulin)
Step 3: GLP-1 then Basal Insulin, if not already on, then add:
i. 1 dose regular insulin with largest meal, or other (See page 3)
ii. 2 doses of regular insulin with meals
iii. Adjust insulin based on post-prandial blood sugars
Step 4: GLP-1, SGLT2, dipeptidyl peptidase-4 Inhibitor (DPP-4) if not already on for special indication and all non-formulary requirements are met for Basal Insulin.

MONITORING

- PCP/Care Team visits as clinically appropriate
- A1C at goal: at least every 180 days, or as clinically appropriate
- A1C NOT at goal: at least every 90 days – more frequently if actively titrating meds (See page 8). Consult the dietitian. Set goals, actively titrate until at goal
- Continuous glucose monitoring (CGM) patients (See Attachment 2)

TABLE OF CONTENTS

CCHCS Care Guide: Type 2 Diabetes

PHARMACOLOGIC THERAPY IN TYPE 2 DM: 2021 ADA[1] AND CCHCS RECOMMENDATIONS

[1]*Adapted from ADA 2021, Diabetes Care Volume 44, Supplement_1_S111 and Figure 9.1.*

STEP 1 Monotherapy

-If A1C < 8 %, start here*
-If lifestyle changes do not bring A1C to < 7% or target start medication*

Metformin

* All A1C targets should be individualized

- *Start 500 mg qd. Check FSBS. Titrate to target q 3-7 days to max dose of 2500 mg qd.*
- *Monitor B12 level periodically and at least annually if at risk for deficiency.*

STEP 2 Dual Therapy

-If A1C ≥ 8 %, start here*
-If not at goal add second agent

[#] Due to strong evidence for a much favorable effect on weight and hypoglycemia, GLP-1 is preferred to insulin when possible

2 A. If NO ASCVD**

Metformin +	or	Metformin +	or	Metformin +	or	Metformin +
Sulfonylurea***		Pioglitazone Thazolidinedione (TZD)		Liraglutide (GLP-1)		Basal Insulin[#] Long-acting

or

2 B. With Known or High Risk of ASCVD**

Metformin +	or	Metformin +	or	Metformin +	or	Metformin +
Liraglutide (GLP-1)^ or Empagliflozin (SGLT2)^^ Preferred		Pioglitazone TZD		Basal Insulin[#] Long-acting		Sulfonylurea***

Endocrinologist recommendation no longer needed for:
- *GLP-1/SGLT-2 if active ASCVD or high ASCVD risks^*
- SGLT-2 in HFrEF or CKD
- GLP-1 before starting insulin

or

2 C. HFrEF or CKD

Metformin +	or	Metformin +	or	Metformin +	or	Metformin +
Empagliflozin (SGLT2)^^ Preferred		Pioglitazone TZD		Basal Insulin[#] Long-acting		Sulfonylurea***

STEP 3 Triple Therapy

-If A1C ≥ 10 %, start here
-If not at goal start 3rd agent

*Consider **latent autoimmune disease in adults (LADA).** Some adults (typically > 30 years old) have a slow autoimmune beta cell destruction with a long duration of marginal insulin secretory capacity that can mimic Type 2 DM. Estimated to be 10% of all with diabetes. Besides treatment implications, the distinction is important for the risk of diabetic ketoacidosis in Type 1 DM. See lab section (page 8) for how to rule out*

Metformin +	or	Metformin +	or	Metformin +	or	Metformin +
Sulfonylurea or Pioglitazone TZD + GLP-1^		Pioglitazone TZD + Insulin[#] (see page 3)		Sulfonylurea*** + Insulin[#] Start with basal, Lantus or NPH, and add Prandial insulin then adjust based on post-prandial blood sugar as needed *(see page 3)*		Insulin# (basal or 70/30 BID) + *GLP-1^ or SGLT2^^ or DPP-4* *If no special indication or for DPP-4 any use, with non-formulary requirements met [&]*

*Always individualize A1c targets. When possible, ADA recommends an A1c of 7%.

**ASCVD defined here as: coronary artery disease or coronary vascular disease (CAD/CVD), cerebrovascular disease, or peripheral arterial/vascular disease (PAD/PVD) of atherosclerotic origin. 2021 ADA recommends SGLT-2 or GLP-1 in patients with CVD and those at high risk for ASCVD and includes patients with stenosis of > 50% in coronary, carotid or lower-extremity artery, heart failure, LVH and CKD as high risk. 2019 ACC/AHA states it's reasonable to start an SGLT-2 or GLP-1 for primary prevention of ASCVD and includes heart failure and atrial fibrillation as high risk for ASCVD.

***Caution for hypoglycemia when adding sulfonylurea to regimen. With start of basal insulin, strongly consider taper and stop of sulfonylurea. Taper and stop sulfonylurea when starting insulin other than basal insulin. The 2019 Clinical Practice Guidelines of the American Endocrine Society recommends avoid using sulfonylureas in patients ≥ 65 years of age.

^ GLP-1 is recommended in ASCVD and **before** starting insulin when possible.

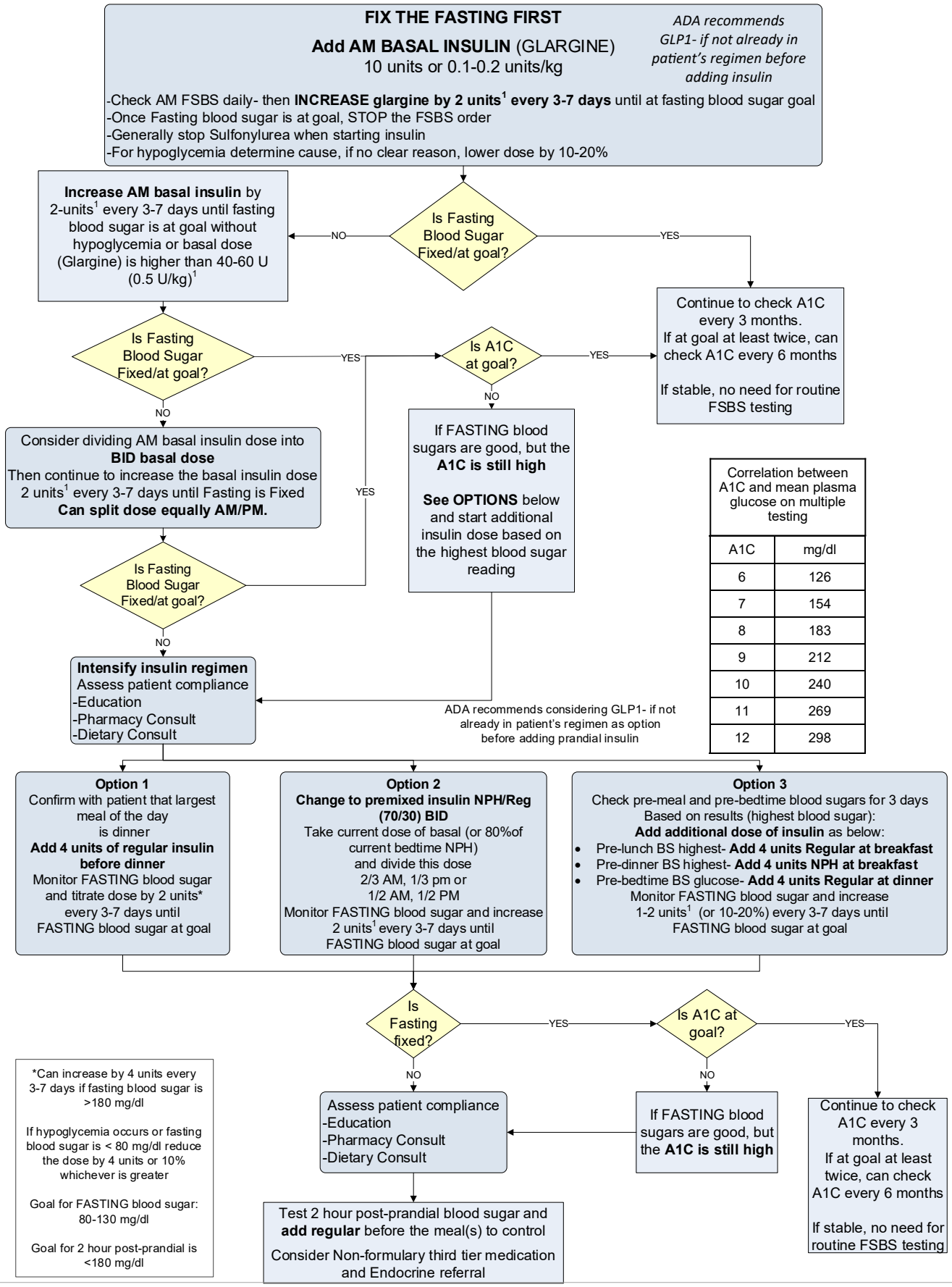
^^ SGLT-2 shown to have benefit in ASCVD, systolic heart failure with low volume ejection fraction (EF) <45% and to have a renal protective effect (reducing progression). A recent retrospective study has shown very limited glycemic lowering impact from SGLT-2 in Type 2 DM, and suggested consideration of its use for cardiorenal protection as opposed to glycemic control.

ADA states GLP-1 preferred to insulin and recommends GLP-1 **before** starting insulin when possible. Level of evidence **[A]**

& 4 NF requirements: Failed to reach goal with adequate trial of maximally tolerated oral medications and at least a 3 month trial of basal insulin and 1 dose daily of prandial insulin, had a consult with a Registered dietitian, is engaging in lifestyle changes and is recommended by an endocrinologist.

CCHCS Care Guide: Type 2 Diabetes

INSULIN ALGORITHM[1]



[1]ADA 2021; AACE/ACE 2019; EASD 2009; All recommend limiting basal total to 0.5U/kg due to ↑ risk of hypoglycemia without significant benefits in glycemic reduction
Source: Adapted from Standards of Medical Care in Diabetes 2015 American Diabetes Association: Position Statement. http://care.diabetesjournals.org (S43).

CCHCS Care Guide: Type 2 Diabetes

TREATMENT OPTIONS

I. SETTING GLYCEMIC GOALS: A1c < 7%, can be < 6.5% or < 8.0 based on patient factors (See Attachment 1)

II. EDUCATION AND THERAPEUTIC LIFESTYLE CHANGES: ASSESS READINESS FOR BEHAVIOR CHANGE

Patient Self-Management

All patients with DM should participate in DM self-management education/support (DSMES) to assist with implementing and sustaining skills and behaviors needed for ongoing self-management. **[B]*** Use "Consult to Registered Dietitian" when not at A1c target or if HTN and dyslipidemia are not controlled. Patients with ASCVD or CV risk score > 20% will also benefit from dietary counsel.

Nutrition

- Patients who are not at their A1c target, BMI ≥ 30 or lower BMI with CV risk factors, should be referred to the dietitian for nutritional education and the DSMES program. Also refer patients who would benefit from practical education such as food choices. Nutritional counselling by a dietitian can lower A1c by 0.3%-2%.
- Provide DM dietary patient handouts: From the Dietary page on Lifeline (http://lifeline/HealthCareOperations/MedicalServices/Dietary/Pages/Home.aspx) > under Quick Links on the right > select Diabetic Education Handouts

Weight loss

- Consult the registered dietitian. For BMI ≥ 40 (37.5 for Asian Americans), consider bariatric surgery. Please see **CCHCS Weight Management Care Guide** for highly detailed guidance on weight loss. The USPSTF recommends intensive behavioral counseling interventions for all overweight patients (BMI ≥ 25). Achieve and maintain a 7% weight loss **[A]*** (~10 lb for 140 lb person, 14 lb for 200 lb person, 18 lb for 250 lb person) is recommended, but even 5% has been shown to provide a clinical benefit for glycemia, lipids, and blood pressure.
- Use non-judgmental and person-first language (example: "person with obesity" versus "you are obese/obese person")
- Diet, physical activity, and behavioral therapy designed to achieve and maintain weight loss is recommended for most patients with type 2 diabetes who are overweight or have obesity and are ready to achieve weight loss. Greater benefits in control of diabetes and CV risk may be gained from weight loss > 5%. **[B]**[1]
- Studies have shown benefit from a high frequency of counseling (≥ 16 sessions in 6 months) with focus on dietary changes, physical activity, and behavioral strategies to achieve a 500–750 kcal/day energy deficit. **[A]** All energy deficit diets work, Dietary recommendations should be individualized to the patient's preferences and nutritional needs. **[A]**
- For weight loss, encourage higher physical activity levels (200-300 minutes/week) over minimum recommendations. **[A]**

Exercise

- Ensure patients on insulin or sulfonylureas understand the possibility of hypoglycemia with increased activity. Also, patients with severe retinopathy may have exercise restrictions.
- The ADA recommends: at least 150 minutes of moderate/vigorous intensity exercise **[A]***, spread out over ≥ 3 days/wk and at least 10 minutes per session. A maximum of 75 minutes of strength training could be applied toward the 150 min/week goal. Achieving this goal reduces the incidence of diabetes by 44%. 75 minutes/week of vigorous activity for younger and the more fit can be sufficient. Patients should try for no more than 2 consecutive days without exercise. Flexibility and balance for older adults 2-3 times/week is recommended. Patients who need to lose weight should strive for 200-300 minutes/week.

Psychosocial/Mental Health

- Ensure depression or other mental health issues are addressed, especially if the patient is non-adherent.
- Involve and engage the patient, promote self management skills, explore fears, and consider case coordination.

Smoking – advise all patients not to use cigarettes.

**[X] letter grade represents strength of recommendation from 2021 ADA Evidence–Grading System – (See Attachment 5)*

III. MEDICATIONS (See pages 16-18): PLEASE REFER TO PHARMACOLOGIC ALGORITHM ON PAGE 2

*Metformin therapy for **prevention** of type 2 diabetes should be considered in those with **prediabetes**, especially for those with BMI ≥35 kg/m2, those aged < 60 years, and women with prior GDM **[A]**** although not FDA approved for this purpose.

For overt DM, start medications promptly if lifestyle efforts are not sufficient in achieving or maintaining glycemic goals. Titrate every 3-7 days until fasting blood sugar goal is reached. Monitor A1C, continue to adjust to achieve glycemic goal.

Restrictions are removed for the following due to recent studies showing very strong randomized control trial evidence:

1. GLP-1 or SGLT-2 for patients with ASCVD. 2021 ADA recommends SGLT-2 or GLP-1 in patients with or at high risk for ASCVD and includes patients with stenosis > 50% in coronary, carotid or lower-extremity artery, heart failure, LVH and CKD as high risk. 2019 ACC/AHA states, "reasonable to start an SGLT-2 or GLP-1 for primary prevention of ASCVD" and includes heart failure and atrial fibrillation as high risk for ASCVD.

2. GLP-1 **before** starting insulin (less for improved glycemic lowering versus insulin but markedly less weight gain/hypoglycemia).

3. SGLT-2 have limited glycemic lowering capability, but are shown to decrease deaths and hospitalizations in those with systolic heart failure with low volume ejection fraction (HFrEF) <45% and to have a renal protective effect by reducing progression of CKD. Also shown to decrease ASCVD.

For other GLP-1 or SGLT-2 use than those above and any use of DPP-4s, non-formulary (NF) requirements should be met:

(1) Failed to reach goal with an adequate trial of maximally tolerated oral medication doses and at least three month trial of basal insulin and 1 dose daily of prandial insulin (when already on a GLP-1). **(2)** Consulted with a Registered Dietitian. **(3)** Engaging in lifestyle changes. And **(4)** Endocrinologist recommends.

TREATMENT OPTIONS Continued

REQUIREMENTS BEFORE USING NEWER CLASSES OF MEDICINES FOR DIABETES

Scenario	May Order- No special requirements	Must meet 4 Non-formulary criteria+
GLP-1 (glutides) in ASCVD	√	
GLP-1 (glutides) for dual or triple oral maximized before/instead of insulin start	√	
√GLP-1 (glutides) not in scenario 1 or 2		√
SGLT-2 (flozins) for ASCVD	√	
SGLT-2 (flozins) for congestive heart failure (CHF)	√	
SGLT-2 (flozins) for CKD	√	
SGLT-2 (flozins) not in scenario 4-6		√
DPP-4 (gliptins)		√

- *4 Non-formulary criteria: Patient failed to reach goal with adequate trial of maximally tolerated dose of oral medications and a 3 month trial of basal insulin and 1 dose daily of prandial insulin; has had consult with a dietitian, is engaging in lifestyle changes, and an endocrinologist recommends it.*

CLINICAL INERTIA

Physician/Provider Factors:
- Failure to set clear goals
- Failure to initiate treatment
- Failure to titrate treatment to achieve goals
- Failure to identify and manage comorbidities (i.e., depression)
- Reactive rather than proactive care

Patient Factors:
- Denial that disease is serious; absence of symptoms
- Low health literacy
- Too many medications/medication side effects
- Poor communication between the physician and the patient
- Lack of trust in physician
- Depression or substance abuse

Clinical Inertia: The failure of health care providers to initiate or intensify therapy when indicated is a big problem in the management of diabetes and diabetes related co-morbidities such as hypertension. Physician/Provider, patient, and healthcare system related factors all contribute.

Clinical Consequences of Clinical Inertia:
- Delays in treatment intensification can negatively affect a patient's prognosis and contribute to patients living with suboptimal glycemic blood pressure or lipid control for years, leading to adverse outcomes and increased risk of complications.

Overcoming Clinical Inertia:
- Engage with the patient regarding the progressive nature of Type 2 DM, and encourage lifestyle modification behaviors from beginning of diagnosis, and throughout treatment.
- Ensure the patient understands the goals of their treatment, are involved in managing their disease, and trust their care team's medical recommendations.
- Use the Complete Care Model to engage entire team in managing/monitoring the patient's Type 2 DM including BP and lipids.
- Have a care team member see the patient frequently when not at goal and titrate medication aggressively.
- Collaboration

See next page for table on patient-centered diabetes management.

CCHCS Care Guide: Type 2 Diabetes

Decision Cycle for Patient-Centered Glycemic Management in Type 2 Diabetes

Adapted from the 2021 ADA Standards of Care for Diabetes, Chapter 4, Figure 4.1

Assess Key Patient Characteristics	Current lifestyle Comorbidities Clinical status/labs Patient motivation, presence of depression Patient intellectual, cultural and socioeconomic background context
Consider Specific Factors that Impact Choice	Individualized HbA1c target Consider impact on weight and hypoglycemic risks Consider and discuss medication side effects Consider and discuss regimen complexity and impacts and if practical Consider risks, benefits and cost effectiveness/value of medicine choices
Shared Decision Making-Create a Plan	Empower patient by seeking patient preferences Explore self-management skills Optimize regimen for adherence and sustainability Set goals using motivational interviewing and shared decision making
Agree on a "SMART" Management Plan	S- specific to patient M- measurable benefit A-achievable R-realistic T-time limited if trial of new changes
Implement the Management Plan	See monthly if actively titrating, especially insulin More frequent visits may aid in diabetes self-management education and support (DSMES) See at least every 3 months if not at target See at least every 6 months if good control
Ongoing Monitoring	Emotional well being Tolerability of medication Glycemic status and progress ASCVD risk and control of ASCVD risk factors
Review and Agree on Continued or Modified Management Plan	Review the plan Agree on changes Ensure timely therapy changes to avoid clinical inertia Re-evaluate plan at least once or twice a year

Hypertension Management in Patients with Diabetes – 2021 ADA Recommendations

RECOMMENDED BLOOD PRESSURE (BP) GOALS

- High risk factors for CVD include: hypertension, dyslipidemia, smoking, family history, CKD, albuminuria and DM.
- Significant controversy still exists in the literature regarding the target HTN treatment goals. To the right are the recommendations by ADA, American College of Cardiology/American Heart Association (ACC/AHA), and Joint National Committee (JNC).

Recommendation for DM	BP Goal
ADA (2021) Most patients with DM	< 140/90
Individuals at high risk of CVD (**10-year ASCVD risk of ≥10%**)	< 130/80
JNC 8 (2014)	< 140/90
ACC/AHA (2019)	< 130/80

TREATMENT RECOMMENDATIONS for People with DM and HTN

See HTN Care Guide for more details

Blood Pressure*	Treatment Modalities	Evidence Grade	Anti-Hypertensive Medications for Type 2 DM
> 120/80	Lifestyle Changes (↓ Wt, Na, ETOH, ↑K+)	**[B]**	All four of these four first line agents are useful and effective **[A]** ACC/AHA Executive Summary[1] -ACEI or ARB first line for people with diabetes and CAD or if albuminuria (≥ 30 mg/g creatinine) present -Calcium Channel Blockers -Thiazide-like diuretic -DO NOT USE ACEI AND ARB SIMULTANEOUSLY. Do not use ACEI/ARB with direct renin inhibitors (currently only Aliskiren®) **[A]** -Not meeting target on 3 meds: Add mineralocorticoid receptor antagonist (spironolactone) therapy **[B]** and refer to specialist
≥ 140/90	1 Med + Lifestyle Changes Prompt initiation Timely subsequent titration	**[A]**	
≥ 160/100	2 Med + Lifestyle Changes Prompt initiation Timely subsequent titration to meet target	**[A]**	

*For diagnosis: only one blood pressure value has to be high, either systolic or diastolic blood pressure.

[1] Blumenthal and Arnett, co-chairs, 2019 ACC/AHA "Guideline on the Prevention of Cardiovascular Disease" Summary, Journal of the American College of Cardiology, 2019; March 17.

CCHCS Care Guide: Type 2 Diabetes

LIPID MANAGEMENT IN PATIENTS WITH DIABETES (For details see CCHCS Lipid Care Guide 2021 Update)

LOW-DENSITY LIPROPROTEIN (LDL) GOAL FOR PATIENTS WITH DIABETES WITH AND WITHOUT ASCVD

No ASCVD On statins	No LDL treatment goal Monitoring LDL/lipid panel done to confirm adherence
***Overt ASCVD – includes those with CVD, cerebrovascular disease, and peripheral vascular disease	Treatment goal LDL < 70 mg/dL or at least 50% reduction and non-high density liproprotein (HDL) cholesterol ≤100 mg/dL

LIPIDS- STATIN TREATMENT FOR PATIENTS WITH DIABETES[1]

STATINS for patients with Diabetes Mellitus

- Statin treatment initiation and monitoring is based on age and risk factors and ASCVD status (see below).

AGE	RISK FACTORS PRESENCE OF ASCVD	RECOMMENDED STATIN DOSE INTENSITY*	MONITORING AND TREATMENT GOALS FOR ASCVD
< 40 years	None	None	At initiation of therapy, 4-12 weeks after a change, and annually, or more frequently as clinically indicated (monitoring is primarily done to confirm adherence). Moderate dose target 30-49% LDL reduction.
	CVD risk factors** or CV risk score ≥7.5%	Reasonable to initiate Moderate	
	LDL≥190 mg/dL	**High** *ACC/AHA[2] recommends ≥ 190 for any 20-75 years should use high*	
	Overt ASCVD***	High **[A]**	Lipid panel as indicated to achieve target LDL < 70 mg/dL and non-HDL cholesterol ≤100 mg/dL, and/or LDL lowering by at least 50%
≥ 40 years	None	Moderate **[A]**- *patients 40-74 yrs* **[B]**- *patients ≥ 75 yrs*	Moderate dose target: 30-49% LDL reduction High dose target: ≥ 50% LDL reduction, LDL < 70 mg/dL, and total non-HDL cholesterol ≤ 100 mg/dL At initiation of therapy, 4-12 weeks after a change, and annually, or more frequently as clinically indicated (monitoring is primarily done to confirm adherence)
Any Age	CVD risk factors** (2019 ACC/AHA includes or risk enhancing factors***)	High **[A]**- *patients 40-74 yrs* **[B]**- *patients ≥ 75 yrs*	
	LDL≥190 mg/dL	**High** *ACC/AHA[2] recommends ≥ 190 for any 20 -75 years should use high intensity without risk assessment*	
	Overt ASCVD*** **** or CV Risk score ≥20%/very high risk	High **[A]**- *all patients > 40 yrs* unable to achieve target LDL: reasonable to add ezetimbe when CV risk ≥ 20%	Lipid panel as indicated to achieve target LDL < 70 mg/dL and non-HDL cholesterol ≤100 mg/dL and/or LDL lowering by at least 50%. Maximal statin and ezetimibe still not at target, consider PCSK9 inhibitor****

High-intensity statin—Atorvastatin 40 - 80 mg/d
Moderate-intensity statin—Atorvastatin 10 - 20 mg/d [or Rosuvastatin (5 mg, 10 mg) Nonformulary] or Simvastatin 20-40 mg/d

*In addition to lifestyle therapy.

