### Queensland Community Pharmacy Scope of Practice Pilot

### Cardiovascular Disease (CVD) Risk Reduction Program-Clinical Protocol

## **Clinical Protocol**

# Patients who are ineligible for the CVD Risk Reduction Program:

- Patients who are planning a pregnancy or pregnant
- Patients aged under 18 years or over 79 years
- Patients with an existing diagnosis of:
  - Stage 3 to 5 Chronic Kidney Disease (CKD)
  - Familial hypercholesterolaemia
  - Type 1 diabetes

0

- Type 2 diabetes treated with insulin
- Microvascular or macrovascular complications of diabetes
  - Established complex cardiovascular disease (CVD):
    - Severe (stage 3) hypertension
    - Congenital heart disease
    - Rheumatic heart disease
    - Heart failure
    - Arrythmias
    - Atrial fibrillation
    - Other conditions including peripheral arterial disease, heart block, pericarditis, valvular disease, pulmonary hypertension, angina, cardiomyopathy and cardiomegaly, aortic aneurysm
- Asthma, COPD or another serious respiratory illness
- Patients with a history of:
  - Cardiothoracic surgery
  - Acute coronary syndrome (myocardial infarction, unstable angina)
  - Stroke or other cerebrovascular disease
  - $\circ$  Deep vein thrombosis and/or pulmonary embolism
  - Hypertensive urgency or emergency
- Patients under the care of a specialist cardiologist, endocrinologist or nephrologist (within the previous 12 months) without a written referral from the treating specialist(s) for the Program
- Patients currently prescribed anticoagulant pharmacotherapy.

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#### How to use this document

This clinical protocol details how patients in the Cardiovascular Disease (CVD) Risk Reduction Program should be managed, including referral to other health services and medical practitioners, pharmacological interventions, and protocol-based/structured prescribing of specific medicines for the management of dyslipidaemia, hypertension and hyperglycaemia.

The following pages provide detailed information that corresponds to the numbered phases in the CVD Risk Reduction overview algorithm (refer to Figure 1).

When applying the information contained within this clinical protocol, pharmacists are advised to exercise professional discretion and judgement. The clinical protocol does not override the responsibility of the pharmacist to make decisions appropriate to the circumstances of the individual, in consultation with the patient and/or their carer.

#### Key points

- The purpose of the CVD Risk Reduction Program (the Program) is to provide an accessible, community-based health care service to identify and improve outcomes for patients at high risk of CVD.
- CVD is mostly preventable. The majority of patients who experience a cardiovascular event or develop a cardiovascular disease have at least 1 identifiable CVD risk factor. Most risk factors can be minimised through lifestyle modification and pharmacological interventions (1, 2).
- In Australia, approximately 64% of adults have at least 3 modifiable risk factors and it is estimated that modifiable risk factors account for 90% of the risk of a cardiovascular event <sup>(3, 4)</sup>. The rate of CVD in Aboriginal and Torres Strait Islander people is double that of non-Aboriginal and Torres Strait Islander people <sup>(5)</sup>.

### **Refer when**

## During the Program, patients must be referred to a medical practitioner for ongoing management if:

- They are diagnosed with, or develop signs and symptoms of a serious comorbidity or pathology
- They have or develop:
  - Unexplained fluctuations in bp or severe hypertension (≥ 180mmhg and/or ≥ 110mmhg)
  - Severe hyperglycaemia (HbA1c  $\ge$  10% or BGL  $\ge$  20.0mmol/L)
  - Hypoglycaemia (BGL < 4.0mmol/L)</li>
  - $\circ$  TC ≥ 7.5mmol/l, LDL-C ≥ 5.0mmol/L or triglycerides > 6mmol/L
  - UACR ≥ 2.5 mg/mmol (men) or ≥ 3.5 mg/mmol (women) and/or eGFR < 60 ml/min/1.73 m<sup>2</sup>
- They are suspected to have hypertension, hyperglycaemia or dyslipidaemia with a secondary cause
- They receive a high risk or abnormal pathology result (referral to emergency medical care may be required)
- They do not reach or stabilise at clinical targets within appropriate clinical timeframes
- They have type 2 diabetes and are experiencing acute illness.

### Overview of the CVD Risk Reduction Program

There are two entry points for patients who are appropriate for enrolment in the Program:

- Patients **without a previous diagnosis** of hypertension, type 2 diabetes and/or dyslipidaemia may be enrolled in the program and commence management concurrent to referral to a medical practitioner for further review and collaborative care.
- Patients **with an existing diagnosis** of hypertension, type 2 diabetes and/or dyslipidaemia may be enrolled in the program and commence management provided the patient's usual medical practitioner is notified and updates are provided following each occasion of care.

The Program is based on the information provided in the Therapeutic Guidelines and other evidence-based Australian guidelines, and involves:

- **Initial screening** for patient suitability for the Program, as per Figure 2.
- Standardised and structured assessment, as per Figure 3, including:
  - o screening for hypertension, dyslipidaemia and hyperglycaemia
  - **risk estimation** for type 2 diabetes and CVD.
- **Management of CVD risk** through lifestyle modification and targeted interventions for blood pressure, blood glucose and blood lipids for patients at moderate or high risk of CVD, including development of a comprehensive CVD risk reduction plan.
- **Monitoring** of patient progress towards reduced CVD risk and referral to a medical practitioner when required.

Patients at high risk of CVD or with an existing diagnosis of hypertension (mild to moderate), dyslipidaemia and/or type 2 diabetes (not being treated with insulin) may be referred into the Program for management and monitoring. Alternatively, patients may self-refer or request screening/ CVD risk estimation, or the pharmacist may suggest initial screening or enrolment if they believe the patient may be eligible and benefit from the Program.

#### Figure 1 Overview of the CVD Risk Reduction Program

#### **1** Screen for patient suitability for the Program

#### A Initial screening

- Establish suitability for Program
  - Person aged ≥ 18 years and < 79 years
  - Not pregnant, planning a pregnancy or breast feeding
  - No previously diagnosed exclusionary conditions:
    - complex, established CVD/ serious cardiovascular conditions including severe hypertension
    - CKD
    - · familial hypercholesterolaemia
    - type 1 diabetes
    - type 2 diabetes treated with insulin
    - · micro or macrovascular complications of diabetes
    - · serious history of respiratory illness including asthma and/or COPD
  - No history of:
    - cardiothoracic surgery
    - acute coronary syndrome (myocardial infarction, unstable angina)
    - stroke or other cerebrovascular disease
    - deep vein thrombosis (DVT) and/or pulmonary embolism
    - hypertensive urgency/ emergency
  - · Not under the care of a specialist cardiologist (without a referral)
  - Not prescribed anticoagulant pharmacotherapy
- Take first blood pressure (BP) measurement
- Provide Program overview

Document screening results and first BP measurement in patient record

#### Gain consent for phase 2 for suitable patients and enrol in Program

#### 2 Enrol patient and conduct assessment

#### Take detailed patient history:

Patient characteristics

R

E

- Medical history
- Lifestyle/ social history

### Take second BP measurement, calculate Body Mass Index (BMI), measure waist circumference

Estimate type 2 diabetes risk using AUSDRISK tool (if applicable) If person has a previous diagnosis of type 2 diabetes – Skip section D and move to E

Obtain relevant test results

- Determine tests required for each individual
- · Obtain recent test results from other practitioners/ My Health Record
- Perform point of care testing (PoCT) and/or request laboratory testing as required:
  - HbA1c and/or FBG
  - UACR & eGFR
  - Full lipid assessment (total cholesterol, including LDL-C, HDL-C & triglycerides)

F Review test results

#### See over page

Refer patient to a medical practitioner if the person is not suitable for Program at initial screening or does not consent to the Program

Refer patient to a medical practitioner or emergency services for urgent care if: BP ≥ 180 mmHg systolic and/or ≥ 110 mmHg diastolic (severe hypertension)

Refer patient to a medical practitioner for ongoing management if the person has signs or symptoms of a serious comorbidity or pathology

Refer patient to their medical practitioner for ongoing management if:

- Results that may indicate serious pathology or undiagnosed comorbidity
- unexplained BP fluctuations
- HbA1c > 10% or BGL > 20mmol/L
- UACR > 2.5 mg/mmol (men) or 3.5 mg/mmol (women) and/or eGFR < 60 mL/min/1.73 m<sup>2</sup>
- total cholesterol ≥ 7.5 mmol/L, LDL-C ≥ 5.0 mmol/L or triglycerides > 6 mmol/L.

