

Budget Impact of Injectafer (Ferric Carboxymaltose Injection) for the Treatment of Iron Deficiency in Adult Patients With Heart Failure and New York Heart Association Class II/III to Improve Exercise Capacity on a Third-Party US Payer

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abstract and the
supplemental tables.



EXECUTIVE SUMMARY

The expansion of ferric carboxymaltose injection's indication to include the treatment of iron deficiency (ID) in adult patients with heart failure (HF) who are in New York Heart Association (NYHA) class II/III to improve exercise capacity would result in a **cost reduction of \$0.11 per-member per-month (PMPM)** in the first year, which translates to approximately **\$1.3 million in total cost reductions** in the first year. **Cost reductions more than double in the second year.**

BACKGROUND

- Ferric carboxymaltose injection is an intravenous (IV) iron replacement product that is used to treat ID anemia.¹
- Of patients with HF, 50% have ID² and 87.5% are in NYHA class II/III.³
- Ferric carboxymaltose injection's indication in the United States (US) has been expanded to include treatment for ID in adult patients (aged ≥ 18 years) with HF who are in NYHA class II/III to improve exercise capacity.¹
- A cost model can inform payers of the budgetary impact of this indication expansion.

OBJECTIVE

- To estimate the budget impact (difference in total and PMPM costs) to a third-party payer in the US (e.g., a commercial payer and/or Medicare) of managing ID in adult patients with HF and in NYHA class II/III by comparing direct medical costs before and after the expansion of ferric carboxymaltose injection's indication.

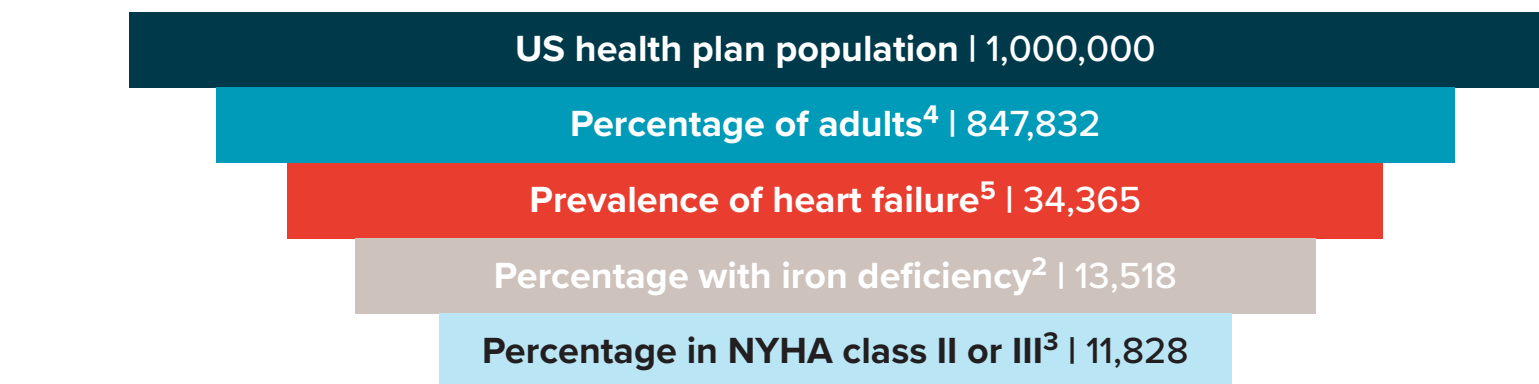
METHODS

- A budget-impact model was developed in Excel to estimate the cost impact of the indication expansion over a time horizon of 2 years.

Patient Funnel

- A patient funnel was used to identify the population eligible for treatment, which comprised adults who are iron deficient with HF and are in NYHA class II/III in need of treatment to improve exercise capacity (Figure 1).
- A blended health plan of 1,000,000 members was assumed (Supplemental Table 1), with 30% of members on a commercial or Medicare Advantage plan and 70% of members on a Medicare Fee-for-Service (FFS) plan. It was assumed that Medicare members were ≥ 65 years of age.

