

Trust Headquarters
Russell's Hall Hospital
Dudley
West Midlands
DY1 2HQ

Ref: FOI-102024-0001187

Date: 28th October 2024

Address / Email:

Dear

Request Under Freedom of Information Act 2000

Thank you for requesting information under the Freedom of Information Act 2000.

Request

Does The Dudley Group NHS Foundation Trust have any local treatment guidelines, pathways or protocols for treatment of COVID-19 infection?

Response

Please find attached the guidelines and procedures in relation to the treatment of Covid 19 from the Dudley Group of Hospitals NHS Foundation Trust.

If you are dissatisfied with our response, you have the right to appeal in line with guidance from the Information Commissioner. In the first instance you may contact the Information Governance Manager of the Trust.

Information Governance Manager
Trust Headquarters
Russell's Hall Hospital
Dudley
West Midlands
DY1 2HQ
Email: dgft.dpo@nhs.net

Should you disagree with the contents of our response to your appeal, you have the right to appeal to the Information Commissioners Office at.

Information Commissioners Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Tel: 0303 123 1113
www.ico.org.uk

If you require further clarification, please do not hesitate to contact us.

FOI/REF FOI-

Yours sincerely

**Freedom of Information Team
The Dudley Group NHS Foundation Trust**

DEXAMETHASONE IN COVID-19 GUIDELINE	DOCUMENT TITLE:	DEXAMETHASONE IN COVID-19 GUIDELINE	
	Name of Originator/Author /Designation & Specialty:	[REDACTED]	
	Local / Trust wide	Trust Wide	
	Statement of Intent:	To outline the treatment protocols of using Dexamethasone in patients with COVID-19	
	Target Audience:	To be referred by all medical staff considering the use of Dexamethasone to treat a patient with COVID-19	
	Version:	2.0	
	Name of Group and Date when Recommended for Ratification	Respiratory local Gov Meeting	Date: 18/04/2024
	Name of Division and Date of Final Ratification:	Medicine and Integrated Care Division (DRGM)	Date: 21/05/2024
	Review Date:	31/05/2027	
	Contributors:	Designation: [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
The electronic version of this document is the definitive version			

CHANGE HISTORY

Version	Date	Reason
1.0	06/2020	This is a new document
2.0	May 2024	Full Timely Review

A translation service is available for this document. The Interpretation/Translation Policy, Guidance for Staff is located on the intranet under Trust-wide Policies.

THE DUDLEY GROUP NHS FOUNDATION TRUST

DEXAMETHASONE IN COVID-19 GUIDELINE

1. GUIDELINE SUMMARY

Dexamethasone for the treatment of COVID-19 is only indicated for adult hospitalised patients with COVID-19 (suspected or confirmed) in patients having oxygen therapy, non-invasive or invasive ventilation, or ECMO.

Oral dosing:

Dexamethasone 6mg Once Daily Orally for 10 days

IV dosing:

Dexamethasone 5.94mg (Base) Once Daily via Intravenous injection for 10 days

Pregnancy:

Oral Dosing:

Prednisolone 40mg Once Daily Orally for 10 days

IV Dosing:

Hydrocortisone 80mg Twice Daily via Intravenous injection for 10 days

2. GUIDELINE DETAIL

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus (SARS-Coronavirus 2) causes coronavirus disease COVID-19¹.

The most common symptoms of COVID-19 are fever, dry cough, and tiredness. Other symptoms that are less common and may affect some patients include aches and pains, nasal congestion, headache, conjunctivitis, sore throat, diarrhoea, loss of taste or smell or a rash on skin or discoloration of fingers or toes. These symptoms are usually mild and begin gradually. Some people become infected but only have very mild symptoms¹.

Most people (about 80%) recover from the disease without needing hospital treatment. Around 1 out of every 5 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart and lung problems, diabetes, or cancer, are at higher risk of developing serious illness. However, anyone can catch COVID-19 and become seriously ill¹.

In March 2020, the RECOVERY (Randomised Evaluation of COVID-19 thERapY) trial was established as a randomised clinical trial to test a range of potential

treatments for COVID-19, including low-dose dexamethasone (a steroid treatment). Over 11,500 patients have been enrolled from over 175 NHS hospitals in the UK².

