Navigating Insulin Management & CGM Technology

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Disclosure

Dr. Fiori has no relevant financial relationship(s) with ineligible companies to disclose.

None of the planners for this educational activity have relevant financial relationship(s) to disclose with ineligible companies whose primary business is marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Overview of Content



Provide a comprehensive overview of insulin therapy based on 2024 American Diabetes Association (ADA) guidelines, including different types of insulin, administration methods, and dosage adjustments

Explore the use of continuous glucose monitoring (CGM) technology in diabetes management



Discuss strategies for integrating insulin therapy with CGM to optimize blood glucose control and improve quality of life for individuals with diabetes

2024 ADA Standards of Care – T1DM

Treat most adults with continuous SQ insulin infusion or multiple daily doses of prandial and basal insulin Early use of CGM is recommended for adults with T1DM to improve glycemic outcomes and minimize hypoglycemia

Automated insulin delivery systems should be considered

Glucagon should be prescribed

Evaluate treatment plan and insulin-taking behavior at regular intervals



As of June 2023

Based upon the recent FDA approval of **teplizumab**, an agent indicated for delaying the onset of symptomatic (stage 3) **type 1 diabetes**, updated recommendations have been made for type 1 diabetes screening diagnostic criteria and delaying of type 1 diabetes:

- Screening for presymptomatic type 1 diabetes (stage 1 or 2) can be achieved by testing positive for the presence of multiple islet autoantibodies
- Individuals who test positive for stage 2 presymptomatic type 1 diabetes, which is diagnosed by the presence of multiple islet autoantibodies plus dysglycemia should be considered for treatment to delay onset of stage 3 (symptomatic) type 1 diabetes (e.g, teplizumab if indicated and appropriate)
- Teplizumab is indicated in individuals aged ≥8 years with stage 2 type 1 diabetes to delay onset of stage 3 (symptomatic) type 1 diabetes

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

HEALTHY LIFESTYLE BEHAVIORS; DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT (DSMES); SOCIAL DETERMINANTS OF HEALTH (SDOH)