Figure 1. Patient Funnel



Budget Impact

- Patients eligible for treatment with ferric carboxymaltose injection identified in the patient funnel are distributed among the additional IV iron treatment options considered in the model via market shares. The treatments modeled are current standards of care for ID:
 - Ferric carboxymaltose injection, Feraheme, ferumoxytol (generic of Feraheme), Monoferic, low-dose IV iron (Venofer, INFeD, Ferlecit), and no treatment (no IV iron)
- Market shares for ferric carboxymaltose injection were assumed to increase by an absolute 10% in year 1 in the market with the indication expansion, plus an additional absolute 10% in year 2, based on a market analysis conducted by Daiichi Sankyo, Inc. (Supplemental Table 2).^{6,7}

- The model (Figure 2) includes the following inputs for each included treatment option:
 - Drug acquisition costs (wholesale acquisition cost [WAC]⁸ for commercial/Medicare Advantage members and average sales price [ASP]⁹ for Medicare FFS members) (Table 1)
 - Drug administration costs (Table 1)^{10,11}
 - Adverse-event (AE) costs,¹² which capture costs associated with an emergency department (ED) visit or a hospitalization related to hypersensitivity and anaphylaxis (Table 2)
 - Other healthcare resource utilization (HCRU) costs,¹² which were characterized as costs for hospitalizations and ED visits (Table 2) related to worsening HF and for other reasons not related to AEs
- Costs were calculated on the basis of the reimbursement amount, minus the proportion of the costs paid by the patient (27% for patients on a commercial health plan or Medicare Advantage and 20% for patients on Medicare FFS).⁷
- The scenarios compared were a market with expanded approval and a market without expanded approval. The difference between these scenarios is the budget impact.
- Drug acquisition and administration costs were calculated on the basis of each treatment's dosing instructions from their respective prescribing information.¹³⁻¹⁹

