Formulary Barriers to Accessing Finerenone for the Treatment of Chronic Kidney Disease (CKD) Associated with Type 2 Diabetes (T2D)

Poster Number 39

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

[1]Bayer U.S. LLC, Whippany, New Jersey, USA ; [2]Analysis Group, Inc., Boston, MA, USA; [3]Department of Pharmacotherapy, University of Utah College of Pharmacy

* Presenting author

Background

- Chronic kidney disease (CKD) is a major public health concern; approximately one in three adults with type 2 diabetes (T2D) develop CKD during their lifetime.[1]
- Finerenone, a non-steroidal mineralocorticoid receptor antagonist (MRA), was approved by the US Food and Drug Administration (FDA) on July 9, 2021 for the treatment of adults with CKD associated with T2D.[2] Clinical guidelines have recommended finerenone as a therapeutic option alongside angiotensin-converting enzyme inhibitors (ACEis)/ angiotensin receptor blockers (ARBs) and sodium-glucose cotransporter-2 inhibitors (SGLT2is) where appropriate to slow CKD progression.[3,4]
- Despite strong clinical evidence and guideline recommendations, real-world access to finerenone remains restricted by prior authorization and formulary exclusions, which often limit or delay finerenone use for clinically eligible patients.[5,6]
- These access delays may prolong exposure to suboptimal therapy and contribute to worse kidney and cardiovascular outcomes and higher healthcare costs; however, real-world evidence on finerenone access and associated barriers remains limited.

Objective

- To characterize real-world patterns of finerenone access, formulary barriers, and associated rejection reasons to inform optimization of care among patients with CKD and T2D in the United States.

Methods

Data source

- This was a retrospective observational study using the Komodo Research Data (KRD+) administrative claims database from January 1, 2016, to June 30, 2024.
  - The database is nationally representative and integrates de-identified medical, pharmacy, and laboratory claims for >330 million US enrollees.
  - Lifecycle pharmacy claims are available and capture the full sequence of transactions for a prescription, including statuses (e.g., "PAID," "REJECTED," "REVERSED") and associated rejection reasons (e.g., prior authorization).

Study design and sample selection

- Adult patients with at least one finerenone pharmacy claim were identified and classified into four cohorts based on the transaction results of the first finerenone prescription's lifecycle claims:
  - (1) Timely approval and dispensation (Cohort 1)
  - (2) Delayed approval and dispensation after initial rejection (Cohort 2)
  - (3) Abandonment of an approved prescription (Cohort 3)
  - (4) Rejection with no subsequent approval (Cohort 4)
- The index date was defined as the prescription written date of the first recorded lifecycle pharmacy claim for finerenone. The baseline period comprised the 6 months prior to the index date; the follow-up period extended from the index date to the earliest of death, end of continuous enrollment, end of data availability.

Outcomes and statistical analysis

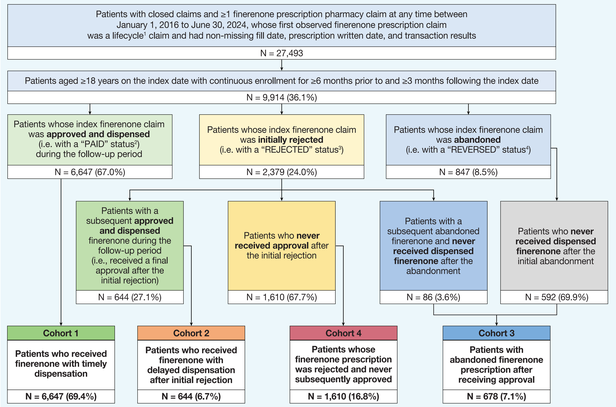
- Approval status was assessed for the index finerenone claim and described overall and by calendar year (2021-2024).
- Rejection reasons associated with the index finerenone claim were summarized descriptively among patients with rejected finerenone prescriptions (i.e., Cohort 2 and Cohort 4) overall and by calendar year (2021-2024).
- Time from prescription written to dispensation was defined as time (in days) from the prescription written date to the fill date of the index finerenone prescription and summarized descriptively among patients who eventually received finerenone (i.e., Cohort 1 and Cohort 2).

