SECTION **Special Authorization/High Cost**	PAGE Page **1** of **4**
SUBJECT/TITLE **SA-30** **Empagliflozin / sitagliptin / linagliptin**	ORIGINAL DATE**: September 13, 2021** LAST REVISION: **February 28, 2025**

PREAMBLE

The Calgary Zone Type A Continuing Care Home Pharmacy and Therapeutics Committee listed empagliflozin, sitagliptin, and linagliptin with restrictions under Special Authorization for the following reasons:

- For many continuing care residents living with diabetes, glycemic goals may not be achievable on monotherapy with metformin.
- Individualized glycemic targets should be **frequently** reassessed due to advancing frailty with a thoughtful consideration of the balance of harm vs. benefits of tighter glycemic control.
- The committee has been monitoring utilization and evidence over the last several years. We are seeing broader and increased use of these agents in the community and continuing care.
- There is utility in using these agents to simplify complex insulin regimens and to reduce frequent blood glucose monitoring when using prandial insulin, and repaglinide.
- Long-term sustainability of drug funding and budget constraints were considered.

ASSESSMENT

Appropriateness is assessed on a case-by-case basis and shall include a thoughtful review of the resident's current health status and Goals of Care Designation. Other factors for consideration are:

- Resident's goals for drug therapy
- Assessment of frailty and medication burden
- RAI-MDS (Resident Assessment Instrument – Minimum Data Set) 2.0 outcome scales (e.g., Changes in Health, End-Stage Disease and Signs and Symptoms [CHESS] and Personal Severity Index [PSI], etc.)
- Recent Blood Glucose (BG) readings
- Hypoglycemia risk[1]
- Consultations with specialists (e.g., endocrinology, cardiology, internal medicine, etc.)
- Duration of illness and comorbid conditions, time-to-benefit
- Volume status and renal function, risk of erratic or inadequate fluids consumption (e.g., dementia, fluid restricted diet, etc.)
- Risk of genital and UTI infection
- Strong consideration for deprescribing, regimen simplification and de-escalation with advancing frailty
    - An example of an insulin regimen simplification can be found in the American Diabetes Association's *Older Adults: Standards of Medical Care in Diabetes – 2023*, -Figure 13.1. Simplification of Complex Insulin Therapy.

[1] Risk factors for severe hypoglycemia: prior episode of severe hypoglycemia, current low A1C (<6%), hypoglycemia unawareness, long duration of insulin use, autonomic dysfunction, CKD, cognitive impairment, unable to respond to mild hypoglycemia on their own, low health literacy, low economic status, food insecurity. Lipsombe L, Booth G, Butalia S, Dasgupta K, et al. *Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada*: Pharmacologic Glycemic Management of Type 2 Diabetes in Adults. Can J Diabetes 2018;42(Suppl 1):S88-S103.

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PROTOCOLS

Protocol 1 – Empagliflozin, sitagliptin, or linagliptin for Type 2 Diabetes (with no established CV disease)

As add-on therapy for residents with Type 2 diabetes who meet the following criteria:

1. On maximally tolerated dose of oral formulary agents, such as metformin, sulfonylurea, repaglinide, and dapagliflozin, unless these products are contraindicated, AND
2. Formulary agents are insufficient to meet personalized glycemic targets.
3. Insulin Consideration:
    - In adults with Type 2 Diabetes, when glycemic targets are not met with formulary oral agents +/- basal insulin, adding or continuing a DPP-4 inhibitor can reduce the need to increase basal insulin or add bolus insulin.
    - Hospital transfers: Acute care often uses insulin for timely glycemic management in hospital. Often, oral medications are held or stopped while receiving in-patient care. On admission/transfer to Continuing Care, insulin regimens should be reassessed.

Exclusions:

1. DPP-4s are excluded when resident is taking prandial insulin.
2. DPP-4s are excluded when resident is using a GLP-1 analog. GLP-1 analogs are non-formulary.

Protocol 2 – empagliflozin for Type 2 Diabetes with Cardiovascular Disease (including heart failure) or chronic kidney disease.

As add-on therapy for residents with Type 2 diabetes who meet the following criteria:

1. On a maximally tolerated dose of metformin (or those unable to take metformin), **AND**
2. Have inadequate glycemic control according to resident's individualized glycemic targets*, **AND**
3. Have a qualifying cardiovascular condition** or albuminuric chronic kidney disease, **AND**
4. Unable to take dapagliflozin

Clinicians are referred to the Health Canada product monograph(s) for approved indications and limitations to use, prescribing and monitoring information.

