

PTHB Process for Covid 19 Treatments – 9th Sept 2024

Referrals received via Powys.covidvacorder@wales.nhs.uk daily (self-referrals from NHS 111 portal, or via an NHS 111 Health Information Advisor).

Enter available details on nMAB AV Treatment Spreadsheet (in MS Teams channel – Covid-19 Treatment Chat)

Contact patient to assess eligibility and suitability for AV/nMAB
(see: [Initial Contact with Patient Guide, Appendix A](#))

Is patient eligible for AV/nMAB?

No

Explain reason for ineligibility and give safety netting advice: **Safety netting** - *If your symptoms worsen, do not improve after 7 days, or you experience breathlessness, vomiting or fatigue that stops you doing your normal activities, contact NHS 111 Wales, your GP or your hospital specialist for advice.*

Yes

Is patient able to take Paxlovid?

No

If the patient meets the eligibility criteria for sotrovimab, discuss this option with them and if appropriate refer to local MIU - Brecon, Welshpool or Llandrindod ([see Appendices G-J](#))

Yes

Is patient/patient representative able to collect Paxlovid from local hospital?

No

Paxlovid to be sent by post (Royal Mail Special Delivery)

Yes

Is there a pharmacy professional/nurse available in that local hospital to supply Paxlovid under PGD?

No

Paxlovid to be collected from Ystradgynlais by Covid Therapies Nurse and posted at Royal Mail Post Office
OR
pharmacy professional/nurse in Bronllys able to supply under PGD to post from hospital

Yes

Discuss with pharmacy professional/nurse and send all supporting communication (e.g. from patient GP or specialist) to enable them to establish eligibility.
PP/Nurse to contact patient and arrange collection

Consider:

- Number of days since symptom onset
- Time of day
- Volume of referrals being managed

Step by Step Guide:

1. Referral received via Powys.covidvacorder@wales.nhs.uk
2. Enter details on nMAB AV Treatment spreadsheet (in MS Teams channel - Covid-19 Treatment Chat)
3. Contact patient – gather information using initial contact checklist (Appx A)
 - Advise them of the risks/benefits of treatment and obtain informed consent to consider antiviral eligibility and consent to access their medical/GP record to enable this
4. Use PGD Checklist and Screening Tool (Appx B) and national eligibility criteria [Eligibility-criteria-updated-24.7.23.pdf \(wales.nhs.uk\)](#) to establish eligibility for antiviral treatment
5. Record information on spreadsheet including details of symptoms and date of onset, detailed reason for AV eligibility, list of patient medications and any other relevant info
 - See below for checklist re documentation/record keeping

If ineligible for treatment – document the reason, inform patient and provide safety netting advice:

contact GP, NHS 111 or hospital specialist if symptoms become concerning e.g. **worsening symptoms, no improvement after 7 days, breathlessness, vomiting or fatigue that prevents**

6. Use PGD Checklist and Screening Tool (Appx B) to establish suitability for Paxlovid
 - Contact patient GP or specialist healthcare provider if more information required or any uncertainty regarding decision to supply Paxlovid
 - Document communication with other HCP or colleagues that has contributed to your decision making
 - Save the Liverpool Drug Interaction Checker interaction report and attach to the spreadsheet

If Paxlovid is contraindicated – if the patient meets the eligibility criteria for sotrovimab, discuss option of sotrovimab with patient and follow process for referral to MIU for sotrovimab infusion (Appendices G-J)

7. If Paxlovid is to be supplied, determine who will make the supply

If you are referring to another HCP working to the PGD to supply Paxlovid, ensure you discuss the case with that person and forward ALL supporting information to them.

Remember: responsibility within a PGD cannot be delegated - **they need to be able to determine for themselves that the patient meets the criteria for supply of Paxlovid under the PGD.**

8. Determine if collection from a community hospital is possible -
 - Consider availability of pharmacy professional and patient/carer ability to collect
 - Posting Paxlovid should be last resort option

OR if collection is not possible, Paxlovid is to be posted via Royal Mail Special Delivery (for delivery by 1pm next day)

The HCP who will supply Paxlovid should then:

9. Inform patient and give instructions regarding how to take Paxlovid (route, dose, frequency), common adverse effects, reporting of serious adverse effects, any information specific to the patient (e.g. swallowing difficulties, breastfeeding, contraception) and instructions for any adjustments to current medications (including advising patient to contact their specialist HCP for advice about whether they need to pause immunosuppressants whilst they have Covid-19) **See Appx C/D**
10. Collect Paxlovid from ward/pharmacy store (ensure correct dose – standard or renal)
11. Enter batch number and expiry date on spreadsheet (and add patient name and date on label)
12. Print copy of Powys-THB Patient Information Leaflet (PIL) (**Appx C standard dose / Appx D renal dose**)
13. Print any instructions for adjustments to current medication whilst taking Paxlovid (**Appx E**)
14. Arrange suitable meeting place to hand over medication, taking into consideration infection prevention and control requirements e.g.
 - Meet outside if possible and wear a fluid resistant surgical mask
 - Ask the patient/carer to wear a mask also if possible (take a spare that you can give to them if they don't have one)
15. Hand over the Paxlovid, PIL and any additional information to patient/carer
16. Document who collected Paxlovid and what time

