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ABSTRACT

Name of company:			
Boehringer Ingelheim			
Name of finished medicinal product: Nintedanib (Ofev)			
Name of active ingredient: Nintedanib (Ofev)			
Report date: 08 November 2022	**Study number:** 1199-0471	**Version/Revision:** 2.0	**Version/Revision date:** 20 December 2022
Title of study:	Real-World Medication Adherence Trajectories of Nintedanib among Idiopathic Pulmonary Fibrosis Patients		
Keywords:	Nintedanib, adherence, group-based trajectory modeling, IPF		
Rationale and background:	Medication adherence is of great importance to health care stakeholders. The most common method to measure adherence in real-world settings is via the proportion of days covered (PDC) in prescription drug claims databases. However, PDC is limited by its inability to distinguish between different patterns of adherence over time. The primary objective was to identify adherence trajectories of nintedanib among Idiopathic Pulmonary Fibrosis (IPF) patients. This study also assessed the association between patients' characteristics and nintedanib adherence trajectory membership among patients with IPF.		
Study design:	This is a non-interventional, retrospective cohort study. The main outcome of this study was adherence trajectories to nintedanib. This study used Group-Based Trajectory Modeling (GBTM) method to identify trajectories of adherence. Proportion of days covered (PDC) was calculated for each of 12 consecutive 30-day months based on nintedanib prescription fill dates and days' supply. PDC was dichotomized, with PDC ≥0.8 considered adherent. A series of GBTMs of adherence was estimated to identify the best-fitting specification. Patients were then grouped based on their estimated adherence trajectories. Associations between baseline patient characteristics, including demographics, comorbidities, and health care use, and group membership probabilities were assessed by using ANOVA for interval variables and Chi-Square test for categorical variables. Given the information available within the database, extraction of adverse events was not feasible. Therefore, information about adverse events is not available. No interim analysis was conducted.		
Setting:	Existing claims data		
Subjects and study size, including dropouts:	In the 100% Medicare Part D claims data during 10/1/2014–12/31/2018, there were 18,733 beneficiaries with at least one claim for nintedanib. This study included community-dwelling older adults (≥66 years) with IPF diagnosis. Included patients had continuous coverage in Medicare Parts A, B and D for one year before (baseline) and after (follow-up) initiating nintedanib. The final analytic sample comprised 1,798 beneficiaries.		

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Results:	Among included population, mean age was 75.4±5.5 years. 1098 (61.1%) were male, and 1638 (91.1%) were non-Hispanic white. The best-fitting GBTM had five adherence trajectory groups: highly adherent, medium adherent, gradual decliners, intermediate decliners, and rapid-decliners. Some of patients' characteristics (e.g., age (p-value<0.001) and sex (p-value<0.001)) were significantly different among adherence trajectories.		
Discussion:	GBTM identified distinct patterns of nintedanib adherence for the IPF patient cohort. Identifying adherence trajectory groups and understanding the characteristics of their members provides more actionable information to personalize interventions than conventional metrics of medication adherence.		
Marketing Authorization Holder(s):	*NA*		
Names and affiliations of principal investigators:	[redacted] Boehringer Ingelheim		