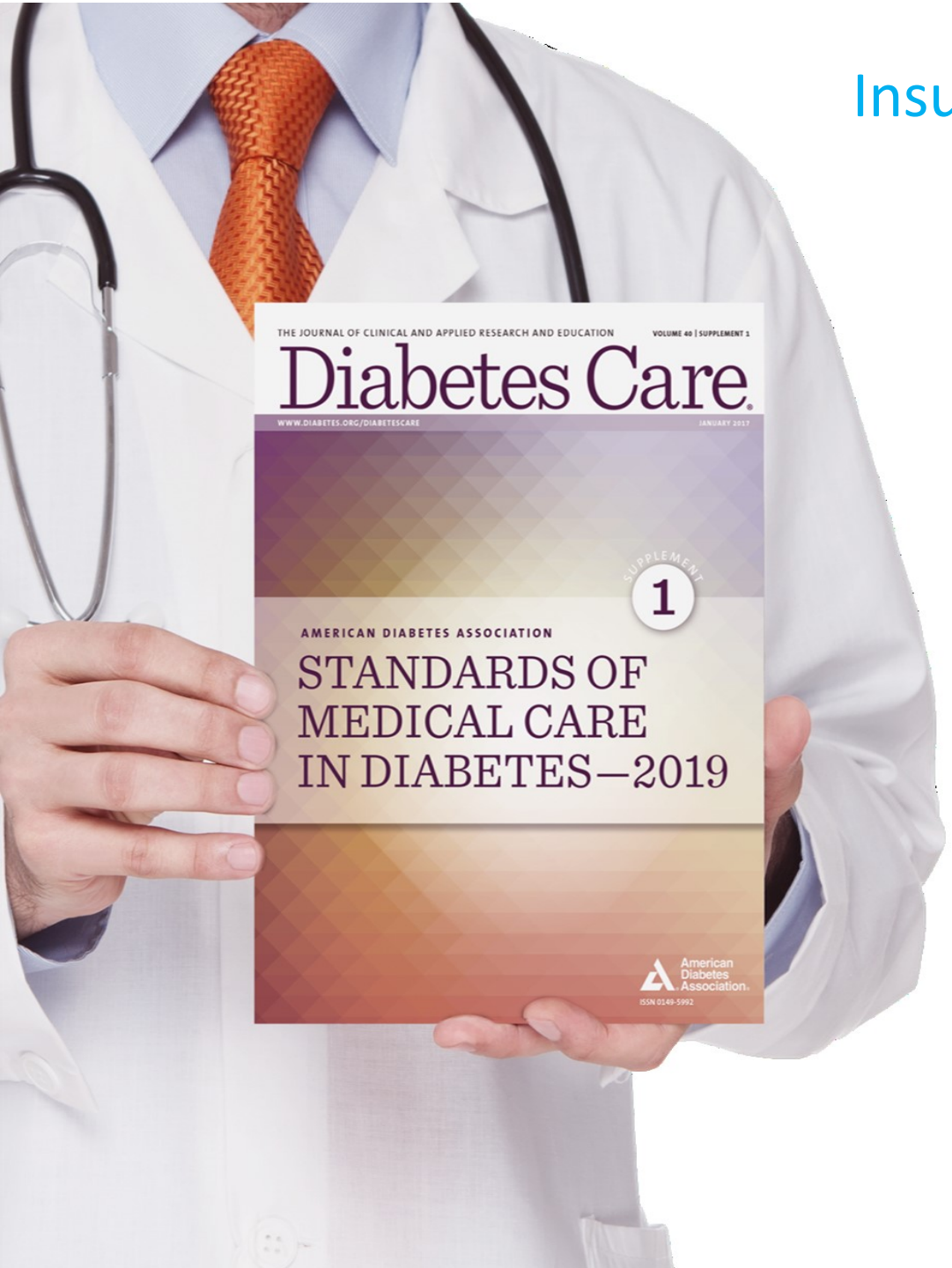
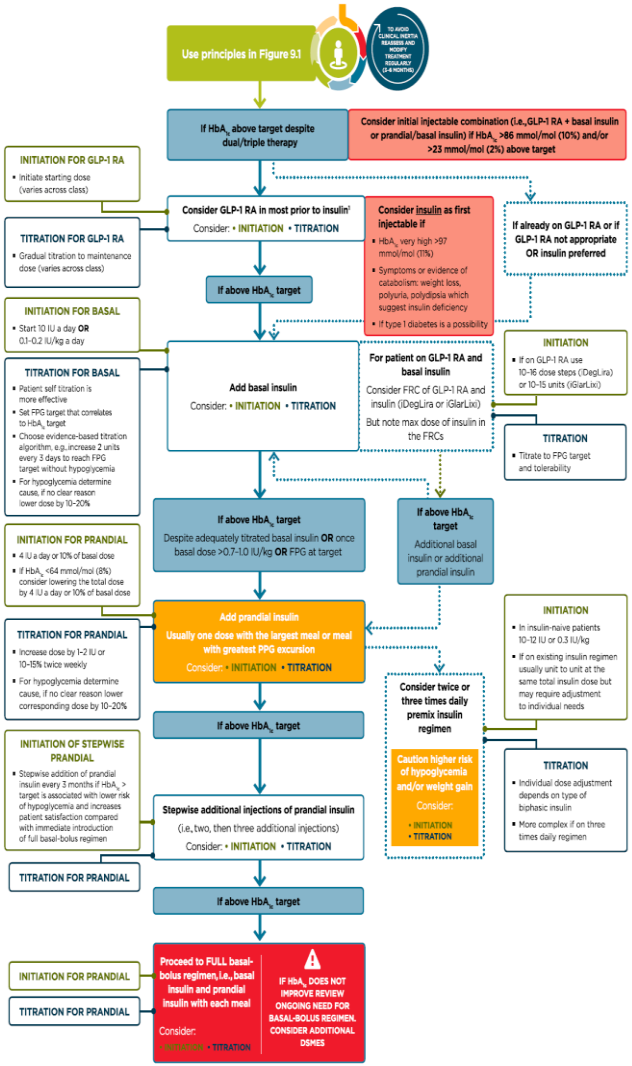
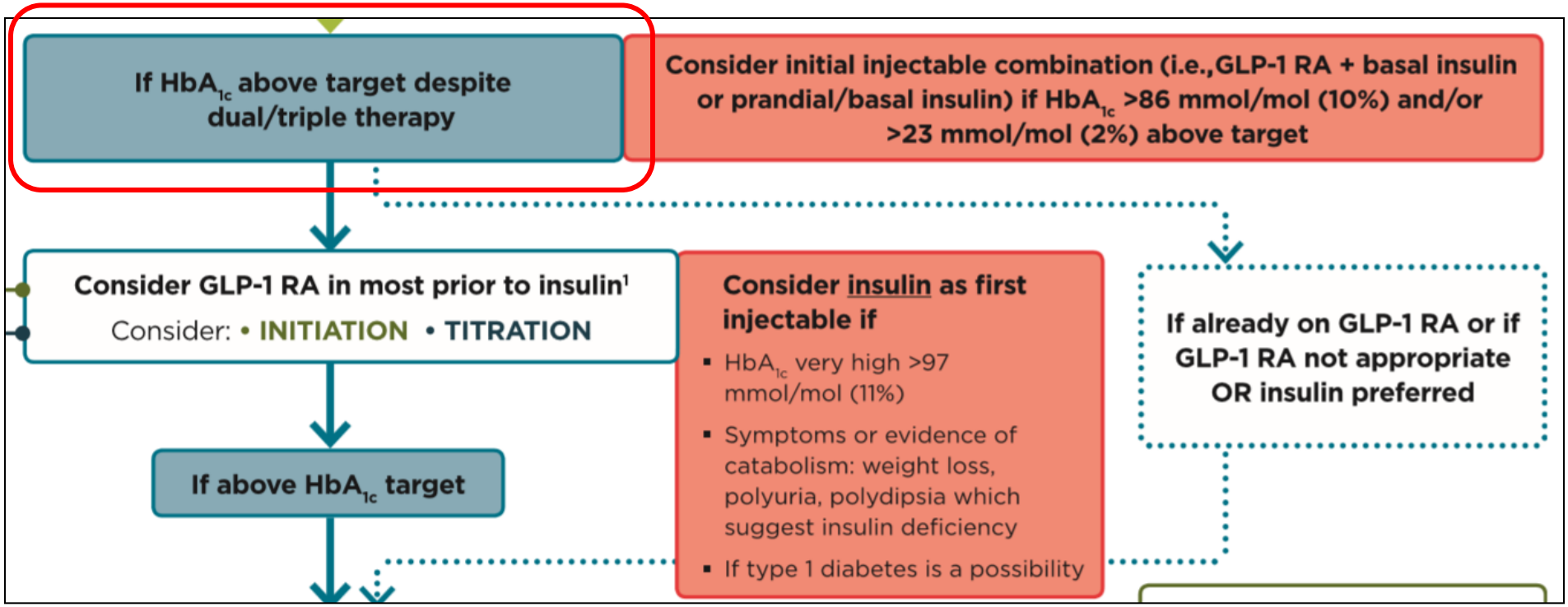


