BlueCross BlueShield Federal Employee Program

**OFEV**
(nintedanib)

## RATIONALE FOR INCLUSION IN PA PROGRAM

### Background

Idiopathic pulmonary fibrosis is a progressive condition in which the lungs develop abnormal tissue changes (fibrosis) over time. As a result, patients with IPF experience shortness of breath, and worsening lung function (1).

Ofev (nintedanib) is a kinase inhibitor that blocks multiple pathways that may be involved in the development of fibrotic lung tissue. It targets various growth factor receptors that affect the fibroblast cells thought to be responsible for disease progression (2).

### Regulatory Status

FDA-approved indications: Ofev is a kinase inhibitor indicated for: (2)

- Treatment of idiopathic pulmonary fibrosis (IPF)
- Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype
- Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Ofev carries warnings for hepatic impairment, elevated liver enzymes and drug-induced liver injury, gastrointestinal disorders, embryo-fetal toxicity, arterial thromboembolic events, bleeding events, and gastrointestinal perforation. Smoking causes decreased exposure to Ofev, which may alter the efficacy profile of Ofev. Patients should be advised to stop smoking prior to treatment with Ofev and to avoid smoking when using Ofev (2).

Ofev is not recommended for patients who have moderate to severe liver problems. The safety and efficacy of Ofev have not been studied in patients with severe renal impairment and end-stage renal disease. Ofev can cause birth defects or death to an unborn baby. Women should not become pregnant while taking Ofev. Women who are able to get pregnant should use adequate contraception during and for at least three months after the last dose of Ofev. Liver function tests in all patients and a pregnancy test in females of reproductive potential should be conducted prior to initiating treatment with Ofev (2).

Eligible patients for clinical studies were to have percent forced vital capacity (%FVC) greater than or equal to 50% at baseline and a percent predicted diffusing capacity of the lungs for carbon monoxide (%$DL_{CO}$) greater than or equal to 30%. The primary endpoint was the annual rate of

decline in forced vital capacity (FVC) from baseline to study end (2).

Ofev is a substrate of P-glycoprotein (P-gp) and, to a minor extent, CYP3A4. A drug interaction assessment should be performed before the start of Ofev therapy (2).

Safety and effectiveness of Ofev in pediatric patients have not been established (2).

**Summary**

Ofev (nintedanib) is a kinase inhibitor indicated for idiopathic pulmonary fibrosis (IPF) and interstitial lung disease (ILD). Ofev carries warnings for hepatic impairment, elevated liver enzymes and drug-induced liver injury, gastrointestinal disorders, embryo-fetal toxicity, arterial thromboembolic events, bleeding events, and gastrointestinal perforation. Safety and effectiveness of Ofev in pediatric patients have not been established (2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Ofev while maintaining optimal therapeutic outcomes.

**References**

1. U.S. National Library of Medicine. (August 2020). Idiopathic pulmonary fibrosis: MedlinePlus Genetics. MedlinePlus. https://medlineplus.gov/genetics/condition/idiopathic-pulmonary-fibrosis/. Accessed on July 15, 2024.
2. Ofev [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2024.