

FDA Approval

Lasix[®] ONYU

(furosemide injection)

80mg/2.67ml for subcutaneous use

Conference Call and Webcast

Thursday, October 9th, 2025 at 4:30pm ET

- **Pieter Muntendam, MD**, Founder, President and CEO of SQ Innovation
- **Dr. Mustafa M. Ahmed, MD**, Professor of Medicine, Section Chief, Heart Failure, University of Florida Health, Gainesville, FL
- **S. Craig Thomas**, Nurse Practitioner - Advanced Heart Failure Center, University of Virginia Health System, Charlottesville, VA and Immediate Past President- American Association of Heart Failure Nurses (AAHFN)



Forward-looking Statement

This webcast may contain "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, timing or outcomes of communications with the FDA, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence clinical studies or complete ongoing clinical studies, and to obtain and maintain regulatory approvals for Lasix® ONYU and other candidates in development, and the success of any efforts to commercialize and market Lasix® ONYU. We undertake no obligation to publicly update any forward-looking statement, whether written or oral (including any forward-looking statements on the Website) that may be made from time to time, whether as a result of new information, future developments, or otherwise.

Important Safety Information

What is Lasix® ONYU (furosemide injection) for subcutaneous use?

Lasix® ONYU is a prescription drug-device combination that treats edema caused by fluid build-up in a person with heart failure. Lasix ONYU comes with a special device that delivers the medicine under the skin. Follow the instructions provided by your healthcare provider when using Lasix ONYU.

IMPORTANT SAFETY INFORMATION

Before using Lasix® ONYU, read the Instructions for Use and tell your healthcare provider about all your medical conditions, including if you are allergic to furosemide or any of the ingredients in Lasix ONYU, have trouble urinating, or if you are allergic to medical adhesives.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines.

Warning: Only use the Lasix ONYU Prefilled Cartridge with the Lasix ONYU Infusor. Do not use insulin cartridges or other medicine cartridges in the Lasix ONYU Infusor. Doing so could cause severe injury.

What are the possible side effects of Lasix ONYU?

Dehydration: Lasix® ONYU is a diuretic that can make you lose a lot of fluid and with it electrolytes. You may get a dry mouth, have increased thirst, get muscle pains or cramps, have reduced urine output or your urine may be more yellow than normal, you may get a headache, get dry skin, or have nausea or vomiting. Your healthcare provider may check your electrolytes while receiving Lasix® ONYU.

Low Blood Pressure: Lasix® ONYU may lower your blood pressure temporarily. You may feel lightheaded or dizzy. This usually happens when you stand. Getting up slowly may help.

High Blood Sugar: Lasix® ONYU may increase blood sugar (glucose) levels if you have diabetes mellitus.

Loss of Hearing: Lasix® ONYU can cause ringing in your ears. If so tell your healthcare provider.

Risk of Sunburn: Your skin may be more sensitive to sunlight while taking Lasix® ONYU.

Infusion Site Reactions: Lasix® ONYU can cause infusion site pain, bruising and temporary swelling or redness at the site of the Infusor.

Incomplete Dosing: Make sure the Infusor does not get wet during use. Also limit your physical activities. Some movements or when it gets wet may stop the infusion and you may not get all the medication.

These are not all the possible side effects of Lasix® ONYU. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

