Real-world characteristics and treatment patterns with nintedanib in patients with idiopathic pulmonary fibrosis: a retrospective US 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

The goal of the study was to demonstrate via real world data, the unmet needs for patients with IPF, despite available therapies in the current market. This study aimed to describe the characteristics of four treatment sub-cohorts of the IPF population:

- 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

A 12-month period prior to the index date was used to assess commonly occurring comorbid conditions and/or complications for patients with IPF

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Figure 1. Study Population Comparator Cohort Design & Methodology

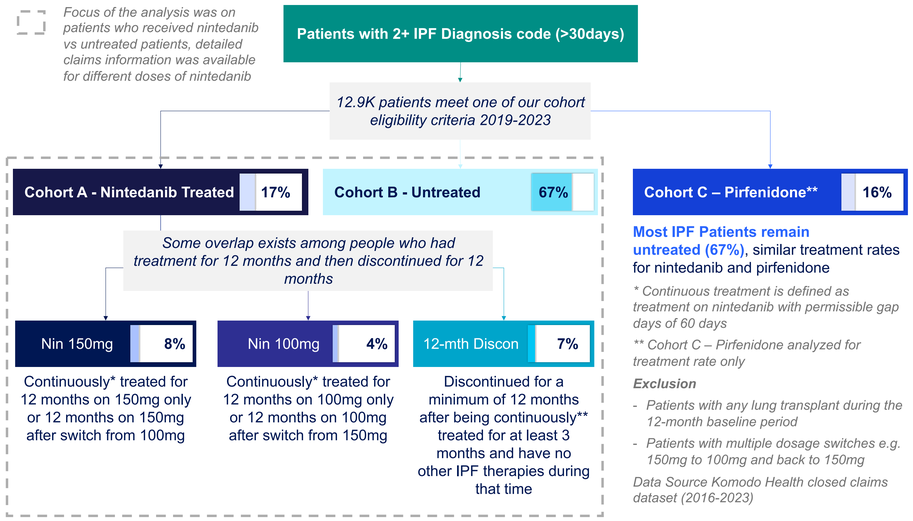
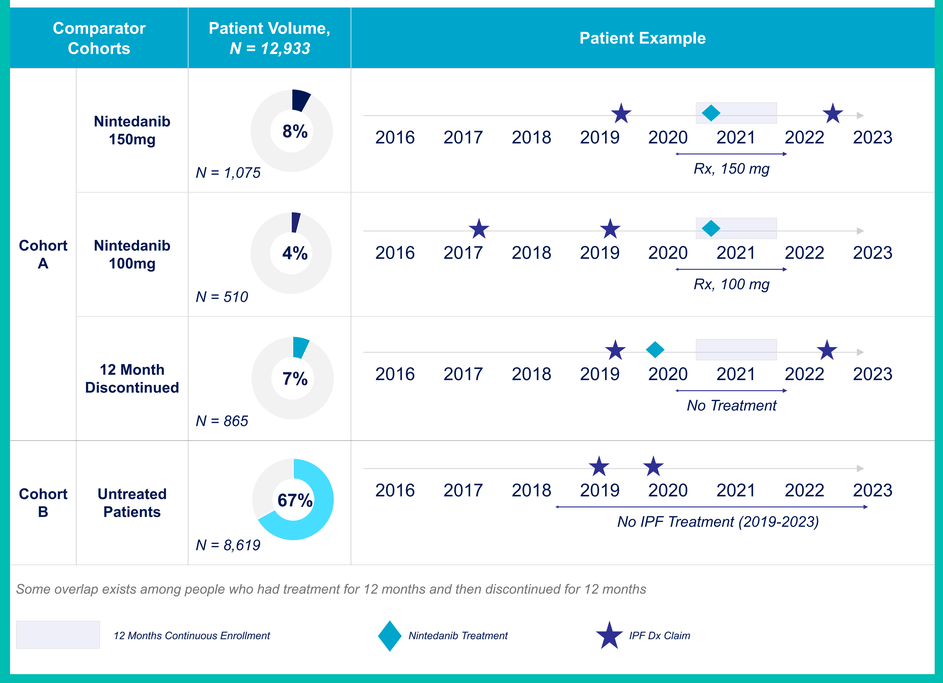


Figure 2. Descriptive Criteria for Cohort Creation



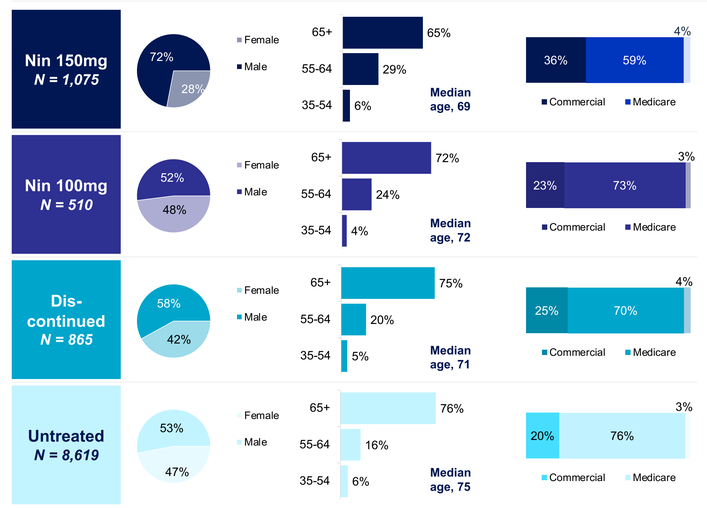
DISCUSSION

Patients who received **nintedanib 150mg skewed younger, male and commercially insured**. This could be driven by different treatment regimens adopted for demographically different patients, such as a lower dose for women or geriatric patients

Comorbidity rates were high across all patients with IPF indicating a **high disease burden** regardless of nintedanib treatment status

Notably the **Charlson Comorbidity Index score increased as the treatment dose decreased or was discontinued,** with the highest score attributed to patients with IPF who remained untreated

Figure 3. Study Population Demographics

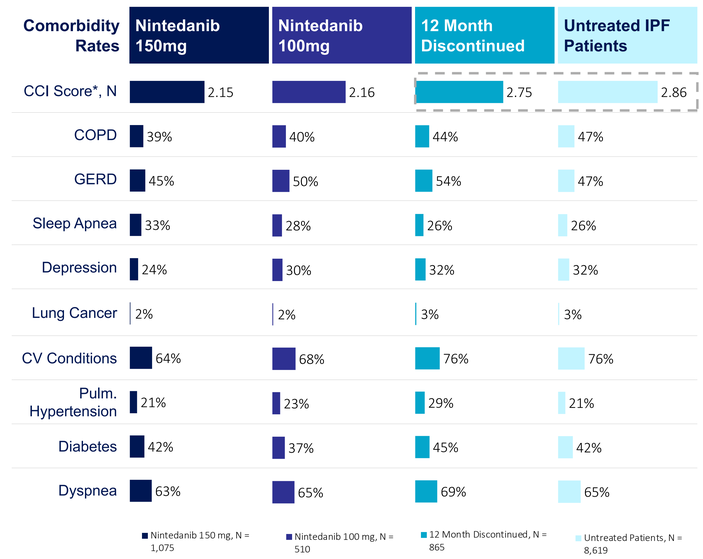


Study Population Demographics

Nintedanib 150mg cohort skewed **more male** (72% vs. 52%-58% in other cohorts), **younger** (median 69 years vs. 71-75 years) and had a higher percentage of **commercially insured** (36% vs. 20%-23%) patients, indicating potential differences in treatment patterns across these demographics

Patients were comparable in other characteristics, such as region and race (data not shown)

Figure 4. Comorbidity Rates Across Cohorts



Comorbidity Rates

Untreated and **discontinued patients** had **higher Charlson Comorbidity Index** (CCI) scores **(~2.8),** compared to treated patients **(~2.15)**

Comorbidity rates were high across all groups with no significant difference in rates across specific conditions for treated patients compared to discontinued or untreated patients. This may indicate that both groups of nintedanib treated patients have comparable high negative clinical outcomes

There was a **high prevalence** of **cardiovascular conditions** (~65%-75%), **Dyspnea** (~63%-69%) and **GERD** (~45%-55%) **across all cohorts**

*The Charlson Comorbidity Index (CCI) is a tool used to predict mortality risk in patients with multiple comorbidities by assigning a weighted score based on 19 medical conditions, with higher scores indicating a greater risk of death
Note: All utilization metrics are statistically significant

CCI score higher for 12 month discontinued and untreated patients

CONCLUSION

Despite known morbidity and mortality of the disease and availability of IPF therapies for nearly a decade, there remains a very large untreated population among patients with IPF. Understanding patient characteristics across treatment groups in a real-world setting can potentially impact treatment decisions 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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