Insulin therapy in Type2 DM ADA & IDF Guidelines

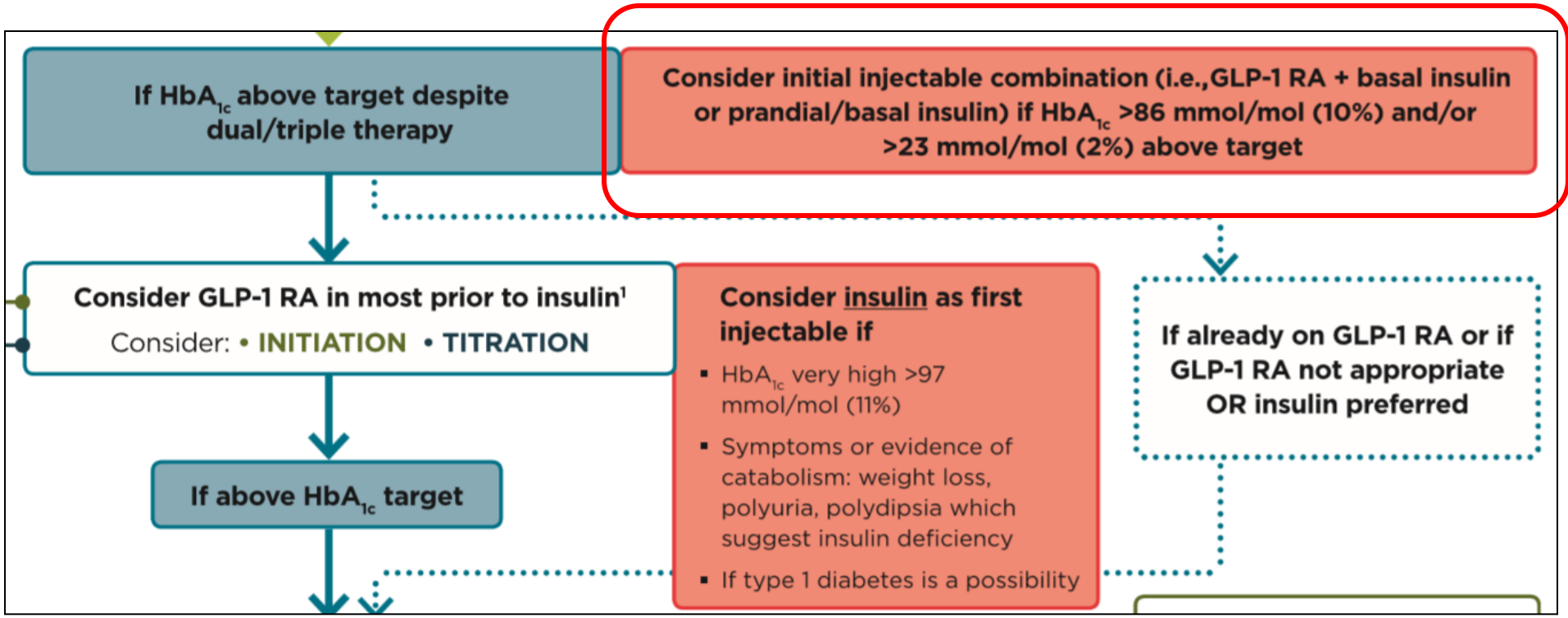
Amir Kamran Nikousokhan, MD
Diabetologist
Managing Director of IDS

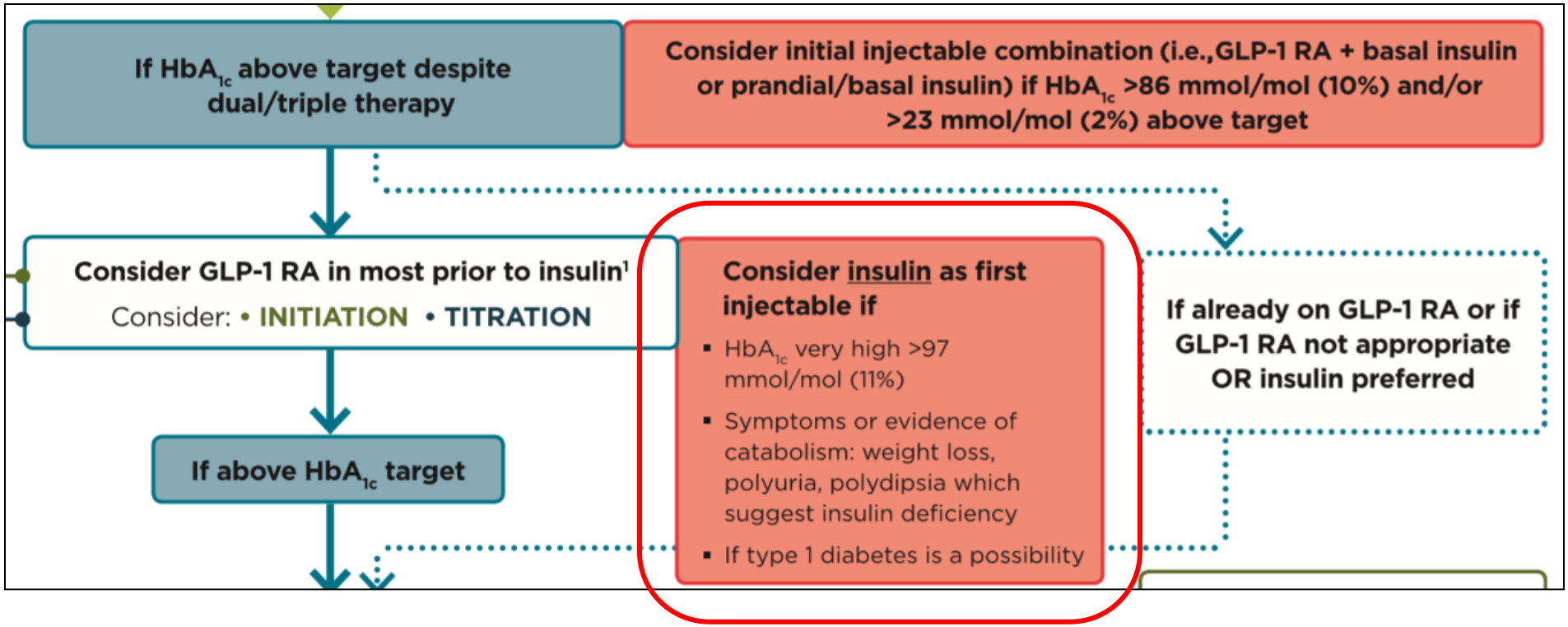
Principles of injection therapy




If HbA_{1c} above target despite dual/triple therapy
Consider initial injectable combination (i.e.,GLP-1 RA + basal insulin or prandial/basal insulin) if HbA_{1c} >86 mmol/mol (10%) and/or >23 mmol/mol (2%) above target
Consider GLP-1 RA in most prior to insulin[1]
Consider: • INITIATION • TITRATION
If above HbA_{1c} target
Consider insulin as first injectable if
▪ HbA_{1c} very high >97 mmol/mol (11%)
▪ Symptoms or evidence of catabolism: weight loss, polyuria, polydipsia which suggest insulin deficiency
▪ If type 1 diabetes is a possibility
If already on GLP-1 RA or if GLP-1 RA not appropriate OR insulin preferred

