



Drug Class Prior Authorization Criteria
Immunoglobulins
Medical Benefit

Line of Business: Medicaid

P & T Approval Date: November 3, 2023

Effective Date: December 1, 2023

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.

COVERAGE CRITERIA

GAMMAGARD, GAMMAKED, GAMUNEX-C, OCTAGAM (IMMUNE GLOBULIN, INTRAVENOUS)

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)
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 500 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
- e. Pregnant women:
 - i. Pregnant women who have previously delivered infants with autoimmune thrombocytopenia
 - ii. Pregnant women who have platelet counts less than 20,000 per cubic millimeter for natural delivery, 50,000 per cubic millimeter for cesarian delivery, if epidural then <70,000 per cubic millimeter
 - iii. 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: *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, mycophenolate, rituximab, 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 500 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

REFERENCES

1. American Academy of Allergy, Asthma & Immunology (AAAAI). Update on the use of immunoglobulin in human disease: A review of evidence. The Journal of Allergy and Clinical Immunology. Vol. 139, Issue 3, Supp S1-S46. March 2017. [https://www.jacionline.org/article/S0091-6749\(16\)31141-1/fulltext](https://www.jacionline.org/article/S0091-6749(16)31141-1/fulltext) Accessed July 14, 2023.

Change Control		
Date	Change	Author
08/23/2023	<ul style="list-style-type: none"> • Update to the list of covered product to mirror the formulary • Retired following indications with low utilization: Guillain Barre syndrome, Kawasaki syndrome, Lambert Eaton myasthenic syndrome, Measles post exposure prophylaxis, symptomatic HIV • Updated the references 	SV
06/23/2022	<ul style="list-style-type: none"> • Acute or chronic inflammatory demyelinating neuropathy, including Guillain-Barre syndrome: Added Failure of clinically 	CK

	<p>significant adverse effects to “1” of the following: azathioprine, chlorambucil, cyclophosphamide, cyclosporine</p> <ul style="list-style-type: none"> • CLL: Updated documented IgG level less than 500 milligram per deciliter • ITP: Combined ITP In Pregnancy with ITP general. Added Pregnant women who have previously delivered infants with autoimmune thrombocytopenia, Pregnant women who have platelet counts less than 20,000 per cubic millimeter for natural delivery, 50,000 per cubic millimeter for cesarian delivery, if epidural then <70,000 per cubic millimeter • LEM: added Failure of clinically significant adverse effects to “1” of the following: pyridostigmine • Myasthenia gravis: added Failure of clinically significant adverse effects to “1” of the following: mycophenolate, rituximab • PID: added IVIG is used with serum IgG levels <500 mg/dl • Indication of IVIG: Postexposure prophylaxis for Measles 	
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 document • Acute or chronic inflammatory demyelinating neuropathy: documentation of deteriorating pulmonary function test, severe disease requiring aid to walk or significant functional disability • ITP: documentation of platelet counts persistently at or below 20,000 per cubic millimeter 	HC