



Taddle Creek

Family Health Team

Title:	Diabetes Management in Adults	Number:	TCFHT-MD05
Activation Date:	12-June-2012	Review Date:	12-June-2018
Next Review Date:	12-June-2019		

Note: Jun 2016 review resulted in a change; addition of Empagliflozin & Komboglyze. Change approved at Jun 14-16 Board Mtg (see minutes) thus negating necessity to get authorizers to re-sign.

Sponsoring/Contact Person(s)
(name, position, contact particulars):

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Order and/or Delegated Procedure:

Appendix Attached: No Yes

Title: Appendix C – Performed Controlled Acts and Procedures

The implementers are authorized to perform the following activities, in accordance with Appendix C when all conditions in this directive and the attached appendices are met:

- 1) Start, Adjust, Hold and Discontinue Basal Insulin already prescribed by Primary Care Provider/Endocrinologist
- 2) Start, Adjust, Hold and Discontinue Intensive Insulin Therapy already prescribed by Primary Care Provider/Endocrinologist
- 3) Adjust, Hold and Discontinue Oral Antihyperglycemic Agents

- 4) Dispense Insulin prescribed by Primary Care Provider or Endocrinologist
- 5) Prescribe Diabetes Supplies (glucose meter, glucose meter strips, needles for insulin pens and lancets)

Recipient Patients:Appendix Attached: No Yes

Title: Appendix A – Authorizer Approval Form

Recipients must:

- Be active patients of a TCFHT primary care provider/endocrinologist who has approved this directive by signing the Authorizer Approval Form
- Have a diagnosis of diabetes mellitus (type 1 or type 2) or pre-diabetes
- Meet the conditions identified in this directive.

Authorized Implementers:Appendix Attached: No YesTitle: Appendix B – Implementer Approval Form;
Appendix D – Competency Checklist

Implementers must be TCFHT employed Regulated Health Care Providers or Physician Assistant (under the supervision of a physician).

Implementers must complete the following preparation and sign the Implementer Approval Form:

- Must become a certified diabetes educator (CDE) as per the Canadian Diabetes Educator Certification Board
- Practice according to the Canadian Diabetes Association's (CDA's) most current Clinical Practice Guidelines
- Assess their own knowledge, skill, and judgment to competently perform these directives

In addition, to implement delegated procedures 1-3 (start, adjust, hold or discontinue basal or intensive insulin therapy and to adjust, hold and discontinue oral antihyperglycemic agents):

- Must have at least 1600 practice hours in providing direct diabetes education with patients living with diabetes
- Must be mentored by an authorized implementer and demonstrate the competencies and review all of the Canadian Diabetes Association's Best Practice Guidelines, as outlined in Appendix D
- Must be supervised by Endocrinologist with at least 3 patient cases involving adjustments to insulin and oral antihyperglycemic agents and complete and sign competency performance checklist (Appendix D)

Indications:Appendix Attached: No Yes

Title: Appendix C – Performed Controlled Acts and Procedures

- In general, each action/procedure under each directive will be implemented in the context of the existing physician/nurse practitioner relationship and as part of the medical diagnosis and plan of care established by the physician/nurse practitioner. These actions/procedures will be implemented without specific prior discussion (but as part of the plan of care) as per the

indications and contraindications for each of these directives (Appendix C).

- Communication to primary care provider/endocrinologist regarding medication/insulin adjustments made following implementation of medical directive (see documentation and communication)
- Implementer obtains verbal patient consent prior to the application of this directive

Contraindications:

- No verbal consent from patient or substitute decision maker for implementer to apply this medical directive
- Indications described in Appendix C are not met

Consent:

Appendix Attached: No Yes
Title:

- Patient's consent is implied, as patient has presented seeking support with diabetes management, and is a Family Health Team patient, where interprofessional practice is expected
- The implementer fully explains potential risks and benefits prior to initiating/adjusting insulin therapy and with any changes to oral antihyperglycemic medications

Guidelines for Implementing the Order/Procedure:

Appendix Attached: No Yes
Title: Appendix C – Performed Controlled Acts and Procedures

As per Appendix C.

Documentation and Communication:

Appendix Attached: No Yes
Title:

- Documentation in the patient's eMR needs to include: name and number of the directive, patient's Capillary Blood Glucose (CBG) patterns, current medications, self-management skills and learning needs, clinical findings and the plan of care, patient's response to the procedure or directions provided
- Implementer will send a message in Practice Solutions to patient's primary care provider, notifying him/her that patient was seen, recommendations were made and that eMR note needs review for details.
- Primary care provider responsible for entering newly prescribed medications into medication list in practice solutions. Implementer responsible for updating medication list in practice solutions.
- Implementer will arrange a follow up plan in collaboration with patient and primary care provider/endocrinologist with any medication/insulin adjustments.

Review and Quality Monitoring Guidelines:

Appendix Attached: No Yes
Title: Appendix D – Competency Checklist

- Routine review will occur annually on the anniversary of the activation date. Review will involve a collaboration between the authorizing primary care providers and the authorized implementers.
- At any such time that issues related to the use of this directive are identified, TCFHT must act upon the concerns and immediately undertake a review of the directive by the authorizing primary care providers and the authorized implementers.

- If new information becomes available between routine renewals, such as the publishing of new Diabetes Canada Best Practice Guidelines, and particularly if this new information has implications for unexpected outcomes, the directive will be reviewed by the authorizing primary care providers and the authorized implementers.
- This medical directive can be placed on hold if routine review processes are not completed, or if indicated for an ad hoc review. During the hold, implementers cannot perform the procedures under authority of the directive and must obtain direct, patient-specific orders for the procedure until it is renewed.
- **Implementer’s competencies will be reviewed on a yearly basis as part of their performance review. Clinicians must consistently demonstrate competency in order to remain an authorized implementer of this directive – see Appendix D**

References:

Canadian Diabetes Association. (2010). Building Competency in Diabetes Education: Advancing Practice.

Canadian Diabetes Association. (2013). Building Competency in Diabetes Education: The Essentials.

Diabetes Canada. (2018). Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada.

Canadian Insulin Injection Recommendations: FIT, 2011.

