

Taddle Creek

Family Health Team

Title:	Requisition of Laboratory Investigations and Prescribing Diabetes Supplies for the Management of Diabetes or Prediabetes	Number:	TCFHT-MD16
Activation Date:	09-Sep-2014	Review Date:	19-Jun-2023
Next Review Date:	19-Jun-2024		

Note: Jun 2016 review resulted in a change; ability to order non-fasting lipid profile. Change approved at Jun 14-16 Board Mtg (see minutes) thus negating necessity to get authorizers to re-sign.

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(name, position, contact particulars):

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TCFHT-MD16_Requisition of Laboratory Investigation for the Management of Diabetes or Prediabetes

Order and/or Delegated Procedure: Appendix Attached: No Yes

Title: Appendix C – Performed Controlled Acts and Procedures (CAPs) Implemented Under this Directive

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) Requisitioning of Laboratory Investigations, by implementers, for patients of the Taddle Creek Family Health Team (TCFHT) Primary Health Care Providers (PCPs) or of Consulting Endocrinologist and who meet specific indications described within this directive.
- 2) Prescribe Diabetes Supplies (flash glucose monitor, flash glucose sensors, glucose meter, glucose meter strips, blood ketone test 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 or Consulting Endocrinologist who has approved this directive by signing the Authorizer Approval Form
- Have a diagnosis of Diabetes Mellitus (type 1 or 2) or Prediabetes
- Meet the conditions identified in this directive

Authorized Implementers:

Appendix Attached: No Yes

Title: Appendix B – Implementer Approval Form

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 be Certified Diabetes Educators (CDEs) who practice according to the most current recommendations for the management of diabetes
- Practice according to Diabetes Canada's (DC's) most current Clinical Practice Guidelines
- Assess their own knowledge, skill, and judgment to competently perform these directives
- Must complete the Implementer Competency Checklist for Prescribing Diabetes Supplies (Appendix E) prior to signing the Implementer Approval Form

Appendix Attached: No Yes

Title: Appendix C – Performed Controlled Acts and Procedures (CAPs) implemented under this directive

Indications:

- Each action/procedure under this directive will be implemented in the context of the existing PCP or Consulting Endocrinologist-patient relationship and as part of the medical diagnosis and plan of care established by the PCP. 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 the directives.
- Specific indications for each laboratory investigation ordered under this medical directive can be found in Appendix C
- Specific indications for flash glucose monitoring, blood glucose monitoring, blood ketone testing and use of needle tips can be found in Appendix C

Contraindications:

- Indications described in Appendix C are not met

Consent: **Appendix Attached:** No Yes

Title:

- Patient's consent is implied for implementer to provide lab requisition or provide prescriptions for flash glucose monitoring, blood glucose monitoring, blood ketone testing or needle tips, as patient has presented seeking support with diabetes management, and is a Family Health Team patient or patient of the Consulting Endocrinologist, where interprofessional practice is expected
- Patient informed of purpose of testing, including when results will be available and contact information to review results (if not contacted by PCP)

Guidelines for Implementing the Order/Procedure:**Appendix Attached:** ___ No X Yes**Title:** Appendix C – Performed Controlled Acts and Procedures (CAPs) implemented under this directive
Appendix D – Sample Lab Requisition

Requisitioning of Laboratory Investigations

- 1) Identify need for laboratory investigation (blood work) and determine whether indications described in Appendix C are met.
- 2) Ensure that no recent blood work has been undertaken that would result in duplication of testing.
- 3) Explain the purpose of the test to the patient.
- 4) Generate a laboratory requisition using the supervising PCP/Authorizers initials.
- 5) Lab Requisition should be signed as below:
 - Signature
 - Implementer Name/Primary Care Provider Name (Medical Directive TCFHT-MD16)
- 6) Send a message in Practice Solutions to the PCP indicating that a lab requisition has been provided.
- 7) PCP will receive completed lab requisitions and forward them to implementers as needed e.g. if earlier follow up with implementer is required
- 8) Implementer documents that the requisition was provided and follow up plan in the eMR.

