ATRIO HEALTH PLANS

Immunologic Agents: Miscellaneous

Saphnelo (anifrolumab-fnia) J0491 is Non-preferred. Preferred alternatives are Benlysta (belimumab) J0490 (Injectable – Part B) and (subcutaneous - Part D) See Part D formulary for full list of potential alternatives.

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

- ☐ Patient is 18 years of age or older; AND
- ☐ Patient has a diagnosis of Systemic Lupus Erythematosus per the American College of Rheumatology (ACR); AND
- ☐ Documentation is provided that disease is considered moderate to severe, and is active and documented by a SLEDAI-2K score greater than or equal to 6 while on current treatment regimen for SLE; AND
- ☐ Documentation is provided that Patient has a positive anti-nuclear antibody (ANA) titer greater than or equal to 1:80 or antidsDNA greater than or equal to 30 IU/mL; AND
- ☐ Patient's SLE disease remains active while on corticosteroids, antimalarials, or immunosuppressants (alone or as combination therapy) for at least the last 30 days; AND
- ☐ Patient is using in combination with standard therapy (for example, corticosteroids, antimalarials, and/or immunosuppressants [but not other biologics or cyclophosphamide]).

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ **Continuation Requests: (Clinical documentation required for all requests)**

☐ Documentation is provided showing improvement in disease activity following treatment with Saphnelo (anifrolumab-fnia) indicating a therapeutic response; AND

☐ Patient has no evidence of severe active central nervous system lupus (such as psychosis or seizures); AND

☐ Patient has no evidence of severe active lupus nephritis (defined as proteinuria greater than 6 gm/d, serum creatinine greater than 2.5 mg/dl, or requiring dialysis);

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Immunologic: Multiple Diagnoses PA

Drug Name(s):

BENLYSTA	**BELIMUMAB**
SAPHNELO	**ANIFROLUMAB-FNIA**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

Prescribed by or in consultation with a Rheumatologist or Lupus specialist.

Coverage Duration:

Approvals will be for 12 months

FDA Indications:

Benlysta

- Lupus nephritis, Active, receiving standard therapy
- Systemic lupus erythematosus, Active, autoantibody-positive, receiving standard therapy

Saphnelo

- Systemic lupus erythematosus (Moderate to Severe), Receiving standard therapy

Off-Label Uses:

Benlysta

- Rheumatoid arthritis

Age Restrictions: **N/A**

Other Clinical Considerations:

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/7623EA/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/7EB152/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Belimumab&UserSearchTerm=Belimumab&SearchFilter=filterNone&navitem=searchGlobal#

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CLINICAL / CMS ONLY