UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Immune Globulin Subcutaneous Utilization Management Medical Policy

- Cutaquig® (immune globulin 16.5% subcutaneous solution – Octapharma/Pfizer)
- Cuvitru™ (immune globulin 20% subcutaneous solution – Takeda)
- Gammagard® Liquid (immune globulin 10% solution – Baxalta [Takeda])
- Gammagard Liquid ERC® (immune globulin 10% solution – Baxalta [Takeda])
- Gammaked™ (immune globulin 10% solution caprylate/chromatography purified – Kedrion)
- Gamunex®-C (immune globulin 10% solution caprylate/chromatography purified – Grifols)
- Hizentra® (immune globulin 20% subcutaneous solution – CSL Behring)
- HyQvia® (immune globulin 10% subcutaneous solution with recombinant human hyaluronidase – Baxalta [Takeda])
- Xembify® (immune globulin 20% subcutaneous solution – Grifols)

REVIEW DATE: 11/19/2025; selected revision 5/13/2026 and 8/19/2026

OVERVIEW

Immune globulin subcutaneous (SCIG) products are concentrated human immunoglobulins, primarily immunoglobulin G (IgG), that are prepared from pooled plasma collected from a large number of human donors. SCIG products are indicated for the following uses:

- **Chronic inflammatory demyelinating polyneuropathy,** for maintenance therapy in adults.[1,4,5]
- **Primary humoral immune deficiency (PID**), for replacement therapy, including but not limited to the humoral defect in the following conditions: common variable immunodeficiency, X-linked agammaglobulinemia (congenital agammaglobulinemia), Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.[1-5,7-9,12] SCIG is also indicated for measles prophylaxis in individuals with PID who have been exposed to measles or who are at high risk of measles exposure.[1,4,5,8,9,12] Inborn errors of immunity include all congenital disorders that primary affect immune function, including primary immunodeficiencies.[20]

Hizentra, Cuvitru, Xembify, and Cutaquig are indicated as a subcutaneous (SC) infusion only.[4,7-9] Gammagard Liquid, Gammaked, Gamunex-C, and Gammagard Liquid ERC may be administered as a SC infusion or an intravenous (IV) infusion for PID.[1-3,12] HyQvia is indicated for SC infusion only, with sequential infusion of the recombinant human hyaluronidase first and followed 10 minutes later with the immune globulin infusion.[5] The recombinant human hyaluronidase acts locally to increase dispersion and absorption of the immune globulin.

Immune globulin also is used for off-label indications. The National Comprehensive Cancer Network (NCCN) recommends specific SC dosing for immune globulin (100 to 200 mg/kg given SC weekly) for toxicities related to CAR-T and lymphocyte-engager related therapies.[13] The therapies themselves can result in secondary immunodeficiency.

- **B-cell chronic lymphocytic leukemia (CLL)**, is FDA-approved if given by the intravenous route.[14]
- **Hematologic neoplasm-associated hypogammaglobulinemia or hypogammaglobulinemia after B-cell targeted therapies (secondary immunodeficiency):** Immune globulin intravenous (IVIG) is used off-label for this indication.[13,15,16]

© 2025. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

- **Hematopoietic cell transplantation (HCT) to prevent infections:** IVIG is used off-label for this indication.[17,18]
- **Multiple myeloma:** IVIG is used off-label for this indication.[13,19]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of SCIG products. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with SCIG as well as the monitoring required for adverse events and long-term efficacy, initial approval requires SCIG products to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of immune globulin subcutaneous products is recommended in those who meet one of the following criteria:

FDA-Approved Indications

---

1. Primary Immunodeficiencies. Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets BOTH of the following (i and ii):

i. Patient meets ONE of the following (a, b, or c):

Note: An exception can be made for the impaired antibody response if, according to the prescriber, the delay caused by pre-vaccination and post-vaccination antibody measurement would be deleterious to the patient's health.

a) Patient has a diagnosis of congenital agammaglobulinemia, X-linked agammaglobulinemia, other agammaglobulinemia due to the absence of B-cells, Wiskott-Aldrich syndrome, ataxia telangiectasia, DiGeorge syndrome, severe combined immunodeficiency, Hyper-Immunoglobulin M (IgM) syndromes, an IgG level lower than 250 mg/dL, or a primary immune deficiency which has been confirmed by genetic or molecular testing; OR

