

Taddle CreekFamily Health Team

Title:	Diabetes Management i Adults	n Number:	TCFHT-MD05				
Activation Date:	12-June-2012	Review Date:	12-June-2019				
Next Review Date:	12-June-2020						
	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):	Karen Finch, Registered Nurse, Certified Diabetes Educator 790 Bay St. Suite 508 Toronto, Ontario M5G 1N8 416- 204-1256						
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Order and/or Delega		Appendix Attached: No Title: Appendix C – Performe 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:							
 Start, Adjust, Hold and Discontinue Basal Insulin already prescribed by Primary Care Provider/Endocrinologist 							
	 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: <u>No X</u> 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: <u>No X</u> Yes
	Title: 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: <u>No X</u> 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

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	adjustments made following implementation o communication)	f medical directive (see documentation and					
•	Implementer obtains verbal patient consent prior to the application of this directive						
Co	ontraindications:						
•	No verbal consent from patient or substitute of medical directive	decision maker for implementer to apply this					
•	Indications described in Appendix C are not m	et					
С	onsent:	Appendix Attached: <u>X</u> No Yes Title:					
•	Patient's consent is implied, as patient has pres management, and is a Family Health Team pati The implementer fully explains potential risks a therapy and with any changes to oral antihyper	ent, where interprofessional practice is expected and benefits prior to initiating/adjusting insulin					
	uidelines for Implementing the order/Procedure:	Appendix Attached:No _X Yes Title: Appendix C – Performed Controlled Acts and Procedures					
As	per Appendix C.						
D	ocumentation and Communication:	Appendix Attached: <u>X</u> No Yes Title:					
•	and learning needs, clinical findings and the pla directions provided Implementer will send a message in Practice So notifying him/her that patient was seen, recom review for details. Primary care provider responsible for entering	ns, current medications, self-management skills an of care, patient's response to the procedure or olutions to patient's primary care provider, mendations were made and that eMR note needs newly prescribed medications into medication list for updating medication list in practice solutions. ollaboration with patient and primary care					
R	eview and Quality Monitoring Guidelines:	Appendix Attached: No _X_ Yes Title: Appendix D – Competency Checklist					
•	Routine review will occur annually on the anniv a collaboration between the authorizing prima implementers.	versary of the activation date. Review will involve					
•	At any such time that issues related to the use upon the concerns and immediately undertake						

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

Communication to primary care provider/endocrinologist regarding medication/insulin

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- If new information becomes available between routine renewals, such as the publishing of new Diabetes Canada Best Practice Guidelines, and particularily 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 performace 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
	Last Updated 12-06-201	.8 by Karen Finch, RN, CDE

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

Name	Signature	Date

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)

Name	Signature	Date
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	Last Updated 12-06-20	18 by Karen Finch, RN, CDE

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 Lispro (Humalog) Aspart (Novorapid) Glulisine (Apidra) Lispro 200 (Humalog 200) Aspart (Fiasp) 	2-15 minutes	1-2 hours/ 3-5 hours	 2 hr post-meal and/or pre-meal blood sugars (lunch, dinner) are either elevated or hypoglycemia occurs 	 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 selfmonitor 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 Humulin R Novolin Toronto 	30 minutes	2-3 hrs/6.5 hours	 Pre-meal blood sugars (lunch, supper) and/or bedtime are elevated or hypoglycemia occurs 	 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 Humulin N Novolin NPH 	1-3 hours	5-8 hours/up to 18hours	 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) 	 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

			•	Increase or decrease morning dose if 5-8 hour pre-meal blood sugars are out of target		
Pre-Mix Analogues NovoMix 30 Humalog Mix 25 Humalog Mix 50 Regular Insulin Novolin 30/70, 40/60, 50/50 Humulin 30/70	10-15 minutes 30-60 minutes	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	•	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	•	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 Detemir (Levemir) Glargine (Lantus, Basaglar) Glargine 300 (Toujeo) Degludec (Tresiba) U-100, U-200 	90 minutes	No peak/16-24hrs No peak/up to 24 hrs No peak/ up to 30hrs No peak/up to 42h	•	Increase/decrease dose if fasting or pre-supper sugars (if injecting in the morning) are out of target	•	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
- o Disordered eating pattern resulting in calorie restriction
- Significant error in dose or timing of insulin administered by person or caregiver
- o 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
Alpha-Glucosidase Inhibitor <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	 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 	 Not recommended as initial therapy in people with severe hyperglycemia (AIC ≥8.5%) 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
Biguanides <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>	 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 	 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

1-1.5% ODB Coverage: Yes Glumetza (Metformin HCL ER) Initial Dose: 500 mg daily (ideally with dinner) Average Dose (Max dose): 1000-2000 mg daily (2500 mg) Onset/peak/duration: 1-2h/4-8h/17.6-19.8h Expected HbA1C reduction: 1-1.5% ODB Coverage: No	 with meals 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 	 unable to keep down fluids) 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)
Insulin Secretagogues Sulfonylureas: Diamicron (Gliclazide) Initial Dose: 40-80 mg daily or bid with meals Average Dose (Max dose): 80-160 mg bid (320 mg) Onset/peak/duration: 1-2h/4-6h/10-14h Expected HbA1C reduction: 0.8% ODB Coverage: Yes Diamicron MR (Gliclazide MR) Initial Dose: 30 mg daily with first meal Average Dose (Max dose): 30-120 mg daily (120 mg) Onset/peak/duration:	 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 	 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)

1-2h/6-12/>24h		
Expected HbA1C reduction: 0.8%	See above.	See above.
ODB Coverage: Yes		
<u>Diabeta (Glyburide)</u>		
Initial Dose:		
2.5 mg – 5.0 mg daily or bid with meals		
Average Dose (Max dose):		
5-10 mg bid with meals (20 mg)		
Special Instructions:		
Take 30min prior to meal)		
Onset/peak/duration:		
1-2h/4-6h/10-14h		
Expected HbA1C reduction:		
0.8%		
ODB Coverage: Yes		
Amaryl (Glimepiride)		
Initial Dose:		
1 mg daily with first meal		
Average Dose (Max dose):		
1-4 mg daily (8 mg)		
Onset/peak/duration:		
20min/2-4h/24h		
Expected HbA1C reduction:		
0.8%		
ODB Coverage: No		
Insulin Secretagogues		
Non-Sulfonylureas:	Frequent hypoglycemia	• Less likely to cause weight gain and hypoglycemia than sulfonylureas
Meglatinides	(decrease or discontinue if	• Safe to use in renal impairment and mild hepatic impairment but
	hypoglycemia persists 1-2 times	requires slower dose titration
<u>Gluconorm (Repaglinide)</u>	per week)	 In the elderly Repaglinide should be initiated at 0.5mg TID and titrate
Initial Dose:	• Less hypoglycemia compared to	dose slowly (especially with CrCl 20-39mL/min)
0.5-1mg tid with meals	sulfonylurea's and are ideal for	 Preferred for use in elderly individuals with erratic eating patterns
Average Dose (Max dose):	patients with irregular meal	The concomitant use of Repaglinide and Clopidigrel (Plavix) is
0.5-4 mg tid (16 mg)	times	contraindicated as it may lead to a significant decrease in blood
Special Instructions: take 1-30min before	Inadequate blood glucose	glucose levels due to a drug-drug interaction
meals	control (blood glucose remains	0

Onset/peak/duration: 30min/1h/4-5h Expected HbA1C reduction: 0.7% ODB Coverage: Exceptional Access Program (EAP)	 above target consistently) Doses should be titrated weekly as required to obtain glycemic targets 	
Thiazolidinediones (TZD's) Actos (Pioglitazone) Initial Dose: 15 mg daily Average Dose (Max dose): 15-45 mg daily (45 mg) Onset/peak/duration: 30min/2-4h/4 weeks Expected HbA1C reduction: 0.8% ODB Coverage: EAP Avandia (Rosiglitazone) Initial Dose: 4 mg daily Average Dose (Max dose): 2-8 mg daily (8 mg) Onset/peak/duration: 30-60min/1-2h/4 weeks Expected HbA1C reduction: 0.8% ODB Coverage: EAP	 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 	 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 no longer approved for use with Metformin and 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

