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Impact of Formulary Adoption of Sacubitril/Valsartan on Medication Uptake and Adherence Among Medicare Patients with Chronic Heart Failure

Christine Ferro,[1] Gabriela Dieguez,[1] Melissa Caplen,[1] Cindy Nguyen,[2] Xian Shen[2]

[1]Milliman USA, New York, NY, United States. [2]Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States.

KEY POINTS

1. **Patients with chronic heart failure in plans that added formulary coverage of sacubitril/valsartan (SAC/VAL) in March 2016 reported higher SAC/VAL uptake than patients in plans where SAC/VAL was not covered on formulary throughout the analysis period.**
2. **Proportion of days covered (PDC) for SAC/VAL and overall use of RAASis did not appear to be impacted by the formulary change for up to 18-months post-index.**

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INTRODUCTION

- Sacubitril/Valsartan (SAC/VAL) is guideline recommended as the first-choice renin-angiotensin-aldosterone system inhibitor (RAASi) over angiotensin converting enzyme inhibitors (ACEi) for patients with chronic heart failure (CHF) with reduced ejection fraction and New York Heart Association Class II-III symptoms.[1]
- SAC/VAL was approved by the Food and Drug Administration (FDA) in July of 2015, with many Medicare Part D plans adding SAC/VAL to their formulary in March 2016.

OBJECTIVE

- To assess impacts of formulary adoption of SAC/VAL on 1) uptake and adherence of SAC/VAL, and 2) overall utilization of RAASi in Medicare patients with CHF.

METHODS

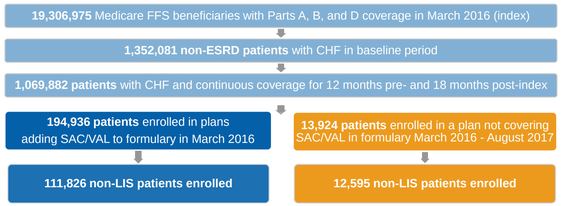
STUDY DESIGN

- A retrospective claims analysis using the Centers for Medicare & Medicaid Services (CMS) Medicare research identifiable files data, which included Medicare fee-for-service (FFS) beneficiaries with continuous enrollment of Parts A, B, and D from 12 months prior (baseline) through 18 months post formulary adoption (index).

STUDY POPULATION

- Formulary coverage of SAC/VAL was determined using CMS's Medicare Part D Formulary Files. The timing of changes in coverage was empirically determined by analyzing the mode copay for SAC/VAL.
- Patients with CHF were defined as those with one or more inpatient, or two or more outpatient, professional, or emergency department evaluation and management services in different dates reporting an ICD-CM diagnosis code for heart failure in a primary position on the claim over March 2015 – February 2016.
- Patients were excluded if they were enrolled in employer group waiver plans as their formulary coverage was not available from the publicly available CMS files and if original Medicare eligibility was due to End Stage Renal Disease (ESRD).
- To control for patient selection, analysis was limited to non-low-income subsidy (LIS) patients for the entire analysis period pre- and post-index.

Figure 1. Patient identification flow chart



- We divided patients with CHF into two cohorts:
  - Patients enrolled in Medicare Part D Plans (PDPs) that adopted SAC/VAL on their formularies at Tier 3 (preferred brand) with a prior authorization requirement in March 2016 (index).
  - Patients enrolled in PDPs with no coverage of SAC/VAL on their formularies throughout the study period.

UTILIZATION METRICS

- SAC/VAL uptake was measured as the number of patients per 1,000 with at least 30 days supply of SAC/VAL in the 6, 12, and 18 months post-index, with no SAC/VAL scripts in the baseline period.
- SAC/VAL adherence was measured as the proportion of days covered (PDC) in the 12 months starting with the first SAC/VAL script identified among patients with a first SAC/VAL script in the 6 months post-index.
- RAASi utilization was measured as the percent of patients with at least 30 days supply of SAC/VAL, angiotensin-converting enzyme inhibitors (ACEi), or angiotensin II receptor blockers (ARB) in the 18 months post-index.

STATISTICAL TESTING

- A chi-square test of independence was used to test for the statistical significance of differences in SAC/VAL uptake and in RAASi use.
- A student t-test was used to test for the statistical significance of differences in the mean SAC/VAL PDC.

RESULTS

BASELINE CHARACTERISTICS

- Both groups had comparable demographic and risk profiles, as measured by the absolute value of standardized differences (< 0.21), and similar rates of baseline comorbidities related to CHF (< 0.10) **(Table 1)**

Table 1. Baseline characteristics

	Plans Not Covering SAC/VAL	Plans Adding SAC/VAL to Formulary	Standardized Differences
Patients in Group	12,595	111,826	
Cohort Demographics			
Average/Median Age	81/81	79/79	-0.21
Gender - % Female	53%	52%	-0.03
Average/Median Medicare Risk Score	2.33/1.99	2.19/1.88	-0.10
Comorbidity Rates (% of patients in baseline year)			
Diabetes Mellitus	38%	38%	0.01
Hypertension	91%	90%	-0.02
Atrial fibrillation/flutter	53%	49%	-0.06
Ischemic heart disease	59%	60%	0.02
Stroke	17%	16%	-0.04
Dyslipidemia	70%	69%	-0.04
Renal disease	25%	23%	-0.05
COPD	28%	29%	0.02
Sleep apnea	15%	16%	0.04
Anemia and iron deficiency	19%	17%	-0.06
Heart Failure Treatment Rates (% patients in baseline year)			
SAC/VAL (30+ days supply)	0.3%	0.1%	-0.03
RAASi (30+ days supply)	64%	66%	0.04
ICD/pacemaker	28%	28%	0.01