On 8 June, recruitment to the dexamethasone arm was halted since, in the view of the trial Steering Committee, sufficient patients had been enrolled to establish whether or not the drug had a meaningful benefit².

A total of 2104 patients were randomised to receive dexamethasone 6 mg once per day (either by mouth or by intravenous injection) for ten days and were compared with 4321 patients randomised to usual care alone. Among the patients who received usual care alone, 28-day mortality was highest in those who required ventilation (41%), intermediate in those patients who required oxygen only (25%), and lowest among those who did not require any respiratory intervention (13%)².

Dexamethasone reduced deaths by one-third in ventilated patients (rate ratio 0.65 [95% confidence interval 0.48 to 0.88]; $p=0.0003$) and by one fifth in other patients receiving oxygen only (0.80 [0.67 to 0.96]; $p=0.0021$). There was no benefit among those patients who did not require respiratory support (1.22 [0.86 to 1.75]; $p=0.14$)².

Based on these results, 1 death would be prevented by treatment of around 8 ventilated patients or around 25 patients requiring oxygen alone².

The parameters for starting Dexamethasone for treating COVID-19 infection are²:

- Adult hospitalised patients
- Patients with a positive SARS-CoV-2 swab having oxygen therapy, non-invasive or invasive ventilation, or ECMO.
- Patients requiring oxygen therapy, non-invasive or invasive ventilation, or ECMO but without a positive SARS-CoV-2 swab should only be started on Dexamethasone once other conditions have been ruled out and there is a very strong clinical suspicion of COVID-19 based on CXR or other clinical parameters.
- Patients requiring oxygen therapy but without a positive SARS-CoV-2 swab and indeterminate clinical suspicion of COVID-19 should only be started on Dexamethasone if there is a continued need for oxygen using $>4\text{ l/min}$ or 28% O_2 via Venturi mask to maintain saturations $>94\%$ or unable to wean oxygen for >12 hours.

Patients who are **NOT** ventilated or are **NOT** requiring oxygen support should **NOT** be prescribed dexamethasone for COVID-19².

Corticosteroids should be continued for up to 10 days unless there is a clear indication to stop early, which includes discharge from hospital or a hospital-supervised virtual COVID ward I.e. the complete course should be prescribed even after discharge.

Treatment Protocols:

The recommended regime for patients who are able to tolerate oral medications²:

Dexamethasone 6mg Once Daily Orally for 10 days

Patients who are unable to take medication orally may be given Dexamethasone via intravenous injection²:

Dexamethasone 5.94mg (Base) Once Daily via Intravenous injection for 10 days

Administration:

Please Note: Currently the strength of Dexamethasone injection kept within the Dudley Group NHSFT is 3.3mg/ml as base. The following administration guidelines are based upon this strength. Always check the strength of the product to ensure you have the correct dose. For help with calculations please contact pharmacy.

- *To measure a 5.94mg dose using the 3.3mg/ml base injection you would need to withdraw **1.8ml** of Dexamethasone³.*
- *The dexamethasone can be given **undiluted**, however it can be diluted with Sodium chloride 0.9 or Glucose 5% for ease of administration³.*
- *The injection can be given as a **slow bolus** over **at least 3 minutes**³.*
- *If preferable, the Dexamethasone can be diluted in 50ml to 100ml sodium chloride 0.9% or Glucose 5% and given over 15-20 minutes³.*

Pregnancy / Breast feeding:

In pregnancy or breastfeeding women, prednisolone 40 mg administered by mouth (or intravenous hydrocortisone 80 mg twice daily) should be used instead of dexamethasone².

The recommended regime for patients who are able to tolerate oral medications:

Prednisolone 40mg Once Daily Orally for 10 days

Patients who are unable to take medication orally may be given Hydrocortisone via intravenous injection:

Hydrocortisone 80mg Twice Daily via Intravenous injection for 10 days

Administration:

Please Note: Hydrocortisone injection comes in two bases: Sodium phosphate or Sodium succinate, both are kept at Dudley Group NHSFT. Prior to administration please ensure you check which version you have as they have slightly different methods of reconstitution. For help with calculations please contact pharmacy.

