curative

Benlysta Prior Authorization

Drug(s) Applied:	**Benlysta** (belimumab)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria
- **A. Active systemic lupus erythematosus (SLE)** as indicated by chart notes within past 120 days
  1. ONE of the following:
     a) Patient has a history of positive antinuclear antibody (ANA) results **or**
     b) Patient has a history of low complement levels (C3 or C4 below the lower limit of normal) and/or positive anti-phospholipid antibodies (aPL) (IgA, IgG, IgM, or lupus anticoagulant) **and**
  2. Patient has a SLE additive diagnostic criteria score ≥10 **and**
  3. Patient is currently being treated with hydroxychloroquine or chart notes document contraindication to hydroxychloroquine **and**
  4. Patient is currently being treated with or has had an intolerance or failure to at least ONE immunosuppressive therapy (e.g. mycophenolate, azathioprine, methotrexate, tacrolimus, cyclosporine) or has an FDA labeled contraindication to ALL guideline-recommended immunosuppressive therapies **and**
  5. Patient is 5 years of age and over **and**
  6. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., rheumatology) **and**
  7. Chart notes and/or prescriber do not provide documentation of severe active central nervous system lupus **and**
  8. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another biologic agent or with Lupkynis

  Approval Duration: 12 months

- **B. Active lupus nephritis (LN)** as indicated by chart notes within past 120 days
  1. Lupus nephritis is confirmed by percutaneous kidney biopsy unless contraindicated or not feasible **and**
  2. ONE of the following:
     a) Patient has Class III/IV LN with or without Class V LN **or**

b) Patient has any Class LN with refractory disease (e.g. failed 2 standard therapy courses, minimum of 6 months each) **and**

3. Patient is currently being treated with hydroxychloroquine or chart notes document contraindication to hydroxychloroquine **and**
4. Patient is currently being treated with mycophenolate or cyclophosphamide for a minimum of 6 months or chart notes document contraindication to both **and**
5. Patient has had failure to an adequate trial (minimum 6 months) of at least ONE calcineurin inhibitor (e.g. tacrolimus, cyclosporine) or has an FDA labeled contraindication to ALL calcineurin inhibitors **and**
6. If documentation shows evidence of proteinuria (above normal range), patient is starting or is currently on a renin-angiotensin-aldosterone system (RAAS) inhibitor (e.g. lisinopril, enalapril, losartan, valsartan) **and**
7. Patient is 5 years of age and over **and**
8. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., rheumatology, nephrology) **and**
9. Chart notes and/or prescriber do not provide documentation of severe active central nervous system lupus **and**
10. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another biologic agent or with Lupkynis

Approval Duration: 12 months

II. Continued Therapy Criteria

A. Active systemic lupus erythematosus (SLE) as indicated by chart notes within past 12 months

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
1. Patient is currently being treated with hydroxychloroquine or chart notes document contraindication to hydroxychloroquine **and**
2. Documented clinical benefit since starting the requested agent (e.g. remission or lower level of disease activity) **and**
3. Chart notes and/or prescriber do not provide documentation of severe active central nervous system lupus **and**
4. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another biologic agent or with Lupkynis

Approval Duration: 12 months

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B. Active lupus nephritis (LN) as indicated by chart notes within past 12 months

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
2. Patient is currently being treated with hydroxychloroquine and mycophenolate or chart notes document contraindication to both **and**
3. Within 6-12 months of starting Benlysta, there is documented clinical benefit of BOTH of the following:
    a) Stabilization or improvement in kidney function **and**
    b) Reduction in proteinuria by at least 50% and level is either < 3 g/g (300 mg/mmol) i.e., partial renal response or < 0.5 g/g (50 mg/mmol) i.e. complete renal response **and**
4. If documentation shows evidence of proteinuria (above normal range), patient is starting or is currently on a renin-angiotensin-aldosterone system (RAAS) inhibitor (e.g. lisinopril, enalapril, losartan, valsartan) **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., rheumatology, nephrology) **and**
6. Chart notes and/or prescriber do not provide documentation of severe active central nervous system lupus **and**
7. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another biologic agent or with Lupkynis

Approval Duration: 12 months

If submitting for medical billing:
J0490, belimumab (Benlysta), 1 unit = 10 mg

Policy Owned by: Curative PBM team