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SCALING HOME-BASED DECONGESTION IN HEART FAILURE WITH FUROSCIX® (FUROSEMIDE INJECTION)

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ROADMAP

With Support From:

mannkind

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EXECUTIVE SUMMARY

Heart failure (HF) remains one of the most common and costly drivers of hospitalization in the U.S., accounting for more than one million admissions annually and substantial downstream total cost of care.[1] Despite advances in guideline-directed medical therapy (GDMT), congestion remains the principal precipitant of emergency department (ED) visits, readmissions and symptom burden.[2]

Nearly half of patients discharged following HF hospitalization have persistent residual congestion, significantly increasing early post-discharge risk.[3]

A substantial proportion of HF hospitalizations are driven by the need for intravenous (IV) diuresis alone rather than true hemodynamic instability.[2] This highlights a fundamental limitation in traditional care models: oral diuretics often fail in the setting of worsening congestion, while effective IV therapy has historically required facility-based care.

This challenge is further compounded by the high prevalence of chronic kidney disease (CKD) in patients with HF, contributing to diuretic resistance, impaired natriuresis and increased risk of adverse outcomes.[4] The intersection of HF and CKD further limits the effectiveness of conventional oral strategies.

In 2027, the Centers for Medicare & Medicaid Services (CMS) Ambulatory Specialty Model (ASM) for HF shifts accountability to the ambulatory setting through a mandatory, value-based model for selected cardiologists, advancing value-based care in specialty practice. Under ASM, quality and total cost-of-care performance are attributed at the individual physician level, with clinicians evaluated within a defined cohort. The model incorporates two-sided financial risk, where performance on both cost and quality metrics including medication management, functional status assessment, avoidable hospitalizations and ED utilization directly influence reimbursement.[5] This structure creates meaningful financial and operational consequences for programs that remain dependent on inpatient-based decongestion management and necessitates deliberate redesign of ambulatory congestion strategies.

Subcutaneous furosemide delivery systems have emerged as an important option for addressing gaps in HF management by enabling outpatient and home-based decongestion. The implementation experience described in this paper is based on FUROSCIX® (Mannkind). FUROSCIX enables home-based administration of loop diuretic therapy and may provide an alternative to selected episodes of facility-based intravenous diuresis.

Additional Resources for ASM-HF Readiness:

- CMS ASM (Innovation Center)
- ACC ASM Resource Hub
- MedAxiom Care Transformation Services
- APM Connect

Experience from ambulatory HF programs suggests that the value of subcutaneous furosemide is maximized when it is deployed within a structured operational framework rather than as a standalone therapeutic intervention. Key elements include clearly defined patient selection criteria, integrated pharmacy workflows, protocolized monitoring and timely clinical follow-up. Within such a model, FUROSCIX can serve as a standardized component of an ambulatory HF management program, supporting earlier intervention for decongestion while maintaining protocolized clinical oversight.

Within an ASM, the question is not whether home-based decongestion is feasible, but how to operationalize it safely, consistently and at scale. Subcutaneous furosemide offers health systems an additional pathway for managing appropriate patients in the ambulatory setting, with the potential to reduce avoidable hospital utilization, preserve inpatient capacity, and support broader value-based care objectives.

Drawing on real-world experience from Cone Health, Greensboro, NC, and Emory Healthcare, Atlanta, GA, this overview provides a scalable roadmap for administrative and physician dyads seeking to implement home-based decongestion safely, efficiently, and in alignment with CMS ASM and value-based care.

STRATEGIC CONTEXT: CLOSING THE CONGESTION GAP

HF decompensation rarely begins in the ED; it evolves over days to weeks through progressive fluid accumulation.[2] Traditional care models often intervene too late, after ED visits or hospitalization becomes clinically necessary.

Residual congestion is strongly linked to early readmission and adverse outcomes.[3] Under value-based models such as ASM, delayed intervention translates directly into measurable cost exposure.[5] Without a mechanism to intervene between clinic visits, or immediately post-discharge, organizations expose themselves to avoidable utilization.

For some programs, the objective was reducing 30-day readmissions. Others focused on ED avoidance, infusion chair strain or advanced HF stabilization. Successful implementation began with a clearly defined use case.

