Clinical Policy Title:	anifrolumab-fnia
Policy Number:	RxA.701
Drug(s) Applied:	Saphnelo®
Original Policy Date:	8/19/2021
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Systemic lupus erythematosus (must meet all):

1. Diagnosis of active systemic lupus erythematosus, without severe active central nervous system lupus or severe active lupus nephritis;
2. Laboratory testing has documented the presence of autoantibodies (e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB);
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Member is receiving standard-of-care therapy with at least one of the following unless contraindicated or clinically significant side effects experienced: glucocorticoids (e.g., prednisone), antimalarial (e.g., hydroxychloroquine, chloroquine), non-biologic immunosuppressants (azathioprine, mycophenolate mofetil or methotrexate);
6. Dose does not exceed 300 mg intravenously every 4 weeks.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Systemic lupus erythematosus (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy based on reduction in signs and symptoms of SLE, which may include number of flares, disease activity in specific organs;
3. Member is receiving standard-of-care therapy with at least one of the following unless contraindicated or clinically significant side effects experienced: glucocorticoids (e.g., prednisone), antimalarial (e.g., hydroxychloroquine, chloroquine), non-biologic immunosuppressants (azathioprine, mycophenolate mofetil or methotrexate);
4. If request is for a dose increase, dose does not exceed 300 mg intravenously every 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. A Multicentre, Randomised, Double-Blind, Placebo-Controlled, Phase 3 Study Evaluating the Efficacy and Safety of Two Doses of Anifrolumab in Adult Subjects with Active Systemic Lupus Erythematosus. clinicaltrials.gov; 2022. Available at: https://www.clinicaltrials.gov/ct2/show/NCT02446912. Accessed May 30, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	8/19/2021	9/14/2021
Policy was reviewed: 1. Initial Approval Criteria, 1.A.1: Updated indication from Diagnosis of active systemic lupus erythematosus to Diagnosis of active systemic lupus erythematosus, without severe active central nervous system lupus or severe active lupus nephritis. 2. Initial Approval Criteria, 1.A.2: Updated to include new diagnostic criteria Laboratory testing has documented the presence of autoantibodies (e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB). 3. Initial Approval Criteria, I.A.5: Standard of care therapy criteria was restructured and updated to include chloroquine under antimalarial category. 4. Initial Approval Criteria, I.A.5: Updated to remove prior diagnostic criteria “Member does not have severe active central nervous system (CNS) lupus.” 5. Initial Approval Criteria, I.A.6: Updated to remove prior diagnostic criteria “Member does not have active lupus nephritis.” 6. Initial Approval Criteria, I.A.6: Updated to include new combination therapy criteria Member is not receiving Saphnelo™ in combination with a biologic agent or Benlysta. 7. Continued Therapy Approval, II.A.3: Updated to include new standard of care therapy criteria Member is receiving standard-of-care therapy with at least one of the following unless contraindicated or clinically significant side effects experienced: glucocorticoids (e.g., prednisone), antimalarial (e.g., hydroxychloroquine, chloroquine), non-biologic immunosuppressants (azathioprine, mycophenolate mofetil or methotrexate). 8. References were reviewed and updated.	06/27/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.6: Member is not receiving Saphnelo™ in combination with a biologic agent or Benlysta. 2. References were reviewed and updated.	05/30/2023	07/13/2023

Policy was reviewed.	10/19/2023	10/19/2023