

# The Dose Winter 2024

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Have you seen our summary from November about tirzepatide? You can find it <u>here</u> Did you see the message from your clinic pharmacist about the new <u>Ozempic LU criteria</u>? Reach out to your TVFHT pharmacist if you have any questions about these info blasts

## Two guideline updates you should know about

This fall, two key guidelines published updates with important implications for chronic disease management in primary care. Here, we have summarized the updated PEER Simplified Lipid Guidelines, and the Canadian Osteoporosis Guidelines for quick reference.

### PEER Simplified lipid guideline (SLG) 2023 update

The <u>PEER</u> (Patients Experience Evidence Research) group from Alberta is a group who, in their own words, "is a primary care led evidence-based medicine team focused on providing relevant evidence to family physicians and primary care providers". We have featured their risk calculators in previous issues of The Dose. Their <u>simplified guidelines</u> aim to focus on primary prevention, prioritize high-level evidence, incorporate shared decision making, and provide simplified recommendations.



The Simplified Lipid Guideline, updated this fall, incorporates the results of a <u>systematic review</u> and input from an interdisciplinary team without industry conflicts of interest, and aims to guide practice using the best evidence while also considering the concept of **time needed to treat** – recognizing the competing priorities and interests that exist in primary care, and aiming to make practical, feasible recommendations.

As with any condition, there are often several guidelines that have been published which interpret the available evidence in different ways, resulting in different recommendations. We have highlighted some of the main recommendations here from PEER and offered in contrast what the Canadian Cardiovascular Society Dyslipidemia guideline has recommended in similar circumstances. We hope this helps you consider the available evidence and guidelines to help inform your practice decisions.

