Reference:	FOI.13739.24
Subject:	NICE recommended use of a drug or treatment
Date of Request:	5 February 2024

Requested:

Rimegepant for treating migraine.

Technology appraisal guidance [TA919] Published 18 October 2023
Hywel Dda UHB Inform https://hddformulary.wales.nhs.uk/ section 04.07.04.01 - Treatment of acute migraine has Rimegepant listed as RED (H) - Hospital only drugs (drugs only suitable for secondary care use and initiated by appropriate team or specialist. Primary care prescribers should not be asked to prescribe). This is an update, as in January 2024, Rimegepant was listed as yellow, ie, S = Specialist initiated or recommended medicines (Secondary Care Consultant Team, GP with specialist interest or authorised independent prescribers). Medicines are suitable for continuation by Primary care. Check monograph whether recommended or initiated. Shared care agreements may apply.

1.1 Given that patients in Cardiff & Vale UHB and Powys tHB who are sat in front of their primary care GP, nurse or pharmacist suffering an acute migraine (provided they meet NICE criteria) can be prescribed Rimegepant by their primary care HCP, but a patient in HDUHB sat in front of their primary care GP, nurse or pharmacist suffering an acute migraine (provided they meet NICE criteria) must be referred and put on a waiting list (6-12 months) to see a hospital physician to be prescribed Rimegepant, how do you intend to rectify this health inequality?

1.2 Does the term “authorised independent prescribers” mean that any GP, or nurse or pharmacist in primary care who has completed the required training and regarded as an independent prescriber can prescribe Rimegepant to appropriate patients presenting in primary care with acute migraine?

1.3 In this case, what exactly is meant by “authorised independent prescribers” and how do they differ from “independent prescribers” and what or who dictates whether someone is authorised?

1.4 Given that Hywel Dda has no Neurology department, how many Secondary Care Consultant Teams can genuinely prescribe Rimegepant in Hywel Dda UHB, assuming it is those that manage migraine patients, eg, neurology, and not those who don’t, eg, dermatology?

1.5 How many prescriptions for Rimegepant were written in Hywel Dda UHB in 2023?

1.6 What arrangement does Hywel Dda have with Swansea Bay UHB for its neurology support, eg, block contract, payment by results etc?

1.7 Would you say you have genuinely made Rimegepant available for patients suffering acute migraine as Cardiff and Vale UHB have, or have you simply done the bare minimum by listing it on your formulary, but with such restrictions as to make it de facto unavailable for those appropriate patients?

1.8 What are the job titles of the people in Hywel Dda UHB responsible for deciding that Rimegepant should have first been listed as yellow for acute migraine and then listed as red in Hywel Dda UHB and in which departments do they work?

1.9 What is the job title of the person responsible for outpatient waiting lists for Acute Migraine in Hywel Dda UHB and what involvement did they have in the decision to list Rimegepant as yellow?

1.10 What is the current waiting time in Hywel Dda UHB for a patient referred by their GP with Acute Migraine to be seen in secondary care and not just reviewed, but for the patient to receive a prescription for acute migraine?

1.11 How many patients in Hywel Dda UHB meet the criteria for Rimegepant, and if they were all referred to secondary care, (rather than treated by the GP/Practice Nurse/Pharmacist they were in front of suffering there and then with an acute migraine), what effect would this have on waiting lists, and how long would a patient have to wait to receive a prescription for a prescription for Rimegepant?

1.12 How could you engage primary care providers in Hywel Dda UHB to ensure that they can manage appropriate acute migraine patients in primary care with Rimegepant at the point when the patient presents in need of intervention? Would you expect primary care HCPs to just prescribe a new medication, or would there be training interventions from consultants in secondary care?

1.13 How many prescriptions for Rimegepant were written in Hywel Dda UHB in 2023?

1.14 For the last 12 month period for which you have data, how many patients presented to A&E with migraine, how many patients presented to SDEC with migraine and how many presented to out of hours with migraine?

1.15 Will you please provide me with a copy of the minutes of the meetings at which it was decided to list Rimegepant first as yellow (S = Specialist initiated or recommended medicines (Secondary Care Consultant Team, GP with specialist interest or authorised independent prescribers). Medicines are suitable for continuation by Primary care. Check monograph whether recommended or initiated. Shared care agreements may apply) and then as **red (H - Hospital use only)?**

1.16 Do you consider primary care prescribers in Hywel Dda too stupid to prescribe a simple and straightforward migraine treatment, or is there some other reason you prevent them from prescribing medicine to patients in pain, when primary care prescribers in other health boards can? If so, what is this other reason? It can't be money, as NICE TA shows that the intervention is cost effective and must be made available. What is the real reason to keep your patients suffering the pain of migraine? Are you deliberately putting pressure on secondary care services in the hope that they will fail? Is this political?