Hydrocortisone Sodium phosphate³:

- This comes in a ready diluted 100mg/ml vial, to measure an 80mg dose you would need to withdraw 0.8ml of Hydrocortisone.
- The Hydrocortisone can be given undiluted as a slow bolus over at least 30 seconds.
- If preferable, the Hydrocortisone can be diluted in 50ml to 100ml sodium chloride 0.9% or Glucose 5% and given over 20-30 minutes.

Hydrocortisone Sodium Succinate⁴:

- This comes in a ready diluted 100mg powdered vial - Reconstitute with 2mL of water for injections and shake vial until solution is clear.
- To measure an 80mg dose you would need to withdraw 1.6 ml of the reconstituted liquid.
- This must then be further dilute with 5 – 10ml and given via slow intravenous injection over at least 1 minute, up to 10 minutes.
- If preferable, the Hydrocortisone can be diluted in 100ml sodium chloride 0.9% or Glucose 5% and given over 20-30 minutes.

Paediatrics – dosage for children with a greater than 44-week gestational age

Dexamethasone 150micrograms/kg (as a base) orally or intravenously once a day for a maximum of 10 days (maximum 6mg per dose).

Please prescribe oral formulations unless there are concerns about enteral absorption or oral formulations are inappropriate or unavailable.

For further recommendations, please contact the paediatrics team.

Seek specialist advice for preterm babies with a corrected gestational age of less than 44 weeks.

Ideally where possible steroids should be given as a morning dose to minimise the risk of sleep disturbance. For further information regarding side effects, cautions and contra-indications please consult the British National Formulary.

Patients who are already on **regular long term steroid** treatment should **continue** their regular medication alongside the COVID-19 treatment.

Treatment should be discontinued if discharged from hospital within the 10 days².

Common interactions:

Citalopram, Amiodarone, Clarithromycin, Haloperidol - Hypokalaemia, Increased risk of torsade de pointes

Digoxin – Increased digoxin toxicity

NSAIDS – Increased risk of gastrointestinal bleeding

Warfarin – Increased warfarin effect

For a complete list of all interactions please refer to the British National Formulary.

Remdesivir is also indicated for the treatment of COVID-19, dexamethasone is a substrate of CYP3A4 and although remdesivir inhibits CYP3A4, due to remdesivir's rapid clearance after intravenous administration, remdesivir is **unlikely** to have a significant effect on dexamethasone exposure. Dexamethasone is **unlikely** to have a clinically significant effect on remdesivir as remdesivir has a moderate-high hepatic extraction ratio, and is used for a short duration in the treatment of COVID-19.²

3. REFERENCES

1. Q&A on coronaviruses (COVID-19), World Health Organisation, 04/2020, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-coronaviruses> [accessed 25th June 2020]
2. Medicines and Healthcare Regulatory Authority. 2020. *COVID-19 Therapeutic Alert*. 24/06/2020, Alert ref: CEM/CMO/2020/026
3. Injectable Medicines Guide, Version 6, Hydrocortisone Sodium Phosphate, 02/2016, <https://medusa.wales.nhs.uk/IVGuideDisplay.asp> [accessed 25th June 2020]
4. Injectable Medicines Guide, Version 7, Hydrocortisone Sodium Succinate, 09/2018, <https://medusa.wales.nhs.uk/IVGuideDisplay.asp> [accessed 25th June 2020]
5. Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press <<http://www.medicinescomplete.com>> [accessed 1st July 2020]

COVID-19 SCREENING FOR PATIENTS AND STAFF STANDARD OPERATING PROCEDURE	DOCUMENT TITLE:	COVID-19 SCREENING FOR PATIENTS AND STAFF STANDARD OPERATING PROCEDURE	
	Name of Originator/Author /Designation & Specialty:		
	Local / Trust wide	Trust Wide	
	Statement of Intent:	This SOP is intended to describe the COVID-19 screening process for patients through the Trust.	
	Target Audience:	All staff	
	Version:	2.0	
	Name of Group and Date when Recommended for Ratification	Infection Prevention and Control Group Meeting	Date: April 2024
	Name of Division and Date of Final Ratification:	Chief Nurse /Director of Infection prevention and control	Date: 12/04/2024
	Review Date:	30/04/2027	
	Contributors: Individuals involved in developing the document.	Designation: 	
The electronic version of this document is the definitive version			