Fit Forum for Injection Technique Canada. (2011). Fit Forum for Injection Technique Canada: Recommendations for Best Practice in Injection Technique.

Health Canada. Drug Product database. Retrieved from hc-sc.gc.ca.

Levin A, Hemmelgarn B, Culleton B et al. (2008) Guidelines for the management of chronic kidney disease. *CMAJ*, 179, 1154-1162.

Up to Date. Retrieved from uptodate.com.

Insulin Initiation and Titration Suggestions (for type 2 diabetes). Ontario College of Family Physicians (prescription tear pad).

NOTE:

This medical directive is based on TCFHT’s previous medical directive DEP1 entitled, “Diabetes Management in Adults Medical Directive,” which required revision in formatting to reflect the growth of the TCFHT organization. The majority of the content of DEP1 has remained the same for the revised TCFHT-MD05 version. Therefore, all approved Implementers and Authorizers for medical directive DEP1 “Diabetes Management in Adults Medical Directive” have grandfathered approval for TCFHT-MD05 “Diabetes Management in Adults.”

Appendix A:
Authorizer Approval Form

Name	Signature	Date
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Appendix B:

Implementer Approval Form

To be signed when the implementer has completed the required preparation, and feel they have the knowledge, skill, and judgement to competently carry out the actions outlined in this directive.

Delegated Procedures 1-3:

- Start, Adjust, Hold and Discontinue Bedtime Insulin
- Start, Adjust, Hold and Discontinue Intensive Insulin Therapy
- Adjust, Hold and Discontinue Oral Antihyperglycemic Agents

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Delegated Procedures 4-5:

- Dispense Insulin Prescribed by Primary Care Provider or Endocrinologist
- Prescribe Diabetes Supplies (glucometer, glucometer strips, needles for insulin pens and lancets)

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Appendix C

Performed Controlled Acts and Procedures

Table 1: List of Medications (Insulin) Implemented under this Directive with Detailed Indications/Contraindications

Insulin Type	Onset	Peak/ Duration	Indications for Adjustment	Therapeutic Considerations
Rapid-Acting <ul style="list-style-type: none"> Lispro (Humalog) Aspart (Novorapid) Glulisine (Apidra) Lispro 200 (Humalog 200) Aspart (Fiasp) 	2-15 minutes	1-2 hours/ 3-5 hours	<ul style="list-style-type: none"> 2 hr post-meal and/or pre-meal blood sugars (lunch, dinner) are either elevated or hypoglycemia occurs 	<ul style="list-style-type: none"> Patient's should eat within 0-15minutes after injection In certain circumstances injecting shortly after eating is appropriate e.g. GI disturbance resulting in early satiety, vomiting etc. For Patient's on MDI (multiple daily injections) using a rapid-acting insulin it is recommended that they self-monitor blood glucose (SMBG) at least QID for safe titration of doses Humalog 200 must only be used in the pre-filled pen. It must not be drawn up in a syringe Fiasp is best injected 2 minutes before and up to 20 minutes after a meal. It may not be best in people with delayed gastric emptying & has not been studied in pregnancy
Short-Acting <ul style="list-style-type: none"> Humulin R Novolin Toronto 	30 minutes	2-3 hrs/6.5 hours	<ul style="list-style-type: none"> Pre-meal blood sugars (lunch, supper) and/or bedtime are elevated or hypoglycemia occurs 	<ul style="list-style-type: none"> Patient's should inject insulin 30 minutes prior to eating For Patient's on MDI (multiple daily injections) using a short-acting insulin it is recommended that they SMBG at least QID for safe titration of doses
Intermediate-Acting <ul style="list-style-type: none"> Humulin N Novolin NPH 	1-3 hours	5-8 hours/up to 18hours	<ul style="list-style-type: none"> Increase evening dose if high fasting blood sugar (if rebound hyperglycemia has been eliminated) Decrease dose if hypoglycemia (recommend CBG testing in the night to rule out nocturnal hypoglycemia) 	<ul style="list-style-type: none"> Must be adequately re-suspended before injecting Higher risk of hypoglycemia compared to long-acting insulin Recommended for Patient's to SMBG OD-BID for safe titration of doses

			<ul style="list-style-type: none"> • Increase or decrease morning dose if 5-8 hour pre-meal blood sugars are out of target 	
Pre-Mix Analogues <ul style="list-style-type: none"> • NovoMix 30 • Humalog Mix 25 • Humalog Mix 50 Regular Insulin <ul style="list-style-type: none"> • Novolin 30/70, 40/60, 50/50 • Humulin 30/70 	<p>10-15 minutes</p> <p>30-60 minutes</p>	<p>Contains a fixed ratio of insulin (% of rapid-acting or short-acting insulin to % of intermediate-acting insulin: see above for information about peak actions based on insulin contained</p>	<ul style="list-style-type: none"> • Increase/ decrease morning dose if lunch/supper readings are out of target • Increase/decrease evening dose if HS or fasting sugars are out of target • Recommend CBG testing in the night to rule out nocturnal hypoglycemia 	<ul style="list-style-type: none"> • Must be adequately re-suspended before injecting • Patient's should eat within 0-15 min after injecting Mix 30, Mix 25 or Mix 50 • Patient's should inject 30/70, 40/60 or 50/50 30 minutes prior to eating • Recommended for Patients to SMBG at least BID (AC breakfast and dinner) for safe titration of doses
Long-Acting <ul style="list-style-type: none"> • Detemir (Levemir) • Glargine (Lantus, Basaglar) • Glargine 300 (Toujeo) • Degludec (Tresiba) U-100, U-200 	<p>90 minutes</p>	<p>No peak/16-24hrs</p> <p>No peak/up to 24 hrs</p> <p>No peak/ up to 30hrs</p> <p>No peak/up to 42h</p>	<ul style="list-style-type: none"> • Increase/decrease dose if fasting or pre-supper sugars (if injecting in the morning) are out of target 	<ul style="list-style-type: none"> • Do not mix with other insulin in the same syringe • Recommended for patient's to SMBG at least OD (FBG or AC meals) for safe titration of dose • Toujeo can be stored for 42 days at room temperature • Toujeo and Tresiba U-200 must only be used in the pre-filled pen. They must not be drawn up in a syringe • Degludec can be stored for 8 weeks at room temperature • Use a 1:1 conversion using total daily dose when switching from intermediate or long-acting insulin to Tresiba • Use a 1:1 conversion using total daily dose when switching from long-acting insulin to Toujeo or 80% of total daily intermediate dose