OR

17. Follow steps 9-13 above. Seal PIL and any additional instructions in envelope with Paxlovid and take to post room (Bronllys) or Post Office
18. Document special delivery reference number on spreadsheet
19. Inform patient when to expect delivery
 - Provide with MM office phone number in case they need to contact us (01874 71 2641)
20. Send email to GP practice using template (**Appx F**) to inform them that patient has been supplied with Paxlovid under a PGD = record Y/N on spreadsheet to indicate if done
21. Inform Nikki Mathers and Gemma Morgan of Paxlovid supply (and location taken from) to enable stock replenishment (nikki.mathers@wales.nhs.uk, gemma.morgan9@wales.nhs.uk)
22. Contact patient after 1pm the following day to check that Paxlovid has been delivered and that they are happy with the instructions/if they have any further questions

Documentation and Record Keeping:

The record needs to clearly document how you determined that the patient met the eligibility criteria for antivirals/nMAB and that it was appropriate to supply Paxlovid or refer for sotrovimab. If the advice of other health care professionals has been sought and contributed to decision-making, this also needs to be documented clearly.

Documentation:

- Complete all sections of nMAB AV treatment spreadsheet
- Ensure you have included the following in the documentation:
- Patient consent
- Covid symptoms experienced and date of onset
- Detailed reason eligible for treatment e.g. specific condition and relevant medication
 - ✓ IMID – Rheumatoid arthritis, on rituximab
 - ✗ IMID (no further details)
- **OR** reason not eligible for treatment and explanation/advice given to patient
- Brief description of conversation with patient including relevant details about their medical condition and medications, any questions they've asked regarding antivirals and your response
- Details of any reported allergies and the reactions they experience
- Brief description of other HCP you have contacted for advice, including name of specialist, method of contact, date, time, questions asked and their response
- Brief description of arrangements made with patient/carer for supply of Paxlovid
- That patient has been provided with general information about how to take Paxlovid
- Any specific instructions or warnings given to that patient (e.g. medication adjustments or contraception warning)
- That GP has been informed of Paxlovid supply
- If sotrovimab referral made, include details of which MIU and name of person spoken to/email address referral sent to

Record Keeping:

The nMAB AV Treatment spreadsheet is the record of the decision to supply Paxlovid or refer for sotrovimab. All the documentation points above need to be present for compliance with the PGD.

The Interaction Report from the Liverpool Drug Interaction Checker (LDIC) should be attached to the spreadsheet.

Additional documentation can be saved to the relevant folder in the Covid-19 Treatment MS Teams Channel.

This includes:

Folder = Sotrovimab Referrals

- Referrals to MIU for sotrovimab infusion (folder = Sotrovimab Referrals)

Folder = Pax Supply, Subfolder = relevant month/year

(Save documents to include patient initials and date of correspondence)

- Record of written advice for adjustments to existing medication whilst taking Paxlovid

- Any documentation regarding the decision to supply or not supply paxlovid that you feel is necessary to keep e.g. blood results or specific advice from a specialist

NB: In many cases, provided the relevant details are included in the spreadsheet, it will not be necessary to upload emails, unless there is a specific reason for keeping the email in its entirety.

The PTHB Clinical Record Keeping Procedure states:

*If email correspondence takes place between a clinician and another clinician or staff member regarding patient care, then a **summary** of this activity should be entered into the patient's record. Full email threads should not be copied and pasted into the patient record. Only clinically relevant information should be included in the patient record. If it is deemed that whole email threads contain information necessary for patient care, and they need to be recorded in their entirety, then the email should be uploaded into the relevant system as an attachment. All staff should follow the email policy (IMT 013) The use of jargon and emojis in email correspondence regarding patient care is not acceptable.*

Appendix A: Initial contact with patient - guidance / check list

Introduction:

Check who you are speaking with:	
<ul style="list-style-type: none"> If the person referred has not answered the phone/is unable to speak on the phone, ask if they can give permission for you to speak to someone else on their behalf 	Consent Y / N
Check they are aware of the referral for Covid-19 antivirals	
Explain you will need to ask some questions about their Covid symptoms, their medical condition and medications, to check their eligibility for antivirals	
Explain that you will need to access their medical and GP record to check information and ensure antivirals are safe to give	
<ul style="list-style-type: none"> Ask for their consent to access the GP record and contact any relevant specialist health care providers 	Consent Y / N