Figure 2. Model Structure

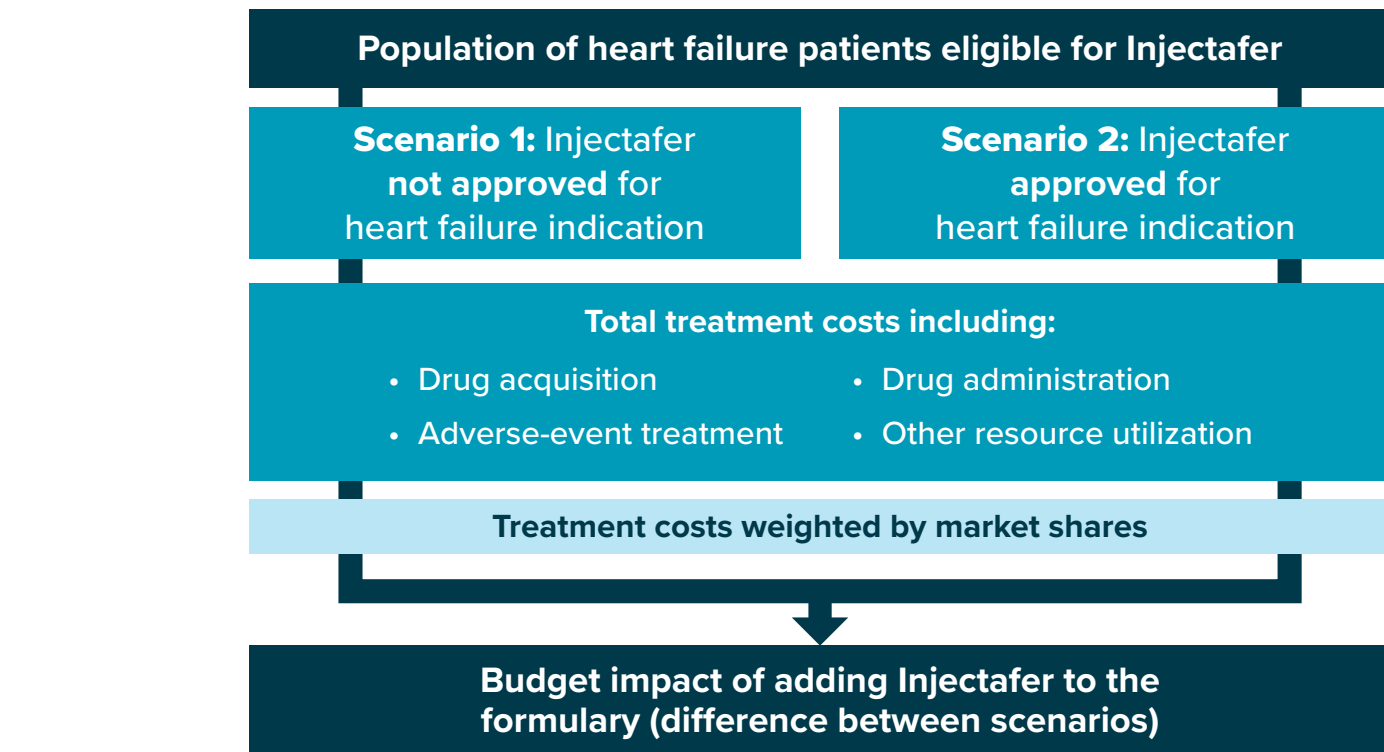


Table 1. Model Inputs: Drug Acquisition and Administration Costs

Treatment	Commercial/ Medicare Advantage (WAC)	Medicare FFS (ASP base + 6%)	Source
Drug acquisition			
Injectafer			
750-mg package	\$1,388.06	\$860.25	WAC pricing is from Merative Micromedex Red Book (2024) ⁸
100-mg package	\$185.08	\$114.70	
Feraheme			
Brand	\$11,588.50	\$1,820.70	
Generic (ferumoxytol)	\$869.14	\$182.07	ASP pricing is from ASP Pricing File (CMS, 2024) ⁹
Monoferic	\$3,246.77	\$2,014.38	
Venofer	\$360.00	\$221.00	
INFeD ^a	\$355.08	\$346.48	
Ferlecit	\$318.00	\$118.70	
Administration	Value		
Medicare FFS	\$39.02		CMS Physician Fee Schedule (CMS, 2024) ^{10,b}
Commercial/Medicare Advantage	\$65.24		Calculated using American Hospital Association Trendwatch Chartbook 2020 ^{11,c}

CDC = Centers for Disease Control and Prevention; CMS = Centers for Medicare and Medicaid Services; CPT = Current Procedural Terminology; LBW = lean body weight.
Note: Drug acquisition and administration costs were calculated on the basis of each treatment's dosing instructions from their respective prescribing information.¹³⁻¹⁹
^a INFeD is dosed based on hemoglobin level and LBW. An average patient was modeled with a hemoglobin level of 12.13 from Anker et al.¹³ and LBW of 64.09, which was calculated based on data from the CDC.²⁰
^b Administration cost was based on the cost of an initial IV push (CPT 96374).¹⁰
^c Commercial costs are derived using the Medicare reimbursement adjusted by the ratio (1.67) of payment-to-cost between Medicare and Commercial from American Hospital Association Trendwatch Chartbook 2020.¹¹

Table 2. Costs Related to Hypersensitivity, Anaphylaxis, Worsening HF, and Other HCRU

Treatment	Hospitalization		ER visit	
	Cost	Average annual no. per patient	Cost	Average annual no. per patient
Hypersensitivity¹²				
Injectafer	\$2,025.12	0.016	\$613.14	0.008
Feraheme	\$2,085.62	0.017	\$646.14	0.007
Low-dose IV iron ^a	\$3,401.36	0.016	\$569.16	0.009
No IV iron	\$0.00	0.000	\$0.00	0.000
Anaphylaxis¹²				
Injectafer	\$1,078.18	0.005	\$1,093.47	0.001
Feraheme	\$1,426.21	0.007	\$1,332.35	0.001
Low-dose IV iron ^a	\$1,090.78	0.010	\$643.99	0.001
No IV iron	\$0.00	0.000	\$0.00	0.000
Worsening HF¹²				
Injectafer	\$1,701.21	0.125	\$889.50	0.013
Feraheme	\$1,221.34	0.115	\$1,032.35	0.012
Low-dose IV iron ^a	\$1,566.94	0.177	\$1,319.83	0.042
No IV iron	\$1,368.81	0.302	\$1,071.37	0.067
Other HCRU costs¹²				
Injectafer	\$3,783.69	2.05	\$868.25	0.67
Feraheme	\$3,678.84	2.31	\$891.55	0.69
Low-dose IV iron ^a	\$4,164.69	2.58	\$964.46	0.82
No IV iron	\$3,698.04	2.76	\$867.58	1.00

