

Immunoglobulins

Goal(s):

- Ensure that medications for immunoglobulins are used appropriately for OHP-funded conditions.
- Provide coverage for off-label indications that have evidence for use.

Length of Authorization:

- Up to 12 months

Requires PA:

- Non-preferred immunoglobulin

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. FDA Approved Indications and Off-label Immune Globulin Indications

FDA Approved Indications	Adults	Pediatrics
B-cell chronic lymphocytic leukemia variant (CLL)	Yes	No
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	Yes	No
Dermatomyositis	Yes	No
Hepatitis A Prophylaxis	Yes	No
Idiopathic thrombocytopenic purpura (ITP)	Yes	Yes -2 years and up
Kawasaki Disease	No	Yes
Measles Prophylaxis and post-exposure prophylaxis	Yes	Yes
Multifocal motor neuropathy (MMN)	Yes	No
Primary humoral immunodeficiencies (PI)*	Yes	Yes - 2 years and up
Rubella in pregnancy	Yes	No
Varicella prophylaxis	Yes	No
Off-Label Indications with Evidence for Efficacy	Adults	Pediatrics
Autoimmune hemolytic anemia	Yes	No
Autoimmune necrotizing myopathy	Yes	No
Autoimmune neutropenia	Yes	No
Cytomegalovirus infection	Yes	No
Guillain-Barre syndrome	Yes	Yes
Human Immunodeficiency Virus (HIV)	No	Yes
IgA nephropathy	Yes	No
Multisystem inflammatory syndrome in children; associated with SARS-CoV-2	No	Yes
Myasthenia Gravis	Yes	No
Neonatal jaundice	No	Yes
Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)	No	Yes
Pemphigus	Yes	No
Respiratory syncytial virus	No	Yes
Toxic shock syndrome	Yes	No
Transplant rejection or desensitization	Yes	No

Uveitis	Yes	No
Von Willebrand disorder	Yes	No

* Primary humoral immunodeficiency includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Will the prescriber consider a change to a preferred product? Message: Preferred products do not generally require a PA. Preferred products are evidence-based and reviewed for comparative effectiveness and safety by the P&T Committee.	Yes: Inform prescriber of covered alternatives in class.	No: Go to #3
3. Is the request for continuation of therapy previously approved by fee-for-service?	Yes: Go to Renewal Criteria	No: Go to #4
4. Is the request for an FDA-approved indication or for an off-label indication, with evidence of efficacy, listed in Table 1?	Yes: Approve for 6 months	No: Go to #5
5. Is the request for continuation after a hospital discharge?	Yes: Approve for 6 months	No: Go to #6
6. Is the medication prescribed by, or in consultation with a neurologist, transplant provider, infectious disease, or other relevant specialist for the requested condition?	Yes: Go to #7	No: Pass to RPh. Deny; medical appropriateness
7. Is the request for acute treatment anticipated to last less than 3 months?	Yes: Approve for requested duration	No: Go to #8
8. Is there objective documentation of disease severity using a validated measure? Examples could include number of hospitalizations, quality of life assessed using the Short-Form 36, clinical test results, or other symptom assessment scale relevant to the requested condition.	Yes: Go to #9 Document disease severity	No: Pass to RPh. Deny; medical appropriateness

Approval Criteria

9. All other diagnoses must be evaluated as to the OHP-funding level and evidence for clinical benefit.

- Evidence supporting treatment for conditions which are not outlined above is currently insufficient and should be denied for “medical appropriateness”

If new evidence or guideline-recommendations are provided by the prescriber, please forward request to Oregon DMAP for consideration and potential modification of current PA criteria.

Renewal Criteria

1. Is there documentation to demonstrate clinically meaningful improvement in symptoms, function, disease severity, or quality of life since initiation of treatment?

The same clinical measure used to document disease severity is recommended to document clinical benefit.

Yes: Approve for 12 months

No: Pass to RPh. Deny; medical appropriateness.

P&T/DUR Review: 10/24 (KS)

Implementation: 12/1/2024