Submission Process

Requests for coverage will be submitted using Special Authorization Form (SA-30). For residents newly admitted or readmitted from hospital, form submission is required withing 3 weeks (grace period). For new starts, form

submission is required prior to initial drug provision. The distribution of the form to pharmacy providers will be via email. A sample form is attached below.

Monitoring and Duration of Coverage

The risk/benefit assessment, including review of resident's goals, shall occur initially and annually, or more often as necessary. Appropriate laboratory indices shall be monitored to assess disease status and renal function. If there is a significant decline in health status, the benefit and ongoing use of the medication should be reassessed. The clinical pharmacist shall document their assessment and any resulting recommendations in the resident's chart.

Qualifying cardiovascular conditions

Presence of one or more of the following (plus type 2 diabetes):

- History of MI
- Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status)
- Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within 12 months prior to selection
- Last episode of unstable angina > 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease
- History of ischemic or hemorrhagic stroke
- Occlusive peripheral artery disease
- Heart Failure

Glycemic Targets

Clinicians are referred to current clinical practice guidelines to guide the selection of individualized glycemic targets. Of particular interest to the population in continuing care is a set of guidelines developed by PATH (Palliative and Therapeutic Harmonization) that take into account frailty-specific recommendations for Type 2 Diabetes. For residents living with severe, very severe, or terminally ill frailty (scores of 7-9 on the Clinical Frailty Scale), the guidelines recommend to "maintain HbA1c at or above 8% rather than below a specific level, in keeping with the conclusion that lower HbA1c levels are associated with increased hypoglycemic events without accruing meaningful benefit for frail older adults with type 2 diabetes." See link for complete recommendations.

Guideline Links

Diabetes Canada Clinical Practice Guidelines

References

CADTH. *New Drugs for Type 2 Diabetes: Second-Line Therapy – Recommendations Report.* Ottawa: 2017 May. (CADTH therapeutic review; vol.4, no 1c).

CADTH. *CADTH CDEC Final Recommendation: Empagliflozin (Jardiance – Boehringer Ingelheim (Canada) Ltd.) Indication: Type 2 Diabetes Mellitus*. Ottawa: 2015.

CADTH. *CADTH CDEC Recommendation (Final): Dapagliflozin (Forxiga – AstraZeneca Canada Inc.)* Version 1.0, Jan 6, 2021

Diabetes Canada Clinical Practice Guidelines Expert Committee. Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Can J Diabetes. 2018;42(Suppl 1):S1-S325.

Mallery LH, Ransom T, Steeves B, Cook B, Dunbar P, Moorhouse P. Evidence-informed guidelines for treating frail older adults with type 2 diabetes: from the Diabetes Care Program of Nova Scotia (DCPNS) and the Palliative and Therapeutic Harmonization (PATH) program. *J Am Med Dir Assoc*. 2013;14(11):801-808. doi:10.1016/j.jamda.2013.08.002

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Strain WD, Down S, Brown P, Puttanna A, Sinclair A. Diabetes and Frailty: An Expert Consensus Statement on the Management of Older Adults with Type 2 Diabetes. *Diabetes Ther*. 2021;12(5):1227-1247. doi:10.1007/s13300-021-01035-9

Zinman B, Wanner C, Lachin JM, et al. Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. *N Engl J Med*. 2015;373(22):2117-2128. doi:10.1056/NEJMoa1504720

Alberta Health Services

Calgary Zone Type A Continuing Care Home Formulary
Pharmacy and Therapeutics Committee

Last Name *(Legal)*	First Name *(Legal)*	
Preferred Name ☐ Last ☐ First	DOB*(dd-Mon-yyyy)*	
PHN	ULI ☐ Same as PHN	MRN
Administrative Gender ☐ Male ☐ Non-binary/Prefer not to disclose (X)	☐ Female ☐ Unknown	

A-30 empagliflozin /sitagliptin / linagliptin
Special Authorization Funding Request

Form submission is required within 3 weeks (grace period) following admission/readmission to a Type A Continuing Care Home (CCH) from hospital. For new starts at the home, form submission is required before initial drug provision

