



Inland Empire Health Plan

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*Drug Class Prior Authorization Criteria*  
**Immunoglobulins**  
*Medical Benefit*

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**Line of Business:** Medicaid

**P & T Approval Date:** August 5, 2022

**Effective Date:** September 2, 2022

*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:**

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

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**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
  - iv. Failure of clinically significant adverse effects to “1” of the following: azathioprine, chlorambucil, cyclophosphamide, cyclosporine

**Age Restrictions:** N/A

**Prescriber Restrictions:** N/A

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

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**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

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**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
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<b>Covered Uses:</b>	*Dermatomyositis, Polymyositis (*Subject to review by Clinical Pharmacist)
<b>Exclusion Criteria:</b>	CCS eligible
<b>Required Medical Information:</b>	Must meet "1" of the following requirements: <ul style="list-style-type: none"><li>a. Failure of clinically significant adverse effects to "1" of the following: corticosteroid therapy, azathioprine, methotrexate, or cyclophosphamide</li><li>b. Rapidly progressive form of the disease</li></ul>
<b>Age Restrictions:</b>	N/A
<b>Prescriber Restrictions:</b>	N/A
<b>Other Criteria:</b>	Reauthorization criteria: <ul style="list-style-type: none"><li>a. Must meet the following requirement:<ul style="list-style-type: none"><li>i. Clinical review by IEHP pharmacist</li></ul></li></ul>

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<b>Covered Uses:</b>	*Idiopathic Thrombocytopenia Purpura (ITP) (*Subject to review by Clinical Pharmacist)
<b>Exclusion Criteria:</b>	CCS eligible
<b>Required Medical Information:</b>	Must meet "1" of the following requirements: <ul style="list-style-type: none"><li>a. To increase platelet count prior to surgery</li><li>b. To control excessive bleeding or symptomatic thrombocytopenia</li><li>c. To defer or avoid splenectomy following treatment with corticosteroids</li><li>d. Platelet counts persistently at or below 20,000 per cubic millimeter</li><li>e. Pregnant women:<ul style="list-style-type: none"><li>i. Pregnant women who have previously delivered infants with autoimmune thrombocytopenia</li><li>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 &lt;70,000 per cubic millimeter</li><li>iii. Pregnant women with history of splenectomy</li></ul></li></ul>
<b>Age Restrictions:</b>	N/A

**Prescriber Restrictions:** N/A

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

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**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

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**Covered Uses:** \*Lambert-Eaton myasthenic syndrome (LEM)  
(\*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: azathioprine, prednisone, pyridostigmine  
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

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**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

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**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

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<b>Covered Uses:</b>	*Postexposure prophylaxis for Measles (*Subject to review by Clinical Pharmacist)
<b>Exclusion Criteria:</b>	CCS eligible
<b>Required Medical Information:</b>	Must meet all of the following requirements: <ul style="list-style-type: none"><li>a. Exposure to measles</li><li>b. Must meet "1" of the following:<ul style="list-style-type: none"><li>i. Immunocompromised</li><li>ii. Pregnant women without evidence of immunity</li></ul></li></ul>
<b>Age Restrictions:</b>	N/A
<b>Prescriber Restrictions:</b>	N/A
<b>Other Criteria:</b>	Reauthorization criteria: <ul style="list-style-type: none"><li>a. Must meet the following requirement:<ul style="list-style-type: none"><li>i. Clinical review by IEHP pharmacist</li></ul></li></ul>

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<b>Covered Uses:</b>	*Symptomatic Human Immunodeficiency Virus (HIV) (*Subject to review by Clinical Pharmacist)
<b>Exclusion Criteria:</b>	CCS eligible
<b>Required Medical Information:</b>	Must meet all of the following requirements: <ul style="list-style-type: none"><li>c. Age less than 13 years of age</li><li>d. Must meet "1" of the following:<ul style="list-style-type: none"><li>i. Baseline CD4+ lymphocyte counts greater than or equal to 200 per cubic millimeter</li><li>ii. Clinically symptomatic or asymptomatic, but immunologically abnormal</li></ul></li></ul>
<b>Age Restrictions:</b>	N/A
<b>Prescriber Restrictions:</b>	N/A
<b>Other Criteria:</b>	Reauthorization criteria: <ul style="list-style-type: none"><li>b. Must meet the following requirement:<ul style="list-style-type: none"><li>j. Clinical review by IEHP pharmacist</li></ul></li></ul>

Change Control		
Date	Change	Author
6/23/2022	<ul style="list-style-type: none"> <li>Acute or chronic inflammatory demyelinating neuropathy, including Guillain-Barre syndrome: Added Failure of clinically significant adverse effects to "1" of the following: azathioprine, chlorambucil, cyclophosphamide, cyclosporine</li> <li>CLL: Updated documented IgG level less than 500 milligram per deciliter</li> <li>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 &lt;70,000 per cubic millimeter</li> <li>LEM: added Failure of clinically significant adverse effects to "1" of the following: pyridostigmine</li> <li>Myasthenia gravis: added Failure of clinically significant adverse effects to "1" of the following: mycophenolate, rituximab</li> <li>PID: added IVIG is used with serum IgG levels &lt;500 mg/dl</li> <li>Indication of IVIG: Postexposure prophylaxis for Measles</li> </ul>	CK
07/15/2021	<ul style="list-style-type: none"> <li>Added PANZYGA and XEMBIFY</li> </ul>	SV
08/28/2020	<ul style="list-style-type: none"> <li>Renew with no changes</li> </ul>	RR
08/21/2019	<ul style="list-style-type: none"> <li>Renew</li> </ul>	SV/ND
08/15/2018	<ul style="list-style-type: none"> <li>Reformatted document</li> <li>Acute or chronic inflammatory demyelinating neuropathy: documentation of deteriorating pulmonary function test, severe disease requiring aid to walk or significant functional disability</li> <li>ITP: documentation of platelet counts persistently at or below 20,000 per cubic millimeter</li> </ul>	HC