

WARNING: EMBRYO-FETAL TOXICITY

Females of reproductive potential: Exclude pregnancy before the start of treatment. To prevent pregnancy, females of reproductive potential must use effective forms of contraception during treatment and for one month after stopping treatment. Do not administer VERQUVO to a pregnant female because it may cause fetal harm.

A significant proportion of heart failure (HF) patients have a reduced ejection fraction (EF) and experience worsening HF events

Heart Failure Patients

- Based on data from NHANES from 2013 to 2016, **an estimated 6.2 million Americans (or 2% of the US population in US) aged 20 years or older in the US had heart failure.**¹
 - Based on ARIC Community Surveillance data, **the estimated incidence of HF in the US in people aged ≥ 55 years was close to 1 million cases** in 2014.¹
 - HF prevalence is estimated to increase 46% from 2012 to 2030 with an estimated prevalence of over 8 million adults in 2030.¹

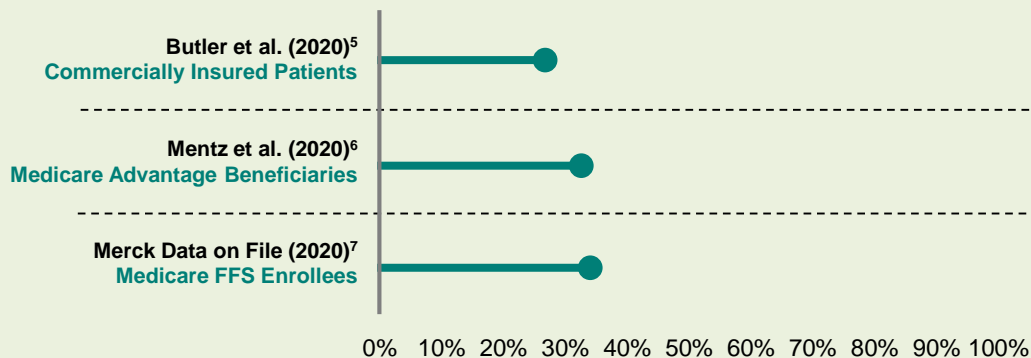
Heart Failure Patients with Reduced Ejection Fraction

- A study that analyzed 99,825 HF admissions from 305 hospitals in the Get With The Guidelines-HF (GWTG-HF) database between January 2005 and September 2013 found that **approximately 50% of patients with HF had a reduced EF (EF <40%).**²
 - **HFrEF (Heart failure with reduced ejection fraction) is defined by the ACCF/AHA guidelines as HF and a LVEF ≤ 40%**, although the cutoff levels to distinguish HFrEF varies across studies (e.g., LVEF ≤ 35% to ≤ 50%).^{3,4}

HFrEF Patients Who Experience Worsening HF Events

- **Approximately 30% of patients with chronic HFrEF annually experience at least one worsening HF event, defined as a hospitalization for HF or outpatient IV diuretic administration for HF.**^{5,6,7}

Percentage of Patients Who Developed a Worsening HF Event Within 12 Months^a



ACCF, American College of Cardiology Foundation; AHA, American Heart Association; ARIC, Atherosclerosis Risk in Communities; EF, ejection fraction; FFS, fee-for-service; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; IV, intravenous; LVEF, left ventricular ejection fraction; NHANES, National Health and Nutrition Examination Survey.

^aFor commercially insured patients and Medicare Advantage beneficiaries: within 12 months of first claim for HFrEF,^{5,6} for Medicare FFS enrollees: within 12 months of earliest diagnosis of HFrEF⁷

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Worsening HF is associated with clinical and economic burden

The clinical burden associated with a worsening HF event was described in various publications



A study that analyzed data from the GWTG-HF registry found that **the cumulative incidence of 5-year HF-related readmission was 48% for patients with HFrEF who were previously hospitalized for HF (n = 18,398).**⁸



