

CLINICAL AUDIT

Reviewing **type 2 diabetes management** in patients at **high risk** of cardiovascular and renal **complications**



This audit helps health professionals in primary care identify patients with type 2 diabetes who are eligible for funded treatment with empagliflozin or dulaglutide*, new medicines available for those at high risk of cardiovascular disease or renal complications, including all Māori and Pacific peoples.

* Availability pending Medsafe approval

Background

Sodium-glucose co-transporter 2 (SGLT-2) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists have been recommended for the treatment of type 2 diabetes for some time, but until now have not been funded in New Zealand. As of 1 February, 2021, empagliflozin, a SGLT-2 inhibitor, is available fully funded for the treatment of people with type 2 diabetes who are at high risk of cardiovascular disease or renal complications; dulaglutide, a GLP-1 receptor agonist, will be available once it has Medsafe approval later this year.

To initiate funded empagliflozin or dulaglutide treatment, patients must have type 2 diabetes and meet **all** of the following criteria:

1. Have **at least one** of the following characteristics:
 - a) Māori or any Pacific ethnicity; or
 - b) Pre-existing cardiovascular disease (CVD) or risk equivalent*; or
 - c) An absolute five-year CVD risk of $\geq 15\%$ according to a validated cardiovascular risk assessment calculator; or
 - d) A high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult; or
 - e) Diabetic kidney disease†; and
2. HbA_{1c} level > 53 mmol/mol despite the regular use of at least one blood-glucose lowering medicine (e.g. metformin, vildagliptin or insulin) for at least three months; and
3. Treatment will not be used in combination with a funded GLP-1 receptor agonist/SGLT-2 inhibitor (as appropriate)

* Defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia

† Defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3–6-month period) and/or eGFR less than 60 mL/min/1.73m² in the presence of diabetes, without alternative cause

Patients who are likely to benefit from treatment, but are not eligible for funding

While the Special Authority criteria for empagliflozin and dulaglutide ensure access for those at high risk of cardiovascular and renal disease, there are patients who are likely to benefit from these medicines who are not eligible for funded treatment, including those:


- With cardiovascular or renal disease or heart failure with an HbA_{1c} < 53 mmol/mol or eGFR 60 – 90 mL/min without albuminuria
- With cardiovascular or renal disease or heart failure who are already taking funded empagliflozin or dulaglutide (i.e. dual treatment with these medicines is recommended if HbA_{1c} levels remain above target, but only one can be funded at a time)
- Who are overweight or obese and have HbA_{1c} levels above target despite regular use of or inability to tolerate metformin, but who do not have cardiovascular or renal disease and are not of Māori or Pacific ethnicity
- With an HbA_{1c} above target despite regular use of or inability to tolerate metformin and vildagliptin, but who do not have cardiovascular or renal disease and are not of Māori or Pacific ethnicity
- With an HbA_{1c} within the target range but where an SGLT-2 inhibitor is preferred to reduce adverse effects, e.g. weight gain or hypoglycaemia with a thiazolidinedione or sulfonylurea, respectively.

Discuss the recommendation with patients and the option to self-fund treatment, unless there are contraindications or significant cautions. This may be a challenging conversation to negotiate as there will be patients who are unable to meet the financial burden of self-funding treatment and may find this distressing.

Choosing between empagliflozin and dulaglutide

The decision to initiate a SGLT-2 inhibitor versus a GLP-1 receptor agonist is based primarily on the predominant comorbidity, i.e. CVD, heart failure or diabetic kidney disease, and patient preference, particularly regarding the route of administration (i.e. oral versus once-weekly injection). If heart failure or diabetic kidney disease predominates, a

SGLT-2 inhibitor (i.e. empagliflozin) is preferred. If they do not, either a SGLT-2 inhibitor or a GLP-1 receptor agonist is recommended; a GLP-1 receptor agonist treatment will likely lead to greater improvements in glycaemic control and weight loss than SGLT-2 inhibitor treatment. Dual treatment with empagliflozin and dulaglutide is the preferred next step for patients who have an HbA1c level above target taking one of these medicines alone, however, this is not funded.

