

SUMMARY

beclometasone/formoterol/glycopyrronium

TRIMBOW 87 µg/5 µg/9 µg,

solution for inhalation in a pressurised container

TRIMBOW 88 µg/5 µg/9 µg,

powder for inhalation

Reassessment

Original French opinion Adopted by the Transparency Committee on
1 June 2023

The legally binding text is the original French opinion version

Committee's conclusions**Clinical benefit**

- ➔ COPD leads to disability and a marked deterioration in quality of life and may be life-threatening.
- ➔ TRIMBOW (beclometasone / formoterol / glycopyrronium) is a symptomatic medicinal product.
- ➔ TRIMBOW (beclometasone / formoterol / glycopyrronium) combines two long-acting bronchodilators, formoterol (LABA) and glycopyrronium (LAMA) as well as an inhaled corticosteroid, beclometasone (ICS), recommended in combination in the management of severe COPD. This triple fixed-dose combination has demonstrated its superiority compared to a LAMA and LABA combination and an ICS and LABA combination on the occurrence of exacerbations, the improvement of respiratory function (FEV₁ evolution) and quality of life. However, the differences observed were modest. The efficacy/adverse effects ratio is moderate.
- ➔ The therapeutic alternatives represented by ICS, LABA and LAMA used in triple fixed-dose or free combinations are numerous.
- ➔ TRIMBOW is a third-line treatment in patients with severe COPD, who are not adequately treated by a LABA/LAMA or LABA/ICS combination. Escalation to LABA/LAMA/ICS triple therapy should be reserved for patients who continue to present exacerbations under dual therapy.
- ➔ The data supplied are not of a nature to modify the previous assessments concerning the public health benefit: TRIMBOW (beclometasone / formoterol / glycopyrronium) is unlikely to have an impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of TRIMBOW (beclometasone / formoterol / glycopyrronium) remains moderate as maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or a combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist.

The clinical benefit of TRIMBOW (beclometasone / formoterol / glycopyrronium) remains insufficient to justify its public funding cover in the treatment of moderate COPD.

The Committee issues a favourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use as maintenance treatment in adult patients with severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled Corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist and at the MA dosages.

The Committee issues an unfavourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use as maintenance treatment in adult patients with moderate chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled Corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist.

Clinical Added Value

The Committee considers that the data supplied are not of a nature to modify the assessment of the clinical added value formulated in its previous opinions of 18 September 2019.