**CVD risk factors include Age > 55, LDL cholesterol ≥ 100 mg/dL, high blood pressure, smoking, albuminuria, CKD, and overweight and obesity, family history of premature ASCVD (< 55 yr/o males, < 65 yr/o females).

*** Metabolic syndrome (3 or more of: waist circumference, triglycerides ≥ 175 mg/dL, BP, glucose, low HDL) chronic inflammatory conditions (SLE/HIV -AIDS/RA/psoriasis etc.), South Asian ancestry, persistently elevated triglycerides, premature menopause (< 40 yr/o), elevated lipoprotein a, apoprotein B, elevated c-reactive protein (CRP), elevated coronary artery calcium (CAC), history of preeclampsia, erectile dysfunction, ABI < 0.9)

***Overt CVD includes those with cardiovascular disease, cerebrovascular disease, and peripheral vascular disease.

****In patients with very-high ASCVD risk (multiple major events or 1 major event and multiple high-risk risk factors and the LDL remains ≥ 70 mg/dL or LDL-C ≥ 190mg/dL or LDL ≥ 100 mg/dL) and multiple risk factors, AND on both maximally tolerated statin PLUS ezetimibe, may be considered for PCSK9 (praluent®/(alirocumab) inhibitor therapy with specialist recommendation. Please see the Dyslipidemia Care Guide for more details.

[1]2021 ADA Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes – 2021. [2] 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease

HYPERTRIGLYCERIDEMIA on Statin: Combination Therapy

- For patients with fasting triglyceride levels ≥ 500 mg/dL, evaluate for secondary causes of hypertriglyceridemia and consider medical therapy to reduce the risk of pancreatitis. **[C]**
- Elevated triglycerides (TGs) 175-499mg/dL: Check for secondary causes (lifestyle, chronic liver disease, CKD, nephrotic syndrome, hypothyroidism, meds)
- Statin/fibrate combination has not been shown to improve atherosclerotic cardiovascular disease outcomes and is generally not recommended. **[A]**
- However, therapy with statin and fenofibrate may be considered for men with both:
  - Triglyceride level ≥ 204 mg/dL (2.3 mmol/L) AND
  - HDL cholesterol level < 34 mg/dL (0.9 mmol/L) **[B]**

MONITORING - ADAPTED FROM 2018 ADA RECOMMENDATIONS

EXAMS	
BMI	• Annually at minimum, or more frequently. Assess readiness for change • Assess trajectory to inform treatment considerations and behavior change discussions
Blood pressure	• Check vitals (In Cerner under "Results Review/vitals") for average BP since last visit • If not at goal – Test between visits as clinically indicated while titrating medication • At goal – Check each visit
Comprehensive foot exam and pulses	• At diagnosis and at least annually – All patients • Document in Health Maintenance (Can add a reminder of when next exam is due) • See page 12 for details on Diabetic Foot Care (teach patients to check their feet daily if loss of protective sensation (LOPS) • Monofilament exam by care team member (See Attachment 3)
Dental exam	• Annually – Upon patient request
Retinal Exam	• Optometrist (do most screening at CDCR) or Ophthalmologist: at diagnosis and annually; more frequently if retinopathy develops • Patients with normal eye exam and well controlled DM – may consider exam every 1-2 years • Before pregnancy (or 1st trimester) and then every trimester and for 1 year post-partum • Diabetic Retinopathy (refer to ophthalmology): Optimize glycemic, BP, and lipid control to reduce risk **[A]**
LABS	
A1C	• Not at goal – Check every 90 days (minimum) • At goal – Can be every 180 days (minimum) if stable over several months
Lipid panel	• At initial visit and if not on medication/statin: check every 5 years (or more often if indicated) • If started on lipid medication, check baseline then: 4 – 12 weeks after initiation or change in dose. Annually or more frequently as clinically indicated (monitoring while on a statin is primarily done to confirm adherence unless known ASCVD) • Patients with known ASCVD monitoring at least annually for goal of LDL < 70 mg/dL is recommended (2021 ADA)
B12* (For patients on Metformin)	• If hemoglobin, hematocrit, red cell indices suggestive or symptoms suggestive of anemia, neuropathy, or deteriorating renal function • Consider annual level, as anemia is poor indicator of B12 deficiency • Annual- patients at risk for deficiency such as decreased intake (vegan diets, anorexia) or poor absorption
Urine albumin to Creatinine Ratio (UACR) (previously micro-albuminuria/ proteinuria)	• Annually – All patients (Spot urinary albumin to creatinine ratio) regardless of treatment • Moderately increased albuminuria (previously microalbuminuria) = ≥ 30 mg/g to ≥ 300 mg/g creatinine • Twice a year – If urinary albumin ≥ 300 mg/g creatinine (severely increased albuminuria) or eGFR 30-60 mL/min/1.73m^2 • Cerner order – "Microalbumin, Random Urine with Creatinine"- provides microalbumin concentration in mg/dL and the ratio to creatinine concentration • UACR measures only albumin whereas urine protein to creatinine ratio measures all proteins (globulins, etc.)
Serum Creatinine and Glomerular Filtration Rate (GFR) estimate	• Annually in all patients with albuminuria • See page 11 for GFR Estimation
Potassium	• Annually in all patients with albuminuria, on ACE inhibitors (ACEI), Angiotension II receptor blockers (ARBs), or diuretics

See next page for additional Labs

MONITORING - ADAPTED FROM 2018 ADA RECOMMENDATIONS

LABS (Continued)

FSBS	• If ordered, check/document results at each visit – In Cerner under "Results Review/Vitals" • Act on results, assess need for continued Fingerstick (FS) • Average pre-prandial FSBS goal is 80-130 mg/dL. Average post-prandial (1-2 hours after beginning of meal) goal is < 180 mg/dL. (goals should be individualized) • Do not order if not acting on results. (FS testing is very burdensome to patients & staff) • May not be necessary for Type 2 diabetics who are diet treated or on only oral medications that are not associated with hypoglycemia • Oral medication and basal insulin regimens: Once insulin dose stabilizes, may discontinue or monitor FS much less frequently especially if A1C is at goal • Note: A fasting or pre-meal FS test is of little value if patient has eaten, defer test • Consider a Keep-on-Person (KOP) glucometer if fasting or pre-meal tests are needed but difficult to obtain • See Role of Sliding Scale Insulin on page 13 • Reading CGM Print outs – See Attachment 2
Rule out **latent autoimmune disease in adults** (LADA) (Latent type 1 DM)	• Diagnostic tests for Type 1 DM include: Insulin autoantibodies (IAA), common beta cell antibodies: insulinoma-associated-2/islet cell 512 antibody (IA-2) and glutamic acid decarboxylase (GAD65) autoantibodies- Also: Islet cell cytoplasmic autoantibodies (80% of Type 1 DM) and Zinc Transporter-antibody (ZnT8AB). C-Peptide may not become low or undetectable until most of the beta cells are destroyed. Islet cell antibodies appear well before complete beta cell destruction. The presence of persistent antibodies is highly predictive for Type 1 DM. **Order Quest Diabetes Type 1 antibody panel: TEST CODE 10584** (tests for: IAA, IA-2 and GAD65).

DIAGNOSTICS

Liver ultrasound	• Patients with Pre-DM or DM and elevated liver function tests (LFTs) (evaluate for Non-Alcoholic Steatohepatitis (NASH) and liver fibrosis)

[1] Adapted from: CDC and http://eziz.org/assets/docs/IMM-1152.pdf
[2] ACC/AHA 2019
*Wexler, Metformin in the treatment of adults with type 2 DM, Up to Date Feb 2021

PREVENTIVE CARE

The ACC/AHA has changed the recommended CV risk tool from the older version of the CV Risk Calculator to the new CV Risk Estimator Plus (also available as handy app for phones). This new tool has expanded capability to demonstrate the effect on risk for different interventions and gives advice. This provides well-known and respected AHA patient education and can help when having discussions with patients for shared decision making. A similar tool is the Mayo Clinic Heart Disease Risk Calculator, which has the added benefit of including family history, diet and exercise.

CV SCREENING

10-year Cardiovascular Risk Calculator Low 5-7.5% Intermediate ≥ 7.5 to < 20 High ≥ 20%	• Based on: Age, gender, race, total cholesterol, HDL, LDL, use of statins, systolic and diastolic blood pressure, HTN therapy, aspirin therapy, DM, and smoking. • Online ACC ASCVD risk estimator plus • Consider DM-Specific CV Risk Enhancing Factors[2] for DM Type 2: DM > 10 yrs, albuminuria ≥ 30 mcg, eGFR < 60 mL/min/1.73m^2 retinopathy, neuropathy, Ankle-brachial Index < 0.9 • Consider ACC/AHA General CV Risk Enhancing Factors[2]: See Dyslipidemia Care Guide page 5 • Calculate once per year; result affects management • Coronary artery calcium score when risk unclear (borderline or for example an older person for whom age is the sole driver of the calculated CVD risk, someone reluctant to start statins and wants to understand risk better, intermediate risk adults with risk enhancements but still borderline, etc.) See Dyslipidemia Care Guide page 6

ASA for Primary Prevention	• Consider ASA 81mg in patients 40-70 years with increased CV risk (and not at increased bleeding risk)
	• Retinopathy is not a contraindication to ASA therapy and does not increase risk of retinal hemorrhages
	  • If 10-yr CV risk > 10% (calculate using ASCVD Risk calculator) and/or men > 50 years of age or women > 60 who have at least one additional major risk factor for CVD other than DM (e.g., dyslipidemia, HTN, smoking, albuminuria, family history of premature CVD) after a comprehensive discussion on the benefits versus the risks of bleeding
	  • Clopidogrel 75mg/day should be used for those with ASA allergy

ASA for Secondary Prevention	• Use ASA 81 mg/day in patients with ASCVD if tolerated • Retinopathy is not a contraindication to ASA therapy and does not increase risk of retinal hemorrhages • Dual platelet therapy of 81 mg ASA and clopidogrel for a year after acute coronary syndrome and possibly longer **[A]** • Consider long term dual platelet therapy of 81 mg ASA and clopidogrel in those with history of prior coronary intervention, high ischemic risk and low bleeding risk **[A]**

PREVENTIVE CARE (Continued)

VACCINES

Influenza vaccine	• Annually – Offer and encourage for all patients with DM
COVID-19	• Offer vaccine. Discuss risks and benefits. May need booster. Follow current CDC Advisory committee on Immunization Practices (ACIP) guidelines.
Pneumococcal vaccine[1]	**Age 19-64 with underlying conditions**
	Smoker or chronic conditions* **PPSV 23**
	Immunocompromised** **PCV 13** → **8 weeks** → **PPSV 23** → **5 years** → **PPSV 23** **Q 5 years until 65 yo**
	CSF leaks or cochlear implants **PCV 13** → **8 weeks** → **PPSV 23**
	Chronic conditions* include: heart disease (excluding HTN), lung disease, liver disease, **DM, alcoholism **Immunocompromised conditions include: chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease/hemoglobinopathies.*
	Age 65 and older
	*CCHCS patients may be at higher risk of exposure, consider PCV 13 (shared decision-making) in persons who have not received it before and have at least one of the following conditions: May be exposed to PCV serotypes (areas with low childhood immunization rates), resides in a long-term care facility, smokes or has heart disease [except hypertension], lung disease, liver disease, **DM**, alcoholism, or ≥ one chronic medical condition) or is being paroled to settings with low rates of pediatric immunization with PCV*
For more information see CDC Pneumococcal Vaccine Recs	**Above conditions apply** **First give PCV 13** → **1 year** → **PPSV 23**
	Above condition and rcvd PPSV23 < 65 years **1 year** → **PCV 13** → **1 year after PCV13 and 5 years after prior dose of PPSV23** → **PPSV 23**
	Above condition and rcvd PPSV23 ≥ 65 years **1 year** → **PCV 13**
	General population, NO DM or underlying conditions above **PPSV 23**
	Immunocompromised, CSF leak, or cochlear implant** **PCV 13** → **8 weeks after PCV13 and 5 years after prior dose of PPSV23** **AND** **PPSV 23**
Hepatitis B (HBV) vaccine	• Recommended – 2017 CDC and 2021 ADA: ▸ Offer to all patients age 19-59 years and consider HBV vaccine in patients age > 59 years • ACP Dec 2017: ▸ Vaccinate all unvaccinated adults at risk for infections due to sexual, percutaneous, blood, or mucosal exposure, chronic kidney disease, end stage renal disease, dialysis patients, or HIV infection, or travel to HBV-endemic regions

CCHCS Care Guide: Type 2 Diabetes

DIABETIC NEPHROPATHY MONITORING

MODERATELY INCREASED ALBUMINURIA (previously MICROALBUMINURIA)– False Positives occur - ensure 2 tests over 3 - 6 MONTHS)

- Measure urine albumin excretion annually starting at diagnosis.
- Measure urine albumin twice a year once albuminuria is ≥ 300 mg/g creatinine or eGFR 30-60 mL/min/1.73m^2
- Order "Microalbumin, Random Urine with Creatinine."
  (Order includes microalbumin/creatinine ratio = UACR.
- Normal albuminuria: < 30 mg/day. Normal UACR is also < 30 mg/g creatinine.
- Moderately Increased Albuminuria (microalbuminuria): 30 to < 300 mg/day (UACR 30-300 mg/g creatinine). Start treatment, reduces progression.
- Severely Increased Albuminuria (proteinuria or macroalbuminuria): ≥ 300 mg/day.

TREATMENT OF ALBUMINURIA

DM with normal albumin and normal BP	No treatment indicated. Normotensive primary prevention is NOT recommended.
DM with hypertension and normal albumin	**ACEI or ARB**[1] (discontinue if serum Cr increases > 30% over baseline on initiation)
DM with albuminuria (≥ 30 mg/day) and/or eGFR < 60 mL/min/1.73m^2 and normal BP	**ACEI or ARB**[1] (discontinue if serum Cr increases > 30% over baseline on initiation)

Treatments to reduce albuminuria should not reduce GFR. ACEI or ARB should be discontinued when serum creatinine concentration increases > 30% above the baseline value.**

**Major side effects of angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers. Normal M. Kaplan, M.D. et al. Up-to-Date July 10, 2014.

GLOMERULAR FILTRATION RATE (GFR) ESTIMATION

- **eGFR done *automatically* with Cerner order of: "Creatinine, Creatinine Clearance, BUN/Creatinine ratio, Basic Metabolic Panel or Comprehensive Metabolic Panel" (but NOT with Creatinine – 24 hour urine).**
- Complications of kidney disease correlate with **eGFR** (see table on Stages of CKD below) and albuminuria.

STAGES OF CKD[2]

Stage	Description	GFR (mL/min/1.73m^2)
1	Kidney damage* with normal or increased GFR	≥ 90
2	Kidney damage* with normal or decreased GFR	60-89
3	Moderately decreased GFR	30-59
4	Severely decreased GFR	15-29
5	Kidney failure	< 15 or dialysis

*Kidney damage is defined as abnormalities on pathological, urine, blood, or imaging tests.

MANAGEMENT OF CKD IN DM[1]

See algorithms pages 2-3 for more details on pharmacological treatment of DM and CKD

GFR (mL/min/1.73m^2)	Recommended Management
All diabetic patients	Yearly measurement of creatinine, urinary albumin excretion, potassium
45-60	Referral to a nephrologist recommended for CKD stage 3 or higher
30-44	Monitor estimated GFR (eGFR) every 3 months. Evaluate risk of continuing metformin.
	Monitor electrolytes, bicarbonate, calcium, phosphorus, parathyroid hormone, hemoglobin, albumin, weight every 3-6 months
	Consider the need for adjustment of medication doses due to reduction in renal function
< 30	Referral to a nephrologist. Metformin is contraindicated in patients with eGFR < 30mL/min/1.73m^2

[1]National Kidney Foundation. KDOQI Clinical Practice Guideline for diabetes and CKD: 2012 update and ADA 2021

[2]Adapted from: Levey et al. National Kidney Foundation practice guidelines for chronic kidney disease; evaluation, classification, and stratification. Annuals Internal Medicine 2003; 139: 137-147.

DIABETIC FOOT CARE

HIGH RISK FEET

Risk for ulcers or amputations increased in patients with diabetes with any of the following:

- Previous amputation
- Past foot ulcer/open ulcers
- Peripheral neuropathy/loss of protective sensation (LOPS)
- Foot deformity, Charcot foot
- Peripheral vascular disease
- Smoking
- Poor glycemic control
- Visual impairment
- Diabetic kidney disease, especially if on dialysis
- Pre-ulcerative callouses or corns

Provide diabetic foot care education at least annually for all patients with High Risk Feet.

SUGGESTED FOOT EXAM ELEMENTS

History	• High risk feet conditions from above • Neuropathic symptoms: pain, numbness, tingling, prickling, pins and needles sensation • Vascular symptoms: claudication • Impaired vision • Tobacco use • Foot care practices, shoe wear, advise daily foot checks in LOPS
Inspection	• Skin: focal lesions e.g., calluses, maceration, ulcers, dry skin, tinea pedis • Nails: onychomycotic or dystrophic nails • Deformities: hammer toe, bunion, pes planus or pes cavus
Vascular Exam	• Peripheral arterial disease (PAD) suggested by absence of dorsalis pedis and posterior tibial pulses, dependent rubor, and capillary filling time of > 3 seconds • **Consider Ankle Brachial Index (ABI) in any patient with signs and symptoms of PAD, especially in diabetics > 50 years**
Neurologic Sensory Exam	Test for LOPS using: • **10-g monofilament test** (See Attachment 3) • **And at least one of the following:** ▸ Vibration using 128 Hz tuning fork tested at tip of great toe bilaterally ▸ Pinprick sensation, using a disposable pin applied just proximal to the toenail on dorsal surface of hallux using just enough pressure to deform skin. Inability to perceive pinprick over either hallux is an abnormal test result. ▸ Ankle reflexes One or more abnormal results suggests LOPS At least two normal tests (and no abnormal) rules out LOPS

CONSULTATION, DIABETIC SHOES, AND ORTHOTICS

- Consider consultation and/or authorization of diabetic shoes and/or orthotics for diabetic patients with high risk feet as defined above.
- Also consider consultation with Podiatry for patients with onychomycosis causing deformity of the nail or nail bed.
- Patients with diabetes and a diagnosis of diabetic sensory neuropathy with LOPS should be referred to podiatry for what might ordinarily be considered routine primary or personal care. The following procedures may pose a hazard when performed by a non-trained professional:
  -Cutting or removing corns and calluses
  -Trimming, cutting, clipping or debriding nails

Note: Formulary medical treatment for neuropathic pain: duloxetine (pregabalin and gabapentin non-formulary)

SWITCHING BETWEEN NPH AND INSULIN GLARGINE

NPH to insulin glargine

- NPH once daily: Convert unit-for-unit (1:1) to glargine and give once daily.
- NPH twice daily: Glargine dose should be 80% of total NPH dose and given once daily.

Insulin glargine to NPH

- Convert unit-for-unit from glargine to NPH and give twice daily (e.g., 1/2 AM and 1/2 PM or 2/3 AM and 1/3 PM).

ROLE OF SLIDING SCALE INSULIN (SSI)

OUTPATIENT

National Guidelines - SSI:	Reasons not to use SSI:	Appropriate use:
• 2009: ADA - DO NOT USE for outpatients and stop using long term SSI in DM. • 2008: American Medical Directors Association recommends to AVOID. • 2012: American Geriatrics Society - Beers Criteria Update Expert Panel recommends to AVOID. • 2016: Federal Bureau of Prisons (FBOP) - SSI NOT a recommended strategy for long-term management.	• Nonphysiologic – Reactive to high blood sugar that already occurred and doesn't prevent elevation in future and leads to rollercoaster effect. *(Nalysnyk, Glycaemic variability and complications in patients w DM, 2010)* • Requires patient to become hyperglycemic before treatment given as most SSI start at 180 mg/dL and provider alerts often > 300 mg/dL. *(Konrad, Glycemic control in hospitalized patients not in ICU, beyond SSI, Am Family Physician 2010)* • Greater patient discomfort. • Increased nursing time due to increased monitoring. • Increased nursing time due to increased number of injections administered. • Typical notifications (e.g., < 60 and > 400 mg/dL) may result in periods of hypoglycemia or hyperglycemia without adjustments in therapy. • SSI lends itself to a failure of adjustment: A large medical center retrospective study: 84% of SSI patients with hyperglycemia, only 18% had dose adjustments. *(Golightly, Management of DM in hospitalized patients, Pharmacotherapy 2006)*	• Use short term SSI when titrating insulin, THEN STOP. • May use temporarily when patient is acutely ill, or nothing by mouth for any reason.

INPATIENT

• 2010 American Family Physician Traditional SSI should be abandoned as the sole means of controlling blood sugar in hospitalized patients. • 2016 to 2021: ADA - sole use of sliding scale insulin in the inpatient hospital setting is strongly discouraged. **[A]**	• Patients treated with SSI alone had hyperglycemia > 300 mg/dL three times more often than other regimens. *(Queale, Glycemic control and SSI use in medical inpatients with DM, 1997)* • Basal insulin shown to provide superior glycemic control with less risk of hypoglycemia. *(Maynard, improved inpatient use of basal insulin 2009)*	• Recommended to use basal and basal/prandial insulin as the foundation. Correction Factor insulin is ordered to be given prospectively with prandial insulin if needed and if used frequently, is added to the basal/prandial at previous meal. • Limited use of SSI is occasionally needed on a temporary basis in extremely sick patients.

For FBOP Strategies to Replace SSI, go to the Provider Resource Library on Lifeline: http://lifeline/Pages/Home.aspx ⟶ Select Medical Services on the left⟶Select Provider Resource Library on the right⟶Under What's New⟶Select Diabetes CME Toolkit 2018⟶Go to page 177 of 178.

