MASSACHUSETTS

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Pharmacy Medical Policy

Heart Failure, Chronic Kidney Disease and Hypertrophic Cardiomyopathy (HCM) Policy

Table of Contents

Policy Number: 063

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply and can be found in Medical Policy #**621B**
- Diabetes Step Therapy Medical Policy #**041**

Prior Authorization Information

Policy	☒ Prior Authorization ☒ Step Therapy ☒ Quantity Limit ☐ Administrative	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**4/2024**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ Rx ☐ MED	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below. **Blue Cross Blue Shield of Massachusetts** **Pharmacy Operations Department** 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289 **Individual Consideration for the atypical patient:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary **Policy does NOT apply to**: • Medicare Advantage			

Summary

This is a comprehensive policy covering step therapy, prior authorization and quantity limit requirements for medications used to treat Heart Failure, Chronic Kidney Disease and Hypertrophic Cardiomyopathy (HCM).

Due to only modest improvements in glycemic control and a lack of long-term safety data on the effects of prolonged glycosuria, SGLT2 inhibitors are not considered as first line therapy for most patients with

diabetes. However, in patients with comorbid cardiovascular and/or kidney disease, some SGLT2 inhibitors have shown some benefit in cardiovascular and kidney outcomes.

The following policy applies only when below medications are used for the treatment of heart failure and/or hypertrophic cardiomyopathy. For coverage criteria of other FDA-approved indications (i.e. Type 2 Diabetes) Please see section above on related medical polices.

Policy

Step Therapy Requirements

Length of Approval	24 months
Formulary Status	All requests must meet the Step Therapy requirement and for non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

The step therapy requirements for covered formulary medications used in the management of heart failure and hypertrophic cardiomyopathy is as follows:

Heart Failure Step Therapy Table

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
Beta-Blockers (e.g. sotalol, atenolol, metoprolol, nadolol)	Preferred	Covered with no requirements
Angiotensin-converting Enzyme (ACE) Inhibitors (e.g. lisinopril, benazepril, enalapril, ramipril)	Preferred	
Angiotensin Receptor Blockers (ARBs) (e.g. candesartan, irbesartan, losartan, valsartan)	Preferred	
Step 2		
Entresto ® (sacubitril and valsartan)	ST	Requires prior use of ONE step 1 medication OR history of prior use of any step 2 medication within the previous 130 days. See below for prior use criteria.
Farxiga ® (dapagliflozin)	ST, QCD	
Jardiance ® (empagliflozin)	ST, QCD	
Verquvo ™ (vericiguat)	ST, QCD	
Step 3		
Inpefa ™ (sotagliflozin)	ST, QCD	Requires prior use of TWO step 2 medications **OR** if on the formulary history of prior use of any step 3 medication within the previous 130 days
dapagliflozin	NFNC, QCD	

QCD - Quality Care Dosing (quantity limits policy #621B); ST – Step Therapy

Chronic Kidney Disease and Risk Factor Step Therapy Table

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
loop diuretics% (e.g. furosemide, bumetanide, torsemide)	Preferred	% - Covered with no requirements
phosphate binders% (e.g. calcium acetate, lanthanum, sevelamer, Fosrenol, Renvela)	Preferred	
statins (e.g. atorvastatin, fluvastatin, pitavastatin, simvastatin)	Preferred, QCD	
Step 2		
Farxiga ® (dapagliflozin)	ST, QCD	Requires prior use of ONE step 1 medication OR history of prior use of any step 2 medication within the previous 130 days. See below for prior use criteria.
Jardiance ® (empagliflozin)	ST, QCD	
Step 3		
dapagliflozin	NFNC, QCD	Requires prior use of TWO step 2 medications **OR** if on the formulary history of prior use of any step 3 medication within the previous 130 days

Prior Use Criteria

The plan uses prescription claim records to support criteria for prior use within previous 130 days or the trial and failure of formulary alternatives when available. Additional documentation will be required from the provider when historic prescription claim data is either not available or the medication fill history fails to establish criteria for prior use or trial and failure of formulary alternatives. Documentation will also be required to support any clinical reasons preventing the trial and failure of formulary alternatives. Please see the section on documentation requirements for more information.

Prior Authorization Requirements

Length of Approval	12 months
Formulary Status	All requests must meet the PA requirement. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement
Camzyos ™ (mavacamten)	PA, *QCD	Covered if PA criteria below are met
Lodoco ® (colchicine)	PA	

QCD - Quality Care Dosing (quantity limits policy #621B); PA – Prior Authorization

CAMZYOS ™

Camzyos (mavacamten) may be covered when **ALL** of the following criteria are met:

1. Diagnosis of obstructive hypertrophic cardiomyopathy (OHCM) consistent with current ACC/AHA and ESC guidelines (unexplained LV hypertrophy with maximal LV wall thickness of ≥15 mm OR ≥13 mm with family history of HCM; LVOT gradient ≥50 mm Hg); **AND**
2. Age 18 years or older; **AND**
3. Documented LVEF ≥55%; **AND**
4. NYHA class II or III; **AND**
5. Member has had prior therapy with, or a contraindication or intolerance to, beta blockers (e.g. metoprolol, propranolol, atenolol) and/or calcium channel blockers (e.g. verapamil, diltiazem); **AND**
6. The drug is prescribed by a board-certified or board eligible Cardiologist.

Lodoco ®

Lodoco (colchicine) may be covered when **ALL** of the following criteria are met:

1. Diagnosis of atherosclerotic disease **OR** the member has documented multiple risk factors for cardiovascular disease; **AND**
2. Age 18 years or older; **AND**
3. Being used for a reduction of the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death.

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's

unique clinical circumstances. This is also referred to as “individual consideration” or an “exception request.”

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
4/2024	Updated to add a new step table for Kidney and other risk factors.
3/2024	Updated to add dapagliflozin to Step 3 and Non-covered.
1/2024	Updated to add Lodoco ® to the policy.
9/2023	Reformatted policy. Updated IC to align with 118E MGL § 51A.
8/2023	Updated to add Inpefa ™ to the policy.
7/2023	Reformatted Policy.
8/2022	Updated to include Camzyos ™ and updated Policy Name.
7/2022	Clarified Step requirements.
10/2021	Updated to add Farxiga and Jardiance to the policy.

4/2021	Updated to add Verquvo to the policy at step 2 and changed Policy name to Heart Failure Step Therapy.
1/1/2020	Implement new Step therapy policy

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

1. Entresto ® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation: 11/2018.
2. Verquvo ™ [package insert]. Whitehouse Station, NJ: MERCK & CO., INC.: 1/2021.
3. Farxiga ® [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP: 5/2021.
4. Jardiance ® [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.: 8/2021.
5. Camzyos ™ [package insert]. Brisbane, CA: Myokardia, Inc.: 4/2022.
6. Inpefa ™ [package insert]. The Woodlands, TX: Lexicon Pharmaceuticals, Inc.: 6/2023.
7. Lodoco ® [package insert]. Parsippany, NJ: AGEPHA Pharma USA, LLC.: 8/2023.