PEER Guideline	CCS Guideline	Rationale from PEER
Lipids do not need to be checked more often than every 5-10 years for reassessment of risk stratification CAC scores, Lp(A) or apoB to are not needed to determine CV risk, and baseline creatine kinase and alanine transaminase do not need to be measured without a clinical indication	Re-check lipids and treat to LDL-C, non- HDL-c and apoB targets (targets differ depending on risk category/other risk factors <sup>†</sup> ) Measurement of Lp(A) once in a lifetime with initial screening for risk stratification (high Lp(A) associated with possible higher incidence of ASCVD, discuss this as part of SDM) CAC scoring for some patients with specific risk factors <sup>†</sup>	The evidence shows that this additional testing does not result in significantly different CV risk reduction. Majority of trials have used fixed statin doses based on CV risk. Best evidence suggests both strategies (targeting LDL levels or using statins at proven doses) are similarly effective in reducing CVD risk. Targeting cholesterol levels is more complex than use of proven doses. These recommendations recognize the burden that additional testing puts on patients and health care providers.
Initiate a statin for a 10-19% 10-year CV risk (moderate dose preferred) and for ≥20% 10-year CV risk (high dose preferred). Lifestyle management only for low risk patients. Discuss initiation of add-on therapy for <b>secondary</b> prevention if additional CV risk reduction is desired. Ezetimibe and PCSK9 inhibitors should be considered before icosapent. May be considered as monotherapy if patient is unable to tolerate a statin rechallenge for <b>secondary</b> prevention	Same; though they do also list several exceptions of characteristics <sup>+</sup> where they would also recommend statins for low- risk patients Intensification with second-line treatments (ezetimibe, PCSK9 inhibitors, icosapent for high TG) based on lipid targets and patient risk factors for both primary and secondary prevention	Only statins have evidence of decreasing MACE, CV mortality and all-cause mortality, which is why they are the preferred first-line treatment There is little evidence about the use of other lipid lowering agents outside of use in tandem with statins. Ezetimibe and PCSK9 inhibitors have more favorable safety than icosapent which is known to have risks of causing atrial fibrillation and bleeding.
Recommends against the use of other lipid lowering agents in the context of <b>primary</b> prevention or as monotherapy in primary prevention without a statin on board.	Suggests that ezetimibe or a PCSK9 inhibitor are reasonable options as monotherapy in patients with complete statin intolerance for LDL-C lowering. Does mention that there is limited evidence to support either class as an alternative to statin therapy for ASCVD risk reduction.	The other medication classes either showed no benefit in primary prevention, lacked evidence as monotherapy, or predominantly enrolled special populations (such as patients with familial hypercholesterolemia) in primary prevention
Troubleshoot reported lipid intolerance by discussing a rechallenge (with same statin same dose, same statin lower dose, change to less potent statin, or alternate day dosing) Any intensity statin is preferred over no statin if one is indicated	No discussion of management of statin intolerance, aside from consideration of other treatments	The risk of muscle symptoms in the first year of statin therapy is estimated to be 15%, compared to 14% with placebo. This recommendation considers that most patients will tolerate a statin re-trial and appreciates the benefits of statins in primary and secondary prevention
Suggests against use of CV risk calculators for persons over the age of 75 Suggests against initiating statins routinely in persons over age 75 for <b>primary</b> prevention without SDM (there may be some patients with good health status who choose to use a statin for primary prevention or secondary prevention with SDM) Recommends against stopping or reducing statin dose in a patient who is taking and tolerating a statin simply because the patient has aged beyond 75 years. Also recommends against changing statin prescribing on the basis of cognitive	No specific recommendations for older adults	The diagnostic accuracy of CV risk calculators is lower for those over age 75 Best evidence suggests that statins are not effective at <b>primary</b> prevention of MACE in this group No evidence to support stopping statins based on age in primary prevention. Two large systematic reviews found no increased risk of cancer incidence or death with statins. The evidence also does not support a link between
	Lipids do not need to be checked more often than every 5-10 years for reassessment of risk stratification CAC scores, Lp(A) or apoB to are not needed to determine CV risk, and baseline creatine kinase and alanine transaminase do not need to be measured without a clinical indication linitiate a statin for a 10-19% 10-year CV risk (moderate dose preferred) and for 220% 10-year CV risk (high dose preferred). Lifestyle management only for low risk patients. Discuss initiation of add-on therapy for secondary prevention if additional CV risk reduction is desired. Ezetimibe and PCSK9 inhibitors should be considered as monotherapy if patient is unable to tolerate a statin rechallenge for secondary prevention Recommends against the use of other lipid lowering agents in the context of primary prevention or as monotherapy in primary prevention without a statin on board. Troubleshoot reported lipid intolerance by discussing a rechallenge (with same statin same dose, same statin lower dose, change to less potent statin, or alternate day dosing) Any intensity statin is preferred over no statin if one is indicated Suggests against use of CV risk calculators for persons over the age of 75 Suggests against use of CV risk calculators for persons over the age of 75 Suggests against initiating statins routinely in persons over age 75 for primary prevention or secondary prevention with SDM) Recommends against stopping or reducing statin dose in a patient who is taking and tolerating a statin simply because the patient has aged beyond 75 years. Also recommends against changing statin prescribing on the basis of cognitive concerns.	Prest Guideline       CC Soudeline         Upipds do not need to be checked more often than every 5-10 years for reassessment of risk stratification       Re-check lipids and treat to LDL-C, non- HDL-c and apo8 targets (targets differ depending on risk category/other risk factors')         CAC scores, Lp(A) or apoB to are not needed to determine CV risk, and baseline creatine kinase and alanine transaminase do not need to be measured without a clinical indication       Measurement of Lp(A) once in a lifetime with initial screening for risk stratification (high Lp(A) associated with possible higher incidence of ASCVD, discuss this as part of SDM)         Initiate a statin for a 10-19% 10-year CV risk (moderate dose preferred) and for 20% 10-year CV risk (high dose preferred). Lifestyle management only for low risk patients.       Same; though they do also list several exceptions of characteristics' where they would also recommend statins for low- risk patients         Discuss initiation of ad-on therapy for secondary prevention.       Same; though they do also list several exceptions of characteristics' where they would also recommend statins for low- risk patients         Intensification vith second-line treatments (ezetimibe, PCSK9 inhibitors, icospent. May be considered as monotherapy if patient is unable to tolerate a statin rechallenge for secondary prevention primary prevention ar asonotherapy in primary prevention ar astatin on board.       Suggests that ezetimibe or a PCSK9 inhibitor are reasonable options as monotherapy in patients with complete statin intolerance for LD-C lowering. Does mention that there is limited evidence to support either class as an alternative to statin ferany for ASCVD risk reduction.         Troubleshoot reported lipid intolerance day dosing

