# Economic Impact of Delayed Access to Finerenone Due to Formulary Restrictions in Chronic Kidney Disease (CKD) and Type 2 Diabetes (T2D)

Poster EE87

**Jacob Earl,[1]* Brian Hocum,[1] Keith A. Betts,[2] Aozhou Wu,[2] Arvind Katta,[1] Travis Wang,[2] Mauricio Ferri,[1] Zihe Zheng,[1] Yunxun Wang,[1] Jon Mares,[1] Diana I. Brixner[3]**

[1] Bayer, Whippany, NJ, USA; [2]Analysis Group, Inc., Boston, MA, USA; [3] Department of Pharmacotherapy, University of Utah College of Pharmacy, Salt Lake City, UT, USA
* Presenting author

## Objective

- **To evaluate healthcare costs and HRU associated with delayed finerenone access for patients with CKD and T2D.**

## Conclusions

- **Formulary policies, particularly prior authorization and non-formulary status, were key drivers of delayed finerenone access in patients with CKD and T2D.**
- **Delayed approval was associated with higher annual healthcare costs and increased outpatient visits, while inpatient and ED use remained similar, suggesting limited downstream cost offsets.**
- **These findings suggest that payers may consider re-evaluating restrictive coverage criteria for finerenone, as streamlining access could support guideline-concordant care without increasing total costs and may reduce avoidable outpatient burden.**

## Background

- Chronic kidney disease (CKD) is common and affects about one-third of patients with type 2 diabetes (T2D), which often necessitates intensive medical care and is associated with high healthcare expenditures.[1]
- Finerenone, a non-steroidal mineralocorticoid receptor antagonist (MRA), was approved by the US Food and Drug Administration (FDA) in July 2021[2] and is recommended by clinical guidelines for adults with CKD associated with T2D who are at high risk of CKD progression or cardiovascular events.[3,4]
- Despite guideline recommendations, prior authorization and formulary restrictions often delay or limit finerenone access,[5] which may worsen clinical outcomes and increase downstream healthcare resource utilization (HRU) and costs; however, the real-world economic impact of these delays is not well characterized.

## Methods

### Data source and study design

- This was a retrospective observational study using the Komodo Health administrative claims database from January 1, 2016, to June 30, 2024.
- Lifecycle pharmacy claims capture prescription and cost information as well as transaction status (e.g., "PAID", "REJECTED", "REVERSED") and associated rejection reasons (e.g., prior authorization).
- Eligible adult patients with T2D and CKD who received finerenone were classified into two cohorts based on the transaction results of the index finerenone prescription and subsequent finerenone claims (see **Figure 1**), with follow-up of up to 12 months after the index date.
  1) Timely approval and dispensation (Cohort 1)
  2) Delayed approval and dispensation after initial rejection (Cohort 2)

### Outcomes and statistical analysis

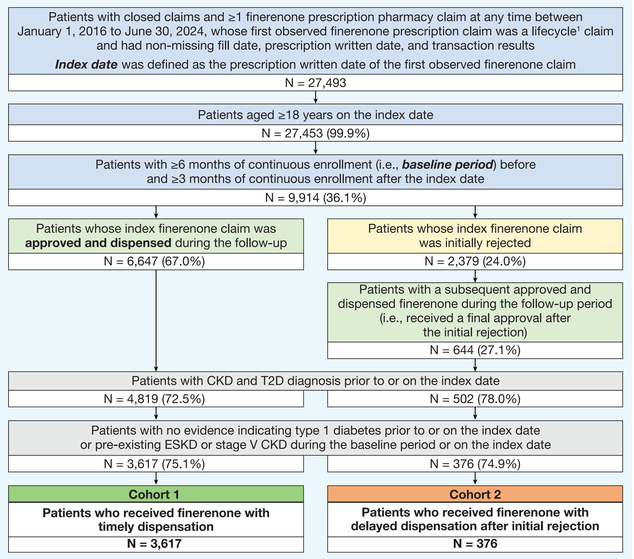
- Annual all-cause healthcare costs (total, medical, and pharmacy) were summarized per-patient-per-year (PPPY) and compared between the two cohorts using generalized linear models (GLMs) (Gaussian distribution, identity link) to estimate cost differences.
- Annual event rates of HRU outcomes (inpatient [IP], emergency department [ED], and outpatient [OP] visits) were summarized and compared using GLMs (Poisson distribution, log link), with event rate ratios reported.
- All GLMs adjusted for demographics, clinical characteristics, comorbidities, and baseline HRU and costs.
- Subgroup analyses were conducted to compare economic outcomes between Cohort 1 and two subgroups of Cohort 2: (1) shorter delay: <61 days (i.e., the median time of treatment delay) and (2) longer delay: ≥61 days.