G	<ul> <li>G Estimate CVD risk</li> <li>Consider modifiable and non-modifiable risk factors and comorbidities for all participants</li> <li>CVDCheck (absolute CVD risk) for validated populations</li> </ul>			
lf pe	erson has low CVD risk AND test results wit and lipid p <b>Provide brief advice for lifestyle modif</b>	thin normal ranges (BP, HbA1c, UACR, eGFR profile): <b>ication and discharge from Program</b>		
	Initiate collaborative care for	persons suitable for phase 3		
E: typ	xisting diagnosis of hypertension, pe 2 diabetes and/or dyslipidaemia – Notify the person's medical practitioner	High CVD risk or test results indicative of hypertension, type 2 diabetes and/or dyslipidaemia – The person must be concurrently referred their medical practitioner		
3	Develop and implement the CVI	D Risk Management Plan		
	<ul> <li>Smoking cessation</li> <li>Diet and nutrition</li> <li>Alcohol consumption</li> <li>Exercise and physical activity</li> <li>Weight management</li> </ul>			
<ul> <li>Pharmacotherapy</li> <li>Hypertension         <ul> <li>angiotensin-converting enzyme (ACE) inhibitors</li> <li>angiotensin receptor blockers (ARB) (sartans)</li> <li>dihydropyridine calcium channel blockers</li> <li>thiazide and thiazide-like diuretics.</li> </ul> </li> <li>Type 2 diabetes         <ul> <li>biguanide (metformin)</li> <li>glucagon-like peptide-1 (GLP-1) receptor agonists</li> <li>sodium-glucose co-transporter 2 (SGLT2) inhibitors</li> <li>dipeptidyl peptidase-4 (DPP-4) inhibitors</li> </ul> </li> <li>Dyslipidaemia         <ul> <li>statins</li> <li>ezetimibe</li> <li>fenofibrate</li> </ul> </li> </ul>				
J	Confirm management plan is appro	priate		
К	Communicate agreed management	plan		
с •	Communicate with person's usual medic care (with perso Provide a copy of the CVD Risk Manageme	al practitioner to enable collaborative on's consent): ent Plan and include:		

- relevant medical history and pathology/ PoCT results
  - changes to existing pharmacotherapy or new pharmacotherapy prescribed
  - a summary of advice provided to the patient including recommendations for multidisciplinary care and referrals
- the next scheduled review appointment.

#### See over page

4 Ongoing management and monitoring	The patient's suitability for
<ul> <li>Clinical review         <ul> <li>Timeframes determined by specific condition and pharmacotherapy</li> <li>Prior to appointment, request laboratory testing (if applicable)</li> </ul> </li> <li>At each review appointment (either scheduled or unscheduled):         <ul> <li>review and update patient history</li> <li>Repeat BP measurements</li> <li>review pathology/ undertake required PoCT</li> <li>Review changes to CVD risk factors and reassessment of CVD risk.</li> <li>Reinforce and check adherence to lifestyle modification.</li> <li>Review and update the CVD Risk Management Plan (if required)</li> <li>Ensure the patient has enough medicines and prescriptions until their next scheduled review.</li> <li>Provide referrals to the patient's multidisciplinary health team (if required).</li> <li>Consider the patient's ongoing suitability to be managed in the Program.</li> </ul> </li> </ul>	<ul> <li>any point.</li> <li>Refer to a medical practitioner for ongoing management if:</li> <li>the person is diagnosed with, or develops signs or symptoms of a serious undiagnosed comorbidity or pathology</li> <li>the person experiences serious adverse effects</li> <li>the person develops severe hypertension, hyperglycaemia or hypoglycaemia</li> <li>secondary hypertension or</li> </ul>
Communicate with person's medical practitioner to enable collaborative care (with person's consent): • Advise of changes to CVD Risk Management Plan	• clinical targets are not reached within appropriate timeframes
Person no longer suitable for Program - Refer for ongoing management     Completion of the Program	Refer the patient back to their medical practitioner with a
Patients who leave the Program for any reason	handover at Program

### **Phase 1: Screen for patient suitability** A. Brief screening

Conduct initial screening for Program suitability. Refer to Figure 2.

Figure 2 Initial screening algorithm

Potential Program participant identified through pharmacist, self, or other health practitioner referral:

- existing diagnosis/ prescribed pharmacotherapy for type 2 diabetes, hypertension or dyslipidaemia
- current pharmacotherapy may be suboptimal
- the person requests advice or screening for CVD
- the person has risk factors for CVD e.g., smoking, overweight or obesity, male aged over 45 years etc.



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- 1. Ask the initial screening questions to assess the patient's eligibility and suitability for the Program, as per Figure 2.
- 2. Take an initial blood pressure measurement
  - Refer to the National Heart Foundation of Australia <u>Guideline for the diagnosis and</u> <u>management of hypertension in adults</u> <sup>(6)</sup>.
- 3. Provide an overview of the Program including: the aims, expected outcomes, and what the Program may involve (which will vary between patients), including:
  - possible timeframes for involvement, such as the number of appointments and testing required, including the costs of appointments and testing
  - how the patient's medicines may be managed and how medicine costs may differ when prescribed by a pharmacist or medical practitioner
  - other interventions that may be recommended as part of the Program e.g., smoking cessation and weight management, and the likely costs
  - that the patient may leave the Program, including by opting-out or becoming ineligible at any time and be referred to a medical practitioner.
- 4. Gain informed consent from the patient for participation, as per the Pilot Handbook.
- 5. Document all findings in the patient record and refer as required.

### Phase 2: Comprehensive assessment

Take a detailed patient medical and clinical history, obtain and review test results and conduct a comprehensive CVD risk assessment. Refer to Figure 3.

Figure 3 Conducting an assessment



### B. Patient history

Sufficient information should be obtained from the patient to assess the patient's overall health, suitability for participation in the program, and the safety and appropriateness of any recommendations and medicines.

#### Responses to the previous screening questions in phase 1 should inform the patient history:

- age
- pregnancy and lactation status (if applicable).

#### Additional information required:

- ethnic or cultural background, including Aboriginal and Torres Strait Islander status
- underlying or associated conditions and comorbidities that are risk factors for CVD including (but not limited to):
  - Conditions requiring comprehensive management by patient's usual medical practitioner (not suitable for the Program): CKD, familial hypercholesterolaemia, type 1 diabetes, microvascular or macrovascular complications of diabetes (e.g., retinopathy, nephropathy, neuropathy), established complex CVD, other cardiovascular conditions, serious respiratory illness, asthma and/or chronic obstructive pulmonary disease (COPD).
  - Conditions associated with increased CVD risk that require collaborative management with the patient's usual medical practitioner, including previous management of CVD e.g., obstructive sleep apnoea (OSA), mental health conditions, thyroid and endocrine disorders, polycystic ovarian syndrome (PCOS)
- history of cardiothoracic surgery, acute coronary syndrome (myocardial infarction, unstable angina), stroke or other cerebrovascular disease, DVT and/or pulmonary embolism, hypertensive urgency/emergency (not suitable for the Program)
- clinical signs and symptoms of insulin resistance (acanthosis nigricans, skin tags, central obesity, hirsutism)
- clinical signs of undiagnosed familial hypercholesterolaemia e.g., tendinous xanthomata, arcus cornealis before 45 years of age, xanthelasma
- other symptoms that may indicate an undiagnosed comorbidity or serious pathology e.g., unexplained weight loss or gain, frequent headache and dizziness, chronic nausea and vomiting, lethargy, polyuria, polydipsia, frequent fungal or bacterial infections, blurred vision, poor wound healing
- family history of CVD, particularly premature CVD (diagnosed before age 60) in a first degree relative, familial hypercholesterolaemia, CKD, diabetes and/or other autoimmune conditions
- smoking status and history of smoking (number of cigarettes per day, length of time, starting age) (if applicable)
- patients with type 2 diabetes: current monitoring of blood glucose and the last sick day management plan (if available)
- patients with past pregnancy: history of hypertensive disorders of pregnancy (including pre-eclampsia) or gestational diabetes
- all current and recently commenced medication (including prescribed medicines, vitamins, herbs, other supplements and over-the-counter medicines)
- drug allergies/adverse drug events

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- diet/nutrition (fruit and vegetable consumption, volume of processed carbohydrates)
- levels of physical activity (minutes of physical activity per day, days of the week, intensity and type of activity)
- recreational drug and alcohol use.

# Reminder

Pharmacists can access a range of clinical information in a patient's My Health Record, including details about current and past medication history, allergies and current medical conditions.

### C. Take measurements

Record blood pressure (BP), Body Mass Index (BMI) and waist circumference.

- 1. BP measurement
  - All BP measurements should be conducted in accordance with the National Heart Foundation of Australia <u>Guidelines for the diagnosis and management of hypertension in</u> <u>adults 2016</u> <sup>(6)</sup>, including for review appointments.
  - In-clinic BP measurements are required for the purposes of calculating the absolute CVD risk score <sup>(6)</sup>.
  - Take three measurements and average the last two. Where there is variation > 10 mmHg systolic or > 6 mmHg diastolic, have the patient rest quietly for 5 minutes then remeasure.
- 2. BMI
  - Refer to the <u>Department of Health and Aging BMI and waist measurement</u> <sup>(7)</sup> for information about of BMI ranges and exceptions.
- 3. Waist circumference
  - Measure waist and interpret in accordance with the <u>Department of Health and Aging BMI</u> and waist measurement <sup>(7)</sup>.

### D.Estimate type 2 diabetes risk (if applicable)

All patients without an existing diagnosis of type 2 diabetes should have their risk of developing type 2 diabetes (in the next 5 years) assessed every 3 years using the validated <u>Australian type 2</u> <u>Diabetes Risk Assessment Tool (AUSDRISK)</u><sup>(8, 9)</sup>.

### E. Obtain relevant test results

Required relevant test results, based on the patient's personal and clinical circumstances are outlined in Table 1.

