EX GRATIA PROVISION OF XYREM TO PANDEMRIX AND NARCOLEPSY PERSONAL INJURY CLAIMANTS BY THE DEPARTMENT OF HEALTH

Introduction

1. This note describes the Department of Health’s (DH) ex gratia and time-limited Scheme to fund the provision of Xyrem (sodium oxybate) to personal injury claimants who claim that they developed narcolepsy with cataplexy following immunisation by the NHS with Pandemrix vaccine. The health departments in Scotland, Wales and Northern Ireland will also participate in the Scheme.

Overview of Scheme

2. The Department of Health (DH) is intending to fund, on an ex gratia and time limited basis, provision of Xyrem to a small number of personal injury claimants with narcolepsy with cataplexy, who have made claims against the manufacturer, GSK, that they developed the condition after immunisation with Pandemrix vaccine. Immunisation with Pandemrix took place mainly during the swine flu pandemic in 2009/2010, but also to a lesser extent in the 2010/2011 flu season when Pandemrix was used as a seasonal flu vaccine.

3. Provision of Xyrem will take place as an ex gratia and exceptional arrangement “outside of the NHS”, taking account of DH guidance on NHS patients receiving private care. Xyrem will be provided by issue of a private prescription by the claimant’s NHS sleep medicine consultant, with DH funding the cost of the drug and its dispensing. The Scheme will be funded for at least 3 years from March 2015. At any time before the expiry of the Scheme, the funded provision will be withdrawn whenever a claimant’s personal injury claim is no longer in existence or is no longer actively being pursued. Additionally as this is an ex gratia Scheme, it may be withdrawn at any time by the Secretary of State. New applications for funding will not be accepted after the termination of the Scheme.

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1 “Claimant” and “claims” is used in this document to refer to claims made both before and after the institution of formal court proceedings.


3 All relevant legal and regulatory requirements that relate to the issuance of private prescriptions or the provision of care on a private basis must be complied with including but not limited to the establishment of suitable indemnity arrangements pursuant to the Medical Act 1983.

4 This will include notification before the claim has been issued, that it is not being proceeded with against GSK. It will also include any disposal of any issued claim by the parties or by the Court, whether by being compromised, discontinued, withdrawn, dismissed, stayed (for longer than 6 months) or adjourned generally (for longer than 6 months) or where any final or other dispositive judgment has been given. It will also include any situation where a claim (before or after issue) has not been actively pursued for 6 months.

5 The Secretary of State may withdraw the Scheme in its entirety or may only do so in respect of any one or more individual cases (where for example it becomes apparent that the case was or is not eligible for the Scheme.)
A question and answer briefing about the Scheme is at Appendix A.

4. Where a sleep medicine consultant has an outstanding individual funding request (IFR) for Xyrem for the claimant with NHS England or a clinical commissioning group, this should not be withdrawn because an application is made to the Scheme. If the IFR was successful, then provision of Xyrem under the Scheme would be stopped once the NHS was providing it as a result of the IFR.

Eligibility conditions

5. Provision of Xyrem under this Scheme will be subject to the following main conditions:

a) The Scheme will be open only to individuals who have developed narcolepsy with cataplexy after immunisation with Pandemrix by the NHS in the United Kingdom and who have sent a Letter of Claim to GSK seeking damages in the UK Courts for their condition

b) DH will not fund the provision of Xyrem where the individual is already receiving it as part of NHS treatment.

c) The provision of Xyrem will be subject to DH approval of a funding application made on behalf of the individual by their sleep medicine consultant on clinical grounds, including the provision of information and associated documentary evidence about:

i. NHS immunisation of the patient with Pandemrix vaccine in the United Kingdom;

ii. Diagnosis of narcolepsy with cataplexy following immunisation with Pandemrix;

iii. Treatments previously and currently used, and why Xyrem might be more effective.

d) Where Xyrem is to be prescribed “off label” for children, in line with usual clinical practice, responsibility for the clinical consequences of the treatment would rest with the prescriber, and guidance from the General Medical Council should be followed - Good Practice in Prescribing and Managing Medicines and Devices (2013).

6. The application form for the Scheme is at Appendix B. A flowchart showing how the Scheme works is at Appendix C.
How system for provision of Xyrem will work

7. Initially a letter explaining the Scheme and enclosing an application form will be sent in advance to the claimant’s sleep medicine consultant. This will happen when DH has been notified by a particular claimant or their solicitor that they wish to apply to the Scheme and once they have consented to their personal data being shared. All claimants who have sent a letter of claim to GSK will be informed of the Scheme.