Note: Molecular testing is a type of genetic testing.

b) Patient has a diagnosis of common variable immunodeficiency or other immunodeficiencies with significant hypogammaglobulinemia and meets ALL of the following [(1), (2), and (3)]:

(1) Patient's pretreatment IgG level is below the normal range (age-adjusted and according to the normal reference range for the reporting laboratory); AND

(2) Patient has an impaired antibody response (e.g., failure to produce antibodies to specific antigens); AND

(3) Patient has recurrent infections; OR

c) The patient has an IgG subclass deficiency, selective antibody deficiency (SAD), or another confirmed primary immunodeficiency and meets BOTH of the following [(1) and (2)]:

(1) Patient has an impaired antibody response (e.g., failure to produce antibodies to specific antigens); AND

© 2025. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

(2) Patient has recurrent infections; AND

ii. The medication is prescribed by or in consultation with one of the following physician specialists: an allergist, immunologist, otolaryngologist (ear nose and throat [ENT] physician), pulmonologist, or an infectious diseases physician who treats patients with primary immune deficiencies; OR

B) Patient is Currently Receiving Immune Globulin. Approve if the patient has been diagnosed with a primary immunodeficiency and according to the prescriber the patient is continuing to receive benefit from the product.
Note: Examples of continued benefit with the product includes increased IgG levels or prevention and/or controlling of infections.

Dosing. Approve ONE of the following dosing regimens (A, B, C, D, E, or F):

A) The patient is transitioning from immune globulin intravenous (IVIG), and the maintenance dose (given once weekly, every 2 weeks, or more frequently than once weekly [e.g., 2 to 7 times per week]) is based on the patient's previous monthly IVIG dose; OR

B) The patient is transitioning from another immune globulin subcutaneous (SCIG) product, and the maintenance dose (given once weekly, every 2 weeks, or more frequently than once weekly) is based on the patient's previous weekly SCIG dose; OR

C) The patient is initiating SCIG therapy without previous IVIG or SCIG therapy and meets ONE of the following (i or ii):

i. Patient is receiving a loading dose (e.g., 100 mg/kg once daily for 5 consecutive days) followed by once weekly (or more frequently as necessitated by volume) maintenance dosing; OR

ii. The prescriber has determined the dose is clinically appropriate; OR

D) The dose and interval between doses have been adjusted based on clinical response, as determined by the prescriber; OR

E) For a patient with primary immune deficiency and exposure to measles (previous exposure or risk of future measles exposure), the minimum dose has been determined by the prescriber; OR

F) For HyQvia only: Approve if the patient meets ONE of the following (i, ii, or iii):

i. Patient is starting HyQvia and the dose and interval is being ramped-up to determine tolerability; OR
Note: The patient may be switching from IVIG or from another SCIG product OR the patient may be naïve to immune globulin therapy. See prescribing information for ramp-up schedule.

ii. Patient has already been started on HyQvia after the initial dose ramp-up and ONE of the following applies (a, b, or c):

a) The dose is 300 mg/kg to 600 mg/kg given at 3 to 4 week intervals; OR

b) The dose and frequency are the same as previously used when receiving IVIG; OR

c) The dose and interval between doses have been adjusted based on clinical response as determined by the prescriber; OR

iii. For a patient with primary immune deficiency and exposure to measles (previous exposure or risk of future measles exposure), the minimum dose has been determined by the prescriber.

---

2. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

ii. Electrodiagnostic studies support the diagnosis of CIDP; AND

© 2025. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

iii. The medication has been prescribed by or in consultation with a neurologist; OR

B) Patient is Currently Receiving Immune Globulin. Approve for 1 year if the patient has a clinically significant improvement in neurological symptoms as determined by the prescriber.
Note: Examples of improvement in neurologic symptoms include improvement in disability; nerve conduction study results improved or stabilized; physical examination show improvement in neurological symptoms, strength (e.g. grip strength), and sensation.

Dosing. Approve ONE of the following dosing regimens (A, B, or C):

A) The dose is either 0.2 g/kg or 0.4 g/kg per week administered in one or two sessions over 1 or 2 consecutive days; OR

B) The dose and interval between doses have been titrated and adjusted based on clinical response as determined by the prescriber; OR

C) For HyQvia only: Approve if the patient meets ONE of the following (i, ii, or iii):

i. Patient is starting HyQvia and the dose and interval are being ramped-up to determine tolerability; OR

ii. Patient has already been started on HyQvia after the initial dose ramp-up and ONE of the following applies (a, b, or c):

a) The dose and frequency are the same as the patient's previous IVIG treatment; OR

b) The dosing range is 0.4 g/kg to 2.4 g/kg, given in a frequency of 2-, 3-, or 4-week intervals; OR

c) The dose and interval between doses have been adjusted based on clinical response as determined by the prescriber; OR

iii. If the dose is ≤ 0.4 g/kg HyQvia may be administered without a ramp-up.

Other Uses with Supportive Evidence

---

3. B-Cell Chronic Lymphocytic Leukemia for Prevention of Infections. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 4 months if the patient meets BOTH of the following (i and ii):

i. Patient meets ONE of the following (a or b):

a) Patient has an immunoglobulin G (IgG) level < 600 mg/dL (6.0 g/L); OR

b) Patient has a history of recurrent infections; AND

ii. The medication is prescribed by or in consultation with an oncologist, hematologist, or infectious diseases physician; OR

B) Patient is Currently Receiving Immune Globulin. Approve for 1 year if the patient has a positive response to therapy, according to the prescriber.
Note: Examples of a positive response to therapy include maintaining an increased IgG trough level or a decrease in the number of infections.

Dosing. Approve ONE of the following dosing regimens (A, B, C, D, E, F, or G):

A) The subcutaneous dose is 100 to 200 mg/kg given weekly; OR

B) The patient is transitioning from immune globulin intravenous (IVIG), and the maintenance dose (given once weekly, every 2 weeks, or more frequently than once weekly [e.g., 2 to 7 times per week]) is based on the patient's previous monthly IVIG dose; OR

C) The patient is transitioning from another immune globulin subcutaneous (SCIG) product, and the maintenance dose (given once weekly, every 2 weeks, or more frequently than once weekly) is based on the patient's previous weekly SCIG dose; OR

D) The patient is initiating SCIG therapy without previous IVIG or SCIG therapy and meets ONE of the following (i or ii):

© 2025. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

i. Patient is receiving a loading dose (e.g., 100 mg/kg once daily for 5 consecutive days) followed by once weekly (or more frequently as necessitated by volume) maintenance dosing; OR
ii. The prescriber has determined the dose is clinically appropriate; OR

E) The dose and interval between doses have been adjusted based on clinical response, as determined by the prescriber; OR
F) For a patient with primary immune deficiency and exposure to measles (previous exposure or risk of future measles exposure), the minimum dose has been determined by the prescriber; OR
G) For HyQvia only: Approve if the patient meets ONE of the following (i, ii, or iii):
i. Patient is starting HyQvia and the dose and interval is being ramped-up to determine tolerability; OR
Note: The patient may be switching from IVIG or from another SCIG product OR the patient may be naïve to immune globulin therapy. See prescribing information for ramp-up schedule.
ii. Patient has already been started on HyQvia after the initial dose ramp-up and ONE of the following applies (a, b, or c):
a) The dose is 300 mg/kg to 600 mg/kg given at 3 to 4 week intervals; OR
b) The dose and frequency are the same as previously used when receiving IVIG; OR
c) The dose and interval between doses have been adjusted based on clinical response as determined by the prescriber; OR
iii. For a patient with primary immune deficiency and exposure to measles (previous exposure or risk of future measles exposure), the minimum dose has been determined by the prescriber.

