REAL WORLD ECONOMIC BURDEN AND TREATMENT PATTERNS IN IDIOPATHIC PULMONARY FIBROSIS: UNDERUTILIZATION OF GENERIC PIRFENIDONE DESPITE LOWER COST BURDEN - A RETROSPECTIVE U.S. CLAIMS STUDY

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SUMMARY

Idiopathic pulmonary fibrosis (IPF) is a rare and life-threatening condition leading to a progressive decline in lung function.

The U.S. Food and Drug Administration (FDA) has approved two branded antifibrotic drugs, Ofev (nintedanib) and Esbriet (pirfenidone), which slow the progression of IPF when taken as recommended, as shown in clinical trials and real-world studies. Generic pirfenidone was approved in 2022.

Comparative studies suggest that Ofev and pirfenidone have broadly similar effectiveness in slowing IPF progression; however, both assets have seen limited uptake to date, potentially due to high out-of-pocket costs and AEs.

This study providers further evidence that most IPF patients today remain untreated and finds that generic pirfenidone saw less uptake than Ofev despite lower associated costs and similar healthcare resource utilization (HCRU). Untreated patients demonstrated higher HCRU, including in the acute setting, and higher medical costs but still had lower overall costs.

INTRODUCTIONS & OBJECTIVES

IPF is associated with considerable mortality, high HCRU and economic burden. Antifibrotic therapies are a key component of IPF management and may influence both clinical and economic outcomes.

This study aimed to assess the real-world impact of antifibrotic therapy on HCRU and healthcare costs in patients with IPF, making specific comparison between Ofev treated, pirfenidone treated, and untreated cohorts to better understand differences in HCRU and cost of care based on treatment choice. The study further characterized whether generic treatments offer a more economical alternative to branded drugs at similar HCRU, while also profiling generic treatment uptake and potential remaining unmet needs.

METHODS

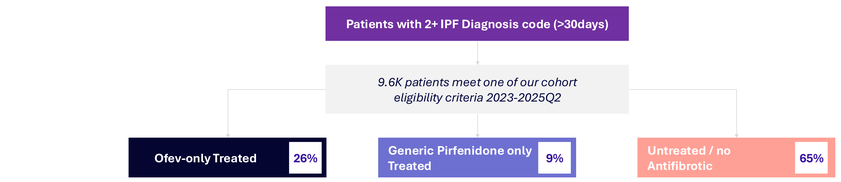
A retrospective, descriptive claims analysis was conducted using Komodo Healthcare Map™ closed claims cost of care data between 1st January 2023 and 30th June 2025. The study profiled prevalent treated and untreated patients with IPF and measured HCRU and costs, described via estimated allowed amounts, over a 12-month period during which patients were required to be continuously enrolled.

For treated patients, the index date was defined as the first observed antifibrotic claim in the study period (Ofev or generic pirfenidone) and required at least 300 days supply to allow for sufficient treatment exposure so that impacts to HCRU could be observed. Switch patients were excluded from this study. Branded pirfenidone (Esbriet) was not evaluated separately due to low sample, which is expected post launch of generic pirfenidone.

The untreated cohort was comprised of prevalent IPF patients, where the index date was the first observed IPF claim during the study period.

No clean lookbacks were applied for either the untreated or treated patient cohorts. Patients with a lung transplant during the 12-month baseline period were excluded from this study.

Figure 1. Study Population Comparator Cohort Design & Methodology



Medicare	84%	91%	91%
Medicaid	3%	2%	2%
Commercial	14%	7%	7%

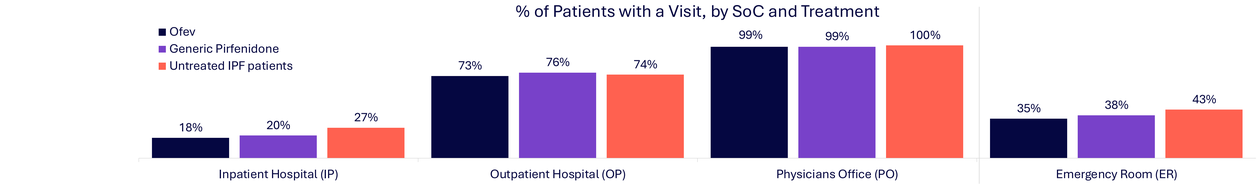
Three mutually exclusive comparator cohorts were defined (“Ofev-only treated”, “generic pirfenidone-only treated”, and “untreated”), all patients had to have at least 2 claims for IPF (J84.112) to confirm diagnosis. Most IPF Patients were untreated (65%), highlighting a substantial untreated population in real-world practice.