Table 1 Notes:

- The implementer will adhere to the indications and contraindications outlined in Table 1
- The implementer is responsible for teaching patient safe injection technique according to FIT 2011 guidelines. Implementer is also responsible for recommending needle length appropriate to patient.
- A prescription is required from the primary health care provider and/or endocrinologist prior to insulin initiation
- Most patients new to insulin are started on 10 units HS of a basal insulin, or 0.1-0.2 units per kg/d for patients < 50 kg. Alternatively, they can be started on a premixed insulin at 5 – 10 U twice daily before breakfast and before supper or started on Basal + Bolus insulin with initial total daily dose of 0.3 – 0.5 units per kg/d (40% of this as basal and 20% of this a bolus with each meal). However individual considerations need to be assessed i.e. patient's who are hypoglycemic unaware or have a fear of insulin-induced hypoglycemia can be initiated on a smaller dose etc.
- Evidence-based recommendations are to adjust insulin by 1-2u q 3-4 days or by 1u per day. Under certain circumstances patients may need insulin adjustment greater or less than 5-10% of total daily dose i.e. extreme hyperglycemia, medications and/or lifestyle factors that can increase/decrease glycemic levels
- Glargine 300 and Degludec should be titrated q3-4 days by 2-3 units
- Implementer should determine a communication plan with the patient for further insulin adjustment
- Implementer will instruct a patient starting insulin around hypoglycemia treatment, driving instructions and instruct family/caregivers on using a glucagon kit when applicable i.e. type 1 diabetes and high risk for hypoglycemia
- In the case of high CBG readings and low CBG readings, always correct for hypoglycemia first
- Patients should be instructed as to how to adjust insulin during times of illness, travel and physical activity following current best practice guidelines
- Allergic reactions are rare but can occur with a few patients. Reactions may be local (i.e. rash/weal at site) or systemic (i.e. shortness of breath, wheezing or severe weakness). Implementer should instruct Patient to hold insulin and get in contact with primary care provider a.s.a.p. and/or proceed to the nearest emergency department
- Patient should be instructed to store unopened insulin vials/cartridges in the refrigerator, store open insulin vials/cartridges at room temperature, not expose insulin to heat or direct sunlight, not freeze insulin, and to use by expiration date
- The primary care provider or endocrinologist must be available to provide consultation as required
- Primary care provider and/or endocrinologist should be consulted in the following circumstances:
 - Recurrent or severe hypoglycemia with no apparent cause
 - Glycemic control is not improving or is deteriorating despite adjustments made to insulin or other component of the treatment plan

- Total daily dose exceeds what is generally expected for age/body type
- Patient shows signs and symptoms of Diabetic Ketoacidosis (DKA), dehydration or other serious problems *send to the Emergency Department immediately
- Recurring/persistent vomiting/diarrhea
- Disordered eating pattern resulting in calorie restriction
- Significant error in dose or timing of insulin administered by person or caregiver
- Situations requiring prolonged fasting i.e. for religious or medical reasons
- Change in brand or type of insulin
- Change in frequency of injections i.e. BID to TID
- For patients with additional complex medical or endocrine disorders which may influence insulin requirements or patient safety
- In all situations that are beyond the implementer's scope of practice and/or competency level

Table 2: Non-Insulin Antihyperglycemic agents: List of Medications Implemented under this Directive with Detailed Indications/Contraindications

Antihyperglycemic Agent	Indications for Adjustment	Contraindications/Precautions
<p>Alpha-Glucosidase Inhibitor</p> <p><u>Acarbose (Glucobay, Prandase)</u> <i>Initial Dose:</i> 25-50 mg daily <i>Average Dose (Max dose):</i> 50-100 mg tid (300 mg) <i>Special Instructions:</i> Take with first bite of meal <i>Onset/peak/duration:</i> 1h/2h/4-6h <i>Expected HbA1C reduction:</i> 0.6% ODB Coverage: limited use</p>	<ul style="list-style-type: none"> • Gastrointestinal (GI) side effects • Inadequate blood glucose control • Very low frequency of hypoglycemia unless combined with a sulfonylurea • Initiate therapy with 25mg OD-BID and titrate slowly by 25mg/day every 2-4 weeks as tolerated • Maximum effectiveness with at 50mg TID; higher doses associated with increased adverse events 	<ul style="list-style-type: none"> • Not recommended as initial therapy in people with severe hyperglycemia (A1C \geq8.5%) • Gastrointestinal side effects in approx. 30% of Patient's i.e. cramps, diarrhea, abdominal distension, flatulence (effects usually decrease with continued use but there is a high discontinuation rate based on GI side effects) • Treat hypoglycemia with Dextrose tablets, milk or honey as Acarbose interferes with glucose absorption • Contraindicated in Patient's with DKA, inflammatory bowel disease, intestinal ulcers, cirrhosis, partial intestinal blockage or predisposed to blockage • Renal dosing: discontinue use if creatinine clearance (CrCl) <25ml/min or eGFR <30 mL/min • In patients with known liver impairment or liver disease, liver enzymes should be monitored prior to start of Acarbose, and monitored on a regular basis within the first year • Case reports of reduction in absorption of digoxin and increased absorption of warfarin Maximum doses based on weight <132 lbs: 50mg TID; >132 lbs: 100mg TID
<p>Biguanides</p> <p><u>Metformin (Glucophage)</u> <i>Initial Dose:</i> 250-500 mg daily <i>Average Dose (Max dose):</i> 500-1000 mg bid or 850 mg tid (2550 mg) <i>Special Instructions:</i> Take with meals to reduce GI side effects <i>Onset/peak/duration:</i> 1-2h/6h/6-12h <i>Expected HbA1C reduction:</i></p>	<ul style="list-style-type: none"> • Initiate Glucophage 500mg twice daily or 850mg OD • Initiate Glumetza 500mg once or twice daily • GI side effects in 20-30% of Patient's (Glumetza associated with fewer GI side effects than short-acting Metformin). Side effects can be reduced by slow titration (500mg/day every 2 weeks and taking medication 	<ul style="list-style-type: none"> • Contraindicated in people with a history of lactic acidosis, severe hepatic dysfunction, severe infection/dehydration, trauma or cardiorespiratory insufficiency, surgery or alcohol abuse • Reduced dose recommended if CrCl/eGFR <60 ml/min and contraindicated if CrCl/eGFR <30 ml/min • 5-10% of people are unable to tolerate due to substantial GI side effects (upset stomach, nausea, diarrhea, anorexia, metallic taste) • Metformin should be stopped during acute illness (severe infections, trauma, surgery) and the recovery phase afterwards. Should also be put on hold in patients with severe dehydration (i.e., vomiting and

<p>1-1.5% ODB Coverage: Yes</p> <p><u>Glumetza (Metformin HCL ER)</u> <i>Initial Dose:</i> 500 mg daily (ideally with dinner) <i>Average Dose (Max dose):</i> 1000-2000 mg daily (2500 mg) <i>Onset/peak/duration:</i> 1-2h/4-8h/17.6-19.8h <i>Expected HbA1C reduction:</i> 1-1.5% ODB Coverage: No</p>	<p>with meals</p> <ul style="list-style-type: none"> • Decrease in FBG levels seen within 3-5 days; maximal effect in 1-2 weeks • 80-85% of glucose lowering effect is seen with 1500mg/day • Maximum effective dose is 2000mg/day • Renal insufficiency • Hypoglycemia (rare as monotherapy) • Blood glucose remains above target 	<p>unable to keep down fluids)</p> <ul style="list-style-type: none"> • Should do baseline liver function tests (LFT's) • Higher doses (above 2000mg/day) associated with increased risk of adverse events with no additive effect • Hold for 48 hours if undergoing radiologic studies with administration of iodinated contrast material (hold on day of procedure until 2-3 days after) • Not recommended in the elderly (over 80yrs) unless CrCl/eGFR is >60 mL/min due to decreased muscle mass • Recommend conservative dosing in the elderly • Lactic acidosis is rare 0.03/1000 patients and 0.015 fatal cases/1000 patients; more likely to occur in patients with renal insufficiency, alcohol or liver disease. Hold dose in hypoxic states, shock, severe infection or septicemia • Measurements of serum vitamin B12 are advisable at least every 1 to 2 years in patients on long-term treatment (Product Monograph – Health Canada)
<p>Insulin Secretagogues Sulfonylureas:</p> <p><u>Diamicron (Gliclazide)</u> <i>Initial Dose:</i> 40-80 mg daily or bid with meals <i>Average Dose (Max dose):</i> 80-160 mg bid (320 mg) <i>Onset/peak/duration:</i> 1-2h/4-6h/10-14h <i>Expected HbA1C reduction:</i> 0.8% ODB Coverage: Yes</p> <p><u>Diamicron MR (Gliclazide MR)</u> <i>Initial Dose:</i> 30 mg daily with first meal <i>Average Dose (Max dose):</i> 30-120 mg daily (120 mg) <i>Onset/peak/duration:</i></p>	<ul style="list-style-type: none"> • Frequent hypoglycemia (decrease or discontinue if hypoglycemia persists 1-2 times per week) • Inadequate blood glucose control (blood glucose remains above target consistently) • Dose should be started low and titrated every 1-2 weeks until glycemic targets are met 	<ul style="list-style-type: none"> • Associated with weight gain (unless dietary modifications are made) • Associated with hypoglycaemia; annual rate of any hypoglycaemia is 20%. Major hypoglycemic events occur in 1-2 % of individuals • Consider using other class(es) of oral antihyperglycemic agents first in patients at high risk of hypoglycemia i.e. the elderly • Requires lower dose and slower titration in patients with hepatic/renal impairment and the elderly • Increased risk for hypoglycemia with insulin • Glyburide not recommended with eGFR <30 mL/min, and should be used with caution in eGFR 30-45 mL/min. • Gliclazide and Glimepiride are contraindicated in severe renal impairment (CrCl eGFR<15 ml/min). Lower dose should be used if eGFR <30 mL/min • Sulfonylureas should be put on hold in patients with severe dehydration (i.e. vomiting and unable to keep down fluids)

<p>1-2h/6-12/>24h <i>Expected HbA1C reduction:</i> 0.8% ODB Coverage: Yes</p> <p><u>Diabeta (Glyburide)</u> <i>Initial Dose:</i> 2.5 mg – 5.0 mg daily or bid with meals <i>Average Dose (Max dose):</i> 5-10 mg bid with meals (20 mg) <i>Special Instructions:</i> Take 30min prior to meal) <i>Onset/peak/duration:</i> 1-2h/4-6h/10-14h <i>Expected HbA1C reduction:</i> 0.8% ODB Coverage: Yes</p> <p><u>Amaryl (Glimepiride)</u> <i>Initial Dose:</i> 1 mg daily with first meal <i>Average Dose (Max dose):</i> 1-4 mg daily (8 mg) <i>Onset/peak/duration:</i> 20min/2-4h/24h <i>Expected HbA1C reduction:</i> 0.8% ODB Coverage: No</p>	<p>See above.</p>	<p>See above.</p>
<p>Insulin Secretagogues Non-Sulfonylureas: Meglatinides</p> <p><u>Gluconorm (Repaglinide)</u> <i>Initial Dose:</i> 0.5-1mg tid with meals <i>Average Dose (Max dose):</i> 0.5-4 mg tid (16 mg) <i>Special Instructions:</i> take 1-30min before meals</p>	<ul style="list-style-type: none"> • Frequent hypoglycemia (decrease or discontinue if hypoglycemia persists 1-2 times per week) • Less hypoglycemia compared to sulfonylurea's and are ideal for patients with irregular meal times • Inadequate blood glucose control (blood glucose remains 	<ul style="list-style-type: none"> • Less likely to cause weight gain and hypoglycemia than sulfonylureas • Safe to use in renal impairment and mild hepatic impairment but requires slower dose titration • In the elderly Repaglinide should be initiated at 0.5mg TID and titrate dose slowly (especially with CrCl 20-39mL/min) • Preferred for use in elderly individuals with erratic eating patterns • The concomitant use of Repaglinide and Clopidigrel (Plavix) is contraindicated as it may lead to a significant decrease in blood glucose levels due to a drug-drug interaction