Phase-Based Rollout

Both organizations implemented FUROSCIX in deliberate phases (**Figure 1**). Programs that attempt to expand too quickly are at risk for workflow strain and follow-up gaps. Deliberate sequencing will promote optimal implementation.

Common Strategic Objectives

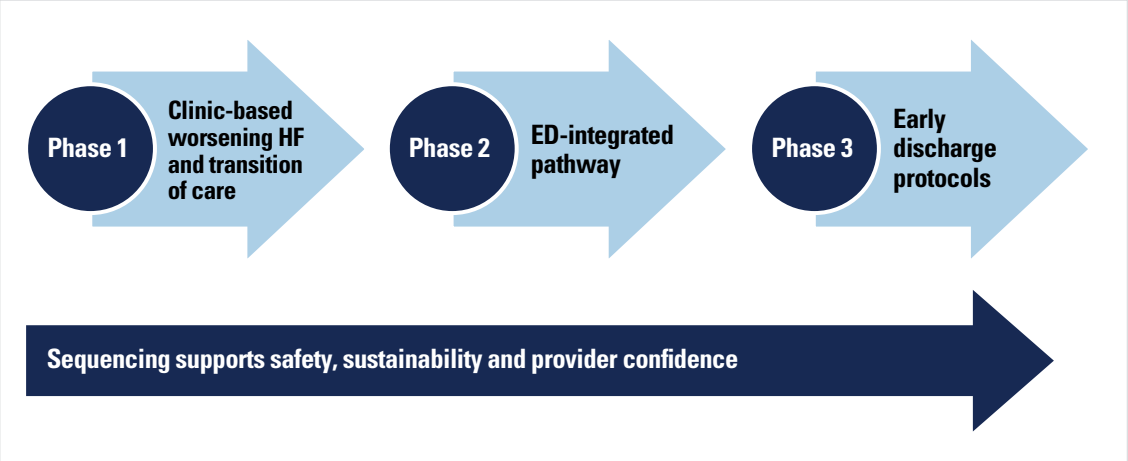
- Reducing 30-day readmissions
- Avoiding unnecessary ED utilization
- Relieving infusion clinic strain
- Strengthening transition-of-care stability
- Supporting early discharge in appropriate patients
- Improving symptom burden and patient experience
- Expanding access for patients with geographic or transportation barriers

INITIAL STRATEGIC QUESTIONS

WHERE'S YOUR PAIN POINT? *What do you want to do with this drug?"*

Dan Bensimhon, MD
Non-Invasive Cardiology, Cone Health

Figure 1: FUROSCIX Implementation Phases



GOVERNANCE: THE DYAD MODEL

Successful implementation requires defined ownership across clinical and operational domains. Common key stakeholders include:

- Clinical leadership: Physician champion, advanced practice provider (APP) leader, nursing leadership
- Operational oversight: Clinic manager, program supervisor
- Pharmacy partnership: Clinical pharmacists, medication access specialists, pharmacy technicians and specialty pharmacy teams
- Executive sponsorship
- Nursing-navigator/case manager
- IT analyst: Supporting provider and pharmacy

Without these pre-launch elements in place, therapy risks inconsistent application and diminished value realization. Successful implementation began with a clearly defined use case. Once that use case was established, programs were able to design acquisition and operational workflows to support consistent execution.

Pre-Launch Checklist

- ✓ Defined initial use case
- ✓ Clear inclusion/exclusion criteria
- ✓ Three-to-seven-day follow-up capacity
- ✓ Authorization workflow ownership
- ✓ Electronic health record (EHR) order set integration
- ✓ Escalation pathway
- ✓ Staff training on device use, patient selection and clinical workflows
- ✓ Patient education materials and device-training process

> **WITH THE RIGHT SUPPORT STRUCTURE,** *early discharge becomes a powerful extension of ambulatory care."*
>
> **Amy Clegg, MSN, AGNP-C**
> Nurse Practitioner, Cardiology, Cone Health



ACQUISITION PATHWAYS AND PHARMACY INTEGRATION

Across both Cone Health and Emory Healthcare, the primary barrier was not clinical acceptance. It was establishing an access plan that worked for each health system. Authorization workflows, fulfillment speed and payer variability ultimately determine whether home-based decongestion functions as reliable infrastructure or episodic therapy.