 For further information on empagliflozin and dulaglutide, see: [link](#)

Audit plan

Summary

This audit identifies people with type 2 diabetes who are eligible for funded SGLT-2 inhibitor or GLP-1 receptor agonist treatment to ensure that they are switched to a regimen that includes empagliflozin or dulaglutide.*

* Availability pending Medsafe approval

N.B. While not the focus of this audit, patients who are likely to benefit from empagliflozin or dulaglutide treatment, but are not eligible for funding, may also be identified. Consider flagging these patients for a discussion about treatment options, including the possibility of self-funding.

Recommended audit standards

Ideally, all patients with type 2 diabetes who are at high risk of cardiovascular or renal complications will be taking empagliflozin or dulaglutide as part of their diabetes management regimen. However, empagliflozin has only been funded since 1 February, 2021 and dulaglutide is still awaiting Medsafe approval. Therefore, the first cycle of this audit will help to identify patients who are eligible for funded empagliflozin or dulaglutide treatment and flag them for review; after the second cycle ideally all eligible patients will be receiving funded treatment.

Audit data

Identifying eligible patients

All patients aged over 18 years with type 2 diabetes are eligible for inclusion in this audit. Many practitioners will be able to do this by running a “query” through their PMS. Review the clinical notes (or some practitioners may be able to include this in their query) to determine whether the patient meets the eligibility criteria for funded treatment based on their glycaemic control and risk of cardiovascular disease or renal complications, i.e.:

- HbA_{1c} level > 53 mmol/mol despite regular use of at least one blood-glucose lowering medicine (e.g. metformin, vildagliptin or insulin) for at least three months; AND
- Established CVD or high CVD risk,* diabetic kidney disease or heart failure; OR
- Māori or Pacific ethnicity

* Defined as five-year CVD risk of $\geq 15\%$ or a high lifetime CVD risk due to being diagnosed with type 2 diabetes during childhood or as a young adult

Sample size

The number of eligible patients will vary according to your practice demographic. If a large number of results are returned, a sample size of 30 patients is sufficient for this audit. However, all eligible patients will need to be reviewed subsequently.

Criteria for a positive outcome

A positive result is any eligible patient with type 2 diabetes who is prescribed empagliflozin or dulaglutide.

As empagliflozin has only been funded since February, 2021 and dulaglutide is not yet available (as of March, 2021), it is likely that only a small number of patients will meet the criteria for a positive result in Cycle 1 of the audit if this is completed in early to mid-2021. Aim for a higher number of positive results in Cycle 2. Alternatively, you may wish to set the criteria for a positive result in Cycle 1 as “any patient eligible for funded treatment who is flagged for review”.

Data analysis

Use the sheet provided to record your data. A positive result is any eligible patient with type 2 diabetes who is prescribed empagliflozin or dulaglutide. The percentage achievement can be calculated by dividing the number of patients with a positive result (i.e. ‘YES’ in column G) by the number of patients eligible for treatment (i.e. ‘YES’ in column F).

N.B. if you have been able to build a query in your PMS that only identifies patients eligible for funded treatment, then you can proceed with the audit using columns G and H only.

Identifying opportunities for Audit of Medical Practice

The first step to improving medical practice is to identify the criteria where gaps exist between expected and actual performance and then to decide how to change practice.

Once a set of priorities for change have been decided on, an action plan should be developed to implement any changes.

Taking action

It may be useful to consider the following points when developing a plan for action (RNZCGP 2002).

Problem solving process

- What is the problem or underlying problem(s)?
- Change it to an aim
- What are the solutions or options?
- What are the barriers?
- How can you overcome them?

Overcoming barriers to promote change

- Identifying barriers can provide a basis for change
- What is achievable – find out what the external pressures on the practice are and discuss ways of dealing with them in the practice setting
- Identify the barriers
- Develop a priority list
- Choose one or two achievable goals

Effective interventions

- No single strategy or intervention is more effective than another, and sometimes a variety of methods are needed to bring about lasting change
- Interventions should be directed at existing barriers or problems, knowledge, skills and attitudes, as well as performance and behaviour

Review

Monitoring change and progress

It is important to review the action plan developed previously at regular intervals. It may be helpful to review the following questions:

- Is the process working?
- Are the goals for improvement being achieved?
- Are the goals still appropriate?
- Do you need to develop new tools to achieve the goals you have set?