An analysis of data from the National Cardiovascular Data Registry PINNACLE registry between January 2011 to December 2014 found that **patients with HFrEF who experienced a worsening HF event (n = 1851) were at high risk for recurrent HF-related hospitalizations** with the number increasing from **0.7 hospitalizations per patient at 30 days post-worsening event to 2 at 24 months post-worsening event.**⁹



Results from the same analysis demonstrated that **HFrEF patients who developed worsening HF (n=1,851) had a 2-year mortality rate of 22.5%.**⁹

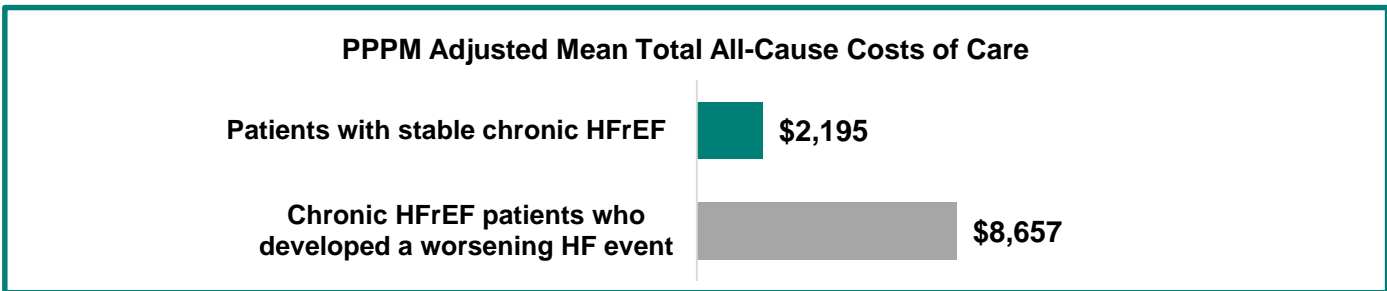


Results from a study that analyzed data from the Medicare-linked OPTIMIZE-HF registry demonstrated that **HFrEF patients who experienced a prior HF hospitalization had significantly higher rates of mortality compared to HFrEF patients not hospitalized for HF (HR=1.17; 95% CI: 1.06-1.26; P < 0.001).**¹⁰

An analysis comparing stable chronic HFrEF patients to patients who developed a worsening HF event highlights the differences in the economic burden of the two cohorts



In a retrospective study using the IBM MarketScan Commercial Database which included patients aged <65 years with chronic HFrEF, patients who developed a worsening HF event (n = 4,460) compared to patients with stable chronic HFrEF (n = 12,186) had **significantly greater PPPM adjusted mean total all-cause costs of care (\$8,657 vs \$2,195; P < 0.0001)** and **significantly greater healthcare utilization** (e.g., all-cause hospitalizations, length of stay, outpatient visits, and ED visits; all comparisons P < 0.0001) during the 12-month period following a worsening HF event.⁵



ED, emergency department; GWTG-HF, Get With The Guidelines-Heart Failure; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; PPPM, per patient per month.

References

1. Virani SS, et al. *Circulation*. 2020;141(9):e139-e596. 2. Kapoor JR, et al. *JACC Heart Fail*. 2016;4(6):464-472. 3. Yancy CW, et al. *J Am Coll Cardiol*. 2013;62(16):e147-e239. 4. Alonso-Betanzos A, et al. *Clin Med Insights Cardiol*. 2015;9(Suppl 1):57-71. Published 2015 May 21. 5. Butler J, et al. *Adv Ther*. 2020;37(9):4015-4032. 6. Mentz RJ, et al. *J Am Coll Cardiol* 2020;75:809. 7. Merck, Formulary Dossier for VERQUVO™ (vericiguat), 2021. 8. Shah KS, et al. *J Am Coll Cardiol*. 2017;70(20):2476-2486. 9. Butler J, et al. *J Am Coll Cardiol*. 2019;73(8):935-944. 10. Malik A, et al. *Am J Med*. 2020;133(1):84-94.

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