



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 September 2025
EMA/CHMP/290671/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Uplizna inebilizumab

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 Uplizna. The marketing authorisation holder for this medicinal product is Amgen Europe B.V.

The CHMP adopted a new indication as follows:

Immunoglobulin G4-related disease (IgG4-RD)

Uplizna is indicated for the treatment of adult patients with active IgG4-RD (see section 5.1).

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

Neuromyelitis optica spectrum disorders (NMOSD)

Uplizna is indicated as monotherapy for the treatment of adult patients with ~~neuromyelitis optica spectrum disorders (NMOSD)~~ who are anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive (see section 5.1).

Immunoglobulin G4-related disease (IgG4-RD)

Uplizna is indicated for the treatment of adult patients with active IgG4-RD (see section 5.1).

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, removed text as strikethrough.