For the chart on the previous page: ASCVD = atherosclerotic cardiovascular disease, ApoB = apolipoprotein B, Lp(A) = lipoprotein A, CAC = coronary artery calcium, SDM = shared decision making, TG = triglycerides; <sup>†</sup>refer to guideline for more details

<u>Appendix 1 of this newsletter</u> contains the two page summary of this guideline. The supplemental <u>patient handout</u> and <u>visual CVD decision aid</u> are also excellent resources.

# Clinical practice guideline for the management of osteoporosis and fracture prevention in Canada: 2023 update

<u>This guideline</u> builds on the 2010 guidelines with recommendations reflecting advancements in risk assessment and pharmacological and non-pharmacological management of osteoporosis. For the first time, patients were included on the advisory panel.

### Highlights

**Non-pharmacological:** Balance and functional training at least twice a week to reduce risk of falls, and resistance training at least twice a week (these sometimes will overlap). Other forms of exercise that the patient enjoys should be encouraged in addition to, not in place of, these exercises.

### Supplementation/diet:

Post-menopausal women and men ≥ 50 years of age not receiving pharmacotherapy for osteoporosis

Suggest eating balanced diet, foods rich in calcium and protein (no supplementation recomended for fracture prevention, aim to meet Health Canada RDAs with diet)

Suggest minimum vitamin D supplement of 400 units daily (higher if risk factors for deficiency - see guideline for list) People initiating pharmacotherapy

Target Health Canada RDA of calcium (1000-1200 mg/d) by assessing diet and individualizing supplementation advice where necessary (in trials, patients received supplementation up to 1000 mg/d)

Target Health Canada RDA of 600-800 units/day of vitamin D by assessing diet and individualizing supplementation advice using at least 400 units/d (minimum dose in trials was 400 units/d)

**Risk assessment:** FRAX (Canadian) tool is preferred over CAROC. BMD testing is recommended in postmenopausal females and males who a.) are aged 50–64 years with a previous osteoporosis-related fracture or  $\ge 2$  clinical risk factors OR b.) are aged  $\ge 65$  years with 1 clinical risk factor for fracture OR c.) are aged  $\ge 70$  years.

**Treatment:** FRAX low and intermediate risk cut offs are changed (low <15%, intermediate 15-20%, high > 20). Bisphosphonates are first line with the exception of history of vertebral fracture or contraindications. See <u>Appendix 2 of this newsletter</u> for an algorithm from the guideline outlining risk assessment.

**Monitoring considerations**: Reassess bisphosphonate treatment after 3-6 years for consideration of a drug holiday – harms (atypical femur fractures, osteonecrosis of the jaw) increase with longer duration of use of bisphosphonates >5-6 years; no increased difference in hip or overall fractures when shorter treatment durations are compared to  $\geq$  6 year treatment duration (moderate to small increase in clinically and radiologically discovered vertebral fractures). At 6 years, harms likely outweigh the benefits of continued therapy, except in people at higher risk of fractures (e.g., previous hip or vertebral fractures, recent fracture, multiple fractures). Reassess holiday, if one is taken, 3 years after discontinuation. For denosumab – there does not seem to be an increased risk of these harms or waning benefit at 10 years of treatment, though there is a risk of rapid bone loss or vertebral fracture if dose is delayed or when drug is discontinued. See <u>Appendix 2 of this newsletter</u> for a figure on initiating and monitoring pharmacotherapy and <u>this handout</u> to explain benefits and harms of bisphosphonates with patients.