Prescribe Diabetes Supplies

- 1) Identify need for prescribing diabetes supplies and determine whether indications described in Appendix C are met.
- 2) Patient education provided on self-monitoring of blood glucose, flash glucose and/or blood ketones as per DC's most current Clinical Practice Guidelines
- 3) Enter a Rx for diabetes supplies following the steps outlined in DEP – 12 Prescribing Diabetes Supplies and/or making Medication Changes in Practice Solutions (Program Folders/Diabetes/Procedures/DEP – 12 Prescribing Diabetes Supplies and/or making medication changes in Practice Solutions)

Documentation and Communication: Appendix Attached: X No ___ Yes**Title:**

- Documentation in the patient's eMR needs to include: name and number of the directive and name of the implementer (including credential)
- Information regarding implementation of the procedure, the patient's response and follow up plan should be documented in the patient's eMR, in accordance with standard documentation practices (College of Nurses, 2008).

Review and Quality Monitoring Guidelines:Appendix Attached: No Yes**Title:**

- Review will occur annually. Review will involve a collaboration between the authorizing primary care providers and the approved implementers.
- If new information becomes available between routine reviews, such as the publishing of new clinical practice guidelines, and particularly if this new information has implications for unexpected outcomes, the directive will be reviewed by an authorizing primary care provider and a minimum of one implementer.
- 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.
- 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.

References

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

College of Nurses of Ontario. (2008). *Practice Standard: Documentation*. Retrieved from https://www.cno.org/globalassets/docs/prac/41001_documentation.pdf

Pearson et al. (2021). 2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adults.

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Goldenberg, R.M., Cheng A.Y.Y, Punthakee, Z., et al. 2011. Use of glycated hemoglobin (A1C) in the diagnoses of type 2 diabetes in adults. *Canadian Journal of Diabetes*; 35: 247-248.

Canadian Insulin Injection Recommendations: FIT Technique Plus, 2020. Retrieved from <http://www.fit4diabetes.com/canada-english/fit-technique-plus/>

Fit Forum for Injection Technique Canada. (2020). Fit Forum for Injection Technique Canada: Recommendations for Best Practice in Injection Technique. Retrieved from http://www.fit4diabetes.com/files/7816/0803/3133/FIT_Recommendations_2020.pdf

Note: This medical directive is for the routine monitoring of laboratory investigations for the management of diabetes or prediabetes and does not include other laboratory investigations (ALT, AST, CK or CPK, CBC etc.), which are recommended for starting or monitoring the effects of medications e.g. oral antihyperglycemic medications, statin medications etc.

Appendix C

Table 1: Controlled Acts and Procedures (CAPs) Implemented Under this Directive

Laboratory Investigation	Indications
Fasting Blood Glucose (FBG) or Random Blood Glucose (RBG) & Glycated Hemoglobin (HbA1C)	<p>Every 3 months when glycemic targets are not being met and/or when diabetes therapy is being adjusted.</p> <p>Every 6 months should be performed in adults during periods of treatment and lifestyle stability when glycemic targets have been consistently achieved.</p> <p>Every 6-12 months is recommended for people with prediabetes.</p> <p>FBG should be obtained after an 8-12hr fast.</p> <p>A Random Blood Glucose (RBG) along with an HbA1C should be considered for most patients for routine monitoring to improve adherence and lower risk for hypoglycemia.</p> <p>An HbA1C may be misleading in some people with various hemoglobinopathies, iron deficiency, hemolytic anemias, and severe hepatic and renal disease. A fructosamine test can be used in these cases for a cost of approximately \$35. The RN or RD to consult with the PCP and can obtain a verbal order for this test if indicated.</p>

TCFHT-MD16_Requisition of Laboratory Investigation for the Management of Diabetes or Prediabetes

