



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Dapagliflozin

Page:

1 of 5

Effective Date: 5/1/2025

Last Review Date: 3/2025

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Maryland
	<input checked="" type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Florida Kids	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> 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:

Indications

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 m². 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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Page:

2 of 5

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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. Dapagliflozin-metformin 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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Name: Dapagliflozin

Page:

3 of 5

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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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Page: 4 of 5

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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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Page:

5 of 5

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