## Climate conscious inhaler prescribing: How do I initiate a "greener" practice in my own patients who have never been prescribed an inhaler before?

This article was contributed by Ashley Domingues, PharmD candidate (University of Toronto)

Your patient steps into your office complaining of a 1-month history of dyspnea with exertion with no past history of asthma or COPD. They don't currently use an inhaler. Your first thought process is whether this could be asthma, COPD or a reactive airway. You may consider spirometry that day if the respiratory therapist is available, however their symptoms bother them now. You determine this is likely COPD given their 20-year pack history of smoking cigarettes.



<u>You've recently heard about the environmental impacts</u> of <u>MDIs</u> and ask yourself if prescribing a dry powder inhaler (DPI) is an option for this patient. If it isn't, you choose an environmentally conscious MDI. If DPI is an option, you prescribe one that has less plastic waste. You educate the patient on proper inhaler use and safe disposal and send them on their way. You call them to follow-up in 2 weeks and their symptoms have improved

greatly. The spirometry test from their appointment 1 week ago comes back and confirms COPD.

Source: https://cascadescanada.ca/resources/sustainable-inhaler-prescribing-in-primary-care-playbook/

The above scenario sounds like an ideal situation. However, you ask yourself: how do I know which inhalers are more environmentally conscious and how do I know which inhalers are an affordable option for my patient?

CASCADES has introduced a guide to choosing low-carbon inhaler prescribing in Canada with province-specific coverage information called <u>www.greeninhalers.ca</u>. The guide makes it easy to choose based on province, indication, criteria such as "green inhalers only" or "ODB formulary only" and filter based on the patient's age (indicated inhalers per age group). For example, in the above scenario your patient was 62 years old. The guide would look something like the diagram below (green meaning the best, yellow moderate and red the worst environmentally conscious option):



Source: www.greeninhalers.ca

The practice of climate conscious inhaler prescribing may feel daunting if you consider going back and switching every patient in your practice who has been prescribed a MDI. However, starting with changing your practice for product selection for new starts can be a manageable first step in reducing the environmental impact of your prescribing.

**Would you like to learn what is new in the most recent COPD guidelines?** Our pharmacists will be offering academic detailing visits on this topic in the coming months—reach out to your clinic pharmacist to learn more!

## Caring for trans patients in primary care part 3: masculinizing hormone therapy

Completing the series of highlights of the Sherborne Health/Rainbow Health Ontario guideline for gender affirming primary care for trans and non-binary patients, our last segment summarizes masculinizing hormone therapy. *Note that there was a November 2023 medication update to this guideline, which is at the beginning of the document found <u>here</u>. (yes, another guideline update in Nov 2023...)* 

Masculinizing therapy is used in transmasculine patients (patients who were assigned the female gender at birth but identify in the male spectrum). The goal is the development of masculine secondary sex characteristics (keeping in mind individual patient's goals). This therapy includes testosterone products. As with feminizing hormone therapy, some physical changes occur quickly (e.g. cessation of menses) while others take much longer (years) to see the full effect (e.g. body hair growth, increased muscle mass), see the figure below.



Source: Guidelines for gender-affirming primary care with trans and non-binary patients: a quick reference guide for primary care providers

There are a few contraindications to testosterone therapy – pregnancy or breastfeeding, active sex hormone-sensitive cancer, active homocidality or uncontrolled psychosis, inability to provide informed consent and known hypersensitivity.

