

progression with belimumab compared to matched controls receiving conventional therapies. Such long-term studies are not yet available with anifrolumab. In terms of the critical issue of predictors of response, serologic activity predicts response to belimumab and to anifrolumab compared to conventional therapies. As a result of the distinct effects on pathways involved with host defence, the safety profile between belimumab and anifrolumab is quite distinct. Belimumab has consistently demonstrated a reassuring safety profile in comparison to conventional therapies with one exception being the increased risk of depression-related adverse events. In contrast, anifrolumab has been associated with an increased risk of mild-moderate infections, including herpes zoster and influenza. Thus, all patients should be strongly encouraged to receive appropriate vaccinations prior to start of therapy.

The pipeline of therapies for the treatment of SLE is full of promising agents targeting a variety of important immunologic pathways. An ongoing area of active investigation is learning how to select the right therapy for the right patient at the right stage of their disease. In this way, we will continue to make significant progress towards disease modification in SLE.

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Learning Objectives

- Describe the evolving framework for disease modification in SLE
- Distinguish the mechanisms of action of belimumab and anifrolumab
- Explain the key differences in efficacy and safety between belimumab and anifrolumab

Lupus academy 12th annual meeting

Opening session (hybrid)

Hot topic: new era of treatments for SLE

05

APPROVED BIOLOGICS FOR SLE: WHICH TO TRY FIRST AND IN WHICH PATIENTS? – THE CASE FOR BELIMUMAB

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The monoclonal anti-Blys antibody belimumab was approved for the treatment of systemic lupus erythematosus more than ten years ago, based on findings in two large, randomized trials demonstrating clinical efficacy and safety.^{1–2} A further analysis of these two trials clarified that patients with anti-DNA and low complement had the highest likelihood of benefiting from the treatment.³ In subsequent years, many additional studies have further defined the efficacy of belimumab: it was shown to be effective in a subcutaneous formulation as well as intravenously, to reduce flares, maintain responses for many years, allow glucocorticoid dose reductions, reduce the accrual of damage, and last but not least, as an add-on to conventional treatment, to improve the renal response in patients with lupus nephritis – leading to approval for this indication as well.^{4–6} Belimumab has an excellent safety profile, and is associated with slight increases in infections and an increase in certain psychiatric adverse events.

For the clinician, the main reasons to consider belimumab are:

- Proven efficacy both for general lupus and for lupus nephritis
- Biomarkers for higher likelihood of response
- More than a decade of experience
- Safety
- Flexibility in administration: subcutaneous or intravenous

As with all treatments available today, response in the individual patient is impossible to predict. Therefore, a trial of belimumab may reasonably be considered for any patients who are not responding sufficiently to conventional therapy.

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Learning Objectives

- Describe the demonstrated efficacy and safety of belimumab in the treatment of SLE
- Explain the established biomarker combination anti-DNA and low complement for identifying patients at higher likelihood to benefit from belimumab
- Discuss the evidence base for use of belimumab in practice, both for general SLE and lupus nephritis
- Recognize the features of belimumab that may, in practice, help choose this therapeutic option for the patient