8. The application for funding of Xyrem will be submitted to DH on behalf of the patient by their sleep medicine consultant.

9. Subject to DH approval of the application, DH will notify the consultant and the chief executive of the Trust. Notification to the Trust will include explanation of the Scheme.

10. The consultant will issue a private prescription with the dispensing hospital pharmacy invoicing DH for the cost of the drug and any prescription fee. The local Trust will determine any local arrangements for issue and dispensing fulfilment of the private prescription and for invoicing DH.

11. When prescribing Xyrem to a claimant, the claimant’s consultant will need to consider that this is a time-limited Scheme and that the funding could be withdrawn as set out above.
Ex gratia provision of Xyrem (sodium oxybate) to Pandemrix and narcolepsy personal injury claimants by the Department of Health

Question and answer (Q&A) sheet

Q. How will the Scheme to provide Xyrem work?

A. The Department of Health will fund, on an ex gratia and time-limited basis, provision of Xyrem to personal injury claimants to whom the NHS provided immunisation with Pandemrix, subject to a recommendation by their NHS sleep medicine consultant on clinical grounds and the provision of necessary supporting documentary evidence. Xyrem will not be funded for claimants who are already receiving it from the NHS.

The request for funding of Xyrem will be submitted to the Department of Health on behalf of the claimant by their NHS sleep medicine consultant who will have to provide the necessary information to address eligibility. Once approved, a private prescription will need to be issued by the consultant with the dispensing hospital pharmacy invoicing the Department of Health for the cost of the drug and any prescription fee. The NHS trust will need to take account of DH guidance on NHS patients receiving private care. The Scheme will be funded for at least 3 years from March 2015 and may also cease in any one case if any individual claim for compensation comes to an end or is not being actively pursued. As this is an ex gratia Scheme, the Secretary of State may also decide to withdraw it at any time. New applications will not be accepted once the Scheme has ended.

Q. What happens when the Scheme ends?

A. If a claimant is in receipt of compensation as a result of their claim, then this may be used to fund the costs of private provision of relevant future medical treatment alternatively, funding may be sought via the NHS.

Q. How much does Xyrem cost?

A. The annual cost for an adult dose of Xyrem is around £13,000.
Q. What happens if a claimant received Pandemrix in Scotland, Wales or Northern Ireland but now lives in England?

A. The health departments in Scotland, Wales and Northern Ireland are also participating in the Scheme.

Q. What happens if a claimant’s sleep medicine consultant does not recommend Xyrem but the claimant/claimant’s parents etc. want it?

A. As is usual practice, the claimant could seek a second medical opinion from another consultant.

Q. How does a hospital fill a prescription for Xyrem under this scheme?

A. A clinician prescribes Xyrem in the ordinary course of the doctor-patient relationship. The prescription must be issued on a private basis, not on the NHS, and it is the responsibility of the prescriber to comply with all relevant legal, regulatory, and ethical requirements, including those relating to controlled drugs. In this regard, the scheme is no different from any other scenario involving prescriptions. Where the scheme is unique is that these private prescriptions for Xyrem are funded by DH, rather than from any other source of funds.

Q. Why can’t clinicians fill an NHS prescription for Xyrem under this scheme?

A. Provision of Xyrem needs to take place through a private prescription because the NHS cannot provide preferential treatment to individuals other than on grounds of clinical need.

Q. What if the clinician doesn't have indemnity to issue a private prescription for Xyrem?

A. It is a legal requirement that a medical practitioner has in place suitable indemnity arrangements. It is the responsibility of each clinician to ensure compliance with this requirement and with all other legal and regulatory requirements. Any prospective applicant who is uncertain as to what is required should seek advice from his or her Trust, or from an independent legal adviser. DH cannot and will not accept any responsibility for failure to comply with legal or other requirements, nor will DH make arrangements for individual clinicians. DH cannot give legal advice to clinicians.

Q. What about other patients with narcolepsy who might benefit from Xyrem provided on the NHS?

A. That is a matter for NHS organisations to consider in line with their commissioning policy and procedures for handling individual funding requests.
Q. What about the Vaccine Damage Payment Scheme?

A. The Vaccine Damage Payment Scheme (VDPS) provides a one-off, tax-free lump sum payment for people who become severely disabled as a result of vaccination against specified diseases.

The Department for Work and Pensions administers the VDPS, and takes professional medical advice on the degree of disability involved.