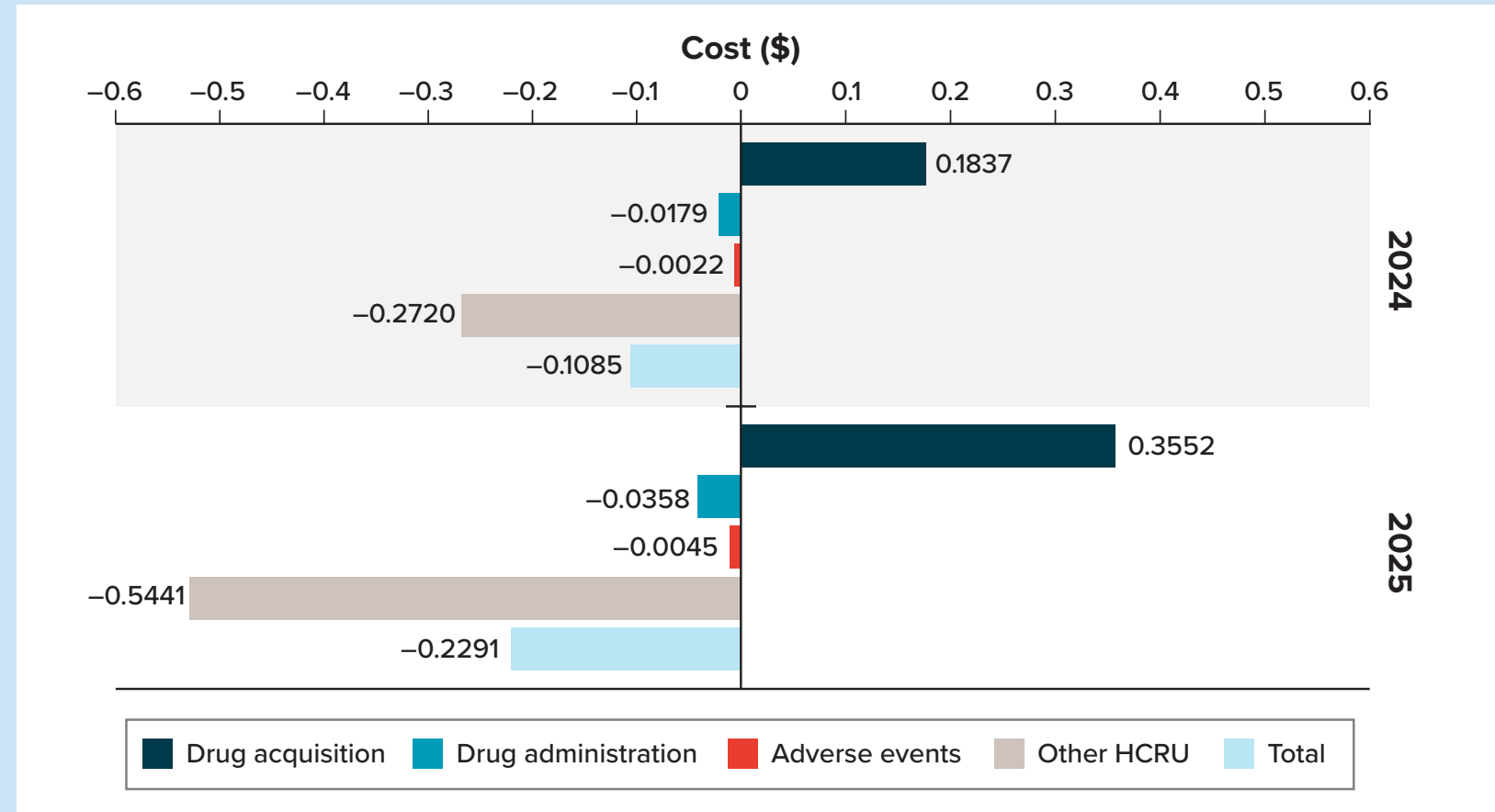
^a Monoferic, Venofer, INFeD, and Ferlecit.