Both Cone Health and Emory Healthcare have an internal health system specialty pharmacy that allowed them to embed FUROSCIX within their internal workflow for proactive fluid overload management. Prescriptions routed first to the Medication Access Team for benefits investigation and prior authorization before pharmacy dispensing.

Two Scalable Acquisition Models

Implementation experience across both organizations identified two viable pathways.

OPERATIONAL REALITIES

YOU CAN PROVIDE THE BEST COUNSELING…
but if you can't actually get the patient the medication, there's no outcome tied to it."

Vishal Shah, PharmD
Specialty Pharmacy Manager

Model 1:

Specialty Pharmacy Distribution (FUROSCIX Direct)

This model centralizes benefits verification, prior authorization, and direct-to-patient shipment through FUROSCIX Direct via an online ordering system, enabling a streamlined, coordinated specialty pharmacy workflow.

Core elements include:

- Real-time benefits investigation
- Prior authorization management
- Direct-to-patient shipment
- Standardized clinic–pharmacy communication

When prior authorization responsibilities are clearly assigned and supported through programs such as FUROSCIX Direct®, tasks can be routed efficiently, executed in a timely manner, and tracked through completion, reducing administrative variability, and supporting more consistent therapy initiation timelines.

At Cone Health, embedding and standardizing pharmacy workflows reduced early friction and consistently achieved 24–48-hour authorization turnaround.

Model 2:

Internal Health-System Direct Purchase and Dispensing

Emory Healthcare leveraged its internal specialty pharmacy to stock FUROSCIX and ship directly to patients. This approach provided:

- Reduced fulfillment delays
- Greater operational control
- Integrated documentation within Epic
- Immediate coordination between pharmacy and cardiology teams

THE IMPACT

OUR PHARMACY TEAM CAN CHECK AUTHORIZATION RIGHT THEN AND THERE…
patients usually have it within 24 to 48 hours."

Heather Schub
HF Clinic Coordinator, Cone Health

The Critical Role of Pharmacy Integration

Across both models, one principle remained constant: prior authorization ownership must not default to nursing without infrastructure support.

Where pharmacy technicians or medication access teams were embedded:

- Authorization turnaround accelerated
- Clinical staff burden decreased
- Fewer delays in therapy initiation
- Workflow confidence increased

The determining factor was not organizational structure. It was clarity of process and accountability.

Administrative–physician dyads should confirm:

- Who owns prior authorization?
- What is the average turnaround time?
- How are denials escalated?
- How is copay variability communicated?

Predictable access must precede clinical expansion (**Figure 2**).

Figure 2: Structured Acquisition Workflow for Home-Based Decongestion Example



Reliable access infrastructure creates the foundation upon which safe clinical deployment depends. Once acquisition becomes predictable, the next determinant of success is patient selection. Patients experiencing worsening congestion over several days, previously managed with ED-based IV diuresis, were able to initiate treatment at home, resulting in symptom improvement and avoidance of hospitalization.



Patient Selection Framework

Patient selection is the highest-impact determinant of program success. The goal is early intervention, not rescue from instability. Intentional inclusion and exclusion protect safety and workflow integrity (**Table 1**).

Table 1: Patient Selection Considerations

Appropriate Candidates	Exclusion Considerations
Unresolved congestion	Hemodynamic compromise
Inadequate response to oral diuretic escalation	Advanced renal dysfunction requiring inpatient monitoring
Mild-to-moderate worsening HF	Inability to self-administer without caregiver support
Residual congestion post-discharge	Unsafe home environment
Hemodynamic stability	Inadequate follow-up access

Successful programs aligned patient selection to clearly defined clinical use cases. Rather than broad deployment, early adoption focused on specific populations where home-based decongestion could meaningfully alter the clinical trajectory.

Common starting use cases included:

- **Advanced HF/high-risk patients** (diuretic resistance, recurrent admissions, infiltrative cardiomyopathies, pre transplant/left ventricular assist device)
- **Post-discharge residual congestion** (transition-of-care stabilization)
- **Ambulatory worsening HF** (symptom escalation prior to ED presentation)
- **Infusion clinic alternatives** (patients requiring IV diuresis without hospitalization)

Home-based decongestion is most powerful when deployed with clinical discipline.



