Sotrovimab (Xevudy®) Guidance for Non-Hospitalised COVID-19 Patients



CONSIDER SOTROVIMAB in non-hospitalised patients if:

- ✓ SARS-CoV-2 infection is confirmed by polymerase chain reaction (PCR) testing or formally registered (via gov.uk or 119) lateral flow test within the last 5 days.
- As an <u>alternative second-line</u> option if oral antiviral Paxlovid (Nirmatrelvir with Ritonavir) is excluded AND oral molnupiravir is not considered suitable.
- Onset of symptoms of COVID-19 within the last 5 days* (feverish, chills, sore throat, cough, shortness of breath or difficulty breathing,
- ✓ nausea, vomiting diarrhoea, headache, red or watery eyes, body aches, loss of taste or smell, fatigue, loss of appetite, confusion,
- √ dizziness, pressure or tight chest, chest pain, stomach ache, rash, sneezing, sputum or phlegm, runny nose). *7-days if clinically indicated
- ✓ Patient not already clinically improving.
- ✓ A member of a 'highest' risk group (as defined on previous page).
- ✓ If patient is a child they are aged 12 or older AND over 40kg refer to paediatrics for assessment
- ✓ After assessment patient does not require hospitalisation or supplemental oxygen for COVID-19 management.
- ✓ No known hypersensitivity reaction to the active substance or to any of the excipients.

CONSIDER THE FOLLOWING CAUTIONS (SPC):

- **Pregnancy:** SPC states Sotrovimab may be used during pregnancy where the expected benefit to the mother justifies the risk to the fetus. RCOG guidance states sotrovimab is recommended for pregnant patients who meet criteria above. All cases should be discussed with Obstetrics Team
- **Breastfeeding:** BNF states specialist sources indicate use with caution no information available. Large molecular weight suggests limited excretion into milk. Monitor breast-fed infants for adequate feeding and hypersensitivitiy reactions. Discuss all patients with Obstetrics Team.

DOSAGE/DURATION/REVIEW:

- The recommended dose of Sotrovimab is a single **500 mg dose intravenous infusion**.
- · No dosage adjustment is required for elderly / renal or hepatic impairment and there are no drug-drug interactions
- Hypersensitivity reactions, including serious and/or life-threatening reactions such as anaphylaxis, have been reported following infusion of
 sotrovimab. Hypersensitivity reactions typically occur within 24 hours of infusion. Signs and symptoms of these reactions may include nausea, chills,
 dizziness (or syncope), rash, urticaria and flushing. If signs and symptoms of severe hypersensitivity reactions occur, administration should be
 discontinued immediately and appropriate treatment and/or supportive care should be initiated.
- If mild to moderate hypersensitivity reactions occur, slowing or stopping the infusion along with appropriate supportive care should be considered.
- Any suspected adverse reactions should be reported to MHRA via the new dedicated COVID-19 Yellow Card reporting website.

PREPARATION AND ADMINISTRATION MEDUSA LINK:

- Minimum PPE required for preparation and administration is FRS mask, plastic apron, gloves and face shield.
- To prepare an 500mg infusion of sotrovimab:
 - o Remove the vial from the fridge and check it is free from particulate matter.
 - Allow the vial to reach room temperature, protected from light, prior to dilution (about 15 minutes).
 - $\circ\quad$ Gently swirl the vial several times before use; do not shake as air bubbles may form.
 - Withdraw 8mL (500mg) sotrovimab from the vial and add to a 100mL sodium chloride 0.9% infusion bag. There is no need to remove fluid from the bag prior to addition of sotrovimab.
 - Gently rock the bag back and forth 3 to 5 times. Do NOT invert the bag.
- Administer over a minimum of 30 minutes via a giving set with in line 0.2 to 5micron low-protein binding filter (polyethersulfone (Supor[®]), polysulfone or polyamide) using an infusion pump.
- nMABs should not be infused concomitantly in the same intravenous line with other medication.
- Check observations at 15 minutes and 30 minutes post infusion.
- Record medication name, batch number, date & time on patients EPR

SUPPLIES:

- Medication stock is held in NW and PRI pharmacy.
- Dedicated filters for administration of this product are available in NW ward 22 and PRI.
- Keep the vials in the original carton in order to protect from light and store in a refrigerator (2 °C 8 °C).