



May 2019

Belimumab ▼ for treating systemic lupus erythematosus

Dear colleague,

This letter is a reminder of the agreed NICE and NHS England process for using belimumab to treat active systemic lupus erythematosus (SLE).

In June 2016, NICE published technology appraisal guidance on [belimumab for treating active autoantibody-positive SLE](#). In September 2016, NICE published a signed [managed access agreement](#) (MAA) for belimumab between NICE, the University of Manchester (acting on behalf of BILAG-BR), LUPUS UK, NHS England and GSK. The MAA applies until October 2020 or the publication of NICE's review (whichever is sooner).

As part of the MAA, funding is available from NHS England for up to 300 patients who meet the criterion for treatment continuation in section 4.1.2 of the agreement. Compulsory data recording on the BILAG-BR is a condition of this agreement to support the gathering of real-world evidence for the effectiveness of belimumab. An evaluation of these data will inform NICE's review of the guidance, which is expected in 2020.

As of March 2019, only 113 patients had been prescribed belimumab in the NHS in England. This is fewer than expected. This letter addresses some of the main issues that have been suggested as contributing to the lower than anticipated uptake of belimumab.

Eligibility

Belimumab is recommended for active SLE if there is evidence for serological disease activity, defined as:

- positive anti-double-stranded DNA and
- low complement and
- a SELENA-SLEDAI score of greater than or equal to 10 despite standard treatment.

NHS England has advised that if these criteria are met, belimumab should be used instead of rituximab. A flow chart summarising the use of belimumab and rituximab in SLE is attached.

It is a condition of reimbursement that all eligible patients must sign a consent form to show that they understand and accept the terms of the agreement (including that they may not be able to continue with treatment when the MAA no longer applies). Patients must also sign the consent form before their data can be submitted to the BILAG-BR. Patients should sign the consent form before starting treatment to avoid any delays in submitting patient data to the registry.

Six-month follow-up BILAG-BR data and BlueTeq forms should be completed and submitted as early as possible. This is essential for both data evaluation and reimbursement.

Specialist centre prescribing

NHS England Specialised Commissioning recommends that the decision to give belimumab be made by a specialised rheumatology centre. If you have any specific clinical or funding questions or concerns, please contact your local NHS England commissioning hub.

Feedback indicates that some patients may not be able (or may not want) to travel to a distant specialist centre for belimumab and may instead prefer to receive treatment from their local provider. It may be possible to arrange this under the direction of the specialist centre. A contract between the 2 sites would be needed to support any arrangement. Please contact [Bridget Griffiths](#) (Chair, NHS England Specialised Rheumatology CRG) for more information.

Training

The LFA Point training platform is available if training in SELENA-SLEDAI scoring is needed.

Renal impairment

Some healthcare professionals have expressed concerns about using belimumab in patients with renal impairment.

- Although belimumab is not recommended in severe active lupus nephritis (as per the treatment decision flow chart), it may be used in patients with mild or moderate renal involvement. See section 4.4 of the [summary of product characteristics](#).
- Dose adjustment is not needed in patients with mild, moderate or severe renal impairment. But caution is recommended in patients with severe renal impairment because of limited data for belimumab in these patients.

Availability

Some healthcare professionals have expressed concerns that belimumab may not be available when the MAA ends in October 2020.

Even if continued reimbursement is not recommended after NICE's review of the guidance in early 2021, belimumab would still be available until early 2022. This means that any patients who start taking belimumab this year will still have at least 2 years of treatment.

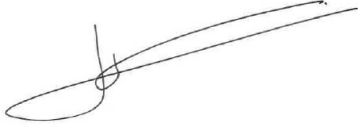





Efficiency

If possible, order and use the appropriate number of 120 mg/400 mg vials to reduce wastage.

Advice for healthcare professionals

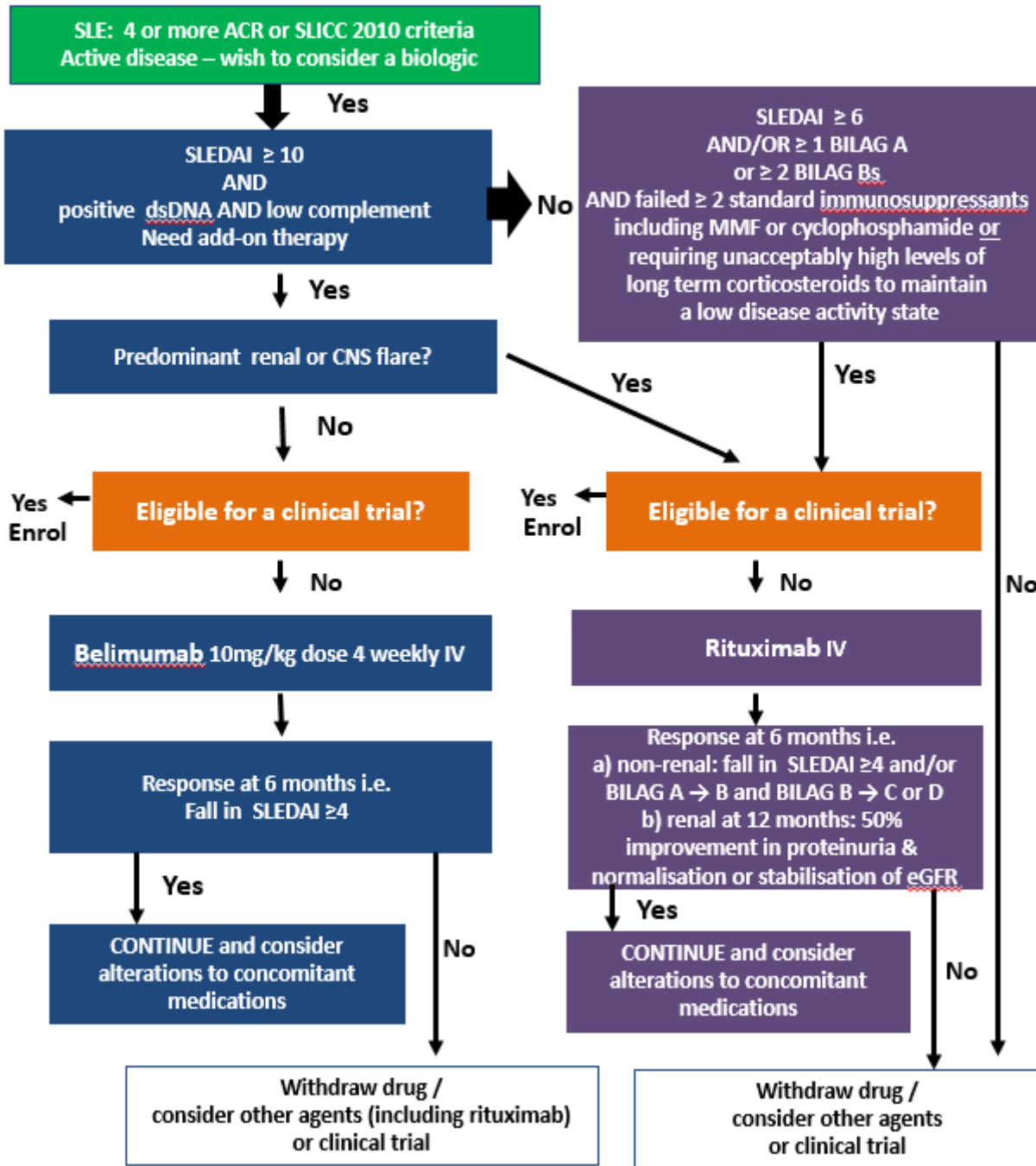
Please note that GSK has recently written to healthcare professionals about an increased risk of serious psychiatric events (depression, suicidal ideation or behaviour, or self-injury) seen in patients with SLE receiving belimumab plus standard therapy in clinical trials. This includes recent results from a 1-year, randomised, double-blind, placebo-controlled study (BEL115467) in 4,003 patients with SLE. Please see the [belimumab drug safety update](#) for further information, including a link to the full text of the GSK letter.

Yours sincerely,

 Meindert Boysen (Director of CHTE, NICE)	 Malcolm Qualie (Pharmacy Lead, NHS England Specialised Commissioning)	 Bridget Griffiths (Chair, NHS England Specialised Rheumatology CRG)
 Professor Ian Bruce (Chief Investigator, BILAG-BR)	 Martijn Akveld (Portfolio Medical Director UK & Ireland, GSK)	 Chris Maker (CEO, LUPUS UK)

Treatment decision flow chart

NHSE and NICE Guidance for the use of belimumab and rituximab (RTX) in patients with SLE:
NB 1) licensed and NICE approved agent i.e. belimumab to be considered first;
2) all patients receiving either drug must be enrolled in BILAG-BR and be managed at or in collaboration with a specialised centre



References

NHS England Clinical Commissioning Policy Statement: Rituximab for the treatment of Systemic Lupus Erythematosus in adults: published September 2013 A13/PS/a
Belimumab for treating active auto-antibody positive SLE: TA397, published June 2016