<p>Lipid Panel (total cholesterol, triglycerides, HDL-cholesterol, LDL-cholesterol, non-HDL-C, total cholesterol/ HDL-C ratio)</p> <p>Lipoprotein(a)</p>	<p>A lipid profile (TC, HDL-C, TG, and calculated LDL-C) should be measured at the time of diagnosis of diabetes. If lipid-lowering treatment is not initiated, repeat testing is recommended yearly. More frequent testing (every 3-6 months) should be performed after treatment for dyslipidemia is initiated (lifestyle and/or medications).</p> <p>A non-fasting lipid profile should be considered for most patients to improve adherence and to lower the risk for hypoglycemia. New evidence indicates minimal differences exist between fasting and non-fasting HDL, LDL, and total cholesterol levels. The differences that occur are less than the within-person variability from repeat lipid testing. Tests of non-fasting HDL and non-HDL levels correlate with future CVD events. Although triglycerides are most susceptible to change without fasting, they contribute minimally to total cholesterol levels and are not consistently associated with CVD, however, for individuals with a history of triglyceride levels > 4.5 mmol/L, measurement of fasting lipid levels are recommended.</p> <p>CCS 2021 guidelines indicate that for any patient with triglycerides > 1.5 mmol/L, non-HDL-C (screened as part of the lipid panel) or ApoB be used instead of LDL-C as the preferred lipid parameter for screening. DEP providers will routinely order non-HDL-C as part of the standard lipid panel, however ApoB can be added as recommended by the primary care provider.</p> <p>A fasting lipoprotein profile should be obtained after a 10hr-12hr fast, preferably with the subject refraining from alcohol for 24h-48h.</p> <p>People with diabetes >40years old, or diabetes >15 years duration and age >30 years, or with established macrovascular or microvascular disease are considered at high risk for cardiac disease (Framingham Risk Score >20%) People with prediabetes and diabetes (who do not meet the criteria above) should be screened following the recommendations outlined in Table 1: CCS Dyslipidemia at a Glance.</p> <p>Dyslipidemia treatment recommendations are outlined in Table 2: CCS Dyslipidemia Treatment Algorithm – Primary Prevention, and Table 3: CCS Dyslipidemia Treatment ASCVD.</p> <p>There is now a large body of evidence supporting the potential causal association between Lp(a) and future ASCVD. Testing Lp(a) is recommended once in a person’s lifetime. For all patients in the setting of primary prevention with a Lp(a) ≥ 50 mg/dL (or ≥ 100 nmol/L), earlier and more intensive health behaviour modification counselling and management of other ASCVD risk factors is recommended.</p>
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TCFHT-MD16_Requisition of Laboratory Investigation for the Management of Diabetes or Prediabetes

Laboratory Investigation	Indications

TCFHT-MD16_Requisition of Laboratory Investigation for the Management of Diabetes or Prediabetes

Laboratory Investigation	Indications
<p>Urine Albumin-to-Creatinine Ratio (ACR) & Serum Creatinine (eGFR)</p>	<p>At diagnosis of type 2 diabetes or 5 years after diagnosis of type 1 diabetes and yearly thereafter.</p> <p>As the ACR can be elevated with recent major exercise, fever, urinary tract infection, congestive heart failure, menstruation or acute severe elevations of blood pressure (BP) or blood glucose (BG), screening for albuminuria should be delayed in the presence of these conditions.</p> <p>Intravascular volume contraction e.g. dehydration or any acute illness can transiently lower kidney function, and GFR estimation for screening purposes should be delayed until such conditions resolve.</p> <p>If ACR >20.0 mg/mmol (macroalbuminuria), then this is indicative of chronic kidney disease (CKD). RN or RD should refer to the PCP.</p> <p>If eGFR \leq 60 ml/min OR ACR \geq 2.0 mg/mmol (microalbuminuria) and there is no established diagnosis of CKD, then order serum creatinine for eGFR in 3 months AND 2 repeat random urine ACRs performed over the next 3 months. If eGFR \leq 60mL/min or 2 or 3 ACRs \geq 2.0 mg/mmol (indicative of chronic kidney disease) refer to PCP.</p> <p>If ACR and/or eGFR is indicative of CKD. It is recommended that a urine dipstick test be performed (by the PCP), either in the laboratory or at point of care, as a screen for renal disease other than diabetic nephropathy.</p> <p>People with diabetes and CKD should have a random urine ACR and a serum creatinine converted into an eGFR performed at least every 6 months.</p>
<p>Cobalamin (Vitamin B₁₂)</p>	<p>At least every one to two years in patients on long-term treatment with Metformin.</p> <p>If vitamin B12 levels are below range, then discuss with PCP.</p>

Table 1: CCS Dyslipidemia at a Glance



AT A GLANCE: 2021 CCS Guideline for the Management of Dyslipidemia in Adults

Who to screen with fasting or non-fasting TC, TG, HDL-C, calculated LDL-C and non-HDL-C with ApoB when appropriate and Lp(a) once:

- Men ≥ 40 yrs old; Women ≥ 40 yrs old or postmenopausal; at younger age in Indigenous and South Asian individuals
- At any age in patients with:
 - Clinical ASCVD
 - Evidence of preclinical ASCVD (e.g. CACS or carotid ultrasound abnormalities)
 - Abdominal aortic aneurysm (AAA)
 - Diabetes
 - Arterial hypertension
 - Currently smoking
 - Stigmata of dyslipidemia: tendinous xanthomas (also corneal arcus, xanthelasma if < 45 yrs old)
 - Family history of premature CVD in first degree relative (male < 55 yrs old; female < 65 yrs old)
 - Family history of dyslipidemia (including Elevated Lp(a), especially ≥ 50 mg/dL or ≥ 100 nmol/L)
 - Chronic kidney disease (eGFR ≤ 60 mL/min/1.73 m² or ACR ≥ 3 mg/mmol)
 - Obesity (BMI ≥ 30 kg/m²)
 - Inflammatory diseases (e.g., RA, SLE, PsA, AS, IBD)
 - HIV infection
 - Erectile dysfunction
 - Chronic obstructive pulmonary disease
 - Pregnancy-related complications (hypertensive disease of pregnancy, gestational diabetes, pre-term birth, stillbirth, low birthweight infant, placental abruption)

Who to treat based on clinical factors (Framingham Risk Score [FRS] not needed):

- Statin-indicated Conditions:
 - Clinical ASCVD/AAA
 - Diabetes mellitus if > 40 yrs old, or > 30 yrs old with microvascular disease or > 15 years duration
 - Chronic kidney disease (non-dialysis, eGFR < 60 mL/min or urine ACR ≥ 3.0 mg/mmol)
 - FH or LDL-C ≥ 5.0 or non-HDL-C ≥ 5.8 mmol/L or ApoB ≥ 1.45 g/L
- Patients with very high TG ≥ 10 mmol/L and/or history of TG-related pancreatitis.

Who to treat based on FRS:

- High FRS ($\geq 20\%$ /10yrs)
- Intermediate FRS (10-19.9%/10-yrs) and LDL-C ≥ 3.5 mmol/L or non-HDL-C ≥ 4.2 mmol/L or ApoB ≥ 1.05 g/L
- Intermediate FRS (10-19.9%/10-yrs) and LDL-C < 3.5 mmol/L or non-HDL-C < 4.2 mmol/L or ApoB < 1.05 g/L or other risk modifiers FHx, Lp(a) ≥ 50 mg/dL [or ≥ 100 nmol/L] or CAC > 0 AU)
- Low FRS (5-9.9%/10-yrs) with LDL-C ≥ 3.5 mmol/L or non-HDL-C ≥ 4.2 mmol/L or ApoB ≥ 1.05 g/L or other risk modifiers FHx, Lp(a) ≥ 50 mg/dL [or ≥ 100 nmol/L] or CAC > 0 AU)

Factors not in FRS suggesting that calculated risk may be underestimated:

- From RCTs:
 - JUPITER: CRP > 2.0 mg/L
 - HOPE-3: Waist/hip ratio ≥ 0.85 (women) or ≥ 0.90 (men), IFG/IGT, (pre-diabetes, metabolic syndrome)
 - ASCOT: LVH/other EKG abnormalities
- From epidemiology (consider ethnicity and factors g – p Step 1)

Factors not in FRS suggesting that calculated risk may be overestimated:

- CAC = 0 Agatston Units in Moderate FRS patients

What to monitor:

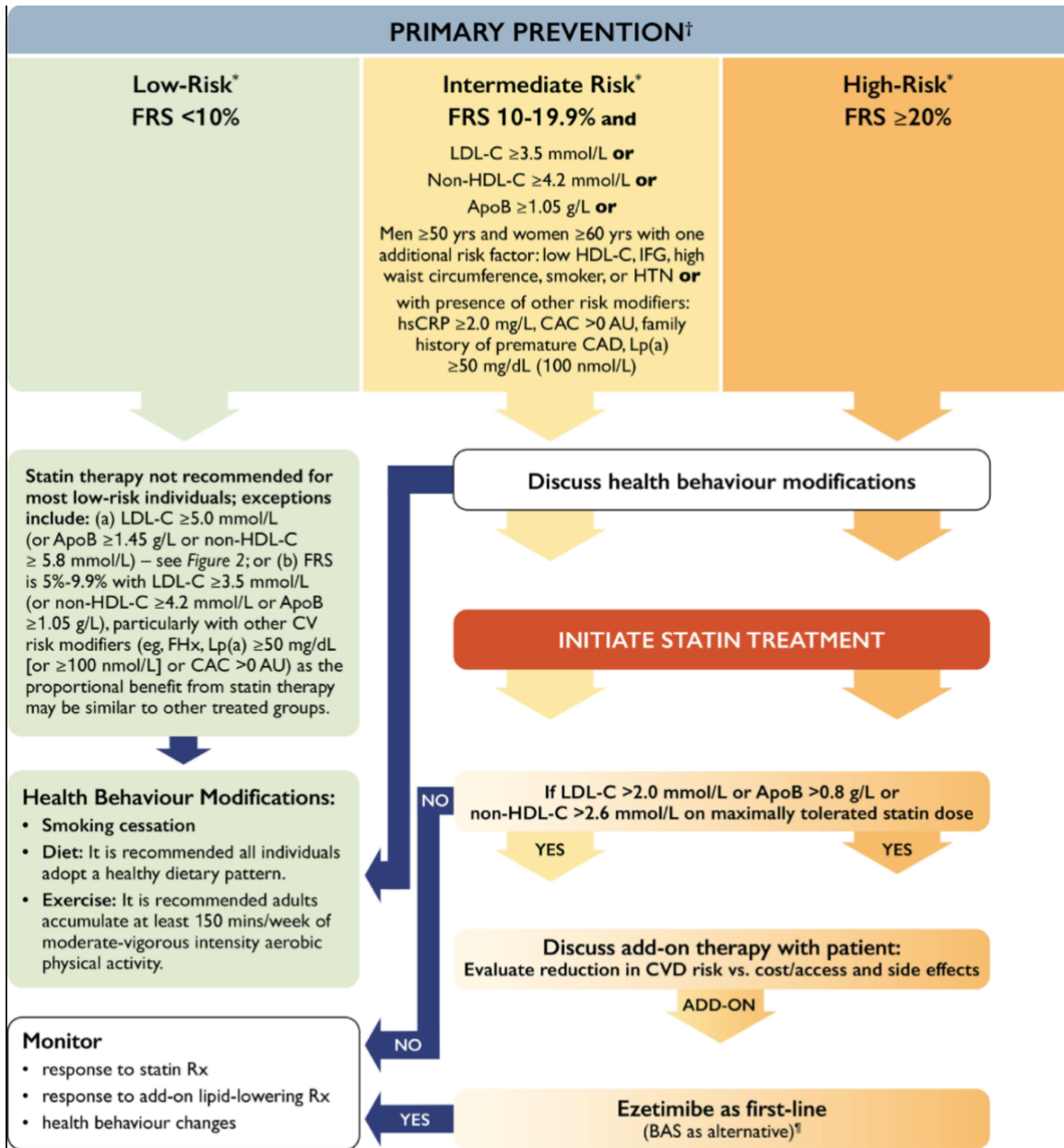
- If TG < 1.5 mmol/L, monitor treatment with LDL-C, non-HDL-C or ApoB (fasting or non-fasting)
- If TG ≥ 1.5 mmol/L, monitor treatment with non-HDL-C or ApoB (fasting or non-fasting)

What to use:

- Behavioural advice to optimize diet (including alcohol use), weight, and activity levels and to promote smoking cessation (including specific pharmacotherapy when warranted)
- Maximally tolerated statin for those described in Tables 2 and 3
- In CV primary prevention of patients with FH, using threshold of LDL-C ≥ 2.5 mmol/L, non-HDL-C ≥ 3.2 mmol/L, ApoB ≥ 0.85 g/L, or $< 50\%$ lowering of LDL-C, consider adding PCSK9 inhibitor, with/without ezetimibe
- In other settings of CV primary prevention, using threshold of LDL-C ≥ 2.0 mmol/L, non-HDL-C ≥ 2.6 , ApoB ≥ 0.80 g/L or $< 50\%$ lowering of LDL-C, consider use of ezetimibe (or bile acid sequestrant)
- Add therapy in CV secondary prevention, using thresholds of LDL-C ≥ 1.8 mmol/L, non-HDL-C ≥ 2.4 , ApoB ≥ 0.70 g/L
 - Ezetimibe \pm PCSK9 inhibitor (if LDL-C 1.8 – 2.2 mmol/L, non-HDL-C 2.4 – 2.9 mmol/L, or ApoB 0.7 – 0.8 g/L, ezetimibe may suffice)
 - PCSK9 inhibitor \pm ezetimibe (PCSK9 inhibitor particularly if LDL-C > 2.2 mmol/L, non-HDL-C > 2.9 mmol/L or ApoB > 0.8 g/L) or in very high risk patients who derive the most benefit from PCSK9 inhibitors, e.g. ACS within 1 year, diabetes mellitus or metabolic syndrome, poly-vascular disease, MI within 2 years, recurrent MI, prior coronary artery bypass surgery, symptomatic peripheral arterial disease, FH or residual LDL-C ≥ 2.6 on maximal statins, elevated Lipoprotein (a) ≥ 60 mg/dL.)
- Icosapent ethyl in primary prevention patients with diabetes and an additional risk factor or secondary prevention patients when, in both instances, TG is ≥ 1.5 mmol/L and ≤ 5.6 , on maximally tolerated statin
- When icosapent ethyl is not indicated but TG requires management (e.g., very high TG ≥ 10 mmol/L or concern about TG-related pancreatitis), use micronized fenofibrate