RESULTS

Base-Case Analysis

- For a blended plan of commercial and Medicare patients, 11,828 adults were eligible for treatment per 1 million lives covered. Of these patients, 3,548 were on a commercial/ Medicare Advantage health plan, and 8,280 patients were on a Medicare health plan.
- In the scenario in which ferric carboxymaltose injection received approval for the expanded indication and experienced an increase in uptake, there was an incremental PMPM cost reduction of \$0.11 in the first year and \$0.23 in the second year compared with the market without approval and without an increase in uptake (Figure 3). This translates to approximately \$1.3 million and \$2.7 million in total cost reductions each year, respectively, per 1 million lives covered (Figure 5).
- Overall, with the expansion to ferric carboxymaltose's labeling, drug acquisition costs increased but were more than completely offset by cost reductions in drug administration, AEs, and other HCRU.

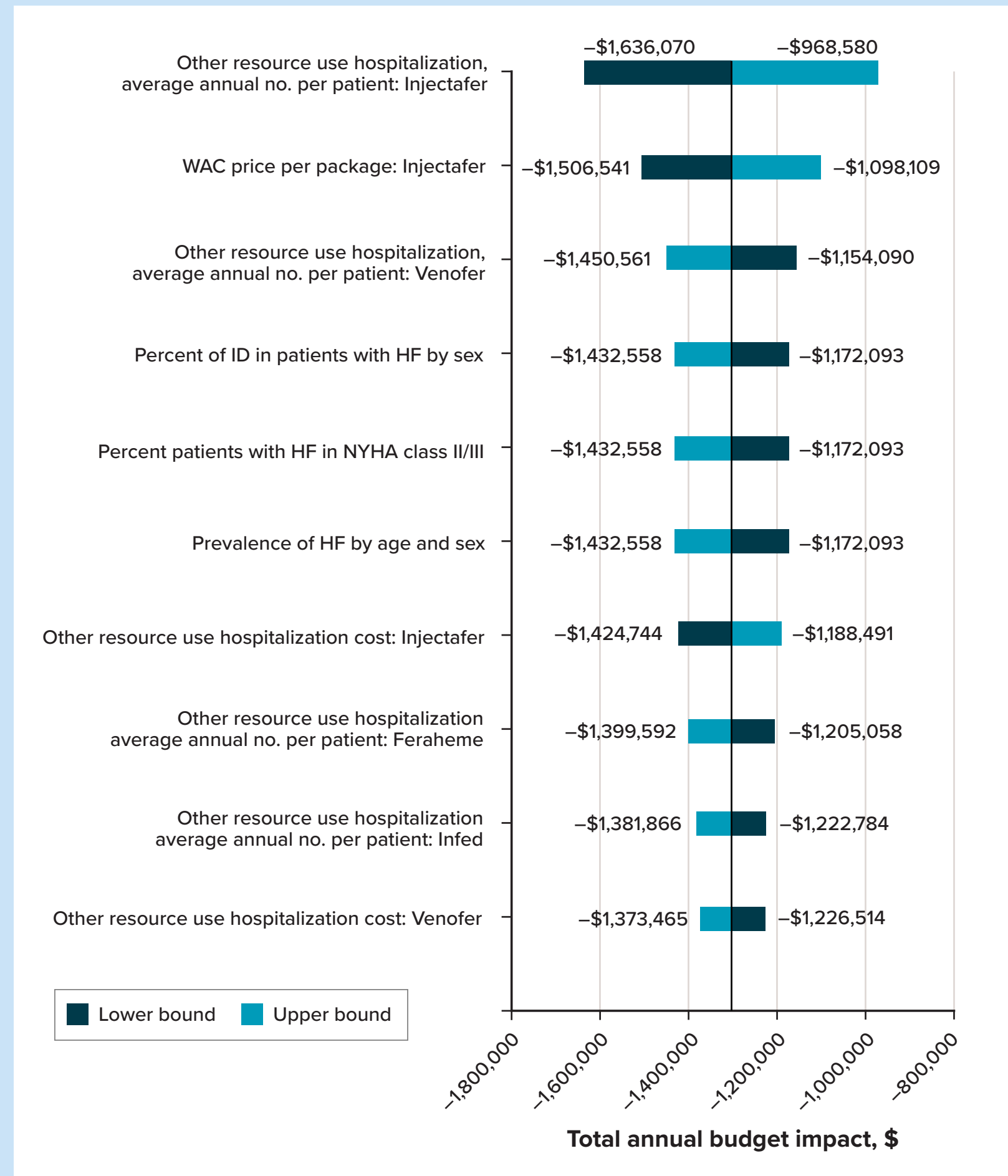
Figure 3. PMPM Annual Healthcare Plan Costs



Sensitivity Analysis

- The model results in the 1-way sensitivity analysis were robust to reasonable changes in model parameters (Figure 4). Key inputs were varied by ± 10% in a 1-way sensitivity analysis. The tornado diagram shows that model results were most sensitive to the average number of non-AE-related hospitalizations per patient on Injectafer and per patient on Venofer and to WAC price per package for Injectafer.

