SENTARA HEALTH PLAN

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Benlysta® (belimumab) **Intravenous Infusion (J0490) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosage & Administration: Intravenous administration in adults and pediatric patients ≥ 5 years of age with SLE or Lupus Nephritis −10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter. Reconstitute, dilute, and administer as an intravenous infusion over a period of 1 hour.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

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❑ Diagnosis: Active Systemic Lupus Erythematosus (SLE) in patients who are receiving standard therapy

Initial Authorization: 12 months

- ❑ Must be prescribed by or in consultation with a rheumatologist
- ❑ Member is 5 years of age or older with a diagnosis of active, autoantibody-positive SLE confirmed by **ONE** of the following **(must submit lab results)**:
  - ❑ anti-nuclear antibody (ANA) titer ≥ 1:80
  - ❑ anti-double stranded DNA (anti-dsDNA) ≥ 30 IU/mL
- ❑ Member's SLE activity has been confirmed by **ONE** of the following **(must submit results)**:
  - ❑ Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of 6-12
  - ❑ ≥ 2 British Isles Lupus Assessment Group (BILAG) B organ domain scores
- ❑ Member has tried **three (3)** of the following and is established on **TWO** of the following therapies taken for the last 90 days **(please submit chart notes documenting therapy trials with insufficient disease control)**:

❑ mycophenolate	❑ hydroxychloroquine	❑ azathioprine
❑ cyclophosphamide	❑ methotrexate	❑ cyclosporine
❑ corticosteroids	❑ Other: _____	

- ❑ Member does **NOT** have any of the following limitations to therapy: severe active central nervous system lupus; current or previous diagnosis of progressive multifocal leukoencephalopathy (PML); or concurrent use with other biologics

❑ Diagnosis: Active Lupus Nephritis in patients who are receiving standard therapy

Initial Authorization: 12 months

- ❑ Must be prescribed by or in consultation with a nephrologist or rheumatologist
- ❑ Member is 5 years of age or older with a diagnosis of active lupus nephritis Class III, IV, or V as confirmed by renal biopsy
- ❑ Member's diagnosis of active, autoantibody-positive SLE was confirmed by **ONE** of the following **(must submit lab results)**:
  - ❑ anti-nuclear antibody (ANA) titer ≥ 1:80
  - ❑ anti-double stranded DNA (anti-dsDNA) ≥ 30 IU/mL
- ❑ Member has active renal disease and has received standard therapy for the last 90 days with corticosteroids along with **ONE** of the following (**chart notes documenting established therapy must be submitted)**:
  - ❑ mycophenolate
  - ❑ cyclophosphamide

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- ❑ Provider must obtain a baseline measurement of **ONE** of the following collected within the last 30 days **(must submit lab results)**:
  - ❑ urine protein:creatinine ratio (uPCR)
  - ❑ urine protein
- ❑ Member does **NOT** have any of the following limitations to therapy: severe active central nervous system lupus; current or previous diagnosis of progressive multifocal leukoencephalopathy (PML); or concurrent use with other biologics

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ **Diagnosis: Systemic Lupus Erythematosus (SLE) in adults**

- ❑ All of the initial authorization criteria continue to be met
- ❑ Member's response to therapy has been confirmed by **ONE** of the following **(must submit results)**:
  - ❑ Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score has improved by and/or maintained at a level that is ≥4 points below baseline score
  - ❑ No new BILAG-A organ domain score OR 2 new BILAG-B organ domain scores
- ❑ Member has an absence of intolerable side effects such as serious infections, signs or symptoms of progressive multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reactions/anaphylaxis, or serious infusion reactions

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ **Diagnosis: Active Lupus Nephritis in adults**

- ❑ All of the initial authorization criteria continue to be met
- ❑ Member has had improvement from baseline and/or stabilization since last approval of **ONE** of the following **(must submit current labs completed within the last 30 days)**:
  - ❑ Urine protein:creatinine ratio (uPCR)
  - ❑ Urine protein
- ❑ Member has an absence of intolerable side effects such as serious infections, signs or symptoms of progressive multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reactions/anaphylaxis, or serious infusion reactions

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Medication being provided by a Specialty Pharmacy - PropriumRx

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy , not meet step edit/ preauthorization criteria.*****
****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee:** ~~3/8/2021;~~ **9/15/2022**
REVISED/UPDATED: ~~6/11/2021; 10/8/2021;~~ **10/4/2022**;