



Parkland

Community Health Plan

Medical Policy

Medical Necessity Determination and Appeal Overturn Policy for Off-Label Use of Farxiga® (dapagliflozin) in Pediatric members with Heart Failure and Complex Cardiac Conditions

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PURPOSE:

The purpose of this policy is to establish clinical criteria and an evidence-based framework for reviewing appeals requesting coverage of off-label use of Farxiga® (dapagliflozin) in pediatric members (<18 years of age) diagnosed with heart failure (HF) and related complex cardiac conditions.

This policy ensures consistent, equitable, and medically appropriate determinations while balancing clinical innovation, patient safety, regulatory standards, and financial stewardship from a Parkland Community's Health Plan (PCHP) perspective.

SCOPE:

This policy applies to all members enrolled in **STAR** and **CHIP** benefit plans pediatric members who are prescribed off-label dapagliflozin with:

- Systolic heart failure (HFrEF)
- Post-heart transplant heart failure or graft dysfunction
- Congenital heart disease, including unbalanced atrioventricular canal (AVC)
- Tracheobronchomalacia when associated with documented cardiac-related heart failure

This policy does **NOT** apply to FDA-approved indications or to adult members (≥18 years of age).

DEFINITIONS / ACRONYMS:

AVC (Atrioventricular Canal): A congenital heart defect involving abnormalities of the atrial and ventricular septa and atrioventricular valves.

CHD (Congenital Heart Disease): Structural heart abnormalities present at birth.

GDMT (Guideline-Directed Medical Therapy): Evidence-based pharmacologic and

device therapy recommended in national cardiology guidelines.

HF (Heart Failure): A clinical syndrome characterized by symptoms and signs resulting from impaired ventricular filling or ejection of blood.

HFrEF (Heart Failure with Reduced Ejection Fraction): Systolic HF typically defined by reduced ventricular ejection fraction.

NYHA (New York Heart Association) Functional Classification: A classification system describing HF symptom severity.

Ross Classification: Pediatric functional classification system for HF severity.

SGLT2 (Sodium-Glucose Cotransporter-2) Inhibitor: A class of medications that inhibit renal glucose reabsorption and exert natriuretic and cardiometabolic effects.

POLICY:

Coverage may be approved on appeal when **ALL** of the following criteria are met:

1. Diagnosis

Member is <18 years of age with one of the following:

- Symptomatic systolic HF (Ross or NYHA Class II–IV)
- Post–heart transplant graft dysfunction with HF
- Complex CHD (e.g., unbalanced AVC) with documented ventricular dysfunction
- Tracheobronchomalacia with objective evidence that HF is contributing to clinical instability

2. Disease Severity

- NYHA/Ross Class II–IV symptoms
- Objective evidence of ventricular dysfunction (echo/MRI)
- Elevated natriuretic peptides (if available)

3. Failure of Standard Therapy

Documentation of optimized guideline-directed medical therapy for age and physiology, including:

- ACE inhibitor/ARB or ARNI (if tolerated)
- Beta-blocker (if appropriate)
- Diuretics
- Mineralocorticoid receptor antagonist (if indicated)
- Device therapy when clinically indicated

4. Prescriber Requirements

- Member is managed by a board-certified pediatric cardiologist or pediatric heart failure/transplant specialist

5. **Safety and Monitoring Plan**

- No history of recurrent Diabetic Ketoacidosis (DKA)
- Baseline renal function assessment
- No severe renal impairment (age-adjusted)
- Monitoring plan for volume status, renal function, and ketosis

6. **Approval Timeframe**

If approved on appeal:

- Initial authorization: 3–6 months
- Continued therapy requires documentation of:
 - Clinical improvement or stabilization
 - Absence of serious adverse effects
 - Ongoing specialist management

Re-approval for 3-6 months

CROSS-REFERENCED DOCUMENTATION:

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