Where recent test results are unavailable, appropriate testing (point of care testing (PoCT) where clinically appropriate and/or laboratory testing) should be undertaken.

Where a patient has a previous Coronary artery calcium (CAC) measurement, the result can influence the assessment of CVD risk, see appendix 2 <sup>(4)</sup>. CAC measurement cannot be requested as part of the Pilot.

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PoCT can be used for screening/ case finding, diagnosis and monitoring, however, the PoCT device must be of suitable analytical quality for the clinical purpose <sup>(10, 11)</sup>. Refer to the Pilot handbook for further information regarding the use of PoCT.

Where PoCT is not available or clinically appropriate, laboratory testing will be required. Refer to the Pilot handbook for further information regarding the laboratory testing process.

Table 1 Tests (or recent results) required based on personal and clinical circumstances

Table 1. Tests (or recent results) required based on personal and clinical circumstances			
Test	Who and when		
Glycated haemoglobin (HbA1c) or fasting blood	• Patients with a current diagnosis of type 2 diabetes should have results no older than 1 month.		
glucose (FBG)	<ul> <li>Patients who have not been diagnosed with type 2 diabetes + testing hasn't been performed in the previous 3 years (or results not available) + one of the following: <ul> <li>AUSDRISK score of ≥ 12</li> <li>Aboriginal and Torres Strait Islander person aged ≥ 18 years</li> <li>Pacific Island, Indian sub-continent, Southern European and Asian background</li> <li>women with a history of gestational diabetes</li> <li>women with PCOS</li> <li>taking antipsychotic drugs</li> <li>aged ≥ 40 who are overweight or obese</li> <li>history of impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) (if known)</li> <li>a first degree relative with diabetes</li> </ul> </li> </ul>		
	<ul> <li>1 or more classical symptoms of diabetes (weight loss,</li> </ul>		
	Based on information in the RACGP <u>Management of type 2 diabetes:</u> <u>A handbook for General Practice</u> <sup>(12)</sup> .		
Urinary albumin: creatinine ratio (UACR) and estimated	<ul> <li>If testing has not been performed in the previous 12 months (or results are not available) for the following patients:</li> <li>current diagnosis of type 2 diabetes (including those</li> </ul>		
Glomerular Filtration Rate (eGFR)	identified within the Program)		
	<ul> <li>hypertension</li> <li>family history of CKD</li> </ul>		
	<ul> <li>Aboriginal and Torres Strait Islander descent aged ≥ 18 years <sup>(13)</sup></li> </ul>		
	◦ obese, or overweight + aged ≥ 60		
	<ul> <li>current or past smoker (within the previous 12 months).</li> </ul>		
	Based on information in the Kidney Health Australia <u>Chronic Kidney</u> <u>Disease (CKD) Management in Primary Care guideline</u> <sup>(14)</sup> .		
Full lipid assessment (fasting): total cholesterol (TC) low-	<ul> <li>If testing has not been performed in the previous 5 years (or results are not available) for the following patients:</li> </ul>		
density lipoprotein	• Aboriginal and forres strait islander people aged $\geq$ 18 years		
cholesterol (LDL-C),	$\circ$ all patients aged $\geq$ 45 years.		
high-density lipoprotein	Based on information in the RACGP Guidelines for preventive		
triglycerides (TGs)	<u>activities in general practice</u> <sup>(15)</sup> .		

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### F. Review test results

Guidance around the review of test results is included in Appendix 1

Where a patient has a previous Coronary artery calcium (CAC) measurement, the result can influence the assessment of CVD risk (refer to Appendix 2) (4). CAC measurement cannot be requested as part of the Pilot.

#### Check referral points

### G. Estimate CVD risk

All patients should have their CVD risk assessed, considering modifiable and non-modifiable risk factors and related comorbidities (refer to Appendix 2) <sup>(4)</sup>.

In addition to assessment of risk factors, assess absolute CVD risk in the following patient groups without known CVD using <u>CVDCheck</u> (Australian absolute cardiovascular disease risk calculator):

- all patients aged ≥ 45 years
- patients with diabetes aged ≥ 35 years
- Aboriginal and/or Torres Strait Islander people aged  $\geq$  30 years <sup>(3, 4, 13, 16, 17)</sup>.

<u>CVDCheck</u> has not been validated for patients with known CVD aged 30 to 79 years who are not clinically pre-determined to be at high risk of CVD (Table 2) <sup>(4)</sup>:

Interpretation of absolute CVD risk scores is in accordance with the <u>Australian Guideline for</u> assessing and managing cardiovascular disease risk <sup>(4, 13, 18)</sup>.

Younger patients aged < 45 years (or < 30 for Aboriginal and/or Torres Strait Islander people) are generally considered to be low risk <sup>(4)</sup>. A younger person may be considered at moderate risk if they have risk factors or high risk if they have a family history or premature CVD or familial hypercholesterolaemia.

• Screen Aboriginal and/or Torres Strait Islander people for modifiable risk factors.

Consider the patients' health literacy, social and cultural background when discussing CVD risk and communicate CVD risk as either a percentage or a frequency (e.g., 15% or "15 out of 100 people like you will have a heart attack or stroke in the next 5 years") <sup>(4)</sup>.

The <u>Australian Guideline for assessing and managing cardiovascular disease risk</u> defines intervals for the reassessment of CVD risk, this must consider the patient's initial CVD risk and presence or development of a CVD risk factors.

Table 2 Patients clinically pre-determined to have a high absolute cardiovascular risk

Table 2. Patients clinically pre-determined to have a high absolute cardiovascular risk <sup>(1, 4)</sup>

#### Patients with:

- diabetes and aged over 60 years
- diabetes with micro or macro-albuminuria\* (> 20 micrograms/min or UACR > 2.5 mg/mmol (men)/ >3.5 mg/mmol (women))
- moderate or severe CKD (stage 3-5)\* (eGFR < 45 mL/min/1.73m<sup>2</sup> or persistent UACR >25mg/mmol (men)/ >35mg/mmol (women))
- diagnosed familial hypercholesterolaemia\*
- severe hypertension\* (≥180 mmHg systolic and/or ≥ 110 mmHg diastolic)
- serum total cholesterol > 7.5 mmol/L
- Aboriginal and Torres Strait Islander people aged over 74 years\*.

\*These patients are not eligible for the Program and must be referred to a medical practitioner for management of CVD risk.

### Pharmacist resources

- Australian Journal of General Practice: <u>Absolute cardiovascular disease risk and</u> <u>the use of the Australian cardiovascular disease risk calculator</u> <sup>(16)</sup>
- <u>Therapeutic Guidelines: Cardiovascular (Cardiovascular disease risk stratification)</u>
  <sup>(1)</sup>
- Medical Journal of Australia: <u>Cardiovascular disease risk assessment for Aboriginal</u> <u>and Torres Strait Islander adults aged under 35 years: a consensus statement <sup>(13)</sup></u>
- Australian absolute cardiovascular disease risk calculator <u>CVDCheck</u> <sup>(4)</sup>.

#### Collaborative care

Patients with a **low or intermediate CVD risk** and test results within normal ranges should be provided with brief advice for lifestyle modification (or reinforcement) and discharged from the Program with the advice to see their medical practitioner if they have any concerns regarding their cardiovascular health.

Patients with a **high CVD risk** or test results indicating hypertension, type 2 diabetes and/or dyslipidaemia **without** a previous diagnosis may be enrolled in the Program and management may commence concurrent to referral to a medical practitioner for further review and collaborative care.

Patients **with** a previous diagnosis of mild to moderate hypertension, type 2 diabetes (not treated with insulin) and/or dyslipidaemia who are suitable to participate in the Program may be enrolled in the Program and commence management provided the patient's usual medical practitioner is notified and updates are provided following each occasion of care.

If the patient was referred into the Program by a medical practitioner, they may proceed directly to phase 3 if they are eligible.

Relevant diagnostic information should be shared with the patient's medical practitioner, with the patient's consent, to avoid duplication.

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# **Phase 3:** Develop and implement a management plan

A holistic approach to managing overall CVD risk is more effective than managing individual clinical risk factors (hypertension, dyslipidaemia and hyperglycaemia) in isolation <sup>(1, 4, 17)</sup>.

Decisions regarding the management approach for individual CVD risk factors, including non-pharmacological and pharmacological interventions should be made in the context of the individual's overall CVD risk <sup>(1)</sup>.

Each patient should have a CVD Risk Management Plan (a template for guidance is provided in Appendix 3) developed that addresses each modifiable risk factor in accordance with the Therapeutic Guidelines and other relevant Australian guidelines, that may include:

- appropriate clinical targets
- lifestyle modification (non-pharmacological interventions) for relevant risk factors (see section <u>H: Non-pharmacological lifestyle interventions)</u>
- pharmacotherapy to treat hypertension, hyperglycaemia and/or dyslipidaemia (see section <u>I: Pharmacotherapy</u>).

Pharmacists should encourage patients to be involved in shared decision making and the development of their CVD Risk Management Plan, including setting of appropriate targets.

### H.General measures

All Program participants should be counselled and provided with information regarding modification of lifestyle related CVD risk factors, regardless of whether pharmacotherapy is also prescribed.

For patients with a low risk of CVD (including most young patients), lifestyle modification alone may be sufficient to manage CVD risk.

