Canada's Drug and Health Technology Agency

Dapagliflozin

FMEC Responses to Questions From the Drug Programs

Table 1: Response Summary

Drug program implementation questions	FMEC response
Initiation of therapy	
At what point in therapy would dapagliflozin be appropriate to initiate in patients with CKD to reduce the risk of declined eGFR and cardiovascular and renal death?	FMEC agreed that initiation of dapagliflozin for CKD should align with the inclusion criteria of the DAPA-CKD trial and patients should have an eGFR of 25 mL/min/1.73 m^2 to 75 mL/min/1.73 m^2 with a UACR of 200 mg/g to 5,000 mg/g and be treated with an ACE inhibitor or ARB at the maximum-tolerated dose (refer to Final Recommendation).
Are there other drugs (i.e., ACE inhibitors or ARBs) in the treatment of CKD that would be required prior to initiating dapagliflozin?	FMEC agrees with the clinical experts that initiation should align with the DAPA-CKD protocol. Patients should be on the maximum-tolerated dose of an ACE inhibitor or ARB before initiating dapagliflozin (refer to Final Recommendation).
If patients are not able to tolerate either an ACE inhibitor or ARB, can dapagliflozin still be initiated?	FMEC noted that a contraindication or intolerance to ACE inhibitors or ARBs would not preclude a patient from receiving dapagliflozin for CKD; however, there remains an evidence gap (refer to Final Recommendation). In DAPA-CKD, participants who were unable to take ACE inhibitors or ARBs were eligible to participate in the trial; however, these were a small proportion of the patients enrolled (less than 2%).
Based on the evidence of the DAPA-CKD trial, would FMEC now include dapagliflozin in the standard of care for the treatment of patients with CKD?	Based on the results of DAPA-CKD, it would be reasonable to add dapagliflozin to background therapy in patients with CKD (with or without diabetes) to reduce residual risk.
Continuation or renewal of therapy	
Will the patient have to show a specific percentage of improvement in eGFR or stabilization as a renewal criteria?	Improvement in eGFR is not expected or required. FMEC acknowledged that the primary goal of treatment with dapagliflozin for patients with CKD is to slow the progression of CKD and dapagliflozin also has benefits on renal and CV outcomes, including mortality. FMEC agreed that renewal criteria were not required for continuation of dapagliflozin for patients with CKD, and dapagliflozin should be discontinued in patients prescribed dapagliflozin solely for CKD whose renal function deteriorates to Stage 5, who commence on dialysis, and/or who undergo renal transplant (refer to Final Recommendation).
Prescribing of therapy	
Would a nephrologist be the only specialist to prescribe and manage this medication in patients with CKD?	FMEC agreed that dapagliflozin for CKD can be prescribed by appropriate specialists and primary care providers (refer to Final Recommendation).

ACE = angiotensin-converting enzyme; ARB = angiotensin II receptor blocker; CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate; FMEC = CADTH Formulary Management Expert Committee; UACR = urinary albumin to creatinine ratio.