

## Extraordinary meeting of the Devon Formulary Interface Group

### Minutes

Friday 15<sup>th</sup> December 2023

Via Microsoft Teams

#### Present:

Name	Job Title	Organisation
Glen Allaway	GP	NHS Devon ICB
Ailene Barclay	Pharmacist	UHP NHS Trust
Andy Craig	GP	NHS Devon ICB
Susie Harris (Chair)	Consultant (Elderly Care)	RDUH NHS FT
Matt Howard	Clinical Evidence Manager	NHS Devon ICB
Jess Parker	GP	NHS Devon ICB
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon ICB
Darren Wright	Joint Formulary Specialist Pharmacy Technician	NHS Devon ICB

#### Guests:

Name	Job Title	Organisation
Alex Degan	Primary Care Medical Director	Devon ICS

#### In attendance:

Rebecca Owen	Clinical Effectiveness Governance Manager	NHS Devon ICB
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### 1. Welcome and announcements

#### Meeting etiquette

Susie Harris thanked the group for attending this extraordinary meeting at short notice. It was explained that this was being held as the last FIG meeting on 6<sup>th</sup> December was not quorate and a decision is required on the proposed formulary guidance for COVID-19 medicines for non-hospitalised patients, and the proposed updates to the relevant drug entries, before the next meeting in February. Due to the complexity of this topic, it is not appropriate to use the e-FIG process for this.

#### Chairman's welcome

Susie Harris welcomed attendees to the extraordinary meeting of the Devon Formulary Interface Group.

The extraordinary meeting had been arranged to enable attendance by the GP FIG members and the Chair. It was confirmed that the meeting was quorate and noted that although Nick Keysell may not be able to attend, his feedback in relation to this item has been received in advance and noted by the group.

Although some of the FIG members were unable to attend due to the short notice of the meeting, it was confirmed that they had participated in the discussion at the meeting on 6<sup>th</sup> December and that the proposed formulary guidance and entries presented today have been updated in line with the discussion.

### Apologies

NAME	JOB TITLE	ORGANISATION
Beverley Baker	Non-Medical Prescribing Lead	NHS Devon ICB
Nick Keysell	GP	NHS Devon ICB
Carole Knight	Medicines Information Pharmacist	RDUH NHS FT
James Leavy	Medicines Information Pharmacist	RDUH NHS FT
Rebecca Lowe	Joint Formulary Technician	NHS Devon ICB
Sarah Marner	Senior MO Pharmacist	NHS Devon ICB
Larissa Sullivan	Pharmacist	T&SD NHS FT

### Declarations of Interest

The Declarations made did not result in anyone being excluded from the meeting or from the discussion of the item.

DRUG TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER
<b>COVID-19 medicines:</b> <ul style="list-style-type: none"> <li>• Nirmatrelvir and ritonavir tablets (<b>Paxlovid</b>)</li> <li>• Molnupiravir capsules (<b>Lagevrio</b>)</li> <li>• Remdesivir IV infusion (<b>Veklury</b>)</li> <li>• Sotrovimab IV infusion (<b>Xejudy</b>)</li> </ul>	Pfizer Ltd Merck, Sharpe and Dohme UK Ltd Gilead Sciences Ltd GlaxoSmithKline UK

Name	Job Title	Declaration
Dr Alex Degan	Primary Care Medical Director	Shareholder in above manufacturing company/companies:  My wife holds a single share in Pfizer.  Work as paid advisor to above manufacturing company/companies:  I work on a consultancy basis for advisory boards but don't believe I have done this for Pfizer for at least 3 years.
Dr Nick Keysell	GP	Any other interests (Including personal or family medical conditions) which could be seen as influencing views of the drug(s) under consideration.  As per the previous meeting. There is a potential for unconscious bias due to my involvement with the CMDU meetings and writing the CRGs.

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## 2. COVID-19 medicines for patients who do not require hospitalisation

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An overview was given that NICE issued a Technology Appraisal (TA878) for COVID-19 treatments at the end of March which recommended Paxlovid and sotrovimab for patients at risk of progression to severe COVID-19 who do not require hospitalisation. At the same time, the oral antivirals, Paxlovid and molnupiravir, were made available to prescribe on FP10.

COVID-19 treatments are currently red (hospital-only) in the Devon Formulary. At the July FIG meeting, the FIG was asked to consider draft formulary guidance for COVID-19 treatments for non-hospitalised patients including proposals to reclassify Paxlovid from red (hospital-only) to green (first-line) and molnupiravir from red to amber (to be prescribed in primary care on the advice of a specialist). The FIG was undecided on whether it was clinically appropriate for Paxlovid and molnupiravir to be reclassified from red (hospital-only) and considered that a decision would need to be taken in the context of the service provided by the COVID medicine delivery units (CMDUs).

Key areas of concern were the extensive list of drug interactions for Paxlovid and the clinical significance of these interactions, and whether the support offered to primary care by the CMDUs outlined in the draft clinical referral guidance (CRG) would change in the future.

There has been no change to the treatment pathway since the discussion in July. An enhanced level of CMDU support for primary care was included in the draft formulary guidance discussed at the December 6<sup>th</sup> meeting. All patients must meet all initial assessment criteria for a COVID-19 treatment before a decision can be taken on the appropriate treatment. There is advice and guidance from the CMDU at a number of points in the treatment pathway. If the patient meets the initial criteria for a COVID-19 treatment, the GP may assess the patient's suitability for initiating Paxlovid in primary care without specialist support, or alternatively a GP can refer the patient for the CMDU to assess suitability for Paxlovid and prescribe a COVID-19 treatment if required.

If there is a change to the level of support offered to primary care by the CMDUs, the decision taken by the FIG on the reclassification of Paxlovid and molnupiravir will be reconsidered in light of any new arrangements.

At the time of the July FIG meeting, Paxlovid was green in four formularies in England (including Cornwall, Dorset, and Somerset). The formulary team sought further information which clarified that a primary care pathway was under discussion in Cornwall and the CMDU was providing the service. In Dorset and Somerset, the secondary care CMDUs have closed and the ICBs have commissioned COVID-19 primary care services to support GPs. In Dorset and Somerset, GPs can either assess a patient for suitability for Paxlovid and prescribe if appropriate or they can refer a patient to the COVID-19 primary care service. Unlike Devon, there is no support from CMDU specialists. The primary care service is run by a PCN in Dorset and the Out of Hours service in Somerset.

Bearing in mind that some formularies and decision-making committees are in a state of flux, it was noted that currently Paxlovid is green in six formularies in England (Cornwall, Dorset, Somerset and three formularies outside SW England), and amber in two formularies outside SW England. Molnupiravir is green in three formularies (Dorset, Somerset and one formulary outside SW England) and blue in Cornwall.

It was acknowledged that NICE are undertaking a rapid appraisal of the TA878 recommendations for Paxlovid to consider additional patient groups at risk of progression to severe COVID-19. NHS England has sent a submission to NICE requesting the proposed additional patient groups are reconsidered with an extended implementation period of one year rather than the usual three months, which NICE has indicated they are minded to accept. However there is no confirmed date

for publication of an update to the TA as yet; when this is published it will be scheduled for discussion by the FIG.

At the FIG meeting on 6th December, the proposed formulary guidance and proposed update to the entries were discussed. These were accepted in principle with minor amendments, which have been incorporated into the drafts under consideration at the extraordinary meeting. The FIG did not specifically discuss the reclassification of Paxlovid and molnupiravir at the December 6<sup>th</sup> meeting.

The FIG considered the draft guidance and agreed amendments in a number of areas:

- The treatment pathway - the FIG discussed the support available for assessment of whether a patient is eligible for a Covid-19 treatment. It is important that the pathway is clear, and that GPs can seek support from the CMDU as needed. It was agreed that the wording under section 1a of the treatment pathway should be revised to clarify that "Advice & Guidance or referral to CMDU is available if there is uncertainty as to whether the patient meets the criteria."
- Reference to CMDU advice and guidance beneath the table in section 1) Initial assessment for consideration of a COVID-19 treatment to similarly be updated in line with the discussion above.
- Assessment for treatment with Paxlovid - it was agreed that the proposed statement to "Take into account the patient's vaccination status, the time since last booster vaccine, and their medical history in the decision to prescribe Paxlovid" should be removed. These factors would form part of standard clinical assessment and it was considered that without advice on what to specifically do with this information there is limited value in including it.
- Availability of oral antiviral COVID-19 treatments in the community – it was agreed to simplify this whole section to ensure it reflects realistic expectations of GPs and patients. It was agreed that the wording should be amended to "Ask the patient to call back if the pharmacy is unable to confirm treatment will be provided within the 5 day treatment window."
- Information on the Specialist Pharmacy Service Medicines Advice service will be separately retained as standalone information regarding the advice line for community pharmacists.

With the amendments suggested above, the FIG considered and agreed:

- the treatment pathway set out is clear and easy to follow;
- initiation of Paxlovid (nirmatrelvir/ritonavir) in primary care is acceptable in the context of the support from the CMDUs outlined in the guidance with green (first-line) classification;
- prescribing of molnupiravir in primary care on the advice of a specialist is acceptable in the context of the support from CMDUs outlined in the guidance with an amber (to be prescribed in primary care on the advice of a specialist) classification;
- there is sufficient supporting information provided to support GPs to appropriately prescribe Paxlovid and molnupiravir for COVID-19;
- support for the proposed changes to the introductory text in section 5.3.6 nMABs and other antiviral drugs, and the individual formulary entries for Paxlovid and molnupiravir.

**ACTION: Formulary Team to update and publish the Devon Formulary guidance for COVID-19 treatments for non-hospitalised patients in line with the discussion**

Alex Degan added his thanks to the group for their time in attending this extraordinary meeting, noting that it is important that prescribing is done safely following proper discussion and appropriate guidance.

Summary of actions			
	Action	Lead	Status
23/86	COVID-19 treatments for non-hospitalised patients – update and publish the revised guidance in line with the FIG discussion	Formulary Team	Complete