

September 2026

Dear Ataxia UK,

Thank you for your request for an update on Biogen's engagement in efforts to secure reimbursement of omaveloxolone for the treatment of Friedreich's ataxia (FA) in people aged 16 years and older within the NHS in the United Kingdom (UK).

Firstly, I would like to reaffirm Biogen's commitment to the FA community across the country. We recognise that FA is a devastating condition and appreciate the profound burdens it places on people living with the disease and their families.

Biogen remains committed to working with health authorities in England to identify solutions that could enable broad access to omaveloxolone. We will continue to work in collaboration with stakeholders across England to support a positive outcome for the FA community. Encouragingly, national reimbursement for omaveloxolone has already been achieved in twelve comparable European countries, and we know how important it is to deliver similar progress for patients in England.

In response to your enquiry regarding Biogen's engagement in commercial discussions with NHS England, we continue to maintain regular dialogue with both NHS England and the National Institute for Health and Care Excellence (NICE) regarding omaveloxolone. During the past year, Biogen representatives have met with senior leaders at NICE, NHS England and the Department of Health and Social Care. We are also developing an innovative solution, including scoping a potential omaveloxolone-specific service, and will continue to engage with the clinical community on how we move forward with NICE and NHS England.

In July, the Government [announced](#) four pilot programmes designed to explore ways of providing NHS patients with faster access to innovative medicines. One of the pilot programmes will seek to reform managed access arrangements and will include therapies for rare diseases.

While further details of the pilot have yet to be announced, Biogen has approached NICE and NHS England system leaders to seek exploratory discussions regarding the pilot and its potential implications for access to innovative treatments such as omaveloxolone.

Biogen will continue to pursue all appropriate opportunities to support access for people living with FA in England. It is Biogen's intention to resubmit to NICE. We will do so once we are confident that the submission will progress to a committee meeting, ensuring the appropriate level of stakeholder input is considered as part of the assessment.

Finally, I would like to extend my thanks to Ataxia UK and the FA community for their ongoing collaboration and support as we work together to advance access to omaveloxolone across England.

Yours sincerely,

Kylie Bromley BSc (Hons), PhD

General Manager and Managing Director, United Kingdom & Ireland
Biogen

Appendix

Further information requested.

1. Does the approval of omaveloxolone by the Health Service Executive (HSE) in Ireland have any implications for the UK?

We are very happy with the HSE's decision to approve Skyclarys (omaveloxolone) and Biogen is proud to be able to bring this option to the Friedreich's ataxia community in Ireland.

Biogen remains committed to continue working with health authorities in the UK to identify solutions that could enable broad access to omaveloxolone. We will continue to work in collaboration with stakeholders to support a positive outcome for the FA community. Encouragingly, national reimbursement for omaveloxolone has now been achieved in twelve comparable European countries, and we know how important it is to deliver similar progress for patients across the UK.

2. Would you be able to provide more details on the "innovative solution, including scoping a potential omaveloxolone-specific service" and explain how this might help our FA community access treatment.

Biogen is working hard to develop the innovative solution; at this stage we are unable to provide further details. This is in part because we are in dialogue with clinicians and in part due to the importance of commercial confidentiality, which has helped deliver reimbursement in twelve countries across Europe.

With the innovative solution, we are seeking to prepare a proposal for the Government and the NHS that will help to provide predictability as to the budget impact of the medicine. We hope it will help the FA community access treatment, as it has in other countries where the medicine is nationally reimbursed.

3. Are you able to provide an approximate timeline of when you plan to resubmit to NICE?

It is Biogen's intention to resubmit to NICE. We will do so once we are confident that the submission will progress to a committee meeting, ensuring the appropriate level of stakeholder input is considered as part of the assessment.

Biogen will continue to pursue all appropriate opportunities to support access for people living with FA in England.

4. What is involved in Biogen preparing for a resubmission to NICE? For example, does this involve further evidence gathering?

Uncertainty will remain a factor in the appraisal process, but we are continuing to gather evidence from patients treated with omaveloxolone in other countries which will be helpful in demonstrating outcomes when used in clinical practice. The burden of illness study that Ataxia UK contributed to will also be useful in demonstrating the impact of FA on patients and their carers.

We have now seen the medicine approved in twelve different countries in Europe, and are hopeful a successful process could also be feasible in England. We know that we will be able

to bring a proposal to NICE and NHSE that will be in line with what has been approved in other countries, including Ireland, most recently.

5. Please can you provide further information on the pilot schemes.

The pilot schemes are still in development. We are seeking dialogue with NICE and NHS England on this topic.

Biogen would like to see the Managed Access Pilot provide an opportunity to take a different approach to the assessment of rare disease medicines. These medicines often struggle to meet NICE's standard cost-effectiveness thresholds, which are applied in the same way to rare conditions as they are to more common diseases.

6. Are you able to provide an update on devolved nations? Do Biogen plan to submit to the Scottish Medicines Consortium (SMC) after NICE?

We will continue to explore opportunities to secure NHS funding in Wales, Northern Ireland and Scotland both through routine commissioning and individual patient funding routes.

In Scotland, Biogen submitted omaveloxolone to the SMC for a full Health Technology Assessment (HTA) for the treatment of FA in adults and adolescents aged 16 years and older in 2025. Following its assessment, in March 2026, the [SMC](#) did not recommend omaveloxolone for use within NHS Scotland.

Biogen continues to explore opportunities through the SMC. We have meetings scheduled with representatives of the Scottish NHS and Government and will keep the community updated on next steps.

In Scotland, we also provide information to clinicians, at their request, to support their requests for funding for individual patients as required.