Daridorexant for treating long-term insomnia.

Technology appraisal guidance [TA922] Published: 18 October 2023
Hywel Dda UHB Inform https://hddformulary.wales.nhs.uk/ section 04.99 – Other Central Nervous System has Daridorexant listed as yellow, ie, S = Specialist initiated or recommended medicines (Secondary Care Consultant Team, GP with specialist interest or authorised independent prescribers). Medicines are suitable for continuation by Primary care. Check monograph whether recommended or initiated. Shared care agreements may apply. Cwm Taf & Vale UHB Inform https://cttformulary.wales.nhs.uk/ section 04.99 – Other Central Nervous System has Daridorexant listed as green, ie, G = General Use – all prescribers.

2.1 Given that a patient in **Cwm Taf & Vale** UHB who is sat in front of their primary care GP, nurse or pharmacist suffering from long-term insomnia (provided they meet NICE criteria) can be prescribed Daridorexant by their primary care HCP, but a patient in HDUHB sat in front of their primary care GP, nurse or pharmacist suffering from long-term insomnia (provided they meet NICE criteria) must be referred and put on a waiting list (6-12 months) to see a hospital physician to be prescribed Daridorexant, how do you intend to rectify this health inequality?

2.2 Or, does the term "authorised independent prescribers" mean that any GP, or nurse or pharmacist in primary care who has completed the required training and regarded as an independent prescriber can prescribe Daridorexant to appropriate patients presenting in primary care with acute migraine?

2.3 In this case, what exactly is meant by "authorised independent prescribers" and how do they differ from "independent prescribers" and what or who dictates whether someone is authorised?

2.4 Can any GP with specialist interest prescribe Daridorexant to appropriate patients, or only those with a specialist interest in managing long-term insomnia?

2.5 How many GPs with specialist interest within Hywel Dda UHB are currently allowed to prescribe Daridorexant to appropriate patients under this formulary listing?

2.6 How many Secondary Care Consultant Teams can genuinely prescribe Daridorexant in Hywel Dda UHB, assuming it is those that manage long-term insomnia, eg, respiratory, neurology, psychiatry etc, and not those who don't, eg, dermatology?

2.7 How many prescriptions for Daridorexant were written in Hywel Dda UHB in 2023?

2.8 Would you say you have genuinely made Daridorexant available for patients suffering long-term insomnia as Cwm Taf and Vale UHB have, or have you simply done the bare minimum by listing it on your formulary, but with such restrictions as to make it de facto unavailable for those appropriate patients?

2.9 What are the job titles of the people in Hywel Dda UHB responsible for deciding that Daridorexant should be listed as yellow for acute migraine in Hywel Dda UHB and in which departments do they work?

2.10 What is the job title of the person responsible for waiting lists for long-term insomnia in Hywel Dda UHB and what involvement did they have in the decision to list Daridorexant as yellow?

2.11 What is the current waiting time in Hywel Dda UHB for a patient referred by their GP with long-term insomnia to be seen in secondary care and not just reviewed, but for the patient to receive a prescription for long-term insomnia?

2.12 How many patients in Hywel Dda UHB meet the criteria for Daridorexant, and if they were all referred to secondary care, (rather than treated by the GP/Practice Nurse/Pharmacist they were in front of suffering there and then with long-term insomnia), what effect would this have on waiting lists, and how long would a patient have to wait to receive a prescription for Daridorexant?

2.13 How could you engage primary care providers in Hywel Dda UHB to ensure that they can manage appropriate long-term insomnia patients in primary care with Daridorexant at the point when the patient presents in need of intervention? Would you expect primary care HCPs to just prescribe a new medication, or would there be training interventions from consultants in secondary care?

2.14 How many prescriptions for Daridorexant were written in Hywel Dda UHB in 2023?

2.15 Will you please provide me with a copy of the minutes of the meeting at which it was decided to list Daridorexant as yellow, ie, S = Specialist initiated or recommended medicines (Secondary Care Consultant Team, GP with specialist interest or authorised independent prescribers). Medicines are suitable for continuation by Primary care. Check monograph whether recommended or initiated. Shared care agreements may apply?

2.16 Do you consider primary care prescribers in Hywel Dda too stupid to prescribe a simple and straightforward insomnia treatment, or is there some other reason you prevent them from prescribing medicine to patients in need, when primary care prescribers in other health boards can? If so, what is this other reason? It can't be money, as NICE TA shows that the intervention is cost effective and must be made available. What is the real reason to keep your patients at increased risk of hypertension, diabetes, obesity, depression, heart attack and stroke? Are you deliberately putting pressure on secondary care services in the hope that they will fail? Is this political?

Tirzepatide for treating type 2 diabetes.

