The economic burden of illness for patients with idiopathic pulmonary fibrosis utilizing treatment cohorts: A US retrospective 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 nintedanib and pirfenidone, which have been shown in clinical trials and real-world studies to slow the progression of IPF when taken as recommended[12]

Previous real-world studies have compared adherence/discontinuation or dosage patterns for nintedanib and shown poor adherence to IPF therapies and increased HCRU and costs among treated vs untreated patients[34]

However, current literature has not considered the comparison of cohorts across 3 criteria - differential dosing regimens (nintedanib 150mg/nintedanib 100mg), permanent discontinuation, and an untreated cohort, leveraging a data source with a representative payer mix

There remains a high unmet medical need for treatment of patients with IPF

INTRODUCTIONS & OBJECTIVES

Idiopathic pulmonary fibrosis (IPF) is a chronic, progressive disease associated with high morbidity and mortality

This study aimed to understand burden of illness (BOI) and impact of treatment dosage and adherence on healthcare resource utilization (HCRU) across 4 sub-cohorts of the IPF patient populations:

- Patients with usage of nintedanib 150mg
- Patients with usage of nintedanib 100mg
- 12-month discontinuation of patients initiating nintedanib
- Patients untreated with an IPF Therapy (nintedanib or pirfenidone)

METHODS

A retrospective, descriptive claims analysis was conducted using Komodo Healthcare Map™ data between 1st January 2019 – 31st December 2023

Patients were included in the study at the start of a specific dosage of nintedanib or pirfenidone or IPF diagnosis in the study period

Amongst them three distinct populations were identified, with the nintedanib treated population further stratified into three sub cohorts for further analysis

- Cohort A (Treated with nintedanib): at least 1 prescription claim for Nintedanib, that occurred on or after the first observed IPF diagnosis claim between 2019-2023. Sub-cohorts included:
  - nintedanib 150mg BID
  - nintedanib 100mg BID
  - nintedanib discontinued for 12-months
- Cohort B – (Untreated): required first observed IPF diagnosis claim between 2019-2023 (the index Dx date is defined by the first diagnosis claim) and have no exposure to any IPF treatment in the study period of 2019-2023
- Cohort C (Treated with pirfenidone): at least 1 prescription claim for pirfenidone, that occurred on or after the first observed IPF diagnosis claim between 2019-2023

All outcomes were assessed in the 12-month period after initiation of a specific dosage of nintedanib, from discontinuation, or from diagnosis for untreated patients

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Figure 1. Study Population Comparator Cohort Design & Methodology

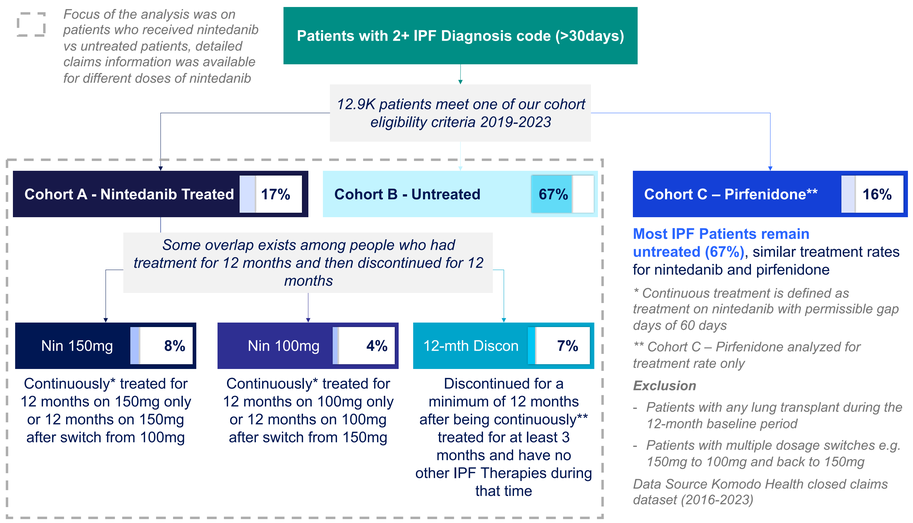
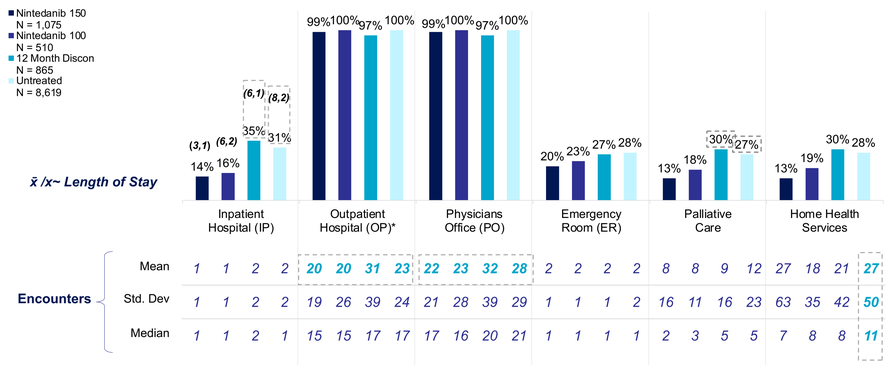


Figure 2. Setting Of Care



Patients who **discontinued treatment** or **remained untreated** had a **higher rate of hospitalization (~35% and ~31% vs ~14% and ~16%)** and a slightly higher rate of ER utilization (~27% and ~28% vs ~20% and ~23%) as compared to both treated cohorts, pointing to an unmet need among these cohorts