Covid Symptoms:

Ask what Covid-19 symptoms they are experiencing	
Check when the Covid symptoms started and when they had a positive test	

If symptoms started more than 7 days ago – explain they are not eligible for antivirals and give safety netting advice

Current Medical Condition and Medications:

Ask about their current medical condition (i.e. establish reason they are in 'at risk' cohort)	
Ask for a list of all medications they take including treatments prescribed/administered in a secondary care setting	
<ul style="list-style-type: none"> Regular prescribed PRN prescribed Supplements and any other OTC medications they take 	
Check if their medications are supplied in a pre-packaged compliance aid/dosette box	
Explain potential for paxlovid to interact with some prescribed and OTC medicines and emphasise importance of them telling you ALL items they take	

If able to ascertain straight away that they are not eligible, explain this and give safety netting advice

If able to ascertain that they are eligible for treatment but Paxlovid is contraindicated (e.g. due to concomitant medication) explain this and discuss option of Sotrovimab

Additional Information and Cautions:

Check if they have any allergies and record:	
<ul style="list-style-type: none"> the substance/s they have an allergy to the reaction it causes (e.g. rash/vomiting/anaphylaxis) 	
Check if they have ever had any problems with kidney or liver function	
If yes, ask for details including:	
<ul style="list-style-type: none"> do they have regular blood tests do they have a specialist we can contact for more information 	
Check if they are pregnant or breastfeeding	

Logistics:

If able to ascertain during conversation that they are eligible for antivirals and there are no contraindications to Paxlovid:

Explain that you will double check the information they have given you to ensure Paxlovid is safe to supply	
Arrange collection from a community hospital <ul style="list-style-type: none"> Check nearest hospital and that patient or a representative could collect meds 	
OR explain medication will be posted out by Royal Mail Special Delivery <ul style="list-style-type: none"> Check address and postcode are correct 	

If unable to ascertain eligibility or suitability for Paxlovid during initial conversation:

Explain what you need to check (e.g. eligibility/drug interactions/kidney or liver function)	
Explain if you need to contact GP or specialist	
<ul style="list-style-type: none"> Ask for specialist details if needed 	
Advise patient you will contact them again once you have the relevant information	
<ul style="list-style-type: none"> Give approximate time scale for contacting them (e.g. if you don't hear from me today it's because I haven't been able to get the information I need, but I/someone will contact you tomorrow morning to update you) Consider giving them the MM office 01874 712641 or other suitable phone number in case they need to contact you with additional information 	

Appendix B: Paxlovid PGD Checklist and Screening Tool

Inclusion Criteria		Exclusion Criteria	
<i>All inclusion criteria must be present and no exclusion criteria, for patient to be considered for Paxlovid supply</i>		<i>If any exclusion criteria are present, the patient cannot have Paxlovid. Consider if suitable for Sotrovimab, or in case of rapidly worsening symptoms, advise to immediately contact GP, NHS 111 or 999 in an emergency</i>	
1	Informed consent	No consent or 'best interests' decision	
2	Age 18 years or over	Under 18 years old	
3	Symptoms of Covid-19	exhibiting sudden onset of symptoms of confusion, chest pain, breathing difficulties or any other symptoms giving cause for concern.	
4	Positive PCR or LFT in last 5 (or 7) days	they have long term conditions such as chronic respiratory or cardiovascular disease exhibiting rapidly worsening symptoms.	
5	Symptom onset in last 5 (or 7) days	they have a known allergy to nirmatrelvir or ritonavir or any of the excipients in the preparation	
6	Increased risk of progression to severe disease OR Over 70 and resident in a care home	the pattern of clinical presentation indicates that there is recovery rather than risk of deterioration from infection.	
		They require hospitalisation for Covid-19	
7	Access to reliable list of current medications (from patient or medical record/other HCP)	they require supplemental oxygen specifically for the management of COVID-19 symptoms.	
8	No contraindications to nirmatrelvir/ritonavir (see exclusion criteria and screening tool)	they are on concomitant medication that is contraindicated with Paxlovid (unless otherwise instructed to do so by a prescriber with expertise in the management of COVID-19 with Paxlovid)	
<p>If No to 1-6 above, patient should be provided with self-care advice and told to contact GP, NHS 111 or hospital specialist if symptoms become concerning e.g. Worsening symptoms, no improvement after 7 days, breathlessness, vomiting or fatigue that prevents normal activities</p> <p>If yes to 1-6 above and no to 7-8 or an exclusion criterion is present, consider Sotrovimab. Or in case of rapidly worsening symptoms, advise patient to seek further medical advice/help</p>		their usual medicines are supplied in a pre-packaged compliance aid, where doses cannot be omitted or adjusted easily, AND one of these medicines cannot be given with Paxlovid	
		they have severe hepatic impairment (Child-Pugh Class C).	
		they have rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.	
		they are pregnant.	
		they are participating in a clinical trial of a therapeutic agent for acute COVID-19	