The 5As Framework for behavioural risk modification may be used as the basis for identifying modifiable lifestyle risk factors and implementing lifestyle interventions in accordance with Royal Australian College of General Practitioners <u>Smoking, nutrition, alcohol and physical activity (SNAP)</u> guide <sup>(19)</sup>.

#### Smoking cessation (if applicable)

Refer to the Smoking Cessation Clinical Practice Guideline for detailed information, including pharmacological and non-pharmacological management of smoking cessation.

#### Diet and nutrition

Patients should be advised to follow a healthy eating pattern, that is low in saturated and trans fats, and incorporates:

- plenty of vegetables, fruit and wholegrains
- a variety of healthy protein-rich foods from animal and/or plant sources
- unflavoured milk, yoghurt and cheese
- foods that contain health fats and oils (e.g., nuts, seeds and fish)<sup>(4)</sup>.

Nutritional recommendations and advice should be sourced from the <u>Australian Dietary</u> <u>Guidelines</u> <sup>(20)</sup>.

Nutritional management should focus on a balanced diet with foods from each of the 5 food groups in appropriate portions to maintain a healthy weight. Foods that are high in saturated fat, sugar and sodium (e.g., highly processed foods) should be limited <sup>(15, 20, 21)</sup>.

- Patients with hypertension should be advised to reduce salt intake to < 4g per day <sup>(6)</sup>.
- Patients with dyslipidaemia should:
  - reduce saturated and trans-fat intake by replacing them with mono and polyunsaturated fats (avocado, nuts, seeds and vegetable oils)
  - increase soluble fibre intake (including oats, psyllium and legumes)
  - use products enriched with plant sterols
  - include soy protein through soy milk and/or soy cheese
  - $\circ$  aim for 2 to 3 servings of oily fish per week (salmon, mackerel and tuna) <sup>(1, 22)</sup>.

All patients with a moderate or high CVD risk should be encouraged to see a dietitian for individualised nutritional advice.

#### Alcohol consumption

Recommendations and advice regarding alcohol consumption should be sourced from the <u>Australian guidelines to reduce health risk from drinking alcohol</u><sup>(23)</sup>.

#### Exercise and physical activity

All patients should be encouraged to undertake regular exercise and physical activity in line with their age group in the <u>Physical activity and exercise guidelines for all Australians</u><sup>(24)</sup>.

Consider the patient's ability to safely exercise, including current mobility and flexibility, glycaemic control (if diabetic) and BP. Referral to a medical practitioner, physiotherapist and/or exercise physiologist for collaborative care should be considered.

#### Weight management

Refer to the Weight Management Clinical Practice Guideline for pharmacological and non-pharmacological management of overweight and obesity.



### Pharmacist resources

- National Heart Foundation of Australia: <u>Reducing risk in heart disease An expert</u> <u>guide to clinical practice for secondary prevention of coronary heart disease</u> <sup>(25)</sup>
- Royal Australian College of General Practitioners: <u>The Handbook of Non-Drug</u> <u>Interventions (HANDI)</u> <sup>(26)</sup>.

### I. Pharmacotherapy

To determine whether pharmacotherapy for hypertension, dyslipidaemia and hyperglycaemia should be initiated (or modified), consider the patient's:

- age and absolute CVD risk
- relevant CVD risk factors
- presence of related comorbidities
- clinical targets relevant to the individual
- response to previous interventions (non-pharmacological and pharmacological) including adverse effects
- patient preference.

Decisions to initiate pharmacotherapy should be made on a case-by-case basis in younger age groups with low CVD risk without identified risk factors, this includes:

- patients aged < 45 years
- Aboriginal and Torres Strait Islander people < 30 years
- patients with diabetes <35 years of age <sup>(4)</sup>.

#### Patients entering the program with an existing drug regimen

When managing patients who enter the Program already on a drug regimen, the pharmacist should ask for the patient's most recent CVD Action Plan (if they have one) and consider whether the current (or most recently prescribed) regimen is:

- concordant with the Therapeutic Guidelines and other relevant guidelines
- appropriate for the patient's symptoms and medical history
- optimised for patient, including response and progress towards clinical targets and for minimisation of adverse effects.

When modifying drug regimens within the Program that have been prescribed by another health practitioner, pharmacists should attempt to make changes in collaboration with the original prescriber or the patient's usual medical practitioner (whichever is most appropriate). Pharmacists may modify or deprescribe pharmacotherapy, particularly if:

- the patient's response is inadequate (within appropriate clinical timeframes)
- the patient is experiencing intolerable/unmanageable adverse effects
- the medicine is not used for the treatment of another condition.

### Pharmacotherapy for hypertension

The primary objective of BP-lowering pharmacotherapy is to prevent the long-term effects of hypertension, including CVD, heart failure and CKD <sup>(1) (4)</sup>.

The process of initiating and modifying pharmacotherapy for hypertension (where pharmacotherapy is indicated) is summarised in Figure 4.

Pharmacotherapy for hypertension prescribed within the Program must be in accordance with the <u>Therapeutic Guidelines: Hypertension and blood pressure reduction</u><sup>(1)</sup> and the National Heart Foundation's <u>Guidelines for the diagnosis and management of hypertension in adults</u><sup>(6)</sup>.

If clinically appropriate, pharmacists may prescribe up to 2 compatible first-line medicines (ACE inhibitor, ARB, dihydropyridine calcium channel blockers or thiazide/thiazide-like diuretics) for hypertension and modify doses to optimise management.

As at 1 November 2023, the <u>Therapeutic Guidelines: Hypertension and blood pressure reduction</u> has not been updated to reflect the <u>2023 Guideline for assessing and managing CVD risk</u><sup>(4)</sup>. Current recommendations within this Guideline consider the <u>2012 Guidelines for the management of</u> <u>absolute cardiovascular disease risk</u> and the National Heart Foundation's <u>Guidelines for the</u> <u>diagnosis and management of hypertension in adults</u><sup>(6, 27)</sup>. Information will be updated in line with updates to the Therapeutic Guidelines.

**NB1:** A single drug is sufficient to adequately reduce BP in approximately 25-50% of patients; patients at high CVD risk and/or moderate hypertension ( $\geq$  160/100 mmHg) may commence with 2 first-line drugs <sup>(6, 28, 29)</sup>.

Figure 4 Process for initiating and modifying antihypertensive pharmacotherapy (in the Program)

#### If pharmacotherapy to reduce BP is indicated (refer to table 3 and table 4)

#### Determine appropriate treatment regimen:

- Commencement of one or two drugs (based on BP and CVD risk)
- Drug choice:
  - ACE inhibitor
  - ARB
  - Dihydropyridine calcium channel blocker
  - Thiazide/thiazide like diuretic
- Consider patient's response to previous antihypertensive pharmacotherapy and preferences
- Appropriate initial dose (low to moderate dose)
- Appropriate review intervals

#### Confirm treatment regimen is appropriate

- Request and review relevant pathology testing (refer to table 5)
- Consult the Therapeutic Guidelines, Australian Medicines Handbook and other relevant resources for:
  - contraindications and precautions
  - drug interactions.

### Prescribe and review response after 4-6 weeks (or sooner if patient

experiences adverse effects):

- Check BP at every appointment
- Reinforce lifestyle modification
- Consider:
  - Response to pharmacotherapy and progress towards target
  - Adherence with pharmacological and non-pharmacological treatment regimen
  - Adverse effects
- Modify treatment regimen if response is inadequate or drug is not tolerated:
  - 1. Incrementally increase dose of first drug
  - 2. Add a second drug if required (and/or incrementally increase dose of second drug), up to therapeutic dose
  - 3. Change drug classes

Is BP target reached (and stable) after 3 months of treatment with 2 first-line antihypertensives at therapeutic doses?

yes If BP is stable at target, arrange necessary clinical review and continue to monitor response to therapy. If response to treatment changes, consider ongoing eligibility for the Program

### Initiating antihypertensive pharmacotherapy

The decision to initiate antihypertensive drug therapy is based on the patient's age and CVD risk, and persistent BP <sup>(1, 4, 6, 28-30)</sup>. Refer to Table 3 and Table 4.