---

4. Hematologic Neoplasm-Associated Hypogammaglobulinemia or Hypogammaglobulinemia or treatment after B-cell Targeted Therapies (Secondary Immunodeficiency [SID]). Approve for 6 months if the patient meets ONE of the following (A or B):
Note: Some examples of B-cell targeted therapy are chimeric antigen receptor (CAR)-T cell therapy (e.g., Kymriah [tisagenlecleucel intravenous infusion], Abecma [idecabtagene vicleucel intravenous infusion], Breyanzi [lisocabtagene maraleucel intravenous infusion], Tecartus [brexucabtagene autoleucel intravenous infusion], Yescarta [axicabtagene ciloleucel intravenous infusion]), a rituximab product, Besponsa (inotuzumab ozogamicin intravenous infusion), Blincyto (blinatumomab intravenous infusion).
Note: Refer to B-Cell Chronic Lymphocytic Leukemia (CLL) for Prevention of Infections and Multiple Myeloma for diagnosis-specific criteria.
A) Initial Therapy. Approve if the patient meets ONE of the following (i or ii):
i. Patient meets ALL of the following (a, b, and c):
a) Patient has an immunoglobulin G (IgG) level of < 600 mg/dL (6.0 g/L) [excluding paraprotein]; AND
b) Patient has recurrent or severe infections or there is a high risk of infection according to the prescriber; AND
c) The medication is being prescribed by or in consultation with an oncologist, hematologist, infectious disease physician, or immunologist; OR
ii. Patient meets BOTH of the following (a and b):
a) Patient is < 18 years of age; AND
b) Patient will be starting, has taken, or is currently receiving chimeric antigen receptor (CAR)-T cell therapy or other B-Cell targeted therapy; OR
Note: Examples of CAR-T cell therapy includes: Abecma (idecabtagene vicleucel intravenous infusion), Carvykti (ciltacabtagene autoleucel intravenous infusion).
Note: Examples of other B-Cell targeted therapy includes: Besponsa (inotuzumab ozogamicin intravenous infusion), Blincyto (blinatumomab intravenous infusion).

© 2025. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

B) Patient is Currently Receiving Immune Globulin. Approve if the patient is having a positive response to therapy, according to the prescriber.
Note: Examples of a positive response to therapy include maintaining an increased IgG trough level or a decrease in the number of infections.

Dosing. Approve ONE of the following dosing regimens (A, B, C, D, E, F, or G):
A) The subcutaneous dose is 100 to 200 mg/kg given weekly; OR
B) The patient is transitioning from immune globulin intravenous (IVIG), and the maintenance dose (given once weekly, every 2 weeks, or more frequently than once weekly [e.g., 2 to 7 times per week]) is based on the patient's previous monthly IVIG dose; OR
C) The patient is transitioning from another immune globulin subcutaneous (SCIG) product, and the maintenance dose (given once weekly, every 2 weeks, or more frequently than once weekly) is based on the patient's previous weekly SCIG dose; OR
D) The patient is initiating SCIG therapy without previous IVIG or SCIG therapy and meets ONE of the following (i or ii):
- **i.** Patient is receiving a loading dose (e.g., 100 mg/kg once daily for 5 consecutive days) followed by once weekly (or more frequently as necessitated by volume) maintenance dosing; OR
- **ii.** The prescriber has determined the dose is clinically appropriate; OR

E) The dose and interval between doses have been adjusted based on clinical response, as determined by the prescriber; OR
F) For a patient with secondary immune deficiency and exposure to measles (previous exposure or risk of future measles exposure), the minimum dose has been determined by the prescriber; OR
G) For HyQvia only: Approve if the patient meets ONE of the following (i, ii, or iii):
- **i.** Patient is starting HyQvia and the dose and interval is being ramped-up to determine tolerability; OR
  Note: The patient may be switching from IVIG or from another SCIG product OR the patient may be naïve to immune globulin therapy. See prescribing information for ramp-up schedule.
- **ii.** Patient has already been started on HyQvia after the initial dose ramp-up and ONE of the following applies (a, b, or c):
  - **a)** The dose is 300 mg/kg to 600 mg/kg given at 3 to 4 week intervals; OR
  - **b)** The dose and frequency are the same as previously used when receiving IVIG; OR
  - **c)** The dose and interval between doses have been adjusted based on clinical response as determined by the prescriber; OR
- **iii.** For a patient with secondary immune deficiency and exposure to measles (previous exposure or risk of future measles exposure), the minimum dose has been determined by the prescriber.

