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Coverage	Policy/Guideline			
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Effective Date: 10/6/2025			Last Review Date: 9/2025	
Applies to:	□Illinois	□Florida	⊠Maryland	
	⊠New Jersey	⊠Florida Kids	□Michigan	
	⊠Pennsylvania Kids	□Virginia		

#### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for dapagliflozin with or without metformin under the patient's prescription drug benefit.

### **Description:**

**FDA-approved Indications** 

## **Dapagliflozin**

Dapagliflozin is indicated:

- To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.
- To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adults with heart failure.
- To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors.
- As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.

#### **Limitations of Use**

- Dapagliflozin is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.
- Dapagliflozin is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 45 mL/min/1.73 m<sup>2</sup>. Dapagliflozin is likely to be ineffective in this setting based upon its mechanism of action.
- Dapagliflozin is not recommended for the treatment of chronic kidney disease in
  patients with polycystic kidney disease or patients requiring or with a recent history
  of immunosuppressive therapy for kidney disease. Dapagliflozin is not expected to
  be effective in these populations.

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# Dapagliflozin-metformin ER

Dapagliflozin-metformin ER is a combination of dapagliflozin and metformin hydrochloride (HCl) extended-release, indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.

Dapagliflozin, when used as a component of Dapagliflozin-metformin ER, is indicated in adults with type 2 diabetes to reduce the risk of:

- Sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in patients with chronic kidney disease at risk of progression.
- Cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in patients with heart failure.
- Hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.

#### **Limitation of Use**

- Dapagliflozin-metformin ER is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.
- Because of the metformin component, the use of dapagliflozin-metformin ER is limited to adults with type 2 diabetes for all indications.
- Dapagliflozin-metformin ER is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. Dapagliflozinmetformin ER is not expected to be effective in these populations.

### **Applicable Drug List:**

Dapagliflozin tablet Dapagliflozin-metformin ER 5-1000mg tablet Dapagliflozin-metformin ER 10-1000mg tablet

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## Policy/Guideline:

## **Coverage Criteria**

### **Chronic Kidney Disease**

Authorization may be granted when the patient has a diagnosis of chronic kidney disease at risk of progression when the following criteria is met:

The request is for dapagliflozin

### Heart Failure

Authorization may be granted for a diagnosis of heart failure when the following criteria is met:

The request is for dapagliflozin

### Type 2 Diabetes Mellitus

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when the patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months when ONE of the following criteria are met:

- The patient experienced an inadequate treatment response, intolerance, or has a contraindication to metformin.
- The patient requires combination therapy AND has an A1C of 7.5 percent or greater.
- The patient has established cardiovascular disease and the following criteria is met:
  - The request is for dapagliflozin
- The patient has multiple cardiovascular risk factors, and the following criteria is met:
  - The request is for dapagliflozin.
- The patient has a diagnosis of heart failure, and the following criteria is met:
  - The request is for dapagliflozin
- The patient has a diagnosis of chronic kidney disease at risk of progression and the following criteria is met:
  - The request is for dapagliflozin

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## **Continuation of Therapy**

### **Chronic Kidney Disease**

All patients (including new patients) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

## **Heart Failure**

All patients (including new patients) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

### Type 2 Diabetes Mellitus

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when the patient has been receiving a stable maintenance dose of the requested drug for at least 3 months when ONE of the following criteria are met:

- The patient has demonstrated a reduction in A1C since starting this therapy.
- The patient has established cardiovascular disease and the following criteria is met:
  - The request is for dapagliflozin
- The patient has multiple cardiovascular risk factors, and the following criteria is met:
  - The request is for dapagliflozin.
- The patient has a diagnosis of heart failure, and the following criteria is met:
  - The request is for dapagliflozin
- The patient has a diagnosis of chronic kidney disease at risk of progression and the following criteria is met:
  - The request is for dapagliflozin

## **Approval Duration and Quantity Restrictions:**

**Approval:** 12 months

### **Quantity Level Limit:**

- Dapagliflozin: 1 tablet per day
- Dapagliflozin-metformin ER 5-1000mg: 2 tablets per day
- Dapagliflozin-metformin ER 10-1000mg: 1 tablet per day

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