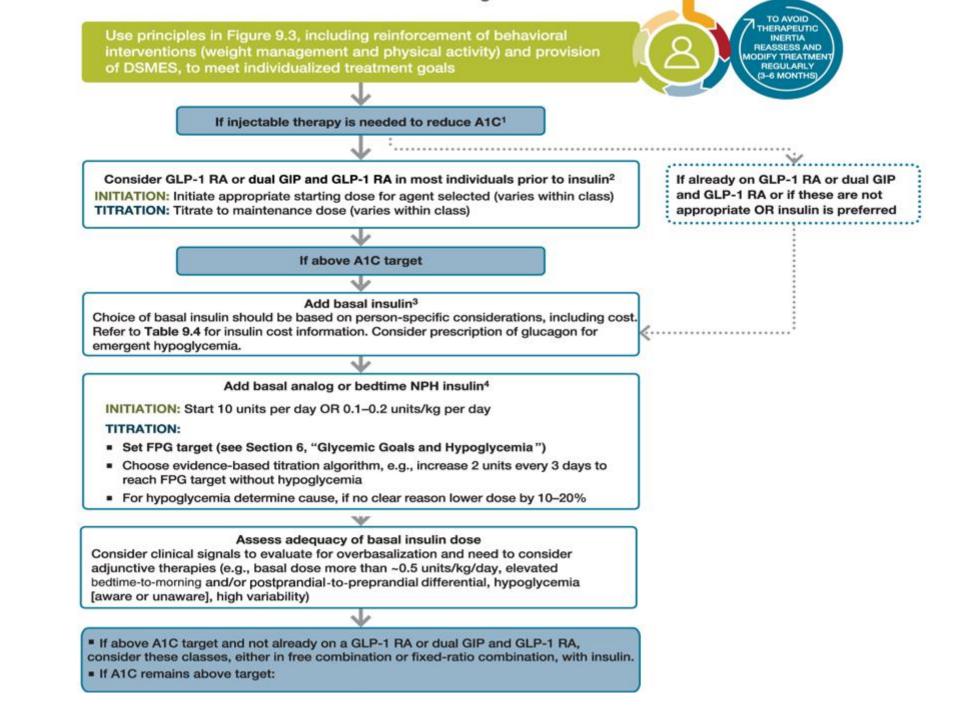


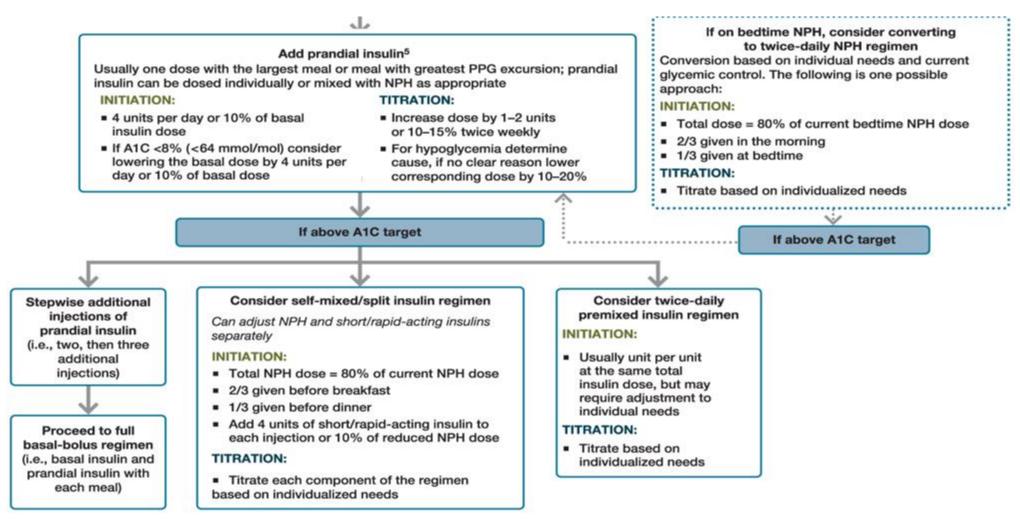
Goal: Cardiorenal Risk Reduction in High-Risk Patients with Type 2 Diabetes (in addition to comprehensive CV risk management)* **Goal: Achievement and Maintenance of Glycemic and Weight Management Goals** +Indicators of high risk +ASCVD[†] +HF +CKD Achievement and Maintenance of **Glycemic Management: Choose** Weight Management Goals: While definitions vary, most eGFR <60 mL/min per 1.73 m² OR Defined differently across approaches that provide the Current or prior albuminuria (ACR ≥3.0 mg/mmol CVOTs but all included comprise ≥55 years of age efficacy to achieve goals: symptoms Set individualized weight management goals individuals with established [30 mg/g]). These measurements with two or more additional of HF with Metformin OR Agent(s) including risk factors (including obesity may vary over time; thus, a repeat CVD (e.g., MI, stroke, any documented **COMBINATION** therapy that provide revascularization procedure) HFrEF or HFpEF measure is required to document CKD General lifestyle advice: Intensive evidencehypertension, smoking, adequate EFFICACY to achieve dyslipidemia, or albuminuria) Variably included: conditions medical nutrition based structured and maintain treatment goals therapy/eating patterns/ weight management such as transient ischemic Consider avoidance of hypoglycemia a physical activity program attack, unstable angina, +CKD (on maximally tolerated dose priority in high-risk individuals amputation, symptomatic of ACEi/ARB) or asymptomatic coronary +HF Consider medication **Consider metabolic** artery disease for weight loss surgery PREFERABLY In general, higher efficacy approaches SGLT2i[§] have greater likelihood of achieving SGLT2i[§] with primary evidence of with proven glycemic goals When choosing glucose-lowering therapies: **HF** benefit reducing CKD progression +ASCVD/Indicators of High Risk Efficacy for glucose lowering Consider regimen with high-to-very-high dual in this Use SGLT2i in people with an eGFR glucose and weight efficacy Very High: ≥20 mL/min per 1.73 m²; once initiated population Dulaglutide (high dose), EITHER/ should be continued until initiation GLP-1 RA[#] with proven SGLT2i[§] with proven of dialysis or transplantation Semaglutide, Tirzepatide OR **CVD** benefit **CVD** benefit - - - - - OR - - - - - -Efficacy for weight loss Insulin GLP-1 RA with proven CVD benefit if Very High: **Combination Oral. Combination** SGLT2i not tolerated or contraindicated Semaglutide, Tirzepatide Injectable (GLP-1 RA/Insulin) If A1C above target High: High: Dulaglutide, Liraglutide GLP-1 RA (not listed above), Metformin, If A1C above target, for patients on SGLT2i, Sulfonylurea, TZD Intermediate: SGLT2i, consider incorporating a For patients on a GLP-1 RA, consider adding SGLT2i with GLP-1 RA (not listed above). SGLT2i GLP-1 RA or vice versa Intermediate: proven CVD benefit or vice versa DPP-4i Neutral: TZD^ DPP-4i, Metformin If additional cardiorenal risk reduction or glycemic lowering needed If A1C above target

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

Identify barriers to goals:

- · Consider DSMES referral to support self-efficacy in achievement of goals
- Consider technology (e.g., diagnostic CGM) to identify therapeutic gaps and tailor therapy
- Identify and address SDOH that impact achievement of goals





- 1. Consider insulin as the first injectable if evidence of ongoing catabolism is present, symptoms of hyperglycemia are present, when A1C or blood glucose levels are very high (i.e., A1C >10% [>86 mmol/mol] or blood glucose ≥300 mg/dL [≥16.7 mmol/L]), or when a diagnosis of type 1 diabetes is a possibility.
- 2. When selecting GLP-1 RAs, consider individual preference, A1C lowering, weight-lowering effect, or frequency of injection. If CVO is present. consider GLP-1 RA with proven CVO benefit. Oral or injectable GLP-1 RAs are appropriate.
- 3. For people on GLP-1 RA and basal Insulin combination, consider use of a flxed-ratio combination product (IDegLira or iGlarLixi).
- 4. Consider switching from evening NPH to a basal analog if the individual develops hypoglycemia and/or frequently forgets to administer NPH in the evening and would be better managed wtth an A.M. dose of a long-acting basal Insulin.
- 5. If adding prandial insulin to NPH, consider initiation of a self-mixed or premixed insulin plan to decrease the number of injections required.