CHANGE HISTORY

Version	Date	Reason
1.0	June 2023	This is a new document changes to COVID-19 swabbing criteria full review of SOP, inclusion of LFD testing requirements removal of zoning. Changes to SOP title was previously known as Covid-19 Staff Isolation SOP.
2.0	April 2024	Changes to screening guidance for discharges to care homes

A translation service is available for this document. The Interpretation/Translation Policy, Guidance for Staff is located on the intranet under Trust-wide Policies.

THE DUDLEY GROUP NHS FOUNDATION TRUST

COVID-19 SCREENING FOR PATIENTS AND STAFF STANDARD OPERATING PROCEDURE

1 STANDARD OPERATING PROCEDURE SUMMARY

Objective

This SOP provides guidance to staff, patients, visitors, and members of the public of the segregation of patients and health care resources for COVID-19. It is vital to ensure that the influx of COVID-19 positive cases, while receiving optimal treatment, do not pose an added threat to the existing hospital population.

Rationale

The two of most important interventions in limiting the transmission of the Covid -19 are:

- i) limiting the person-to-person transmission
- ii) Early diagnosis, isolation, and treatment of the positive cases (including prompt isolation of patients).

2 STANDARD OPERATING PROCEDURE DETAIL

Introduction

All symptomatic patients who require an overnight stay where a Positive COVID-19 result will change their clinical management (e.g., require COVID-19 treatment) will be tested for Covid-19.

Those symptomatic patients whose management will not be altered by a Positive COVID-19 result do NOT require a swab however they should be placed in isolation and managed clinically.

Personal Protective Equipment (PPE)

Wherever possible all inpatients suspected or confirmed positive should wear a surgical face mask (if tolerated and does not compromise their clinical care). Refusal or non-compliance should be documented in patients notes.

2.1 Screening for COVID-19

Patient Testing

The following tables outlines the instances where testing should be undertaken and the types of modality testing that should be used.

TABLE 1

Symptomatic testing approach from 1 April 2023	
All respiratory symptomatic patients requiring admission	PCR
All current inpatients that develop new respiratory symptoms	PCR

(¹) For patients who would be considered eligible for COVID-19 therapeutics presenting with a suspected COVID-19 infection, but in whom the LFD test result is negative, consider sending a PCR test to confirm diagnosis and support early access to COVID-19 therapeutics.

TABLE 2

Asymptomatic testing approach from 1 April 2023	
Asymptomatic patients within Elective pathway (day case and overnight), and transfer of care admissions in all settings	No routine testing OR LFD where e.g. for placement on wards that predominantly care for patients who are severely immunocompromised ² or to support pre-operative risk assessment for elective surgery.
Asymptomatic emergency admissions to wards that predominantly care for patients who are severely immunocompromised ² or to support pre-operative risk assessment for elective surgery	LFD
Outbreak testing in healthcare settings	LFD testing for asymptomatic contacts is appropriate to support outbreak management in line with local IPC guidance.
Release from side room/cohort isolation for patients in acute settings.	Symptomatic patients and patients with a confirmed positive COVID-19 results should be isolated or co-horted together for a minimum of five days with release from isolation guided by clinical judgement when well and free of fever for 48 hours
Transfers into hospital for immunocompromised patients e.g., renal dialysis	No routine testing

(²) Severely immunocompromised refers to patients who are unlikely to mount an effective vaccine response, such as haemato-oncology and solid organ or stem cell or bone marrow transplant patients.

3 CO-HORTING OF SYMPTOMATIC PATIENTS

COVID-19 positive patients can be co-horted if clinical pressures require.

