Appendix Two – Proposed Special Authority changes

Proposed SA Changes: Removal of ethnicity criteria with reduction of CVD risk from 15% (5-yr risk) to 10%

Empagliflozin / empagliflozin with metformin is currently funded subject to the following Special Authority criteria (Type 2 Diabetes Indication):

Special Authority for Subsidy
Initiation – Type 2 Diabetes
Any of the following:
1. For continuation use; or
2. Patient has previously had an initial approval for a GLP-1 agonist; or
3. All of the following:
   - 3.1. Patient has type 2 diabetes; and
   - 3.2. Any of the following:
     - ~~3.2.1. Patient is Māori or any Pacific ethnicity*; or~~
     - 3.2.2. Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or
     - 3.2.3. Patient has an absolute 5-year cardiovascular disease risk of 10~~15~~% or greater according to a validated cardiovascular risk assessment calculator*; or
     - 3.2.4. Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or
     - 3.2.5. Patient has diabetic kidney disease (see note b)*; and
   - 3.3. Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months.

Notes: * Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.
a) Pre-existing cardiovascular disease or risk equivalent 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.
b) Diabetic kidney disease 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. c) Funded [empagliflozin / empagliflozin with metformin hydrochloride] treatment is not to be given in combination with a funded GLP-1 unless receiving (empagliflozin / empagliflozin with metformin hydrochloride] for the treatment of heart failure.

Liraglutide/ dulaglutide is currently funded subject to the following Special Authority criteria:

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
All of the following:
1. Patient has type 2 diabetes; and
2. Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of all of the following funded blood glucose lowering agents for a period of least 6 months, where clinically appropriate: empagliflozin, metformin, and vildagliptin; and
3. Any of the following:
   - ~~3.1. Patient is Māori or any Pacific ethnicity*; or~~
   - 3.2. Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or
   - 3.3. Patient has an absolute 5-year cardiovascular disease risk of 10~~15~~% or greater according to a validated cardiovascular risk assessment calculator*; or
   - 3.4. Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or
   - 3.5. Patient has diabetic kidney disease (see note b)*.

Notes: * Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.
a) Pre-existing cardiovascular disease or risk equivalent 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.
b) Diabetic kidney disease 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 identified.

c) Funded GLP-1a treatment is not to be given in combination with (empagliflozin / empagliflozin with metformin hydrochloride) unless receiving (empagliflozin or empagliflozin in combination with metformin hydrochloride) for the treatment of heart failure.