> **IT'S ABOUT IDENTIFYING THE RIGHT PATIENT AT THE RIGHT TIME.** *When we do that well, the impact is significant."*
>
> **Daphne Wood,** Cone Health

Protocols and Dosing Strategy: Building a Reproducible Pathway

Home-based decongestion must operate within a defined clinical protocol – not as episodic rescue therapy. Scalability depends on reproducibility, and reproducibility depends on structure.

Both organizations transitioned from individualized prescribing to structured EHR order sets designed to standardize dosing, monitoring and follow-up.

Structured patient selection criteria and defined reassessment intervals reinforced clinical discipline and expanded provider comfort.

Building those guardrails requires intentional protocol design. When developing a FUROSCIX pathway, leadership should address several foundational elements to ensure consistency across providers and clinics.

1. Dosing Framework

- Defined dosing strategy; multidose approach was preferred
- Quantity aligned with payer limits
- Potassium supplementation parameters clarified
- Defined reassessment timing

2. Embedded Order Set Design

Protocol reliability requires EHR integration. Standardized order sets should include:

- Dose selection and quantity parameters
- Supplementation prompts
- Follow-up scheduling triggers
- After-visit summary instructions
- Escalation guidance

3. Structured Follow-Up

Minimum standards should include:

- RN outreach within 24 to 48 hours
- Clinic reassessment within three to seven days
- Symptom and weight evaluation
- Laboratory monitoring when clinically indicated

This structure aligns with evidence describing the heightened risk during the vulnerable phase following HF decompensation.[2]

PATIENT SELECTION

"When we're thoughtful about who we select and we build guardrails around how we use it, this becomes a really powerful tool. **IT GIVES US ANOTHER WAY TO KEEP PATIENTS STABLE AND OUT OF THE HOSPITAL."**

Matt Brown, Emory

WORKFLOW

"If it's not built into the workflow, it won't happen. **WE HAVE TO MAKE IT EASY."**

Amy Clegg, Cone Health

Disclaimer: Structured decision pathways operationalize protocol design into consistent clinical practice. The pathways, protocols and dosing strategies presented here are intended to serve as an implementation framework and should be adapted and approved by each institution in accordance with its clinical governance processes, organizational policies and applicable product labeling. It is not intended to establish a standard of care or replace independent clinical judgment. Decision pathways should be reinforced with established heart failure self-management frameworks. For example, the American Heart Association (AHA) Self-Check Plan provides patient-facing guidance on symptom monitoring and weight thresholds, which can be incorporated into education and follow-up workflows to support early identification of worsening congestion.[6]

4. Defined Escalation Criteria

Protocols must specify thresholds for escalation to in-person evaluation or inpatient care, including:

- Inadequate weight response
- Inadequate urine output
- Lack of symptom improvement (persistent dyspnea, orthopnea, paroxysmal nocturnal dyspnea)
- Hypotension
- Worsening renal function
- Therapy intolerance

Clear escalation pathways reinforce safety and physician confidence.

For clinician support and downloadable educational materials, visit the FUROSCIX Provider Resources Hub. Resources include access guides, prescribing support and workflow tools. FUROSCIX® HCP & Patient Resources | Fluid Buildup Symptom Tracker, FAQs & More. For more information about FUROSCIX, including important safety information, see full Prescribing Information at FUROSCIX.com/PI.

5. Education Standardization

Patient education should be embedded within the protocol to ensure consistent delivery. Operational considerations include:

- Demo device availability
- Standardized instruction materials or video
- Dedicated education space when needed
- Documentation templates

Standardization reduces variation and improves adoption across providers and nursing teams.

Structured patient education improves adherence and safety. Patient-facing instructions and video guides are available through the FUROSCIX helpful resources page and on-body infuser demonstration pages. FUROSCIX Resources | Instructions for Use & More | FUROSCIX®



6. Home-Based Decongestion Decision Pathway

With protocol components defined, the next step is translating these elements into a consistent clinical decision pathway.

Both organizations emphasized that structured guidance improves provider confidence, supports nursing triage, and reduces variability in patient selection and escalation decisions.

The following decision pathway outlines a practical framework for identifying appropriate patients, initiating therapy, and defining clear thresholds for reassessment and escalation.