## Results

### Key findings

- Delayed finerenone access due to formulary restrictions are not negligible and represent real-world access barriers.
- The observed patterns suggest that access barriers may shift spending toward outpatient care without overall cost reduction.
- Longer delays were associated with higher medical costs, driven primarily by outpatient care.

**Figure 1. Sample Selection Flow Chart and Cohort Identification Based on Index Finerenone Transaction Results**




**Abbreviations:** CKD, chronic kidney disease; ESKD, end-stage kidney disease; T2D, type 2 diabetes.
**Note:**
[1] A lifecycle claim refers to a prescription claim that is tracked across all stages of processing in the claims system, capturing all status changes from initial submission to final resolution. This may include submission to the pharmacy, transmission to the payer, rejections (e.g., due to prior authorization requirements), dispensing (if approved), and subsequent events such as reversals, refills, or other adjustments.

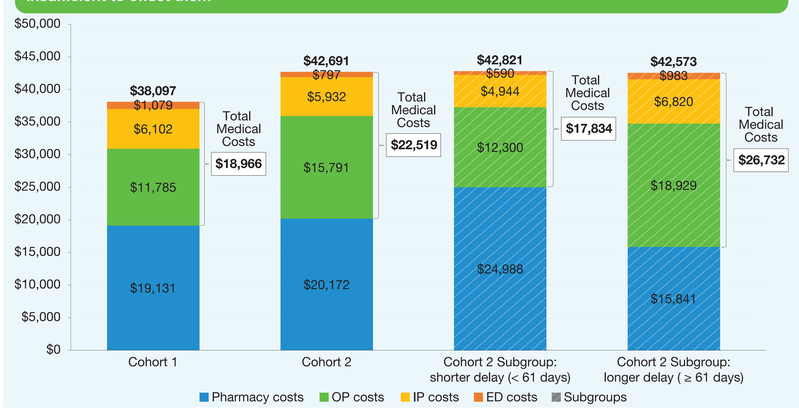
**Table 1. Baseline patient and prescription characteristics**

| | Cohort 1 (N=3,617) | Cohort 2 (N=376) |
|---|---|---|
| **Length of follow-up duration (months), mean ± SD** | 9.9 ± 2.9 | 10.5 ± 2.5 |
| **Demographic characteristics** | | |
| Age on the index date (years), mean ± SD | 67.4 ± 11.0 | 68.2 ± 11.0 |
| Sex, n (%) | | |
| Male | 2,013 (55.7) | 217 (57.7) |
| Female | 1,494 (41.3) | 152 (40.4) |
| Unknown | 110 (3.0) | 7 (1.9) |
| Insurance type, n (%) | | |
| Medicare | 2,086 (57.7) | 259 (68.9) |
| Commercial | 1,239 (34.3) | 83 (22.1) |
| Medicaid | 292 (8.1) | 34 (9.0) |
| **Index CKD stage, n (%)** | | |
| Stage 1 | 78 (2.2) | 7 (1.9) |
| Stage 2 | 315 (8.7) | 29 (7.7) |
| Stage 3 | 1,785 (49.4) | 195 (51.9) |
| Stage 4 | 431 (11.9) | 48 (12.8) |
| Unspecified | 159 (4.4) | 15 (4.0) |
| Missing | 849 (23.5) | 82 (21.8) |
| **All-cause healthcare costs (2024 USD), PPPM** | | |
| Total healthcare costs, mean ± SD | $2,520 ± $3,681 | $2,576 ± $4,115 |
| Total medical costs, mean ± SD | $1,449 ± $3,262 | $1,556 ± $3,532 |
| Total pharmacy costs, mean ± SD | $1,072 ± $1,568 | $1,020 ± $1,581 |
| **All-cause HRU, PPPM** | | |
| Number of IP admissions, mean ± SD | 0.02 ± 0.08 | 0.02 ± 0.07 |
| Number of ED visits, mean ± SD | 0.10 ± 0.47 | 0.09 ± 0.40 |
| Number of OP visits, mean ± SD | 2.83 ± 4.32 | 2.98 ± 4.58 |

