



**Final Appraisal Recommendation**

Advice No: 0720 – July 2020

**Belimumab (Benlysta®) 120 mg, 400 mg powder for concentrate for solution for infusion**

**Limited submission by GlaxoSmithKline**

**Recommendation of AWMSG**

**Belimumab (Benlysta®) is recommended as an option for restricted use within NHS Wales.**

**Belimumab (Benlysta®) is licensed as add-on therapy in patients aged 5 years to < 18 years old with active, autoantibody-positive systemic lupus erythematosus with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy.**

**Belimumab (Benlysta®) is restricted for the treatment of patients who have serological disease activity (defined as positive anti-double-stranded DNA and low complement) and a Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score greater than or equal to 10 despite standard treatment. Belimumab (Benlysta®) treatment should be continued beyond 24 weeks only if the SELENA-SLEDAI score has improved by 4 points or more.**

**Belimumab (Benlysta®) is not recommended for use within NHS Wales outside of this subpopulation.**

**This recommendation applies only in circumstances where the approved Patient Access Scheme (PAS) is utilised or where the list/contract price is equivalent or lower than the PAS/WPAS price.**

**Additional note(s):**

- Please refer to the Summary of Product Characteristics for the full licensed indication.



NICE has accredited the process used by the All Wales Medicines Strategy Group (AWMSG) to produce its final appraisal recommendations. Accreditation is valid for 5 years from October 2016. More information on accreditation can be viewed at <http://www.nice.org.uk/about/what-we-do/accreditation>

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 3778), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

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All Wales Medicines Strategy Group Final Appraisal Recommendation – 0720:  
Belimumab (Benlysta®). Reference number 3778. 120 mg, 400 mg powder for concentrate for solution for infusion. July 2020