Outpatient and **physician offices** had **high utilization**, with **mean visits ranging from ~20-30 visits** in the 12-month period across all cohorts, pointing to the **need for active engagement** with little else available to mitigate symptoms

Palliative care was **utilized ~2x more often** by **patients who discontinued treatment** or **remained untreated,** patients who remained untreated had the most home health visits further emphasizing the lack of other treatment measures available as the disease progresses

Note: All utilization metrics are statistically significant and reported in the 12 months post index except for length of stay. Visit frequency is only among patients with a visit. Visits have been annualized. Outpatient visits includes Outpatient Facility Services, Outpatient Drug Admin/Supply

DISCUSSION

A higher proportion of the **12-month discontinued** and **untreated patients** were hospitalized, **~2x the hospitalization**, compared to those who were actively treated with nintedanib 150mg/ 100 mg

Patients who **discontinued treatment** or **remained untreated** had **higher utilization** of **palliative care** and **home health services** (~30% and ~28%) compared to patients on treatment (~13% and ~19%)

A higher proportion of patients who **discontinued treatment required oxygen support (~64%)** suggesting that patients who discontinued nintedanib continued to require ongoing supportive care

The need for **high supportive care is evident across cohorts**, resulting in frequent interactions with the healthcare system. **PCP's and pulmonologists saw the highest utilization across all cohorts**, with median PCP all-cause encounters ~17-19 per year. Treated patients had more frequent interactions with a pulmonologist likely required for monitoring lab test results (~18 vs ~6)

Figure 3. Procedure – Proportion of Patients by Specific Procedure Type

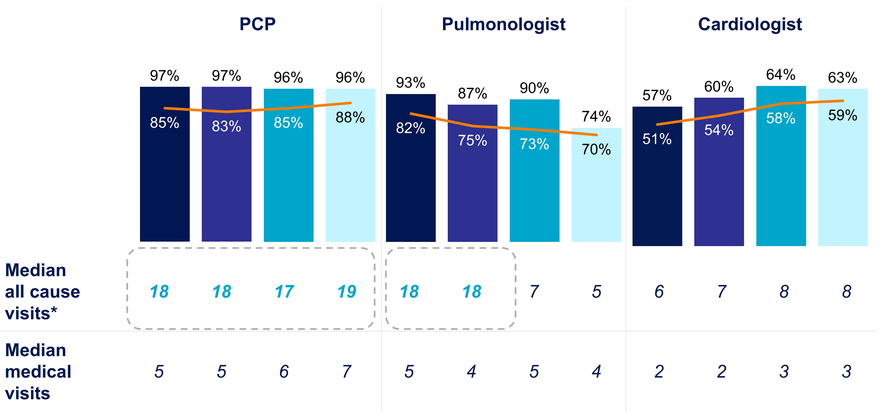
Procedure	Proportion of Patients by Procedure Utilization											
	Nin 150			Nin 100			12 Month Discon			Untreated		
	% N= 1,1075	Median	Mean	% N= 510	Median	Mean	% N= 865	Median	Mean	% N= 8,619	Median	Mean
Pulm Function Test	83%	2	3	81%	2	3	72%	2	6	71%	2	3
Liver Function Test	55%	2	3	46%	2	3	25%	1	2	16%	1	2
Oxygen Support	57%	12	14	57%	12	14	64%	12	13	43%	12	14

The proportion of **patients tested or monitored** with pulmonary function tests (~83% and ~81% vs ~72% and ~71%) and liver function tests (~55% and ~46% vs ~25% and ~16%) **presented higher for patients who took nintedanib treatment**, suggesting a **correlation between testing and treatment utilization**

Oxygen therapy utilization was **high across cohorts** with frequency being ~12 median encounters for both the treated patients as well as discontinued and untreated patients, pointing to a **high need for supportive care for all patients with IPF**

Note: Median/ mean refers to median/ mean encounters for the specific procedures

Figure 4. Specialty Type – Proportion of Patients by Specialty All cause & Medical utilization



PCP's and **pulmonologists** saw the **highest utilization** across **all cohorts**, all cause visits to a PCP ranged from ~17-19 encounters/year (including pharmacy encounters) with ~6 median medical visits. **Treated patients** saw a **pulmonologist more than 2x as often** as patients who discontinued treatment or remained untreated **(~18 and ~18 vs ~7 and ~5 median all cause visits/year)**

Discontinued and untreated patients had slightly higher utilization of cardiovascular specialists as compared to the treated cohorts (~64% and ~63% vs ~57% and 60%)

Note: All utilization metrics are statistically significant and reported in the 12 months post index. Encounter frequency is only among patients with an encounter
** All cause visits include pharmacy related visits*

CONCLUSION

In this real-world cohort, a large proportion of patients diagnosed with IPF remained untreated despite known efficacy of IPF therapy in reducing the rate of decline in lung function. We further observed a high rate of oxygen therapy and hospitalization amongst patients discontinuing treatment, highlighting a gap in the care paradigm. Further research is needed to understand this treatment gap, despite the high burden of illness and an increasing need for medical support in patients with IPF

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Abbreviations: IPF – Idiopathic Pulmonary Fibrosis | Nin – Nintedanib | HCRU – Healthcare Resource Utilization | CCI – Charlson Comorbidity Index | CV – Cardiovascular

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