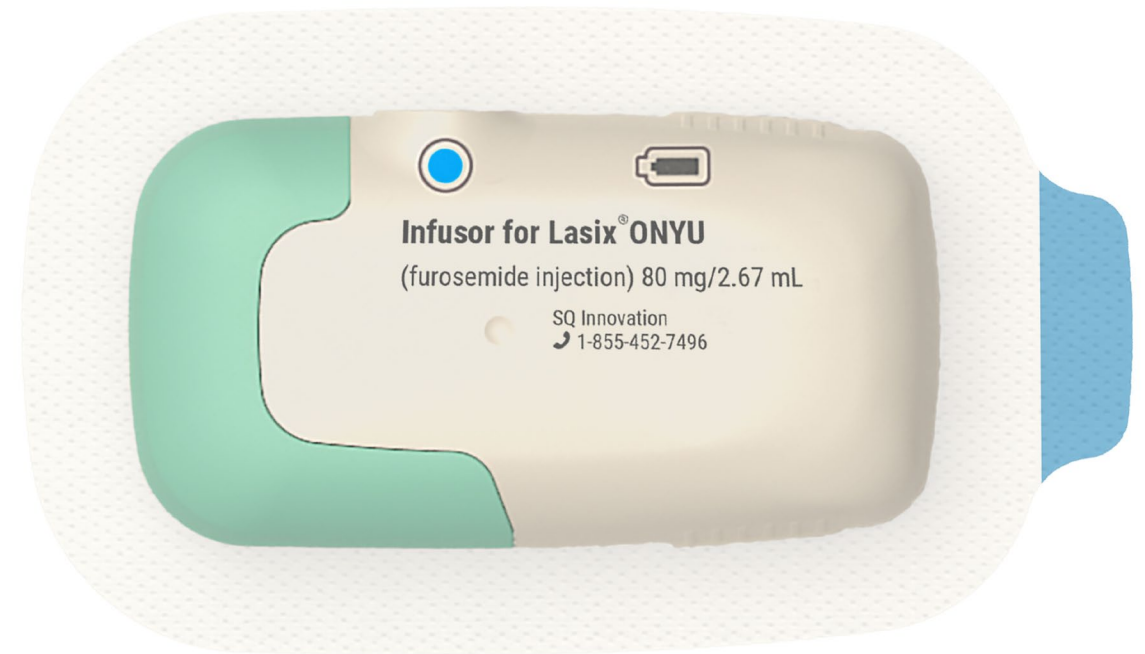
Please see the full [Prescribing Information](#) and [Instructions for Use](#).

For Important Safety Information and Instructions for Use visit www.lasix-onyu.com

Now FDA Approved

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(furosemide injection)
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INDICATIONS AND USAGE

Lasix ONYU is a loop diuretic indicated for the treatment of edema in adult patients with chronic heart failure.

The trademark LASIX[®] is registered for Validus Pharmaceuticals L.L.C. in the United States and used by SQ Innovation under license.

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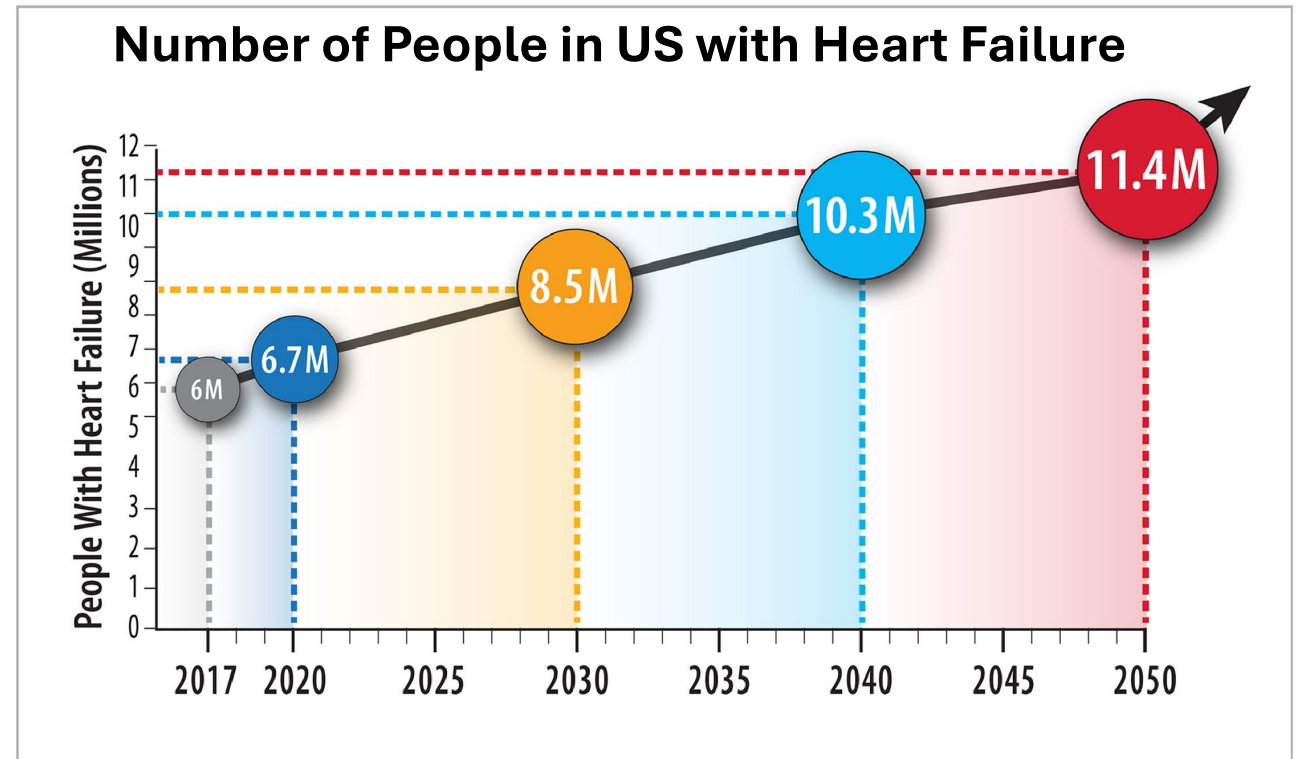
Our Goal:

Cost-effective, hospital-strength diuretic treatment option as an alternative to hospitalization for select patients as directed by their healthcare provider



The Crisis:

- The burden is rapidly increasing
- We already do NOT have enough:
 - Beds
 - Providers
 - Money

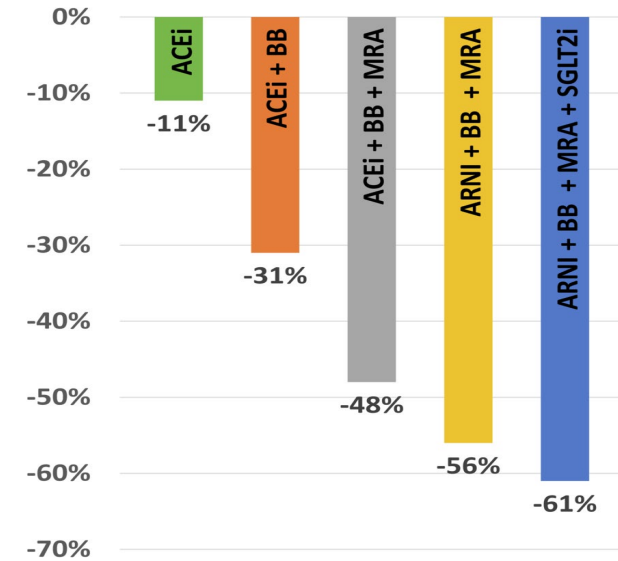


Data from Joynt Maddox KE, Elkind MSV, Aparicio HJ, Commodore-Mensah Y, de Ferranti SD, Dowd WN, et al. Forecasting the burden of cardiovascular disease and stroke in the United States through 2050: prevalence of risk factors and disease: A Presidential Advisory from the American Heart Association. *Circulation*. 2024 Jun 4; Van Nuys KE, Xie Z, Iysinger B, Hlatky MA, Goldman DP. Innovation in heart failure treatment: life expectancy, disability, and health disparities. *JACC Heart Fail*. 2018; 6:401–9.; and Heidenreich PA, Albert NM, Allen LA, Blumenthal DA, Butler J, Fonarow GC, et al. Forecasting the impact of heart failure in the United States: A policy statement from the American Heart Association. *Circ Heart Fail*. 2013; 6:606–19.

Only Two Actionable Paths:

- **Increase GDMT** (Guideline-Directed Medical Therapy)
 - Use of 4 drug classes
 - Marked mortality and hospitalization benefit
- **Treat More Patients at Home**
 - Approximately 25-30% of episodes can likely be treated at home*

Change in Relative-Risk of All Cause Mortality



Baudry, G., Monzo, L., Petrie, M.C. et al. *npj Cardiovasc Health* 1, 27 (2024). <https://doi.org/10.1038/s44325-024-00028-4>