---

5. Hematopoietic Cell Transplantation (HCT) to Prevent Infection. Approve for the duration noted if the patient meets ONE of the following (A, B, or C):
A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, and iv):
- **i.** Patient has had a HCT within the previous year; AND
- **ii.** Patient has an immunoglobulin G (IgG) level < 600 mg/dL (6.0 g/L) OR the patient has multiple myeloma or malignant macroglobulinemia; AND
- **iii.** According to the prescriber, the patient has a significant risk of having frequent and/or severe infections; AND
- **iv.** The medication is prescribed by or in consultation with a hematologist, oncologist, or infectious diseases physician; OR

B) Initial Therapy. Approve for 3 months if the patient meets ONE of the following (i, ii, or iii):
- **i.** Patient is a recipient of an umbilical cord blood transplant; OR

© 2025. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

ii. Patient is undergoing transplantation for inherited or acquired disorders associated with B-cell deficiency; OR

iii. Patient with chronic graft versus host disease with recurrent sinopulmonary infections; OR

C) Patient is Currently Receiving Immune Globulin. Approve for 6 months if the patient is having a positive response to therapy according to the prescriber.
Note: Examples of a positive response to therapy include maintaining an increased IgG trough level, controlling the number of infections, or a decrease in the number of infections.

Dosing. Approve ONE of the following dosing regimens (A, B, C, D, E, F, or G):

A) The subcutaneous dose is 100 to 200 mg/kg given weekly; OR

B) The patient is transitioning from immune globulin intravenous (IVIG), and the maintenance dose (given once weekly, every 2 weeks, or more frequently than once weekly [e.g., 2 to 7 times per week]) is based on the patient's previous monthly IVIG dose; OR

C) The patient is transitioning from another immune globulin subcutaneous (SCIG) product, and the maintenance dose (given once weekly, every 2 weeks, or more frequently than once weekly) is based on the patient's previous weekly SCIG dose; OR

D) The patient is initiating SCIG therapy without previous IVIG or SCIG therapy and meets ONE of the following (i or ii):

i. Patient is receiving a loading dose (e.g., 100 mg/kg once daily for 5 consecutive days) followed by once weekly (or more frequently as necessitated by volume) maintenance dosing; OR

ii. The prescriber has determined the dose is clinically appropriate; OR

E) The dose and interval between doses have been adjusted based on clinical response, as determined by the prescriber; OR

F) For a patient with secondary immune deficiency and exposure to measles (previous exposure or risk of future measles exposure), the minimum dose has been determined by the prescriber; OR

G) For HyQvia only: Approve if the patient meets ONE of the following (i, ii, or iii):

i. Patient is starting HyQvia and the dose and interval is being ramped-up to determine tolerability; OR
Note: The patient may be switching from IVIG or from another SCIG product OR the patient may be naïve to immune globulin therapy. See prescribing information for ramp-up schedule.

ii. Patient has already been started on HyQvia after the initial dose ramp-up and ONE of the following applies (a, b, or c):

a) The dose is 300 mg/kg to 600 mg/kg given at 3 to 4 week intervals; OR

b) The dose and frequency are the same as previously used when receiving IVIG; OR

c) The dose and interval between doses have been adjusted based on clinical response as determined by the prescriber; OR

iii. For a patient with secondary immune deficiency and exposure to measles (previous exposure or risk of future measles exposure), the minimum dose has been determined by the prescriber.

---

6. Multiple Myeloma. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):

i. Patient meets ONE of the following (a or b):

a) Patient has or is at risk of severe, recurrent infections according to the prescriber; OR

b) Patient will be starting, has taken, or is currently receiving chimeric antigen receptor (CAR)-T cell therapy, or bispecific antibody therapy, or other B-Cell targeted therapy; AND

© 2025. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

Note: Examples of CAR-T cell therapy includes: Abecma (idecabtagene vicleucel intravenous infusion), Carvykti (ciltacabtagene autoleucel intravenous infusion).
Note: Examples of bispecific antibody therapy or other B-Cell targeted therapy includes: Elrexfio (elranatamab-bcmm subcutaneous injection), Tecvayli (teclistamab-cqyv subcutaneous injection), Talvey (talquetamab-tgvs subcutaneous injection).

ii. The medication is prescribed by or in consultation with a hematologist, oncologist, or infectious diseases specialist; OR

B) Patient is Currently Receiving Immune Globulin. Approve for 1 year.

Dosing. Approve ONE of the following dosing regimens (A, B, C, D, E, F, or G):

A) The subcutaneous dose is 100 to 200 mg/kg given weekly; OR

B) The patient is transitioning from immune globulin intravenous (IVIG), and the maintenance dose (given once weekly, every 2 weeks, or more frequently than once weekly [e.g., 2 to 7 times per week]) is based on the patient's previous monthly IVIG dose; OR

C) The patient is transitioning from another immune globulin subcutaneous (SCIG) product, and the maintenance dose (given once weekly, every 2 weeks, or more frequently than once weekly) is based on the patient's previous weekly SCIG dose; OR

D) The patient is initiating SCIG therapy without previous IVIG or SCIG therapy and meets ONE of the following (i or ii):

i. Patient is receiving a loading dose (e.g., 100 mg/kg once daily for 5 consecutive days) followed by once weekly (or more frequently as necessitated by volume) maintenance dosing; OR

ii. The prescriber has determined the dose is clinically appropriate; OR

E) The dose and interval between doses have been adjusted based on clinical response, as determined by the prescriber; OR

F) For a patient with secondary immune deficiency and exposure to measles (previous exposure or risk of future measles exposure), the minimum dose has been determined by the prescriber; OR

G) For HyQvia only: Approve if the patient meets ONE of the following (i, ii, or iii):

i. Patient is starting HyQvia and the dose and interval is being ramped-up to determine tolerability; OR

Note: The patient may be switching from IVIG or from another SCIG product OR the patient may be naïve to immune globulin therapy. See prescribing information for ramp-up schedule.

ii. Patient has already been started on HyQvia after the initial dose ramp-up and ONE of the following applies (a, b, or c):

a) The dose is 300 mg/kg to 600 mg/kg given at 3 to 4 week intervals; OR

b) The dose and frequency are the same as previously used when receiving IVIG; OR

c) The dose and interval between doses have been adjusted based on clinical response as determined by the prescriber; OR

iii. For a patient with secondary immune deficiency and exposure to measles (previous exposure or risk of future measles exposure), the minimum dose has been determined by the prescriber.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of immune globulin subcutaneous is not recommended in the following situations:

1. **Selective Immune Globulin A (IgA) Deficiency as the Sole Immunologic Abnormality.** Evidence does not support use of immune globulin.[10,11] Selective IgA deficiency is defined as a serum IgA level less than 0.07 g/L, but normal serum IgG and immunoglobulin M (IgM) levels in a patient greater than 4 years of age in whom other causes of hypogammaglobulinemia have been excluded.[11] Selective IgA

