NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
Health Technology Evaluation

Obinutuzumab for treating serologically active extra-renal lupus ID6670

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of obinutuzumab within its marketing authorisation for treating serologically active extra renal lupus.

Background

Serologically active extra-renal lupus is a subtype of systemic lupus erythematosus (SLE) characterised by abnormal serological biomarkers (for example, positive anti-double-stranded DNA or low complement levels), indicating disease activity in organs and tissues outside the kidneys. SLE is a chronic autoimmune condition that causes inflammation in the body's tissues. The cause is not known, but is thought to be a combination of genetic, environmental and hormonal factors.

The main symptoms of SLE include joint and muscle pain, extreme tiredness and rashes. Symptoms range from mild to severe, and many people will have long periods with few or no symptoms before having a sudden flare-up, when their symptoms are particularly severe.

SLE can lead to mucocutaneous disease (affecting the mucous membranes and skin), arthritis, kidney failure, heart and lung inflammation, central nervous abnormalities and blood disorders. Over 90% of people with SLE develop problems with their joints and muscles such as arthralgia (joint pain) and myalgia (muscle pain). Disease activity and side effects from corticosteroids can mean long-term organ damage.

In 2019, the incidence rate of SLE in the UK was 6.72 for women and 1.31 for men per 100,000 patient years. Overall prevalence in 2020 was 107 per 100,000, or around 72,000 people with lupus in total.[1] In England in 2024 to 2025 there were 8,630 hospital admissions for SLE.[2] As well as being more common in women (especially young and middle aged women) than men, it is also more common in people with Black African, Caribbean or Asian backgrounds.[3]

People with extra-renal lupus and SLE have limited treatment options. There is no cure, and treatment aims to control symptoms, reduce disease activity, and prevent organ damage. Standard care includes non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and conventional disease-modifying antirheumatic drugs (DMARDs) such as hydroxychloroquine, and immunosuppressive agents (for example, cyclophosphamide, azathioprine, methotrexate and mycophenolate mofetil). Corticosteroids and conventional immunosuppressants can have limited efficacy and come with associated toxicities. Cyclophosphamide and biological DMARDs, including belimumab and rituximab, are typically used in more severe or treatment-refractory disease. Cyclophosphamide is not often used in SLE because of the risk of side effects. NICE recommends belimumab as an option as add-on treatment for active autoantibody-positive systemic lupus erythematosus in people with high disease activity despite standard treatment, only if:

- high disease activity is defined as at least 1 serological biomarker (positive anti-double-stranded DNA or low complement) and a SELENA SLEDAI score of greater than or equal to 10
- treatment is continued beyond 24 weeks only if the SELENA SLEDAI score has improved by 4 points or more.

Other treatments may be used to manage SLE-related comorbidities.

The technology

Obinutuzumab (Gazyvaro, Roche) does not currently have a marketing authorisation for serologically active extra-renal lupus. It has been studied as an add-on to standard treatment with corticosteroids in a clinical trial compared with placebo plus standard treatment in adults with SLE:

- without significant lupus-associated renal disease and/or renal impairment
- with high disease activity
- with lupus-related auto-antibodies
- with low complement.

Obinutuzumab has a marketing authorisation in combination with mycophenolate mofetil for treating active class 3 or 4, with or without class 5, lupus nephritis in adults.

Intervention(s)	Obinutuzumab as an add on to standard treatment for SLE
Population(s)	Adults with serologically active extra-renal SLE
Comparators	• Belimumab • Established clinical management without obinutuzumab including but not limited to: – rituximab – NSAIDs – corticosteroids (such as prednisolone) – conventional DMARDs (such as hydroxychloroquine) – conventional immunosuppressive agents (such as cyclophosphamide, azathioprine, methotrexate, mycophenolate mofetil)

Outcomes	The outcome measures to be considered include: • disease activity • rate and duration of response • rate and duration of remission • incidence and severity of flares • impact on disease manifestations • incidence of long-term complications and/or • organ damage • corticosteroid use • rate and duration of corticosteroid-free • remission • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** Belimumab for treating active autoantibody-positive systemic lupus erythematosus (2021) NICE technology appraisal guidance 752. **Related technology appraisals in development:** Obinutuzumab with mycophenolate mofetil for treating lupus nephritis. NICE technology appraisal guidance [ID6420] Publication expected March 2026.

Questions for consultation

Where do you consider obinutuzumab will fit into the existing care pathway for serologically active extra-renal lupus?

Have all the relevant comparators been included? Which treatments would continue as supportive care, alongside obinutuzumab if it were recommended?

To what extent does the patient population covered in NICE technology appraisal guidance 752 (belimumab for autoantibody-positive systemic lupus erythematosus) overlap with the patient population in the proposed appraisal of obinutuzumab for treating serologically active extra-renal lupus?

Please select from the following, will obinutuzumab be:

A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would obinutuzumab be a candidate for managed access?

Do you consider that the use of obinutuzumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which obinutuzumab will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. Ellis J, McHugh N, Pauling JD et al. (2024) Changes in the incidence and prevalence of systemic lupus erythematosus between 1990 and 2020: an observational study using the Clinical Practice Research Datalink (CPRD). Lupus Science and Medicine 11(2):e001213.

2. Hospital Admitted Patient Care Activity, 2024-25. NHS England. Accessed January 2026.

3. What is lupus? Lupus Trust. Accessed January 2026.