1. *Clinical Stability*
   Hemodynamically stable?
   - No hypotension (ex: systolic blood pressure (SBP) ≥90 mm Hg or clinically stable)
   - No active ischemia/unstable arrhythmia
   - No severe renal dysfunction requiring inpatient monitoring

   No → Inpatient evaluation
   Yes → Proceed

2. *Confirm Congestion*
   Evidence of volume overload?
   Weight gain (ex.: >2-3 lbs in 24 hours or >5 lbs in 1 week[1]).
   - Edema
   - Dyspnea/orthopnea
   - Elevated jugular venous pressure or pulmonary congestion

   No → Optimize GDMT
   Yes → Proceed

3. *Oral Diuretic Response*
   Failed or plateaued after oral escalation, defined as one or more of the following:
   - Unresolved symptoms despite dose escalation
   - Inadequate diuresis
   - Insufficient weight reduction
   - Recurrent need for short-term oral dose doubling

   No → Continue oral titration
   Yes → Proceed

4. *Defined Use Case*
   Eligible scenario:
   - Post-discharge residual congestion
   - Clinic-based worsening HF
   - ED avoidance candidate (hemodynamically stable)
   - Early discharge candidate (with institutional support)

   If eligible → Proceed
   If not → Reassess strategy

5. *Home Readiness*
   Patient able to self-administer OR reliable caregiver available? AND:
   Follow-up secured (RN 24-48 hours + clinic visit three-to-seven days)?
   No → Do not initiate Yes → Initiate therapy

Initiate Structured Decongestion Protocol
- Multi-dose plan (typically three to four doses)
- Potassium supplementation parameters
- Escalation criteria defined
- Follow-up documented

Escalation Criteria
- Unresolved dyspnea or worsening symptoms
- Inadequate weight or urine response
- Hypotension
- Worsening renal function
- Intolerance of therapy

Ultimately, the success of home-based decongestion depends not only on implementation, but on performance. Programs must measure both clinical response and downstream utilization to ensure alignment with value-based care expectations.

Metrics and Performance Monitoring

Sustainable implementation requires measurement. Early adoption may focus on workflow stabilization; long-term scalability under the CMS ASM depends on demonstrable performance (**Table 2**).

Table 2: Recommended Performance Metrics

Clinical Metrics	Operational Metrics	Financial Indicators
30-day HF readmission rate	Order-to-administration time	Admission trends
ED revisit rate	Authorization turnaround	ED utilization trends
Therapy completion (completion of prescribed dosing pathway)	Follow-up completion rate	Infusion clinic volume shifts
Escalation rate (requiring higher level of care post initiation)	ED visit, IV diuresis or hospitalization following FUROSCIX initiation	Directional cost-of-care performance

Metrics should be reviewed quarterly within the administrative–physician dyad structure and incorporated into ongoing quality and performance meetings. This measurement converts innovation into infrastructure and sustains leadership support for the program.

Organizational Value Under ASM

HF hospitalizations remain a substantial contributor to cardiovascular spending nationally.[1] Contemporary analyses estimate the cost of an HF hospitalization in the U.S. to range from approximately $15,000 to over $30,000 per admission, depending on patient complexity and comorbid conditions.[7] Even modest reductions in preventable admissions and length of stay can materially influence total cost-of-care performance.

When protocolized, home-based decongestion supports value across four domains:

- Admission avoidance
- ED diversion
- Capacity optimization
- Transition-of-care stabilization during the vulnerable phase[2]

The opportunity is not simply to shift care from the hospital to the home, but to manage worsening heart failure proactively across the continuum of care. Structured ambulatory management pathways may help reduce avoidable utilization, preserve capacity, and support value-based performance, aligning with the goals of emerging heart failure care models, including the ASM.

CONCLUSION

The shift toward ambulatory accountability under the CMS ASM for HF requires deliberate redesign of congestion management strategies.

Home-based decongestion, when deployed with disciplined patient selection, structured acquisition, protocolized dosing, and measurable follow-up, enables earlier intervention along the worsening HF trajectory.

The organizations highlighted in this paper demonstrate that FUROSCIX can be operationalized safely and sustainably within diverse health system structures. The strategic imperative is clear: ambulatory decongestion is no longer optional innovation. It is infrastructure for value-based performance.

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Related Resource: FUROSCIX Prescribing Information & Instructions for Use

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