#### Table 3 Pharmacotherapy for hypertension in patients aged $\ge$ 45 years

Table 3. Pharmacotherapy for hypertension in patients aged ≥ 45 years (≥ 30 years for Aboriginal and Torres Strait Islander people) <sup>(1, 4, 6, 13, 15, 29)</sup> .				
Low CVD Risk				
BP	Recommendation			
≥ 160/100 mmHg	Pharmacotherapy is recommended*. Treat to 140/90 mmHg (or lower if drug therapy is tolerated). Review 4-6 weeks after pharmacotherapy initiation.			
> 140/90 mmHg	Reinforce lifestyle modification and repeat BP measurement in 2 months			
2 140770 mmig	<ul> <li>If no reduction in BP after 2 months: Consider initiating pharmacotherapy (in the context of other risk factors).</li> </ul>			
	• If BP reduced after 2 months (but still >140/90 mmHg): Reinforce lifestyle modification and repeat BP measurement in 4 months.			
	• If BP reduced to < 140/90 mmHg: Discharge patient if other risk factors have been managed, or continue to monitor BP at future appointments.			
Moderate CVD Ris	k			
BP	Recommendation			
≥ 160/100 mmHg <b>OR</b>	Pharmacotherapy is recommended*. Treat to a target of 140/90 mmHg (or lower if drug therapy is tolerated).			
≥ 130/85 mmHg¹	Review 4-6 weeks after pharmacotherapy initiation.			
	<b>NB1:</b> If patient has a family history of premature CVD or in a population group at higher risk of CVD.			
≥ 130/85 mmHg²	Reinforce lifestyle modification, review and repeat BP in 2 months.			
	<ul> <li>If no reduction in BP (BP &gt;140/90 mmHg): Consider initiating pharmacotherapy (in the context of other risk factors).</li> </ul>			
	• If BP reduced (but still >140/90 mmHg): Reinforce lifestyle modification and repeat BP measurement in 4 months.			
	• If BP reduced to < 140/90 mmHg: Discharge if all other risk factors have been managed or continue to monitor BP at future appointments.			
	<b>NB2:</b> If patient does NOT have a family history of premature CVD or NOT in a population group at higher risk of CVD.			
High CVD Risk				
BP	Recommendation			
≥ 130/85 mmHg	Pharmacotherapy is recommended*.			
	Treat to a target of SBP 120 mmHg. Even if target is not reached, any sustained reduction in BP reduces the risk of morbidity and mortality due to CVD.			
	Review 4-6 weeks after pharmacotherapy initiation.			

#### \*Refer patient to a medical practitioner if pharmacotherapy is contraindicated.

#### Initiating antihypertensive pharmacotherapy in young patients

Higher BP in younger patients is associated with increased rates of left ventricular hypertrophy (LVH) and adverse impacts on cardiovascular and brain health, and is a predictor for secondary hypertension <sup>(31)</sup>.

The presence of hypertension at a young age contributes to earlier onset CVD and CVD events in middle age, however there is a lack of high-quality evidence that shows reducing BP in younger patients with hypertension reduces the likelihood of poor cardiovascular outcomes later in life <sup>(30, 31)</sup>.

Investigation of secondary hypertension is of considerable importance in younger patients; this may direct specific treatment strategies and is associated with better blood pressure control <sup>(31)</sup>.

#### Table 4 Initiating pharmacotherapy for hypertension in younger patients

Table 4. Initiating pharmacotherapy for hypertension in younger patients (aged < 45 years/ < 30 years for Aboriginal and Torres Strait Islander people) (13, 30, 31) BP Recommendation ≥ 160/100 Patient not suitable for Program, refer to a medical practitioner for investigation mmHg and ongoing management. ≥ 140/90 Reinforce lifestyle modification and repeat BP measurement in 3 months. mmHg Consider ambulatory monitoring (refer to <u>Guidelines for the diagnosis and</u> management of hypertension in adults). If no reduction in BP after 3 months: Refer to a medical practitioner for • investigation and ongoing management. If BP reduced after 3 months (but still > 140/90 mmHg): Consider initiating • pharmacotherapy (in the context of other risk factors)\*. Repeat BP measurement in 4-6 weeks. If BP remains >140/90 mmHg - Refer to a medical practitioner for investigation and ongoing management. If BP reduced to < 140/90 mmHg: • Consider discharge if all other risk factors have been managed. Otherwise, continue to monitor BP at subsequent appointments.

#### \*Refer patient to a medical practitioner if pharmacotherapy is contraindicated.

The pathology testing that is required before pharmacotherapy is initiated or modified, and during treatment is summarised in Table 5.

Table 5 Testing and monitoring for antihypertensive pharmacotherapy

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Table 5. Testing and monitoring for antihypertensive pharmacotherapy <sup>(6, 28, 29, 32)</sup>			
Drug class	Test		
ACE Inhibitors: • Captopril • Perindopril • Enalapril • Quinapril • Fosinopril • Ramipril • Lisinopril • Trandolapril	<ul> <li>Check renal function (eGFR) and electrolytes before commencing and 1-2 weeks later.</li> <li>A small rise in serum creatinine (up to 25%) or serum potassium (within the normal range) should not necessarily prompt dose reduction or cessation.</li> </ul>		
<ul> <li>ARBs (sartans):</li> <li>Candesartan</li> <li>Eprosartan</li> <li>Telmisartan</li> <li>Irbesartan</li> <li>Losartan</li> </ul>	<ul> <li>Check renal function (eGFR) and electrolytes before commencing and 1-2 weeks later.</li> <li>A small rise in serum creatinine (up to 25%) or serum potassium (within the normal range) should not necessarily prompt dose reduction or cessation.</li> </ul>		
Dihydropyridine calcium channel	Assess on a case-by-case basis		
<ul> <li>blockers:</li> <li>Amlodipine</li> <li>Felodipine modified-release</li> <li>Lercanidipine</li> <li>Nifedipine modified-release</li> </ul>			
<ul> <li>Thiazide and thiazide-like diuretics:</li> <li>Chlortalidone</li> <li>Hydrochlorothiazide</li> <li>Indapamide</li> <li>Indapamide modified-release</li> </ul>	<ul> <li>Electrolytes, specifically plasma sodium and potassium concentration should be reviewed 3 to 6 weeks after commencing.</li> <li>Patients with sodium and potassium outside of normal ranges/reference intervals should be referred to a medical practitioner for comprehensive management.</li> <li>The Royal College of Pathologists of Australasia (RCPA) reference interval for sodium is 135-145 mmol/L; potassium reference interval is 3.5 to 5.2 mmol/L <sup>(33)</sup>.</li> </ul>		

### Pharmacotherapy for type 2 diabetes

- The management of type 2 diabetes (pharmacological and non-pharmacological) should be individualised to the patient, considering:
  - the patient's glycaemic profile including symptoms and episodes of hyperglycaemia and hypoglycaemic unawareness
  - the patient's self-management capability including adherence to lifestyle interventions
  - $\circ$   $\;$  contraindications, adverse effects and other drug interactions
  - o management of comorbidities
  - o psychosocial wellbeing
  - accessibility to support and cultural appropriateness, particularly for Aboriginal and Torres Strait Islander people and people from a non-English speaking background
  - o patient choice (including cost and PBS subsidy)<sup>(9, 12, 34)</sup>.
- The objectives of management of hyperglycaemia in patients with type 2 diabetes are to improve quality of life, relieve symptoms, reduce the incidence of chronic complications and avoid acute complications e.g., diabetic ketoacidosis, hyperosmolar hyperglycaemia and hypoglycaemia <sup>(9)</sup>.
- Lifestyle modification on its own can markedly improve HbA1c, and sustained weight loss in a newly diagnosed patient (within 1 to 2 years) can also lead to remission <sup>(9, 34)</sup>.
  - All patients with type 2 diabetes should receive ongoing advice, support and reinforcement lifestyle modification as part of the Program.
- Antihyperglycaemic pharmacotherapy prescribed within the Program must be in accordance with the <u>Therapeutic Guidelines</u>: <u>Approach to antihyperglycaemic treatment for adults with type 2 diabetes</u> <sup>(9)</sup>, Australian Diabetes Society <u>Australian type 2 Diabetes</u> <u>Glycaemic Management Algorithm</u> <sup>(35)</sup> and the <u>Australian Medicines Handbook (type 2 diabetes</u>) <sup>(36)</sup>.
- If clinically appropriate, pharmacists may:
  - prescribe metformin if it is not already part of the patient's treatment regimen and modify the dose to optimise management
  - prescribe a second drug (from the following) and modify the dose to optimise management:
    - sodium-glucose co-transporter 2 (SGLT2) inhibitors
    - glucagon-like peptide-1 (GLP-1) receptor agonists
    - dipeptidyl peptidase-4 (DPP-4) inhibitors (linagliptin, sitagliptin or vildagliptin).
- A general target for HbA1c is  $\leq$  7% (53 mmol/mol), however an individualised target may be considered based on the patient's risks, benefits and preferences. Refer to Table 6.
- The process of initiating and modifying pharmacotherapy for glycaemic management in type 2 diabetes (where pharmacotherapy is indicated) is summarised in Figure 5.
- The pathology testing that is required before pharmacotherapy is initiated or modified, and during treatment is summarised in Table 7.

Table 6 Clinical targets for HbA1c for patients with type 2 diabetes

Table 6. Clinical targets for HbA1c for patients with type 2 diabetes <sup>(9, 12)</sup>				
Patient/disease char	Patient/disease characteristics HbA1c treatment target			
Recently diagnosed	using lifestyle modification and metformin	≤ 6% (42 mmol/mol)*		
type 2 diabetes without CVD	using metformin plus another non-insulin antihyperglycaemic medicine for diabetes	≤ 6.5% (48 mmol/mol)*		
	using insulin	≤ 7% (53 mmol/mol)		
• type 2 diabetes of longer duration or with CVD ≤ 7% (53 mmol/mol)				
• younger patients with a longer life expectancy ≤ 6.5%		≤ 6.5% (48 mmol/mol)*		
<ul> <li>patients with no (or few) comorbidities or vascular complications</li> </ul>				
newly diagnosed patients				
• highly motivated	highly motivated patients with good capability for self-care			
Patients at risk of hypoglycaemia and/or taking multiple A less stringent target glucose-lowering medicines or insulin, closer towards 8%				

\*if there are no adverse effects of treatment and the target can be safely achieved without causing hypoglycaemia

Table 7 Testing a	nd monitoring	required for	patients <b>v</b>	with type 2	diabetes
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Table 7. Testing and monitoring required for patients with type 2 diabetes <sup>(9)</sup>		
Drug class	Test	
Metformin	Check renal function (eGFR) before starting treatment and then every 4 to 6 months.	
SGLT-2 Inhibitors (dapagliflozin, empagliflozin, ertugliflozin)	Check renal function (eGFR and serum creatinine) before commencing, then periodically as clinically indicated.	