Screening Tool

Risk factors for progression to severe disease: [Eligibility-criteria-updated-24.7.23.pdf \(wales.nhs.uk\)](#)

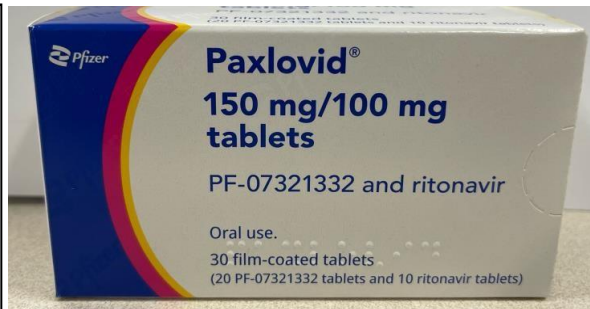
Drug Interactions															
<p>Check for any drug-drug interactions with Paxlovid on Liverpool COVID-19 Interactions (covid19-druginteractions.org)</p> <p>If a medication is not listed in the Liverpool tool, consider use of BNF, SPC, Drugdex or Stockley.</p> <p>In absence of other information, advice from NAV: <i>look at SPC, if no liver metabolism or interactions with ritonavir listed, proceed</i></p>	No interactions (Green)	Continue													
	Potential interactions (Amber)	<p>Can adjustments be made? See LDIC report</p> <p>Contact prescriber of medication requiring adjustment (GP or specialist), attach interaction report, seek agreement for dose adjustments or alternative recommendations. If adjustments not possible – consider if eligible for Sotrovimab</p>													
	Contraindicated (Red)	Paxlovid cannot be given – consider if eligible for Sotrovimab													
Renal and Hepatic function															
Has the patient ever been told they have a problem with their liver or kidneys?															
Yes	seek further information	No	where possible confirm this from medical record												
Is there evidence of impairment on WCP/GP record? - check medical conditions listed, blood results, current medications (If blood results available check eGFR, Bilirubin and ALT and document on spreadsheet including date of tests*)															
Yes	<p>determine severity - seek GP/specialist advice if required. Refer to LDIC prescribing resources: Liverpool COVID-19 Interactions (covid19-druginteractions.org)</p> <p>If LFTs deranged, refer to SPS guidance: Assessing liver function and interpreting liver blood tests – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice</p> <p>seek GP/specialist advice if required</p>	No	<p>In absence of any evidence of renal or hepatic impairment – continue with Paxlovid</p> <p>*</p> <table border="1"> <thead> <tr> <th colspan="3">Normal Reference Range</th> </tr> </thead> <tbody> <tr> <td>eGFR</td> <td>>60ml/min Standard dose</td> <td><60ml/min Renal dose</td> </tr> <tr> <td>ALT</td> <td colspan="2">0 – 40 IU/L</td> </tr> <tr> <td>Bilirubin</td> <td colspan="2">5 – 21 micromol/L</td> </tr> </tbody> </table>	Normal Reference Range			eGFR	>60ml/min Standard dose	<60ml/min Renal dose	ALT	0 – 40 IU/L		Bilirubin	5 – 21 micromol/L	
Normal Reference Range															
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Bilirubin	5 – 21 micromol/L														
Severe Hepatic Impairment															
<p>The following are indications of severe hepatic impairment and presence of any of these factors will likely mean Paxlovid is contraindicated and Sotrovimab should be considered. If unsure, seek advice from patient GP or specialist HCP:</p> <ul style="list-style-type: none"> • They have Jaundice • They are currently or have previously been admitted to hospital with liver disease 															