Product	Formulation	Strength**	Starting Dose	Usual Dose	ODB/OHIP + Coverage
Testosterone	IM/subcut	200mg/mL	20-50mg q weekly or 40-100mg q	Variable, up to 100mg q weekly	*
Enanthate†	Injection		2 weeks	or 200mg q 2 weeks	(EAP*)
Testosterone	IM/subcut	100mg/mL	20-50mg q weekly or 40-100mg q	Variable, up to 100mg q weekly	*
Cypionate	Injection		2 weeks	or 200mg q 2 weeks	(EAP*)
Testosterone	Transdermal Gel		2.5-5g (2-4 pumps) daily	Variable, up to 5-10g (4-8 pumps) daily	×

\*Rainbow Health recommends applying for an EAP for both the enanthate and cypionate formulations due to the ongoing risks of backorders. Prepopulated EAP request forms are available on Rainbow Health Website.

\*\*Testosterone products can be interchanged 1:1 but caution about the strength of the product, which are different and could lead to dosing errors

+ Testosterone enanthate injection uses sesame oil as a carrier oil – caution with allergies (not an issue with cypionate – both products use cottonseed oil)

Note that testosterone patches have been discontinued in Canada and are no longer a therapeutic option.

### Safety and Monitoring

Safety of both feminizing and masculinizing hormone therapy for trans patients is considered by the Endocrine Society to be "safe without a large risk of adverse effects when followed carefully for a few well-documented medical concerns". For transmasculine patients, CBC and total testosterone checks are recommended at 3, 6 and 12 months after initiation of therapy, and yearly thereafter; liver enzymes, fasting glucose or HbA1c, and lipids should be checked at baseline and between 6-12 months of therapy (for a full list of recommended labs, see the <u>Rainbow Health quick</u> reference). Checklists for ongoing preventative care are also available in the full guidelines.

## **Practice tip:** reconciling minor ailments prescribing in the EMR

Upon receiving communication from the pharmacy of minor ailments prescribing, consider **updating the patient's medication list** to document what was prescribed. This can help inform future clinical decisions, particularly related to recent use of anti-infectives, should the patient seek care for recurring/unresolved symptoms, or a subsequent episode of the ailment. Reconciling the chart also helps prevent medication errors and drug interactions.

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### Osteoporosis

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### Transmasculine care

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- 2. Sherbourne Health's Guidelines for Gender-Affirming Primary Care with Trans and Non-Binary Patients. 4th Edition. 2019. <u>https://www.rainbowhealthontario.ca/resource-library/sherbourne-healths-guidelines-for-gender-affirming-primary-care-with-trans-and-non-binary-patients/</u>
- 3. Delatestryl Product Monograph https://pdf.hres.ca/dpd\_pm/00026379.PDF
- 4. Depo-testosterone Product Monograph <u>https://pdf.hres.ca/dpd\_pm/00046306.PDF</u>
- 5. Taro-testosterone Product Monograph <u>https://pdf.hres.ca/dpd\_pm/00054845.PDF</u>

## **PEER Simplified Lipid Guideline 2023: Summary**

Simplified approach

Shared decision making

Reduce unnecessary testing



### **Lipid Lowering Agents**

Drug	Prescribing Considerations	CVD Relative Risk Reduction	90-day cost <sup>1</sup>	
Statins	<ul> <li>The only lipid lowering agent that decreases all-cause mortality.</li> <li>Muscle symptoms in first year: 15% versus 14% placebo.</li> <li>Do not worsen cognition or dementia.</li> </ul>	25-35%	\$30-50	
Ezetimibe	<ul> <li>Mostly studied when added to statins in secondary prevention.</li> <li>Well tolerated; 10mg daily.</li> </ul>	7%	\$30-45	
PCSK9 inhibitors	<ul> <li>Mostly studied when added to statins in secondary prevention.</li> <li>Injection site reactions: 3.5% versus 2.1% placebo.</li> <li>Subcutaneous injections every 2 weeks: alirocumab 75-150mg or evolucumab 140mg.</li> </ul>	-15%	\$1500-2400	
Fibrates	<ul> <li>Increase serum creatinine (2-11% more than placebo), pancreatitis (-0.1% more), altered liver function tests (-5% more); example: fenofibrate.</li> </ul>	0-14%*	\$60-150	
EPA ethyl ester (icosapent)	<ul> <li>Mostly studied when added to statins.</li> <li>Atrial fibrillation (5.3% versus 3.9% placebo), serious bleeds (2.7% versus 2.1% placebo); 2g twice daily.</li> </ul>	~20%	\$1000	

