Pharmacy Drug Policy & Procedure

Policy Name:	IVIG	Policy #:	1815P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Immune Globulin products (Asceniv, Atgam, Bivigam, Carimune NF, Cutaquig, Cuvitru, Flebogamma DIF, Gamastan, Gammagard, Gammagard S/D Less IgA, Gammaked, Gammaplex, Gamunex, Gamunex-C, Hizentra, Hyqvia, Nabi-HB, Octagam, Panzyga, Privigen, and Xembify).

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Asceniv, Atgam, Bivigam, Carimune NF, Cutaquig, Glebogamma DIF, Gamastan S/D, Gammagard, Gammaked, Gammaplex, Gamunex, Gamunex-C, Nabi-HB, Octagam or Privigen under the Specialty Medical benefit or Cuvitru, Hizentra, Hyqvia, or Xembify under the Specialty Pharmacy benefit when the following criteria have been met.

Criteria

1. Initial treatment with IVIG is a covered benefit for the following conditions:

1.1 Acute disseminated encephalomyelitis unresponsive to intravenous corticosteroids
- Methylprednisolone, dexamethasone

1.2 Acute infective polyneuritis (Guillain-Barre syndrome)

1.3 Autoimmune hemolytic anemia with:
- hemoglobin less than 7g/dl, OR
- abnormal enlargement of the liver (hepatomegaly)

1.4 Autoimmune mucocutaneous blistering diseases if member has failed corticosteroids or immunosuppressives or has rapidly progressive disease
- Some examples are: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita
- First-line therapies include systemic glucocorticoids such as prednisone, prednisolone, methylprednisolone and immunosuppressives such as azathioprine, mycophenolate, cyclophosphamide

1.5 Birdshot retinochoroidopathy
- First-line therapies include cyclosporine, prednisone, methotrexate

1.6 Graft-versus-host-disease [GVHD]
- Early transplant period of bone marrow transplantation
- Age 20 years or older
- Resistant to steroids

1.7 Chronic enteroviral meningoencephalitis in agammaglobulinemia

1.8 Chronic inflammatory demyelinating polyneuropathy (or CIDP)

1.9 Chronic lymphocytic leukemia with:
- Hypogammaglobulinemia, OR
- Recurrent bacterial infections

1.10 Churg-Strauss syndrome with failure of corticosteroids taken with cyclophosphamide

1.11 Dermatomyositis/polymyositis - may be used in patients with severe active illness for whom other interventions have been unsuccessful or intolerable
- Corticosteroids, methotrexate, azathioprine

1.12 Hemolytic disease of newborn (Erythroblastosis Fetalis)

1.13 HIV-related thrombocytopenia

1.14 HIV, Pediatric
- HIV-positive children who either have been exposed to measles or who live in a high-prevalence

measles area
- In conjunction with AZT or other antiretroviral treatment, to prevent mild to severe bacterial infection in children with CD4+ counts >200/uL
- In conjunction with AZT, to prevent maternal transmission of HIV infection

1.15 Idiopathic thrombocytopenic purpura in patients with:
- bleeding complications, OR
- unsafe platelet counts, OR
- requiring invasive interventions

1.16 Inclusion - body myositis
1.17 Kawasaki disease (acute febrile mucocutaneous lymph node syndrome) when administered with aspirin within 10 days of symptom onset
1.18 Lennox Gastaut, West Syndrome (refractory)
1.19 Moersch-Woltmann (Stiff-man) syndrome unresponsive to benzodiazepines and/or baclofen, phenytoin, clonidine, and tizanidine
1.20 Multifocal motor neuropathy
1.21 Primary humoral immunodeficiency diseases (such as congenital agammaglobulinemia, hypogammaglobulinemia, common variable immunodeficiency, Wiscott-Aldrich syndrome, Good syndrome, severe combined immunodeficiency) with supporting evidence of functional deficiency
1.22 Pure red cell aplasia
1.23 Selective IgG subclass deficiencies with:
- severe infection despite adequate treatment
- deficiencies in one or more IgG subclass to levels less than 2 SD below the age-specific mean

2. Approval Period

Initial: 6 months
Reapprovals: 6 months with documentation of beneficial response
Per 215 ILCS 5/356z.24, if member has been on therapy for at least 2 years and has beneficial response, approval will be for 12 months at a time.

Atgam, Bivigam, Carimune NF, Cuvitru, Glebogamma DIF, Gamastan S/D, Gammagard, Gammaplex, Gamunex, Gamunex-C, Hizentra, Hyqvia, Nabi-HB, Octagam and Privigen	
90281	Immune globulin (Ig), human, for intramuscular use
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each

HCPCS Codes	
J1459	Injection, immune globulin (Privigen), intravenous, nonlyophilized (e.g., liquid), 500 mg

J1460	Injection, gamma globulin, intramuscular, 1 cc
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1560	Injection, gamma globulin, intramuscular, over 10 cc
J1561	Injection, immune globulin, (Gamunex-c/Gammaked), nonlyophilized (e.g. liquid), 500 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (Octagam), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), nonlyophilized, (e.g. liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma / Flebogamma Dif), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase, (Hyqvia), 100 mg immunoglobulin
J1599	Injection, immune globulin, intravenous, non-lyophilized (eg, liquid), not otherwise specified, 500 mg

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