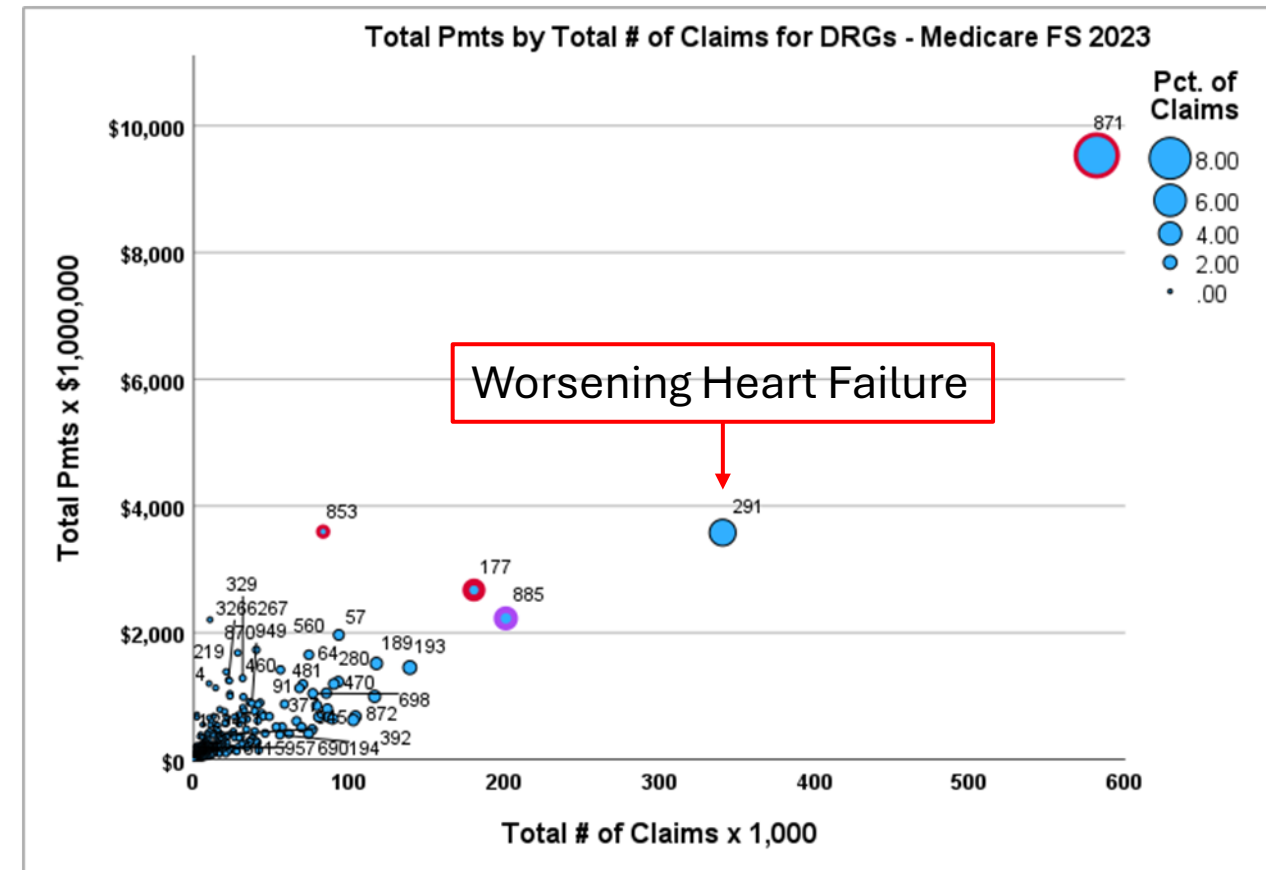


*Source: Primary research; Alira Health analysis.

Leading Cause of Hospital Admissions

Worsening Heart Failure (DRG 291) is the 2nd most common reason for hospital admissions in the elderly

- Out of 773 identified Medicare admission reasons, DRG 291 ranks second
- The top 5 DRGs account for approximately 20% of all Medicare inpatient admissions
- Adoption of Lasix ONYU can have a measurable and material impact on Medicare Part A spending

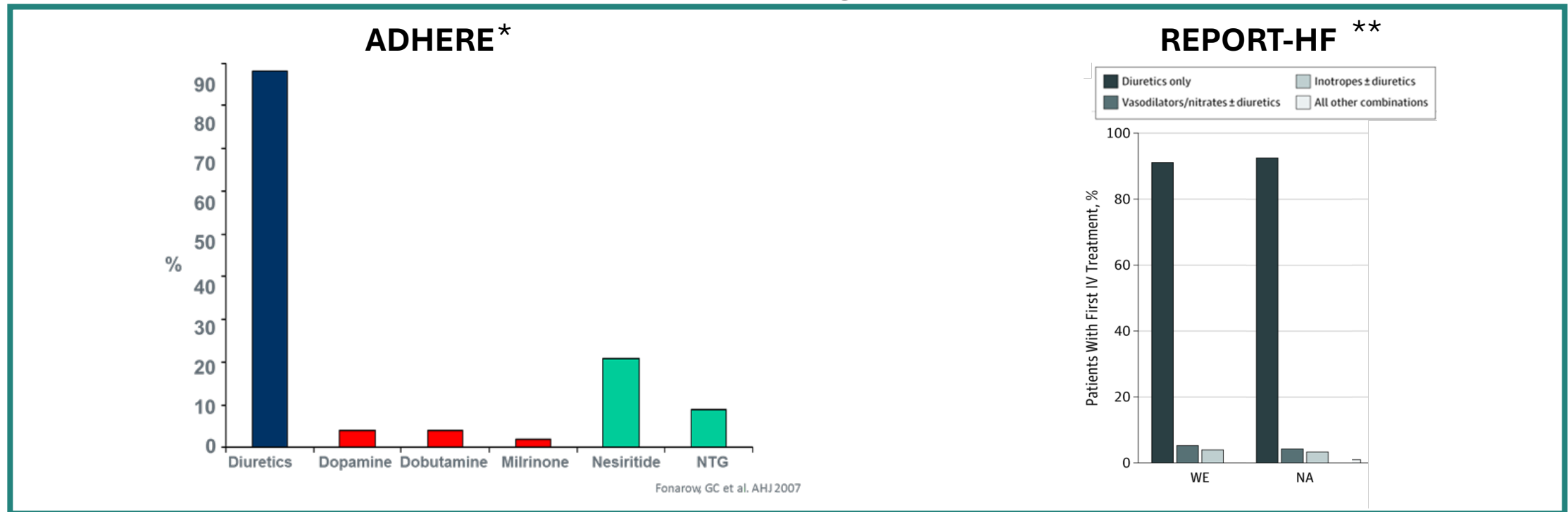


Source: DEFINITIVE HEALTHCARE

Parenteral Diuretics are the Cornerstone

For around 95% of patients hospitalized for worsening HF, diuretics are the only treatment they receive

- Furosemide is the diuretic of choice globally



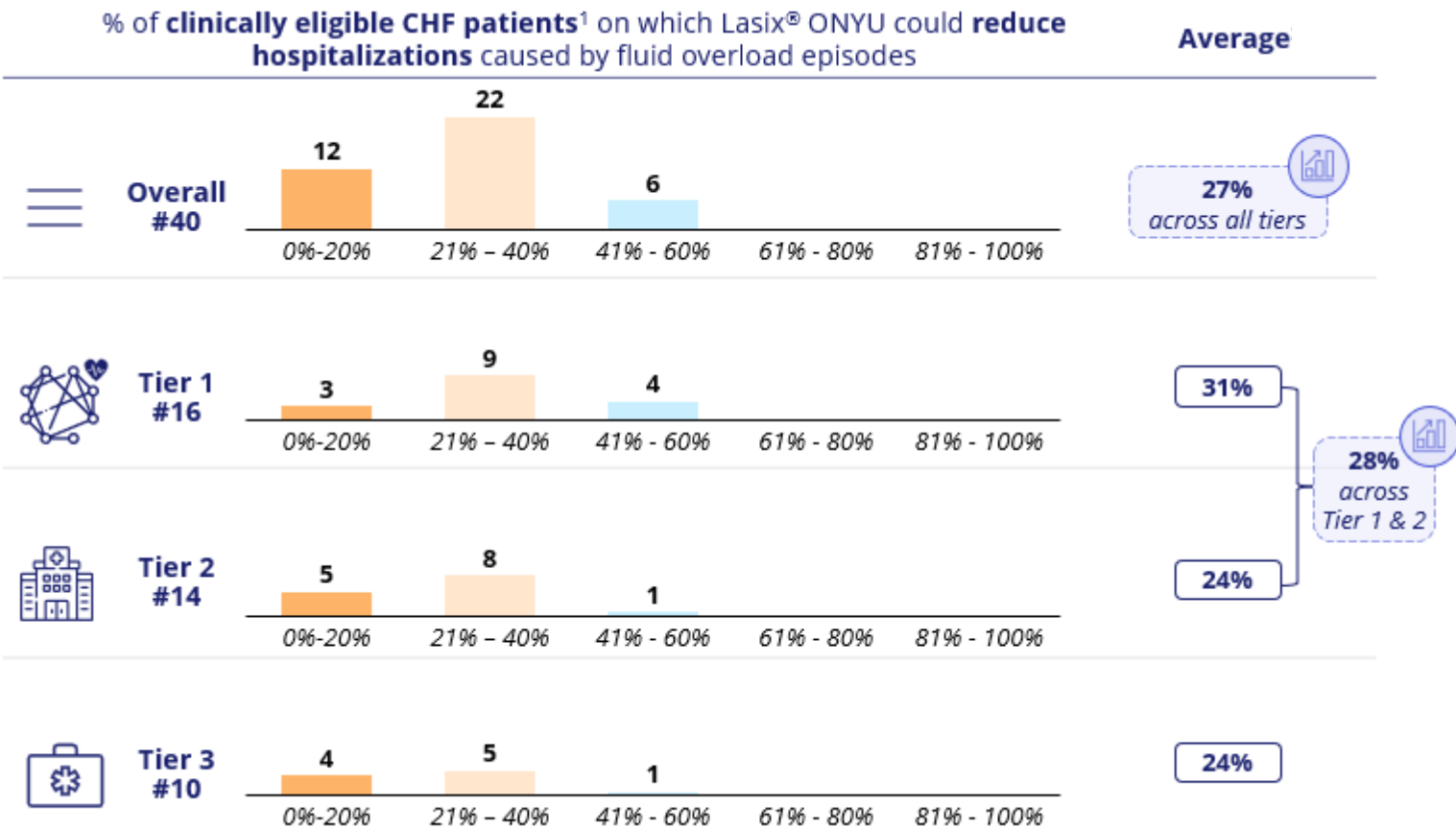
*Am Heart J. 2007 Jun;153(6):1021-8. doi: 10.1016/j.ahj.2007.03.012.
**JAMA Cardiol. 2020;5(4):401-410. doi:10.1001/jamacardio.2019.5108

The Potential:

2024 Survey Among 40 HF Programs

- Potential to impact 25-30% of the HF admission
 - If so, this would have a measurable and material impact on overall Part A Medicare spending

