SUMMARY

nintedanib

OFEV 100 mg and 150 mg,

soft capsule

Reassessment

Original French opinion adopted by the Transparency Committee on 18 January 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion for maintenance of reimbursement in the idiopathic pulmonary fibrosis indication.

Committee's conclusions

Clinical benefit

- Idiopathic pulmonary fibrosis (IPF) is the most common clinical form of idiopathic diffuse interstitial lung disease. It generally develops between the ages of 60 and 70 years, and rarely before the age of 50. The clinical picture includes progressive effort dyspnoea, a non-productive cough and, more rarely, systemic signs. It is a rare, chronic fibrosing and inflammatory disease that is life-threatening. It gradually progresses to chronic respiratory failure and death, with a median survival or around 2 to 3 years and a 10-year survival in the region of 10%.
- This proprietary medicinal product is a symptomatic treatment.
- The efficacy/adverse effects ratio in the MA indication is moderate.
- There is a therapeutic alternative in mild to moderate forms of IPF, but no alternative in severe forms.
- OFEV (nintedanib) can be used as an alternative to pirfenidone in patients with a confirmed clinical, radiological and/or histopathological diagnosis of idiopathic pulmonary fibrosis, with the following respiratory function criteria: FVCp ≥ 50% and DLCO ≥ 30%. In particular, the choice of treatment takes into account the safety and drug interactions of each treatment, as well as the comorbidities of patients, the clinician's experience and the patient's preferences.

➔ Public health impact:

OFEV (nintedanib) is unlikely to have an additional impact on public health.

The Committee deems that the clinical benefit of OFEV (nintedanib) remains moderate in patients with a confirmed clinical, radiological and/or histopathological diagnosis of idiopathic pulmonary fibrosis, with the following respiratory function criteria: FVCp ≥ 50% and DLCO ≥ 30%.

The Committee issues a favourable opinion for maintenance of inclusion in the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in patients with a confirmed clinical, radiological and/or histopathological diagnosis of idiopathic pulmonary fibrosis, with the following respiratory function criteria: CVFp ≥ 50% and DLCO ≥ 30% and at the MA dosages.

Clinical Added Value

The Committee considers that the data from the RaDiCo-FPI post-registration study is not of a nature to modify its assessment of the clinical benefit formulated in its previous opinion of 20 May 2015: CAV IV, in patients with a confirmed clinical, radiological and/or histopathological diagnosis of idiopathic pulmonary fibrosis, with the following respiratory function criteria: FVCp ≥ 50% and DLCO ≥ 30%.