Figure 5 Process for initiating/ modifying pharmacotherapy for type 2 diabetes (in the Program)

#### If pharmacotherapy for glycaemic management for type 2 diabetes is required (refer to table 10)

#### Determine appropriate treatment regimen:

 Metformin is the usual monotherapy and recommended as first line for all adults with type 2 diabetes (unless contraindicated or not tolerated)

- If the patient is already using metformin, the pharmacist should review the dose and patient's adherence to the treatment regimen (including lifestyle modification).
- A second antihyperglycaemic drug may be added if the patient's HbA1c is significantly higher (> 1.5% (16 mmol/mol) than their individualised target or the patient has been taking the optimal dose of metformin for 3 months (including prior to commencing in the Program) and they have not reached their target (refer to table 10).
  - If a second medicine is required, an SGLT2 inhibitor is recommended first.
  - A **GLP-1 receptor agonist** may be prescribed if a SGLT2 inhibitor is contraindicated or not tolerated.
  - A **DPP-4 inhibitor** may be used if both SGLT2 inhibitors and GLP-1 receptor agonists are contraindicated or not tolerated.

#### Confirm treatment regimen is appropriate

- Request and review relevant pathology testing (refer to table 7)
- Consult the Therapeutic Guidelines, Australian Type 2 Diabetes Glycaemic Management Algorithm, Australian Medicines Handbook and other relevant resources for:
  - contraindications and precautions
  - drug interactions.

### Prescribe and review patient for HbA1c every 3 months (or sooner if patient experiences adverse effects):

- Retest HbA1c
- Reinforce lifestyle modification
- Consider:
  - Response to pharmacotherapy and progress towards target
    - Consider stopping antihyperglycaemic medicines (with the exception of metformin) that have not reduced HbA1c by ≥ 0.5% after 3 months and trial another medicine (after balancing glycaemic and non-glycaemic benefits).
  - Patient's understanding and efficacy of self-management including adherence with pharmacological and non-pharmacological treatment regimen and adverse effects
- Modify treatment regimen if response is inadequate or drug is not tolerated:
  - 1. Increase dose of metformin (if not at therapeutic dose)
  - 2. Add a second drug if required (and/or incrementally increase dose of second drug) up to therapeutic dose.

Has HbA1c target been reached after at least 3 months of treatment with 2 medicines at therapeutic doses?

no

If HbA1c is stable at target, arrange necessary clinical review and continue to monitor response to therapy. If response to treatment changes, consider ongoing eligibility for the Program

yes

Refer to a medical practitioner for ongoing management.

#### Antihyperglycaemic therapy supporting management

#### Self-monitoring

- Patients undergoing changes to their treatment regimen or intensive lifestyle modification should be encouraged to self-monitor blood glucose concentrations <sup>(9, 37)</sup>
  - Detailed information on self-monitoring blood glucose levels is available in Diabetes Australia's position statement: <u>Glucose self-monitoring in adults with type 1 diabetes</u> or type 2 diabetes <sup>(37)</sup>.
  - Patients should be counselled and educated on when and how to self-monitor.

#### Hypoglycaemia

- Patients with type 2 diabetes should be educated on how to recognise and manage hypoglycaemia (BGL <4 mmol/L), particularly patients previously prescribed drugs that can cause hypoglycaemia (e.g., insulin or sulfonylureas)
  - Pharmacists may provide patients with appropriate education and supporting resources, such as the <u>Managing hypoglycaemia fact sheet</u> from the National Diabetes Services Scheme <sup>(38)</sup>.

#### Sick day management

- Patients with type 2 diabetes should be educated about the impact of acute illness on blood glucose concentrations, and provided with the <u>sick day management factsheet</u> from the National Diabetes Services Scheme <sup>(9, 39)</sup>.
- Patients with type 2 diabetes should have a sick day plan developed by a medical practitioner. Changes to pharmacotherapy in the Program must be promptly advised to the patient's medical practitioner to enable update of the sick day management plan.

#### **Check referral points**

### Pharmacotherapy for dyslipidaemia

- The decision to initiate lipid modifying drug therapy is primarily based on the patient's CVD risk and lipid levels <sup>(4, 40)</sup>.
  - $_{\rm O}$  Lipid modifying drug therapy is recommended in all patients who have high CVD risk  $^{\rm (4,}$   $^{\rm 40)}$
  - Not all patients with dyslipidaemia require lipid modifying therapy; for most patients at a low or moderate CVD risk, the benefits of lipid-modifying pharmacotherapy are limited and a trial of lifestyle modification is sufficient to manage CVD risk <sup>(4, 40)</sup>.
  - The decision of whether to initiate lipid-modifying pharmacotherapy should be shared between the pharmacist and patient, based on the likely benefits and harms.
- Lipid lowering pharmacotherapy prescribed within the Program must be in accordance with the <u>Therapeutic Guidelines: Lipid modification</u><sup>(1)</sup>, and the <u>Australian Medicines</u> <u>Handbook (Drugs for dyslipidaemia)</u><sup>(41)</sup>.
- As at 1 November 2023, the <u>Therapeutic Guidelines: Lipid modification</u> has not been updated to reflect the <u>2023 Guideline for assessing and managing CVD risk</u> <sup>(4)</sup>.
- If clinically appropriate, pharmacists may:
  - prescribe a statin if it is not already part of the patient's treatment regimen and modify the dose to optimise management
  - prescribe a second drug (ezetimibe<sup>1</sup> or fenofibrate) and modify the dose to optimise management.

**NB1:** Ezetimibe may be used as monotherapy if statins are contraindicated.

- Refer to table 11 for blood lipid clinical targets.
- The process of initiating and modifying pharmacotherapy for dyslipidaemia (where pharmacotherapy is indicated) is summarised in Figure 6.
- The pathology testing that is required before pharmacotherapy is initiated or modified, and during treatment is summarised in Table 8.

Table 8. Tests and monitoring required for lipid modifying therapies (4, 40)			
Drug class	Test		
Statins (HMG CoA Reductase Inhibitors: rosuvastatin, simvastatin, fluvastatin, pravastatin, atorvastatin)	<ul> <li>Blood tests for liver function and creatine kinase (CK) should be taken before initiating and at 6 monthly intervals.</li> <li>If CK is elevated but the patient is asymptomatic, recheck after avoidance of exercise for several days.</li> <li>In a patient without muscle symptoms, statin therapy may continue (provided serum CK concentration does not exceed 5 times the upper limit of normal (ULN)), but the patient should be referred to a medical practitioner for investigation and ongoing management.</li> </ul>		
Fenofibrate	<ul> <li>Blood tests for full blood count and liver function should be taken before initiating and at 3 monthly intervals during the first year of treatment</li> <li>Serum CK should be taken before initiating and repeated if clinically indicated.</li> </ul>		

Table 8 Tests and monitoring required for lipid modifying therapies

Clinical Protocol – CVD Risk Reduction Program. Printed copies uncontrolled.

Figure 6 Process for initiating and modifying pharmacotherapy for dyslipidaemia

#### If pharmacotherapy for dyslipidaemia is required (refer to table 11)

#### Determine appropriate treatment regimen:

- **Statins** are first-line drug therapy for lipid modification (unless contraindicated or not tolerated)
  - High-intensity statin therapy (high dose of a high potency statin) should be initiated if the patient has a high CVD risk or particularly elevated LDL-C levels e.g., > 4.0 mmol/L.
  - If the patient is already using a statin but not at clinical target, the pharmacist should reinforce lifestyle modification, review the patient's adherence to the treatment regimen and consider increasing the statin to a higher dose and/or a high-potency statin (if tolerated).
- If statins are contraindicated, the patient may commence with ezetimibe.

#### Confirm treatment regimen is appropriate

- Request and review relevant pathology testing (refer to table 8)
- Consult the Therapeutic Guidelines, Guidelines for the Management of Absolute Cardiovascular Disease Risk, Australian Medicines Handbook and other relevant resources for:
  - contraindications and precautions
  - drug interactions.

Prescribe and review patient every 4-6 weeks (or sooner if patient

experiences adverse effects):

- Retest lipid levels as required
- Reinforce lifestyle modification
- Consider:
  - Response to pharmacotherapy and progress towards target
  - Adherence with pharmacological and non-pharmacological treatment regimen
  - Adverse effects
- Modify treatment regimen if lipid targets have not been achieved after 3 months of statin monotherapy at the therapeutic dose or if drug is not tolerated:
  - add ezetimibe if triglycerides are < 4 mmol/L (if not contraindicated)</li>
  - consider fenofibrate for patients with triglycerides > 4mmol/L AND HDL-C < 1 mmol/L.

Have normal lipid levels/ targets been reached within 6 months of commencing lipid modifying therapy within the Program?



