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| **Clinical Policy Title:** | belimumab |
| **Policy Number:** | RxA.037 |
| **Drug(s) Applied:** | Benlysta® |
| **Original Policy Date:** | 03/06/2020 |
| **Last Review Date:** | 08/28/2024 |
| **Line of Business Policy Applies to:** | 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

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 |
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| Policy established. | 01/2020 | 03/06/2020 |
| Policy was reviewed:<br>1. Policy title table was updated: Line of business policy applies was updated to All lines of business.<br>2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”.<br>3. Approval duration was updated (HIM removed).<br>4. References were reviewed and updated. | 10/05/2020 | 12/07/2020 |
| Policy was reviewed:<br>1. Initial Approval Criteria I.B was updated to include a new indication, “Lupus Nephritis”.<br>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”.<br>3. Continued Therapy Criteria II.B was updated to include a new indication, “Lupus Nephritis”.<br>4. References were reviewed and updated. | 08/30/2021 | 12/07/2021 |
| Policy was reviewed:<br>1. Continued Therapy Approval Criteria II.A.1 & II.B.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".<br>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.<br>3. References were reviewed and updated. | 03/16/2022 | 07/18/2022 |
| Policy was reviewed:<br>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- | 10/03/2022 | 10/19/2022 |

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| 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).<br>2. Initial Approval Criteria, I.B.2: Updated age criteria from Age ≥ 18 years to Age ≥ 5 years.<br>3. Initial Approval Criteria, 1.B.3: Updated to include new prescriber criteria Prescribed by or in consultation with a nephrologist or a rheumatologist.<br>4. Initial Approval Criteria, 1.B.4: Updated to remove prior diagnostic criteria "Member does not have severe active central nervous system lupus."<br>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."<br>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.<br>7. Continued Therapy Approval Crtieria, II.B.4.b: Updated to include new dosing criteria Pediatrics (Age ≥ 5 years): Dose does not exceed 10 mg/kg/dose intravenously.<br>8. References were reviewed and updated. | | |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |
| Policy was reviewed:<br>1. Removed age restrictions.<br>2. Removed prescriber restrictions.<br>3. Removed dose restrictions.<br>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. | 08/28/2024 | 09/13/2024 |

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| 5. Removed other reauthorization requirements including positive response to therapy.<br>6. Updated approval duration verbiage.<br>7. Reauthorization criteria for all the diagnosis merged under “All Indications in Section I”.<br>8. References were reviewed and updated. | | |