Following the completion of the first cycle, it is recommended that the doctor completes the first part of the Audit of Medical Practice summary sheet (Appendix 1).

Undertaking a second cycle

In addition to regular reviews of progress with the practice team, a second audit cycle should be completed in order to quantify progress on closing the gaps in performance.

It is recommended that the second cycle be completed within 12 months of completing the first cycle. The second cycle should begin at the data collection stage. Following the completion of the second cycle it is recommended that practices complete the remainder of the Audit of Medical Practice summary sheet.

Claiming credits for Continuing Professional Development (CPD)

This audit has been endorsed by The Royal New Zealand College of General Practitioners (RNZCGP) and has been approved for **10 CME credits** for a first cycle and **10 CME credits** for a second cycle for the General Practice Educational Programme (GPEP) and Continuing Professional Development (CPD) purposes. The second cycle is optional and only two cycles are permissible.

To claim points go to the RNZCGP website:

www.rnzcgp.org.nz

Record your completion of the audit on the **CPD Online Dashboard**, under the **Audit of Medical Practice**

section. From the drop down menu select **“Approved practice/PHO audit”** and record the audit name.

General practitioners are encouraged to discuss the outcomes of the audit with their peer group or practice.

As the RNZCGP frequently audit claims you should retain the following documentation, in order to provide adequate evidence of participation in this audit:

1. A summary of the data collected
2. An Audit of Medical Practice (CQI activity) summary sheet (included as Appendix 1).



Data sheet – cycle 1

Reviewing type 2 diabetes management in patients at high risk of cardiovascular and renal complications

Patient with type 2 diabetes	A	B	C	D	E	F	G	H
	HbA _{1c} > 53 mmol/mol	CVD/risk > 15%	DKD	HF	Māori or Pacific ethnicity	Eligible for funded treatment (tick in column A + at least one tick in columns B – D)	If Yes in column F, prescribed empagliflozin or dulaglutide	If No in column G, flag for review
	✓/✗	✓/✗	✓/✗	✓/✗	✓/✗	Yes/No	Yes/No	
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AUDIT RESULT: Total 'YES' in column G divided by total 'YES' in column F :

Please retain this sheet for your records to provide evidence of participation in this audit.

Data sheet – cycle 2 Reviewing type 2 diabetes management in patients at high risk of cardiovascular and renal complications

Patient with type 2 diabetes	A	B	C	D	E	F	G	H
	HbA _{1c} > 53 mmol/mol	CVD/risk > 15%	DKD	HF	Māori or Pacific ethnicity	Eligible for funded treatment (tick in column A + at least one tick in columns B – D)	If Yes in column F, prescribed empagliflozin or dulaglutide	If No in column G, flag for review
	✓/✗	✓/✗	✓/✗	✓/✗	✓/✗	Yes/No	Yes/No	
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AUDIT RESULT: Total 'YES' in column G divided by total 'YES' in column F :

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SUMMARY SHEET

Audit of medical practice (CQI activity)

Topic:

Reviewing type 2 diabetes management in patients at high risk of cardiovascular and renal complications

Date:

Activity designed by (name of organisation, if relevant):

Bpac^{nz}

Doctor's name:

Results discussed with peer group or colleagues?

Yes

No

Date:

FIRST CYCLE

DATA: Date of data collection:

CHECK: Describe any areas targeted for improvement as a result of analysing the data collected. (If the findings have any implications for health equity, please include this.)

ACTION: Describe how these improvements will be implemented.

MONITOR: Describe how well the process is working. When will you undertake a second cycle?

SECOND CYCLE

DATA: Date of data collection:

CHECK: Describe any areas targeted for improvement as a result of analysing the data collected. (If the findings have any implications for health equity, please include this.)

ACTION: Describe how these improvements will be implemented.

MONITOR: Describe how well the process is working.

COMMENTS: