Standard Operating Procedure for Ordering, Management, Preparation and Administration of Sotrovimab for IV Infusion for the Treatment of COVID-19 Infection

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1	Initial Issue SOP 0144	20/12/2021
2	• Transferred from Medicines Management SOP template to PTHB SOP template. • Updates to definitions. • Inclusion of staff responsibilities. • Removal of reference to emergency packs and batch specific variations • Inclusion and reference to NICE TA878 re. eligibility criteria for treatment with sotrovimab for COVID-19. • Inclusion of advice re. treatment of children aged 12-17 years with sotrovimab. • Update to objectives section to include cold chain management and temperature excursions. • Inclusion of ordering and expiry dates section. • Inclusion of cold chain management section.	16/08/2024

Engagement & Consultation

Key Individuals/Groups Involved in <u>Developing</u> this Document

Role / Designation
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Circulated to the following for Consultation

Date	Role / Designation
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16/08/2024	COVID-19 Therapies Nurse
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1 Introduction

NICE TA878 recommends sotrovimab as an option for treating COVID-19 in adults and young people aged 12 years and over and weighing at least 40 kg, only if:

- they do not need supplemental oxygen for COVID-19 and
- they have an increased risk for progression to severe COVID-19, as defined by NICE (see section 5, page 54) and
- nirmatrelvir plus ritonavir is contraindicated or unsuitable.

Sotrovimab is only recommended if the company provides it according to the commercial arrangements.

In Powys Teaching Health Board (PTHB), sotrovimab can be administered under the guidance of the approved Patient Group Directions (PGD) to individuals aged 18 years and over who meet the NICE eligibility criteria.

Paediatric/adolescent patients (aged 12-17 years inclusive) should be referred to a paediatric multi-disciplinary team (MDT) for assessment to determine clinical capacity to benefit from the treatment. Individuals aged 12-17 years of age require a Patient Specific Direction (PSD) to support administration of sotrovimab.

Treatment should ideally be given within 5 days of a positive PCR test AND within 5 days of the onset of COVID-19 symptoms[1]. However, treatment commencement may be extended up to a maximum of 7 days from symptom onset if clinically indicated (NB: treatment commencement beyond 5 days from symptom onset is off-label, but still supported by the PGD).

Administration will only be carried out after the patient has made an informed decision and consented to treatment.

Administration must be under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.

All current available stock is GB licensed Xevudy▼® 500mg concentrate for infusion (each vial contains 500mg of sotrovimab in 8ml (62.5 mg/ml). Sotrovimab (Xevudy▼®) 500mg in 8mL is a

[1] sotrovimab (Xevudy®) - All Wales Therapeutics and Toxicology Centre (nhs.wales)

black triangle drug and is subject to additional monitoring. This will allow quick identification of new safety information[2].

Healthcare professionals are asked to report any suspected adverse reactions via the MHRA Yellow Card Reporting System[3].

Administration will take place in areas identified in each of the three MIUs (Brecon hospital, Llandrindod hospital and Welshpool hospital) where a patient can be isolated during administration and observed for 1 hour afterwards.

In addition to standard infection prevention and control measures, staff should continue to wear FRSM (type IIR) when clinically caring for suspected/confirmed COVID-19 patients. Further advice if required can be sought from the IP&C team.

This process is following compliance with current legislative requirements and good practice guidance.

PGDs can be accessed via the Medicines Management internet site. Access here:
Information for Health Care Professionals - Powys Teaching Health Board (nhs.wales)

2. Objective

- To support appropriately trained and professionally registered healthcare staff to prepare and administer sotrovimab via IV infusion in accordance with the approved PGD or a PSD in a clinical setting and using aseptic technique.
- To assure good governance around cold chain maintenance to ensure products remain safe and effective.
- To ensure that corrective action is taken if the product is subject to a temperature excursion.
- To ensure appropriate stock management within MIUs

3. Definitions

- **IV** - intravenous

- **PTHB** – Powys Teaching Health Board

[2] Xevudy 500 mg concentrate for solution for infusion - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)
[3] Official MHRA side effect and adverse incident reporting site for coronavirus treatments and vaccines | Coronavirus (COVID-19)

- **nMABs** - Neutralising monoclonal antibodies - synthetic monoclonal antibodies that bind to the spike protein of SARS-CoV-2, preventing subsequent entry of the virus into the host cell and its replication.

