Benlysta® (belimumab)

When requesting Benlysta® (belimumab), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indication[1]

- For the treatment of an adult with active, autoantibody-positive, systemic lupus erythematosus who is receiving standard therapy

Approved Off-label Compendial uses[2]

- No off-label uses meet evidence standards

Coverage Guidelines

- Active systemic lupus erythematosus (SLE)[1]
- The individual is autoantibody (eg, antinuclear antibody test [ANA], antibodies to double-stranded DNA [anti-dsDNA], antibodies to Sm [anti-Sm]positive)[1,3]
- The individual does **not** have severe active lupus nephritis or severe active central nervous system lupus[1]
- Benlysta® (belimumab) will **not** be used in combination with other biologics or intravenous cyclophosphamide[1]
- The individual is receiving standard therapy for SLE including any of the following (alone or in combination)[1]:
    - Corticosteroids
    - Antimalarials
    - Nonsteroidal anti-inflammatory drugs (NSAIDs)
    - Immunosuppressive agents

Approve for 12 months

Additional Information for Prescribers[1]

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

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References

1. Benlysta® prescribing information. Research Triangle Park, NC: GlaxoSmithKline: January 2017. https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Benlysta/pdf/BENLYSTA-PI-MG.PDF. Accessed April 17, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed April 17, 2017. http://www.micromedexsolutions.com.
3. Bertsias G, Cervera R, Boumpas DT, et al. Systemic lupus erythematous: pathogenesis and clinical features. May 2012. Accessed April 17, 2017. http://www.eular.org/myUploadData/files/sample%20chapter20_mod%2017.pdf.

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