IMPACT OF THE EXPANDED HEART FAILURE INDICATION FOR EMPAGLIFLOZIN ON THE PERFORMANCE OF MEDICARE STAR RATINGS DIABETES MEDICATIONS ADHERENCE MEASURE

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Background

- Sodium-glucose transport protein 2 (SGLT-2) inhibitors are a class of prescription medication FDA-approved in 2013 for management of type 2 diabetes (DM) and serve as second-line treatment. The mechanism of action of this drug class involves the inhibition of SGLT2 to assist in glucose reabsorption and increased glucose excretion.[1]
- SGLT-2 inhibitors have shown potential benefits in the 3-point major adverse cardiovascular event outcomes and renal benefits.[2] On August 18, 2021, empagliflozin was approved by the FDA to reduce cardiovascular death and hospitalization for adult patients with heart failure (HF) with reduced ejection fraction.[3]
- Type 2 DM has a high prevalence in the US, and about 27.5% of Medicare beneficiaries had diabetes in 2019.[4] In an effort to improve adherence to diabetes medication use in this population, the Centers for Medicare & Medicaid Services (CMS) implemented a Medication Adherence for Diabetes Medications Star Rating measure for Medicare beneficiaries.
- CMS defines the diabetes adherence measure as the percentage of members with a prescription for diabetes medication who fill their prescription often enough to cover 80% or more of the time they are supposed to be taking the medication.
- Existing literature does not demonstrate the impact of the expanded indication for any SGLT-2 inhibitor on the Medicare Star Ratings Medication Adherence for Diabetes Medications measure.

Objective

To identify and evaluate the impact of the expanded heart failure indication for empagliflozin on the performance of the Medicare Star Ratings diabetes medications adherence measure within a Medicare Advantage Prescription Drug Plan (MA-PD) population.

Methods

An observational cohort study design utilizing medical and pharmacy claims data from a large Medicare insurer was used in the study.

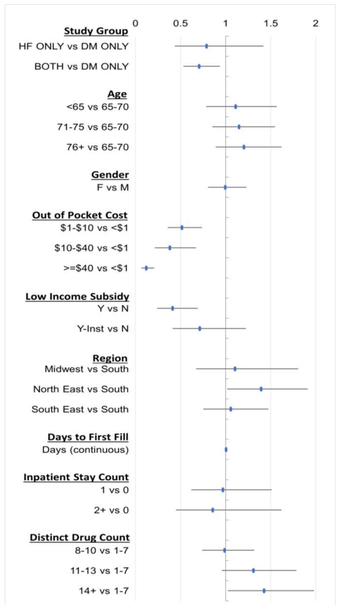
- MA-PD members were included if they were continuously enrolled within the cohort timeframe, defined as follows:
  - Baseline Year: August 18, 2020 – August 17, 2021
  - Study Period: August 18, 2021 – June 17, 2022
- The baseline period was chosen based on one year prior to the heart failure approval date of empagliflozin, and the study period spans the 10 most recent months following approval date.
- Inclusion Criteria:
  - At least 2 or more prescription fills of empagliflozin during the study period
  - Diagnosis of DM or HF, or both in either the baseline or study period
- Exclusion Criteria:
  - End-stage renal disease (ESRD)
  - Hospice
  - 1 or more prescription fills of insulin
  - Members with fewer than a 90 day study period
- The primary endpoint of this study was whether a member's proportion of days covered (PDC) was at least 80%, an indication of medication adherence.
- Chi-Square tests were used to determine differences in proportions for categorical variables between study groups.
- The likelihood of being adherent (Y/N) for the three study groups was assessed using multivariate logistic regression, adjusting for the independent variables described above.
- Statistical significance was defined by $p < 0.05$.

