Reference number(s)
2541-A

STANDARD MEDICARE PART B MANAGEMENT

SUBCUTANOUS IMMUNE GLOBULINS

CUTAQUIG (immune globulin subcutaneous [Human] - hipp, 16.5%)
CUVITRU (immune globulin subcutaneous [Human] 20%)
HIZENTRA (immune globulin subcutaneous [Human] 20%)
HYQVIA (immune globulin subcutaneous [Human] 10%)
XEMBIFY (immune globulin subcutaneous [Human] – klhw, 20%)

POLICY

I. INDICATIONS

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

FDA-Approved Indications

A. Cutaquig
Treatment of primary humoral immunodeficiency (PI) in adults

B. Cuvitru
Treatment of primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older

C. Hizentra
1. Treatment of primary humoral immunodeficiency in adults and pediatric patients two years of age and older
2. Treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment

D. HyQvia
Treatment of primary immunodeficiency (PI) in adults

E. Xembify
Treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older.

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.

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II. CRITERIA FOR INITIAL APPROVAL

A. Primary immunodeficiency
Authorization of 12 months may be granted for treatment of primary immunodeficiency.

B. Chronic inflammatory demyelinating polyneuropathy (Hizentra only)
Authorization of 12 months may be granted for the maintenance treatment of chronic inflammatory demyelinating polyneuropathy.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when all of the following criteria are met:
A. The member has previously received therapy with a subcutaneous immune globulin product.
B. The requested product is being used to treat an indication enumerated in Section II.
C. The medication has been effective for treating the diagnosis or condition.

IV. REFERENCES

1. Cutaquig [package insert]. Hoboken, NJ: Octapharma USA Inc.; November 2019.
2. Cuvitru [package insert]. Lexington, MA: Baxalta US Inc.; May 2019.
3. Hizentra [package insert]. Kankakee, IL: CSL Behring LLC; March 2020.
4. HyQvia [package insert]. Lexington, MA: Baxalta US Inc.; February 2020.
5. Xembify [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; July 2019.