<ul style="list-style-type: none"> • They have ascites • They take rifaximin • They have deranged LFTs 		
Pregnancy	Yes	Contact the patient's obstetric/midwifery team to discuss the possibility of Sotrovimab – will require risk/benefit assessment Sotrovimab (medicinesinpregnancy.org)
	No	Continue with Paxlovid Advise individuals of childbearing potential that they should use effective barrier contraception for the duration of treatment and until after one complete menstrual cycle after stopping the last dose (including if they use a combined hormonal contraception)
Breastfeeding	Yes	Paxlovid can be supplied off-label Patient can stop breastfeeding during treatment with Paxlovid, or can continue breastfeeding and be advised to contact their health visitor or GP if: <ul style="list-style-type: none"> • their baby isn't feeding as well as usual • they are unable to settle their baby • their baby has sickness or diarrhoea • their baby is not sleeping well • they develop a hypersensitivity reaction e.g. a rash • they develop yellowing of the skin and eyes, pale stools and dark urine
	No	
Chemotherapy	Yes	Check chemotherapy regime on LDIC for interactions and determine where patient is in chemo cycle. Seek advice from patient oncologist if needed. Drug-drug interactions with chemo - seek advice from patient oncologist and consider Sotrovimab if eligible
	No	
Active participant in any Covid-19 treatment clinical trial	Yes	Not eligible for treatment Advise to contact trial investigators for advice
	No	Continue with Paxlovid
Any allergies/intolerances to nirmatrelvir or ritonavir or any of its excipients	Yes	Consider Sotrovimab
	No	Continue with Paxlovid
Rare genetic hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption	Yes	Consider Sotrovimab
	No	Continue with Paxlovid
NB: whilst Paxlovid contains lactose, individuals with a simple lactose intolerance may still be eligible		

Appendix C

Paxlovid® Patient Information Leaflet

Paxlovid® is an antiviral medicine that works by stopping the virus that causes Covid-19 from multiplying in your body. It is used to treat early COVID-19 infection and help to prevent more severe symptoms. It may help you to get better faster



Paxlovid® is a combination of two medicines (Nirmatrelvir and Ritonavir). Nirmatrelvir stops the virus from growing and spreading, and Ritonavir makes the effect of nirmatrelvir last longer.

Paxlovid comes as 5 daily dose blister cards. Each daily blister card contains 4 pink nirmatrelvir tablets (150mg each) and 2 white ritonavir tablets (100mg each). The card shows which tablets to take in the morning and which to take in the evening (AM dose and PM dose)



As pictured, you will be taking **THREE** tablets in the morning and in the evening. **TWO PINK** tablets (Nirmatrelvir) and **ONE WHITE** tablet (Ritonavir). You will need to take this medication for 5

Key Points

You will take **TWO PINK** (Nirmatrelvir) tablets and **ONE WHITE** (Ritonavir) tablet twice a day for FIVE days. For each dose, take the three tablets at the same time.

Take the tablets by mouth. You can take them with or without meals. Swallow the tablets whole with plenty of fluid (a full glass of water). If you have swallowing difficulties, the tablets can be crushed or split and mixed with food or liquid immediately before taking them.

Start taking Paxlovid® as soon as you receive it (and within SEVEN days from the start of Covid-19 symptoms). Paxlovid® starts working soon after taking it. Even if you start to feel better, it is important that you finish the course.

Side effects: Paxlovid® may cause side effects. Most are mild and short-lived. Common side effects include nausea, vomiting, diarrhoea, and an unpleasant taste in your mouth that can change how food and drink tastes. If you are concerned about any side effects, talk to your doctor or pharmacist. You can also report side effects directly via the Coronavirus Yellow Card Reporting site: www.coronavirus-yellowcard.mhra.gov.uk

Paxlovid® and other medications: Paxlovid® can interact with other medicines and have serious side effects if you take them together. It is important that you make your healthcare provider aware of any medications you are currently taking, including prescription medicines and over the counter medicines, herbal remedies and supplements. You must also discuss any changes in your medicines with the prescriber and pharmacist and tell them that you are taking Paxlovid®. This is because it can interact with a lot of medicines with potentially serious side effects.

Pregnancy and Contraception: Paxlovid® is **NOT** recommended if you are pregnant. Paxlovid® can also stop combined oral contraceptives from working properly. If you are able to become pregnant, use effective barrier contraception (a condom, female condom, diaphragm or cap) during the full course of treatment and until **AFTER** you have had **ONE FULL MENSTRUAL CYCLE**, even if you are taking the combined oral contraceptive pill. If you find out that you are pregnant or become pregnant whilst taking Paxlovid® or shortly after, inform your doctor as soon as possible.

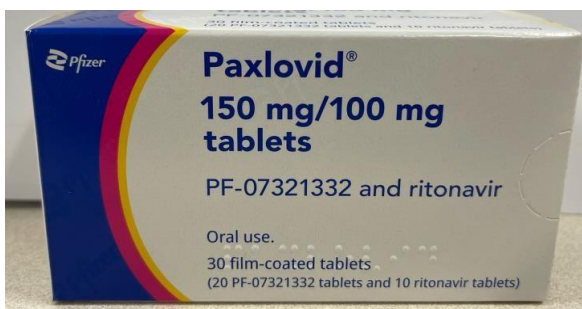
Breastfeeding: if you are breastfeeding and have any concerns about your baby, contact your health visitor or GP, especially if: your baby isn't feeding as well as usual, you are unable to settle your baby, your baby has sickness or diarrhoea, your baby is not sleeping well, they develop a hypersensitivity reaction e.g. a rash, or they develop yellowing of the skin and eyes, pale stools and dark urine.

