

Reference number(s) 5765-A

Jurisdiction Specific Medicare Part B Subcutaneous Immune Globulin (SCIG)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	
Cutaquig	
Cuvitru	
Hizentra	
Hyqvia	
Xembify	

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Cutaquig, Cuvitru, Xembify

 Primary humoral immunodeficiency (e.g., common variable immunodeficiency, congenital agammaglobulinemia, severe combined immunodeficiency, X-linked immunodeficiency hyperimmunoglobulin M, Wiskott-Aldrich syndrome)

Hizentra, Hyqvia

- Primary humoral immunodeficiency (e.g., common variable immunodeficiency, congenital agammaglobulinemia, severe combined immunodeficiency, X-linked immunodeficiency hyperimmunoglobulin M, Wiskott-Aldrich syndrome)
- Chronic inflammatory demyelinating polyneuropathy (CIDP)

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All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Cutaquig, Cuvitru, Xembify

Primary Humoral Immunodeficiency

Authorization of 6 months may be granted for the treatment of primary humoral immunodeficiency.

Hizentra, Hyqvia

Primary Humoral Immunodeficiency

Authorization of 6 months may be granted for the treatment of primary humoral immunodeficiency.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Authorization of 6 months may be granted for the treatment of chronic inflammatory demyelinating polyneuropathy.

References

- 1. Immune Globulin LCD (L34007). Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed May 15, 2024.
- 2. Immune Globulin LCA (A57778). Version R7. Available at: https://www.cms.gov/medicare-coverage-database/details/article
 - details.aspx?articleId=57778&ver=5&Date=06%2f22%2f2020&DocID=A57778&SearchType=Advanced&bc=EgAAAAgAAAAA&. Accessed May 15, 2024.