14 October 2021
EMA/CHMP/490034/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Hizentra

human normal immunoglobulin

On 14 October 2021, 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 Hizentra. The marketing authorisation holder for this medicinal product is CSL Behring GmbH.

The CHMP adopted an extension to the existing indication as follows:[2]

Replacement therapy in adults, children and adolescents (0-18 years) in:

- Primary immunodeficiency syndromes with impaired antibody production (see section 4.4).

- **Secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF)* or serum IgG level of < 4 g/l.**

~~- Hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia (CLL), in whom prophylactic antibiotics have failed or are contra-indicated.~~

~~- Hypogammaglobulinaemia and recurrent infections in multiple myeloma (MM) patients.~~

~~- Hypogammaglobulinaemia in patients, pre- and post-allogeneic haematopoietic stem cell transplantation (HSCT).~~

***PSAF = failure to mount at least a 2-fold rise in IgG antibody titre to pneumococcal polysaccharide and polypeptide antigen vaccines.**

Immunomodulatory therapy in adults, children and adolescents (0-18 years):

- Hizentra is indicated for the treatment of patients with chronic inflammatory demyelinating

[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

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polyneuropathy (CIDP) as maintenance therapy after stabilization with IVIg.

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