If your symptoms worsen, do not improve after 7 days, despite completing the course of treatment, or you experience breathlessness, vomiting or fatigue that stops you doing your normal activities, you should contact NHS 111 Wales, your GP or hospital specialist for advice

Appendix D

Paxlovid® Patient Information Leaflet (RENAL dose)

Paxlovid® is an antiviral medicine that works by stopping the virus that causes Covid-19 from multiplying in your body. It is used to treat early COVID-19 infection and help to prevent more severe symptoms. It may help you to get better faster



Paxlovid® is a combination of two medicines (Nirmatrelvir and Ritonavir). Nirmatrelvir stops the virus from growing and spreading, and Ritonavir makes the effect of nirmatrelvir last longer.

Paxlovid® comes as 5 daily dose blister cards. Each daily blister card contains 4 pink nirmatrelvir tablets (150mg each) and 2 white ritonavir tablets (100mg each). The card shows which tablets to take in the morning and which to take in the evening (AM dose and PM dose). Details of how to take your reduced **RENAL** dose are provided below



You have been prescribed a reduced **RENAL** dose of Paxlovid®. It is important that you only take **TWO** tablets **TWICE** a day.

Each morning and evening take:

ONE PINK tablet (Nirmatrelvir) and **ONE WHITE** tablet (Ritonavir). You will need to take this medication for 5 days.

Please **DISPOSE** of the third **PINK** tablet provided per dose.



Key Points

You have been prescribed a reduced **RENAL** dose of Paxlovid®. You will take **ONE PINK** (Nirmatrelvir) tablet and **ONE WHITE** (Ritonavir) tablet twice a day for **FIVE** days. For each dose, take the two tablets at the same time and **DISPOSE** safely of the third **PINK** tablet provided.

Take the tablets by mouth. You can take them with or without meals. Swallow the tablets whole with plenty of fluid (a full glass of water). If you have swallowing difficulties, the tablets can be crushed or split and mixed with food or liquid immediately before taking them.

Start taking Paxlovid® as soon as you receive it (and within SEVEN days from the start of Covid-19 symptoms). Paxlovid® starts working soon after taking it. Even if you start to feel better, it is important that you finish the course.

Side effects: Paxlovid® may cause side effects. Most are mild and short-lived. Common side effects include nausea, vomiting, diarrhoea, and an unpleasant taste in your mouth that can change how food and drink tastes. If you are concerned about any side effects, talk to your doctor or pharmacist. You can also report side effects directly via the Coronavirus Yellow Card Reporting site: www.coronavirus-yellowcard.mhra.gov.uk

Paxlovid® and other medications: Paxlovid® can interact with other medicines and have serious side effects if you take them together. It is important that you make your healthcare provider aware of any medications you are currently taking, including prescription medicines and over the counter medicines, herbal remedies and supplements. You must also discuss any changes in your medicines with the prescriber and pharmacist and tell them that you are taking Paxlovid®. This is because it can interact with a lot of medicines with potentially serious side effects.

Pregnancy and Contraception: Paxlovid® is **NOT** recommended if you are pregnant. Paxlovid® can also stop combined oral contraceptives from working properly. If you are able to become pregnant, use effective barrier contraception (a condom, female condom, diaphragm or cap) during the full course of treatment and until **AFTER** you have had **ONE FULL MENSTRUAL CYCLE**, even if you are taking the combined oral contraceptive pill. If you find out that you are pregnant or become pregnant whilst taking Paxlovid® or shortly after, inform your doctor as soon as possible.

Breastfeeding: if you are breastfeeding and have any concerns about your baby, contact your health visitor or GP, especially if: your baby isn't feeding as well as usual, you are unable to settle your baby, your baby has sickness or diarrhoea, your baby is not sleeping well, they develop a hypersensitivity reaction e.g. a rash, or they develop yellowing of the skin and eyes, pale stools and dark urine.

If your symptoms worsen, do not improve after 7 days, despite completing the course of treatment, or you experience breathlessness, vomiting or fatigue that stops you doing your normal activities, you should contact NHS 111 Wales, your GP or hospital specialist for advice

Appendix E

Written advice to citizens on adjusting other medications

Patient Name:	
Patient Address:	
Date of Review:	
Medicine Name	Action to be taken
Any other information	

Appendix F

Template to inform GP of Paxlovid Supply

Dear Secretaries / Practice Manager

Please see details below for a patient that has received Paxlovid® (nirmatrelvir/ritonavir tablets 150mg/100mg (30)) under a PGD via the Powys Teaching Health Board antiviral service following a positive SARS-COV-2 diagnostic test.

Patient Name	D.o.B	NHS Number	Date of Supply	Paxlovid Standard or Renal Dose

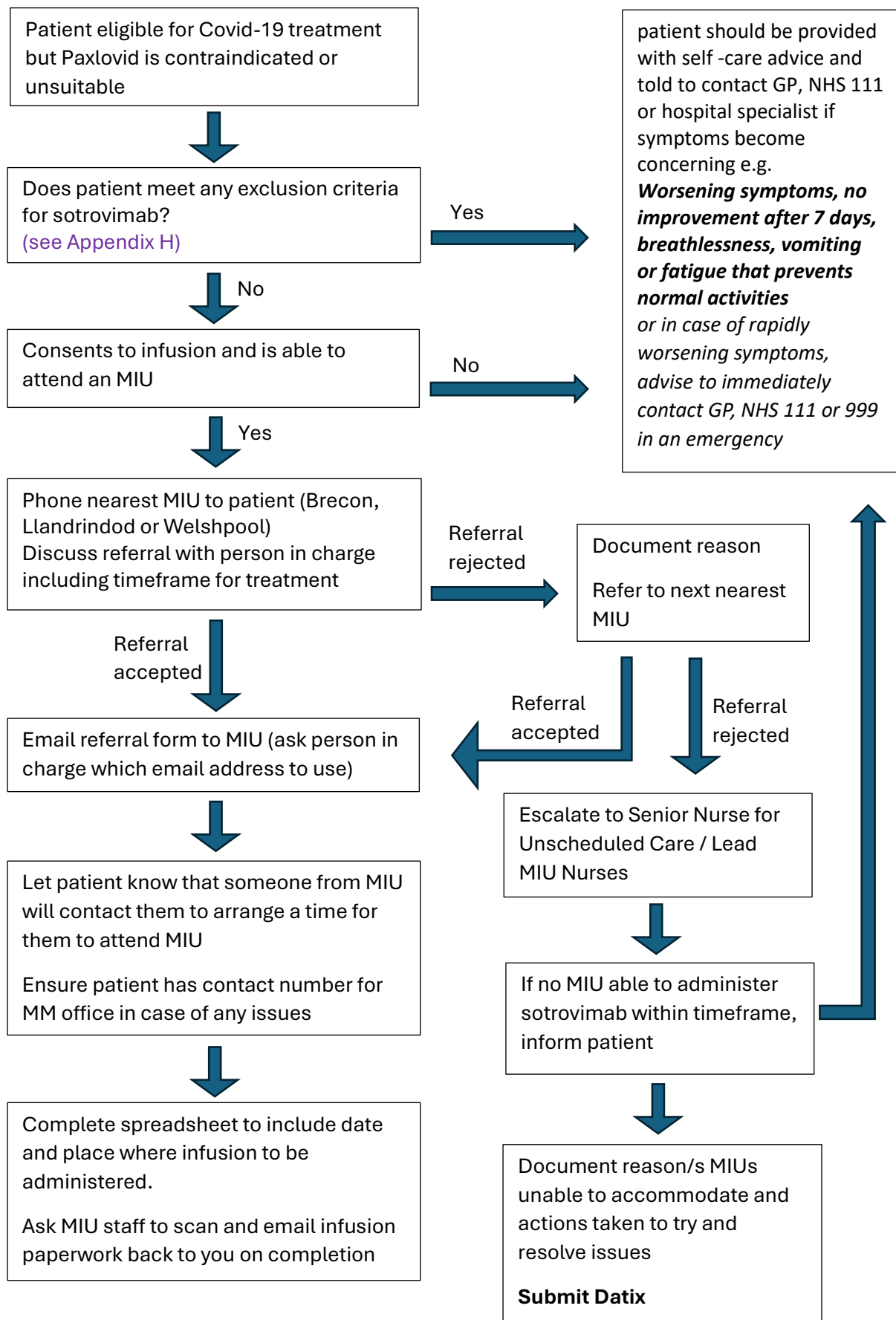
Please add an entry to the patient's file.