<p><i>Onset/peak/duration:</i> 30min/1h/4-5h <i>Expected HbA1C reduction:</i> 0.7% ODB Coverage: Exceptional Access Program (EAP)</p>	<p>above target consistently)</p> <ul style="list-style-type: none"> • Doses should be titrated weekly as required to obtain glycemic targets 	
<p>Thiazolidinediones (TZD's)</p> <p><u>Actos (Pioglitazone)</u> <i>Initial Dose:</i> 15 mg daily <i>Average Dose (Max dose):</i> 15-45 mg daily (45 mg) <i>Onset/peak/duration:</i> 30min/2-4h/4 weeks <i>Expected HbA1C reduction:</i> 0.8% ODB Coverage: EAP</p> <p><u>Avandia (Rosiglitazone)</u> <i>Initial Dose:</i> 4 mg daily <i>Average Dose (Max dose):</i> 2-8 mg daily (8 mg) <i>Onset/peak/duration:</i> 30-60min/1-2h/4 weeks <i>Expected HbA1C reduction:</i> 0.8% ODB Coverage: EAP</p>	<ul style="list-style-type: none"> • Edema • Shortness of breath • Discontinue TZD if insulin is initiated • Titrate every 2-4 weeks • Full BG-lowering effect seen within 6-12 weeks • Discontinue if ALT >3 X upper limit of normal 	<ul style="list-style-type: none"> • Should do baseline LFT's prior to initiation, every 2 months for the first year and then periodically • May induce edema, fluid retention (recommended to monitor weight) • Pioglitazone may increase risk of bladder cancer and is not recommended for use with Patient's who have or have had bladder cancer, are at high risk, have blood or a red color in their urine. Patient's taking pioglitazone should be assessed regularly for potential symptoms of bladder cancer i.e. blood or red color in urine, painful urinate etc. • Can cause weight gain (subcutaneous fat + fluid retention) 1.5-4.84kg but decrease in visceral and hepatic fat. Weight gain is generally dose dependent • Associated with increased risk for bone loss and fractures in women 55yrs or older (0.78 per 100) • Used in combination with insulin may increase risk of edema and CHF. The combination of a TZD plus insulin is currently not an approved treatment in Canada • Rosiglitazone is no longer approved for use alone to treat DM2 except when Metformin use is contraindicated or not tolerated and all other oral agents have been tried alone or together and targets are not reached • Rosiglitazone is not indicated for triple therapy and is only indicated in combination with Metformin or a sulfonylurea • Pioglitazone is no longer approved for use with Metformin and a sulfonylurea • Can be used safely in mild to severe renal impairment • Contraindicated for people with CHF New York Heart Association (NYHA) Class I to IV cardiac status; evidence of left ventricular dysfunction or serious hepatic impairment (ALT 2.5 X upper limit of

		<p>normal)</p> <ul style="list-style-type: none"> • Prior to prescribing Avandia practitioners must 1) document the individual’s eligibility to meet the above criteria; 2) counsel the individuals on the risks and benefits of Avandia, including the CV risks; and 3) obtain the person’s written informed consent to take the drug
<p>DPP4 Inhibitors</p> <p><u>Sitagliptin (Januvia)</u> <i>Initial Dose:</i> 100 mg daily qam with/without food <i>Average Dose (Max dose):</i> 100 mg daily (100 mg) <i>Onset/peak/duration:</i> Rapidly absorbed/1-4h/24h <i>Expected HbA1C reduction:</i> approx. 0.7% ODB Coverage: Yes</p> <p><u>Saxagliptin (Onglyza)</u> <i>Initial Dose:</i> 5 mg daily with/without food <i>Average Dose (Max dose):</i> 5 mg daily (5 mg) <i>Onset/peak/duration:</i> Rapidly absorbed/2.5h/26.9h <i>Expected HbA1C reduction:</i> approx. 0.7% ODB Coverage: Yes</p> <p><u>Linagliptin (Trajenta)</u> <i>Initial Dose:</i> 5 mg daily with/without food <i>Average Dose (Max dose):</i> 5 mg daily (5 mg) <i>Onset/peak/duration:</i> Rapidly absorbed/1.5h/24h <i>Expected HbA1C reduction:</i> approx. 0.7% ODB Coverage: Yes</p>	<ul style="list-style-type: none"> • Nasopharyngitis, cough and headache (rare cases) • Severe joint pain (rare cases), usually within 1 month of initiation • Inadequate glucose control • Increased risk for hypoglycemia if combined with a sulfonylurea • Discontinue if suspicion of pancreatitis i.e. severe ongoing stomach or back pain with/without vomiting 	<ul style="list-style-type: none"> • Linagliptin can be used in renal insufficiency (eGFR <15 ml/min and dialysis) • Saxagliptin dose should be decreased to 2.5 mg od if eGFR <50 mL/min, and discontinued if eGFR <15 mL/min. It should not be used in patients on dialysis (assess renal function prior to treatment and periodically after) • Sitagliptin dose should be decreased to 50 mg od if eGFR is 30-49 mL/min, and decreased further to 25 mg od if eGFR <30 mL/min (assess renal function prior to treatment and periodically after) • Alogliptin dose should be decreased to 12.5 mg if eGFR is 30-60 mL/minute, 6.25 mg od if eGFR is 15-30 mL/minute and can be used at 6.25mg of in ESRD with hemodialysis (has not been studied with peritoneal dialysis) • Use in caution in the elderly (as per renal guidelines) • Safety profile has not been studied and is unclear in individual’s who are immunocompromised e.g. lymphocyte abnormalities, HIV, or people who have undergone organ transplant • Approved for use with Metformin and a sulfonylurea • Approved for use with insulin except for Linagliptin • Linagliptin , Sitagliptin and Alogliptin are not recommended in severe hepatic insufficiency and Saxagliptin is not recommended in moderate to severe hepatic impairment (monitor hepatic function before initiating treatment and periodically after) • Not recommended if history of pancreatitis • Caution if history of alcoholism, high triglycerides (higher risk for pancreatitis) • Not recommended for people with heart failure

<p><u>Alogliptin (Nesina)</u> <i>Initial Dose:</i> 25 mg daily with/without food <i>Average Dose (Max dose):</i> 25 mg daily (5 mg) <i>Onset/peak/duration:</i> Rapidly absorbed/1-2h/approx. 24h <i>Expected HbA1C reduction:</i> approx. 0.7% ODB Coverage: No</p>		
<p>GLP-1 Receptor Agonist</p> <p><u>Liraglutide (Victoza)</u> <i>Initial Dose:</i> 0.6 mg SC daily <i>Average Dose (Max dose):</i> 1.2-1.8 mg SC daily (1.8 mg) <i>Expected HbA1C reduction:</i> 1-1.5% ODB Coverage: No</p> <p><u>Exenatide (Byetta)</u> <i>Initial Dose:</i> 5 mcg (1.2 mL) SC bid <i>Average Dose (Max dose):</i> 5-10 mcg (1.2 mL–2.4 mL) bid (20 mcg) <i>Special Instructions:</i> inject <60minutes before two meals (breakfast and dinner) <i>Onset/peak/duration:</i> Rapid onset/2.1h/10h <i>Expected HbA1C reduction:</i> 1.3-1.5% ODB Coverage: No</p> <p><u>Dulaglutide (Trulicity)</u> <i>Initial Dose:</i> 0.75mg (0.5 mL) SC qweekly <i>Average Dose (Max dose):</i> 1.5mg(1.5mg)</p>	<ul style="list-style-type: none"> • Liraglutide to be increased to ideal therapeutic dose of 1.2mg OD after 1 week as tolerated. Can further increase to 1.8mg OD if needed based on response after 1 week at 1.2mg • Dulaglutide to be increased to ideal therapeutic dose of 1.5mg q 1week after 1 week as tolerated. • Exenatide should be titrated up to 10ug BID after 1 month if tolerating well • Increased risk of hypoglycemia if used with sulfonylurea (assess need to decrease sulfonylurea dose by 50%) 	<ul style="list-style-type: none"> • Common adverse effects are nausea (10.7-18.6%), diarrhea (8.3-14.9%), headache (5.4-12.4%), vomiting (5.4-7.4%) and dyspepsia (2.1-7.0%) • Symptoms usually improve over time • Should be stored in the refrigerator and unused medication discarded after 30 days • Increase in heart rate/ PR interval prolongation • Liraglutide is only approved for use with Metformin and/or a sulfonylurea in Canada • Exenatide is approved for use with Metformin and/or a sulfonylurea and with insulin Glargine • Use with prandial insulin has not been studied and cannot be recommended • Rare cases of pancreatitis have been reported. Should be discontinued in the presence of persistent severe abdominal pain and vomiting • Contraindicated with type 1 diabetes, DKA, personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome • May slow absorption of medications; caution with medications that require rapid absorption (acetaminophen, pain medications) • Liraglutide not recommended for moderate to severe renal impairment (eGFR <50 mL/min) • Exenatide dose should be decreased to 5 mcg bid if eGFR 30-59 mL/min, and discontinued if eGFR <30 mL/min • Assess renal function prior to treatment and periodically thereafter

<p><i>Special Instructions:</i> can be taken with or without meals <i>Onset/peak/duration:</i> 24 hrs/48hrs/120hrs <i>Expected HbA1C reduction:</i> 1.1% ODB Coverage: No</p>		<ul style="list-style-type: none"> • Caution in patients with recent MI, unstable angina, CHF, IBS or gastroparesis (no studies) • Exenatide should not be taken after meals or if dose was missed • Dulaglutide can be used with Metformin, with Metofrmin & a Sulfonylurea, with mealtime insulin. • Dulaglutide has not been studied in combination with a basal insulin • Dulaglutide’s day of weekly administration can be changed if necessary, as long as the last dose was at least 3 days before
<p>SGLT2 Inhibitors</p> <p><u>Canagliflozin (Invokana)</u> <i>Initial Dose:</i> 100 mg daily qam ideally before meal <i>Average Dose (Max dose):</i> 300mg daily (300mg) <i>Onset/peak/duration:</i> Rapidly absorbed/1-2 hrs/approx. 24 hrs <i>Expected HbA1C reduction:</i> 0.77-1% * up to 2.56% with HbA1C >10% ODB Coverage: Yes</p> <p><u>Dapagliflozin (Forxiga)</u> <i>Initial Dose:</i> 5 mg daily with/without food <i>Average Dose (Max dose):</i> 10 mg daily (10 mg) <i>Onset/peak/duration:</i> Rapidly absorbed/2h/approx. 24 hrs <i>Expected HbA1C reduction:</i> 0.7-0.99% * up to 2.04% with HbA1C >9% ODB Coverage: No</p> <p><u>Empagliflozin (Jardiance)</u> <i>Initial Dose:</i> 10 mg daily with/without food <i>Average Dose (Max dose):</i> 25 mg daily (25 mg) <i>Onset/peak/duration:</i></p>	<ul style="list-style-type: none"> • Start Canagliflozin at 100mg and increase to 300mg if well tolerated and eGFR >60 mL/min • Start Dapagliflozin at 5mg od and increase to 10mg od if well tolerated and eGFR >60 mL/min • Start Empagliflozin at 10mg od and increase to 25mg od if well tolerated and eGFR >60 mL/min • Canagliflozin and Empagliflozin should be discontinued when eGFR is <45 mL/min as it would not be effective in these patients and adverse reactions are more severe • Dapagliflozin should be discontinued when eGFR is <60 mL/min • Increased risk for hypoglycaemia if combined with sulfonylurea or insulin (may need to adjust diabetes medications) 	<ul style="list-style-type: none"> • Indicated as monotherapy in patients with type 2 diabetes for whom Metformin is inappropriate due to contraindications or intolerance • Indicated in combination therapy with Metformin, sulfonylureas or insulin (with or without Metformin) • Invokana and Forxiga are indicated in combination with Januvia • Common adverse effects are increased serum potassium >5.4 mEq/ml (12-27%) and >6.5 mEq/ml (2%), genital mycotic infections (7-11% in women and 3-4% in men), urinary tract infections (4-6%), nasopharyngitis (6-7%), polyuria (3-5%) • Renal function should be assessed prior to initiation of and regularly after with more frequent monitoring for patients taking Canagliflozin or Empagliflozin with eGFR 45-60 mL/min • Should not be initiated in patients with an eGFR <60 mL/min or <45 mL/min for Empagliflozin • Monitor serum potassium levels periodically after initiating in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions • May increase the risk for ketoacidosis. Patients experiencing signs and symptoms of ketoacidosis (e.g., difficulty breathing, nausea, vomiting, abdominal pain, confusion, unusual fatigue or sleepiness) should be evaluated and SGLT2 inhibitor should be discontinued if acidosis is confirmed • LDL levels should be monitored due to dose dependent increases in LDL-C seen with therapy • Dapagliflozin should not be used in patients with active bladder cancer and should be used with caution in patients with a prior history of bladder cancer • Dapagliflozin is not recommended in combination with pioglitazone (Actos)