Results

Patient baseline characteristics

- The study included 9,579 adult patients prescribed finerenone. Among them, 6,647 (69.4%) received timely dispensation (Cohort 1), 644 (6.7%) experienced delayed dispensation (Cohort 2), 678 (7.1%) abandoned the approved prescription (Cohort 3), and 1,610 (16.8%) never received approval (Cohort 4) (**Figure 1**).
- In the overall population, the mean (SD) age at index was 65.5 (11.9) years, and 55.9% were male. Approximately 54% of patients were enrolled in Medicare, with the highest proportion observed in Cohort 3 (76.8%).
- Among patients who received a finerenone prescription and had a documented CKD stage, the majority had stage 3 CKD (65.1%) at index, representing the largest proportion of treated patients, followed by stage 1/2 (17.5%) and stage 4 (17.5%).
- Baseline CKD-related treatments included ACEi/ARBs (75.7%), SGLT2i (40.2%), glucagon-like peptide-1 receptor agonists (32.7%), and steroidal MRAs (6.3%).

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



Notes:
[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.
[2] Finerenone claims with a "PAID" status indicate that the finerenone prescription was approved and dispensed.
[3] Finerenone claims with a "REJECTED" status indicate that the finerenone prescription was rejected and not dispensed.
[4] Finerenone claims with a "REVERSED" status indicate that the prescription was approved but ultimately not picked up by the patient.

Finerenone prescription characteristics and treatment patterns (Table 1)

- About 44.7% of finerenone prescriptions were written by primary care physicians (PCPs) or internists, followed by nephrologists (30.1%), and endocrinologists (9.0%).
- The most common index finerenone dose was 10 mg (81.6% overall), with a slightly lower proportion seen in Cohort 2 (77.5%).
- The median time to finerenone discontinuation was 7.8 months, which was slightly longer in Cohort 2 (8.9 months) than Cohort 1 (7.6 months).

Table 1. Finerenone Prescription Characteristics and Treatment Patterns

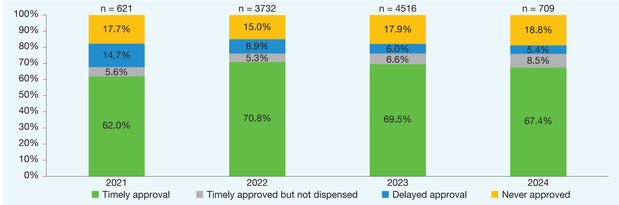
	Overall (N=9,579)	Cohort 1 (N=6,647)	Cohort 2 (N=644)	Cohort 3 (N=678)	Cohort 4 (N=1,610)
Prescriber specialty for index finerenone, *n* (%)					
Primary care physicians (PCP) or internists	4,280 (44.7)	2,877 (43.3)	284 (44.1)	286 (42.2)	833 (51.7)
Nephrologists	2,886 (30.1)	2,120 (31.9)	205 (31.8)	216 (31.9)	345 (21.4)
Endocrinologists	863 (9.0)	611 (9.2)	47 (7.3)	68 (10.0)	137 (8.5)
Cardiologists	236 (2.5)	145 (2.2)	22 (3.4)	22 (3.2)	47 (2.9)
Nurse practitioner or physician assistant	618 (6.5)	436 (6.6)	25 (3.9)	52 (7.7)	105 (6.5)
Other	624 (6.5)	410 (6.2)	49 (7.6)	34 (5.0)	131 (8.1)
Missing	72 (0.8)	48 (0.7)	12 (1.9)	0 (0.0)	12 (0.7)
Starting dose of index finerenone, n (%)					
10 mg	5,952 (81.6)	5,453 (82.0)	499 (77.5)	-	-
20 mg	1,339 (18.4)	1,194 (18.0)	145 (22.5)	-	-
Median time to finerenone discontinuation (months) [95% CI]	7.8 [7.3, 8.2]	7.6 [7.0, 8.0]	8.9 [8.0, 10.1]	-	-

Abbreviations: CI, confidence interval.

Finerenone approval status and rejection reasons

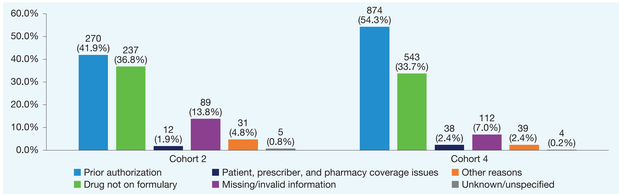
- From 2021 to 2024, the proportions of patients with timely approved and never approved finerenone prescriptions remained relatively stable (**Figure 2**).
  - The percentage of patients experiencing delayed dispensation due to initial rejection decreased from 14.7% in 2021 to 5.4% in 2024 (**Figure 2**).

Figure 2. Approval Status for the Index Finerenone Claim, 2021-2024



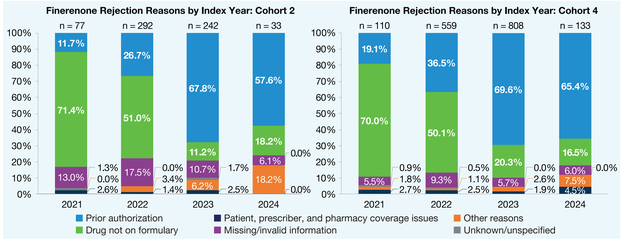
- In Cohort 2 and 4, the leading rejection reasons were prior authorization and drug not on formulary. Among index prescriptions rejected due to prior authorization and drug not on formulary, only 23.6% and 30.4% were subsequently approved (**Figure 3**).

Figure 3. Rejection Reasons for the Index Finerenone Claim Among Patients in Cohort 2 and 4



- Over time, the most common rejection reason in both Cohort 2 and 4 changed from drug not on formulary to prior authorization (**Figure 4**).

Figure 4. Rejection Reasons for the Index Finerenone Claim Among Patients in Cohort 2 and 4 by Index Year



Conclusions

- **Formulary restrictions, particularly prior authorization requirements, remain barriers to finerenone access among patients with CKD associated with T2D, highlighting ongoing administrative and coverage-related challenges despite growing clinical adoption.**
- Patients who received a prescription for finerenone experienced rejection reasons which changed over time. This research underscores the need for careful evaluation of managed care coverage policies, including prior authorization requirements, and their impact on clinical and economic outcomes.
- Future studies should evaluate the potential impact of finerenone access barriers on clinical outcomes and healthcare spending in the CKD and T2D population.

Time from prescription written to dispensation

- The mean (SD) time from the finerenone prescription written to dispensation was 11.3 (33.2) days in Cohort 1 and 101.2 (126.1) days in Cohort 2.
- Within Cohort 2, the longest time from prescription to dispensation occurred among patients whose finerenone prescriptions were rejected because the drug was not on formulary, with a mean delay of 138.4 (156.4) days. Patients whose finerenone was rejected due to prior authorization had an average delay of 84.6 (95.7) days (**Table 2**).

Table 2. Time from Prescription Written to Dispensation Among Cohort 2 by Rejection Reasons

	Cohort 2 (Patients with delayed dispensation of finerenone) (N=644)
Time from prescription written to dispensation (days), mean ± SD [median]	
Prior authorization	84.6 ± 95.7 [45.5]
Drug not on formulary	138.4 ± 156.4 [85.0]
Patient, prescriber, and pharmacy coverage issues	60.9 ± 71.9 [47.0]
Missing/invalid information	80.4 ± 120.2 [31.0]
Other reasons	44.8 ± 53.3 [23.0]
Unknown/unspecified	44.8 ± 36.6 [36.0]

Abbreviations: SD, standard deviation.

Strengths

- This study leveraged a large, nationally representative claims database with detailed pharmacy transaction data, enabling direct assessment of real-world finerenone access, formulary barriers, and rejection reasons that are often unavailable in traditional claims datasets.

Limitations

- Results are subject to potential misclassification and measurement error due to reliance on administrative claims data, including diagnosis coding, CKD staging, finerenone transaction results, and rejection reasons.
- Medical services, laboratory tests, or prescriptions obtained outside of the health plan may not be captured; however, use of closed claims likely minimizes missing data.
- The post-approval follow-up period only extended through June 2024, which may restrict the ability to evaluate the impact of evolving formulary restriction patterns over time.

References

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Disclosures

Funding for this research was provided by Bayer U.S. LLC. (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.B.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.

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