CCHCS Care Guide: Type 2 Diabetes

ANTIHYPERGLYCEMIC MEDICATION CHARACTERISTICS

Medication Class		CV Effects		Cost	Advantages	Disadvantages	Additional Considerations
		ASCVD	CHF				
Metformin **A1C Reduction: 1.0-2.0%***		Potential Benefit	Neutral	Low	•Extensive experience •Rare hypoglycemia •↓ CVD events • Highly efficacious	•Lactic acidosis risk (rare) • Contraindicated with eGFR >30 mL/min/1,71m^2	•Gastrointestinal side effects common (diarrhea, nausea) •Potential for B12 deficiency • Neutral or benefit on weight
Sulfonylureas (2nd Generation) **-Glipizide (**NOT Glyburide) **A1C Reduction: 1.0-2.0%***		Neutral	Neutral	Low	•Extensive experience •↓ Microvascular risk	•Hypoglycemia	•FDA Special Warning on increased risk of CV mortality based on studies of an older sulfonylurea (tolbutamide)
Thiazolidinediones "Glitazones" **-Pioglitazone** **A1C Reduction: 0.5--1.4%***		**Potential Benefit:** pioglitazone	↑ Risk	Low	•Rare hypoglycemia •Durability • ↓ Triglycerides • ↓ Risk of stroke and MI in patients without diabetes and with Insulin resistance and history of recent stroke or TIA • Benefit in Non-alcoholic fatty liver disease-NASH	•Edema/heart failure •Bone fractures •↑ LDL-C (rosiglitazone) • Weight gain	**•FDA Black Box:** • CHF • Fluid retention (edema; heart failure) • Benefit in Nonalcoholic Fatty Liver Disease • Risk of bone fractures • Bladder cancer (pioglitazone • Generally not recommended in renal impairment, no renal dose adjustment if do use
Insulin **A1C Reduction: 1.5-3.5%***	**Human Insulin**	Neutral	Neutral	Low	• Nearly universal response • ↓ Microvascular risk • Highest efficacy	• Hypoglycemia • Training requirements • Patient and provider reluctance • Injectable (except inhaled insulin) • Pulmonary toxicity (inhaled insulin) • Weight gain	• Injection site reactions • Higher risk of hypoglycemia with human insulin (NPH or premixed formulations) vs. analogs • Lower doses with decrease in eGFR per clinical response
	Analogs			High			
GLP-1 Receptor agonists "Glutides" **-Liraglutide (preferred nonformulary)** **-Exenatide** **-Exenatide ER** **-Aliglutide** **-Dulaglutide** **-Lixisenatide** **A1C Reduction: 0.5-1.0%***		**Benefit:** liraglutide+ dulaglutide+, semaglutide+ Neutral: lixisenatide, exenatide ER	Neutral	High	• Rare hypoglycemia • ↓ Postprandial glucose excursions • ↓ Some cardiovascular risk factors • Weight loss • Benefit on renal end points in (albuminuria) studies: liraglutide, semaglutide, dulaglutide	• ↑ Heart rate • C-cell hyperplasia/ medullary thyroid tumors in animals • Injectable • Training requirements	• **FDA Black Box:** Risk of thyroid C-cell tumors in rodents (liraglutide, aliglutide, dulaglutide, exenatide, exenatide ER) • Gastrointestinal side effects common • Injection site reactions • Pancreatitis reported, uncertain causality. D/C in suspect pancreatitis
DPP-4 Inhibitors "Gliptins" **-Sitagliptin** **-Saxagliptin** **-Linagliptin** **-Alogliptin** **A1C Reduction: 0.5%-0.8%***		Neutral	**Potential Risk:** saxagliptin, aloglipton	High	• Rare hypoglycemia • Neutral on weight loss • Well tolerated • Potential for fluid retention	• Angioedema/urticaria and other immune-mediated dermatological effects • ↑ Heart failure hospitalizations	• Potential risk of acute pancreatitis • Joint pain • Generally not recommended in renal impairment, renal dose adjustment if do use except linagliptin
SGLT2 Inhibitors "Flozins" **-Canagliflozin** **-Empagliflozin (preferred nonformulary)** **-Dapagliflozin** **A1C Reduction: 0.5%-0.7%***		**Benefit:** canagliflozin, empagliflozin, dapagliflozin	**Benefit:** canagliflozin, empagliflozin	High	• Rare hypoglycemia • ↓ blood pressure • Shown benefit in slowing progression of diabetic CKD (canag, empag and dapag-lifflozins)	• Polyuria • Dizziness • ↑ LDL-C • ↑ Creatinine (transient)	• **FDA Black Box:** Risk of amputation (canagliflozin) • Risk of bone fractures (canagliflozin) • DKA risk (all agents, rare in T2DM) • Genitourinary infections • Risk of volume depletion, hypotension. D/C before surgery • ↑ LDL cholesterol • Most require renal adjustment

CVD cardiovascular disease; DKA, diabetic ketoacidosis; DKD diabetic kidney disease; NASH, nonalcoholic steatohepatitis; RAs, receptor agonists; SQ subcutaneous; T2DM, type 2 diabetes.

*A1C Reduction values from McCulloch, Management of persistent hyperglycemia in type 2 diabetes mellitus. Options for Diabetes Table. Summary of glucose-lowering interventions. UptoDate. Mar 2018.

MANAGEMENT OF HYPOGLYCEMIA IN CCHCS

PREVENTION

- Patients who are prone to hypoglycemia should have access to glucose tablets, glucose gel, and/or a diabetic snack.
- Staff members should also have ready access to glucose tablets or the equivalent.
- Patients receiving insulin or oral antihyperglycemic agents may develop hypoglycemia during illness, with greatly increased activity (exercise) level, or decreased food intake. Profound hypoglycemia may develop when meals are delayed or missed.
- Ask about hypoglycemic episodes at each visit, special attention: elderly, in long term care or those with worsening CKD
- Custody staff shall ensure that patients receiving insulin have access to their next scheduled meal within 30 minutes of insulin injections.
- Elderly patients should be monitored for signs of hypoglycemia.
- **Patients must be counseled:**
  - -Regarding the importance of a consistent diet and activity level.
  - -To report for insulin injection prior to eating (fasting) to ensure meaningful FS glucose results.
  - -To report for meals promptly after receiving insulin injections.
  - -To discuss with their provider possible insulin or oral hypoglycemic dosage adjustments during illness.
  - -To tell the RN if the FS is in fact, post prandial so it can be documented with the FSBS.

TREATMENT

Classification of Hypoglycemia	Description	Treatment
Alert Value Level 1 ≤ 70 mg/dL	Conscious with or without symptoms Requires treatment and adjustment of therapy	**Acute phase:** 15-20 grams of glucose preferred. But any form of carbohydrate that contains glucose can be used: • Austin Peanut butter/cheese and crackers pack = 16 carbs and 3g of sugar. • Keebler Graham cracker pack = 11 g carbs and 3g sugars. • Clinic and KOP sugar tablets are 4 g of sugar each. • There is also a 40% dextrose gel which have 22 grams of sugar each. Recheck in 15 minutes, if still < 70 mg/dL, repeat above. Follow with high sugar content snack with low protein and fat*. **Once normoglycemic (BS >80 mg/dl)** – eat meal or snack. Consider bedtime snack if at continued risk.
Level 2 Clinically Significant < 54 mg/dL	Serious and clinically important	Same as above with vigilance for progression to severe.
Level 3 Severe Severe cognitive impairment or unconscious Requires third party assistance	Associated with immediate mortality and 5-year mortality and increases risk for development of dementia	**Glucagon 1** mg IM, IV or subQ (Crash carts carry a 1 mg syringe kit). If fails, use IV Dextrose. **Repeat every 15 minutes** as needed. Administer **IV Dextrose** as soon as it is available (Crash carts carry bags of Dextrose 50% solution) Prolonged monitoring may be required if on long-acting insulin or insulin secretagogues. If unexplained or recurrent severe, on long acting insulin or on insulin with poor oral intake: Admission to a medical unit for observation and stabilization may be indicated. ADA advises to increase glycemic targets for at least several weeks as it has been demonstrated to improve counter-regulation and hypoglycemic awareness.

*Fat may retard and then prolong the acute glycemic response. In type II DM, protein may increase insulin response without increasing plasma glucose concentrations.
Adapted from 2018 ADA Vol 41, Supplement 1, Glycemic Targets, pg S61.

ORAL DM MEDICATIONS

DRUG CLASS / MEDICATION	DOSING	ADVERSE EFFECTS / INTERACTIONS*	COMMENTS
BIGUANIDES			
Metformin (Glucophage®) **Tablet (IR): 500 mg, 850 mg, 1000 mg tabs** $	Initial dose: 500 mg twice daily or 850 mg once daily with meals Titration: After 5-7 days if no GI side effects, increase dose by 500 mg weekly or 850 mg twice daily every other week. (Titrate dose slowly to minimize GI effects) Max dose: Max effective dose may be 1000 mg twice daily, often max effect seen at 850 mg twice daily. Modestly greater efficacy seen with doses up to 2500 mg/day Max dose: 2550 mg/day (Doses > 2000 mg/day better tolerated if given three times daily with meals) Hepatic impairment: Avoid Renal impairment: Contraindicated in eGFR < 30 mL/min. eGFR 31-44 mL/min – Use not recommended. If eGFR < 45 mL/min after initiation - assess benefits and risks of continuing treatment; if eGFR falls < 30 – discontinue	• **Black Box Warning:** Lactic acidosis, rare but potentially serious. Risk increases with degree of renal impairment, CHF or impaired liver function. Discontinue during acute illness or during hunger strikes where dehydration may occur. • Adverse events: Nausea, diarrhea, cramping, flatulence • **May cause vitamin B12 deficiency with anemia and neuropathy which may be confused with diabetic neuropathy** • Modest weight loss may occur • Drug interactions: Iodinated contrast agents	• **Expected A1C reduction: 1.0 - 2.0%** • Contraindications: Patients with factors predisposing to lactic acidosis: Renal insufficiency with eGFR < 30 mL/min • Temporarily discontinue metformin prior to or at time of IV iodinated contrast administration and withhold for 48 hours thereafter. Restart upon confirmation of normal renal function • Suspend therapy for surgical procedures and resume with confirmation of normal renal function • Pregnancy: Category B • Lactation: Enters breast milk, not recommended
SULFONYLUREAS			
Glipizide (Glucotrol®) **Tablet (IR): 5 mg, 10 mg**	Initial dose: 5 mg once daily; 2.5 mg once daily in elderly Titration: Increase dose by 2.5 mg or 5 mg every 1-2 weeks Max dose: 40 mg/day (Doses >15 mg/day should be divided into 2 doses) Hepatic impairment: Initial dose 2.5 mg/day **DO NOT USE GLYBURIDE**	• Adverse events: Hypoglycemia, weight gain, dizziness, nausea, asthenia • Increased risk of hypoglycemia when sulfonylurea used with nonbasal insulin • Stop when on basal with prandial insulin regimens	**Expected A1C reduction: 1.0 - 2.0%** • Glyburide is no longer recommended due to hypoglycemic risk • Best given before a meal, preferably breakfast (if once daily dosing) • Possible cross reaction in those allergic to sulfonamides • Pregnancy: Category C • Lactation: Unknown effect, not recommended • Generally taper or d/c when starting insulin
THIAZOLIDINE-DIONES (TZDs)			
Pioglitazone (Actos®) **Tablet: 15 mg, 30 mg, 45 mg**	Initial dose: 15-30 mg once daily Titration: Increase dose by 15 mg increments Max dose: 45 mg/day Concomitant CYP2C8 inhibitors (e.g., gemfibrozil) or CHF (New York Heart Association [NYHA] class I or II): Max 15 mg/day Hepatic impairment: Moderate or severe: Avoid	• **Black Box Warning: May cause or exacerbate heart failure.** Closely monitor for signs and symptoms of heart failure, especially after initiation or dose increase. If heart failure occurs treat accordingly and consider dose reduction or discontinuation. • Adverse effects: Weight gain, edema, CHF, possible hepatic injury; possible increased risk • Drug interactions: Strong CYP2C8 inhibitors (e.g., gemfibrozil); CYP2C8 inducers (e.g., rifampin)	• **Expected A1C reduction: 0.5 - 1.4%** • Contraindications: Symptomatic CHF; CHF NYHA Class III or IV • Caution: Combination use with insulin in patients with heart failure, and CHF NYHA Class I and II and other edematous states • Monitor LFTs, avoid if ALT > 2.5 times normal before starting therapy, discontinue if ALT > 3 times normal during therapy • If used with insulin, reduce insulin dose by 10 -25% once FBG <120 mg/dl • Reduce dose of sulfonylurea when used with TZDs to minimize hypoglycemia risk • Pregnancy: Category C • Lactation: Unknown effect, not recommended

The cost scale $-$$$$$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.

Bold = Formulary

*See prescribing information for complete description of adverse effects and drug interactions.

