Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO038

Description

Immunoglobulin G is a subcutaneously administered immunoglobulin product that supplies a broad spectrum of immunoglobulin g (IgG) antibodies to restore abnormally low immune globulin G levels in patients and help in preventing infections.

Length of Authorization

- Initial: six months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit	DDID
immunoglobulin g (Hizentra)	20% Subcutaneous solution	Primary humoral immunodeficiency (PID); Chronic inflammatory demyelinating polyneuropathy (CIDP)	920 mL/28 days	150266
				150267
				150286
				181366
immunoglobulin g (Gamunex-C)	10% Subcutaneous solution	Primary humoral immunodeficiency (PID)	960 mL/28 days	162470
				162471
				162472
				162473
				162474
				186195
immunoglobulin g (Gammaked)	10% Subcutaneous solution		960 mL/28 days	168450
				168451
				168452
				168453
				168454
immunoglobulin g (Gammagard liquid)	10% Subcutaneous solution		690 mL/28 days	168715
				168717
				168718
				168719
				168720
				168721
			700 mL/28 days	185560
				185561

immunoglobulin g (HyQvia)	10% Subcutaneous solution			185564
				185566
				18567
immunoglobulin g (Cuvitru)	20% Subcutaneous solution		460 mL/28 days	194948
				194949
				194950
				194951
immunoglobulin g (Cutaquig)	16.5% Subcutaneous solution		576 mL/28 days	206622
				206623
				206625
				206626
				206627
				206628

Initial Evaluation

I. Immunoglobulin g may be considered medically necessary when the following criteria below are met:
   A. A diagnosis of one of the following:
      1. **Primary immunodeficiency (PID)/Wiskott-Aldrich syndrome** (including but not limited to x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels) and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome)); **AND**
         i. For Hyqvia and Cutaquig: Patient must be ≥ 18 years old; **OR**
         ii. All other agents (Hizentra, Gamunex-C, Gammaked, Gammagard, Cuvitru); no age restriction; **AND**
         iii. Patient's IgG level is <200 mg/dL; **OR**
         iv. All of the following:
            a. Patient has a history of multiple hard to treat infections as indicated by at least one of the following:
               i. Four or more ear infections within 1 year
               ii. Two or more serious sinus infections within 1 year
               iii. Two or more months of antibiotics with little effect
               iv. Two or more pneumonias within 1 year
               v. Recurrent or deep skin abscesses
               vi. Need for intravenous antibiotics to clear infections

vii. Two or more deep-seated infections including septicemia; **AND**

b. The patient has a deficiency in producing antibodies in response to vaccination; **AND**

i. Titers were drawn before challenging with vaccination; **AND**

ii. Titers were drawn between 4 and 8 weeks of vaccination

2. **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**; **AND**

i. Request is for Hizentra only; **AND**

ii. Patient must be ≥ 18 years old; **AND**

iii. Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e slowing of nerve conduction velocity on electromyogram (EMG)/nerve conduction study (NCS); **AND**

a. Used as initial maintenance therapy for prevention of disease relapses after treatment and stabilization with intravenous immunoglobulin (IVIG); **OR**

b. Used for re-initiation of maintenance therapy after experiencing a relapse and requiring re-induction therapy with IVIG (see renewal for criteria)

II. Immunoglobulin g is considered investigational when used for all other conditions, including but not limited to:

A. Myasthenia gravis
B. Postural Tachycardia Syndrome (POTS)
C. Neuropathy

Renewal Evaluation

I. Renewal based on the following criteria:

A. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity/anaphylaxis, thrombosis, aseptic meningitis syndrome, hemolytic anemia, hyperproteinemia, acute lung injury, etc.; **AND**

B. For the following indications:

1. Primary immunodeficiency (PID)/Wiskott-Aldrich syndrome; AND

i. Disease response as evidenced by one or more of the following:

a. Decrease in the frequency of infection

b. Decrease in the severity of infection

2. **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP); AND**

i. Renewals will be authorized for patients that have demonstrated a beneficial clinical response to maintenance therapy, without relapses, based on an objective clinical measuring tool (i.e slowing of nerve conduction velocity on electromyogram (EMG)/nerve conduction study (NCS); **OR**
ii. Patient is re-initiating maintenance therapy after experiencing a relapse while on Hizentra; **AND**
    a. Patient improved and stabilized on IVIG treatment; **AND**
    b. Patient was NOT receiving maximum dosing of Hizentra prior to relapse

Supporting Evidence

I. BUN and serum creatinine should be monitored in patients at risk for acute renal failure.
II. There is a lack of strong scientific evidence from randomized controlled trials supporting safety and efficacy for an increased dosing frequency. Though a retrospective investigation has been done to evaluate an increased dosing frequency of Stelara retrospective review does not provide strong scientific evidence as do randomized controlled trials.

Investigational or Not Medically Necessary Uses

I. Clinical trials are ongoing for the following indications:
    A. Myasthenia gravis
    B. Postural Tachycardia Syndrome (POTS)
    C. Neuropathy

References

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Policy Implementation/Update:

Date Created	February 2015
Date Effective	April 2016
Last Updated	March 2016
Last Reviewed	02/2015,02/2016, 3/2016, 4/2018, 06/2019

Action and Summary of Changes	**Date**
Conversion to policy and addition of Cutaquig	**06/2019**
Updated criteria to include new indication for Hizentra in chronic inflammatory demyelinating polyneuropathy and added question to allow approval for Cuvitru in the setting of primary humoral immunodeficiency (PI).	04/2018
Criteria creation and implementation	02/2015