Type 2 Diabetes Drug Class Comparison

T2DM Drug Class	ద్ద [ి] ం Mechanism	Q Route	A1C Lowering*	Hypoglycemia Risk	Weight Effect*	\$ Cost
Biguanides (metformin)	Decreases hepatic production of glucose; increases insulin sensitivity	Oral	•••	No	Potential for weight loss	\$
SGLT2 inhibitors	Increases urinary glucose excretion	Oral	••	No	Weight loss	\$\$\$
GLP-1 receptor agonists	Increases glucose-dependent insulin release; decreases glucagon secretion; slows gastric emptying	SQ/Oral	••••"	No	Weight loss**	\$\$\$\$
GLP-1/GIP receptor agonists (e.g. tirzepatide)	Increases glucose-dependent insulin release; decreases glucagon secretion; slows gastric emptying	SQ	••••	No	Weight loss	\$\$\$\$\$
DPP-4 inhibitors	Increases glucose-dependent insulin release; decreases glucagon secretion	Oral	•	No	Neutral	\$\$\$
Thiazolidinediones	Increases insulin sensitivity in muscle, fat and liver cells; increases glucose entry into cells	Oral	••	No	Weight gain	\$^
Sulfonylureas	Stimulates insulin secretion from pancreatic beta cells	Oral	•••	Yes	Weight gain	\$
Insulin Analogs	Stimulates peripheral glucose uptake	SQ				\$\$\$
Human Insulin	by skeletal muscle and fat tissue; inhibits hepatic glucose production	SQ/Inhaled	Titrate to response	Yes	Weight gain	\$
○pyrls	Mo	re clinical pearls at	pyris.com	● 20;	23 Cosmas Health, Inc. and/or	its affiliates

SQ = subcutaneous

*The extent of A1C lowering and weight change is highly variable based upon factors including but not limited to baseline A1C, baseline weight, patient-specific characteristics, lifestyle modifications, and whether monotherapy or a multi-drug regimen is being utilized.

**The GLP-1 receptor agonists dulaglutide and subcutaneous semaglutide have notably greater A1C-lowering efficacy and weight loss effects than other GLP-1 receptor agonists.

^Pioglitazone is generic and has low cost; however, rosiglitazone (Avandia®), which is currently unavailable in the U.S., is not available as a generic.

References: ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: Standards of Care in Diabetes—2023. Diabetes Care 2023;46(Suppl. 1):S140–S157. Individual product manufacturer prescribing information.

Choice of Insulin Regimen in T1DM

Representative relative attributes of insulin delivery approaches in people with type 1 diabetes¹

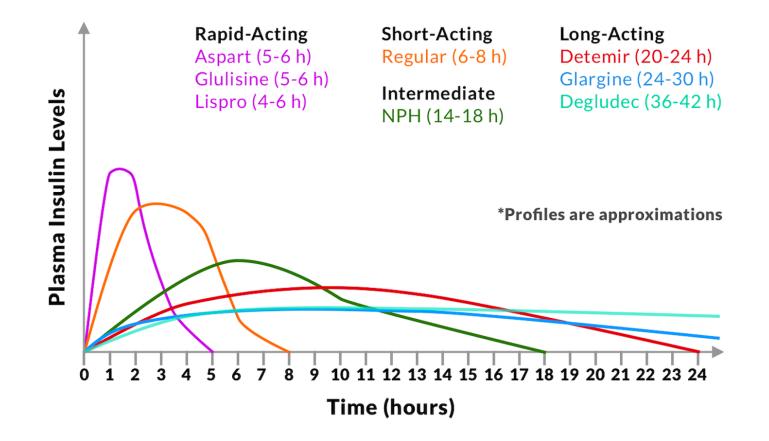
Injected insulin plans	Greater flexibility	Lower risk of hypoglycemia	Higher costs
MDI with LAA + RAA or URAA	+++	+++	+++

Less-preferred, alternative injected insulin plans

MDI with NPH + RAA or URAA	++	++	++
MDI with NPH + short-acting (regular) insulin	++	+	+
Two daily injections with NPH + short-acting (regular) insulin or premixed	+	+	+

Continuous insulin infusion plans	Greater flexibility	Lower risk of hypoglycemia	Higher costs
Automated Insulin delivery systems	+++++	+++++	+++++
Insulin pump with threshold/ predictive low-glucose suspend	++++	++++	+++++
Insulin pump therapy without automation	+++	+++	++++

Insulin Classes and Action Profiles



Adapted and referenced from: Hirsch IB. Insulin analogues. N Engl J Med. 2005 Jan 13;352(2):174-83. https://www.ncbi.nlm.nih.gov/pubmed/15647580 and individual product labels.