© 2025. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

deficiency may co-exist in some patients with poor specific IgG antibody production, with or without IgG2 subclass deficiency.[10,11] Some of these patients with a concomitant specific antibody defect might benefit from therapy with SCIG.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Gammagard® Liquid 10% [prescribing information]. Cambridge, MA: Takeda; September 2024.
2. Gammaked™ 10% solution [prescribing information]. Fort Lee, NJ: Kedrion; January 2020.
3. Gamunex®-C 10% solution [prescribing information]. Research Triangle Park, NC: Grifols; January 2020.
4. Hizentra® 20% subcutaneous solution [prescribing information]. Kankakee, IL: CSL Behring; April 2023.
5. HyQvia® 10% subcutaneous solution with recombinant human hyaluronidase [prescribing information]. Cambridge, MA: Takeda; July 2025.
6. McLean HQ, Fiebelkorn AP, Temte JL, Wallace GS; Centers for Disease Control and Prevention. Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013: summary recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2013;62:1-34.
7. Xembify® 20% subcutaneous solution [prescribing information]. Research Triangle Park, NC: Grifols; July 2024.
8. Cuvitru™ 20% subcutaneous solution [prescribing information]. Cambridge, MA: Takeda; February 2025.
9. Cutaquig® 16.5% subcutaneous solution [prescribing information]. New York, NY: Pfizer; March 2025.
10. Perez EE, Orange JS, Bonilla F, et al. Update on the use of immunoglobulin in human disease: A review of evidence. *J Allergy Clin Immunol.* 2017;139(3S):S1-S46.
11. Bonilla FA, Khan DA, Ballas ZK, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. *J Allergy Clin Immunol.* 2015;136:1186-1205.
12. Gammagard Liquid ERC 10% intravenous or subcutaneous solution [prescribing information]. Cambridge, MA: Takeda; June 2025.
13. NCCN guidelines on the management of CAR-T cell and lymphocyte engager-related toxicities (version 2.2026 – November 11, 2025). ® 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 14, 2025.
14. Gammaked™ 10% solution [prescribing information]. Fort Lee, NJ: Kedrion; January 2020.
15. NCCN Drugs and Biologics Compendium. ® 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 14, 2025. Search term: Immune globulin.
16. Hayden PJ, Roddie C, Prader P, et al. Management of adults and children receiving CAR-T cell therapy. 2021 best practice recommendations of the European Society for Blood and Marrow Transplantation and the Joint Accreditation Committee of ISCT and EBMT and the European Heaemtology Association. *Ann Oncol*. 2022;33:259-75.
17. Tomblyn M, Chiller T, Einsele H, et al; Center for International Blood and Marrow Research; National Marrow Donor program; European Blood and Marrow Transplant Group; American Society of Blood and Marrow Transplantation; Canadian Blood and Marrow Transplant Group; Infectious Diseases Society of America; Society for Healthcare Epidemiology of America; Association of Medical Microbiology and Infectious Disease Canada; Centers for Disease Control and Prevention. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: A global perspective. *Biol Blood Marrow Transplant.* 2009;1:1143-1238.
18. The NCCN guidelines on Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 3.2025 – September 24, 2025). © 2025 National Comprehensive Cancer Network. Available at : http://www.nccn.org. Accessed on November 10,2025.
19. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2026 – November 3, 2025). © 2025 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on November 10, 2025.
20. Orange JS, Chinen J, Horner CC, et al. 2025 Inborn errors of immunity practice parameter: Guidance from the Joint Task Force on Practice Parameters, the American Academy of Allergy Asthma and Immunology (AAAAI), the American College of Allergy, Asthma and Immunology (ACAAI) and the Clinical Immunology Society (CIS). *Ann Allergy Asthma Immunol.* 2026;136(4):426-493.e1.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/25/2023
Selected Revision	Removed drug specific criteria for HyQvia. HyQvia will use the same criteria as the other immune globulin products.	02/07/2024

© 2025. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

	HyQvia dosing for Primary Immunodeficiencies: The dose and interval between doses has been adjusted based on clinical response as determined by the prescribing physician was updated to prescriber. **HyQvia dosing for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy** was added.	
Annual Revision	**Primary Immunodeficiencies:** Added a note that molecular testing is a type of genetic testing. **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy:** Added grip strength as an example of an improvement at physical examination.	11/06/2024
Annual Revision	**Gammagard Liquid ERC was** added to the policy with the same criteria as all other immune globulin products. Criteria created for the following diagnoses: **B-Cell Chronic Lymphocytic Leukemia for Prevention of Infections, Hematologic Neoplasm-Associated Hypogammaglobulinemia or Hypogammaglobulinemia or treatment after B-Cell Targeted Therapies (Secondary Immunodeficiency [SID]), Hematopoietic Cell Transplantation (HCT) to Prevent Infection,** and **Multiple Myeloma.**	11/19/2025
Selected Revision	**Primary Immunodeficiencies; B-Cell Lymphocytic Leukemia for Prevention of Infections; Hematologic Neoplasm-Associated Hypogammaglobulinemia or Hypogammaglobulinemia or treatment after B-cell Targeted Therapies (Secondary Immunodeficiency [SID]); Hematopoietic Cell Transplantation (HCT) to Prevent Infections; Multiple Myeloma**: Added dosing criterion for treatment-naïve patients to include "the prescriber has determined the dose is clinically appropriate."	05/13/2026
Selected Revision	**Primary Immunodeficiencies**: Removed 'unspecified hypogammaglobulinemia' from the criteria. For a diagnosis of common variable immunodeficiency or other immunodeficiencies with significant hypogammaglobulinemia, both an impaired antibody response and recurrent infections are required to be met; previously only one was required. For the criterion, patient has an impaired antibody response (i.e., failure to produce antibodies to specific antigens), 'that is' (i.e.) was replaced with 'for example' (e.g.).	8/19/2026

© 2025. All Rights Reserved.
This document is confidential and proprietary. Unauthorized use and distribution are prohibited.