If lipid levels are stable at targets, arrange necessary clinical review and continue to monitor response to therapy. If response to treatment changes, consider ongoing eligibility for the Program Refer to a medical practitioner for ongoing management.

### J. Confirm management plan is appropriate

Pharmacists must consult the Therapeutic Guidelines, the Australian Medicines Handbook and other relevant references to confirm the management plan is appropriate, including for contraindications, precautions and drug interactions.

### K. Communicate agreed management plan

Comprehensive advice and counselling (including supporting written information when required) as per the Australian Medicines Handbook, the Therapeutic Guidelines and other relevant guidelines and references, should be provided to the patient regarding:

- individual product and medicine use (dosing and administration)
- how to manage adverse effects
- when to seek further care and/or treatment
- when to return to the pharmacist for follow up.

It is the pharmacist's responsibility to ensure the suitability and accuracy of any resources provided to patients (and parents/caregivers if applicable) and that they comply with all copyright conditions.

#### Collaborative care

The pharmacist should provide a copy of the patient's CVD Risk Management Plan to their usual medical practitioner. The communication should also include:

- relevant medical history and pathology/PoCT results
- changes to existing pharmacotherapy or new pharmacotherapy prescribed
- a summary of advice provided to the patient including recommendations for multidisciplinary care and referrals
- the next scheduled review appointment.

# Phase 4: Ongoing management and monitoring

### L. Clinical review

All patients should undergo regular clinical review to participate in the Program, at timeframes consistent with the Therapeutic Guidelines specified in this protocol.

Prior to each periodic review, the pharmacist should arrange any applicable laboratory tests (that are not performed by PoCT) required for monitoring.

At each review appointment (scheduled or unscheduled), the pharmacist should:

- review and update the patient history to reflect changes in the preceding period
- repeat BP measurements (regardless of the initial BP at Program commencement)
- review pathology or undertake any required PoCT (as applicable)
- review changes to CVD risk factors and, where appropriate, reassessment of CVD risk
- review and update the CVD Risk Management Plan (if required), consider whether the patient's response is adequate and review pharmacotherapy (if applicable)
- reinforce and check adherence to lifestyle modification
- ensure the patient has enough medicines and prescriptions until their next review.
- provide referrals to the patient's multidisciplinary health team (if required)
- consider the patient's ongoing suitability to be managed in the Program.

#### Ongoing collaboration during management

The pharmacist should advise the patient's usual medical practitioner when any changes are made to the patient's management plan throughout the Program. Communication should include:

- a copy of the current CVD Risk Management Plan
- relevant medical history and recent pathology/PoCT results
- a summary of any advice and counselling provided to the patient including any recommendations for multidisciplinary care and referrals
- the next scheduled review appointment.

Proactive, planned and/or unplanned review may also occur with the patient's usual medical practitioner at any time while the patient is enrolled in the Program.

#### Patients who are not suitable for further participation in the Program

The pharmacist must refer all patients (with their consent) who are no longer suitable for management within the Program or who do not wish to continue in the Program to a medical practitioner (refer to phase 5).

# Phase 5: Completion of the Program

Patients may continue to participate in the Program for as long as:

- their condition remains suitable to be managed in the Program
- they wish to remain in the Program and continue to consent
- they attend scheduled reviews.

If a patient leaves the program for any reason, the pharmacist should (with their consent) advise the patient's usual medical practitioner. An update should also be provided to other relevant members of the patient's collaborative care team.

# **Appendices**

### Appendix 1 – Guidance for reviewing test results

#### **Blood pressure**

The <u>Guidelines for the diagnosis and management of hypertension in adults</u> outline in-clinic, ambulatory and home BP ranges to aid in the diagnosis, management and treatment decisions for hypertension <sup>(6)</sup>. In-clinic BP measurements form the basis of treatment decisions in the Program. Refer to table 9.

• Ambulatory and/or home BP monitoring is only required to confirm the BP for atypical cases e.g., if the patient has marked fluctuations between in-clinic BP measurements, suspected white-coat or masked hypertension or suspected nocturnal hypertension <sup>(1, 6)</sup>.A comprehensive assessment of blood pressure should be based on multiple measurements taken on separate occasions, at least twice, one or more weeks apart, or sooner if hypertension is severe.

Table 9. Classification of BP using in-clinic measurements <sup>(6, 42)</sup>		
Category	Range (systolic (mmHg), diastolic (mmHg))	
Optimal	< 120 and < 80	
Normal	120-129 and/or 80-84	
High-normal	130-139 and/or 85-89	
Mild hypertension (grade 1)	140-159 and/or 90-99	
Moderate hypertension (grade 2)	160-179 and/or 100-109	
Severe hypertension (grade 3)	≥ 180 and/or ≥ 110	
Isolated systolic hypertension	> 140 and > 90	

#### Table 9 Classification of BP using in-clinic measurements

#### Secondary hypertension

- Consider the possibility of a secondary aetiology.
  - Refer to the <u>Therapeutic Guidelines: Cardiovascular (Secondary hypertension)</u> for secondary causes of hypertension <sup>(1)</sup>.
  - Medicines and other substances that may impact on BP can be found in the National Heart Foundation of Australia <u>Guidelines for the diagnosis and</u> <u>management of hypertension in adults</u><sup>(6)</sup>.

#### Glycated haemoglobin and/or fasting blood glucose

- HbA1c is the preferred diagnostic method for diabetes; however a diagnosis of diabetes can be made using FBG and/or oral glucose tolerance test (OGTT) <sup>(12)</sup>.
- HbA1c, FBG results and/or OGTT results (if required) should be interpreted in accordance with the <u>Therapeutic Guidelines: Diabetes (Tests to diagnose diabetes)</u> <sup>(9)</sup>, and the RACGP <u>Management of type 2 diabetes: A handbook for General Practice</u> (12). Refer to Table 10.

Table 10. Interpretation of HbA1c, FBG and/or OGTT results <sup>(9, 12)</sup>			
HbA1c (non-fasting)	FBG	OGTT (2-hour BGL)	Interpretation
< 6.0% (42 mmol/mol)	< 5.5 mmol/L	< 7.8 mmol/L	<ul> <li>Normal levels <sup>(9)</sup></li> <li>Diabetes is unlikely – re-test in 3 years <sup>(12)</sup>.</li> </ul>
6.0% - 6.4% (42 to 46 mmol/mol)	5.5-6.9 mmol/L*	≥ 7.8 and < 11.1 mmol/L	<ul> <li>FBG 6.1 to 6.9 mmol/L = pre-diabetes (impaired glucose tolerance) <sup>(9)</sup></li> <li>Diabetes is possible - re-test in 1 year</li> </ul>
			<ul> <li>Patients with an FBG in this range may undergo OGTT to confirm diagnosis <sup>(12)</sup>.</li> </ul>
≥ 6.5% (48 mmol/mol)	≥7.0 mmol/L	≥ 11.1 mmol/L	<ul> <li>Diagnostic of diabetes <sup>(9)</sup>.</li> <li>Do not use point of care capillary (finger-prick) testing to diagnose diabetes <sup>(9)</sup>.</li> <li>FBG and HbA1c must be repeated in asymptomatic patients to confirm diagnosis <sup>(12)</sup>.</li> </ul>
≥ 10% (86 mmol/mol) Any BGL ≥ 20.0 mmol/L		20.0 mmol/L	• Severe hyperglycaemia <sup>(9)</sup> – urgent referral to a medical practitioner required. Unwell patients with signs of ketosis, dehydration, vomiting, infection, altered consciousness, confusion or delirium, or suspicion of type 1 diabetes require immediate transport to closest emergency medical care.

#### Table 10 Interpretation of HbA1c, FBG and/or OGTT results

#### Secondary hyperglycaemia

- Consider the possibility of a secondary aetiology.
  - Refer to the <u>Therapeutic Guidelines: Diabetes (Drug-induced hyperglycaemia)</u> for information regarding drug-induced hyperglycaemia <sup>(9)</sup>.

#### Blood lipids

- Normal cholesterol levels, including for patients already taking lipid-modifying pharmacotherapy are included in Table 11.
- Abnormal lipid levels should be confirmed with a second test on a different day before commencement of lipid modifying pharmacotherapy.

Table 11 Normal levels of cholesterol

Table 11. Normal levels of cholesterol (15, 22, 40)			
Cholesterol type	Normal/ target level		
TC	< 5.5 mmol/L, or		
	< 4.0 mmol/L (for individuals taking lipid modifying pharmacotherapy)		

LDL-C	< 2.0 mmol/L
HDL-C	> 1.0 mmol/L
TG	< 2.0 mmol/L

#### Secondary dyslipidaemia

- Consider the possibility of a secondary aetiology.
  - Refer to the <u>Therapeutic Guidelines: Cardiovascular (Secondary dyslipidaemia)</u> for secondary causes of dyslipidaemia <sup>(1)</sup>.
  - Familial hypercholesterolaemia should be considered in adults with a total cholesterol level ≥ 7.5 mmol/L or LDL-C ≥ 5.0 mmol/L, particularly in patients with a family history of coronary heart disease <sup>(43)</sup>.

#### UACR and eGFR

 Normal eGFR is considered to be ≥ 60 mL/min/1.73m<sup>2</sup> and normal UACR is < 2.5 mg/mmol for males and < 3.5mg/mmol for females <sup>(14)</sup>.

### Appendix 2 - Non-modifiable risk factors and related comorbidities

Table 12 Considerations for CVD risk assessment

Table 12 Considerations for CVD risk assessment <sup>(1, 3, 4, 17, 44, 45)</sup>			
Risk factor	Explanatory notes		
Non-modifiable risk factors and related comorbidities			
Age	<ul> <li>The risk of CVD and prevalence of CVD risk factors increases with age.</li> <li>Calculate absolute CVD risk if aged ≥ 45 years (≥ 35 for Aboriginal and/or Torres Strait Islander people)</li> </ul>		
History of pregnancy complications	• Patients with a history of hypertension during pregnancy, pre- eclampsia or gestational diabetes have a higher risk of developing CVD.		
Ethnicity	<ul> <li>Aboriginal and Torres Strait Islander people may experience a faster disease progression and have a higher prevalence of CVD risk factors.</li> <li>The risk of a CVD is higher for Māori people, Pacific Islander people and people of South Asian ethnicity (Indian, Pakistani, Bangladeshi, Sri Lankan, Nepali, Bhutanese or Maldivian ethnicities). Consider reclassification to a higher risk category where this is close to the threshold.</li> <li>The risk of a CVD is lower for in people of East Asian ethnicity (Chinese, Japanese, Korean, Taiwanese or Mongolian ethnicities). Consider reclassification to a lower risk category where this is close to the threshold.</li> </ul>		
Socio-economic status	<ul> <li>Socioeconomic deprivation is an independent risk factor.</li> <li>The CVDCheck calculator uses Socio-economic Indexes for Areas (SEIFA) quintiles obtained from residential postcodes.</li> <li>Absolute CVD risk may underestimate CVD risk in socioeconomically deprived groups.</li> </ul>		
Family history of CVD	<ul> <li>Premature CVD in a 1st degree relative (females &lt; 65 years of age and males &lt; 55 years of age when first diagnosed) increases personal CVD risk, consider reclassification into a higher risk category where this is close to the threshold.</li> <li>Familial hypercholesterolaemia affects 50% of first-degree relatives <sup>(43)</sup>.</li> </ul>		
Diabetes	<ul> <li>Adults with diabetes aged &gt; 60 years or with microalbuminuria are at high CVD risk.</li> </ul>		
Chronic kidney disease	<ul> <li>Patients without diabetes with sustained eGFR 45 – 59mL/min/1.73m<sup>2</sup> or with or persistent UACR 2.5 – 25mg/mmol (men)/ 3.5 – 35mg/mmol (women)) consider reclassification to a higher risk category where this is close to the threshold.</li> </ul>		
Coronary artery calcium (CAC) score	• Where a CAC measurement has been performed, consider reclassification to a higher or lower risk category based on the patients CAC score.		

Severe mental illness	•	CVD is a leading cause of illness and premature death in patients living with severe mental illness. Consider reclassification to a higher risk category where this is close to the threshold. Treatment with second-generation (atypical) antipsychotic agents is associated with an increased CVD risk.
Drugs that worsen CVD	•	Drugs that worsen CVD risk factors include those that affect BP,
risk factors		lipids and weight
Obstructive sleep	•	OSA is associated with hypertension, arrhythmias, cardiovascular and cerebrovascular mortality <sup>(46)</sup>
		Consider using a screening tool such as the STOP-Bang
	-	questionnaire for patients with suspected OSA <sup>(47)</sup> .
Modifiable risk factors		
Elevated BP	•	BP is a major independent determinant of the risk of atherosclerotic
		disease.
Dyslipidaemia	•	Familial hypercholesterolaemia should be considered in adults with a total cholesterol level $\geq$ 7.5 mmol/L or LDL-C $\geq$ 5.0 mmol/L, particularly in patients with a family history of coronary heart disease <sup>(43)</sup> .
BMI and waist	•	Waist circumference (indicating presence of central obesity) is a
circumference		better indicator of CVD risk than BMI.
Smoking	•	There is a dose-dependent association between smoking and CVD events.
Physical activity	•	All forms of exercise have a positive effect on reducing multiple CVD risk factors including LDL-C, HDL-C, TGs, insulin sensitivity, body fat and BP.
Alcohol consumption	•	Excessive alcohol consumption (> 10 standard drinks per week and > 4 standard drinks per day) is a risk factor for elevated BP and impacts on other CVD risk factors.
Nutrition and diet	•	Diet is a risk factor for atherosclerosis and coronary heart disease <sup>(21)</sup> .
	•	Food/diet related risk factors include obesity, hypertension, hyperglycaemia/uncontrolled diabetes and high intake of saturated fats.
Sleep disorders	•	Insomnia and shift-work related sleep disorder can increase an individual's CVD risk.

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### Appendix 3 – CVD Risk Management Plan

Page 1			
C	ueensland Community Pharmac	y Scope of Pra	ctice Pilot
Cardi	ovascular Disease (CVD)	Risk Manas	gement Plan
	Plan date:		<b>,</b>
News		Data of black	
Name:	VD Pick Poduction Program.	Date of birth:	
Program pharmacy de	tails		
Pharmacist name		Phone number	
Pharmacy name and address		Opening hours	
Ny CVD Risk			
Estimated CVD risk:	Low ( %), Moderate ( %), High ( %)		
My CVD risk factors	<ul> <li>Insert applicable risk factors e.g., :</li> <li>high blood pressure</li> <li>type 2 diabetes (hyperglycaemia)</li> <li>overweight/obesity</li> <li>smoking <ul> <li>waist circumference</li> <li>dyslipidaemia, specifically high levels of 'bad' cholesterol and/or low <ul> <li>levels of 'good' cholesterol</li> <li>family history of premature CVD etc.</li> </ul> </li> </ul></li></ul>		
My risk of type 2 diabetes	Low (score), Moderate (score), High (score) (delete if not applicable)		
Ay clinical targets and	test results		
Blood pressure			
Current blood pressure		Blood pressure	target
Systolic blood pressure (SBP):	mmHg	SBP:	mmHg
Diastolic blood pressure (DBP):	mmHg	DBP:	mmHg
Blood glucose (glycated	l haemoglobin)	-	1
Current HbA1c	% (X mmol/mol)	HbA1c target	% (X mmol/mol)
Blood lipids (cholester			
Current blood lipid levels		Blood lipid targe	ets
Total cholesterol	mmol/L	TC:	Less than 5.5/ 4.0 mmol/L
LDL-C	mmol/L	LDL-C:	Less than 2.0 mmol/L
	mmol/L	HDL-C:	Higner than 1.0 mmol/L
Triglycerides	mmol/L	TG:	Less than 2.0 mmol/L

Page 2			
My lifestyle prescription			
Diet and nutrition	<ul> <li>Recommendation for weight loss (if applicable)</li> <li>Summary of nutritional advice for a balanced diet         <ul> <li>more of/ increase</li> <li>less of/ limit</li> </ul> </li> <li>specific advice and food recommendations tailored for individual's risk factors</li> </ul>		
Exercise and physical activity	<ul> <li>Enter recommendations for physical activity for the patient's age and capability based on the national guidelines:         <ul> <li>Informal exercise e.g. building exercise into everyday activities</li> <li>Formal exercise e.g., walking (moderate intensity) for 30 minutes 5 days of the week strength building 2 days per week</li> <li>individualised guidance for building up to recommendations</li> </ul> </li> <li>If required: Referral to a GP, exercise physiologist, physiotherapist or other supports for safe exercise</li> </ul>		
Other lifestyle modification strategies	<ul> <li>If required: Referral to Pilot overweight and obesity management program and/or other supports</li> <li>If required: Smoking cessation         <ul> <li>Refer to Pilot smoking cessation program and/or other supports e.g. Quitline or GP</li> </ul> </li> <li>If required: Referral to a GP, psychologist or other clinician for mental health support</li> <li>If required: summary of advice regarding alcohol consumption</li> </ul>		

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2906 3			
My medicines for reducing cardiovascular disease risk			
<ul> <li>include medicines prescribed by another health practitioner (if applicable)</li> </ul>			
delete rows/sect	tions not required		
Blood pressure (delete	f not applicable)		
Medicine name	Instructions		
	<ul> <li>dose, formulation, frequency, time of day, duration</li> <li>other instructions e.g., take with food</li> <li>serious adverse effects that require immediate medical review</li> </ul>		
type 2 diabetes (delete	type 2 diabetes (delete if not applicable)		
Medicine name Instructions			
Blood lipids (cholestero	l) (delete if not applicable)		
Medicine name	Instructions		

# Advise your pharmacists if you are experiencing side effects from medication or if you have any concerns.

Your next review appointment with your pharmacist in the Program is:	
You need to get the following tests done (using the pathology request provided) before your next appointment:	

#### My health care team

my neatth care team			
General practitioner	Name, address and	Closest 24-hour	Name, address and
and clinic:	phone number	emergency services:	phone number
Dietitian	Name, address and	Other health	Name, address and
	phone number	practitioner	phone number
Other health	e.g. diabetes educator	Other health	Name, address and
practitioner	Name, address and	practitioner	phone number
	phone number		

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