Under the VDPS, the degree of disablement is assessed on the same basis as the Industrial Injuries Disablement Benefit Scheme, which is a widely accepted test of disability. Medical advisers who advise on claims under the VDPS are registered medical practitioners who have received special training in disability assessment and the assessment of disablement.

The VDPS does not prevent individuals from making personal injury claims against the vaccine manufacturer, although any VDPS payment would be taken into account in the resolution of such claims.

Further information about the Vaccine Damage Payment Scheme is available at https://www.gov.uk/vaccine-damage-payment/overview
Application for funding of Xyrem (sodium oxybate) under Department of Health ex gratia Scheme

1. PATIENT’S PERSONAL DETAILS

Patient name:

Date of birth:

Address:

NHS Number:

2. DETAILS OF CONSULTANT APPLICANT

Name: Designation:

Provider trust:

Contact telephone number:

Secure email or postal address for correspondence:

Must be NHS.net email.

Only NHS.net can be used for correspondence about this application.
3. CONSENT

I confirm that this application has been discussed in full with the patient or the patient’s representative.

YES / NO

[Please indicate]

I declare that the information provided in this application is accurate and true to the best of my knowledge.

Signature of applicant: Date:

PATIENT FORM OF AUTHORITY

I, [name]…………………………………………, of [address]………………………………………………………………………………………..,

being the person named below, hereby consent to the release and disclosure to and access by the Department of Health to my medical records, any associated X-rays, scan images, GP and/or hospital notes, treatment and nursing charts, prescription documents, confidential clinical information held by clinical staff involved with their care about them as a patient or other documents to enable full consideration of this funding request.

Date of birth:
National insurance number:
GP name and address:

NAME (in full):
SIGNED:
DATE:

Or

NAME OF PARENT/GUARDIAN (in full):
SIGNATURE OF PARENT/GUARDIAN:
DATE:
The onus lies with the requesting clinician to present a full submission to the Department of Health providing copies of supporting documentary evidence where indicated.

4. DETAILS OF XYREM TREATMENT REQUESTED, INCLUDING:
- What is the number of doses that will be given and at what intervals?
- What is the estimated local cost of Xyrem for this patient in 2014/15 and 2015/16?
- Contact details for the NHS hospital pharmacy (including a named individual) which would dispense your private prescriptions for Xyrem and invoice the Department of Health.

5. INFORMATION ABOUT PANDEMRIX VACCINATION
Please confirm and provide documentary evidence (from patient or GP):
- That the patient was immunised with Pandemrix vaccine; and
- The date of immunisation
6. DIAGNOSIS OF NARCOLEPSY WITH CATAPLEXY FOLLOWING IMMUNISATION WITH PANDEMRIX

Please summarise information relevant to the diagnosis, attaching documentary evidence of:

- Firm diagnosis of narcolepsy with cataplexy;
- Date of first attendance;
- Date of first cataplexy;
- Date of first symptoms and what the symptoms were;
- Results of any investigations confirming the diagnosis.
7. CLINICAL BACKGROUND

Please outline the clinical situation, including:

- Confirmation that established treatments for narcolepsy with cataplexy have been tried, and if not, please explain why not.
- Previous therapies tried and what was the response, including intolerance.
- Current treatment and response, including intolerance.
- Anticipated prognosis if treatment requested is not funded (including what alternative treatment will be given).
- Anticipated clinical benefits for your patient of Xyrem compared to other available options.
- How the benefits of the treatment will be measured.
- ‘Stopping’ criteria to be in place to decide when the treatment is ineffective.
8. OTHER
Are there any other comments/considerations that are appropriate to bring to the attention of the Department of Health?

Please email this form and supporting documents to Immunisation Policy & Strategy, Department of Health: ic-mb@dh.gsi.gov.uk

NB: You must use an NHS.net email from which to send your application.
If you are posting the documents, please send to:

Immunisation Policy & Strategy
Department of Health
Area 147 Richmond House
79 Whitehall
London SW1A 2NS
Appendix C

Flowchart illustrating provision of Xyrem under the Department of Health’s (DH) ex gratia Scheme for Pandemrix and narcolepsy personal injury claimants

1. Patient seen by their NHS sleep medicine consultant
2. Consultant discusses provision of Xyrem with patient
3. Consultant applies to DH for approval to prescribe Xyrem, providing required information to demonstrate patient’s eligibility
4. DH considers the consultant’s application. If it is approved, DH notifies the consultant who issues private prescription to patient to be dispensed at NHS hospital pharmacy
5. Private prescription is dispensed at local hospital pharmacy
6. NHS trust invoices DH