JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS126
		Effective Date	01/17/2024
		Approval Date	01/17/2024
	Subject **Sodium-glucose co-transporter 2 (SGLT-2) inhibitors: Farxiga, Jardiance, and Synjardy**	*Supersedes Date*	N/A
		Page	1 of 4

This document applies to the following Participating Organizations:

Priority Partners

Keywords: Farxiga, Jardiance, Synjardy

Table of Contents		Page Number
I.	**POLICY**	**1**
	A. Jardiance	**1**
	B. Synjardy, Synjardy XR	**1**
	C. Farxiga	**1**
II.	**POLICY CRITERIA**	**1**
	A. Jardiance	**1**
	B. Synjardy, Synjardy XR	**2**
	C. Farxiga	**2**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**3**
IV.	**EXCLUSIONS**	**3**
V.	**REFERENCES**	**4**
VI.	**APPROVALS**	**4**

I. POLICY

A. Empagliflozin (**Jardiance**), empagliflozin-metformin (**Synjardy, Synjardy XR**), and dapagliflozin (**Farxiga**) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Empagliflozin (**Jardiance**) may be approved for patients meeting the following:
   1. Glycemic Control in Diabetes Mellitus
      a. Patient is 10 years of age or older
      b. Documentation has been submitted showing the patient has a diagnosis of type 2 diabetes and both of the following:
         I. Jardiance is being used as adjunct therapy to diet and exercise
         II. Patient has had prior trial and inadequate response, intolerance, or contraindication to metformin
         III. Caveat for patients 18 years of age and older: In addition to a trial with metformin, trial and inadequate response to Steglatro (ertugliflozin) is required, unless its use is contraindicated
   2. Cardiovascular Death Risk Reduction in Diabetes Mellitus and established Cardiovascular Disease
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing the patient has a diagnosis of type 2 diabetes as well as a history of at least one of the following:
         I. coronary artery disease

© Copyright 2024 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University

II. stroke
III. peripheral artery disease
IV. heart failure

3. Heart Failure
   a. Patient is 18 years of age or older
   b. Patient has a documented diagnosis of chronic heart failure with clinical symptoms (New York Heart Association [NYHA] functional class II, III, or IV)
4. Chronic Kidney Disease (CKD)
   a. Patient is 18 years of age or older
   b. Documentation has been submitted showing all of the following:
      I. one of the following:
         i. eGFR greater than or equal to 20 to less than 45 mL/min/1.73 m^2
         ii. eGFR greater than or equal to 45 to less than 90 mL/min/1.73 m^2 with urine albumin to creatinine ratio [UACR] greater than or equal to 200 mg/g
      II. Patient has been established on a medication regimen with an ACE inhibitor (e.g., lisinopril) or ARB (e.g., losartan) unless contraindicated

B. Empagliflozin-metformin (**Synjardy, Synjardy XR**) may be approved for patients meeting the following:
1. Glycemic Control in Diabetes Mellitus
   a. Patient is 10 years of age or older (for Synjardy) or 18 years of age or older (for Synjardy XR)
   b. Documentation has been submitted showing the patient has a diagnosis of type 2 diabetes and both of the following:
      I. Synjardy is being used as adjunct therapy to diet and exercise
      II. Patient has had prior trial and inadequate response, intolerance, or contraindication to metformin
      III. Caveat for patients 18 years of age and older: In addition to a trial with metformin, trial and inadequate response to Steglatro (ertugliflozin) is required, unless its use is contraindicated
2. Cardiovascular Death Risk Reduction in Diabetes Mellitus and established Cardiovascular Disease
   a. Patient is 18 years of age or older
   b. Documentation has been submitted showing the patient has a diagnosis of type 2 diabetes as well as a history of at least one of the following:
      I. coronary artery disease
      II. stroke
      III. peripheral artery disease
      IV. heart failure
3. Heart Failure
   a. Patient is 18 years of age or older
   b. Patient has a documented diagnosis of chronic heart failure with clinical symptoms (New York Heart Association [NYHA] functional class II, III, or IV)

C. Dapagliflozin (**Farxiga**) may be approved for patients meeting the following:
1. Glycemic Control in Diabetes Mellitus
   a. Patient is 18 years of age or older
   b. Documentation has been submitted showing the patient has a diagnosis of type 2 diabetes and both of the following:
      I. Farxiga is being used as adjunct therapy to diet and exercise

© Copyright 2024 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University

II. Patient has had prior trial and inadequate response, or intolerance to at least two formulary sodium-glucose cotransporter 2 (SGLT2) inhibitors (Jardiance, Steglatro, etc.)

