NCPE Assessment

Plain English Summary
July, 2025

Drug name:

Anifrolumab (pronounced an-i-frolue-mab) as an add-on therapy for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus, despite standard therapy

Brand name: Saphnelo®

HTA ID: 23027



What is the NCPE?

The National Centre for Pharmacoeconomics (NCPE) is a team of experts who look at the health benefits and costs of medicines. The HSE asks us to advise on whether or not a new medicine is good value for money. We give unbiased advice to help the HSE provide the most effective, safe and cost-effective (value for money) treatments for patients.

How do we make our recommendations?

Our main focus is on the health benefits and cost effectiveness of a medicine. We look at the wider costs and health benefits associated with a new medicine, for example:

- Does the new medicine work better than other treatments available in Ireland?
- Is the new medicine easier to give or easier to take compared with other treatments available in Ireland?
- Does the new medicine reduce the need for patients to be hospitalised?
- Does the new medicine improve the quality of a patient's life over other treatments available in Ireland?
- Will the new medicine save resources elsewhere within the health system?

We review the information from clinical trials along with the cost and value for money data presented by the pharmaceutical company. We ask doctors and other healthcare professionals for advice about any health benefits of the new medicine compared with current treatments. We also ask patient organisations to send us their views on how the new drug may improve patients' day-to-day experience of living with a disease.

What is anifrolumab used for?

Anifrolumab is a medicine (given in addition to standard treatment) for adults with systemic lupus erythematosus (SLE), a disease in which the immune system (the body's natural defences) attacks normal cells and tissues, causing inflammation and organ damage.

Anifrolumab is given to patients who have antibodies against their own cells (autoantibodies) and whose disease is still moderate to severe despite standard treatment.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider not funding anifrolumab unless its cost effectiveness (value for money) can be improved. The HSE will consider our recommendation and make the final decision about reimbursement (funding). When making the funding decision, the HSE will also consider the additional <u>criteria</u> outlined in the Health (Pricing and Supply of Medical Goods) Act 2013.

We have received a Patient Organisation Submission from Arthritis Ireland about anifrolumab and shared it with the HSE. This submission will form part of the data that the HSE considers.

Why did we make this recommendation?

After reviewing the data presented by the pharmaceutical company, we believe that the medicine may work as well or better than other ways to manage this condition. However, the price of the medicine is too high compared with other ways to manage this condition and we believe that the medicine is very poor value for money.

Next steps

When the HSE receives our recommendation, it will look at all the relevant data about anifrolumab. The HSE makes the final decision on reimbursement.

Where can I get more information?

You can get more information about anifrolumab from the following online options:

- the NCPE Technical Summary Document
- Anifrolumab European Public Assessment Report (EPAR) Medicines Overview or
- searching for 'anifrolumab' on our website (<u>www.ncpe.ie</u>);
- searching for 'anifrolumab' on the European Medicines Agency (EMA) website (www.ema.europa.eu).

Please refer to the NCPE website for updated information on the reimbursement status of this medicine