Principles of injection therapy

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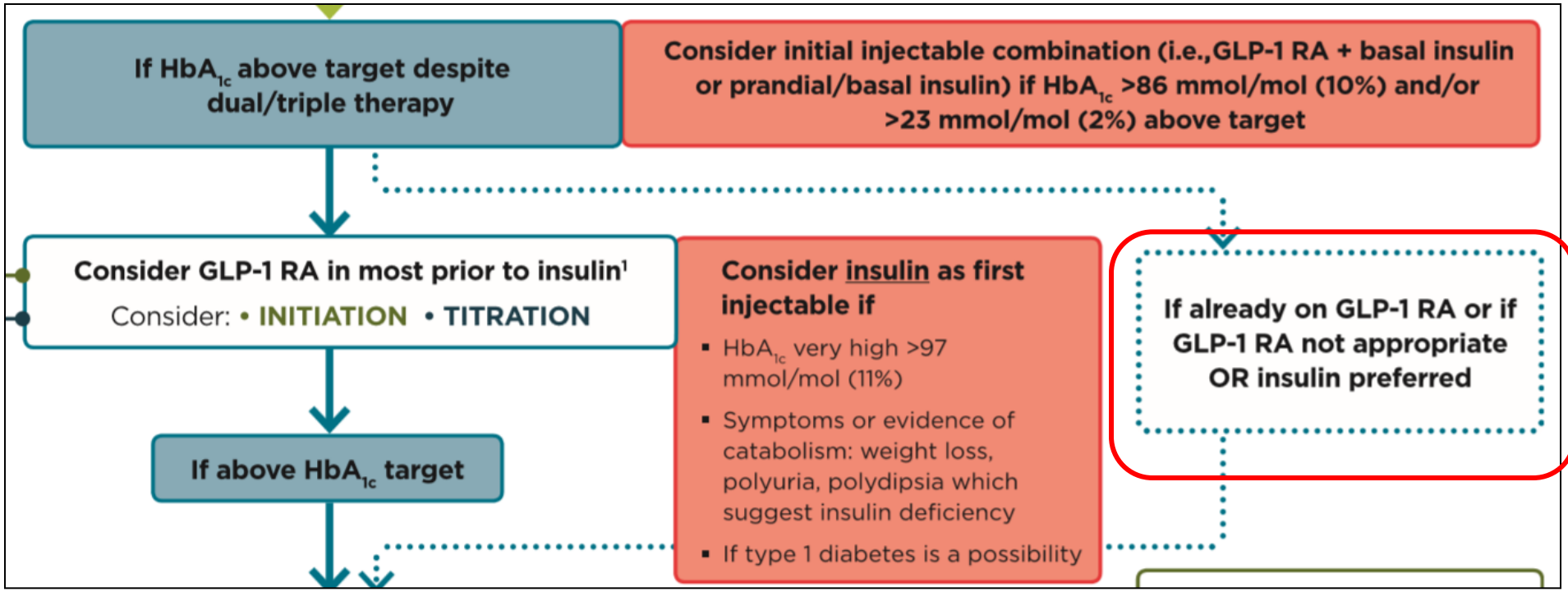
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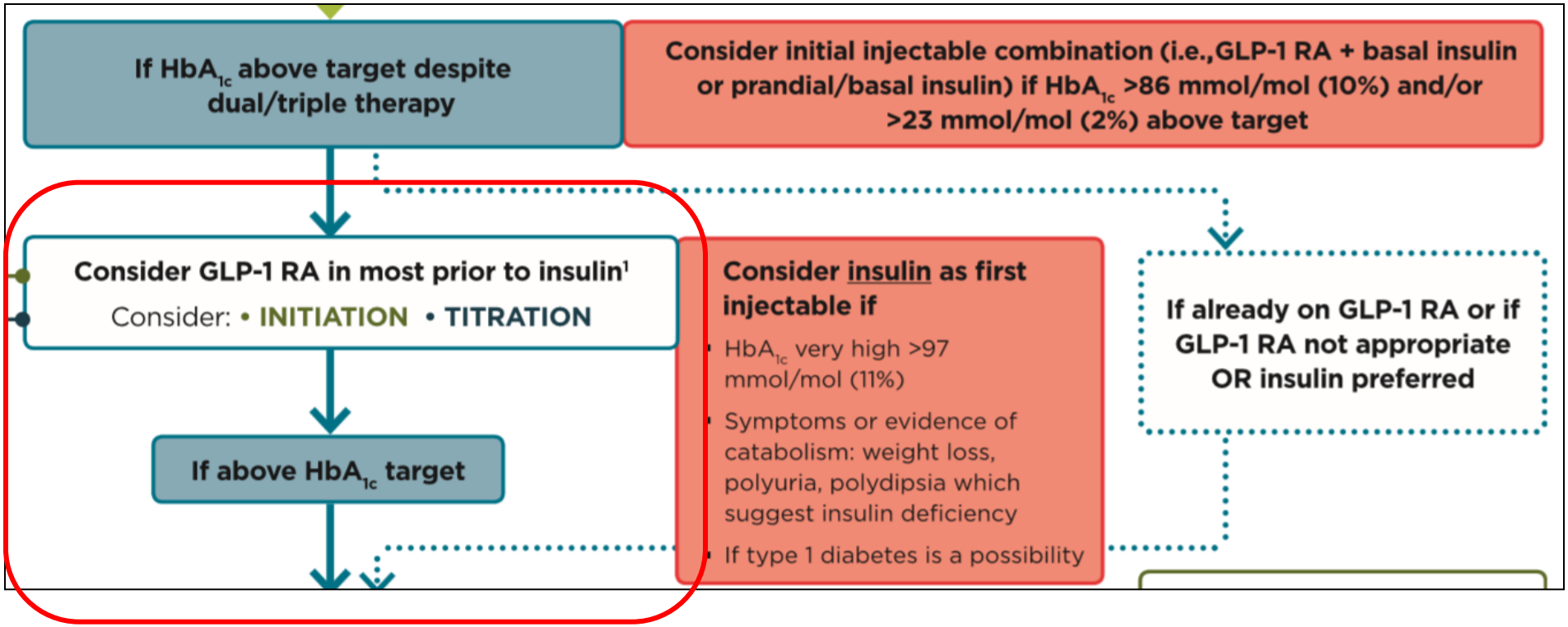
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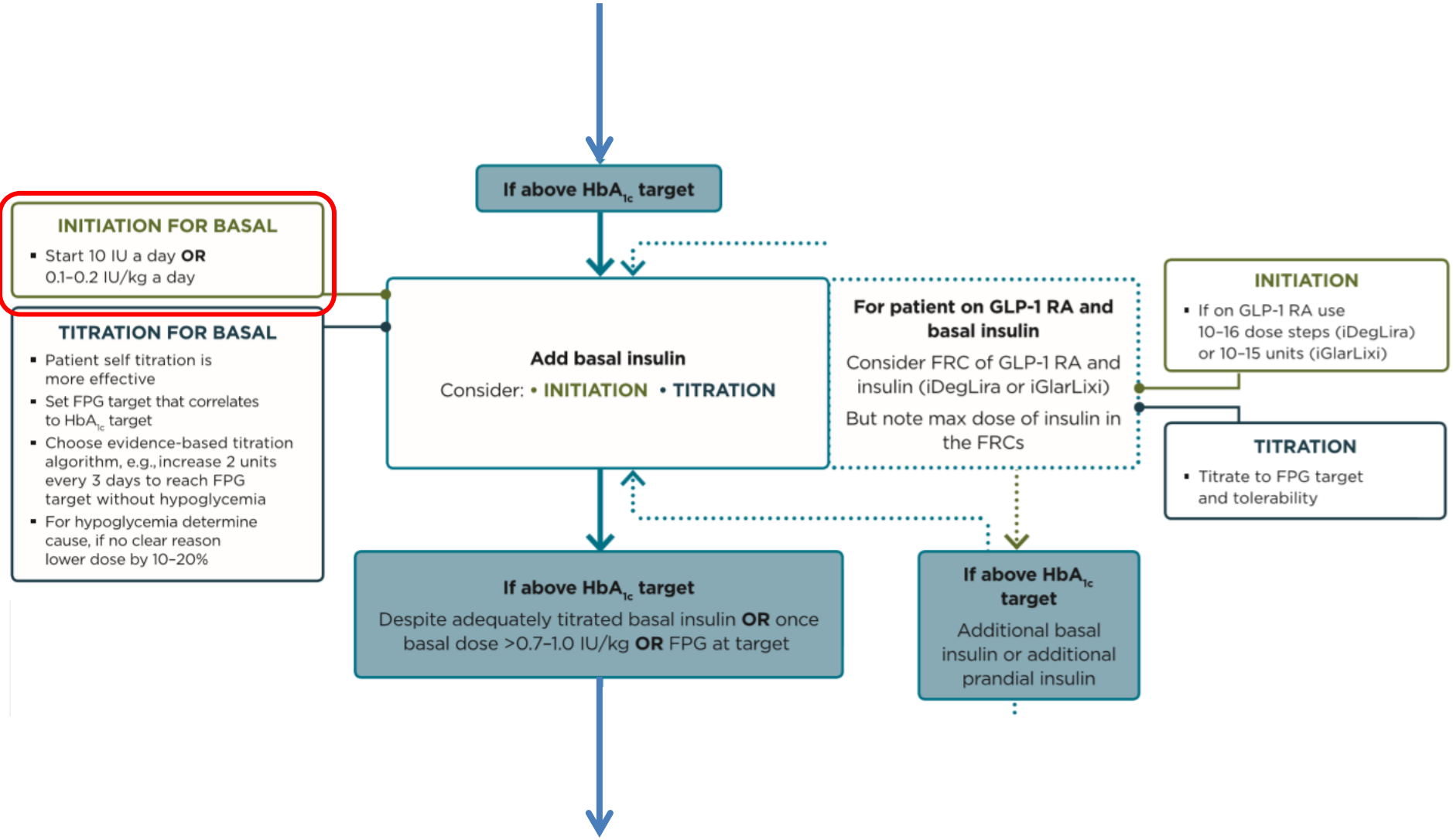
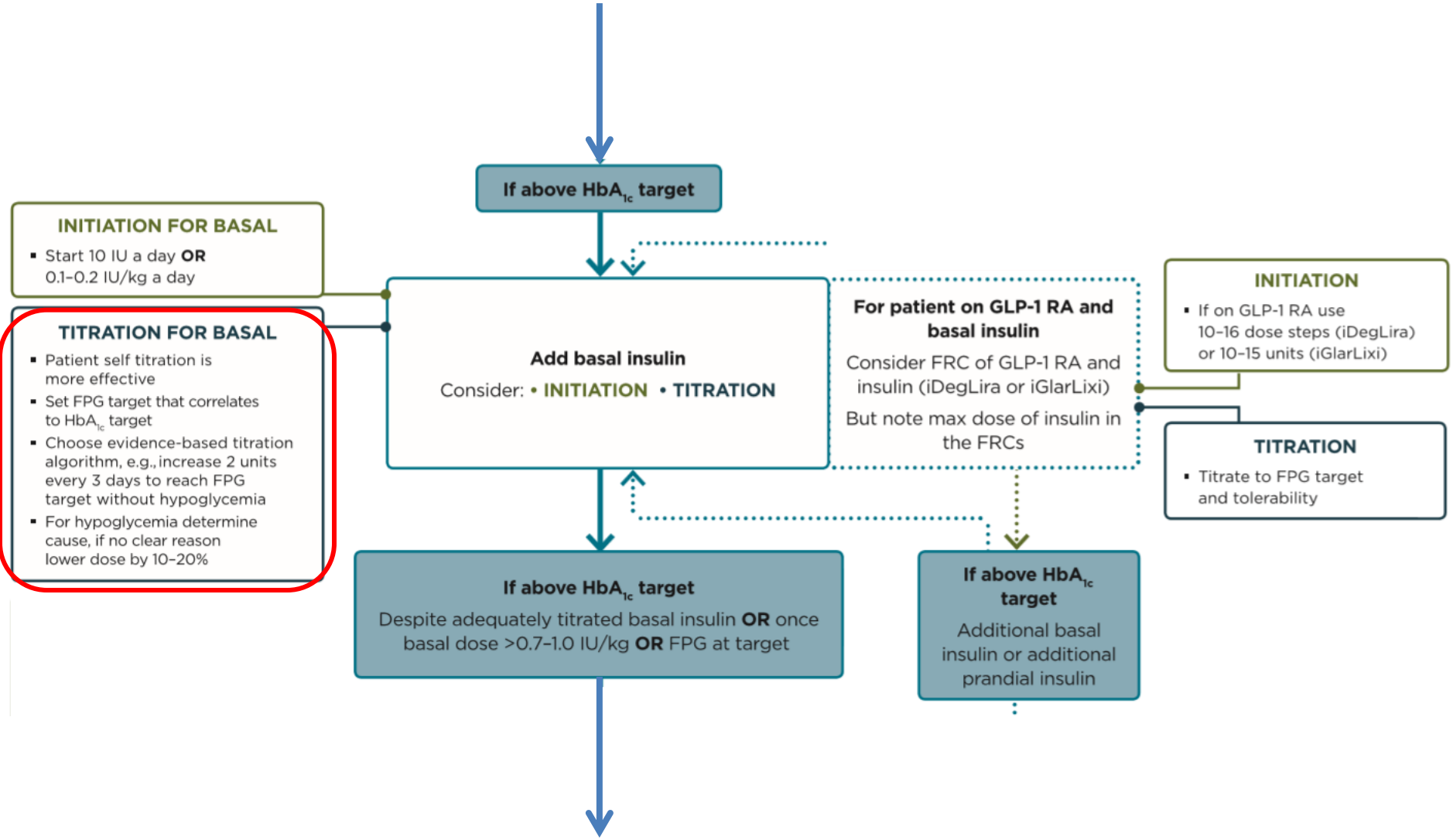