Among treated patients, the Ofev cohort was substantially larger than the pirfenidone cohort, representing 26% versus 9% of the patient population, highlighting lower uptake of generic pirfenidone despite the higher cost of Ofev.

While all cohorts skewed Medicare, treated cohorts had a directionally higher proportion of commercial patients, indicating patients with commercial insurance may have better access to anti-fibrotic treatments. Similarly, untreated patients skewed older (data not shown) and had a higher proportion of females (47% vs 36% for treated cohorts). No meaningful difference in race was observed between cohorts (data not shown).

FINDINGS

Figure 2. All Cause Setting of Care Healthcare Utilization and Associated Costs



Median/Mean Visits	2 , 1	2 ,1	2 , 1	10 , 5	10 , 5	11 , 5	23 , 17	23, 18	27 , 21	2 , 1	2 , 1	2 , 1
Median Estimated Allowed Amount	$19.2K	$16.2K	$18.8K	$1.5K	$1.3K	$2.4K	$2.7K	$2.6K	$3.2K	$0.4K	$0.5K	$$0.5K

Figure 3. All Cause Costs – Median Estimated Allowed Amounts across Medical and Pharmacy

All Cause Estimated Allowed Amounts ($, median)	Ofev only	Pirfenidone only	Untreated
Medical+Pharmacy	160K	37K	17K
Medical	8K	8K	11K
Pharmacy	148K	24K	2K

Overall, the untreated patient cohort had higher healthcare resource utilization, with a larger proportion of patients requiring hospitalization (IP and ER) and more frequent office visits. Generic pirfenidone and Ofev treated patients had similar healthcare resource utilization, both in terms of proportion of patients with a visit across sites of care, as well as frequency of visits.

Median site-of-care allowed amounts were highest in the inpatient setting across all cohorts, highlighting hospitalization as the principal driver of medical economic burden among IPF patients. Inpatient visit rates and associated allowed amounts among treated patients could point towards unmet needs in timely access to treatments and increased efficacy to further limit hospitalizations. Ofev and untreated IPF patients had the highest median all-cause inpatient allowed amounts (~19k), while pirfenidone-only patients had the lowest inpatient allowed amounts (~16k). Untreated patients additionally incurred comparatively higher outpatient and physician office allowed amounts, indicating a potentially greater ambulatory care burden. Emergency room allowed amounts were relatively low and comparable across cohorts. These results indicate that, among untreated patients, overall allowed amounts are primarily attributable to medical allowed amounts.

Median all-cause total allowed amounts were highest among Ofev-only patients ($160K), and lowest among untreated patients ($17K). Differences in total median allowed amounts across cohorts were primarily due to differences in pharmacy allowed amounts, associated with anti-fibrotic treatment.

Median pharmacy allowed amounts were markedly higher in the Ofev-only cohort ($148K) than in the generic pirfenidone ($24K) and untreated ($2K) cohorts. Despite having the lowest overall median cost, untreated patients had the highest median medical cost, suggesting higher disease burden.

Further analyses are recommended to characterize the impact of anti-fibrotic treatment on long term healthcare utilization and allowed amounts, as well as outcomes, relative to untreated patients.

CONCLUSION

In this real-world cohort, a large proportion of patients diagnosed with IPF remained untreated despite the known efficacy of IPF therapy in reducing the rate of decline in lung function. Untreated patients demonstrated a greater need for chronic and acute care management, as reflected by higher medical costs. We further observed that despite lower pharmacy cost burden and comparable HCRU, only ~9% of patients were treated with generic pirfenidone compared to Ofev. In the context of a smaller treated population relative to untreated patients, observed trends consistently suggest that generic pirfenidone is associated with lower pharmacy costs and similar HCRU as its branded competitor yet remains underutilized.

Findings suggest remaining unmet needs for cost-effective treatment approaches and timely access to disease modifying therapies.

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