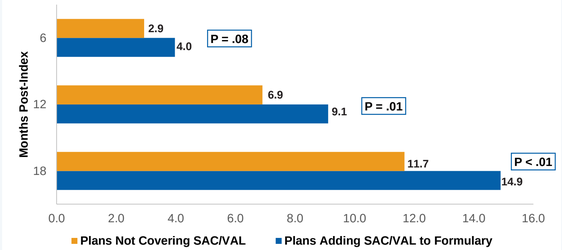
Note: SAC/VAL = sacubitril/valsartan; COPD=chronic obstructive pulmonary disease; RAASi = renin-angiotensin-aldosterone system inhibitor; ICD = implantable cardioverter defibrillator

- Treatment of CHF in the baseline period (March 2015-February 2016) was similar across cohorts:
  - 64% of patients in plans not adding SAC/VAL to formulary and 66% of patients in plans adding SAC/VAL had at least 30 days supply of a RAASi, and 28% in each group had an implantable cardioverter defibrillator (ICD)/pacemaker.
  - Only 0.1% of patients in plans adding SAC/VAL to formulary and 0.3% of patients in plans not covering SAC/VAL had at least 30 days supply of SAC/VAL, as SAC/VAL was approved partway into the period. **(Table 1)**

POST-INDEX UTILIZATION

- SAC/VAL uptake rate per 1,000 patients was 35%, 32%, and 28% higher for patients enrolled in plans adding SAC/VAL to formulary than for patients enrolled in plans not covering SAC/VAL at 6-, 12-, and 18-months post-index, respectively (p-values: .08, .01, <.01). **(Figure 2)**

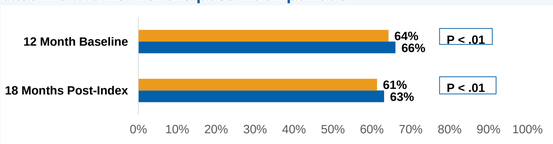
Figure 2. Cumulative new SAC/VAL users per 1,000 CHF patients



Note: SAC/VAL = sacubitril/valsartan; CHF = chronic heart failure
P-values were calculated using a chi-square test of independence. These values measure statistical significance of differences found between plans adding SAC/VAL to formulary and plans not covering SAC/VAL on formulary.

- Mean 12-month SAC/VAL PDC for new users was similar between the plans adding SAC/VAL to formulary (0.72) and plans not covering SAC/VAL (0.70) (p-value: 0.72).
- Plans adding SAC/VAL to formulary reported a higher rate of RAASi use in both baseline and post-index time periods compared to plans not covering SAC/VAL. (p-value: < .01) **(Figure 3)**
  - The rate change from baseline to post-index period was consistent across cohorts: from 66% to 63% and from 64% to 61%, respectively.

Figure 3. Percent of patients with 30+ Days supply of RAASi in the baseline and 18 months post-index periods



Note: RAASi = renin-angiotensin-aldosterone system inhibitor
P-values were calculated using a chi-square test of independence. These values measure statistical significance of differences found between plans adding SAC/VAL to formulary and plans not covering SAC/VAL on formulary.

LIMITATIONS

- This analysis was limited to patient characteristics/outcomes that can be measured using administrative claims data. Data collected for administrative purposes may contain inaccuracies or be subject to miscoding, which might introduce noise or bias.
- Measures of drug use were based on prescription fills and not actual use.
- Patterns observed in the Medicare FFS Part D population with heart failure may not be generalizable to other disease populations or payer segments.
- This analysis was based on the years immediately following FDA approval of SAC/VAL. Formulary coverage/use has changed substantially in more recent years.

CONCLUSIONS

- **SAC/VAL uptake after March 2016 among patients with chronic heart failure was higher within plans that added formulary coverage of SAC/VAL than within plans that did not cover SAC/VAL throughout the study period.**
- **PDC rates for SAC/VAL were not significantly different between plans adding SAC/VAL to the formulary and plans not covering SAC/VAL.**
- **Overall use of RAASi was higher in plans adding SAC/VAL to the formulary compared to plans not covering SAC/VAL, with a consistent difference between baseline and post-index periods.**
- **Further research is needed to determine the impact of other changes in formulary coverage of SAC/VAL on patients with CHF, such as down tiering and removing a prior authorization requirement.**

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DISCLOSURES: CN and XS are employees of Novartis Pharmaceuticals Corporation.
CF, GD, and MC are employees of Milliman and received consulting fees from Novartis Pharmaceuticals Corporation.

REFERENCES: [1] Heidenreich PA, Bozkurt B, Aguilar D, Allen LA, Byun JJ, Colvin MM, Deswal A, Drazner MH, Dunlay SM, Evers LR, Fang JC, Fedson SE, Fonarow GC, Hayek SS, Hernandez AF, Khazanie P, K ittleson MM, Lee CS, Link MS, Milano CA, Nnacheta LC, Sandhu AT, Stevenson LW, Vardeny O, Vest AR, Yancy CW. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145. Available at https://www.ahajournals.org/doi/epdf/10.1161/CIR.0000000000001063 . (Accessed April 13, 2022.)