**Abbreviations:** CI, confidence interval; CKD, chronic kidney disease; ED, emergency department; IP, inpatient; OP, outpatient; PPPM, per-patient-per-month; SD, standard deviation; USD, United States dollar.

**Figure 2. Annual healthcare costs among patients with timely (Cohort 1) and delayed (Cohort 2) finerenone approval, overall and by duration of delay[1] (2024 USD)**

**Delayed finerenone approval was associated with 12% higher total annual costs, driven primarily by outpatient medical spending; longer delays showed higher total medical costs with pharmacy savings insufficient to offset them**




**Abbreviations:** ED, emergency department; IP, inpatient; OP, outpatient; USD, United States dollar.
**Note:**
[1] The median time from prescription written to dispensation (access delay period) among patients in Cohort 2 was 61 days.

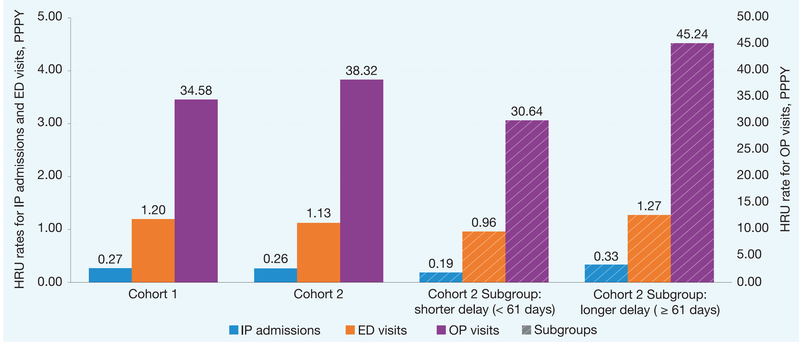
**Table 2. Adjusted comparison of annual all-cause healthcare costs between patients with timely (Cohort 1) and delayed (Cohort 2) finerenone approval, overall and by duration of delay[1]**

| | Cohort 2 vs. Cohort 1 (ref.) | | Cohort 2 subgroup: shorter delay vs. Cohort 1 (ref.) | | Cohort 2 subgroup: longer delay vs. Cohort 1 (ref.) | |
|---|---|---|---|---|---|---|
| **All-cause healthcare costs (2024 USD)** | **Adjusted cost difference (95% CI)** | **P-value** | **Adjusted cost difference (95% CI)** | **P-value** | **Adjusted cost difference (95% CI)** | **P-value** |
| **Total healthcare costs** | 3,947 (-3,354, 11,248) | 0.289 | 4,152 (-5,627, 13,931) | 0.405 | 3,677 (-6,798, 14,152) | 0.491 |
| Total medical costs | 3,129 (-3,317, 9,575) | 0.341 | -1,134 (-6,817, 4,548) | 0.696 | 7,175 (-3,894, 18,243) | 0.204 |
| IP admissions costs | -245 (-2,688, 2,197) | 0.844 | -1,025 (-4,500, 2,450) | 0.563 | 607 (-2,556, 3,770) | 0.707 |
| ED visits costs | -327 (-587, -66) | 0.014* | -506 (-780, -231) | <0.001* | -211 (-596, 174) | 0.282 |
| OP visits costs | 3,701 (-2,341, 9,742) | 0.230 | 396 (-4,020, 4,812) | 0.860 | 6,779 (-4,080, 17,638) | 0.221 |
| Total pharmacy costs | 818 (-2,438, 4,074) | 0.622 | 5,286 (-875, 11,447) | 0.093 | -3,498 (-5,889, -1,106) | 0.004* |

* p<0.05
**Abbreviations:** CI, confidence interval; ED, emergency department; IP, inpatient; OP, outpatient; USD, United States dollar.
**Note:**
[1] The median time from prescription written to dispensation (access delay period) among patients in Cohort 2 was 61 days.

