

<b>Clinical Policy Title:</b>	belimumab
<b>Policy Number:</b>	RxA.037
<b>Drug(s) Applied:</b>	Benlysta®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Systemic Lupus Erythematosus (SLE) (must meet all):

1. Diagnosis of SLE;
2. Documentation confirms that member is positive for an SLE autoantibody (e.g., antinuclear antibody (ANA), anti-double-stranded DNA (anti-dsDNA), anti-Smith (antiSm), anti-ribonucleoprotein (anti-RNP), anti-Ro/SSA, anti-La/SSB, antiphospholipid antibody);
3. Prescribed in combination with standard therapy for SLE that includes one or more of the following agents, unless all agents are contraindicated: glucocorticoids (e.g., prednisone), antimalarial (e.g., hydroxychloroquine or chloroquine), non-biologic immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate).

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

#### B. Lupus Nephritis (must meet all):

1. Diagnosis of active lupus nephritis with class III, IV and/or V;
2. Member is currently receiving standard immunosuppressive therapy (e.g. corticosteroids, cyclosporine, tacrolimus, cyclophosphamide, azathioprine, mycophenolate and rituximab).

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

#### A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## References

1. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Ann Rheum Dis* 2019;0:1–10. doi:10.1136/annrheumdis-2019-215089. Available at: <https://ard.bmj.com/content/annrheumdis/early/2019/03/28/annrheumdis-2019-215089.full.pdf>. Accessed August 28, 2024.
2. Gordon C, Amissah-Arthur MB, Gayed M, et al. The British Society for Rheumatology guideline for the management

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

of systemic lupus erythematosus in adults. Rheumatology 2018;57(1):e1-e45. doi:10.1093/rheumatology/kex286. Available at: <https://academic.oup.com/rheumatology/article/57/1/e1/4318863>. Accessed August 28, 2024

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Policy title table was updated: Line of business policy applies was updated to All lines of business.</li> <li>2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”.</li> <li>3. Approval duration was updated (HIM removed).</li> <li>4. References were reviewed and updated.</li> </ol>	10/05/2020	12/07/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.B was updated to include a new indication, “Lupus Nephritis”.</li> <li>2. Continued Therapy Criteria II.A.4 was updated to remove “at 2-week intervals for the first 3 doses and at 4-week intervals thereafter”.</li> <li>3. Continued Therapy Criteria II.B was updated to include a new indication, “Lupus Nephritis”.</li> <li>4. References were reviewed and updated.</li> </ol>	08/30/2021	12/07/2021
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Continued Therapy Approval Criteria II.A.1 &amp; II.B.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</li> <li>2. Initial Approval Criteria, I.B.6 and I.B.7, “Member has not received dialysis treatment in past 12 months” and “No previous use of belimumab in past 12 months” were removed.</li> <li>3. References were reviewed and updated.</li> </ol>	03/16/2022	07/18/2022
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, 1.A.5: Updated indication from Currently receiving standard therapy for SLE that includes one or more of the following agents, unless all agents are contraindicated: glucocorticoids (e.g., prednisone), antimalarial (e.g., hydroxychloroquine or chloroquine), non-</li> </ol>	10/03/2022	10/19/2022

<p>biologic immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate); to Prescribed in combination with standard therapy for SLE that includes one or more of the following agents, unless all agents are contraindicated: glucocorticoids (e.g., prednisone), antimalarial (e.g., hydroxychloroquine or chloroquine), non-biologic immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate).</p> <ol style="list-style-type: none"> <li>2. Initial Approval Criteria, I.B.2: Updated age criteria from Age ≥ 18 years to Age ≥ 5 years.</li> <li>3. Initial Approval Criteria, 1.B.3: Updated to include new prescriber criteria Prescribed by or in consultation with a nephrologist or a rheumatologist.</li> <li>4. Initial Approval Criteria, 1.B.4: Updated to remove prior diagnostic criteria “Member does not have severe active central nervous system lupus.”</li> <li>5. Initial Approval Criteria, 1.B.5: Updated to remove prior combination therapy criteria “Member is not receiving Benlysta® in combination with other biologic agents or intravenous cyclophosphamide.”</li> <li>6. Initial Approval Criteria, I.B.6.b: Updated to include new dosing criteria Pediatrics (Age ≥ 5 years): Dose does not exceed 10 mg/kg/dose intravenously at 2-week intervals for the first 3 doses and at 4-week intervals thereafter.</li> <li>7. Continued Therapy Approval Criteria, II.B.4.b: Updated to include new dosing criteria Pediatrics (Age ≥ 5 years): Dose does not exceed 10 mg/kg/dose intravenously.</li> <li>8. References were reviewed and updated.</li> </ol>		
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed age restrictions.</li> <li>2. Removed prescriber restrictions.</li> <li>3. Removed dose restrictions.</li> <li>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li> </ol>	<p>08/28/2024</p>	<p>09/13/2024</p>

<ul style="list-style-type: none"> <li>5. Removed other reauthorization requirements including positive response to therapy.</li> <li>6. Updated approval duration verbiage.</li> <li>7. Reauthorization criteria for all the diagnosis merged under "All Indications in Section I".</li> <li>8. References were reviewed and updated.</li> </ul>		
Policy reviewed.	12/11/2025	12/11/2025