Figure 4. One-Way Sensitivity Analysis: Tornado Diagram

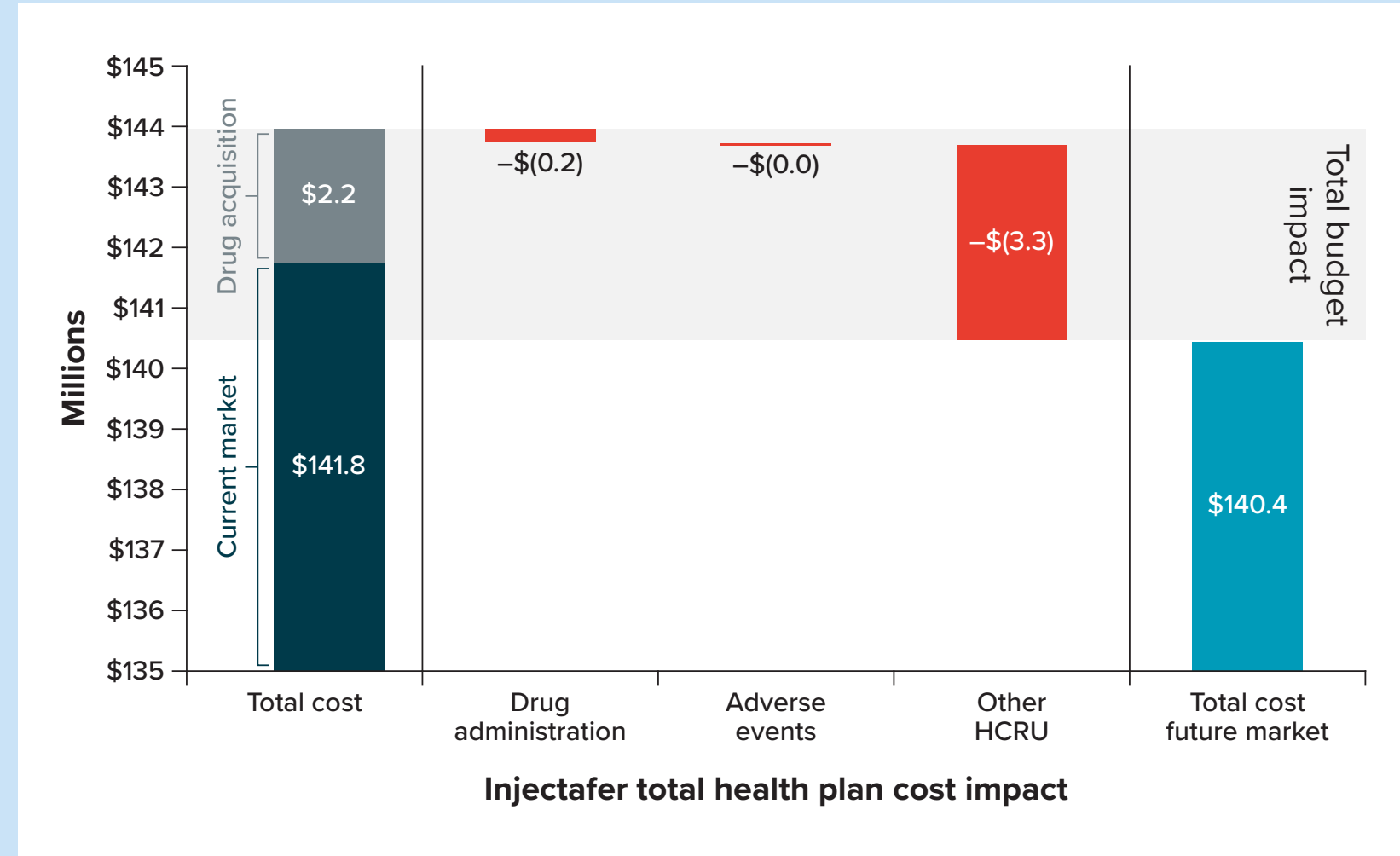


- Majority (93.1%) of decreased costs was attributable to reduction in other HCRU (Figure 3 and Figure 5).

