

Obinutuzumab (GAZYVA®)

Goal(s):

- Promote use that is consistent with national clinical practice guidelines and medical evidence.

Length of Authorization:

- 12 months

Requires PA:

- Gazyva® (obinutuzumab) pharmacy or provider administered claims.

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/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD-10 code.	
2. Is the ICD-10 for an oncology indication?	Yes: Use "Oncology Agents" prior authorization document to adjudicate request.	No: Go to #3
3. Does the patient have severe active central nervous system lupus?	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #4
4. Is this a request for continuation of therapy previously approved by fee-for-service (FFS)?	Yes: Go to Renewal Criteria	No: Go to #5
5. Is the patient an adult diagnosed with active lupus nephritis class III, IV, or V?	Yes: Go to #6	No: Pass to RPh. Deny; medical appropriateness
6. Is the patient currently on another biologic agent without a documented plan to switch therapy?	Yes: Pass to RPh. Deny; medical appropriateness.	No: Go to #7
7. Is the drug being prescribed by or in consultation with a rheumatologist, nephrologist, or a provider with experience treating lupus nephritis?	Yes: Go to #8	No: Pass to RPh. Deny; medical appropriateness

Approval Criteria		
8. Does the patient have a baseline assessment of renal function with both of the following tools within 6 months: - Urinary protein-to-creatinine ratio (UPCR) - estimated Glomerular Filtration Rate (eGFR)	Yes: Go to #9 Document baseline assessment _____.	No: Pass to RPh. Deny; medical appropriateness
9. Is the patient currently taking or have a documented contraindication, intolerance, or inadequate response to all of the following: - Hydroxychloroquine - Mycophenolate - Glucocorticoids (e.g. prednisone)	Yes: Go to #10	No: Pass to RPh. Deny; medical appropriateness.
10. Does the patient have a urine protein-to-creatinine ratio of >500 mg/g?	Yes: Go to #11	No: Pass to RPh. Deny; medical appropriateness.
11. Is the patient currently taking, or have a documented contraindication, intolerance, or inadequate response to, either an angiotensin-converting enzyme inhibitor (ACEI) OR an angiotensin II receptor blocker (ARB)?	Yes: Go to #12	No: Pass to RPh. Deny; medical appropriateness.
12. Is the patient of childbearing potential?	Yes: Go to #13	No: Approve for 12 months
13. Is the patient pregnant or actively trying to conceive?	Yes: Pass to RPh. Deny; medical appropriateness.	No: Go to #14
14. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant?	Yes: Approve for 12 months	No: Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Is the patient currently on another biologic agent?	Yes: Pass to RPh. Deny; medical appropriateness.	No: Go to #2

Renewal Criteria

2. Has the patient's renal function improved or stabilized as assessed by one of the following:

- UPCR
- eGFR

Yes: Approve for 12 months.

No: Pass to RPh; Deny; medical appropriateness.

P&T/DUR Review: 08/26 (SF)
Implementation: 10/01/26