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Title: Insulin or fixed ratio combination of insulin and GLP-1R agonist dose adjustment	Date Issued: May 2014 Date Reviewed: September 2023 Date Revised: October 2023

Authorized by: VP Patient Care and Chief Nursing Officer Kim Mullins Medical Advisor, Dr. David Kennedy M.D. FRCP	Approved: MAC October 2023
Authorization by primary care physician: I authorize the Nurse and Dietitian Educators of the Haldimand-Norfolk Diabetes program to initiate and adjust insulin or fixed ratio combination of insulin and GLP1 agonist as outlined in the medical directive. Name (Print)_____ Signature_____	

MEDICAL DIRECTIVE

Any PRINTED version of this document is only accurate up to the date of printing. Always refer to the NGH Intranet site for the most current version.

Directive Statement:

The purpose of this medical directive is to improve glycemic control for patients with hyperglycemia or hypoglycemia who are referred to the Haldimand Norfolk Diabetes Program.

The directive may be applied to patients of the Haldimand Norfolk Diabetes Program who have been prescribed insulin or a fixed ratio combination insulin/GLP1 by their primary care physician, nurse practitioner (NP), or specialist who has signed authorization for the medical directive.

Insulin and the combination insulin may be adjusted for the purposes of optimizing glycemic control, promoting diabetes self-care and/or enhancing patient safety and quality of life.

- Glycemic targets are ordered by the prescribing physician on the referral form or as defined by the current Diabetes Canada Clinical Practice Guidelines

- Insulin dose or fixed ratio combination of insulin and GLP-1RA adjustments will be made after a careful review of a patient's glucose measurements and a risk assessment that may include nutritional intake, activity levels, weight changes, medical status, cognitive ability, presence of lipohypertrophy and a follow-up plan.

- Unless otherwise directed by the prescribing physician, any dose of insulin may be adjusted (increased or decreased) by an amount that is not to exceed 20% (refer to exceptions listed*). This applies to basal insulin, bolus insulin, pre- mixed or combination insulin, insulin sensitivity factors (ISF) and carbohydrate: insulin ratios.

- A patient's dose of insulin may be adjusted every 1-3 days ·

- Insulin dose adjustments greater than 20%, modification to the frequency of insulin injections, stopping or not starting an ordered insulin, or a change to the brand of insulin that is being utilized requires notification of the prescribing physician~~s~~ and a new order except in the following circumstances*:

    a) To avoid exercise-induced hypoglycemia, a dose of insulin may be reduced by up to 75%
    b) For patients who are ill (i.e. sick day management), or with evidence of lipohypertrophy with hypoglycemia the dose of insulin may be adjusted by up to 50%.

The Diabetes Educator will:

- Follow the established process, parameters and guidelines for initiating/adjusting/sampling insulin as outlined in the clinic operations standards

Authorized to:

Implementers:

Certified Diabetes Educators within the Haldimand Norfolk Diabetes Program at Norfolk General Hospital, who have completed all educational requirements.

Qualifications required

Registered Nurses (RN), and Registered Dietitians (RD) working in the Haldimand Norfolk Diabetes Program who:

- Have obtained and maintained the Certified Diabetes Educator (CDE) accreditation
- Have the necessary knowledge, critical thinking skills, and accept accountability in implementing the medical directive for insulin and combination insulin adjustment
- Maintain current registration in the Regulated Health Professional College and implement the directive as per their governing body.

Criteria for initial qualification or if on a leave for longer than one year.

- Self-assessment of competency skills checklist (Appendix A)
- Any gaps in knowledge where competency is not self-assessed, a learning plan will be developed with the medical advisor or delegate until competency is achieved.
- Completion of the written examination (Appendix B) with a grade not less than 80% corrected by the medical advisor or delegate;
- Completion of 6 case study scenarios reviewed by a certified educator or physician delegate (Appendix C);
- To assess the critical thinking and application of knowledge to practice, the medical advisor or delegate will assign a competency of C(competent), S(requires support) or N (requires knowledge development) for supervised insulin adjustments. There will be 2 components for each type of insulin adjustment (premix, dose scale, set bolus, carbohydrate to insulin ratio, insulin sensitivity factor, basal insulin, basal combination with GLP-1 agonist) (Appendix D)
- If competency is judged to be inadequate, the educator will be required to continue

supervised clinical practice.

