



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 September 2025
EMADOC-1700519818-2094000
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Tezspire tezepelumab

On 18 September 2025 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Tezspire. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted a new indication as follows:

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Tezspire is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control.

For information, the full indications for Tezspire will be as follows:²

Asthma

Tezspire is indicated as an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Tezspire is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold

