



Drug Class Prior Authorization Criteria
Immunoglobulins
Medical Benefit

Line of Business: Medicaid

P & T Approval Date: August 6, 2021

Effective Date: September 17, 2021

This drug class prior authorization criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and was approved by the IEHP Pharmacy and Therapeutics Subcommittee.

CRITERIA:

**BIVIGAM, CARIMUNE NF, FLEBOGAMMA, GAMMAGARD, GAMMAKED, GAMMAPLEX, GAMUNEX-C, OCTAGAM, PANZYGA, PRIVIGEN (IMMUNE GLOBULIN, INTRAVENOUS)
CUVITRU, HIZENTRA, HYQVIA, XEMBIFY (IMMUNE GLOBULIN, SUBCUTANEOUS)**

Covered Uses: *Acute or chronic inflammatory demyelinating neuropathy, including Guillain-Barre syndrome
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet the following requirement:
a. Rapidly progressive form of the disease as evidenced by “1” of the following
i. Deteriorating pulmonary function test
ii. Severe disease requiring aid to walk
iii. Significant functional disability

Age Restrictions: N/A

Prescriber Restrictions: N/A

Other Criteria: Reauthorization criteria:
a. Must meet the following requirement:
i. Clinical review by IEHP pharmacist

Covered Uses: *Autoimmune mucocutaneous blistering diseases including:
*Pemphigus vulgaris
*Pemphigus foliaceus

*Bullous pemphigoid
*Mucous membrane pemphigoid or cicatricial pemphigoid
*Epidermolysis bullosa acquisita
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: CCS eligible

Required Medical Information:

Must meet "1" of the following requirements:
a. Documentation of rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional therapy (e.g., immunosuppressive agents, plasmapheresis)
b. Failure or clinically significant adverse effects to "1" of the following: systemic corticosteroid, cyclophosphamide, azathioprine, or mycophenolate mofetil

Age Restrictions: N/A

Prescriber Restrictions: N/A

Other Criteria: Reauthorization criteria:
a. Must meet the following requirement:
i. Clinical review by IEHP pharmacist

Covered Uses: *Autoimmune retinopathy
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: CCS eligible

Required Medical Information:

Must meet the following requirement:
a. Confirmed diagnosis

Age Restrictions: N/A

Prescriber Restrictions: N/A

Other Criteria: Reauthorization criteria:
a. Must meet the following requirement:
i. Clinical review by IEHP pharmacist

Covered Uses: *Chronic Lymphocytic Leukemia (CLL)
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria:	CCS eligible
Required Medical Information:	Must meet "1" of the following: a. Documented IgG level less than 600 milligram per deciliter b. Documented history of bacterial infection(s)
Age Restrictions:	N/A
Prescriber Restrictions:	N/A
Other Criteria:	Reauthorization criteria: a. Must meet the following requirement: i. Clinical review by IEHP pharmacist

Covered Uses:	*Dermatomyositis, Polymyositis (*Subject to review by Clinical Pharmacist)
Exclusion Criteria:	CCS eligible
Required Medical Information:	Must meet "1" of the following requirements: a. Failure of clinically significant adverse effects to "1" of the following: corticosteroid therapy, azathioprine, methotrexate, or cyclophosphamide b. Rapidly progressive form of the disease
Age Restrictions:	N/A
Prescriber Restrictions:	N/A
Other Criteria:	Reauthorization criteria: a. Must meet the following requirement: i. Clinical review by IEHP pharmacist

Covered Uses:	*Idiopathic Thrombocytopenia Purpura (ITP) (*Subject to review by Clinical Pharmacist)
Exclusion Criteria:	CCS eligible
Required Medical Information:	Must meet "1" of the following requirements: a. To increase platelet count prior to surgery

- b. To control excessive bleeding or symptomatic thrombocytopenia
- c. To defer or avoid splenectomy following treatment with corticosteroids
- d. Platelet counts persistently at or below 20,000 per cubic millimeter

