Reference number
5766-A

JURISDICTION SPECIFIC MEDICARE PART B

Subcutaneous Immune Globulin (SCIG):
Cutaquig, Cuvitru, Hizentra, Hyqvia, Xembify

POLICY

I. 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.

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

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

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
B. Medical record documentation must support the medical necessity of the services are stated in the LCD.
C. The information contained in the medical record should include all relevant diagnostic laboratory studies, prior history of bleeding, infection, disease progression, prior medical/surgical therapies, vaccination response, and any other information essential in establishing that the patient meets the coverage indications as set forth in the NCD and LCD.
D. An accurate weight in kilograms should be documented prior to the infusion since the dosage is based on mg/kg/dosage.

III. CRITERIA FOR APPROVAL

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

B. Chronic inflammatory demyelinating polyneuropathy (CIDP)
Authorization of 6 months may be granted for the treatment of chronic inflammatory demyelinating polyneuropathy.

IV. REFERENCES

1. Intravenous Immune Globulin (IVIG) LCD (L35093) Version R18. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed January 26, 2023.
2. Billing and Coding: Intravenous Immune Globulin (IVIG) (A56786) Version R7. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed January 26, 2023.