Healthcare resource use and cost in antifibrotic-treated vs untreated patients with idiopathic pulmonary fibrosis (IPF) in the US Medicare population

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RATIONALE

- Idiopathic pulmonary fibrosis (IPF) is a form of chronic interstitial lung disease (ILD) of unknown cause prevalent in adults 55 years and older, and is characterized by progressive dyspnea and cough, disability, and ultimately death[1–3]
- In October 2014, 2 antifibrotic therapies, pirfenidone and nintedanib, were approved by the FDA to treat IPF.
- Despite the acceptance of antifibrotic drug therapy into IPF treatment guidelines, research has shown that patients remain untreated[4,7,8]
- Limited real-world evidence data are available about antifibrotic treatment effectiveness among older patients with IPF, especially those not covered by an employee-sponsored healthcare plan[9]
- This study compared all-cause and respiratory healthcare utilization (HCU) and costs in a large sample of patients (pts) with IPF initiating antifibrotics vs. untreated pts.

CONCLUSIONS AND IMPLICATIONS

- Healthcare utilization, all-cause and respiratory-related inpatient hospitalization costs were statistically significantly lower in treated vs untreated patients with IPF.
- Although outpatient medications were higher in the treated group, antifibrotic use may help reduce healthcare utilization and inpatient costs for patients with IPF by reducing hospitalizations and length of stay.

METHODS

Study Design:
- Retrospective analysis
- 2010–2017 administrative claims data from the 100% sample of Medicare beneficiaries (Research Identifiable Files)
- Treated patients were compared with a matched cohort of untreated historical controls

Patient Population:
- All Medicare beneficiaries with IPF defined as having ≥ 1 inpatient or ≥ 2 outpatient claims with an ICD-9-CM diagnosis code for IPF (*ICD-9-CM: 516.3, 516.30, 516.31; ICD-10-CM: J84.111, J84.112*)
- 2 groups were created relative to the US FDA approval date for antifibrotic therapy (10/15/2014):
  1. **Treated patients**: beneficiaries who initiated antifibrotics (≥ 1 prescription refill of pirfenidone or nintedanib) during a treated ID period of 10/15/2014–12/31/2017
     - The first fill date in the ID period was defined as index date (index)
  2. **Untreated patients**: beneficiaries not receiving antifibrotics during an untreated ID period of 1/1/2012–10/14/2014
     - ≥ 1 IPF diagnosis had to occur during the ID period, with the first IPF claim defined as index

Censoring and Follow-up Time:
- Patients who received a lung transplant after index, treated patients who switched or discontinued index treatment were all censored
- Patients were not required to have a minimum follow-up time after index

Matching and Study Measures:
- To optimize the balance of characteristics between the study groups, untreated patients were matched 1:1 to treated patients by using the propensity score
- Study outcomes: all-cause and respiratory-related inpatient hospitalizations, ICU stays, inpatient and outpatient costs during follow-up

Statistical Analyses:
- Descriptive statistics generated for all baseline characteristics
- Means and standard deviations (SD) reported for continuous variables, and frequencies and percentages for categorical data
- The rate of hospitalizations per month was compared between study groups using negative binomial regression
- All statistical tests were carried out as two-sided and at a significance level of 0.05
- All data transformations and statistical analyses will be performed using SAS® version 9.4

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RESULTS

Study Population (Table 1)
- The study identified 4,993 patients diagnosed with IPF who initiated treatment with antifibrotics (2,587 pirfenidone and 2,406 nintedanib) during the study period
- After matching, there were 4,641 treated patients with 4,641 matched untreated controls
- Mean age (treated vs. untreated) was 76.0 vs. 76.1 years, 37.4% vs. 36.1% were female, and mean (SD) modified CCI was 3.3 (2.9) vs. 3.2 (2.8)
- Regarding proxies of disease severity, 14% vs. 8.2% of patients had pulmonary rehabilitation within 1 year prior to index, 95.9% vs 81.9% had respiratory diagnostic services within 1 year prior to index, 12.4% vs. 11.7% had pneumonia, and 4.1% vs. 3.1% had smoking cessation therapy
- Nearly two-thirds of patients in each group were newly diagnosed (64.4% vs. 63.8%)