- **PGD** – Patient Group Directive

- **PCR test** – Polymerase Chain Reaction test – used to confirm a COVID-19 infection.

- **PSD** – Patient Specific Direction (i.e. prescription)

- **MIU** – Minor Injury Unit

- **PPE** – Personal Protective Equipment

- **MHRA** – Medicines and Healthcare products Regulatory Agency

- **Cold chain** – is the system of transporting and storing medicines within the recommended temperature range of +2°C to +8°C from the place of manufacturer to the point of administration to a patient.

- **Temperature deviation/excursion** – any incident where the recorded refrigerator temperature is outside of the recommended range of +2°C to +8°C.

4. Role / Responsibilities

4.1 Senior Pharmacy Technician, Vaccination/Immunisation, Therapies & Pharmacy Stores

The senior pharmacy technician for immunisation / vaccination, therapies and pharmacy stores is responsible for:

- Ensuring that sotrovimab (Xevudy▼®) 500mg in 8mL and associated consumables are kept as stock in pharmacy stores.
- Ensuring that consumable bags are prepared in advance according to the number of sotrovimab packs in stock in the pharmacy stores.
- Maintaining a stock management system in the pharmacy store.
- Ensuring that the three MIUs (Brecon, Llandrindod, Welshpool) maintain an agreed stock level of four

Sotrovimab (Xevudy▼®) 500mg in 8mL vials and four consumable bags.
- Liaising with the community services pharmacy team (ATOs) to regularly check stock levels and expiry dates.
- Providing advice and support on how to respond to ambient temperature fluctuations and to manage temperature excursions.

4.2 COVID-19 Therapies Nurse/Medicines Management Staff

The COVID-19 Therapies Nurse or an appropriately trained member of the Medicines Management Team is responsible for triaging those community patients referred to PTHB who have been identified as high-risk, symptomatic individuals potentially eligible for treatment with COVID therapies.

If a symptomatic, eligible patient in the community is identified by the COVID-19 Therapies Nurse/Medicines Management staff as eligible for treatment with a COVID therapy, but first line treatment with an antiviral is contraindicated, treatment with an nMAB infusion may be offered an alternative if appropriate. It is the responsibility of the COVID-19 Therapies Nurse or suitably trained and competent member of the Medicines Management Team to:

- Confirm eligibility for sotrovimab **NB: The inclusion criteria for sotrovimab are narrower than the inclusion criteria for nirmatrelvir plus ritonavir – always check the NICE guidance:** NICE (see section 5, page 54)
- Obtain informed consent from the patient
- Liaise with MIU staff to identify a suitable MIU location and date for administration of a sotrovimab infusion.
- Email sotrovimab referral to an identified member of MIU staff, ensuring that all necessary information to support the referral is included.
- Transfer detail of the referral to the local Medicines Management spreadsheet.

4.3 Unscheduled Care Managers

Unscheduled care managers are responsible for ensuring that adequately trained and competent registrants are available on MIU sites to support with nMAB infusions during MIU opening hours.

4.4 MIU Registrants

Trained and competent registrants identified as able to administer sotrovimab infusions are responsible for:

- Completing Cold Chain Management Training accessible via ESR: 070 Cold Chain Training- The safe and secure management of refrigerated medicine.
- Maintaining ongoing training and competencies to support the administration of sotrovimab infusions under the guidance of the approved PGD.
- Signing up to the PGD to legally allow administration of Sotrovimab (Xevudy▼®) 500mg in 8mL
- Consulting with patients referred by the COVID Therapies Nurse/Medicines Management Team to the MIU for sotrovimab infusion to confirm that all eligibility criteria detailed in the PGD are met, that there are no contraindications or other reasons to exclude from treatment and, where appropriate arrange a mutually convenient time to attend for treatment.
- Preparing, administering, and recording details of the sotrovimab (Xevudy▼®) infusion as per agreed PGD.
- Once administration of sotrovimab infusion has been completed, scanning and emailing the Medicines Management preparation and administration sheets (appendices A & B) to the pharmacy stores team: Info.MedicinesManagement.Powys@wales.nhs.uk
- Notifying the pharmacy stores team of any stock (sotrovimab and consumables) approaching its expiry date - notification should be provided at least 4 weeks before the expiry date to allow time for replacement stock to be procured, received and distributed. The following email address should be used: Info.MedicinesManagement.Powys@wales.nhs.uk
- Ensuring sotrovimab (Xevudy▼®) 500mg in 8ml vials are stored appropriately and that the cold chain is maintained at between 2°C - 8°C (see section 6 Cold Chain Management)
- Storing consumable bags in a safe, dry area away from heat sources e.g., must be stored within ambient temperature (must not exceed 30°C), away from direct sunlight.

5. Ordering, Expiry Dates, Managing Stock

- Sotrovimab (Xevudy▼®) 500mg in 8mL is kept as stock within PTHB pharmacy stores. There is no requirement for an MIU to order stock, provided that the set up and preparation forms (appendices A & B) are scanned and emailed to the Medicines Management Team following administration to a patient as this will trigger stock replenishment. Forms must be scanned by MIU staff and emailed to Info.MedicinesManagement.Powys@wales.nhs.uk
- A stock of four Sotrovimab vials will be provided to those MIUs identified as locations for administration of Sotrovimab infusions (Brecon, Llandrindod, Welshpool).
- If MIU staff find that stock of sotrovimab or associated consumable bags are running low e.g., have dropped below the agreed stock level of 4, then the pharmacy stores team must be contacted immediately to allow sufficient time to replenish stock.
- Sotrovimab and consumable bags expiry dates must be monitored by MIU staff.
- Any stock nearing its expiry date must be reported to the pharmacy store team (at least 4 weeks in advance of the expiry date) via Info.MedicinesManagement.Powys@wales.nhs.uk. NB. Some batches of Sotrovimab vials are occasionally granted extension expiries by the MHRA. The pharmacy stores team will recall affected stock and over label with the extended expiry date. If in any doubt about the expiry date of sotrovimab, contact the pharmacy store team for advice: Info.MedicinesManagement.Powys@wales.nhs.uk
- Stock must be rotated so that the oldest stock (shortest expiry) is at the front of the fridge to be used first. This is important to avoid waste.
- The Pharmacy Store team supplies each MIU with a bag of consumable stock (one bag per sotrovimab vial) necessary to prepare and administer a sotrovimab infusion, using an infusion set from MIU stock. A consumable bag contains:
    - 1 x Sodium Chloride 0.9% 100mL Infusion Bag
    - 1 x 10mL luer lock syringe
    - Needles
    - 1 x 0.2 micron administration filter
    - infusion additive label
    - swabs
    - set up worksheet
    - preparation worksheet

Each consumable bag is labelled on the outside indicating the contents and the expiry date (expiry will be based on the shortest dated item contained in the consumable bag). Consumable bags

must be returned to the pharmacy store for updating when nearing its expiry date. The pharmacy store team will arrange collection of consumable bags for updating. New consumable bags will be delivered to replenish this stock.

6. Cold Chain Management

- Sotrovimab (Xevudy▼®) 500mg in 8mL must be stored in its original carton (in order to protect from light) in a refrigerator (2°C - 8°C).
- On receipt of a sotrovimab delivery, the product must be transferred immediately from the Helapet vaccine carrier into the MIU fridge.
- Fridges must be monitored daily where possible (during working hours). The actual, minimum, and maximum temperature must be recorded, and the fridge reset.
- Fridges must contain data loggers which must be downloaded and analysed at least every 56 days (or before if a temperature excursion occurs). NB. Data logger data is automatically overridden every 56 days.
- Fridges must not be overfilled (no more than 50% capacity), to allow for adequate air circulation. Products must be stored neatly and must not touch the sides of the fridge, be stored on the bottom of the fridge, or obstruct the fan. NB. It is advised that MIU stocks (other than sotrovimab) are ordered in smaller quantities more frequently, rather than stock piling. Stock piling creates risks e.g., overstock can cause fridge failures, remove stock from the supply chain and create waste.
- Any temperature excursions must be reported to the Medicines Management Team immediately. Stock must be clearly labelled as quarantined and must be stored at 2°C-8°C until further notice (an alternative fridge may need to be located).

For detailed information on the management of refrigerated medicines/vaccines see: Medicines Management - Home (sharepoint.com) SOP MMP 427 Safe & Secure Management of Refrigerated Medicines/Vaccines.

7. Process

7.1 Process for Preparation of Sotrovimab Concentrate for Solution for IV Infusion

Aseptic technique must be used.

- The infusion required is 500mg (8mL) of sotrovimab (62.5mg/mL) added to a 100mL bag of sodium chloride 0.9%. (SPS recommends that 8mL sotrovimab solution is added to the bag of Sodium Chloride 0.9% without removing an aliquot from the bag. This reduces the number of aseptic manipulations and reduces the likelihood of errors. All bags currently in use by the NHS have sufficient capacity to permit this addition)[4].
- Allow the vial to reach room temperature before use. If the diluent bag used is at room temperature, there is no need to allow the vial to warm first.
- Visually inspect the vial to ensure it is free from particulate matter and that there is no visible damage to the vial. If the vial is identified to be unusable, discard and restart the preparation with a new vial.
- Gently swirl the vial several times before use without creating air bubbles. Do not shake or vigorously agitate the vial. Visually inspect the vial to ensure it is free from particulate matter and that there is no visible damage to the vial. If the vial is identified to be unusable, discard and restart the preparation with a new vial.
- Swab the vial bung with sterile 70% alcohol wipe and allow to dry.
- Using aseptic technique draw up 8ml of sotrovimab from the vial.
- Swab the infusion bag additive port with the 70% alcohol wipe and allow to dry. Using aseptic technique, add 8mL of sotrovimab solution to a bag of Sodium Chloride 0.9% without removing an aliquot from the bag.
- Discard any unused portion left in the vial. The vial is single-use only and should only be used for one patient.
- Prior to the infusion, gently rock the infusion bag back and forth 3 to 5 times. Do not invert the infusion bag. Avoid forming air bubbles.
- Attach an infusion additive label to the bag containing the following details:

Sotrovimab 500mg (62.5ml/ml) in Sodium Chloride 0.9% (Total volume = 108mL) date and time prepared, time started, made by, checked by, expiry date

[4] Handling and preparation of sotrovimab – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Intravenous Solution Additives
Patient_____ Room _____
Date _____Time _____ Made By _____
Time started_____Checked By _____

DRUGS ADDED	STRENGTH
Expiry. DATE _____	

This label must be affixed to all infusion fluids containing additional medication

7.2 Process for Administration of Sotrovimab Concentrate for Solution for IV Infusion

- Gather the recommended materials for infusion:
  - Polyvinyl chloride (PVC), polyethylene (PE)-lined PVC, or polyurethane (PU) infusion set (from MIU stock and correct for the infusion pump being used)
  - Infusion pump
  - In-line or add-on 0.2 µm to 5 µm polyethersulfone, polysulfone, or polyamide end filter for IV administration.
- Attach the infusion set to the IV infusion bag.
- Prime the infusion set.
- For IV infusion of Sotrovimab 500mg (8mL) (62.5mg/mL) gather the prepared Sotrivimab 500mg in Sodium Chloride 0.9% (in 108ml) infusion bag and administer as per this SOP and Sotrovimab Concentrate for IV infusion agreed PGD.
- Administer the entire infusion solution in the bag over 30 minutes via infusion pump through an intravenous line containing the sterile, add-on 0.2 µm polyethersulfone, end filter for IV administration.
- The prepared infusion solution should not be administered simultaneously with any other medication.
- After infusion is complete, flush the tubing with 0.9% Sodium Chloride injection to ensure delivery of the required dose. In accordance with the PGD – sodium chloride 0.9% for use as a flush
- Individuals should be monitored for adverse reactions post intravenous infusion for 1 hour. This includes for hypersensitivity and infusion site reactions and 2 sets of full observations – BP, heart rates, O2 saturations, temperature and NEWS score.
- Copies of Set Up and Preparation worksheets (see appendices A and B) must be emailed to the MMT **immediately following administration:** Info.MedicinesManagement.Powys@wales.nhs.uk This will trigger a replenishment of stock.

8. Monitoring Compliance / Audit / Review

Compliance with this SOP will be audited during annual pharmacy audits.

This SOP will be reviewed every three years or earlier should changes to legislation or to practice indicate otherwise.

9. References

PTHB MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines Medicines Management - SOPs - All Documents (sharepoint.com)

Appendix A

Worksheet – Set Up
Sotrovimab 500mg (62.5mg/ml) Aseptically prepared in a 100ml of Sodium Chloride 0.9% infusion bag (108ml total volume).

Prepared by (print name): Checked by (print name):
Location: Date:

Set Up

Step 1
Remove from the refrigerator:
- 1 x Sotrovimab 500mg (62.5mg/mL) Concentrate for Solution for Infusion vial.

Pandemic Kit Batch No:

BN:

Sign/Date:

Sign/Date (checker):

Step 2
Select a Sotrovimab Consumables kit containing:
- 1 x Sodium Chloride 0.9% 100mL Infusion Bag
- 1 x 10mL luer lock syringe
- Needles, infusion set (from MIU stock) administration filter, 1 x 0.2 micron administration filter, infusion additive label, swabs and a set up and preparation worksheet
- Infusion pump (from MIU)

Consumables Kit Batch No:

BN:

Sign/Date:

Sign/Date (checker):

Step 3 – Ensure preparation area has been wiped with a Clinell wipe and is free from clutter.

Sign/Date:

Sign/Date (checker):

Step 4
Visually inspect the Sotrovimab vial.
The solution should be clear, colourless or yellow to brown and free from visible particles
Should particulate matter and discoloration be observed, the vial must be discarded and replaced with a new vial.

Step 5
Place the following in the preparation area:
- 1 x Sotrovimab 500mg (62.5mg/ml) vial
- 1 x Sodium Chloride 0.9% 100ml Infusion Bag
- Infusion set/filter/needles/swabs/infusion additive label/administration worksheet

Step 6
Prepare an infusion additive label with the following details:
- Sotrovimab 500mg in Sodium Chloride 0.9% (Total volume = 108mL)
- Date and time prepared, time started, made by, checked by, expiry date

Sign/Date:
Sign/date (check):

Step 7
Prepare the infusion pump ready for use.

Sotrovimab Batch No: Expiry:

Set up (sign/date):

Set up check (sign/date):

Appendix B

Worksheet - Preparation
Sotrovimab 500mg (62.5mg/ml) Aseptically prepared in a 100ml of Sodium Chloride 0.9% infusion bag (108ml total volume).

Prepared by (print name): Checked by (print name):
Location
Date:

Preparation
Step 1 Take the Sodium Chloride 0.9% 100mL Infusion Bag from the consumables kit, swab the additive port with a sterile 70% alcohol wipe and allow to dry.
Step 2 Take a Sotrovimab 500mg vial, swab the bung with sterile 70% alcohol wipe and allow to dry. Sign/Date: Sign/Date (checker):
Step 3 Gently swirl the vial several times before use without creating air bubbles. **Do not shake or vigorously agitate the vial.**
Step 4 Attach a 21g needle to a 10mL luer lock syringe and draw up **1 x 8mL** of Sotrovimab 500mg (62.5mg/mL) from the vial
Step 5 Add **8mL** of Sotrovimab (62.5mg/mL) to the Sodium Chloride 0.9% 100mL Infusion Bag. Discard the syringe and needle into a yellow lidded sharps bin Sign/Date: Sign/Date (checker):
Step 6 Gently rock the infusion bag back and forth 3 to 5 times. ***NB: Do not invert the infusion bag. Avoid forming air bubbles. Do not shake***
Step 7 Attach the pre-prepared infusion additive label to the bag
Step 8 Attach the IV administration set (appropriate for the infusion pump being used) Ensure the product is administered using a local add-on 0.2µm filter Administer as a single IV infusion for 30 minutes via the infusion pump.
Step 9 Observe patient for 1 hour following administration of infusion. This includes for hypersensitivity and infusion site reactions and 2 sets of full observations – BP, heart rate, O2 saturations, temperature and NEWS score Issue PIL to patient and explain potential side effects.
Step 10 Arrange decontamination of room as per MIU action card.
Record details of patient receiving treatment below
Patient Initials:
NHS Number:
Date of Birth: