

Prescribing Protocol Template for New Drugs	
Title	Empagliflozin for Type 2 Diabetes
Areas where Protocol/Guideline applicable e.g. District, Hospital, ITU, Ward	SESLHD
Areas where Protocol/Guideline not applicable	Nil
Authorised Prescribers	All authorised prescribers
Indication for use	<p>Approved for use in line with PBS criteria: Type 2 diabetes mellitus in combination with metformin and/or a sulphonylurea or in combination with insulin.</p> <ul style="list-style-type: none"> • Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulphonylurea; OR • Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol/L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulphonylurea. <p>For full details see https://www.pbs.gov.au/medicine/item/10202Y</p>
Clinical condition	Type 2 diabetes with eGFR greater than 30 mL/min
Contra-indications	<p>Empagliflozin has been associated with euglycaemic diabetic ketoacidosis which can be life-threatening. It must not to be used in patients with:</p> <ul style="list-style-type: none"> - Type 1 diabetes - fasting patients - eGFR less than 30 mL/min - pregnancy - within 48 hours of surgery or colonoscopy.

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<p>Precautions</p>	<p>Pancreatic insufficiency, lactation, acute illness, dehydration, alcohol abuse, recurrent urinary tract infection, conditions causing fluid loss, hypotension sensitive conditions, loop diuretics.</p> <p>Empagliflozin has been associated with euglycaemic diabetic ketoacidosis in the peri and post-operative period. Empagliflozin must be stopped 2 days prior to surgery and for the day of surgery. It must not be restarted until the patient is tolerating a normal diet. In the interim the patient may require an increase in other anti-hyperglycaemic agents, including insulin.</p> <p>Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Discontinuation of Empagliflozin may be considered in cases of recurrent urinary tract infections.</p>
<p>Place in Therapy</p>	<p>Second line treatment of type 2 diabetes after metformin, may be used in combination with sulfonylureas, metformin and/or insulin</p>
<p>Dosage</p>	<p>Initially 10 mg daily, may be increased to 25 mg daily.</p>
<p>Duration of therapy</p>	<p>Ongoing as tolerated</p>
<p>Important Drug Interactions</p>	<p>Insulin, sulfonylureas: empagliflozin may cause hypoglycaemia when used with these medications. Monitor blood glucose levels QID on starting.</p> <p>Diuretics: empagliflozin can lower blood pressure and increase urinary output. On initiation, monitor blood pressure QID and monitor fluid status daily.</p>
<p>Administration instructions</p>	<p>May be taken with or without food</p>
<p>Monitoring requirements</p>	<p>BGLs, UEC</p> <p>Test for blood ketones if patient is fasting, has nausea or vomiting, or is hypotensive.</p> <p>Test for blood ketones if a patient has been taking empagliflozin prior to surgery or a medical procedure. If blood ketones are >0.6 mmol/l notify the treating Medical Officer. If ketones are >= 1.5 mmol/L perform urgent venous blood gas to measure pH and notify the Medical Officer urgently.</p>
<p>Management of complications</p>	<p>Endocrine team review</p>

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<p>Basis of Protocol/Guideline (including sources of evidence, references)</p>	<p>Jardiance® Pharmaceutical Benefits Scheme. MIMsOnline. Jardiance® (Empaglifozin) Product Information. Euglycaemic Diabetic Ketoacidosis: a predictable, detectable and preventable safety concern with SGLT2 inhibitors. Rosenstock J, Ferrannini E. Diabetes Care 2015. Australian Diabetes Society Alert: Severe Euglycaemic Ketoacidosis with SGLT2 Inhibitor Use in the Perioperative Period 14 Feb 2018 Meyer EJ, Gabb G and Jesudason D. Diabetes Care. 13 Feb 2018</p>
<p>Groups consulted in development of this protocol</p>	<p>N/A</p>

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<p style="text-align: center;">GOVERNANCE</p>	
<p>Enactment date/ Renewal date</p>	<p>July 2018 September 2021</p>
<p>Expiry date: (maximum 36 months from date of original approval)</p>	<p>September 2024</p>
<p>Ratification date by SESLHD QUM Committee</p>	<p>2nd September 2021</p>
<p>Chairperson, QUM Committee</p>	<p>Dr John Shephard</p>
<p>Version Number</p>	<p>3</p>