DPP4 Inhibitors Sitagliptin (Januvia) Initial Dose: 100 mg daily qam with/without food Average Dose (Max dose): 100 mg daily (100 mg) Onset/peak/duration: Rapidly absorbed/1-4h/24h Expected HbA1C reduction: approx. 0.7% ODB Coverage: Yes Saxagliptin (Onglyza) Initial Dose: 5 mg daily with/without food Average Dose (Max dose): 5 mg daily (5 mg) Onset/peak/duration: Rapidly absorbed/2.5h/26.9h Expected HbA1C reduction: approx. 0.7% ODB Coverage: Yes Linagliptin (Trajenta) Initial Dose: 5 mg daily with/without food Average Dose (Max dose): 5 mg daily with/without food Average Dose (Max dose): 5 mg daily (5 mg) Onset/peak/duration: Rapidly absorbed/2.5h/26.9h Expected HbA1C reduction: approx. 0.7% ODB Coverage: Yes Sing daily (5 mg) Onset/peak/duration: Rapidly absorbed/1.5h/24h Expected HbA1C reduction: approx. 0.7% ODB Coverage: Yes	 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 	 normal) 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 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 is 30-49 mL/min, and decreased further to 25 mg of if eGFR is 30-60 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 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
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Alogliptin (Nesina) Initial Dose: 25 mg daily with/without food Average Dose (Max dose): 25 mg daily (5 mg) Onset/peak/duration: Rapidly absorbed/1-2h/approx. 24h Expected HbA1C reduction: approx. 0.7% ODB Coverage: No GLP–1 Receptor Agonist		
Liraglutide (Victoza) Initial Dose: 0.6 mg SC daily Average Dose (Max dose): 1.2-1.8 mg SC daily (1.8 mg) Expected HbA1C reduction: 1-1.5% ODB Coverage: No Exenatide (Byetta) Initial Dose: 5 mcg (1.2 mL)SC bid Average Dose (Max dose): 5-10 mcg (1.2 mL-2.4 mL) bid (20 mcg) Special Instructions: inject <60minutes before two meals (breakfast and dinner) Onset/peak/duration: Rapid onset/2.1h/10h Expected HbA1C reduction: 1.3-1.5% ODB Coverage: No Dulaglutide (Trulicity) Initial Dose: 0.75mg (0.5 mL) SC qweekly Average Dose (Max dose): 1.5mg (1.5mg)	 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%) 	 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

Special Instructions: - Can be taken with or without meals - Dose can be increased to 1.5mg qweekly (if tolerating well) for additional glycemic control Onset/peak/duration:24 hrs/48hrs/120hrs Expected HbA1C reduction: 1-1.5% ODB Coverage: No Semaglutide (Ozempic) Initial Dose: 0.25mg SC qweekly X 4 weeks (not a therapeutic dose) to be increased to 0.5mg SC qweekly at 15 weeks Average Dose (Max dose): 0.5mg (1mg) Special Instructions: - Can be taken with or without meals Onset/peak/duration:24 hrs/24-72hrs/1 week Expected HbA1C reduction: 1-1.5% ODB Coverage: No		 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 Metformin & 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
SGLT2 Inhibitors Canagliflozin (Invokana) Initial Dose: 100 mg daily qam ideally before meal Average Dose (Max dose): 300mg daily (300mg) Onset/peak/duration: Rapidly absorbed/1-2 hrs/approx. 24 hrs Expected HbA1C reduction: 0.77-1% * up to 2.56% with HbA1C >10% ODB Coverage: Yes Dapagliflozin (Forxiga) Initial Dose: 5 mg daily with/without food	 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 Canaglifozin 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 	 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%), nasophyringitis (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

Janumet (Januvia and Metformin)medications included in combination tabletcombination tablet	Average Dose (Max dose): 10 mg daily (10 mg) Onset/peak/duration: Rapidly absorbed/2h/approx. 24 hrs Expected HbA1C reduction: 0.7-0.99% * up to 2.04% with HbA1C >9% ODB Coverage: No Empagliflozin (Jardiance) Initial Dose: 10 mg daily with/without food Average Dose (Max dose): 25 mg daily (25 mg) Onset/peak/duration: Rapidly absorbed/1.5h/approx. 24 hrs Expected HbA1C reduction: 0.7-0.99% * up to 2.04% with HbA1C >9% ODB Coverage: Yes Combination Medications	 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) See the indications for 	 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) 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, 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 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
		medications included in	
Initial Dose: Initiate at higher doses (not	Initial Dose:		

50/500mg bid	initial dose) if already taking	
Average Dose (Max dose):	Metformin at higher doses and	
50/1000mg bid (50/1000mg bid)	tolerating well	
Special Instructions:		
Take with meals to reduce GI side effects		
ODB Coverage: Yes		
Janumet XR (Januvia and Glumetza)		
Initial Dose:		
50/1000mg daily ideally with dinner		
Average Dose (Max dose):		
50/2000mg od (50/2000mg od)		
Special Instructions:		
Take with meal to reduce GI side effects		
ODB Coverage: Yes		
Jentadueto (Trajenta and Metformin)		
Initial Dose:		
2.5/500mg bid		
Average Dose (Max dose):		
2.5/1000mg bid (2.5/1000mg bid)		
Special Instructions:		
Take with meals to reduce GI side effects		
ODB Coverage: Yes		
Komboglyze (Onglyza and Metformin)		
Initial Dose:		
2.5/500mg bid		
Average Dose (Max dose):		
2.5/1000mg bid (2.5/1000mg bid)		
Special Instructions:		
Take with meals to reduce GI side effects		
ODB Coverage: Yes		
Kazano (Nesina and Metformin)		
Initial Dose:		
12.5/500mg bid		
Average Dose (Max dose):		

12.5/1000mg bid (12.5/1000mg bid) Special Instructions: Take with meals to reduce GI side effects ODB Coverage: No

Xigduo (Forxiga and Metformin)

Initial Dose: 5/850mg bid Average Dose (Max dose): 5/1000mg bid (5/1000mg bid) Special Instructions: Take with meals to reduce GI side effects ODB Coverage: No

Invokamet (Invokana and Metformin)

Initial Dose: 50/500mg bid Average Dose (Max dose): 150/1000mg bid (150/1000mg bid) Special Instructions: Take with meals to reduce GI side effects ODB Coverage: No

Synjardy (Jardiance and Metformin)

Initial Dose: 5/500mg bid Average Dose (Max dose): 12.5/1000mg bid (12.5/1000mg bid) Special Instructions: Take with meals to reduce GI side effects ODB Coverage: No

Xultophy (Degludec and Liraglutide)

Initial Dose: 10u SC daily (pts naïve to basal insulin or GLP 1 receptor agonist) OR 16u SC daily (pts currently using basal insulin or GLP1 receptor agonist)

		
<mark>Average Dose (Max dose):</mark>		
N/A (50u daily)		
Special Instructions:		
 Take once daily at the same time with or 		
without meals		
 Dose should be titrated up or down by 2u 		
q3-4 days to achieve fasting blood glucose		
targets		
 Basal insulin and/or GLP1 Receptor Agonist 		
should be discontinued prior to starting		
<mark>Xultophy</mark>		
Soliqua (Glargine and Lixisenatide)		
Initial Dose:		
<mark>15u SC daily (pts taking < 30u basal insulin</mark>		
daily) OR		
<mark>30u SC daily (pts taking 30-60u basal insulin</mark>		
daily)		
<mark>Average Dose (Max dose):</mark>		
N/A (60u daily)		
Special Instructions:		
 Take once daily within an hour prior to the 		
<mark>first meal of the day</mark>		
<mark>- Dose should be titrated up or down by 2-4u</mark>		
every week to achieve fasting blood glucose		
targets		
 Basal insulin and/or GLP1 receptor agonist 		
should be discontinued prior to starting		
Soliqua		
 See dosing information for medications 		
included in combination tablet for more		
information		

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.

	Indications	Contraindications
Prescribe Diabetes Supplies (glucometer, glucometer strips, needles for insulin pens and lancets)	 To assess glycemic control in response to non-insulin antihyperglycemic 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 	 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: Indications and Contraindications for Prescribing Diabetes Supplies

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

Table 4: Indications and Contraindications for Providing Insulin Samples

	Indications	Contraindications
Providing Insulin Samples	 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 	 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 Review	vs	
Diabetes Canada 2018 Clinical Practice Guidelines for the	Date Reviewed	Signature
Prevention and Management of Diabetes in Canada		
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			
9.	insulin: carbohydrate ratios 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		
12.	recommendations for physical		
	activity.		
10	-		
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	_