**Figure 3. Annual healthcare resource utilization among patients with timely (Cohort 1) and delayed (Cohort 2) finerenone approval, overall and by duration of delay[1], PPPY**

**Delayed approval, particularly larger delay, was associated with more frequent outpatient visit, while inpatient and ED visits remained similar to timely approval**




**Abbreviations:** ED, emergency department; IP, inpatient; OP, outpatient, PPPY, per-person-per-year.
**Note:**
[1] The median time from prescription written to dispensation (access delay period) among patients in Cohort 2 was 61 days.

### Study population, baseline characteristics, and index finerenone prescription rejection reasons

- Among adult patients with a finerenone prescription (n = 9,914), about 24% experienced an initial rejection; of those, only 27% ultimately received finerenone (**Figure 1**).
- After applying the eligibility criteria, the final study sample included 3,993 patients (mean age 67.5 years), comprising 3,617 (90.6%) patients with timely approval of finerenone (Cohort 1) and 376 (9.4%) with delayed approval (Cohort 2) (**Figure 1**).
- CKD stage distribution was similar between cohorts, with most patients in stage 3 (Cohort 1: 49.4%; Cohort 2: 51.9%) (**Table 1**).
- Most reasons of initial rejections were formulary-related, including prior authorization (42%) and drug not on formulary (38%).

### All-cause healthcare costs and HRU

- Annual total all-cause healthcare costs were $4,594 higher among patients with delayed approval ($42,691) than among those with timely approval ($38,097) (**Figure 2**).
- After adjustment, delayed approval was associated with a numerically higher total healthcare costs compared with timely approval (adjusted cost difference [aCD] $3,947), mainly driven by OP medical costs (aCD: $3,701) (**Table 2**).
- Patients with delayed approval had a numerically higher rate of OP visits (38.3 vs. 34.6 visits PPPY) and similar IP admissions and ED visits rates compared with those with timely approval (**Figure 3**); adjusted rate ratios were not significantly different from 1.
- Although not statistically significant, the observed patterns suggest that access barriers may shift spending toward outpatient care rather than reduce overall utilization.

### Subgroup analysis

- Patients with shorter (<61 days) and longer (≥61 days) delays both incurred numerically higher costs (aCD $4,152 and $3,677, respectively) compared with timely approval; longer delays showing lower pharmacy costs but higher medical costs, with no net savings (**Table 2**).
- Longer delay was associated with numerically higher OP visit rate compared with timely approval (45.2 vs. 34.6 visits PPPY); IP admission and ED visit rates were comparable across Cohort 2 subgroups and Cohort 1 (**Figure 3**).

## Strengths

- Large, nationally representative claims database with detailed pharmacy transaction data from lifecycle claims enabled direct assessment of real-world finerenone access barriers and associated HRU and costs.

## Limitations

- Coding errors and incomplete claims data may lead to misclassification and missed finerenone use.
- Despite adjustment for key baseline characteristics, residual confounding may remain.
- Relatively short follow-up may limit assessment of evolving formulary restriction patterns and longer-term economic outcomes.

### References

1. Mullins CD et al. *Kidney Med.* 2022.
2. FDA. Kerendia® (finerenone) prescribing information. 2021.
3. Levin A et al. *Kidney Int.* 2024.
4. American Diabetes Association. *Diabetes Care.* 2022.
5. Hydery T, Reddy V. *JMCP.* 2024.

### Disclosures

Funding for this research was provided by Bayer, which also funded the development of the abstract; the study sponsor was involved in all stages of the study research and abstract preparation.

D.I.B. reports serving as a paid consultant for Sanofi and Tandem, and receiving a research grant through the University of Utah with Dexcom.

B.H., J.E., A.K., Z.Z., Y.W., and M.F. are employees of Bayer; J.M. was an employee of Bayer during the conduct of this study; K.A.B., A.W., and T.W. are employees of Analysis Group, Inc., a company that has provided paid consulting services to Bayer.

### Scan QR code to obtain a copy of the E-poster