<p>Rapidly absorbed/1.5h/approx. 24 hrs <i>Expected HbA1C reduction: 0.7-0.99%</i> * up to 2.04% with HbA1C >9% ODB Coverage: Yes</p>		<ul style="list-style-type: none"> • Dapagliflozin and Canagliflozin tablets contain lactose • May cause symptomatic hypotension due to intravascular volume depletion especially in patients with renal impairment (eGFR <60 mL/min), elderly, patients on other antihypertensives, or those with low systolic blood pressure. Assess volume status prior to initiation in patients at risk of hypotension and correct if depleted; monitor for signs and symptoms of hypotension after initiation • Not recommended for use with patients on loop diuretics • Can be used in mild-moderate hepatic impairment • Elderly patients (≥65 years) may have an increased risk of symptoms related to intravascular volume depletion (e.g., hypotension, orthostatic hypotension, dizziness, syncope, and dehydration) during therapy, especially with higher doses; elderly patients ≥75 years may experience a more pronounced risk. HbA1c reductions may be less in patients >65 years compared to younger patients. • Patients should be educated about the increased risk for genital mycotic infections and/or urinary tract infections • Patients should be advised about the possible side effect of increased urination and encouraged to drink sugar-free liquids during the day to avoid dehydration
<p>Combination Medications</p> <p>Janumet (Januvia and Metformin) <i>Initial Dose:</i> 50/500mg bid <i>Average Dose (Max dose):</i> 50/1000mg bid (50/1000mg bid) <i>Special Instructions:</i> Take with meals to reduce GI side effects ODB Coverage: Yes</p> <p>Janumet XR (Januvia and Glumetza) <i>Initial Dose:</i> 50/1000mg daily ideally with dinner <i>Average Dose (Max dose):</i> 50/2000mg od (50/2000mg od) <i>Special Instructions:</i> Take with meal to reduce GI side effects</p>	<ul style="list-style-type: none"> • See the indications for medications included in combination tablet • Initiate at higher doses (not initial dose) if already taking Metformin at higher doses and tolerating well 	<ul style="list-style-type: none"> • See contraindications/precautions for medications included in combination tablet

<p>ODB Coverage: Yes</p> <p>Jentadueto (Trajenta and Metformin) <i>Initial Dose:</i> 2.5/500mg bid <i>Average Dose (Max dose):</i> 2.5/1000mg bid (2.5/1000mg bid) <i>Special Instructions:</i> Take with meals to reduce GI side effects ODB Coverage: Yes</p> <p>Komboglyze (Onglyza and Metformin) <i>Initial Dose:</i> 2.5/500mg bid <i>Average Dose (Max dose):</i> 2.5/1000mg bid (2.5/1000mg bid) <i>Special Instructions:</i> Take with meals to reduce GI side effects ODB Coverage: Yes</p> <p>Kazano (Nesina and Metformin) <i>Initial Dose:</i> 12.5/500mg bid <i>Average Dose (Max dose):</i> 12.5/1000mg bid (12.5/1000mg bid) <i>Special Instructions:</i> Take with meals to reduce GI side effects ODB Coverage: No</p> <p>Xigduo (Forxiga and Metformin) <i>Initial Dose:</i> 5/850mg bid <i>Average Dose (Max dose):</i> 5/1000mg bid (5/1000mg bid) <i>Special Instructions:</i> Take with meals to reduce GI side effects ODB Coverage: No</p>		
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<p>Invokamet (Invokana and Metformin) <i>Initial Dose:</i> 50/500mg bid <i>Average Dose (Max dose):</i> 150/1000mg bid (150/1000mg bid) <i>Special Instructions:</i> Take with meals to reduce GI side effects ODB Coverage: No</p> <p>Synjardy (Jardiance and Metformin) <i>Initial Dose:</i> 5/500mg bid <i>Average Dose (Max dose):</i> 12.5/1000mg bid (12.5/1000mg bid) <i>Special Instructions:</i> Take with meals to reduce GI side effects ODB Coverage: No</p> <ul style="list-style-type: none">• See dosing information for medications included in combination tablet for more information		
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Table 2 Notes:

- The implementer will adhere to the indications/contraindications outlined in this table
- The primary care provider or endocrinologist must be available to provide consultation as required
- The implementer will recommend hold of medication and contact the physician/nurse practitioner immediately if suspicion of a hypersensitivity reaction i.e. anaphylaxis, hives, rash etc.
- Implementer should review medications discontinued or placed on hold within 24-48 hours in collaboration with physician/nurse practitioner.
- Women with type 2 diabetes who are planning a pregnancy should switch from noninsulin antihyperglycemic agents to insulin for glycemic control. Women with pregestational diabetes who also have PCOS may continue metformin for ovulation induction.
- Metformin and glyburide may be used during breastfeeding.