LIMITATIONS

- As with all models, there are limitations that should be recognized because they may impact the analysis results.
 - Injectafer's market uptake is projected, and these values are yet to be confirmed by market performance data.
 - Due to lack of data, the prevalence of HF for patients aged 18 to < 40 years is parameterized with data from patients aged 20 to 39 years, and the prevalence for patients aged 60 to < 65 years and 65 to < 80 years is parameterized with data from patients aged 60 to 79 years.
 - The base-case costs of non-AE-related HCRU were assumed to be equal to that of low-dose IV iron for all other treatments except Feraheme.

Figure 5. Total Budget Impact



CONCLUSIONS

The expansion of ferric carboxymaltose injection's indication to include the treatment of ID in adult patients with HF and who are in NYHA class II/III to improve exercise capacity would result in **cost reductions** for a third-party US payer due to reduced costs from hospitalizations and ED visits related to worsening HF.

CONTACT INFORMATION

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Supplemental Tables for Budget impact of Injectafer (Ferric Carboxymaltose Injection) for the Treatment of Iron Deficiency in Adult Patients With Heart Failure and New York Heart Association Class II/III to Improve Exercise Capacity on a Third-Party US Payer

Supplemental Table 1. Model Inputs: Target Patient Population Estimates for Patient Funnel

Input	Value
Plan size ^a	1,000,000
Percentage of total plan population by age, %⁴	
18 to < 40 years	20.8
40 to < 60 years	17.4
60 to < 65 years	4.4
65 to < 80 years	32.6
≥ 80 years	9.6
Percentage female by age, %⁴	
18 to < 40 years	49.0
40 to < 60 years	49.9
60 to < 65 years	51.2
65 to < 80 years	53.4
≥ 80 years	61.1
Input	Value
Prevalence of HF by age and sex, %⁵	
Females	
18 to < 40 years	0.4
40 to < 60 years	1.2
60 to < 65 years	4.3
65 to < 80 years	4.3
≥ 80 years	10.9
Males	
18 to < 40 years	0.4
40 to < 60 years	2.3
60 to < 65 years	7.5
65 to < 80 years	7.5
≥ 80 years	7.1
Percentage of ID in patients with HF by sex, %²	
Females	32.0
Males	45.9
Percentage of patients with HF and who are in NYHA class II/III, % ³	87.5
Total eligible population, calculated	11,828

HF = heart failure; ID = iron deficiency; NYHA = New York Heart Association; US = United States.

^a Assumption.

Supplemental Table 2. Market Shares

Treatment, %	Scenario 1: Market without Injectafer with HF indication		Scenario 2: Market with Injectafer with HF indication	
	2024	2025	2024	2025
Injectafer	21.6	21.6	31.6	41.6
Feraheme^a	15.8	15.8	13.8	11.8
Monofer^a	4.8	4.8	4.2	3.6
Venofer	28.7	28.7	25.0	21.4
INFeD	15.4	15.4	13.4	11.5
Ferrlecit	10.6	10.6	9.2	7.9
No IV iron	3.1	3.1	2.7	2.3

HF = heart failure; IV = intravenous.

^a The market share for Feraheme is distributed between branded Feraheme and its generic version ferumoxylol based on the brand versus generic split.⁷

Source: DSI data on file.⁶

Supplemental Table References: 2. Klip IT, et al. Am Heart J. 2013 Apr;165(4):575-82.e3. doi:10.1016/j.ahj.2013.01.017. | 3. Greene SJ, et al. JAMA Cardiol. 2021 May 1;6(5):522-31. doi:10.1001/jamacardio.2021.0372. | 4. US Census Bureau. <https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html>. | 5. AHA. American Heart Association. Circulation. Chart 22-3. <https://www.ahajournals.org/doi/epdf/10.1161/CIR.0000000000001123> | 6. DSI data on file. Market share data. 2023. | 7. DSI data on file. Patient Responsibility and Feraheme Brand/Generic Split. 2023.