AAA = abdominal aortic aneurysm; ACR = albumin-to-creatinine ratio; ACS = acute coronary syndrome; ApoB = apolipoprotein B; AS = ankylosing spondylitis; ASCVD = atherosclerotic cardiovascular disease; AU – Agatston unit; BMI = body-mass index; CACS = coronary artery calcium score; CRP = C-reactive protein; CVD = cardiovascular disease; eGFR = estimated glomerular filtration; EKG = electrocardiogram; FH = familial hypercholesterolemia; FHx = family history; FRS = Framingham Risk Score; HIV = human immunodeficiency virus; IBD = inflammatory bowel disease; IFG = impaired fasting glucose; IGT = impaired glucose tolerance; LDL-C = low-density lipoprotein cholesterol; Lp(a) = lipoprotein(a); LVH = left ventricular hypertrophy; MI = myocardial infarction; non-HDL-C = non-high-density lipoprotein cholesterol; PCSK9 = proprotein convertase subtilisin/kexin type 9; PsA = psoriatic arthritis; RA = rheumatoid arthritis; RCT = randomized control trials; SLE = systemic lupus erythematosus; TC = total cholesterol; TG = triglycerides.

Table 2: CCS Dyslipidemia Treatment – Primary Prevention



[†]Statin indicated conditions consists of all documented ASCVD conditions, as well as other high-risk primary prevention conditions in the absence of ASCVD, such as most patients with diabetes, those with chronic kidney disease and those with a LDL-C ≥5.0 mmol/L.

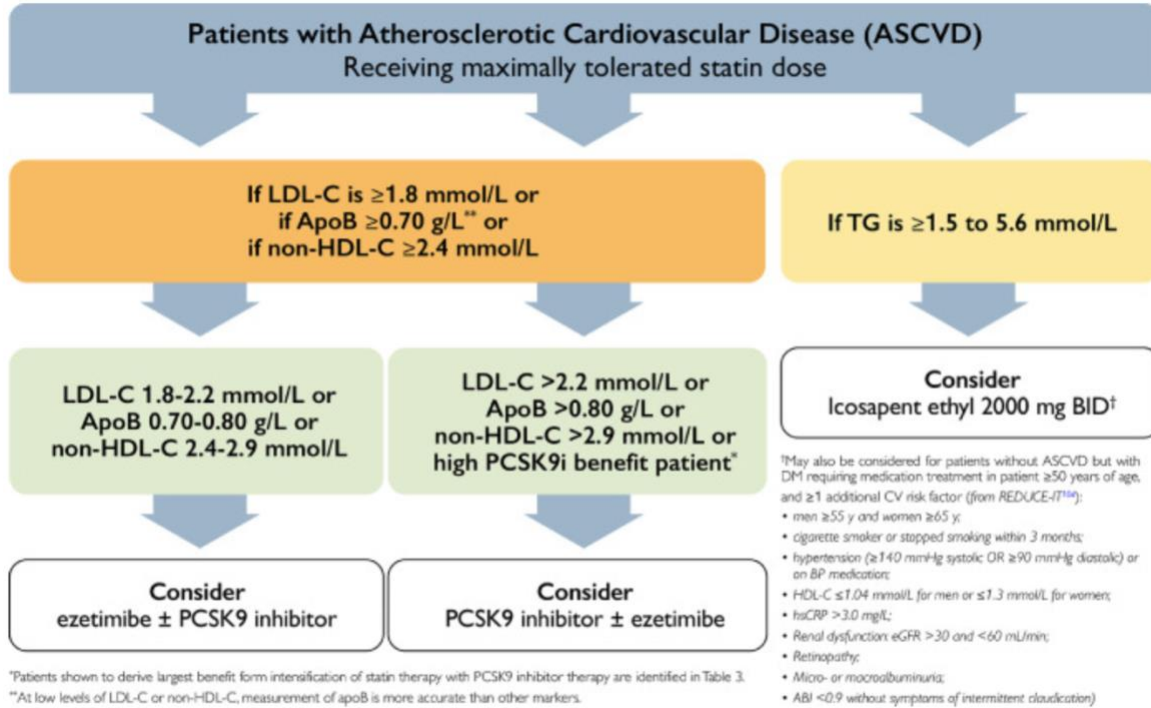
[‡]Calculate risk using the Framingham Risk Score (FRS) – refer to the iCCS available on the App Store or on Google Play

[§]Screening should be repeated every 5 years for men and women aged 40 to 75 years using the modified FRS or CLEM to guide therapy to reduce major CV events. A risk assessment might also be completed whenever a patient's expected risk status changes.

[¶] studies have evaluated the efficacy of BAS for the prevention of ASCVD, but results have been inconclusive.

FRS = Framingham risk score; LDL-C = low-density lipoprotein cholesterol; HDL-C = high-density lipoprotein cholesterol; ApoB = apolipoprotein B; IFG = impaired fasting glucose; HTN = hypertension; hsCRP = high-sensitivity C-reactive protein; CAC = coronary artery calcium; AU – Agatston unit; Rx = prescription; BAS = bile acid sequestrant

Table 3: Dyslipidemia Treatment ASCVD



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Table 4: Indications and Contraindications for Prescribing Diabetes Supplies

	Indications	Contraindications
Prescribe Capillary Blood Glucometer (CBG) & glucometer test strips	<ul style="list-style-type: none"> To assess glycemic control from blood glucose results 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 	<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 DC guidelines, but is ultimately up to RN or RD clinical judgement
Prescribe Continuous Glucometers (CGM) & sensors	<ul style="list-style-type: none"> To assess glycemic control from interstitial fluid glucose results 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 	<ul style="list-style-type: none"> The patient or substitute decision maker refuses to monitor interstitial fluid glucose The patient is unable to monitor interstitial fluid glucose due to physical or cognitive limitations Considerations should be made for patients who are unable to monitor due to financial constraints Continuous Glucose monitoring not recommended due to DC guidelines, but is ultimately up to RN or RD clinical judgement The patient develops skin irritation or other adverse reactions in response to the sensor
Prescribe Blood Ketone test strips	<ul style="list-style-type: none"> To assess blood ketone levels in patients with Type 1 Diabetes The results are used to determine if a patient is at risk for Diabetic Ketoacidosis and so appropriate interventions and education can occur 	<ul style="list-style-type: none"> The patient or substitute decision maker refuses to monitor blood ketone levels The patient is unable to monitor blood ketone levels due to physical or cognitive limitations Considerations should be made for patients who are unable to monitor due to financial constraints
Prescribe lancets & needle tips for insulin pens	<ul style="list-style-type: none"> Insulin pen needles or syringes for patients injecting insulin or GLP1ra 	<ul style="list-style-type: none"> The length of the needles should be determined based on the current best practice recommendations for injections

See Program Folders/Diabetes/Procedures/DEP – 12 Prescribing Diabetes Supplies and/or Making Medication Changes in Practice Solutions

Appendix E

Implementer Competency Checklist for Prescribing Diabetes Supplies

Implementer Name: _____

CDA Guidelines Chapter Reviews		
Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada	Date Reviewed	Signature
Diabetes and Driving		
Appendix 5: Self-Monitoring of Blood Glucose (SMBG) Recommendation Tool for Healthcare Providers		
Fit Forum for Injection Technique Canada. (2020). Fit Forum for Injection Technique Canada: Recommendations for Best Practice in Injection Technique.		
Canadian Insulin Injection Recommendations: FIT Technique Plus, 2020.		