- Curtain between patients must be kept half closed so there is a barrier between patients.
- Doors to bays MUST be kept closed.
- Windows to be opened for 10 mins per hour to aid ventilation.
- Patients to wear face masks where possible, patients are to wear mask when being transported around the hospital.
- Staff to wear fluid resistant surgical facemasks when in contact with symptomatic patients

4 DE-ESCALATION OF COVID-19 ISOLATION PRECAUTIONS

Once patients have completed 5 days isolation and have been 48 hours apyrexial the patient can be de-isolated. No tests are to be undertaken prior to de-isolation.

- Any patient who is admitted during isolation period following a positive result in the community must complete 5 days of isolation.
- Patients within the bay are to be offered a facemask on a daily basis, and if able should wear a face mask when in contact with care staff or when mobilising around the ward or being transported.

5 PROCEDURE IF A PATIENT'S CLINICAL STATUS CHANGES

During a patient's admission there may be occasions where there is new onset of COVID-19 symptoms.

These patients should be isolated and managed as per table 1.

6 MANAGEMENT COVID-19 CONTACTS

Contacts of confirmed COVID-19 patients do not require routine testing unless they develop symptoms. Please refer to table 1 and 2.

Please seek advice from the infection control team in the event of a COVID-19 outbreak regarding the screening of contacts.

7 VISITORS

Fluid resistant surgical face masks are still available for all visitors.

It is advised that the visiting of patients with a confirmed positive COVID-19 result is risk assessed on an individual patient basis. Visitors are advised to wear a surgical face mask (if tolerated and does not compromise clinical care). Refusal or non-compliance should be documented in patients notes.

8 STAFF TESTING

Routine testing for asymptomatic staff was paused in August 2022. This pause remains in place.

Symptomatic staff testing approach from 1 April 2023	
Respiratory Symptomatic staff – Non high risk area	No routine testing - See 8.1 If well and no temperature can work as normal – FRSM advised until respiratory asymptomatic
Respiratory Symptomatic staff – High risk area e.g. C4	LFD – See 8.2 LFD POSITIVE Refrain from work for 5 days. No further LFD required to return to work – Return on day 6 if well. LFD NEGATIVE If well and no temperature can be redeployed to lower risk areas for day 10 after symptom onset - staff to wear a surgical face mask for day 10 after symptom onset
COVID-19 Contact	No routine testing FRSM advised for 10 days

8.1 Healthcare staff who are not providing direct inpatient care to those who are severely immunosuppressed.

Healthcare staff whose job does not primarily involve providing direct inpatient care to severely immunosuppressed patients, who have [symptoms of a respiratory infection](#), and who have a high temperature or do not feel well enough to go to work, are advised to stay at home and avoid contact with other people.

They are not required to take a COVID-19 test and should follow the [guidance for people with symptoms of a respiratory infection including COVID-19](#). They should stay at home until they no longer have a high temperature (if they had one) or until they no longer feel unwell.

If these staff members have a positive COVID-19 test result, regardless of whether they have symptoms, they should follow [guidance for the general public who have a positive test result](#). They should only return if they feel well enough to work, and they do not have a high temperature. Staff do not require a negative LFD to return to work. If they are still displaying respiratory symptoms when they return to work, they should speak to their line manager who should undertake a risk assessment.

Line managers should undertake a risk assessment before patient-facing healthcare staff return to work in line with normal return to work processes and to implement any reasonable adjustments to mitigate risk to self or others.

On returning to work, all staff members must continue to comply rigorously with all relevant [infection control precautions](#), including appropriate personal protective equipment (PPE) use.

8.2 Healthcare staff providing direct care to inpatients who are severely immunosuppressed

Healthcare staff whose job primarily involves providing direct inpatient care to severely immunosuppressed patients, who have [symptoms of a respiratory infection](#), and who have a high temperature or do not feel well enough to go to work, should take an LFD test as soon as possible.

If the result of this LFD test is negative, they can attend work if they are well enough to do so and they do not have a high temperature.

If the result of this LFD test is positive, they are advised not to attend work for at least 5 days. They should only return if they feel well enough to work, and they do not have a high temperature. If they are still displaying respiratory symptoms when they return to work, they should speak to their line manager who should undertake a risk assessment.

A locally decided protocol, following risk assessment and direction from medical directors, nursing directors or infection prevention and control teams, may be used for staff who are returning to work 5 or more days after a positive test result.