Processing Instructions: Please complete the form in its entirety. Pharmacy provider emails to ISFL Type A Pharmacist at: cc.drugmanagement@albertahealthservices.ca **OR** pharmacist/physician fax to **403-943-0232**

New Start ☐ **admission or transfer** ☐		**Date of Drug Provision:**
Resident Code:	**Date of Birth:**	**Date of Admission:**
Prescribing Information (*reason for prescribing, specialist or clinic involvement):*		**Type A Continuing Care Home**
Interdisciplinary Diabetes Assessment		
1. Estimated frailty score/stage[i]:		**Date:**
2. Individualized Glycemic targets[ii]:		
3. Most recent HgA1c:		**Date:**
4. Blood sugar range:	**Date range:**	**Fasting:** ☐ **Random:** ☐
5. Established cardiovascular conditions[iii]:		
6. High hypoglycemic risk? ☐ Yes ☐ No		**Hypoglycemic risk factors[iv]:**
7. Current diabetic medications (list):		
8. SGLT2 - Risk assessed for urogenital infections (e.g. fungal, UTIs)? ☐ Yes ☐ No		
9. Did this review result in intervention related to the resident's diabetes management (select all that apply)? ☐ **Intensification** ☐ **Simplification** ☐ **Deprescribing** ☐ **Other** **Comments:**		

Protocol 1 – empagliflozin, sitagliptin, or linagliptin for Type 2 Diabetes	**Criteria Met**
As add-on therapy for Type 2 diabetes meeting the following criteria: **1.** On a max. tolerated dose of oral formulary agents, such as metformin, sulfonylurea, repaglinide, and dapagliflozin, unless these products are contraindicated, AND **2.** Formulary agents are insufficient to meet individualized glycemic targets. **Comments:** **Exclusions:** a) DPP-4s are excluded when resident is taking prandial insulin. b) DPP-4s are excluded when resident is using a GLP-1 analog. GLP-1 analogs are NF.	☐

Alberta Health Services

Calgary Zone Type A Continuing Care Home Formulary
Pharmacy and Therapeutics Committee

Last Name *(Legal)*	First Name *(Legal)*	
Preferred Name ☐ Last ☐ First	DOB*(dd-Mon-yyyy)*	
PHN	ULI ☐ Same as PHN	MRN
Administrative Gender ☐ Male ☐ Female ☐ Non-binary/Prefer not to disclose (X) ☐ Unknown		

Protocol 2 – empagliflozin for Type 2 Diabetes with cardiovascular disease (including heart failure) or chronic kidney disease.	**Criteria Met**
As add-on therapy for Type 2 Diabetes meeting the following criteria: **1.** On a max. tolerated dose of metformin (or those unable to take metformin), AND **2.** Have an inadequate glycemic control according to resident's individualized glycemic targets, AND **3.** Have a qualifying cardiovascular condition or albuminuric CKD, AND **4.** Unable to take dapagliflozin. **Comments:**	☐

By submitting this application, the care team and pharmacist have reasonably considered consent, alternative therapeutic options (including Formulary alternatives), and risks/benefits.

Funding may be declined or terminated by Calgary Zone Type A CCH Drug Management when criteria are not met.

Pharmacist's Name	***Physician's Name***	***Date of Form Submission*** *(yyyy-Mon-dd)*

TO TYPE WITHIN EACH CELL, USE THE TAB KEY

[i] Confer with the interdisciplinary team if frailty score is not available or documented on chart. See Dalhousie University's Clinical Frailty Scale or Edmonton Frailty Scale for examples.

[ii] Diabetes Targets in LTC

[iii] Established cardiovascular disease is defined based on one of the following: 1) History of myocardial infarction (MI), 2) Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status), 3) Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within the last 12 months, 4) Last episode of unstable angina greater than 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease, 5) History of ischemic or hemorrhagic stroke, 6) Occlusive peripheral artery disease, 7) Heart Failure

[iv] Risk factors for severe hypoglycemia: prior episode of severe hypoglycemia, current low A1C (<6%), hypoglycemia unawareness, long duration of insulin use, autonomic dysfunction, CKD, cognitive impairment, unable to respond to mild hypoglycemia on their own, low health literacy, low economic status, food insecurity. Lipsombe L, Booth G, Butalia S, Dasgupta K, et al. Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada: Pharmacologic Glycemic Management of Type 2 Diabetes in Adults. Can J Diabetes 2018;42(Suppl 1):S88-S103.