Benlysta (belimumab)

Line(s) of Business: HMO; PPO; QUEST Integration
Medicare Advantage

Effective Dates:
Original Effective Date: 10/01/2015
Current Effective Date: 08/23/2019

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no contraindications or exclusions to the prescribed therapy.

FDA-Approved Indication
Treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy.

Limitations of Use
The efficacy of Benlysta has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review (where applicable):
- Initial therapy
  - A completed Systemic Lupus Erythematosus Disease Activity Index SELENA Modification Form documenting member’s SELENA-SLEDAI* score of 6 or greater
  - Autoantibody test results supporting autoantibody positive as demonstrated by anti-nuclear antibody (ANA) titer ≥ 1:80 and/or anti-double-stranded DNA (anti-dsDNA) ≥ 30 IU/ml

*Abbreviation: SELENA-SLEDAI = Safety of Estrogens in Lupus Erythematosus National Assessment – Systemic Lupus Erythematosus Disease Activity Index

C. EXCLUSIONS
Coverage will not be provided for members with any of the following exclusions:
- Severe active lupus nephritis
- Severe active central nervous system lupus

D. CRITERIA FOR INITIAL APPROVAL
Systemic Lupus Erythematosus (SLE)
Authorization of 24 months may be granted for treatment of active SLE when all of the following criteria are met:
1. Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., anti-nuclear antibody or anti-double-stranded DNA antibody).
2. The member is currently receiving standard therapy for SLE (see Appendix) or has tried and had an inadequate response or intolerance to standard therapy for SLE.

E. CONTINUATION OF THERAPY
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

F. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

G. ADMINISTRATIVE GUIDELINES
Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

H. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. APPENDIX
Standard Therapy for SLE
• Antimalarials (e.g., hydroxychloroquine)
• Azathioprine
• Corticosteroids
• Leflunomide
• Methotrexate
• Mycophenolate mofetil
• Non-steroidal anti-inflammatory drugs

J. REFERENCES

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