Kind regards

Powys Antiviral Service

Powys Teaching Health Board

Appendix G: Process for referral for Sotrovimab infusion



Appendix H: Sotrovimab PGD Checklist

Inclusion Criteria		Exclusion Criteria	
<i>All inclusion criteria must be present and no exclusion criteria, for patient to be considered for Sotrovimab infusion</i>		<i>If any exclusion criteria are present, the patient cannot have Sotrovimab. Advise patient to contact their health care specialist or in case of rapidly worsening symptoms, advise to immediately contact GP, NHS 111 or 999 in an emergency</i>	
1	Informed consent	No consent or 'best interests' decision	
2	Age 18 years or over	Under 18 years old	
3	Symptoms of Covid-19	exhibiting sudden onset of symptoms of confusion, chest pain, breathing difficulties or any other symptoms giving cause for concern.	
4	Positive PCR or LFT in last 5 (or 7) days	they have long term conditions such as chronic respiratory or cardiovascular disease exhibiting rapidly worsening symptoms.	
5	Symptom onset in last 5 (or 7) days	they have a known allergy to Sotrovimab or any of the excipients in the preparation	
6	Increased risk of progression to severe disease	the pattern of clinical presentation indicates that there is recovery rather than risk of deterioration from infection.	
	Paxlovid contraindicated or not suitable	they require supplemental oxygen specifically for the management of COVID-19 symptoms.	
7	Able to access medical / drug history	They require hospitalisation for Covid-19	
8	No contraindications to Sotrovimab (see exclusion criteria and SmPC)	They are breastfeeding an infant less than 1 month old or the infant was born premature (before 37 weeks)	
		they are participating in a clinical trial of a therapeutic agent for acute COVID-19	

NB: The inclusion criteria for sotrovimab are narrower than the inclusion criteria for nirmatrelvir plus ritonavir – always check the NICE guidance:

[1 Recommendations | Nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 | Guidance | NICE](#)

Appendix I:

Sotrovimab – Referral to MIU Template

Dear

Please can I refer the following patient for:

Sotrovimab (Xevudy ▼[®]) 500mg Intravenous infusion? (Over 30 minutes via a 0.2 micron filter in 100mL sodium chloride 0.9%)

Patient Name	
NHS Number	
D.o.b	
Address	
Telephone Number	
Eligible Condition	
Reason Paxlovid Contraindicated	
Covid 19 symptom onset	
Covid 19 symptoms	
PCR/LFT Test Date	
Other problems/medication	
Allergies	
Other information	
GP Surgery	

I have advised the patient that you will make contact re arranging treatment. They are aware that the procedure will take around 2 hours with the preparation, infusion time and observation time post dose.

Please contact me if you need any further information.

Many thanks.

Appendix J: Sotrovimab Information / Patient Information Leaflet from NAV (June 2024)

Sotrovimab (Xevudy®)

Sotrovimab is a biological medicine. It's also known as a neutralising monoclonal antibody (nMAB).

nMABs are synthetic proteins that act like human antibodies in the immune system. They are made by cloning an antibody that can stick to the spike protein of the virus and neutralise it. They stick to the virus and stop it from getting into your lungs and causing an infection.

A clinical study showed that sotrovimab decreased the risk of hospitalisation or death by 85% in patients with mild-to moderate disease and at least one risk factor for disease progression.

Who can have sotrovimab?

Sotrovimab can be given to most adults. You may be eligible for sotrovimab if ALL of these apply:

- you're in the high-risk group above
- you've had a positive PCR or LFT test for COVID-19 within the last 5 days
- you've had coronavirus (COVID-19) symptoms within the last 5 days

Who may not be able to have sotrovimab?

Sotrovimab is not suitable for some people. To make sure it's safe for you, tell your health care professional if:

- you have any allergies
- you are pregnant, trying to get pregnant or breastfeeding

How is sotrovimab given?

Sotrovimab is given to you through a drip in your arm (infusion) over 30 minutes. It will be given in hospital or at a local centre. The dose of sotrovimab is 500 mg and you'll only need 1 dose. You will then need to be monitored for around 30 minutes after the infusion is complete.

Does sotrovimab have any side effects?

Like all medicines, sotrovimab can cause side effects in some people, but many people have no side effects or only minor ones.

The most common side effects (happen in up to 1 in 10 people) are a mild allergic reaction (hypersensitivity) which can include feeling sick (nausea), feeling dizzy, an itchy rash and redness (this may be less noticeable on black or brown skin) and warmth on your skin.

These symptoms usually happen within the first 24 hours and should go away on their own.

In rare cases, sotrovimab may cause a serious allergic reaction (anaphylaxis).

If you get any side effects, talk to your doctor or pharmacist. You can also report side effects directly via the Coronavirus Yellow Card Reporting site (www.coronavirus-yellowcard.mhra.gov.uk) or search

for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you are providing more information on the safety of this medicine.

Other medicines and sotrovimab

There's no evidence to say that sotrovimab will affect any other medicine you are taking.

Sotrovimab may affect how well the COVID-19 vaccine works. If you have been treated with sotrovimab, tell your doctor if you are going to have a COVID-19 vaccine or booster.

There's not enough information to say that herbal remedies or supplements are safe to take with sotrovimab