Technology appraisal guidance [TA924]Published: 25 October 2023
Hywel Dda UHB Inform https://hddformulary.wales.nhs.uk/ section 06.01.02.03 Glucagon-Like Peptide-1 Receptor Agonists. I can't see Tirzepatide listed.

3.1 More than two months has passed since TA924 was published, so why has Tirzepatide not been made available?

3.2 How many prescriptions for Tirzepatide were written in Hywel Dda UHB in 2023?

3.3 Will you please provide me with a copy of the minutes of the meeting at which it was decided not to list Tirzepatide on the formulary**?**

3.4 Do you consider primary care prescribers in Hywel Dda too stupid to prescribe a simple and straightforward diabetes treatment, or is there some other reason you prevent them from prescribing medicine to patients in need, when primary care prescribers in other health boards can? If so, what is this other reason? It can't be money, as NICE TA shows that the intervention is cost effective and must be made available. What is the real reason to keep your patients at increased risk of a heart attack, stroke, amputation, blindness etc? Are you deliberately putting pressure on secondary care services in the hope that they will fail? Is this political?

Response:

Hywel Dda University Health Board (UHB) is unable to provide you with all of the information requested, as it is estimated that the cost of answering your request would exceed the "appropriate limit" as stated in the Freedom of Information Act 2000 and the Data Protection (Appropriate Limit and Fees) Regulations 2004. The "appropriate limit" represents the estimated cost of one person

spending 18 hours (or 2½ working days) in determining whether the UHB holds the information, and locating, retrieving and extracting the information.

In order to provide you with the data requested for questions 1.5, 1.10, 1.11, 2.7, 2.11 and 2.12, the UHB would need to undertake a manual trawl of patient medical records to identify any patients that were receiving treatment for migraine and insomnia, to identify any information that would fulfil these parts of your request, as this information is not recorded centrally.

The UHB is therefore applying an exemption under Section 12 of the Freedom of Information Act 2000 (FoIA), which provides an exemption from a public authority's obligation to comply with a request for information where the cost of compliance is estimated to exceed the appropriate limit.

However, under section 16 of the Freedom of Information Act, the UHB has a duty to provide advice and assistance. Therefore, the UHB provides the accessible information it holds below.

1.1. The UHB contracts Neurology services from the Tertiary Care Centre based in Swansea Bay University Health Board (SBUHB). Therefore, the UHB follows their lead on the formulary status of neurological drugs.

1.2. & 1.3. The UHB confirms that the term 'authorised independent prescriber' is a local term from when Independent (non-medical) Prescribers were initially introduced and refers to an Independent Prescriber who is on the UHB register and working within their Scope of Practice. The treatment of headache and/or migraine must be included in their Scope of Practice.

1.4. The UHB confirms that it has visiting Neurologists who carry out clinics, including migraine clinics, for its patients. All medications can be prescribed by any practitioner that is qualified to prescribe. However, Rimegepant is currently a 'Hospital Only medicines but will move to 'Second line including GPs' following changes to the SBUHB formulary after endorsement by the Medicines Management Operational Group (MMOG) on the 13 March 2024.

1.5. Section 12 exemption applied. However, under Section 16, the UHB can confirm that no prescriptions for Rimegepant were dispensed during the 2023 calendar year.

1.6. The UHB confirms that it pays SBUHB to provide 1.5 Whole Time Equivalent (WTE) general Neurologists who deliver face to face and virtual reviews for UHB Neurology patients.

1.7. This is not a valid request for information under the Freedom of Information Act 2000 (FoIA). The FoIA covers any recorded information that is held by a public authority; recorded information includes printed documents, computer files, letters, emails, photographs, and sound or video recordings. The FoIA does not cover information on estimates, opinions or recommendations. The UHB has an obligation to provide information already in recorded form but cannot create new information to answer a question.

1.8. The UHB confirms that the job title of the person responsible is Lead Clinical Development Pharmacist, in the Pharmacy and Medicines Management Department.

1.9. The UHB confirms that it does not have a specific waiting list for Acute Migraine. However, these patients would be managed within the general Neurology waiting list, with the Service Delivery Manager (SDM) for Neurology having responsibility for overseeing the waiting list. Nevertheless, the SDM has no involvement with pharmaceutical decision making; the UHB's

Lead Clinical Development Pharmacist would be directly involved with pharmaceutical decision making.

1.10. A Section 12 exemption has been applied to the wait time for a patient to attend an appointment within secondary care and receive a prescription. However, under Section 16, the UHB can confirm that the current wait for a neurology outpatient appointment is approximately eight (8) months.

1.11. A Section 12 exemption has been applied.

1.12. This would depend on the nature of the medication (interactions, monitoring, adverse effects), the familiarity of the Health Care Professional (HCP) treating that condition and the patient characteristics (selection and exclusion criteria) and is an individual decision for each medicine. Primary Care providers would need to refer to a specialist clinic as this drug currently has 'Specialist only' status on the UHB's formulary.