Initiating insulin for T1DM

Use an empiric dose (best "estimate" based on actual body weight)

Initial 0.5-0.7 units/kg/day [Total Daily Dose (TDD)]

May drop to 0.2-0.5 units/kg/day during "honeymoon period" as glucose toxicity resolves
May increase to 1-1.5 units/kg/day during illness or growth

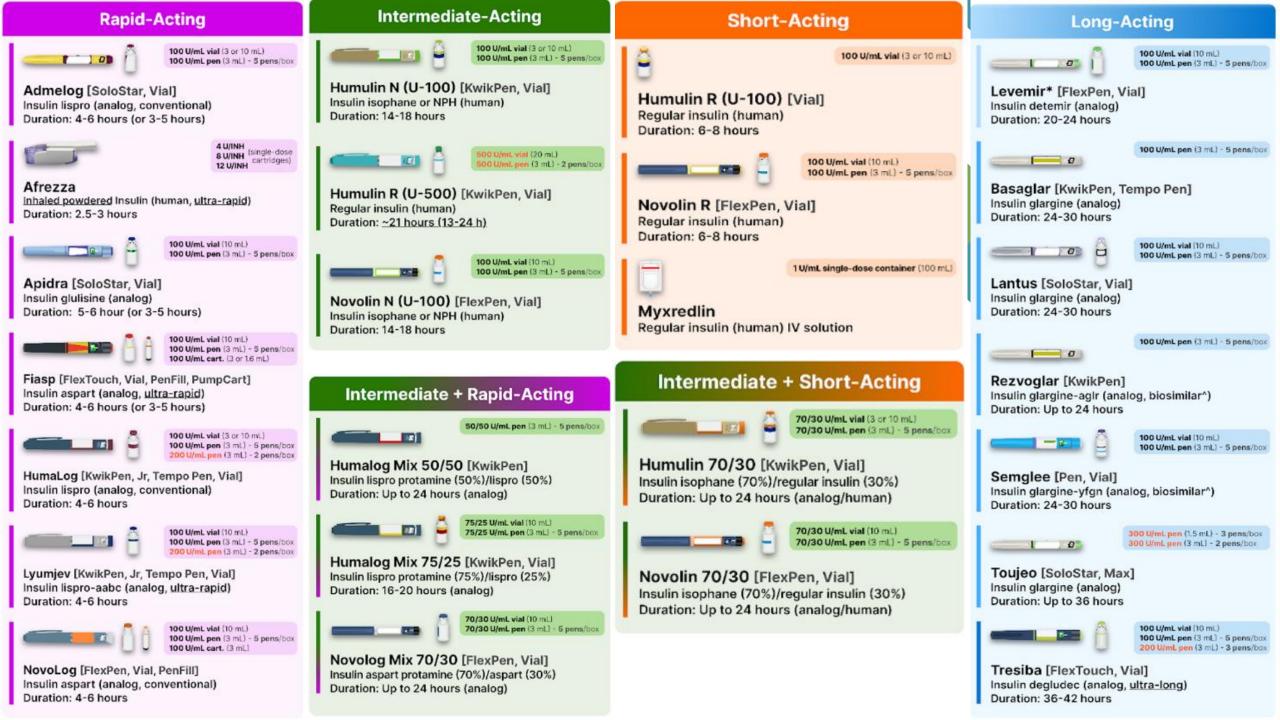
0.5 units/kg/day TDD

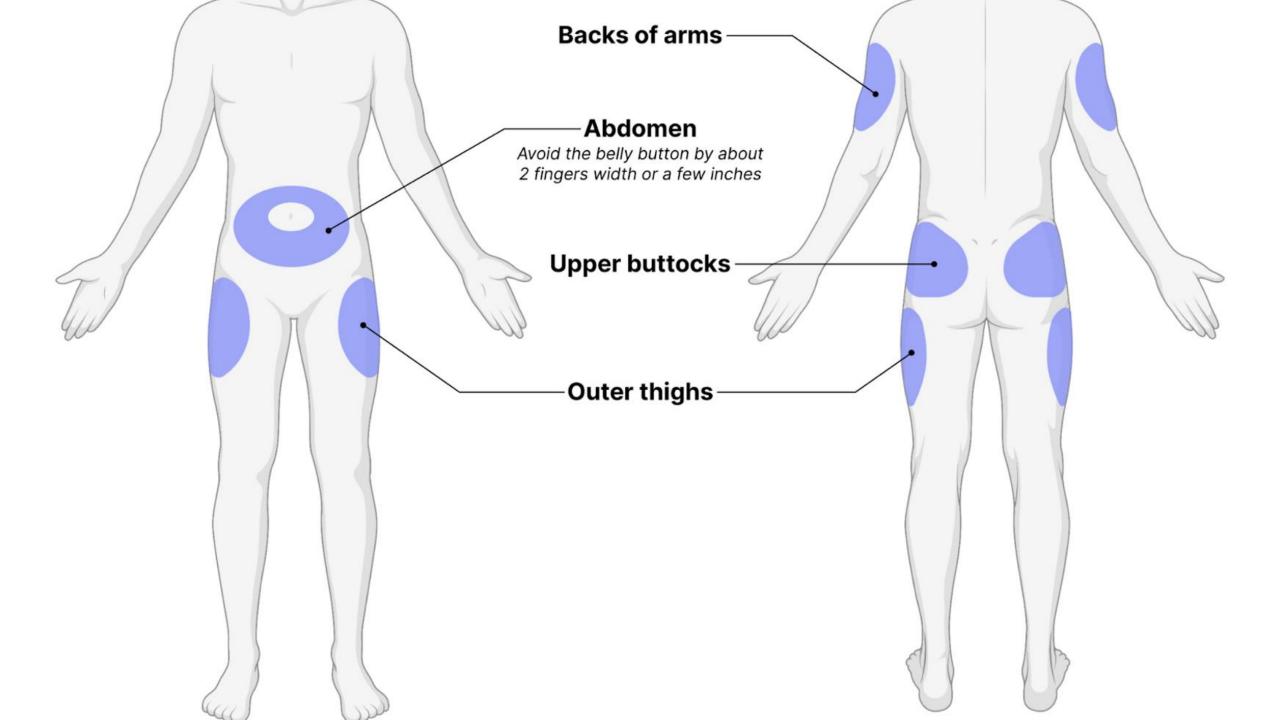
Since individuals with type 1 diabetes need a regimen of BASAL and BOLUS insulin, the TDD needs to be split. Usually start with a **Basal-to-Bolus ratio of 50:50**.