ORAL DM MEDICATIONS CONTINUED

MEDICATION	DOSING	ADVERSE EFFECTS / INTERACTIONS*	COMMENTS
SODIUM-GLUCOSE CO-TRANSPORTER 2 (SLGT2) INHIBITORS			
Empagliflozin (Jardiance®) 10 mg and 25 mg oral tablets $$$$$ Nonformulary preferred	Initial dose: 10 mg PO once daily, taken in the morning, with or without food Titration: The dose can be increased to 25 mg PO once daily in those who require additional glycemic control Maximum dosage: 25 mg/day Renal impairment: eGFR ≥ 45 mL/min: No dosage adjustment needed eGFR < 45 mL/min: Do not initiate empagliflozin in these patients. In patients currently taking the drug, empagliflozin should be discontinued when eGFR is persistently < 45 mL/min/1.73 m^2	• Adverse effects: Intravascular volume contraction. Symptomatic hypotension can occur after initiating empagliflozin • Dehydration, hypotension, urinary frequency, urinary tract infections, including urosepsis and pyelophritis, balanitis, vaginitis, endocrinopathies, hypoglycemia, hypercholesterolemia, polydypsia • Patients with pre-existing hypercholesterolemia. Monitor LDL-C. Dose-related increases in LDL • Geriatric patients ≥ 75 years old experienced an ↑ incidence of S/E • Drug interactions: Major: chloroquines; Moderate: **beta blockers**, **amlodipine**, **thiazides, ACEI and ARBs**, estrogens, progestins and androgens, HIV "avir" medications, **atypical antipsychotics, calcium channel blockers, lithium, corticosteroids, loop diuretics**	• **Expected A1C reduction: 0.5% - 0.7%** • Contraindications: Patients with history of serious hypersensitivity reaction to empagliflozin. Patients with severe renal impairment (eGFR less than 30 mL/min), ESRD/dialysis • Cautions: Serious hypersensitivity reactions or anaphylaxis, including angioedema, have been reported in patients receiving empagliflozin • Patients at risk of acute kidney injury, include those with dehydration or hypovolemia, particularly in patients with impaired renal function (i.e., eGFR 45 to 60 mL/min), the elderly, patients receiving diuretics, or patients with low systolic blood pressure. • Use cautiously in patients with a history of genital fungal infection, including vaginitis or balanitis, and in uncircumcised males • Pregnancy: Category C • Lactation: Unknown - not recommended
DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITORS			
Sitagliptin (Januvia®) Tablets: 25 mg, 50mg, 100 mg $$$$$ Nonformulary preferred	Initial and maintenance dose: 100 mg once daily Max dose: 100 mg/day Renal impairment: CrCl 30-49 mL/min: 50 mg daily CrCl < 30 mL/min: 25 mg daily	• Adverse effects: Nasopharyngitis, diarrhea, nausea, abdominal pain • Rare severe hypersensitivity reactions including anaphylaxis, angioedema, exfoliative dermatitis, especially within first three months of therapy • Acute pancreatitis • Severe and disabling arthralgias • Drug interactions: Major: CYP3A4/5 inhibitors	• **Expected A1C reduction: 0.5 - 0.8%** • Assess renal function prior to initiation and periodically thereafter • Reduce dose of sulfonylurea or insulin when used with sitagliptin to minimize hypoglycemia risk • Pregnancy: Category B • Lactation: Unknown effect, use caution

INJECTABLE MEDICATIONS - (INJECTABLE INSULIN MEDICATIONS)

INSULIN CLASS *Please see treatment algorithm on page 3*	SPECIFIC INSULIN	ONSET	PEAK	DURATION	COST
Short-acting*	**Regular– Humulin R®**	30-60 minutes	2 to 4 hours	5 to 10 hours	$$
Intermediate-acting	**NPH—Humulin N®**	1 to 2 hours	4 to 8 hours	10 to 20 hours	$$
Premixed	**NPH/regular—Humulin 70/30®**	30 minutes	Dual peak	Up to 24 hours	$$
Long-acting (basal)	**Glargine—Lantus®** (Not to be mixed with other insulins)	1 to 2 hours	Relatively flat	20 to 24 hours	$$$$
Rapid or Ultra rapid-acting* ***DO NOT USE** - NOT INDICATED IN CORRECTIONAL SETTING PER CCHCS POLICY*. FBOP in general does not use rapid-acting	*Lispro (Humalog)* *Aspart (Novolog)* *Glulisine (Apidra)*	15-30 minutes 10-20 min 20-30 min	30-90 min 40-50 min 30-90 min	3-5 hours 3-5 hours 1 to 1.5 hours	$$$$

*Every effort should be made to administer rapid-acting insulin before meals. However in rare circumstances when patient movement may be disrupted and risk of hypoglycemia is high, rapid acting insulin may be administered shortly after meals.

The cost scale $-$$$$$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.

Bold = Formulary

*See prescribing information for complete description of adverse effects and drug interactions.

INJECTABLE HYPOGLYCEMIC MEDICATIONS - NONINSULINS

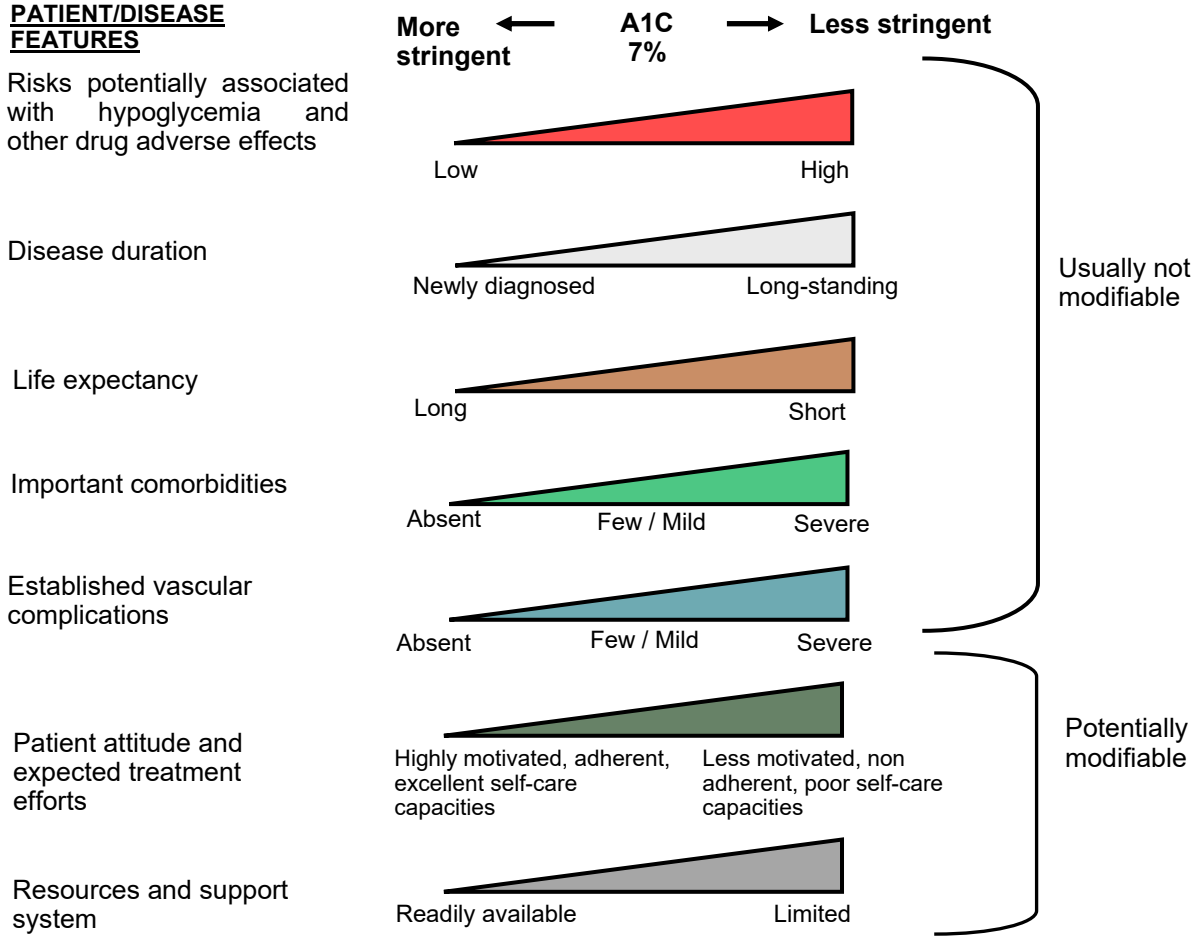
MEDICATION	DOSING	ADVERSE EFFECTS / INTERACTIONS*	COMMENTS
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) AGONIST (INCRETIN MIMETIC)			
Liraglutide (Victoza®) Injection soln: 1 mL, 6 mg $$$$$ Nonformulary preferred	Initial dose: Administer once daily at any time of day, independently of meals. Initially, 0.6 mg subcutaneously once daily for 1 week. The 0.6 mg dose is a starting dose intended to reduce gastrointestinal (GI) symptoms during initial titration and is not effective for glycemic control. Administer by subcutaneous injection only. Do not administer by intravenous or intramuscular injection. Titration: After 1 week, increase the dose to 1.2 mg subcutaneously once daily. If acceptable glycemic control not achieved, the dose can be increased to 1.8 mg subcutaneously once daily. If a dose is missed, resume the once daily regimen as prescribed with the next scheduled dose. If more than 3 days have elapsed since the last dose, reinitiate at 0.6 mg in order to alleviate any GI symptoms associated with re-initiation of treatment. The dose should then be re-titrated appropriately. Max dose: 1.8 mg/day subcutaneously (SC)	• **Black Box Warning:** Liraglutide has been shown to cause dose-dependent and treatment duration-dependent malignant thyroid C-cell tumors at clinically relevant exposures in animal studies at 8 times normal dose. Relevance in humans is not known. • Adverse effects: GI: Slows gastric emptying with resultant nausea, vomiting and diarrhea. Anorexia, dyspepsia, headache, flatulence, constipation, hypoglycemia • Hypoglycemia should be monitored by the patient and clinician when liraglutide treatment is initiated and continued • Fatigue, infections, dizziness, antibody formation, injection site reactions • Severe but less common: Cholecystitis, pancreatitis, AV Block, suicidal ideation, angioedema, anaphylactoid reactions, bronchospasm, palpitations • Drug Interactions: **Major: hydroxyquinalone and chloroquine** • **Moderate: Salicylates**, **Beta Blockers** Acetaminophen, ASA, caffeine, Phenyltoloxamine, lithium Acetazolamide, Aliskiren Valsartan, **Amlodipine, HCTZ**, Androgens, progestins and estrogens, Metoclopramide, **ACE I and ARBs, omeprazole**, **oxycodone, fibric acid derivatives, fluoxetine, Insulins, Sulfanamides, Calcium channel blockers,** Dirunavir**, cyclosporins, Clonidine, Ciprofloxin** • Hypoglycemia was increased when liraglutide was used in combination with a sulfonylurea. Consider lowering sulfonylurea or discontinuing when starting liraglutide • Liraglutide has not been evaluated for use in combination with prandial insulin	• **Expected A1C reduction: 0.5-1.0%** • Contraindications: Patients with a personal or family history of certain types of thyroid cancer, specifically medullary thyroid carcinoma (MTC), or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2). • Patients with a history of serious hypersensitivity reaction to liraglutide • Caution: Patients with a history of angioedema to other GLP-1 receptor agonists. Serious hypersensitivity reactions have been reported during post marketing use with liraglutide, such as anaphylaxis or angioedema • Liraglutide should not be used in patients with Type 1 DM or for the treatment of diabetic ketoacidosis • Use caution in patients with gastroparesis. • There is limited information available on the use of liraglutide in patients with renal impairment • There is limited information available on the use of liraglutide in patients with hepatic disease • Patients with risk factors for pancreatitis (cholelithiasis, gallbladder disease, alcoholism, prior history) • Pregnancy: Category C • Lactation: Unknown effect, use caution • Caution: Patients with depression and avoid use in patients with a history of suicide attempts or active suicidal ideation. Monitor patients receiving liraglutide for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

The cost scale $-$$$$$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.

Bold = Formulary *See prescribing information for complete description of adverse effects and drug interactions.

ATTACHMENT 1

SETTING TARGET FOR GLYCEMIC CONTROL[1]



- This "scale" is not designed to be applied rigidly but to be used as a broad construct to help guide clinical decisions.
- Those with long duration of diabetes, known history of severe hypoglycemia, advanced atherosclerosis, and advanced age/ frailty may benefit from less aggressive targets.
- Providers should be vigilant in preventing severe hypoglycemia in patients with advanced disease and should not aggressively attempt to achieve near-normal A1C levels in patients in whom such targets cannot be safely and reasonably achieved.

[1]Adapted from: Management of Hyperglycemia in Type 2 Diabetes, 2015: A Patient-Centered Approach: Update to a Position Statement of the American Diabetes Association and the European Association for the Study of Diabetes. Silvio E. Inzucchi, Richard, M. Bergenstal, John B. Buse, Michaela Diamant, Ele Ferrannini, Michael Nauck, Anne L. Peters, Apostolos Tsapas, Richard Wender, David R. Matthews. Diabetes Care Jan 2015, 38 (1) 140-149; DOI: 10.2337/dc14-2441.

ATTACHMENT 2

UNDERSTANDING CONTINUOUS GLUCOSE MONITORING (CGM)

CGM devices come in real-time continuous (designed for daily use) and intermittently scanned (minimum scanning once every 8 hours) versions. The ADA[1] states that CGM may be used as an option in DM Type 2 in select patients who can be educated and trained on their use and have the ability to regularly wear the device, monitor, calibrate and verify readings. The ADA states it can be a tool for identifying and correcting patterns of hyper- or hypo- glycemia and for pre-and post-prandial monitoring in pregnancy. The ADA also gives recommendations for consideration of its use to potentially improve glycemic control and/or avoid hypoglycemia, but there are no specific indications or strong evidence-based criteria for patients who may have a benefit over traditional monitoring in Type 2 diabetes.

Given this, CGM are non-formulary and consideration should be advised by an endocrinologist. For CGM use at CDCR, an eRFS and SMART evaluation and approval of the specialist recommendation is also needed.

Understanding CGM Print Outs

Here is an example of the typical CGM Read Out called the Ambulatory Glucose Profile (AGP). The targets are listed for convenience and are: the glucose management indicator (GMI) for glycemic variability (goal ≤ 36%), time in range (goal >70%), time above range (> 180 mg/dL) with a goal of < 25%, and time below target (<70 mg/dL) with a goal of <4%. For more information see the article: Battelino, Clinical targets for continuous glucose monitoring data interpretation, J Diabetes Care 2019. Abstract/FREE Full Text Google Scholar

AGP Report

Name

MRN

GLUCOSE STATISTICS AND TARGETS

	14 days % Sensor Time
Glucose Ranges	**Targets** [% of Readings (Time/Day)]
Target Range 70–180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70–180 mg/dL) is clinically beneficial.

Average Glucose
Glucose Management Indicator (GMI)
Glucose Variability
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

Insulin Pumps

The ADA[1] states that insulin pump therapy may be considered as an option for adults and youth with type 2 diabetes and other forms of diabetes who are on multiple daily injections who are able to safely manage the device (Level of evidence rating: [**B]). There is no consensus to guide choosing which form of insulin administration** is best for a given patient and more research is needed. Nor is their research to aid in the type of pump or settings. Also, reductions in A1c are not consistently seen in people with Type 2 diabetes in studies compared with multiple daily injections. Insulin pumps are most often used with CGM.

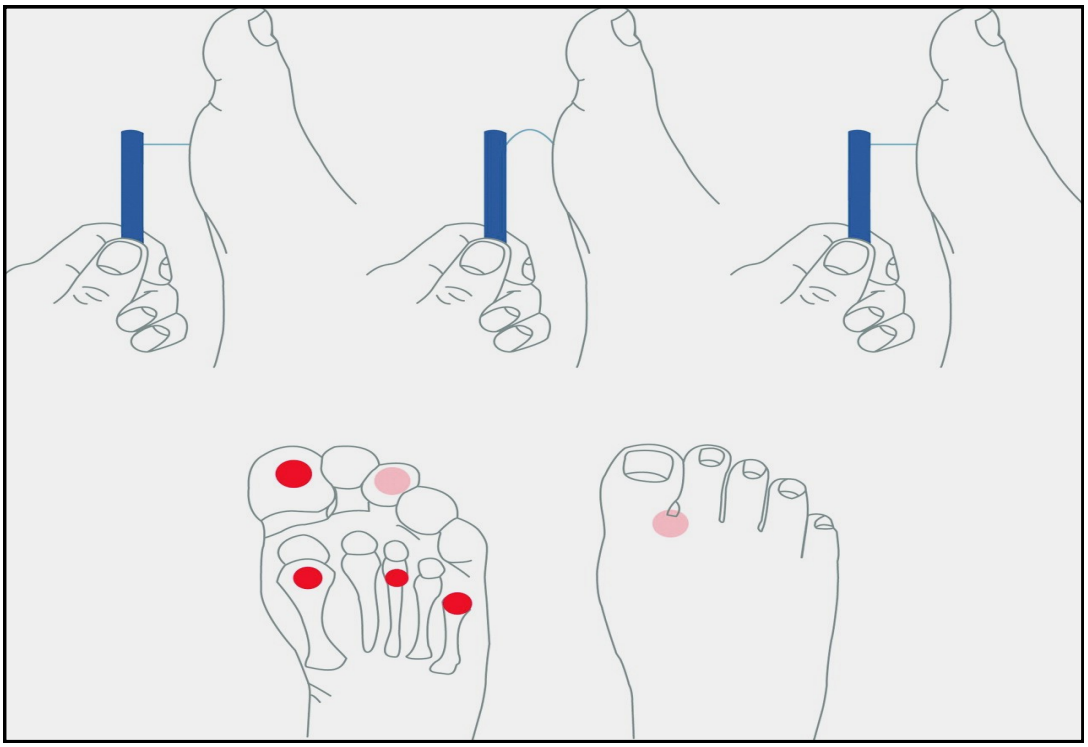
For more in-depth discussion of the research on pumps and CGM and the technology itself, please see the ADA 2021 Diabetes Standards of Care, Chapter 7 on technology.

1American Diabetes Association. 7. Diabetes Technology: Standards of Medical Care in Diabetes– 2021. Diabetes Care 2021; 44 (Supplement 1); S180-S199.

ATTACHMENT 3

MONOFILAMENT TESTING[1]
(SINGLE USE DISPOSABLE MONOFILAMENTS ARE RECOMMENDED)

1. Place patient in supine or sitting position with shoe and socks removed.
2. Touch the disposable monofilament to patient's skin on their arm or hand to demonstrate what the touch feels like.
3. Instruct patient to respond "yes" each time they feels the pressure of the monofilament on their foot during the exam.
4. Instruct patient to close their eyes with toes pointing straight up during the exam.
5. Hold the monofilament perpendicular to the patient's foot (see top panel of diagram below).
6. Press it against the foot, increasing the pressure until the monofilament bends into a C-shape. Do not apply over ulcer, callus, scar, or necrotic tissue. Do not slide monofilament over the skin.
7. Inform the patient you will test each location twice, one touch will be real and one will not. Press the filament to the skin such that it buckles (and hold in place for about 1 second) at one of two times you test each site as you say "time one" or "time two." Have patients identify at which time they were touched.
8. It is recommended to test at least 4 sites on each foot (see lower panel of diagram below: 1st, 3rd, and 5th metatarsal heads and plantar surface of distal hallux, other spots are optional).
9. Randomize the sequence of applying the filament or not throughout the examination.
10. Record response on foot screening form with "+" for yes it was felt and "-" for no. The patient should recognize the perception of pressure and identify the correct site.
11. When the monofilament is not felt, protective sensation is absent, placing the person at high risk for development of a neuropathic ulcer.



Record a "**+**" if the patient can feel the monofilament

Record a "**-**" if the patient is unable to feel the monofilament

[1]Boulton AJM, Armstrong DG, Albert SF, et al. Comprehensive Foot Examination and Risk Assessment: A report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists . *Diabetes Care*. 2008;31(8):1679-1685. doi:10.2337/dc08-9021.

ATTACHMENT 4

DETECTION AND DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS (GDM)[1]

Patients should be screened in the first trimester who have a BMI ≥ 25 kg/m2 and any of the following risk factors:

- Physical inactivity
- First degree relative with DM
- High-risk race/ethnicity (African American, Latino, Native American, Asian American, Pacific Islander)
- Hypertension (BP > 140/90 mmHg or on treatment for Hypertension)
- Hypercholesterolemia
- A1C ≥ 5.5% (36.6 mmol/mol, IGT, IFG on previous testing)
- Delivered a baby weighing > 9 pounds (4.1 kg) or previously diagnosed with GDM
- Clinical conditions associated with insulin resistance (e.g., Acanthosis nigricans, Polycystic Ovarian Syndrome)
- History of CVD
- Smoking

All pregnant patients who were not screened in the first trimester, should be tested for GDM at 24-28 weeks of gestation. **[A]**

Screening and Diagnosis:

1. Perform an 8 hour fasting 75-g oral glucose tolerance test (OGTT) at 24-28 weeks of gestation in women not previously diagnosed with overt DM.

Diagnostic for GDM if:

- ◊ Fasting: 92 mg/dl (a fasting glucose of > 126 is diagnostic of overt DM [Pre-gestational diabetes])
- ◊ 1 h: 180 mg/dl
- ◊ 2 h: 153 mg/dl

2. Two-Step non-fasting 50 g Glucose Load Testing

- ◊ 1 h: if it is ≥ 140 mg/dl, proceed to a fasting 100-g OGTT
- ◊ Diagnostic for GDM if (at least two of the following four):

Fasting	95 mg/dl	105 mg/dl
1 hour	180 mg/dl	190 mg/dl
2 hour	155 mg/dl	165 mg/dl
3 hour	140 mg/dl	145 mg/dl
	Carpenter/Coustan* or	NDDG**

Thresholds vary depending on the organization/authors. The most commonly cited (per Up to Date) are listed here:
*Carpenter MW, Coustan DR. Criteria for screening tests for gestational diabetes. Am J Obstet Gynecol 1982;144:768–773.
**NDDG: National Diabetes Data Group. Classification and diagnosis of diabetes mellitus and other categories of glucose intolerance. Diabetes 1979;28:1039–1057.

DIAGNOSED WITH GDM– WHAT TO DO

REFER to OBSTETRICS. These patients should be followed as high-risk pregnancies; (risks to mother and fetus)

CHECK MEDICATIONS (e.g., ACEIs, statins are teratogenic.) Discharge medications not compatible with pregnancy.

REFER TO DIETITIAN. TREATMENT: Lifestyle change and Insulin

REFER TO OPHTHALMOLOGY/OPTOMETRY—GDM high risk for retinopathy or progression.

1) Retinal eye exams should occur before pregnancy or in the 1st trimester
2) Monitor every trimester and for up to 1 year post-partum as indicated by the degree of retinopathy and recommendations of eye care provider. **[B]**

USE INSULIN for hyperglycemia not controlled with lifestyle. Glycemic control as close to normal as is safely possible, ideally A1C < 6.5%, to reduce the risk of congenital anomalies.* **[B]**

*Uncontrolled glycemia during gestation is associated with miscarriage, stillbirth, preterm labor and delivery, large birthweight and C-Sec, postnatal hypoglycemia, hyperbilirubinemia, neonatal respiratory distress syndrome, anencephaly, microcephaly, spinal cord lesions, congenital heart disease, generic anomalies, and cleft palate.

FUTURE RISKS: GDM carries risk of obesity, HTN, and TYPE 2 DM in mother *and offspring* later in life

[1]American Diabetes Association. 14. Management of diabetes in pregnancy: Standards of Medical Care in Diabetes–2021. Diabetes Care 2021; 41 (Supplement 1); S200-S210.

ATTACHMENT 5

ADA EVIDENCE– GRADING SYSTEM[1]

Level of Evidence	Description
[A]	**Clear evidence** from well-conducted, generalizable randomized controlled trials that are adequately powered, including: • Evidence from a well-conducted multicenter trial • Evidence from a meta-analysis that incorporated quality ratings in the analysis **Compelling nonexperimental evidence**, i.e., "all or none" rule developed by the Centre for Evidence-Based Medicine at the University of Oxford **Supportive Evidence** from well-conducted randomized controlled trials that are adequately powered, including: • Evidence from a well-conducted trial at one or more institutions • Evidence from a meta-analysis that incorporated quality ratings in the analysis
[B]	**Supportive evidence from well-conducted** cohort studies • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies **Supportive evidence** from a well-conducted case control study
[C]	**Supportive evidence from poorly controlled** or uncontrolled studies • Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results • Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls) • Evidence from case series or case reports Conflicting evidence with the weight of evidence supporting the recommendation
[E]	**Expert consensus** or clinical experience

The ADA classification system for grading evidence is used to clarify and codify the evidence that forms the basis for the current recommendations. The ratings of **[A]**, **[B]**, or **[C]** are based on the quality of evidence with **[A]** recommendations having "the best chance of improving outcomes when applied to the population to which they are appropriate." An **[E]** recommendation is a separate category and relies on expert consensus or clinical experience.

[1]Adapted from ADA 2021, "Introduction: Standards of Medical Care in Diabetes, Diabetes Care Volume 44, Supplement 1: S1-S2, Table 1, January 2021.

CCHCS Care Guide: Type 2 Diabetes

PATIENT EDUCATION/SELF MANAGEMENT

DIABETES: WHAT YOU SHOULD KNOW

WHAT IS DIABETES?

Diabetes is a disease that causes high amounts of glucose (sugar) in the blood.
It is caused by the body not making enough insulin or not being able to use the insulin it has.

Diabetes can lead to serious health problems including:

- High blood pressure
- Eye/vision problems
- Kidney disease
- Digestive problems
- Amputation of toes or feet
- Heart attacks
- Strokes
- Nerve damage throughout your body
- Skin problems

SYMPTOMS TO WATCH FOR IF YOU HAVE DIABETES

High blood sugar (hyperglycemia) symptoms

- Thirst
- Frequent urination
- Blurred vision

Low blood sugar (hypoglycemia) symptoms

- Shaky
- Sweating
- Fast Heart beat
- Nausea
- Drowsiness
- Coma
- Hungry
- Headache
- Confusion
- Cranky
- Tired
- Seizures

What are the causes of high blood sugar?

- Too much food
- Too little excercise
- Too little diabetes medicine
- Illness
- Stress

What are the causes of low blood sugar?

- Too little food
- Extra exercise
- Too much diabetes medicine or insulin

What to do if you have symptoms of high blood sugar

- Be sure to drink plenty of water
- Contact your health care team

What to do if you have symptoms of low blood sugar

- Immediately tell someone what is going on.
- If your symptoms are mild you can try to eat or drink something.
- Eat or drink something with sugar in it.
- Contact your health care team if you don't feel better in 15 minutes.

CCHCS Care Guide: Type 2 Diabetes

PATIENT EDUCATION/SELF MANAGEMENT

DIABETES: WHAT YOU SHOULD DO

KNOW THE ABCS OF DIABETES:

A

A1C

- The A1C is a blood test that measures your blood sugar level over the past three months.
- It is different from the blood sugar checks you do from your finger.
- A1C is usually less than 6.5% in people without diabetes. In people with diabetes the goal is an A1C less than 7-8% (your health care provider will tell you what your personal A1C goal should be as the goal is different for different people).

B

Blood pressure

- Blood pressure is the force of your blood against the walls of your blood vessels.
- If your blood pressure gets too high, it makes your heart work too hard.
- High blood pressure can cause a heart attack, kidney disease, or a stroke.
- Your blood pressure should be below 140/90 unless your health care provider tells you a different goal.
- Blood pressure control is important in diabetes. Be sure to have your blood pressure checked at every health care visit.

C

Cholesterol (ko-LESS-tuh-ruhl)

- Cholesterol is a chemical in your blood. LDL is the "bad" cholesterol that can build up and clog your blood vessels, which can cause a heart attack or stroke.
- Most people with diabetes are prescribed medication called "statins" to lower their "bad" cholesterol.
- Your health care provider will check your blood LDL cholesterol level, often once a year, but sometimes less often if you are taking statin medication.

WHAT ELSE SHOULD YOU DO IF YOU HAVE DIABETES?

- Do not smoke.
- Take your medications as directed.
- Control your weight. The best way to maintain a good weight is to eat a healthy diet and exercise more.
  - ► Be active at least 30 minutes on most days. You can walk, jog, or do exercises in your cell, even during lockdowns.
  - ► Eat a healthy diet: limit breads and pastas, canteen-junk foods, candy, and ice cream.
- Try to lower stress levels.
- Check your feet every day for cuts, blisters, red spots, and swelling.
- Report any changes in your vision to your health care provider.
- Be sure to get regular check-ups.
- Talk to health care staff about when you should get lab tests including A1C, and when you should get foot, eye, dental, and EKG exams to monitor your condition.

BENEFITS OF EXERCISE IF YOU HAVE DIABETES

- Weight loss and maintenance of normal weight.
- A stronger, healthier heart.
- Improved sleep.
- Improved mood.
- Improved blood pressure, cholesterol, and blood glucose levels.
- May help lower the amount of medication needed to control your blood sugar.

PATIENT EDUCATION/SELF MANAGEMENT

DIABETES: FOOT CARE

WHY IS FOOT CARE IMPORTANT?

Diabetes can cause you to lose feeling in your feet (feet are numb).

When you have numbness or can't feel your feet, they can get injured, often without you knowing it, from:

- Something that breaks your skin (such as a cut)
- A deep wound (such as stepping on something sharp)
- Walking barefoot on a hot surface
- Constant pressure in one spot (from a tight shoe)

HOW DO I KEEP MY FEET HEALTHY?

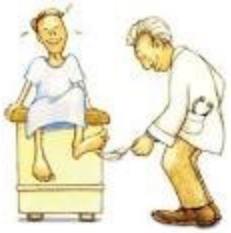
- Check your feet every day.
  - Look for red spots, sores, infected toenails, swelling, cuts, and blisters.
- Wear shoes and socks at all times.
- Wear comfortable shoes that protect your feet and fit well.
- Protect your feet from hot and cold.
- Keep blood flowing to your feet.
  - Put your feet up when sitting.
  - Move your ankles and wiggle your toes throughout the day.
  - Do not cross your legs for long periods of time.

- Wash your feet every day.
  - Dry your feet carefully, especially between the toes.
- Keep the skin of your feet soft and smooth.
  - If you have lotion you can use a thin coat over the tops and bottoms of your feet, but not between your toes.
- Carefully trim your toenails regularly. Ask your health care team for assistance if needed.

- Take care of your diabetes.
  - Work with your health care provider to keep your blood sugar levels in your target range.
- Don't smoke.
- Be more active.

HOW DO I TREAT FOOT PROBLEMS?

- Talk to your health care provider if you have any foot problems.



EDUCACIÓN PARA EL PACIENTE/CONTROL PERSONAL DEL CASO

DIABETES: LO QUE DEBE SABER

¿QUÉ ES LA DIABETES?

La diabetes es una enfermedad que genera altas cantidades de glucosa (azúcar) en la sangre. Es causada cuando el organismo no produce suficiente insulina o no es capaz de usar la que tiene.

La diabetes puede llevar a problemas severos de salud como:

- Presión arterial alta
- Problemas en ojos/visión
- Enfermedades renales
- Problemas digestivos
- Amputación del pie o de sus dedos
- Ataques cardíacos
- Derrames cerebrales
- Daños a los nervios en todo el cuerpo
- Problemas de la piel

SÍNTOMAS QUE DEBE CONTROLAR SI TIENE DIABETES

Síntomas de altos niveles de azúcar en la sangre (hiperglicemia)

- Sed
- Micción frecuente
- Visión borrosa

Síntomas de bajos niveles de azúcar en la sangre (hipoglicemia)

- Tembloroso
- Transpiración
- Latidos cardíacos acelerados
- Náuseas
- Somnolencia
- Coma
- Hambre
- Dolor de cabeza
- Confusión
- De mal humor
- Cansado
- Convulsiones

¿Cuáles son las causas de los altos niveles de azúcar en la sangre?

- Demasiada comida
- Muy poco ejercicio
- Poco medicamento para la diabetes
- Enfermedad
- Estrés

¿Cuáles son las causas de los bajos niveles de azúcar en la sangre?

- Muy poca comida
- Ejercicio extra
- Demasiado medicamento para la diabetes o insulina

Lo que debe hacer cuando hay síntomas de altos niveles de azúcar en la sangre

- Asegúrese de tomar mucha agua
- Comuníquese con su elenco tratante

Lo que debe hacer cuando hay síntomas de bajos niveles de azúcar en la sangre

- Immediamente dile a alguien lo que está pasando.
- Si sus síntomas son leves, puede intentar comer o beber algo.
- Coma o beba algo que contenga azúcar.
- Comuníquese con su elenco tratante si no se siente mejor en los siguientes 15 minutos.

EDUCACIÓN PARA EL PACIENTE/CONTROL PERSONAL DEL CASO

DIABETES: LO QUE DEBE HACER

CONOZCA LOS PUNTOS IMPORTANTES DE LA DIABETES:

1

A1C

- La A1C es una prueba sanguínea que mide su nivel de azúcar en la sangre en los tres meses anteriores.
- Es diferente de las pruebas de azúcar en la sangre de su dedo.
- La A1C es, normalmente, inferior a 6.5% en las personas sin diabetes. En las personas con diabetes, la meta es un A1C inferior al 7-8% (su elenco tratante le dirá cual debería ser su meta A1C personal, ya que esta meta es diferente para cada persona).

2

Presión arterial

- La presión arterial es la fuerza de su sangre contra las paredes de sus vasos sanguíneos.
- Si su presión arterial se eleva mucho, hace trabajar demasiado a su corazón.
- La presión arterial alta puede causar un ataque cardíaco, enfermedad renal o un derrame cerebral.
- Su presión arterial debería ser menor de 140/90 a menos que su médico le indique otra meta a alcanzar.
- El control de la presión arterial es importante en la diabetes. Asegúrese de hacerse revisar su presión arterial en cada consulta médica.

3

Colesterol

- El colesterol es una sustancia química en su sangre. LDL es el colesterol "malo" que puede acumularse y obstruir sus vasos sanguíneos, lo que puede causar un ataque cardíaco o un derrame cerebral.
- A la mayoría de las personas con diabetes se les prescribe medicamentos llamados "estatinas" para reducir su colesterol "malo."
- Su médico controlará su nivel de colesterol LDL en la sangre, frecuentemente una vez al año, pero a veces con menos frecuencia si está tomando estatinas.

¿QUÉ MÁS DEBERÍA HACER SI TIENE DIABETES?

- No fume.
- Tome sus medicamentos tal como le sean prescritos.
- Controle su peso. La mejor manera de mantener un buen peso es llevar una dieta sana y ejercitarse más.
  - ► Haga alguna actividad al menos 30 minutos la mayoría de los días. Puede caminar, trotar o hacer ejercicio en su celda, aún durante un encierro institucional.
  - ► Lleve una dieta sana: limite los panes y pastas, las comidas chatarra compradas en la cantina, golosinas y helados.

- Intente reducir sus niveles de estrés.
- Revise sus pies diariamente; busque cortadas, ampollas, puntos rojos e inflamación.
- Informe a su médico cualquier cambio en su visión.
- Asegúrese de tener chequeos médicos regulares.
- Hable con el personal médico para saber cuándo debe hacerse pruebas de laboratorio, incluyendo la A1C, y cuándo debe recibir exámenes de los pies, los ojos, los dientes, y un electrocardiograma para controlar su condición.

BENEFICIOS DEL EJERCICIO SI TIENE DIABETES

- Pérdida de peso y mantenimiento de un peso normal.
- Un corazón más fuerte y sano.
- Un sueño mejorado.
- Un estado de ánimo mejorado.
- Una presión arterial mejorada, además de niveles de colesterol y glucosa en la sangre mejorados.
- Podría ayudar a reducir la cantidad de medicamentos necesarios para controlar el azúcar en la sangre.

EDUCACIÓN PARA EL PACIENTE/CONTROL PERSONAL DEL CASO

DIABETES: CUIDADO DE LOS PIES

¿POR QUÉ ES IMPORTANTE EL CUIDADO DE LOS PIES?

La diabetes puede hacer que pierda sensación en sus pies (los pies se entumecen).

Cuando tiene entumecimiento o no puede sentir sus pies, estos se pueden herir y frecuentemente sin que usted se dé cuenta, por:

- Algo que le rompa la piel (como una cortada)
- Una herida profunda (como cuando pisa algo puntiagudo)
- Caminar descalzo sobre una superficie caliente
- Presión constante en algún punto determinado (por un calzado apretado)

¿CÓMO MANTENGO MIS PIES SANOS?

- Revise sus pies diariamente.
  - Busque puntos rojos, llagas, uñas infectadas, inflamación, cortadas y ampollas.
- Siempre use zapatos y calcetines.
- Use zapatos cómodos que protejan sus pies y calcen bien.
- Proteja sus pies del calor y del frío.
- Mantenga la sangre circulando a sus pies.
  - Levante los pies mientras esté sentado.
  - Mueva sus tobillos y los dedos de los pies durante el curso del día.
  - No mantenga sus piernas cruzadas durante largos periodos de tiempo.
- Lave sus pies todos los días.
  - Seque sus pies con cuidado, especialmente entre los dedos.
- Mantenga la piel de sus pies suave y terso.
  - Si tiene loción puede usar una capa delgada sobre las partes superiores e inferiores de sus pies, pero no entre los dedos.
- Con cuidado, córtese las uñas de los dedos de los pies regularmente. Pida ayuda a su elenco tratante de ser necesario.

- Atienda su diabetes.
  - Trabaje con su médico para mantener sus niveles de azúcar en la sangre dentro del rango establecido como meta.
- No fume.
- Realice más actividades.

¿CÓMO TRATO LOS PROBLEMAS DE LOS PIES?

- Hable con su médico si tiene algún problema con los pies.