\* 0% if added to statins; up to 14% if not on a statin

EPA = eicosapentaenoic acid; CVD = cardiovascular disease;

PCSK9 = proprotein convertase subtilisin-kexin type 9

### Out of 100 patients on statins, 15 report muscle symptoms, but only 1 is due to statins

### Management of Muscle Symptoms Related to Statins



## If a patient is unable to tolerate

**'RxFiles PEER/ACFP Pricing Document** 

or unwilling to try a re-challenge

Primary prevention Suggest against non-statin lipid lowering therapy

### Secondary prevention

Suggest discussing ezetimibe, fibrate, PCSK9 inhibitor or EPA ethyl ester (icosapent)

### FAQ & Helpful Resources

### Q: Why do PEER guidelines recommend against targeting low-density lipoprotein (LDL) levels?

A: The vast majority of clinical trials have prescribed fixed statin doses based on CVD risk. Best evidence suggests both strategies (targeting LDL levels or using statins at proven doses) are similarly effective in reducing CVD risk. Targeting cholesterol levels is more complex than use of proven doses. A simplified approach of using proven doses reduces the burden of unnecessary testing for both patients and health professionals. Read more about this issue in the guideline.

### Q: Which cardiovascular decision aid should I use?

A: There are many cardiovascular risk calculators. The Framingham model has been validated in Canada. <u>The PEER Cardiovascular Decision Aid</u> (https://decisionaid.ca/cvd/), based on Framingham, has been created for this guideline.

### Q: How can I help patients with positive lifestyle changes?

A: Encourage smoking cessation. Providing exercise prescription and information about the Mediterranean diet may be helpful.



RXFILES EXERCISE PRESCRIPTION









ALBERTA COLLEGE of FAMILY PHYSICIANS





### Appendix 2: Osteoporosis algorithms

https://www.cmaj.ca/content/195/39/E1333.long

Figure 1: Integrated approach to the management of bone health and fracture prevention in postmenopausal females and males aged 50 years and older



#### Figure 2: Approach to pharmacotherapy to prevent fractures.



### Appendix 3: Ozempic message sent out week of January 30 2024

The manufacturer of Ozempic has released a statement saying that ALL STRENGTHS of Ozempic are back in stock as of Jan 17 2024. There are new 3mL sized pens that dispense the 0.25/0.5mg dose that are replacing the old 1.5mL pens which are being phased out. This has no impact on prescribing; rather how it is dispensed at the pharmacy.

Another BIG change is that as of Jan 31 2024, Ozempic is being transitioned out of general benefit status for ODB and will now require a Limited Use (LU) code. The pharmacy will be allowed to give one 3 month fill to transition patients while we get the codes in order.

This is the criteria for all products:

- Type 2 diabetes, not controlled despite maximally tolerated dose of metformin OR documentation of intolerance/contraindication to metformin
- Will not be paid for in combination with DPP-4 inhibitors (sitagliptin, linagliptin, saxagliptin) or oral semaglutide (Rybelsus)

There are three different codes, one for each product. Since for now we will not know which pen (1.5mL or 3mL) the pharmacy will dispense to administer 0.25/0.5mg dose you might consider indicating on the prescription that the patient qualifies for **both LU codes 666 and 667 for the 0.25/0.5 mg dose** to avoid faxes back (going forward when only the 3mL pen is available the code for 0.25/0.5mg will be 667). For the **1mg dose the LU code is 665**. Patients who do not qualify for the LU codes will have to pay out of pocket or change therapy.

As always, do not hesitate to reach out to your TVFHT pharmacist for support or to answer questions about this change.