This may include:

- redeployment to lower risk areas up to day 10 after symptom onset
- asking staff to wear a surgical face mask up to day 10 after symptom onset

Healthcare staff must continue to comply rigorously with all relevant [infection control precautions](#), including appropriate PPE use.

8.3 Staff members who are contacts of a confirmed case of COVID-19

Staff who live in the same household as someone with COVID-19 are at the highest risk of becoming infected because they are most likely to have prolonged close contact. People who stayed overnight in the household of someone with COVID-19 are also at high risk.

If you are a household or overnight contact of someone who has had a positive COVID-19 test result it can take up to 10 days for your infection to develop. It is possible to pass on COVID-19 to others, even if you have no symptoms.

Staff who are identified as a household or overnight contact of someone who has had a positive COVID-19 test result should discuss ways to minimise risk of onwards transmission with their line manager e.g., wearing Fluid resistant surgical face mask (FRSM)

If staff develop any symptoms during these 10 days, they should follow the [advice for staff with symptoms of a respiratory infection, including COVID-19](#).

9 HOW TO ORDER LATERAL FLOW DEVICE TEST KITS

Each ward/department will be responsible for collecting what LFD kits an order can be placed via PPE request line Ext.5280.

10 TRAINING/SUPPORT (IF APPLICABLE)

- All staff should have received mask 'FIT TESTING'
- All staff should be trained in Donning and Doffing.
- All staff should have completed Infection control mandatory training.

11 REFERENCES

UK HSA (2024) Changes to COVID-19 testing from 1 April 2024. Publication Reference 20240325

NHS England (2023) COVID-19 testing policy update – changes to NHS use cases. Department of Health. Classification: Official. Publication Reference PRN00288

APPENDIX 1

A Standing Operating Procedure on How to use an NHS rapid lateral flow test on patients for coronavirus (COVID-19)

This Standing Operating Procedure on How to use an NHS rapid lateral flow test for coronavirus (COVID-19) is to be used for the obtaining a rapid COVID-19 result to facilitate the discharge of patients to Care homes.

A rapid lateral flow test shows you the result on a device that comes with the test.

Check the expiry date before you undertake the test on patient.

Rapid lateral flow tests have expiry dates, so you know when to use them by.

Do not use out-of-date tests. Use a test from a box which is still in date.

You can find the expiry date on the back or the side of the box that the test came in.

Main steps for doing a rapid lateral flow test.

Depending on the test kit supplied the Rapid lateral flow tests require either a:

- throat and nose swab
- nose swab only

The test may be different to one you have used before so it's important to read the instructions carefully before you use the test.

Before taking the swab:

- wash your hands with soap and water or use an alcohol hand sanitiser
- apply single use disposable apron and single use disposable gloves ensure that your type IIR fluid resistant surgical face mask is correctly fitted
- Ensure there is a clear, clean, and dry a flat surface and then lay out all the items in the test kit
- Document patients name on the kit
- if the test does not come with a pre-filled tube, fill the tube with the liquid provided
- place the tube in the tube holder
- ask the patient to blow their nose
- On the lateral flow device please document the patient's name, unit number and the time that the test was undertaken

Taking the swab

For a throat swab and nose swab:

- Ask the patient to open their mouth wide and rub the swab over both the tonsils (or where they would have been) at the back of their throat. Do this 4 times on each side

- using the same swab, wipe the inside of their nose as set out in the test kit instructions

For a nose swab only:

- use the swab to wipe the inside of the patients nose as set out in the test kit instructions.

For throat only swab

- Ask the patient to open their mouth wide and rub the swab over both the tonsils (or where they would have been) at the back of their throat. Do this 4 times on each side

Completing the test:

At the patient's bedside

- label the LFT with patient's names and unit number
- put the end of the swab into the tube so it's in the liquid and swirl the swab around as directed in the test kit instructions, then close the lid
- squeeze the liquid from the tube onto the test strip
- check the waiting time in the instructions that came with the test kit
- wait for the time shown in the test kit instructions (you may need to move the kit to the treatment whilst you await the result)
- check the result and document on Sunrise. