SUMMARY

fluticasone/umeclidinium/vilanterol

TRELEGY ELLIPTA and ELEBRATO ELLIPTA 92/55/22 µg,

powder for inhalation in a single-dose container

Reassessment

Original French opinion adopted by the Transparency Committee on 21 June 2023

The legally binding text is the original French opinion version

Committee recommendations

➔ Specific requests inherent to funding

The provisions of article L. 162-17 of the French Social Security Code concerning the retail formulary list of reimbursed medicinal products and the provisions of article L. 5123-2 of the French Public Health code concerning the hospital formulary list of medicinal products approved for use indicate that the Committee may, in view of the quality and safety of care requirements relative to the medicinal product that it is assessing, issue recommendations that may, in particular, concern the qualification or expertise of prescribers.

In application of these provisions, the proper use of a medicinal product in patients at an advanced stage of the disease, whose management is difficult, may require special supervision of the prescription of the medicinal product.

For the advanced stage of the disease, the Committee indicates that patients eligible for treatment with TRELEGY ELLIPTA (fluticasone / umeclidinium / vilanterol) have:

- **severe COPD, with persistent exacerbations,**
- **despite dual therapy with ICS+LABA or LABA+LAMA, for which the prescription has been optimised based on the recommended indications and dosage,**
- **and taking into account the complementary non-pharmacological approach (quitting smoking, physical activity, differential diagnosis).**

The GOLD and SPLF guidelines also favour the addition of an ICS to dual bronchodilator therapy (LABA/LAMA) in the context of a triple combination, such as TRELEGY ELLIPTA (fluticasone / umeclidinium / vilanterol).

At this advanced stage, the repeated occurrence of exacerbations can be life-threatening. Reducing the number of exacerbations is therefore a major objective in both the short and long term.

For proper use of this medicinal product, the prescription of TRELEGY ELLIPTA (fluticasone / umeclidinium / vilanterol) at this stage of the disease requires a clinical and functional respiratory assessment in order to target the recommended patient population (definite diagnosis) in view of the study data available. In addition, this prescription should take into account the fact that this medicinal product does not enable adjustment of the dose.

Considering:

- **the role of triple fixed-dose combinations reserved for patients with severe COPD, who are not adequately treated by an ICS and LABA combination or a LABA and LAMA combination;**
- **the possibility for any physician to prescribe ICS, LABA and LAMA in the form of free combinations, and the risk of inappropriate separate prescriptions;**
- **the existence of multiple inhalation devices, and the risk of an incorrect technique for use for each device;**
- **the poor compliance with various inhaled products;**
- **the high level of misuse observed with triple combinations in the treatment of COPD;**
- **the similar levels of misuse observed following the initiation of treatment by pulmonologists and general practitioners;**

The Committee deems that:

- **the initial prescription of TRELEGY ELLIPTA (fluticasone / umeclidinium / vilanterol) may be initiated by any physician provided that lung function tests confirming the existence of obstructive airway disease have been performed in the year preceding the initiation of treatment with this medicinal product;**
- **follow-up by a pulmonologist should be performed during the year following initial prescription of TRELEGY ELLIPTA (fluticasone / umeclidinium / vilanterol) in order to ensure that inhaled corticosteroid therapy is necessary.**

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