If above HbA1c target
INITIATION FOR BASAL
Start 10 IU a day OR 0.1–0.2 IU/kg a day
TITRATION FOR BASAL
Patient self titration is more effective
Set FPG target that correlates to HbA1c target
Choose evidence-based titration algorithm, e.g., increase 2 units every 3 days to reach FPG target without hypoglycemia
For hypoglycemia determine cause, if no clear reason lower dose by 10–20%
Add basal insulin
Consider: • INITIATION • TITRATION
For patient on GLP-1 RA and basal insulin
Consider FRC of GLP-1 RA and insulin (iDegLira or iGlarLixi)
But note max dose of insulin in the FRCs
INITIATION
If on GLP-1 RA use 10–16 dose steps (iDegLira) or 10–15 units (iGlarLixi)
TITRATION
Titrate to FPG target and tolerability
If above HbA1c target
Despite adequately titrated basal insulin OR once basal dose >0.7–1.0 IU/kg OR FPG at target
If above HbA1c target
Additional basal insulin or additional prandial insulin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If above HbA_{1c} target

INITIATION FOR BASAL

- Start 10 IU a day **OR** 0.1–0.2 IU/kg a day

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Consider FRC of GLP-1 RA and insulin (iDegLira or iGlarLixi)

But note max dose of insulin in the FRCs

INITIATION

- If on GLP-1 RA use 10–16 dose steps (iDegLira) or 10–15 units (iGlarLixi)

TITRATION

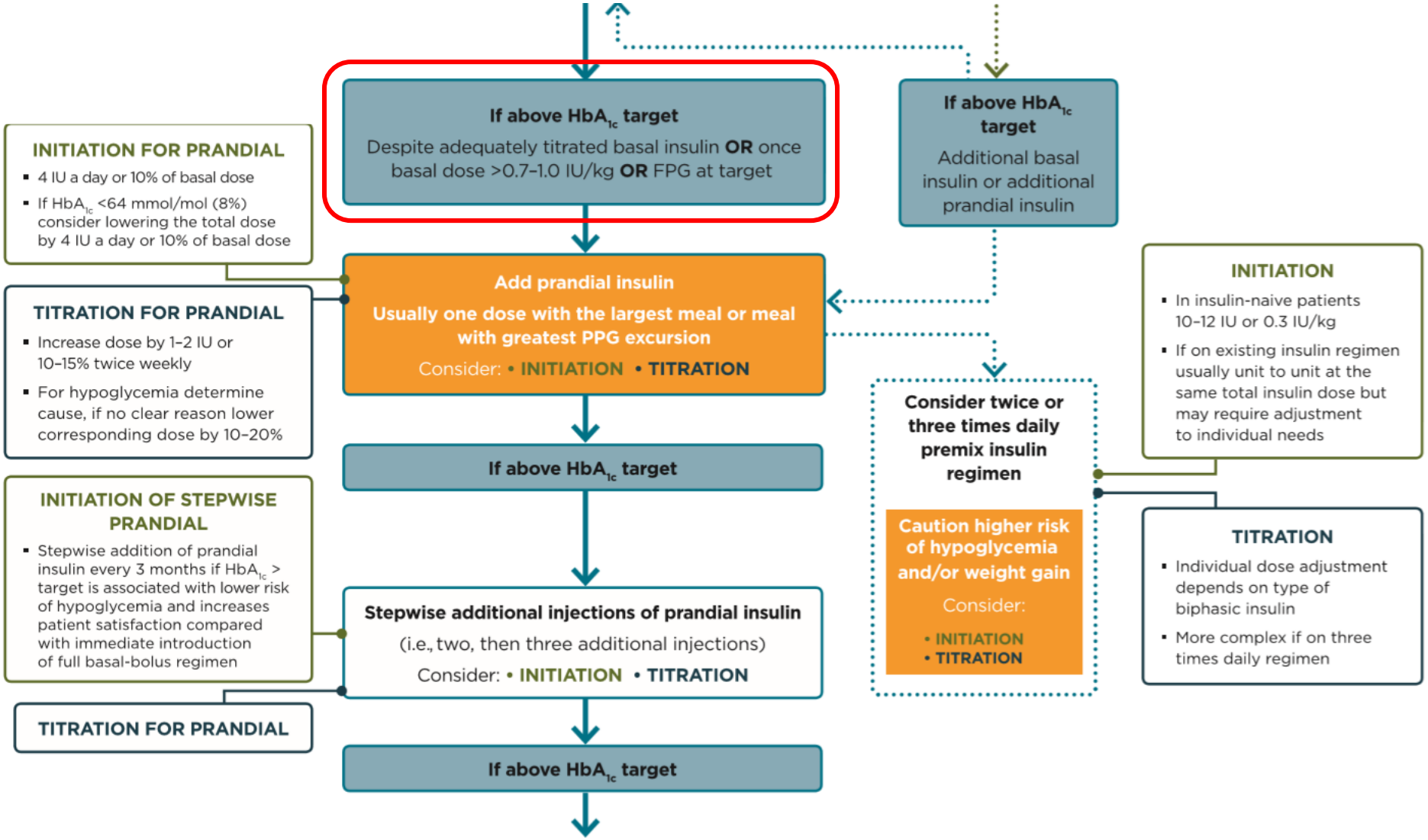
- Titrate to FPG target and tolerability

If above HbA_{1c} target

Despite adequately titrated basal insulin **OR** once basal dose >0.7–1.0 IU/kg **OR** FPG at target