Criteria for Recertification:
Recertification will be required every two years and will consist of:

- Evidence of participation in continuing education- minimum 16 hours per year;
- An assessment of insulin adjustments to assess the critical thinking and application of knowledge to practice. The medical advisor or delegate will assign a competency of C (competent), S (requires support) or N (requires knowledge development) for insulin adjustments. There will be 2 components for each type of insulin adjustment (premix, dose scale, set bolus, carbohydrate to insulin ratio, insulin sensitivity factor, basal insulin, basal combination with GLP-1 agonist).
- If competency is judged inadequate, the diabetes educator will be required to repeat the certification process (including supervised clinical practice and exam).

All implementers will be required to sign that they have the qualifications and agree to the conditions within the Medical Directive.

Indications and Contraindications

Indications:

- Patients with diabetes who are administering insulin or a combination insulin GLP-1 subcutaneously and who are not meeting their targeted glycemic goals.
- Patients with diabetes who are not meeting their targeted glycemic goals -and whom injectable therapy is ordered to start.
- The prescribing physician has provided an order/referral specifying a) insulin type, b) insulin dose, c) frequency of insulin administration, d) glycemic target (AIC or glucose target) if different from Diabetes Canada guidelines) and e) that insulin may be adjusted as per the medical directive or as otherwise indicated.
- The prescribing physician/NP has signed the current medical directive.
- Patient or substitute decision maker has given verbal consent to the prescribed Treatment.
- Nurse or dietitian has had contact with the patient and completed a comprehensive clinical assessment within the last 24 months (about 2 years).
- Patient (or caregiver) demonstrates competency in glucose monitoring and insulin or insulin/GLP1RA administration

Contraindications:

- Patients who do not agree or do not adhere to their prescribed insulin regimen
- If a patient does not demonstrate the potential or interest in safe self-dose adjustment (adjusting the doses outside what is recommended by the health care team).
- Patients who are not able to, or decline to participate in diabetes self- management (or who have no caregiver to assume this responsibility). This includes obtaining regular glucose testing.
- If the patient has not maintained contact with a clinic educator within the past 24 months; a new referral and clinical assessment is required.

Documentation/Communication Plan

- All clinical findings, indications and rationale for insulin adjustment, patient education, patient instructions, and follow-up plans will be documented in the patient's medical record
- The educator implementing the medical directive will communicate with the prescribing physician by phone or fax if:
  a) if the patient requires a change in insulin type or regimen
  b) there are any contraindications to implementing the medical directive
  c) the therapies prescribed have resulted in unresolving side effects
  d) Recurrent or severe hypoglycemia
  f) if glycemic control is not improving or is deteriorating despite adjustments made to the insulin regime and other components of the treatment plan
- The educator will communicate with the prescribing or referring physician and primary care provider, to ensure the physician is informed of the patient 's glycemic control and treatment plan. This communication will be a minimum of one patient visit per year.
- It is an expectation that physicians authorizing the medical directive and ordering insulin/ insulin with GLP1RA will inform the diabetes educator of any changes in health status or medication that will impact glycemic control.
- Untoward events that may be related to the initiation of the medical directive are documented and are verbally communicated to the Program Coordinator, the physician and an incident report completed, if appropriate.

Professional implementing a medical directive is responsible to ensure that consent is obtained.

Distribution to Stakeholders

Every two years the Medical Directive will be updated and approved by the Program Medical Advisor and VP Patient Care and Chief Nursing Officer. The approved Medical Directive will then be distributed to the most responsible physicians for authorization signatures.
This Medical Directive will be communicated to:

The Diabetes Nurse and Dietitian Educators of the Haldimand Norfolk Diabetes Program.

Quality Monitoring Process

The following processes will be used to maintain appropriate implementation of the directive and guide action if inappropriate, unanticipated and/or untoward outcomes result:

- Audits on adverse events
- This Medical Directive will be updated every two years
- Reauthorization to implement the directive will be considered upon annual performance review and/or re-certification
- Any significant changes to medical directive will require re-orientation of authorized persons

Main Contact related to the development of the medical directive:		
Elaine Wylie RN, MN, CDE Name	Program Coordinator Position/Title	Haldimand Norfolk Diabetes Program Department
Medication		

Drug Classification	Drug Name and Dosage Range	Indications	Absolute contraindications	Special Considerations (Including Contraindications)
Rapid Acting Insulin Analogues Faster Acting Insulin Analogues	Insulin Lispro (Humalog U 100, U200) (Admelog) Insulin Aspart (Novorapid) (Trurapi) (Kirsty) Insulin Glulisine (Apidra) . Insulin Aspart (Fiasp)	Mealtime insulin usually taken within 15 minutes of eating Given to correct hyperglycemia (this may in the absence of carbohydrate intake) Fiasp can be administration up to 2 minutes before the start of the meal. or to 20 minutes after starting the meal	Insulin boluses should not be taken if glucose is less than 4 mmol/L.	Rapid insulin should not be mixed in the same syringe with long-acting insulin analogues DO NOT dilute or mix Fiasp® with any other insulin products or solutions
Regular Insulin	Insulin Regular (Humulin® R) Insulin Toronto(Novolin ® ge Toronto) Humulin R U500 (Entuzity)	Mealtime insulin usually taken within 30 minutes of eating Given to correct for acute and severe hyperglycemia Entuzity can be given as premeal, bolus or as a basal insulin. It can be administered once a day up to TID.	Should not be taken if glucose is less than 4mmol/L If prescribed for meal(carbohydrate) coverage, it should not be taken in the absence of food.	Can be used in combination with intermediate or long acting insulin, oral AHA, and GLP1RA

Drug Classification	Drug Name and Dosage Range	Indications	Absolute contraindications	Special Considerations (Including Contraindications)
Intermediate Acting Insulin	NPH insulin (Novolin® ge NPH) N- Insulin (Humulin® N)	A basal insulin to maintain blood sugar levels when NOT eating Usually administered before breakfast and/ or before supper or hs May be benefiscial for steroid induced hyperglycemia		May be used individually or in combination with rapid or fast acting insulin, GLP1RA, or oral anti-hyperglycemic agents. Not approved for use with: thiazolidinediones (TZDs)
Long Acting Insulin Analogues	Insulin glargine (Lantus, Basalglar, and Toujeo U300, Semglee) Titration: every one to three days Insulin detemir (Levemir) Titration: every one to three days Insulin Degludec (Tresiba® U 100 and U200) Titration: every 3 to 5 days	A basal insulin to maintain blood sugar levels when NOT eating longer acting basal analogues have a reduced risk of nocturnal hypoglycemia compared to NPH. Maybe administered at different times of the day (am, hs, as supper)	Must not be mixed or diluted with any other insulin or solution	Used individually or in combination with rapid or fast acting insulin or oral anti-hyperglycemic agents. Cannot be mixed in the same syringe as rapid insulin

Drug Classification	Drug Name and Dosage Range	Indications	Absolute contraindications	Special Considerations (Including Contraindications)
Premixed Insulin Contains a fixed ratio of insulin (the numbers refer to a percent of rapid/fast acting insulin to the percent of intermediate acting insulin)	Premixed regular and intermediate acting insulin : Humulin® 30/70 Novolin® ge 30/70 Premixed insulin analogues: Humalog Mix 25 Humalog Mix 50, NovoMix 30	Usually administered twice daily. Usually given 30 minutes before breakfast and before supper. Usually administered twice daily: Usually given within 15 minutes of meal	Should not be given during episodes of hypoglycemia until glucose levels are above 4 mmol/L	Should not be given with basal insulin.
CombinationProduct: Insulin and GLP-1 Receptor Agonist	Xultophy® pre-filled,:Insulin Degludec 100 units per mL + Liraglutide 3..6mg per mL Soliqua™ pre-filled: Insulin Glargine 100 units per mL + Lixisenatide 33 mcg per mL	Must not be mixed or diluted with any other insulin or solution Contraindicated with personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 and in pregnant or breastfeeding women. It is not recommended as first-line treatment or for individuals with inflammatory bowel disease or delayed gastric emptying, and prior history of pancreatitis. Not recommended for patients with Type 1 diabetes Caution if eGFR is less than 60. Not recommended with an eGFR of less than 30.	Used individually or in combination with rapid or fast acting insulin or oral anti-hyperglycemic agents Used with caution in patients 65 years and older, since a greater sensitivity of some older individuals cannot be ruled out Titration may depend on the patient's glycemic control as well as their tolerance to the product. GLP1 RA portion of the product side effects may include nausea, vomiting, diarrhea.	

Educators for who the directive applies to.	**Professional Designation**	**Educator's Signature**
Jaime Anderson	*RD, CDE*	
Esther Lessard	*RN, CDE*	
Anita Addison	*RN,CDE*	
Jessica Brown	*RD, CDE*	
Bridget Korobka	*RD, CDE*	
Elaine Wylie	*RN, CDE*	

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