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Minister of Medical Care and Sports
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2020050369

Date 15 December 2020
Subject Extension of further conditions for nintedanib (Ofev®)

**National Health Care
Institute**
Care II

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Our reference

2020050369

Dear Ms van Ark,

In your letter of 13 October 2020 (CIBG-20-1022) you asked the National Health Care Institute to advise you concerning the extension of the further conditions for nintedanib (Ofev®) to include the treatment of adults with progressive fibrosing interstitial lung diseases (PF-ILD) other than idiopathic pulmonary fibrosis (IPF). The National Health Care Institute has since completed its assessment. The considerations are included in the pharmaco-therapeutic report and budget impact analysis that are attached to this letter.

Current situation

Nintedanib (Ofev®) has been registered for the treatment of IPF since 2015 and for systemic sclerosis-related (Ssc) ILD and PF-ILD since 2020. The progressive form of Ssc-ILD is also categorised as PF-ILD. The market authorisation holder is not claiming reimbursement for the non-progressive form of Ssc-ILD. At the present time, the Dutch basic healthcare insurance package only reimburses the use of Ofev® for the treatment of IPF. The condition set out in List 2 reads as follows: "*For the treatment of idiopathic pulmonary fibrosis (IPF) in adults only*".

Therapeutic value conclusion

The National Health Care Institute has concluded that the treatment of adults with progressive fibrosing interstitial lung diseases (PF-ILD, including the progressive form of Ssc-ILD), other than idiopathic pulmonary fibrosis (IPF), with nintedanib has added value compared to placebo.

Budget impact analysis conclusion

Taking into account the number of patients, the expected market penetration, and the percentage of dropouts, extension of the medication reimbursement system's (GVS) List 2 conditions for nintedanib (Ofev®) for the treatment of progressive fibrosing interstitial lung diseases (PF-ILD) will be associated with additional costs of €4.9 million to €6.4 million, payable out of the pharmaceutical budget. There is uncertainty regarding prevalence, market penetration, and the percentage of dropouts.

Advice

Nintedanib (Ofev®) has already been included on List 1A, cluster 0L04AXBO,

together with further conditions limiting reimbursement to IPF. Based on the considerations mentioned above, we recommend that you modify the List 2 condition for nintedanib, by adding patients with PF-ILD, as set out below. This modification of the further conditions is accompanied by additional costs. The medical profession has indicated that the use of nintedanib (Ofev®) will take place in the context of a Multidisciplinary Consultation Meeting, based on the inclusion criteria used in the INBUILD trial.

New condition for nintedanib (Ofev®)

For the treatment of progressive fibrosing interstitial lung diseases (PF-ILD, including the progressive form of Ssc-ILD) and idiopathic pulmonary fibrosis (IPF) in adults only.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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