Table 1. Patient Demographics

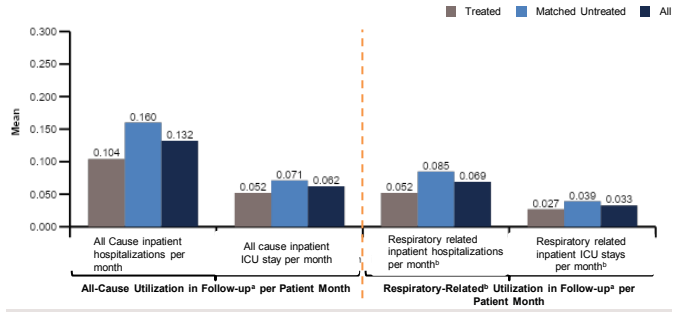
	Treated	Matched Untreated	*P Value*
No. of patients	4641	4641	
Age, mean (SD), years	76.0 (5.6)	76.1 (5.8)	0.642
Age category, n (%)			0.151
67–74 years	2025 (43.6)	2086 (44.9)	
75–84 years	2202 (47.4)	2188 (47.1)	
≥ 85 years	414 (8.9)	367 (7.9)	
Female, n (%)	1735 (37.4)	1674 (36.1)	0.189
White, n (%)	4394 (94.7)	4411 (95.0)	0.424
Modified CCI, mean (SD)†	3.3 (2.9)	3.2 (2.8)	0.103
No. of chronic conditions, mean (SD)	7.8 (2.0)	7.7 (2.0)	< 0.001
COPD, including emphysema, n (%)	2768 (59.6)	2816 (60.7)	0.309
Obstructive sleep apnea, n (%)	1585 (34.2)	988 (21.3)	< 0.001
Lung cancer, n (%)	119 (2.6)	232 (5.0)	< 0.001
Pneumothorax, n (%)	326 (7.0)	135 (2.9)	< 0.001
Gastroesophageal reflux, n (%)	2724 (58.7)	2397 (51.6)	< 0.001
Obesity, n (%)	1174 (25.3)	733 (15.8)	< 0.001
Cardiovascular conditions, n (%)			
Atrial fibrillation	1043 (22.5)	1013 (21.8)	0.453
Congestive heart failure	1404 (30.3)	1408 (30.3)	0.928
Cor pulmonale	200 (4.3)	234 (5.0)	0.095
Ischemic heart disease	2669 (57.5)	2687 (57.9)	0.705
Pulmonary hypertension	483 (10.4)	514 (11.1)	0.299
Stroke	288 (6.2)	266 (5.7)	0.335
Venous thromboembolism	386 (8.3)	353 (7.6)	0.206
Smoking cessation therapy, n (%)	186 (4.0)	144 (3.1)	0.019
Pulmonary rehabilitation within 1 year prior to index, n (%)	651 (14.0)	381 (8.2)	< 0.001
Respiratory diagnostic services within 1 year prior to index, n (%)	4450 (95.9)	3800 (81.9)	< 0.001
Newly diagnosed patients with IPF, n (%)	2989 (64.4)	2961 (63.8)	0.545

Healthcare Resource Use and Cost

Patients treated with antifibrotic therapy vs. untreated had lower Mean (SD): **(Figure 1)**
- All-cause inpatient hospitalizations (treated: 0.104 (0.33), matched untreated: 0.160 (0.41), p<0.001);
- ICU stays (treated 0.052 (0.28), matched untreated: 0.07 (0.29), p<0.001) per month.
- Respiratory-related inpatient hospitalizations (treated: 0.052 (0.24), matched untreated: 0.085 (0.31), p<0.001) and ICU stays (treated: 0.027 (0.20), matched untreated: 0.039 (0.23), p<0.001)

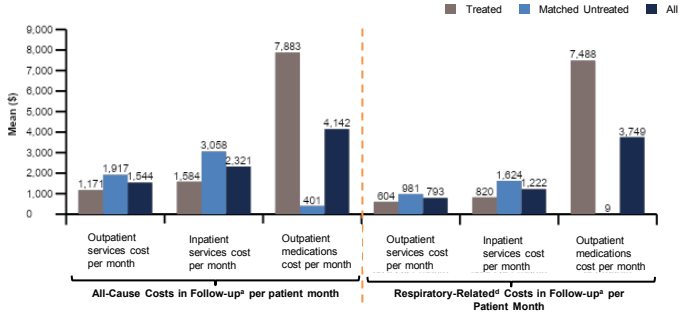
All-cause and respiratory-related costs per patient month (PPM): **(Figure 2)**
- Outpatient services, $1171 vs $1917 and $604 vs $981,
- Inpatient services, $1584 vs $3058 and $820 vs $1624;
- Outpatient medications, $7883 vs $401 and $7488 vs $3749 (p<0.001 for all)

Figure 1. Healthcare Utilization in Follow-up[a]



P Value	<.001[c]	<.001[c]	<.001[c]	<.001[c]

Figure 2. Healthcare Costs (Adjusted to 2017 US Dollars) in Follow-up[a]



P Value	<.001	<.001	<.001	<.001	<.001	<.001

[a]Patients were followed up to end of enrollment, lung transplant, switching or stopping index treatment (censoring occurred 60 days after treatment stop), death, or study end. Patients had various length of follow-up. [b]Inpatient claims with primary diagnosis of respiratory disease (ICD-9-CM: 460.xx - 519.xx; ICD-10-CM: J00.xx-J99.xx) or outpatient claims with any diagnosis of respiratory disease. [c]Wald Chi-square test based on negative binomial model. [d]Inpatient claims with primary diagnosis of respiratory disease (ICD-9-CM: 460.xx - 519.xx; ICD-10-CM: J00.xx-J99.xx) or outpatient claims with any diagnosis of respiratory disease, pharmacy claims include claims for antifibrotic (Esbriet or Ofev), inhaled corticosteroids, azathioprine, *n*-acetylcysteine, and mycophenolate mofetil, as well as antibiotics filled +/- 15 days of claim with a selected pneumonia diagnosis (ICD-9-CM: 465.9, 481, 482.xx – 484.xx, 485, 486; ICD-10-CM: J06.9, J13, J18.1, J15.0, J15.1, J14, J15.3, J15.4, J15.20, J15.211, J15.212, J15.29, J15.6, J15.8, A48.1, J15.9, J15.7, J16.0, J16.8, B25.0, A37.01, A37.11, A37.81, A37.91, A22.1, B44.0, J17, B77.81, J18.0, J18.8, J18.9), which can be treated by antibiotics, as a primary diagnosis in inpatient services or any diagnosis in outpatient services.

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