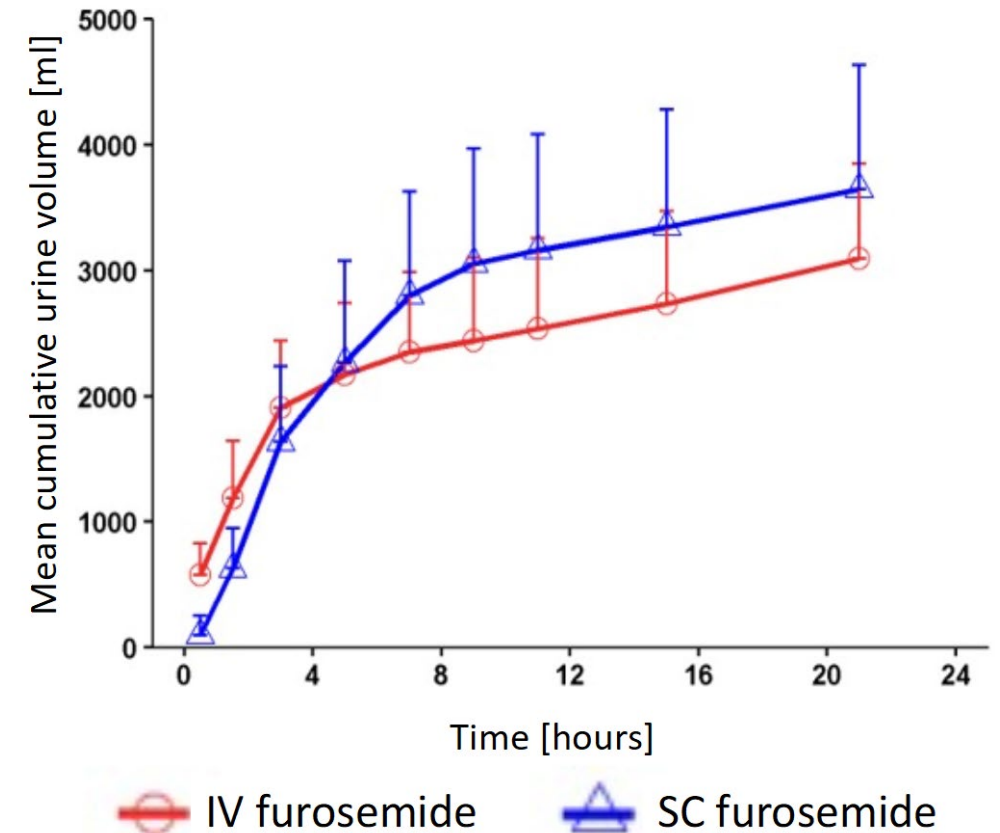
The benefit is not attributable to a product, but to the adoption of new clinical strategies to treat patients at home who are now routinely hospitalized



Source: Primary research; Alira Health analysis.

Clinical Evidence Summary

- Complete bioavailability (112%)
- Diuretic response similar to standard IV hospital treatment (80mg IV bolus)
 - Diuresis (24h): 3.650 L (115%)
 - Natriuresis (24h): 8.8 gr. (117%)
- Tempered diuretic response over 8 hours
- Well tolerated



Eur Heart J Cardiovasc Pharmacother.
2024;10: 35–44.

Lasix[®] ONYU – Combination Product

Lasix ONYU is a combination product delivering pH-neutral furosemide formulation subcutaneously via a pre-programmed patch pump Infusor.

Drug Constituent

- Novel furosemide formulation
 - pH of 7.5 for skin tolerance
 - 30mg/mL to reduce infusion volume (80mg/2.67mL)
- Prefilled standard (3mL) glass cartridge
- Shelf-life: 24 months 20-25 C



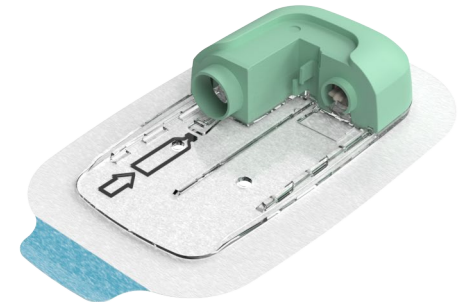
Full Unit



Drug Cartridge



Reusable Unit



Disposable Unit

Device Constituent (Infusor)

- Two component design
 - Single-use sterile Disposable Unit
 - Electromechanical multi-use component rated for 48 infusions (one user - no DME)
- 2nd generation design to reduce cost and offer advanced features

Our Strategy:

- Collaborate with hospital systems to develop and implement novel clinical workflows to prevent (re-)admissions of the highest risk patients
 - **Emergency Room to Home**
 - **Clinic to Home**
 - **Post Discharge**

Home is Where my Bathroom Is™

Summary:

Lasix[®] ONYU
(furosemide injection)
80 mg/2.67 mL for subcutaneous use

- **Lasix[®] ONYU** approved by the FDA for treatment of edema in adult patients with chronic heart failure
 - Providing hospital-strength diuresis
- Second-generation Infusor developed specifically for administration of furosemide with a focus on:
 - Improved manufacturability and reduced cost
 - Features requested by providers and patients
 - Minimizing environmental impact

Ultimate Beneficiary:

- **The Patient** who can now stay at home and be:
 - Comfortable
 - Ambulatory
 - Less-disrupted
 - Preferable
 - Cost-avoidant



Home is Where my Bathroom Is™



For further information send an email to info@sqinnovation.com