Insulin Products

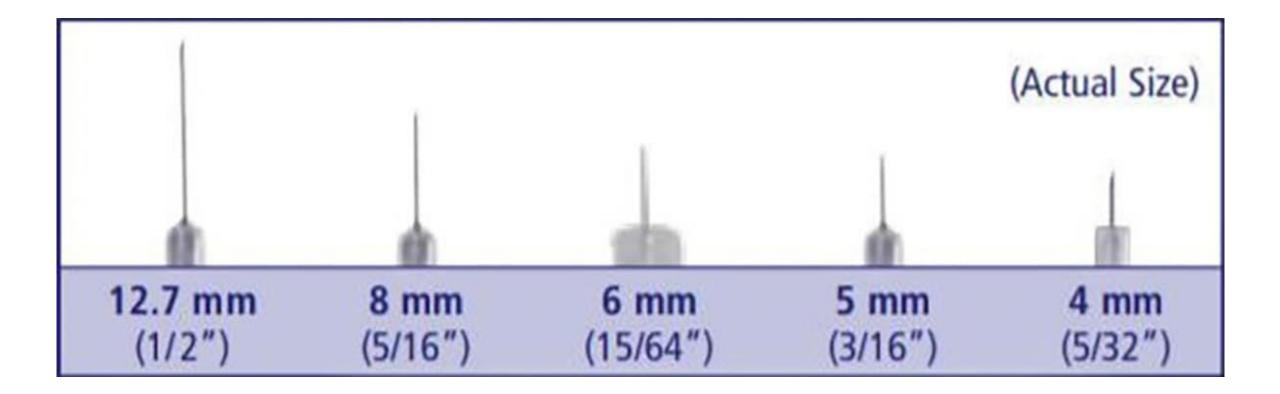
The following image was obtained from Pyrls. Funders of pharmaceutical entities were not involved.

The purpose of this image is to educate the audience and is not intended as marketing. It is a fair and balanced image representing all products equally.



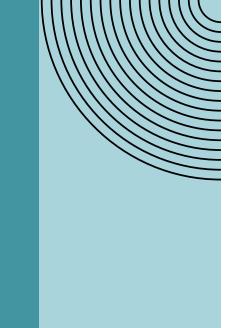


Insulin Pen Needles Lengths



Insulin Pen Needle Gauges

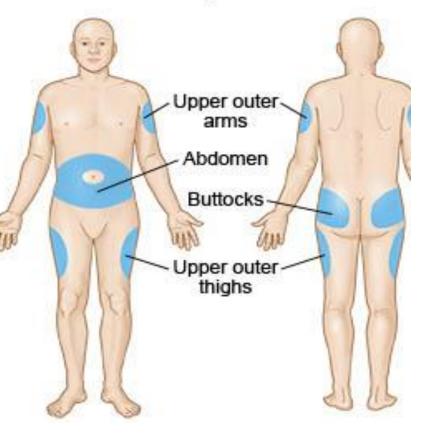


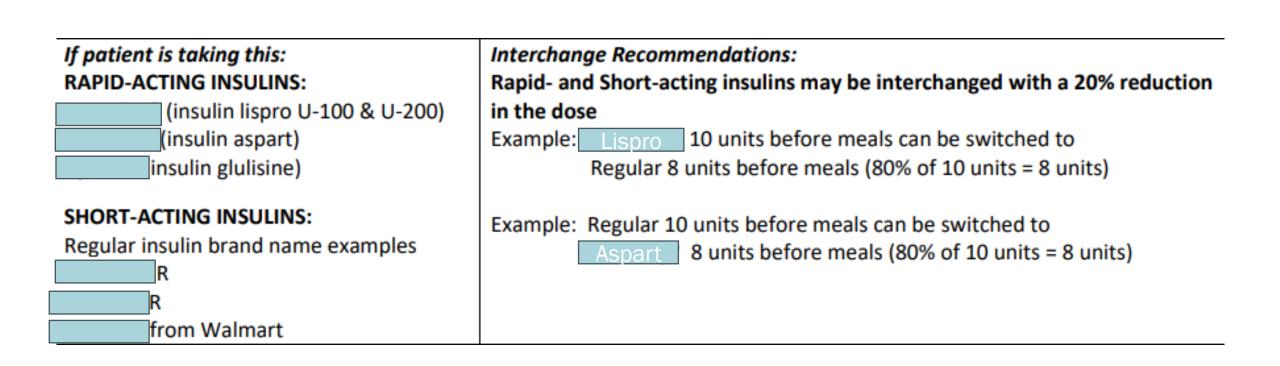


Injecting insulin

- Shortest, thinnest needles available for comfort
 - Using short needles also reduces the risk of reaching muscle
 - Glucose control with 4 mm needle is comparable to loner needles regardless of BMI, age, etc.
- Pen needles- 4 mm; syringe needles- 6 mm
- Pinch a skinfold with 6 mm or longer needles
- Syringes: 30 units (3/10 mL), 50 units (1/2 mL), and 100 unit (1 mL)







If patient is taking this: INTERMEDIATE-ACTING INSULINS:

NPH insulin brand name examples N N NPH from Walmart

Interchange Recommendations:

Intermediate-acting insulins may be interchanged with another intermediate-acting insulin or Basal insulin analog with a 20% reduction in dose

NPH ONCE daily to a Basal insulin analog

Example: NPH 20 units daily can be switched to glargine 16 units daily

NPH TWICE daily to a Basal insulin analog

 Add all the units of NPH injected per day and give 80% as a single dose of a Basal insulin analog daily

Example: NPH 34 units AM and 16 units PM can be switched to

Glargine 40 units daily (80% of 50 units daily = 40 units)

If a patient is taking this: BASAL INSULIN ANALOGS:

detemir) Basalgar[®] (glargine U-100) (glargine U-300) (degludec U-100 & U-200)

Interchange Recommendations:

Basal insulin analogs may be interchanged with NPH with a 20% reduction

in dose and divided based on predicted meal frequency

 if eating 2 meals per day- Split the new dose into ½ NPH with first meal of the day and ½ NPH with second meal of the day

Basal insulin analogs (with the exception of ______) may be interchanged with another Basal insulin analog with a 20% reduction in dose

(80 units or less) may be interchanged with another Basal insulin analog with a 20% reduction in dose

(greater than 80 units) may be interchanged with another Basal insulin analog with a 20% reduction in dose, but the other Basal insulin must be split into two equal doses given 12 hours apart.

40 units (80%

Example 100 units daily can be switched to

of 100 units = 80 units/2) every 12 hours

If patient is taking this:

PREMIXED INSULINS with Regular insulin

NPH/Regular	
70/30	

PREMIXED INSULINS with rapid-acting

insulin



PREMIXED INSULIN with rapid- and ultra-

long acting insulins

70/30 (degludec/aspart)

Interchange Recommendations:

Regular and Rapid-acting PREMIXED insulins may be interchanged with another PREMIXED insulin with a 20% reduction in the dose

- Insulin mixes containing a rapid-acting insulin should be injected <u>no</u> <u>more</u> than 15 minutes before the start of a meal
- Insulin mixes containing Regular insulin can be injected up to 30 minutes before the start of a meal
- PREMIXED insulin may be interchanged with to NPH using a 20% reduction in dose

Insulin Coverage

Affordable Insulin Now Act – caps out-of-pocket cost of insulin to \$35

MaineCare preferred agents include:

- Glargine, detemir (phasing out of production beginning April 1) long-acting
- Aspart, lispro rapid-acting



Hypoglycemia

Table 6.3—Classification of hypoglycemia (44)			
Level	Glycemic criteria/description		
Level 1	Glucose <70 mg/dL (3.9 mmol/L) and glucose ≥54 mg/dL (3.0 mmol/L)		
Level 2	Glucose <54 mg/dL (3.0 mmol/L)		
Level 3	A severe event characterized by altered mental and/or physical status requiring assistance		

Hypoglycemia

Signs and Symptoms

- Mild: excessive hunger, palpitations, sweating, tremors
- Moderate: confusion, decreased attentiveness, drowsiness, headache, irritability, mood changes
- Severe: combativeness, seizures, unconsciousness, unresponsiveness

Hypoglycemia unawareness

- Fail to recognize normal warning symptoms of hypoglycemia
- Develop dangerously low glucose levels (<54 mg/dL) without experiencing any symptoms

The Rule of 15

Mild to Moderate Hypoglycemia Treatment

- Check blood sugar
- Prompt ingestion of 15-20 g of simple carbohydrate
 - 4 oz (1/2 cup) of regular fruit juice (e.g., orange, apple, or grape juice)
 - 4 oz (1/2 cup) of regular soda pop (not diet)
 - 8 oz (1 cup) fat-free milk
 - 1 Tbsp or 3 cubes sugar
 - 3-4 glucose tablets
 - 5-6 pieces lifesaver candies
- Wait 15 min and then check blood sugar again. If it is still low, repeat the same steps above.
- Once blood sugar returns to normal, eat a meal or snack containing a carbohydrate AND protein (e.g., crackers and peanut butter, piece of fruit and cheese, a small protein containing sandwich) to prevent further hypoglycemia



Glucagon is a hormone made by the pancreas to help regulate blood glucose, preventing it from dropping too low (in contrast to the hormone insulin, which reduces blood glucose)



Emergency glucagon kits: 1 mg ampule of glucagon, glucagon nasal powder, glucagon premixed autoinjector

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Persons close to the patient (e.g., family members, caregivers, coworkers) should be instructed in the use of these kits



Severe

Hypoglycemia

Treatment



Glucagon may cause vomiting \rightarrow patients should be turned on their side before glucagon administration to prevent choking

SMBG vs CGM

Self Monitoring of Blood Glucose (SMBG)

Pre-prandial (80-130 mg/dl)

Timing of testing

- Pre-prandial 80-130
 mg/dl before breakfast
- Post-prandial <180 mg/dl
 - 2 hours after large meal

Self monitoring blood glucose (SMBG)

- Patient-specific goals, needs, abilities (e.g., to use devices) and financial burden should determine how frequently they self-monitor their glucose levels.
- Those with type 2 diabetes who are on insulin should monitor multiple times per day, generally before meals and at bedtime if administering multiple injections daily. Less frequent monitoring (such as before breakfast and dinner) may be warranted in those who only take basal insulin.
- Patients should be encouraged to test as frequently as appropriate based on their insulin regimen and according to their provider's instructions. Such times include (but are not limited to): when fasting, prior to meals and snacks, at bedtime, prior to exercise, when hypoglycemia is suspected and after treating hypoglycemia until they are normoglycemic.
- Those who are **not** on insulin may not need to monitor daily, however, they may find benefit from self-monitoring in helping with their diet and informing the provider's treatment plan. Patients who are prescribed self-monitoring devices should receive regular **instruction** and **evaluation** of their testing technique and glycemic management.



Continuous Glucose Monitoring (CGM)



Measures interstitial glucose (which correlates well with plasma glucose, although at times can lag if glucose levels are rising or falling rapidly)

Includes alarms for hypo- and hyperglycemic excursions

Provides glycemic variability and displays numerical and graphic data with trend arrows

May be useful in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes

Real-time CGM vs. Intermittently scanned CGM

Personal vs. Professional CGM

Continuous glucose monitoring (CGM)

- Continuous glucose monitoring devices (CGMs), when used properly, may be beneficial for any patient with diabetes, regardless of their A1C or medication regimen (e.g. insulin-dependent or non-insulin dependent). For most adults with type 1 diabetes, CGMs are the standard method for glucose monitoring.
- CGMs are especially valuable in patients who take multiple daily injections of insulin for diabetes management (both lowering and maintenance of A1C). Real-time CGMs should be used as close to daily as possible and intermittent CGM devices should be scanned at least every 8 hours for maximum benefit.
- In patients with diabetes who are not on insulin therapy or who are only on a basal insulin regimen, CGMs may be beneficial in both identifying and correcting hyperglycemia and hypoglycemia patterns as well as improving A1C levels.
- **Cost/insurance coverage** and the patient's ability to use the device properly are major considerations and **possible barriers** to use for these devices.
- Patients who are prescribed CGMs should receive regular instruction and evaluation of their CGM use, testing technique and glycemic management.

AGP Report

Name

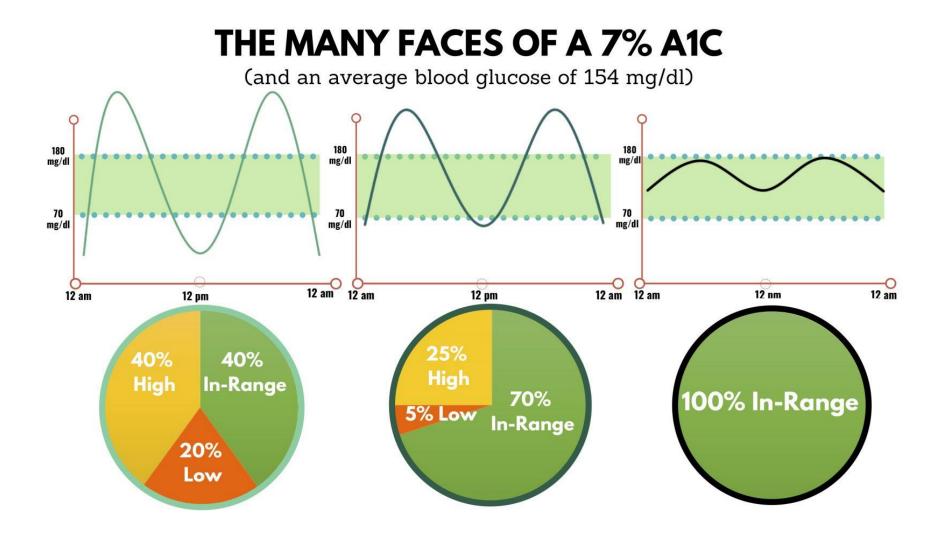
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GLUCOSE STATISTICS AND TAR	GETS	
26 Feb 2019 - 10 Mar 2019	13 days	
% Time CGM is Active	99.9%	
Glucose RangesTargets [% of Readings (Time/Day)]Target Range 70-180 mg/dLGreater than 70% (16h 48min)Below 70 mg/dLLess than 4% (58min)Below 54 mg/dLLess than 1% (14min)Above 250 mg/dLLess than 5% (1h 12min)Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.		
Average Glucose	173 mg/dL	
Glucose Management Indicator	(GMI) 7.6%	
Glucose Variability	49.5%	

