Economic Burden Associated With Nintedanib Non-adherence Among Medicare Beneficiaries With IPF

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Study Finalised

Administrative details

EU PAS number

EUPAS1000001177

Study ID

1000001177

DARWIN EU® study

No

Study countries

United States

Study description

This study has two objectives:
-To assess the association between nintedanib adherence trajectory group (as measured from a Group-based Trajectory Modelling (GBTM)) and health care resource use, with a focus on inpatient hospitalization, among patients with Idiopathic Pulmonary Fibrosis (IPF).
-To assess the association between a patient's nintedanib adherence trajectory group (as measured from a GBTM) and their medical costs among patients with IPF.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Boehringer Ingelheim

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/05/2023

Study start date

Actual: 16/05/2023

Date of final study report

Actual: 30/06/2023

Study protocol

Prot_SAP_1199-0520_redacted.pdf (800.71 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

1199-0520; NCT05870956

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

This is a non-interventional, retrospective cohort study.

Main study objective:

1) Quantify the association between nintedanib adherence trajectory group (as measured from a GBTM) and health care resource use, with a focus on inpatient hospitalization, among patients with IPF.

2) Quantify the association between a patient’s nintedanib adherence trajectory

group (as measured from a GBTM) and their medical costs among patients with IPF.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

OFEV

Study drug International non-proprietary name (INN) or common name

NINTEDANIB

Population studied

Short description of the study population

Community-dwelling Medicare beneficiaries with IPF who initiate treatment with nintedanib.

Study design details

Comparators

High adherers group

Outcomes

The primary outcome was total all cause medical costs, which was calculated as the sum of total amounts paid (by payers and patients) for all medical services. Secondary outcomes were total IPF-related medical costs, which was calculated as the sum of total amounts paid (by payers and patients) for all medical services for an IPF-related reason (at least one IPF diagnosis code), all-cause inpatient hospitalization, and IPF-related inpatient hospitalization.

Summary results

Adherence to nintedanib was associated with all-cause and, to a lesser extent, IPF-related hospitalizations and medical costs during the year adherence was measured. In the year after adherence was measured, patients in the delayed-poor adherence group had higher all-cause hospitalizations and medical costs. Further research is needed to unpack the mechanisms underlying these associations.

Documents

Study results

1199-0520_Synopsis.pdf (352.83 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

federal Medicare program

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No