2. Hospitalization Risk Reduction in Diabetes Mellitus
   a. Patient is 18 years of age or older
   b. Documentation has been submitted showing the patient has a diagnosis of type 2 diabetes and both of the following:
      I. Farxiga is being used to reduce the risk of hospitalization due to heart failure
      II. Patient has established cardiovascular disease, or at least two of the following cardiovascular risk factors:
         i. Age (55 years and older for men, or 60 years and older for women)
         ii. Dyslipidemia
         iii. Hypertension
         iv. Current tobacco use
   c. Patient has been established on an antidiabetes medication regimen
3. Heart Failure
   a. Patient is 18 years of age or older
   b. Documentation has been submitted showing all the following:
      I. Patient has a diagnosis of chronic heart failure with clinical symptoms (New York Heart Association [NYHA] functional class II, III, or IV)
      II. Patient has had trial and inadequate response or contraindication to empagliflozin therapy
4. Chronic Kidney Disease (CKD)
   a. Patient is 18 years of age or older
   b. Documentation has been submitted showing all of the following:
      I. eGFR greater than 25 mL/min/1.73m^2
      II. Evidence of increased albuminuria (urine albumin creatinine ratio [UACR] between 200 and 5000 mg/g)
      III. Patient has been established on a medication regimen with an ACE inhibitor (e.g., lisinopril) or ARB (e.g., losartan) unless contraindicated

III. AUTHORIZATION PERIOD/LIMITATIONS

1. Initial approval will be for 12 months of therapy
2. Approval for continuation of therapy may be extended in 12-month intervals with documentation showing beneficial response to treatment

IV. EXCLUSIONS

A. The SGLT-2 inhibitors will not be approved for the following:
   1. Patients with type 1 diabetes mellitus or diabetic ketoacidosis
   2. Patient on dialysis
   3. Patients with a history of hypersensitivity reactions to product ingredients
   4. Patients that are in the second and third trimesters of pregnancy, or breast-feeding
   5. Concurrent use with another SGLT2 Inhibitor
   6. Any indications or usage that is not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

© Copyright 2024 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University

V. REFERENCES

1. Farxiga [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2023.
2. Jardiance [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; September 2023.
3. Synjardy [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; October 2023.
4. Docherty KF, et.al. Effect of Dapagliflozin on Outpatient Worsening of Patients with Heart Failure and Reduced Ejection Fraction: A Prespecified Analysis of DAPA-HF. Circulation. 2020 Sep 4.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney Int. 2020;98(4S):S1-S115.
6. Januzzi J, et al. Empagliflozin reduces the risk of a broad spectrum of heart failure outcomes regardless of heart failure status at baseline. Eur J Heart Fail. 2019 Mar;21(3):386-388.
7. Fitchett D, et al. Empagliflozin Reduced Mortality and Hospitalization for Heart Failure Across the Spectrum of Cardiovascular Risk in the EMPA-REG OUTCOME Trial. Circulation. 2019 Mar 12;139(11):1384-1395.
8. Heidenreich PA, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2022 May 3;79(17):e263-e421. Available at: https://www.ahajournals.org/
9. Kittleson MM, et al. 2023 ACC Expert Consensus Decision Pathway on Management of Heart Failure With Preserved Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2023 May 9;81(18):1835-1878. Available at: https://www.jacc.org/

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
10/21/2020	Policy Creation
04/21/2021	Added criteria for Jardiance
07/21/2021	Updated criteria for Farxiga and Jardiance based on FDA PI update; added Synjardy as an applicable drug
10/20/2021	Updated criteria for Jardiance to reflect new heart failure indication; clarified eGFR component of Farxiga criteria for CKD
04/06/2022	Updated criteria for Jardiance based on new FDA-approved prescribing information
07/19/2023	Criteria updates
01/17/2024	Criteria updates

Review Date:10/21/2020, 04/21/2021, 07/21/2021, 10/20/2021, 07/19/2023, 01/17/2024

Revision Date: 04/21/2021, 07/21/2021, 09/10/2021, 10/20/2021, 04/06/2022, 07/19/2023, 01/17/2024

© Copyright 2024 by The Johns Hopkins Health System Corporation and/or The Johns Hopkins University