Table 3: Indications and Contraindications for Prescribing Diabetes Supplies

	Indications	Contraindications
Prescribe Diabetes Supplies (glucometer, glucometer strips, needles for insulin pens and lancets)	<ul style="list-style-type: none"> To assess glycemic control in response to non-insulin anti-hyperglycemic agents, insulin and lifestyle management, quality control activities and patient teaching The results are used to determine if a patient is euglycemic, hyperglycemic or hypoglycemic so appropriate interventions and education can occur Insulin pen needles or syringes for patients injecting insulin 	<ul style="list-style-type: none"> The patient or substitute decision maker refuses to monitor capillary blood glucose The patient is unable to monitor capillary blood glucose due to physical or cognitive limitations Considerations should be made for patients who are unable to monitor due to financial constraints SMBG not recommended due to CDA guidelines, but is ultimately up to RN or RD clinical judgement The length of the needles should be determined based on the current best practice recommendations for injections

Table 3 Notes: See Program Folders/Diabetes/Procedures/DEP – 12 Prescribing Diabetes Supplies in Practice Solutions

Table 4: Indications and Contraindications for Providing Insulin Samples

	Indications	Contraindications
Providing Insulin Samples	<ul style="list-style-type: none"> The patient has obtained an Rx from their primary health care provider (PHCP) for the insulin to be provided or the RD or RN has been given a verbal or written order from the PHCP Samples will be provided (as able) when needed for the timely initiation of insulin or due to the financial constraints of the patient. The RN or RD will attempt to link the patient to any relevant financial assistance programs available for insulin and other diabetes management supplies i.e. trillium drug plan etc. The insulin samples will be kept in a fridge with temperatures ranging from 2 – 8 degrees Celsius. The temp. will be monitored and recorded twice per day Insulin samples should be inspected by the RD or RN prior to providing them to a patient to check expiration date and clarity of insulin (see contraindications) The RN or RD will document expiry date, & lot # of the insulin dispensed 	<ul style="list-style-type: none"> Insulin storage fridge temp. has dropped below freezing (insulin will need to be discarded) Insulin has expired Insulin has clumps, solid white particles or clear insulin appears cloudy

Table 4 Notes: Insulin samples cannot be donated by patients.

Appendix D

Implementer Competency Checklist

Implementer Name: _____

CDA Guidelines Chapter Reviews		
Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada	Date Reviewed	Signature
Pharmacologic Management of Type 2 Diabetes		
Diabetes and Driving		
Appendix 9: Examples of Insulin Initiation and Titration Regimes in People with Type 2 Diabetes		
Appendix 5: Self-Monitoring of Blood Glucose (SMBG) Recommendation Tool for Healthcare Providers		
Appendix 7: Therapeutic Consideration for renal impairment		
Appendix 8: Sick Day Medication List		
CDA Building Competency in Diabetes Education: The Essentials	Date Reviewed	Signature
Chapter 6 - Treatment Modalities: Pharmacological Therapy		
Chapter 12 – Intensive Insulin Therapy		
CDA Building Competency in Diabetes Education: Advancing Practice	Date Reviewed	Signature
Chapter 2 – Advanced Insulin Therapy		
Chapter 3 - Acute Care Issues: Driving Employment and Insurance Issues		
Canadian Injection Recommendations: FIT, 2011		

Performance Criteria	Observed ex. through mentoring or chart audits (Date)	Not Observed ex. discussion of cases (Date)	Comments
1. Able to identify the action, dosing, indications & contraindications, possible side effects of all antihyperglycemic oral medications identified in this directive			
2. Able to identify the pharmacokinetics and action times of all insulins described in this medical directive including onset, peak, duration			
3. Identifies potential side effects of insulin therapy and how to avoid/minimize and manage them (i.e. hypoglycemia, lipohypertrophy, weight gain, in rare cases allergy)			
4. Able to counsel Patient's on driving recommendations when there is a higher risk for hypoglycemia i.e. taking insulin and/or sulfonylurea			
5. Identifies drugs and lifestyle factors that can interact with oral antihyperglycemic medications or impact Patient's glycemic control			
6. Describes basic physiologic insulin requirements in type 1 and type 2 diabetes in adults as well as usual starting doses based on age, weight, diagnosis, etc.			
7. Completes comprehensive assessment of learning needs & provides timely, patient-centered education on diabetes management including insulin and medications			
8. Calculates, uses and evaluates insulin: carbohydrate ratios			
9. Calculates, uses and evaluates insulin sensitivity factor, correction doses or insulin scales			
10. Describes the purposes of consistent CHO use and or CHO counting and identifies potential advantages/disadvantages of each, according to client's situation			

11. Identifies effect of alcohol consumption on blood glucose values and provides education and advice to minimize risk and prevent hypoglycemia			
12. Identifies dietary and/or insulin recommendations for physical activity.			
13. Identifies patterns of hyperglycemia or hypoglycemia or changes in routine that require adjustment of insulin, medications and/or other components of treatment plan			
14. Describes sick day management recommendations including dietary, medication/insulin adjustments as necessary			
15. Applies exercise guidelines appropriate to the Patient's insulin schedule			
16. Builds relationships with Patient's to promote self-care and learning; does not encourage ongoing dependence on health professionals for insulin adjustment i.e. increased patient confidence to self-adjust insulin			
17. Able to counsel patient around glucose meter usage and checking for accuracy e.g. lab/meter check or control solution			
18. Able to document process according to established standards and consult referring primary care provider for non-standard situations and/or failure of insulin dose adjustment to improve control.			
19. Familiarity with insulin pens and injections technique based on Canadian Recommendations FIT.			

Endocrinologist and Implementer Signature Sheet

I _____ have supervised _____
(Name of endocrinologist) (Name of Implementer)

with at least three patient cases and feel that they have achieved competency to adjust insulin and/or oral antihyperglycemic medications for patients with diabetes according to medical directive TCFHT-MD05 "Diabetes Management in Adults".

Signed _____ Endocrinologist

Signed _____ DEP Coordinator and/or Preceptor

Signed _____ Implementer

Date _____