Drug Coverage Policy

Effective Date 9/03/2026
Coverage Policy Number.....IP0777
Policy Title.....Immune Globulin – Subcutaneous

Immune Globulin - Subcutaneous

- 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)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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]
- **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]

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for 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.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, prescription receipts and/or other information. All documentation must include patient-specific identifying information.

Immune globulin subcutaneous products are considered medically necessary when ONE of the following are met:

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 **[documentation required]**; 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 **[documentation required]** 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) **[documentation required]**; AND
         - **(2)** Patient has an impaired antibody response (e.g., failure to produce antibodies to specific antigens) **[documentation required]**; AND
         - **(3)** Patient has recurrent infections; OR
       - **c)** The patient has an IgG subclass deficiency, selective antibody deficiency (SAD), or another confirmed primary immunodeficiency **[documentation required]** 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) **[documentation required]**; AND
         - **(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 **[documentation required]**; AND
- **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) **[documentation required]**; OR
  - **b)** Patient has a history of recurrent infections **[documentation required]**; AND
- **ii.** The medication is prescribed by or in consultation with an oncologist, hematologist, immunologist, 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);

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 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] **[documentation required]**; 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 **[documentation required]**; 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).

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 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 **[documentation required]**; 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 **[documentation required]**; 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 **[documentation required]**; OR
ii. Patient is undergoing transplantation for inherited or acquired disorders associated with B-cell deficiency **[documentation required]**; OR
iii. Patient with chronic graft-versus-host-disease with recurrent sinopulmonary infections **[documentation required]**; 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) According to the prescriber, patient has or is at risk of severe, recurrent infections; 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 **[documentation required]**; AND
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.

7. **Patient has already been started on therapy with an SCIG product AND has a diagnosis listed in the Appendix.** Approve for the duration noted in the Appendix below.

   Dosing. Approve ONE of the following dosing regimens (A, B, or C):
   A) Patient transitioned 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]) was based on the patient's previous monthly IVIG dose; OR
   B) Patient transitioned from another immune globulin subcutaneous (SCIG) product, and the maintenance dose (given once weekly, every 2 weeks, or more frequently than once weekly) was based on the patient's previous weekly SCIG dose; OR
   C) The prescriber has determined the dose is clinically appropriate.

Conditions Not Covered

Immune globulin subcutaneous products for any other use are considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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 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. **Pediatric acute-onset neuropsychiatric syndrome (PANS) and Pediatric autoimmune neuropsychiatric disorder associated with group A streptococci (PANDAS)**

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each

HCPCS Codes	Description
J1551	Injection, immune globulin (Cutaquig), 100 mg
J1555	Injection, immune globulin (Cuvitru), 100 mg
J1558	Injection, immune globulin (Xembify), 100 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1561	Injection, immune globulin, (Gamunex/Gamunex-C/Gammaked), non–lyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), non–lyophilized, (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase,100 mg immunoglobulin

***Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.**

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.
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Revision Details

Summary of Changes	Review Date	Effective Date
New Policy.	6/25/2026	8/15/2026
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.).	8/20/2026	9/03/2026

The policy effective date is in force until updated or retired.

APPENDIX

Diagnosis	Approval Duration
Dermatomyositis or Polymyositis	1 year
Multifocal Motor Neuropathy	1 year
Human Immunodeficiency Virus (HIV), to Prevent Recurrent Infections	1 year
Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy	1 year
Lambert-Eaton Myasthenic Syndrome (LEMS)	1 year
Myasthenia Gravis (maintenance therapy)	1 year
Opsoclonus-Myoclonus-Ataxia Syndrome	1 year
Rasmussen Encephalitis	1 year
Stiff-Person Syndrome (Moersch-Woltman Syndrome)	1 year

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