**Initial approval criteria:** Non-formulary nintedanib (Ofev®) will be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Prescriber is a Pulmonologist
- Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by consensus at multidisciplinary conference ("e.g., Chest Conference")
- ALL of the following:
  - Forced Vital Capacity (FVC) 50% to 90% of predicted
  - FEV1/FVC ratio at least 0.7
  - Carbon monoxide diffusing capacity (DLco) of 30% to 90% of predicted
  - Able to walk at least 150 meters during a 6-minute-walk-test
- Patient is a non-smoker
- Patient is NOT receiving concomitant treatment with pirfenidone
- Patient does not have significantly impaired liver function; indicated by:
  - AST or ALT greater than three-times the upper limit of normal
  - Total bilirubin greater than the upper limit of normal
  - Alkaline phosphatase greater than three-times upper limit of normal
- Patient does NOT have significantly impaired kidney function; indicated by:
  - GFR or CrCl less than 30 mL/min
- Patient does NOT have severe hepatic impairment (Child-Pugh class C) or a history of end-stage renal disease (ESRD) requiring dialysis
Criteria Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

nintedanib (Ofev®)

**Continued use criteria:** Non-formulary nintedanib (Ofev®) will continue to be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Patient continues to be under the care of a pulmonologist
- AND-
- Hepatic function and spirometry are monitored (at least annually)
- AND-
- Prescribing Pulmonologist attests patient is receiving benefit from therapy. (i.e., benefits of continuing therapy outweigh known risks)
- AND-
- Patient continues to NOT have contraindications to nintedanib treatment (i.e., significantly impaired liver function, significantly impaired kidney function or ESRD requiring dialysis)
- AND-
- Patient is a non-smoker
- AND-
- Patient is NOT receiving concomitant treatment with pirfenidone

**Notes:**

Nintedanib is not recommended in patients with moderate (Child-Pugh Class B) to severe (Child-Pugh Class C) hepatic impairment, in patients with AST/ALT greater than 1.5 times the upper limit of normal, in patients with severe renal impairment (creatinine clearance less (CrCl) or glomerular filtration rate (GFR) than 30 mL/min) or ESRD.

Monitor AST, ALT, and bilirubin monthly for the first 3 months and every 3 months thereafter.

Nintedanib is teratogenic. Women of child bearing potential should avoid becoming pregnant while taking nintedanib.

Cigarette smoking reduces nintedanib exposure. Cigarette smoking should be avoided within 3 months prior to starting nintedanib and during nintedanib treatment.