Results

Table 1: Member Characteristics

	Heart Failure Only	Diabetes Only	Both Heart Failure & Diabetes	p-value
Age, Years (N, %)				
<65	13 (16.67)	377 (20.28)	56 (12.99)	0.5042
65-70	6 (7.69)	376 (20.23)	69 (16.01)	
71-75	21 (26.92)	566 (30.45)	133 (30.86)	
76+	38 (48.72)	540 (29.05)	173 (40.14)	
Gender				
Female	40 (51.28)	943 (50.73)	204 (47.33)	0.4370
Male	38 (48.72)	916 (49.27)	227 (52.67)	
Receiving LIS? (N, %)				
Yes	10 (12.82)	314 (16.89)	104 (24.13)	0.0023
No	46 (58.97)	894 (48.09)	189 (43.85)	
Yes - Institutionalized	22 (28.21)	651 (35.02)	138 (32.02)	
Out-of-pocket Cost (N, %)				
<$1	18 (23.08)	441 (23.72)	133 (30.86)	0.0070
$1-$10	19 (24.36)	586 (31.52)	112 (25.99)	
$10-$40	13 (16.67)	340 (18.29)	62 (14.39)	
>=$40	28 (35.90)	492 (26.47)	124 (28.77)	
CMS Contract by Region (N, %)				
Midwest	9 (11.54)	105 (5.65)	23 (5.34)	0.0009
North East	14 (17.95)	332 (17.86)	110 (25.52)	
South	42 (53.85)	1234 (66.38)	256 (59.40)	
South East	13 (16.67)	188 (10.11)	42 (9.74)	
Distinct Generic Drug Count (N, %)				
1-7	14 (17.95)	405 (21.79)	35 (8.12)	<0.0001
8-10	22 (28.21)	586 (31.52)	69 (16.01)	
11-13	26 (28.21)	469 (25.53)	135 (31.32)	
14+	16 (20.51)	399 (21.46)	192 (44.55)	
Inpatient Visit (N, %)				
0	65 (83.33)	1752 (94.24)	346 (80.28)	<0.001
1	5 (6.41)	88 (4.73)	50 (11.60)	
2+	8 (10.26)	19 (1.02)	35 (8.12)	
Mean PDC (%)	87.9	87.8	87.5	0.939
Mean days to start	137.192	85.113	99.287	<0.001
Mean distinct generic drug count	11.000	10.721	13.258	<0.001
Adherent (N, %)				
Yes	61 (78.21)	1441 (77.51)	323 (74.94)	0.5042
No	17 (21.79)	418 (22.49)	108 (25.06)	

Figure 1: Logistic Regression Model: Odds Ratio for Adherence {Y/N}



- In total, 1,859 members met the criteria for DM only, 78 members met the criteria for HF only and 431 met the criteria for both conditions.
- Demographic characteristics for age and gender were generally similar between the HF Only, DM Only , and Both groups, but statistically significant differences existed for low income subsidy (LIS) status, out-of-pocket cost, region, distinct generic drug count, number of inpatient visits, and days to start therapy.
- In the unadjusted analysis, adherence to empagliflozin was not statistically different between disease study groups.
- In the adjusted analysis, although there continued to be no statistically significant difference in adherence to empagliflozin between the HF only and DM only groups (p=0.4253), there was a significant likelihood of members with both HF and DM to be less adherent to empagliflozin vs DM only (p=0.0138).
- Empagliflozin users were less likely to be adherent when out-of-pocket costs were higher. Members were 48.5% less likely to be adherent when out-of-pocket costs were between $1 and $10 vs $1 (p = 0.0002), 61.8% less likely to be adherent between $10 and $40 vs $1 (p = 0.0007), and 88.1% less likely to be adherent when costs were >$40 vs $1 (p <0.0001).
- Members who were eligible for LIS (who were not institutionalized in a long term care facility) were 58.8% less likely to be adherent to empagliflozin than those who were not eligible for LIS (p = 0.0007).
- The average days to start empagliflozin in HF only members was 137, which was significantly longer than the other 2 groups.
- Members taking 14 or more distinct generic medications were 42.6% more likely to be adherent to empagliflozin than those taking 1-7 distinct generic medications (p=0.0333).

Conclusions

- No significant differences were found in adherence for HF only members vs DM only members.
- The likelihood of members being adherent to empagliflozin was significantly decreased as out-of-pocket costs increased. Therefore, health plans should carefully consider the member out-of-pocket cost share for empagliflozin.
- It was unexpected that members with the highest distinct number of therapies had an increased likelihood of adherence. One possibility we propose is that some of these members were institutionalized and not fully accounted for in the model. Because medications are administered to the members, adherence is generally not a concern within this patient population.
- In summary, our findings suggest that the new HF indication for empagliflozin should have limited impact on the CMS Stars diabetes adherence measure.

Limitations

- There were a small number of HF only members who were eligible for the study criteria, potentially due to lag period of empagliflozin prescription for HF indication after approval. This was further evidenced by the longer days to start following the beginning of the study period for HF only members.
- Due to the recent approval of empagliflozin for HF, the study period was not able to capture a full year, compared to a more conventional one year adherence observation period.

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