If above HbA_{1c} target

Additional basal insulin or additional prandial insulin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If HbA1c <64 mmol/mol (8%) consider lowering the total dose by 4 IU a day or 10% of basal dose
Add prandial insulin
Usually one dose with the largest meal or meal with greatest PPG excursion
Consider: • INITIATION • TITRATION
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Increase dose by 1–2 IU or 10–15% twice weekly
For hypoglycemia determine cause, if no clear reason lower corresponding dose by 10–20%
INITIATION
In insulin-naive patients 10–12 IU or 0.3 IU/kg
If on existing insulin regimen usually unit to unit at the same total insulin dose but may require adjustment to individual needs
If above HbA1c target
Consider twice or three times daily premix insulin regimen
Caution higher risk of hypoglycemia and/or weight gain
Consider:
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Stepwise addition of prandial insulin every 3 months if HbA1c > target is associated with lower risk of hypoglycemia and increases patient satisfaction compared with immediate introduction of full basal-bolus regimen
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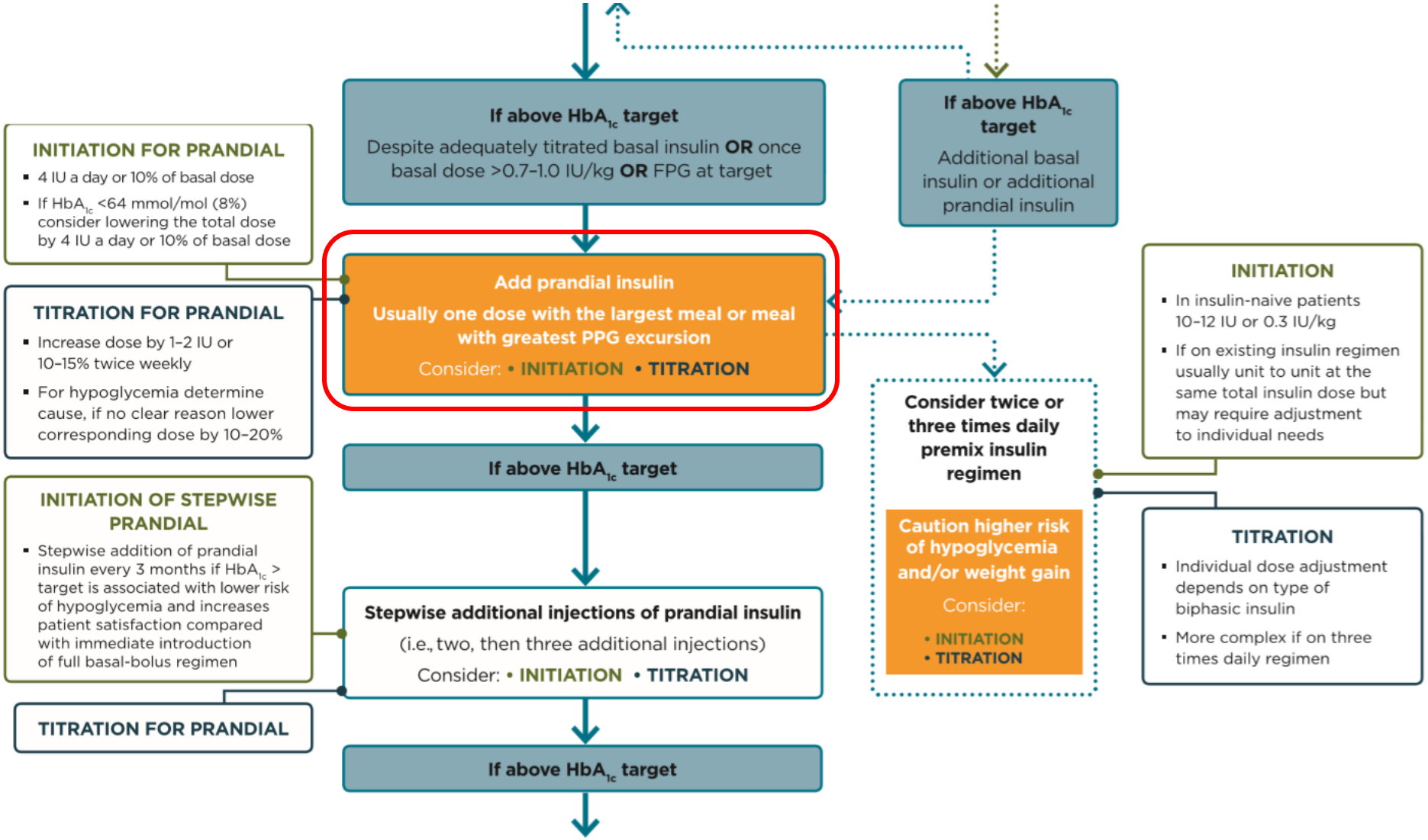
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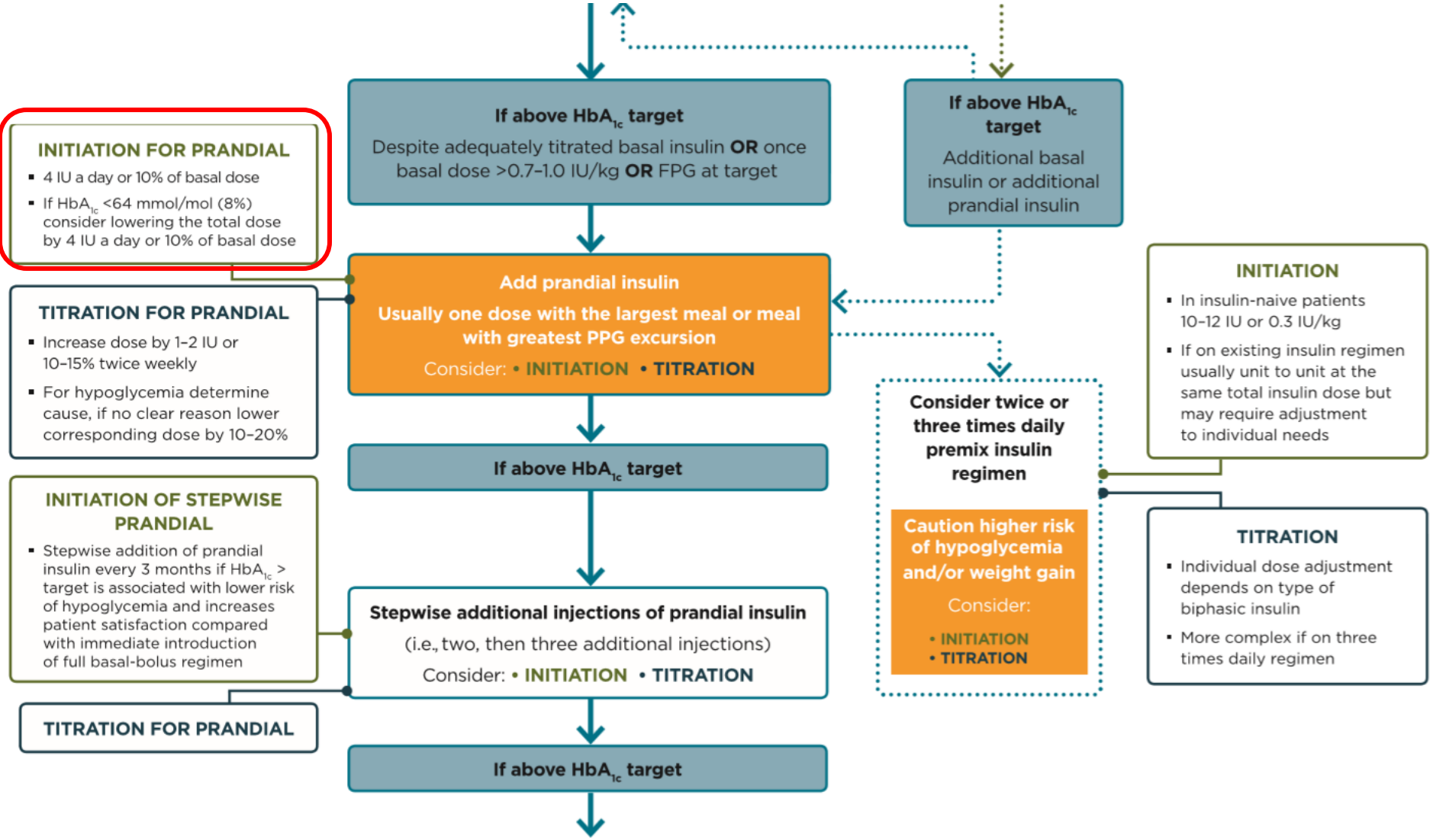
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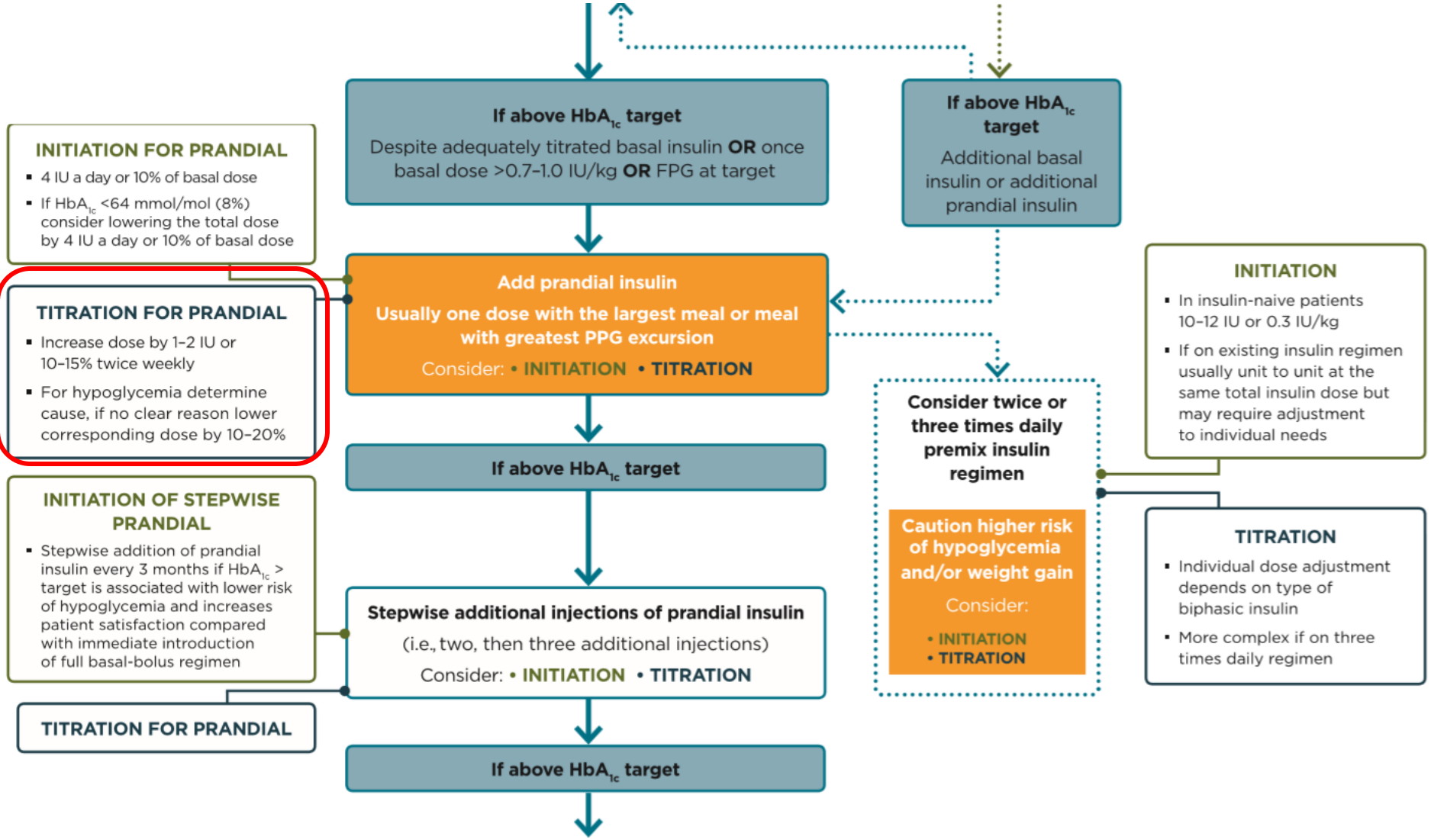
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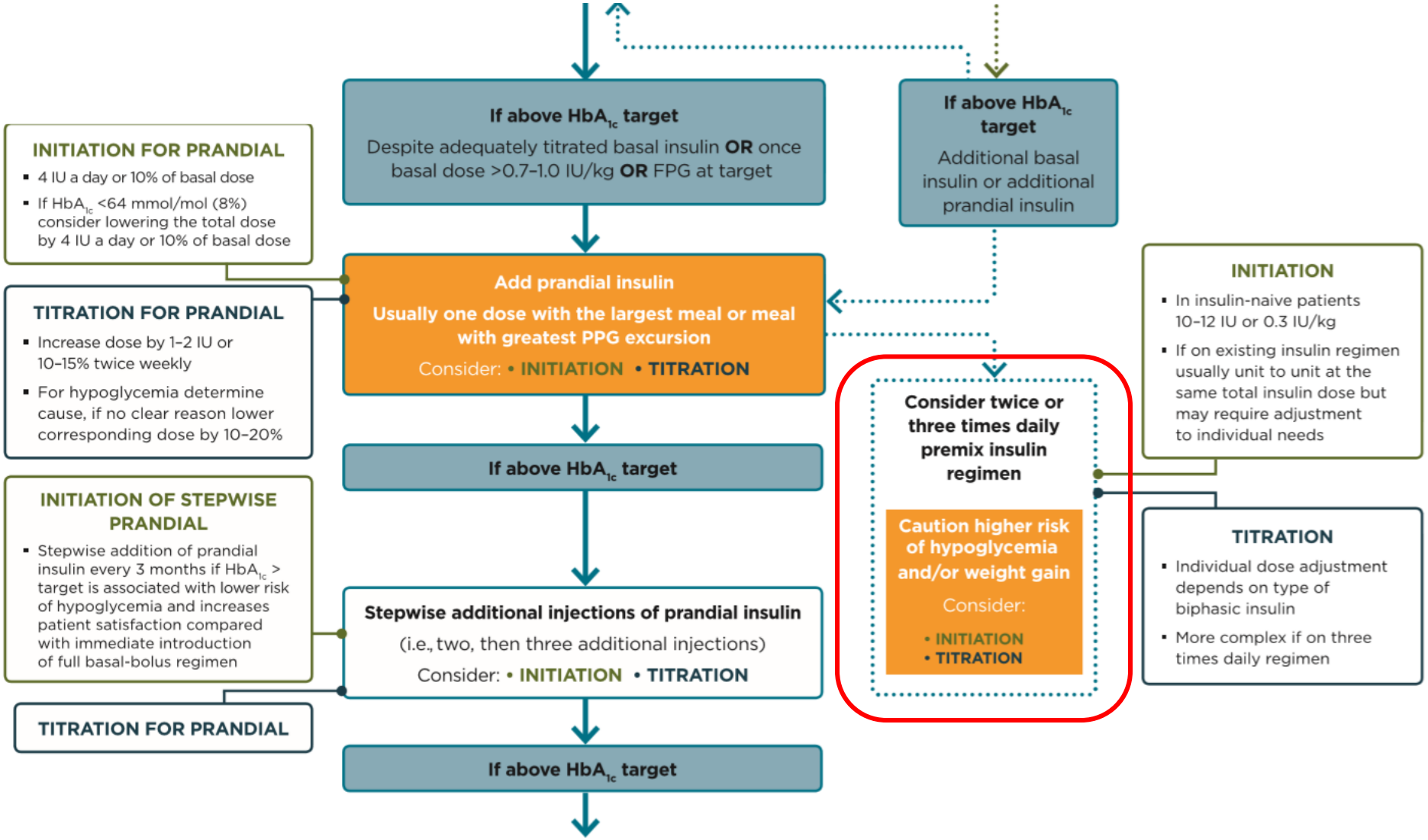
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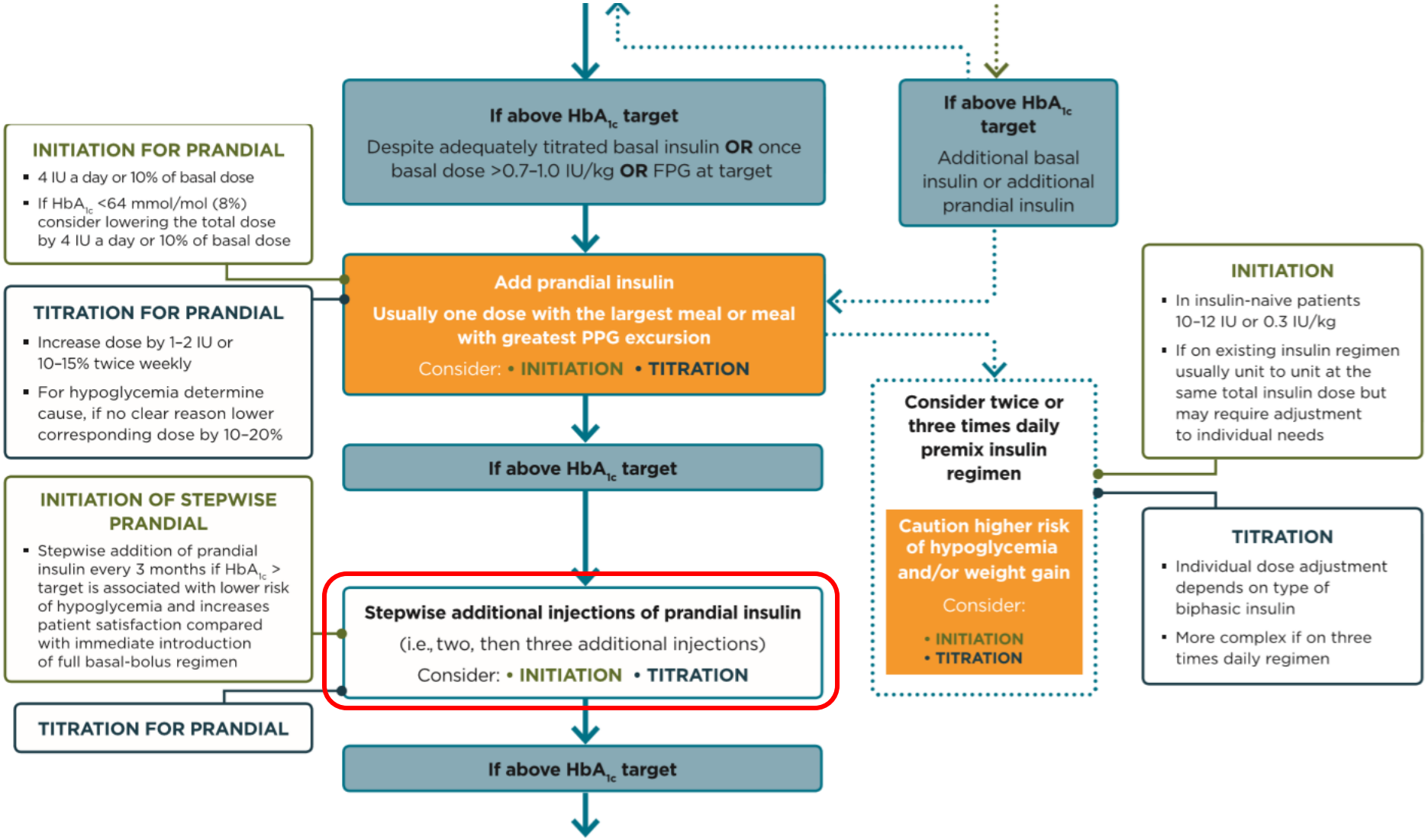
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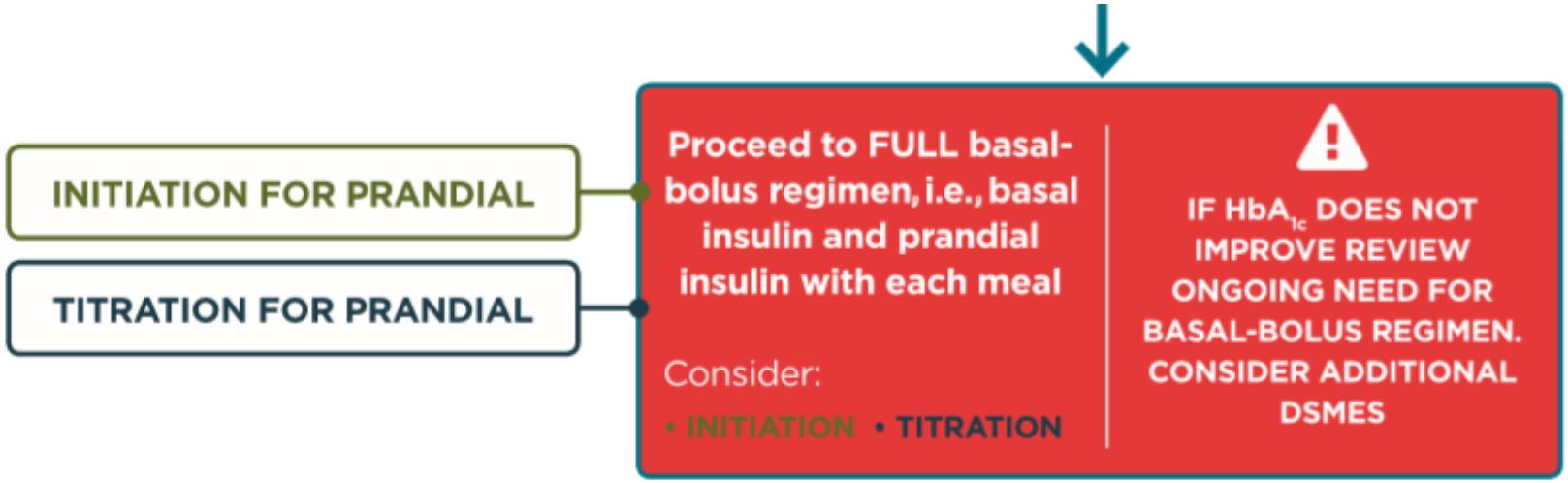
INITIATION FOR PRANDIAL
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Proceed to FULL basal-bolus regimen, i.e., basal insulin and prandial insulin with each meal
Consider:
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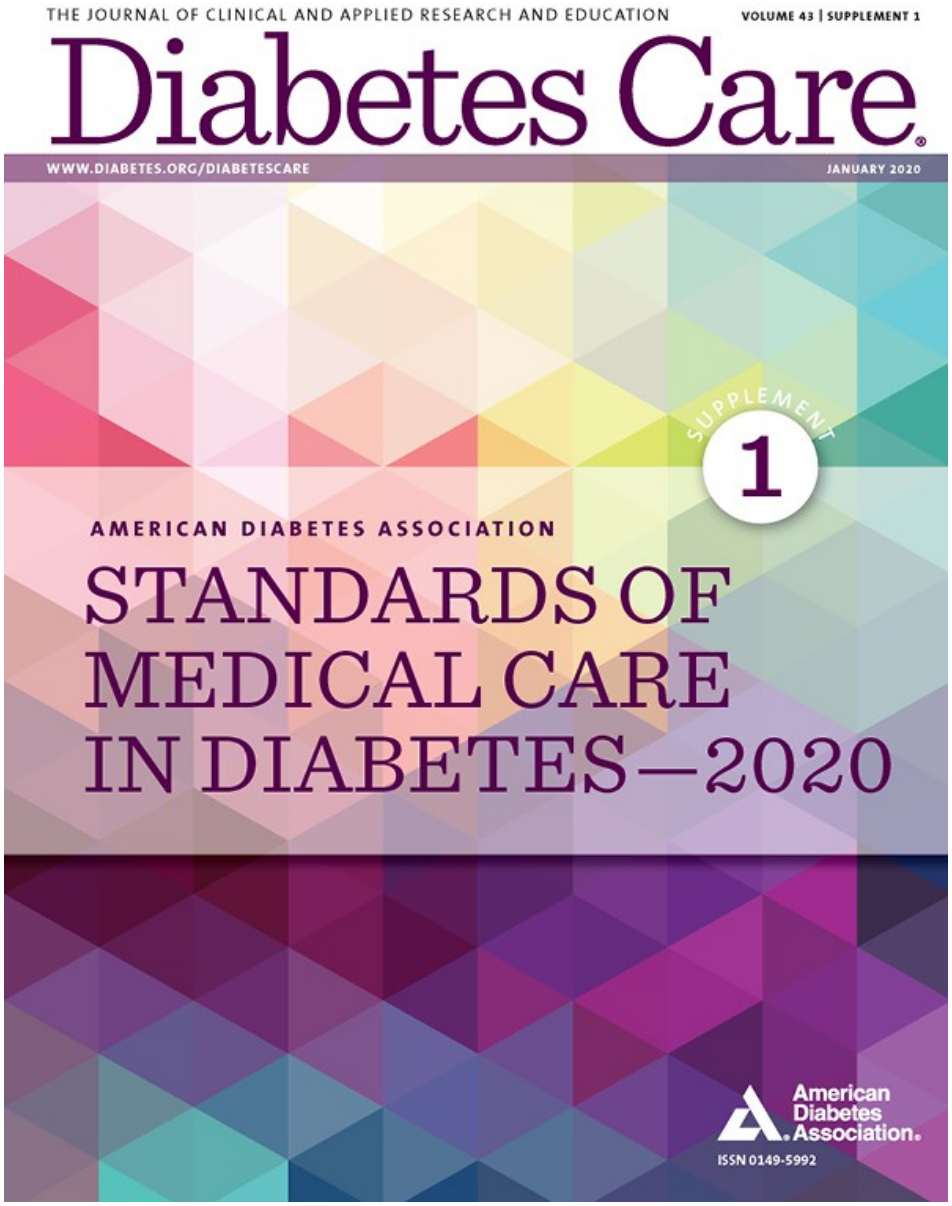
IF HbA1c DOES NOT IMPROVE REVIEW ONGOING NEED FOR BASAL-BOLUS REGIMEN. CONSIDER ADDITIONAL DSMES


THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION
VOLUME 43 | SUPPLEMENT 1
Diabetes Care
WWW.DIABETES.ORG/DIABETESCARE
JANUARY 2020
SUPPLEMENT
1
AMERICAN DIABETES ASSOCIATION
STANDARDS OF MEDICAL CARE IN DIABETES—2020
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ISSN 0149-5992

Use Principles in Figure 9.1, including reinforcement of behavioral interventions (weight management and physical activity) and provision of DSMES to meet individualized treatment goals

↓

If injectable therapy is needed to reduce A1C[1]

↓

Consider GLP-1 RA in most patients prior to insulin[2]

INITIATION: Initiate appropriate starting dose for agent selected (varies within class)

TITRATION: Gradual titration to maintenance dose (varies within class)

Use Principles in Figure 9.1, including reinforcement of behavioral interventions (weight management and physical activity) and provision of DSMES to meet individualized treatment goals

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INITIATION: Initiate appropriate starting dose for agent selected (varies within class)

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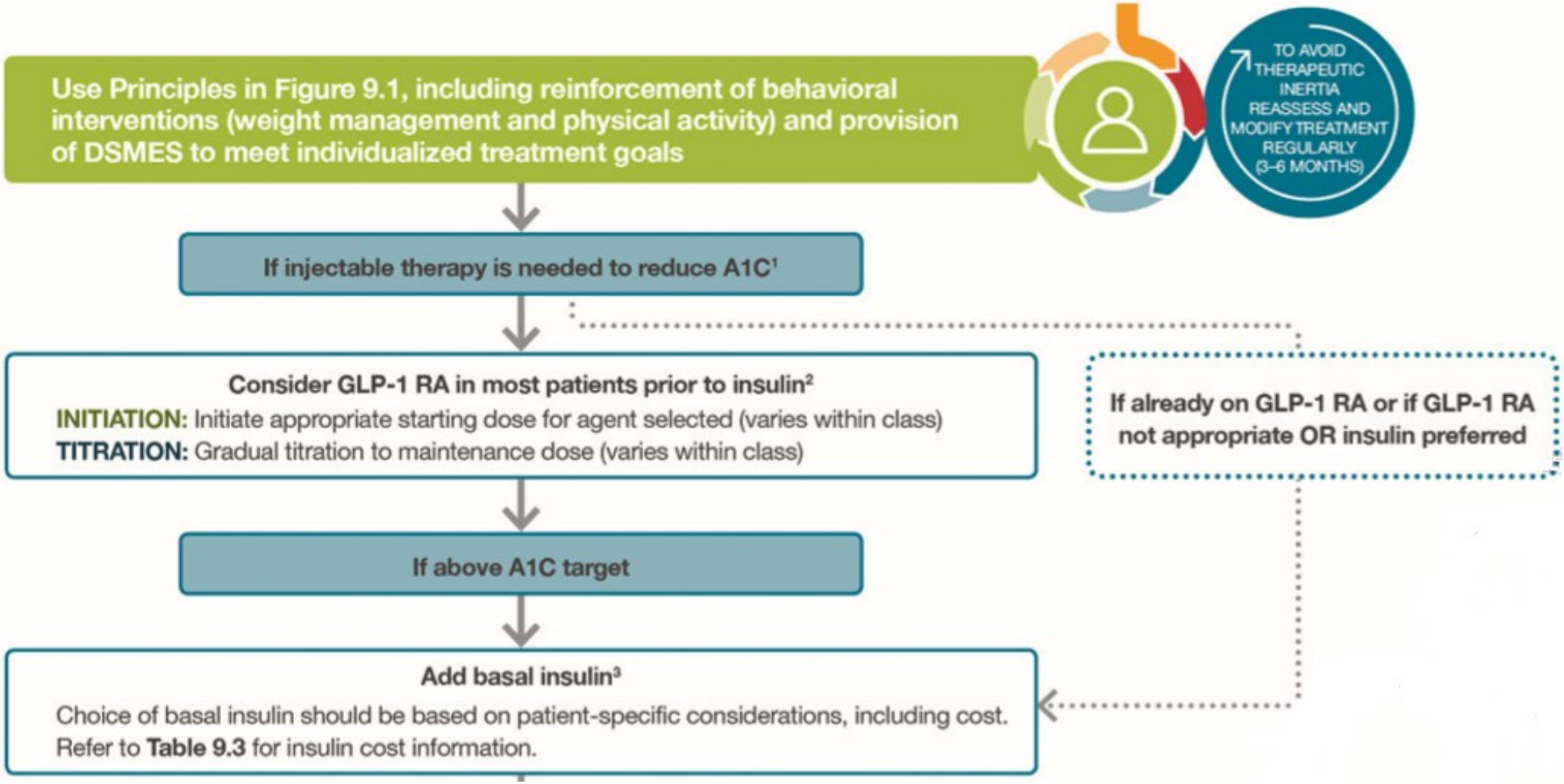
↓

If above A1C target

↓

Add basal insulin[3]

Choice of basal insulin should be based on patient-specific considerations, including cost. Refer to **Table 9.3** for insulin cost information.


Use Principles in Figure 9.1, including reinforcement of behavioral interventions (weight management and physical activity) and provision of DSMES to meet individualized treatment goals
TO AVOID THERAPEUTIC INERTIA REASSESS AND MODIFY TREATMENT REGULARLY (3–6 MONTHS)
If injectable therapy is needed to reduce A1C[1]
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INITIATION: Initiate appropriate starting dose for agent selected (varies within class)
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If already on GLP-1 RA or if GLP-1 RA not appropriate OR insulin preferred
If above A1C target
Add basal insulin[3]
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Use Principles in Figure 9.1, including reinforcement of behavioral interventions (weight management and physical activity) and provision of DSMES to meet individualized treatment goals

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If above A1C target

Add basal insulin[3]

Choice of basal insulin should be based on patient-specific considerations, including cost. Refer to **Table 9.3** for insulin cost information.

Add basal analog or bedtime NPH insulin

INITIATION: Start 10 IU a day **OR** 0.1-0.2 IU/kg a day

TITRATION:

- Set FPG target (see Section 6: Glycemic Targets)
- Choose evidence-based titration algorithm, e.g., increase 2 units every 3 days to reach FPG target without hypoglycemia
- For hypoglycemia determine cause, if no clear reason lower dose by 10-20%

If above A1C target
Despite adequately titrated basal analog or bedtime NPH[4]
OR once basal dose >0.5 IU/kg **OR** FPG at target

Add prandial insulin

Usually one dose with the largest meal or meal with greatest PPG excursion; prandial insulin can be dosed individually or mixed with NPH as appropriate

INITIATION:

- 4 IU a day or 10% of basal insulin dose
- If A1C <8% (64 mmol/mol) consider lowering the basal dose by 4 IU a day or 10% of basal dose

TITRATION:

- Increase dose by 1-2 IU or 10-15% twice weekly
- For hypoglycemia determine Cause, if no clear reason lower Corresponding dose by 10-20%

If on bedtime NPH, consider converting to twice-daily NPH regimen

Conversion based on individual needs and current glycemic control. The following is one possible approach:

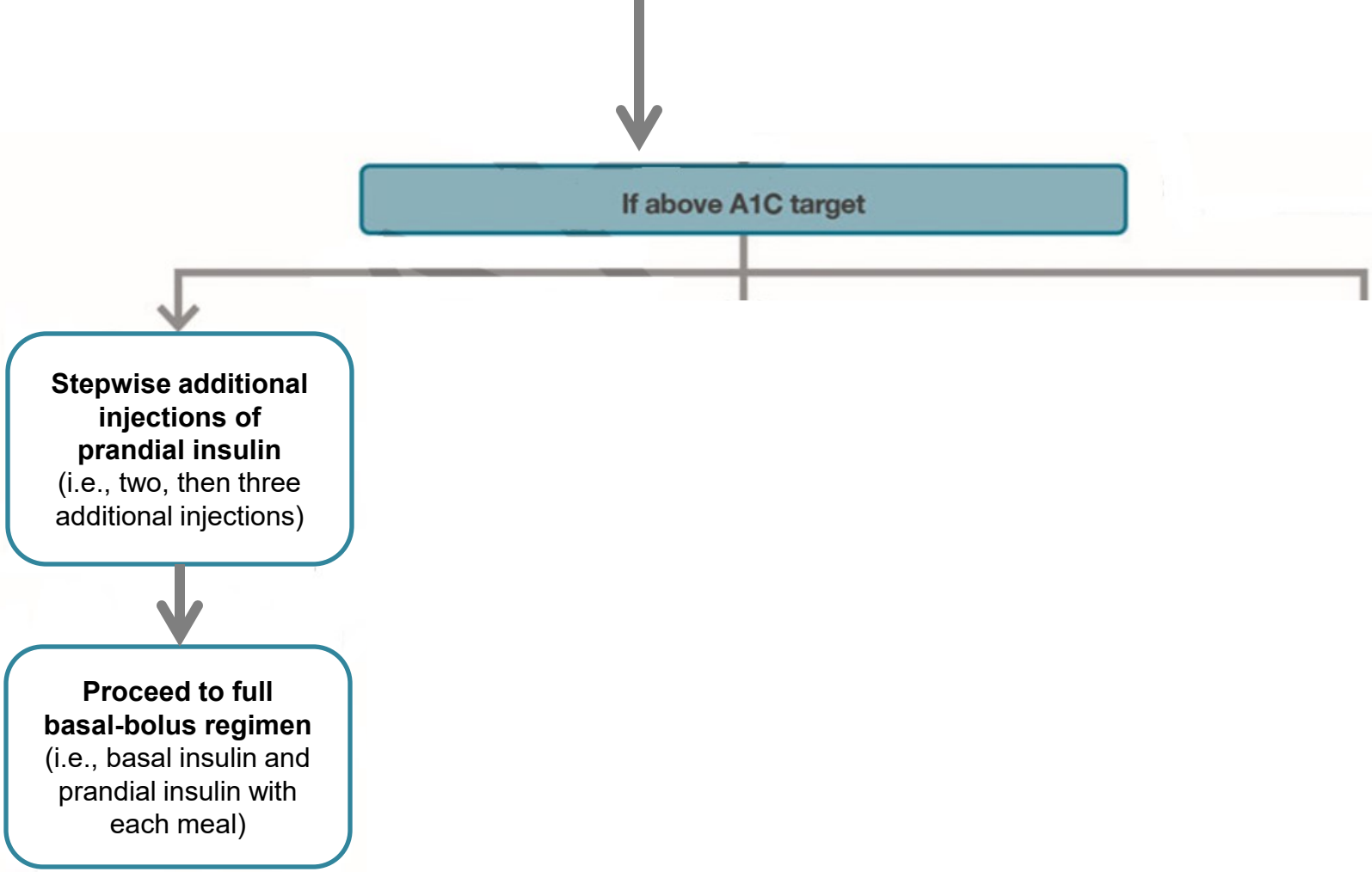
INITIATION:

- Total dose = 80% of current bedtime NPH dose
- 2/3 given in the morning
- 1/3 given at bedtime

TITRATION:

- Titrate based on individualized needs

If above A1C target


If above A1C target
Stepwise additional injections of prandial insulin (i.e., two, then three additional injections)
Proceed to full basal-bolus regimen (i.e., basal insulin and prandial insulin with each meal)

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Consider self-mixed/split insulin regimen

Can adjust NPH and short/rapid-acting insulins Seperately

INITIATION:

- Total NPH dose = 80% of current NPH dose
- 2/3 given before breakfast
- 1/3 given before dinner
- Add 4 IU of short/rapid-acting insulin to each injection or 10% of reduced NPH dose

TITRATION:

- Titrate each component of the regimen based on individualized needs

If above A1C target

Stepwise additional injections of prandial insulin
(i.e., two, then three additional injections)

Proceed to full basal-bolus regimen
(i.e., basal insulin and prandial insulin with each meal)

Consider self-mixed/split insulin regimen

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- Add 4 IU of short/rapid-acting insulin to each injection or 10% of reduced NPH dose

TITRATION:

- Titrate each component of the regimen based on individualized needs

Consider twice daily premix insulin regimen

INITIATION:

- Usually unit per unit at the same total insulin dose, but may require adjustment to individual needs

TITRATION:

- Titrate based on individualized needs

Median cost of insulin products in the U.S. calculated as AWP and NADAC per 1,000 units of specified dosage

Insulins	Compounds	Dosage form/product	Median AWP (min, max)*	Median NADAC (min, max)*
Rapid-acting	• Lispro follow-on product	U-100 vial	$157	$126
		U-100 prefilled pen	$202	$162
	• Lispro	U-100 vial	$330	$264
		U-100 3 mL cartridges	$408	$327
		U-100 prefilled pen; U-200 prefilled pen	$424	$340
	• Glulisine	U-100 vial	$341	$273
		U-100 prefilled pen	$439	$353
	• Aspart	U-100 vial	$347†	$278†
		U-100 3 mL cartridges	$430	$345
		U-100 prefilled pen	$447†	$358†
	• Inhaled insulin	Inhalation cartridges	$924	$606
Short-acting	• human regular	U-100 vial	$165 ($165, $178)††	$134 ($134, $146)††
Intermediate-acting	• human NPH	U-100 vial	$165 ($165, $178)††	$135 ($135, $146)††
		U-100 prefilled pen	$377	$304
Concentrated human regular insulin	• U-500 human regular insulin	U-500 vial	$178	$144
		U-500 prefilled pen	$230	$184
Long-acting	• Glargine follow-on product	U-100 prefilled pen	$261	$210
	• Glargine	U-100 vial; U-100 prefilled pen	$340	$272
		U-300 prefilled pen	$346	$280
	• Detemir	U-100 vial; U-100 prefilled pen	$370	$295
	• Degludec	U-100 vial; U-100 prefilled pen; U-200 prefilled pen	$407	$326

Pharmacologic Approaches to Glycemic Management:
Standards of Medical Care in Diabetes - 2020. Diabetes Care 2020;43(Suppl. 1):S98-S110

International Diabetes Federation Europe

IDF EUROPE POSITION ON BIOSIMILARS IN THE TREATMENT OF PEOPLE WITH DIABETES

November 2017

Facts and Figures

- The global prevalence of diabetes in adults aged 20–79 years was estimated to be 8.8% in 2017 and predicted to rise to 9,9% in 2045.
- 79% of people with diabetes are living in low- and middle-income countries.
- The lack of access to affordable insulin remains a key impediment to successful treatment and results in the development of acute/chronic complications and premature deaths.
- Moreover, insulin is reported as generally available in only a minority of low-income countries .

Rationale and Introduction

- Biosimilars provide an alternative to existing biological medicines that have lost patent protection.
- this therapy is usually offered for a lower price than the original molecules, and speculation is that price reductions of up to 50% might eventually be expected.
- the additional rationale of introducing biosimilars is that this therapy may increase the number of treatment options available to patients, prescribers, and payers

Biosimilars vs. generics

- A biosimilar insulin is a biological drug that is similar to an existing insulin but cannot be considered an exact copy of the original branded insulin because of the different manufacturing processes (different cell lines, protein sources, extraction and purification techniques).
- Theoretically, even very small differences between the original branded insulin and the biosimilar insulin could impact the bioavailability, receptor binding and duration of action.
- The majority of biosimilar insulins have high molecular weight and complex heterogeneous structure which can lead to higher immunogenic risk.

biosimilarity index

- Thus, it is important to first establish a reference standard while assessing biosimilarity between a biosimilar product and the reference product, for example the biosimilarity index approach based on a reference-replicated study, in which the reference product is compared with itself under various scenarios.

Potential impact of biosimilar medicines on patients and healthcare systems

- A biosimilar product may yield a similar efficacy, tolerability and safety to the original, but the switch between these products in patient treatment may require input from a clinician.
- In this case, there is a clear distinction between biosimilarity and interchangeability (the ability of prescribers to switch between the reference product and a biosimilar). Confirmation of biosimilarity does not imply interchangeability or especially substitution (the automatic substitution of the reference product without the prescribers' consent, for example by a pharmacist)

Recommendations

a) Healthcare professionals (HCPs)

- HCPs should ensure that people with diabetes (PWD) well managed on an existing insulin are not changed to another insulin formulation, including biosimilars, without good clinical reason and evidence of interchangeability.
- HCPs should present the reasons and agree jointly with the PWD on the appropriate use of biosimilar insulins, providing clear and sufficient information.
- HCP should take into consideration the person's preference in the choice of biosimilar insulins through individual features such as pen injectors for delivery.
- HCPs should report any adverse reaction to a biosimilar insulin (as they would for other insulin formulations) so that appropriate monitoring can take place.

b) Pharmacists

- Pharmacists should be well-informed about insulin formulations, including biosimilars.
- Pharmacists should be in contact with the prescribing physician in case of substituting the product, in order to track the assessment of the clinical outcomes.

c) People with diabetes (PWD)

- PWD treated with insulin should be acquainted with all relevant aspects of the use of a biosimiliar insulin to ensure they are able to have informed discussions with their HCPs if a suggestion to change is made.
- PWD should report any adverse reaction to a biosimilar insulin (as they would for other insulin formulations), so that appropriate monitoring can take place.

d) Pharmaceutical industry

- Pharmaceutical industry is expected to provide conclusive and reproducible data on pharmacokinetics and pharmacodynamics in comparison to the reference product, as well as comprehensive data showing acceptable batch-to-batch variability and efficient use in delivery devices.
- Pharmaceutical industry should also report the results of the comparison in safety and efficacy to the reference product in all major aspects of the therapeutic use, apart from the cost-benefit ratio. This refers especially to immunogenicity data.
- Pharmaceutical industry should provide comprehensive data on interchangeability in practice, pharmacovigilance and post-marketing surveillance.
- Pharmaceutical industry should work closely with national health authorities, other relevant health administrations, clinicians and PWD to ensure adequate understanding of the properties of their biosimilar insulins

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IRANIAN DIABETES SOCIETY

THANK YOU
FOR YOUR ATTENTION