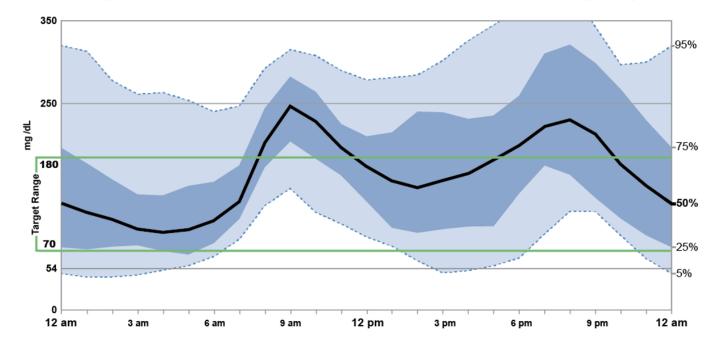
Defined as percent coefficient of variation (%CV); target ≤36%

IME IN	RANGES	
	Very High (>250 mg/dL)	20% (4h 48min)
	High (181–250 mg/dL)	23% (5h 31min)
	Target Range (70–180 mg/dL)	47% (11h 17min)
	Low (54–69 mg/dL) Very Low (<54 mg/dL)	

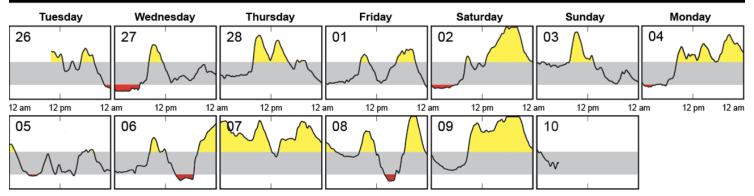


AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



DAILY GLUCOSE PROFILES



Each daily profile represents a midnight to midnight period. Patents pending-HealthPartners Institute dba International Diabetes Center-All Rights Reserved. 2019

capturAGPv 4.0

Insulin Pumps



- More closely mimic the body's natural insulin activity
 - Improved flexibility for the patient
 - Improved glycemic control
- Pumps still require input from the user
- Historically worn on the belt or carried in a pocket, connected with a thin plastic tube/infusion set

NEW Insulin Pumps

- Newer automated, tubeless insulin delivery devices
- Waterproof
- Cannula inserted automatically once the device is placed against skin
- Wireless insulin delivery connected to CGM







INSULIN PUMPS IN TYPE 1 DIABETES

- Eliminates need for multiple daily injections
- Depending on device, pods can delivery insulin nonstop for up to 72 hours
- Tangle-proof, waterproof, very durable
- Painless, stick on device
- Discreet, can be worn under clothing
- Wireless controller can be carried in pocket, backpack, or purse
- Covered by most insurance plans, including Medicare Part D

How long does the sensor last?	UP TO 10 DAYS	UP TO 10 DAYS	UP TO 14 DAYS	UP TO 14 DAYS	UP TO 14 DAYS
Time between readings:	5 MINUTES	5 MINUTES	15 MINUTES	1 MINUTE] MINUTE
Length of warm-up period:	2 HOURS	30 MINUTES	1 HOUR	1HOUR	1 HOUR
Low blood sugar alerts?	\checkmark	\checkmark	×		\checkmark
Smartphone capabilities?		\checkmark	\checkmark		\checkmark
Who can use it?	ADULTS AND CHILDREN 2 YEARS AND OLDER	ADULTS AND CHILDREN 2 YEARS AND OLDER	ADULTS 18 YEARS AND OLDER	ADULTS AND CHILDREN 4 YEARS AND OLDER	ADULTS AND CHILDREN 4 YEARS AND OLDER
CHILDREN 2 YEARS CHILDREN 2 YEARS ADDLIS 18 YEARS CHILDREN 4 YEARS CHILDREN 4 YEARS					

The newest 10-day sensors average cost without insurance is about \$470 for 3 sensors (a typical 30-day supply). Sensors are designed to last for up to 10 days each. This is the only prescription you will need for this CGM. The newest 10-day products are an all-in-one fully disposable system. So, there's no need to order transmitters.



The older version of the 10-day sensors average cost without insurance is about \$450 for the receiver, \$300 for 1 transmitter, and \$440 for 3 sensors. You'd need a separate prescription for each item. A transmitter has a 90-day battery life, but the sensors need to be replaced every 10 days. Receivers are meant to last for years, and insurance providers restrict how often you can get a new one.

14-day readers cost about \$87 without insurance. 14 Day system sensors cost about \$77 for a 28-day supply. The same amount of sensors for the Libre 2 system cost around \$160. Again, you'll need separate prescriptions for the reader and sensors. The newest, most updated 14-day sensors cost about \$150 for a 28-day supply.

CGM Cost

CGM Coverage

- Medicare use DME suppliers
- MaineCare requires that patient be on multiple daily doses of insulin, or high risk of hypoglycemia unawareness, among other criteria
- Commercial depends on the plan, but most will cover CGM
- Manufacturer free trials are available
- Patient Assistance if uninsured/underinsured, may qualify for free or reduced cost device

Resources

- American Diabetes Association Professional Practice Committee;
 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2024. Diabetes Care 1 January 2024; 47 (Supplement_1): S158–S178. <u>https://doi.org/10.2337/dc24-S009</u>
- <u>Dexcom vs. FreeStyle Libre: How Do These CGMs Compare?</u> <u>GoodRx</u>
- <u>switching-between-insulin.pdf (diabetes.org)</u> American Diabetes Association

Thank you

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