1.13. This is a duplicate of question 1.5.

1.14. The UHB does not hold the information requested for those that contacted the Out of Hours (OOH) Service with migraine. The 111 Service is run by the Welsh Ambulance Services NHS Trust (WAST) and they may hold the information required.

We therefore recommend that you redirect your request to the Freedom of Information Team in WAST, who may be able to help you with this part of your enquiry. Contact details are as follows:-

FOI.amb@wales.nhs.uk or alternatively, you can contact: Freedom of Information Officer, Welsh Ambulance Services NHS Trust Headquarters, Ty Elwy, Unit 7, Ffordd Richard Davies, St Asaph Business Park, St Asaph, Denbighshire, LL17 0LJ.

However, the UHB provides, within the table overleaf, the number of patients that presented at the UHB's Accident and Emergency (A&E) and Same Day Emergency Care (SDEC) Departments and were diagnosed with migraine, during the period 1 February 2023 to 31 January 2024.

Department	Number
A&E	192
SDEC	127

1.15. **The UHB confirms that** the formulary status for NICE and All Wales Medicines Strategy Group (AWMSG) recommended medicines, including the medication Rimegepant, has not been discussed in the MMOG and therefore, is not included in the minutes of the meetings. Since the New Treatment Fund (NTF) was introduced in January 2017, the UHB has added to the formulary in line with the minimum standards set by Welsh Government (WG). However, the UHB is in the process of reviewing and changing its systems to aid **the managed entry of** new medications.

1.16. Under the FoIA, this question is not a valid request for information; full explanation provided in response to question 1.7.

2.1. Cwm Taf Morgannwg University Health Board (CTUHB) formulary currently has Daridorexant listed as 'Hospital Product', and Cardiff and Vale University Health Board (CAVUHB) formulary has it currently listed as 'Hospital Only' which requires referral to Specialists (usually based in a hospital). The UHB's formulary is the same as CAVUHB.

2.2. & 2.3. Please see response to questions 1.2 and 1.3.

2.4. The UHB confirms that currently, only GPs with a special interest and training in the management of insomnia, can prescribe Daridorexant.

2.5. The UHB confirms that it does not have any GPs with special interest in insomnia.

2.6. The UHB does not hold this information, as it has not limited which Specialists can initiate and monitor the effect of Daridorexant, as patients with chronic insomnia may present to a variety of specialities with co-morbid conditions.

2.7. Section 12 exemption applied. Additionally, the UHB is unable to provide you with the number of prescriptions dispensed for Daridorexant during the 2023 calendar year, due to the low number of cases (5 and under), as there is a potential risk of identifying individuals if this was disclosed. Therefore, the UHB is withholding these details under Section 40(2) of the FoIA.

This information is protected by the Data Protection Act 2018 (DPA)/UK General Data Protection Regulations, as its disclosure would constitute unfair and unlawful processing and would be contrary to the principles and articles of the UK GDPR. This exemption is absolute and therefore, there is no requirement to apply the public interest test.

In reaching this decision, the DPA and UK GDPR define personal data as data that relates to a living individual who can be identified solely from that data or from that data and other information, which is in the possession of the data controller.

2.8. Under the FoIA, this question is not a valid request for information; please see response to question 1.7.

2.9. Please see response to question 1.8.

2.10. The UHB confirms that it does not have a specific waiting list for insomnia. However, the SDM for the individual service, dependent on the cause, that is treating a patient for long term-insomnia, would be responsible for overseeing the waiting list for their service.

However, the SDM would have no involvement with pharmaceutical decision making; the UHB's Lead Clinical Development Pharmacist would be directly involved with pharmaceutical decision making.

2.11. & 2.12. Section 12 exemption applied.

2.13. Depending on the medicine, prescribing information/guidelines can be provided in training sessions, by presentations via Teams or in person. We would also take into account the promotional activities provided by the pharmaceutical company.

2.14. This is a duplicate of question 2.7.

2.15. **See response to question 1.15; also applies for the medication** Daridorexant.

2.16. Under the FoIA, this is not a valid request for information; please see response to question 1.7.

3.1. NICE published the Final Appraisal Determination for TA924 on 08 September 2023 and the UHB was advised that the product had not been launched in the United Kingdom (UK) at that time. The UK product authorisation was granted on 25 January 2024, with stock being available in the UK on 12 February 2024. The UHB has discussed the formulary status with Diabetic Consultants, and it will be positioned as 'Specialist Initiated' (as per the GLP-1's) which includes the GPs who have signed up to the Insulin and Glucagon-Like Peptide (GLP) initiating National Enhanced Service (NES).

3.2. Not applicable.

3.3. Not applicable.

3.4. Under the FoIA, this is not a valid request for information, please see response to question 1.7.