Age Restrictions: N/A

Prescriber Restrictions: N/A

Other Criteria: Reauthorization criteria:
a. Must meet the following requirement:
i. Clinical review by IEHP pharmacist

Covered Uses: *Idiopathic Thrombocytopenia Purpura (ITP) in pregnancy
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet "1" of the following:
a. Pregnant women who have previously delivered infants with autoimmune thrombocytopenia
b. Pregnant women who have platelet counts less than 75,000 per cubic millimeter during the current pregnancy
c. Pregnant women with history of splenectomy

Age Restrictions: N/A

Prescriber Restrictions: N/A

Other Criteria: Reauthorization criteria:
a. Must meet the following requirement:
i. Clinical review by IEHP pharmacist

Covered Uses: *Kawasaki syndrome (*Subject to review by Clinical Pharmacist)

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet the following requirement:
a. Confirmed diagnosis

Age Restrictions: N/A

Prescriber Restrictions: N/A

Other Criteria: Reauthorization criteria: Must meet the following requirement:
a. Clinical review by IEHP pharmacist

Covered Uses: *Lambert-Eaton myasthenic syndrome
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet "1" of the following requirements:
a. Failure or clinically significant adverse effects to "1" of the following: pyridostigmine, azathioprine or prednisone
b. Rapidly progressive form of the disease

Age Restrictions: N/A

Prescriber Restrictions: N/A

Other Criteria: Reauthorization criteria: Must meet the following requirement:
a. Clinical review by IEHP pharmacist

Covered Uses: *Myasthenia gravis
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet "1" of the following requirements:
a. Rapidly progressive form of the disease (e.g., acute crisis such as respiratory failure, swallowing difficulties)
b. Failure or clinically significant adverse effects to "1" of the following: pyridostigmine, azathioprine, cyclosporine, corticosteroid, or cyclophosphamide

Age Restrictions: N/A

Prescriber Restrictions: N/A

Other Criteria: Reauthorization criteria:
a. Must meet the following requirement:
i. Clinical review by IEHP pharmacist

Covered Uses: *Primary Immunodeficiency Syndrome (PID), including but not limited to:

- a. Hereditary hypogammaglobulinemia
- b. Immunodeficiency with increased immunoglobulin M (IgM)
- c. Severe combined immunodeficiency (SCID)
- d. Major histocompatibility complex deficiency
- e. Combined immunodeficiency, unspecified
- f. Wiskott-Aldrich syndrome
- g. Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function

(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet the following requirement:

- a. Individuals with agammaglobulinemia or hypogammaglobulinemia: documented IgG levels fall below 200 milligrams per deciliter

Age Restrictions: N/A

Prescriber Restrictions: N/A

Other Criteria: Reauthorization criteria:

- a. Must meet the following requirement:
 - i. Clinical review by IEHP pharmacist

Covered Uses: *Symptomatic Human Immunodeficiency Virus (HIV)
(*Subject to review by Clinical Pharmacist)

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet all of the following requirements:

- a. Age less than 13 years of age
- b. Must meet "1" of the following:
 - i. Baseline CD4+ lymphocyte counts greater than or equal to 200 per cubic millimeter
 - ii. Clinically symptomatic or asymptomatic, but immunologically abnormal

Age Restrictions: N/A

Prescriber Restrictions: N/A

Other Criteria: Reauthorization criteria:
a. Must meet the following requirement:
i. Clinical review by IEHP pharmacist

Change Control		
Date	Change	Author
07/15/2021	<ul style="list-style-type: none">Added PANZYGA and XEMBIFY	SV
08/28/2020	<ul style="list-style-type: none">Renew with no changes	RR
08/21/2019	<ul style="list-style-type: none">Renew	SV/ND
08/15/2018	<ul style="list-style-type: none">Reformatted documentAcute or chronic inflammatory demyelinating neuropathy: documentation of deteriorating pulmonary function test, severe disease requiring aid to walk or significant functional disabilityITP: documentation of platelet counts persistently at or below 20,000 per cubic millimeter	HC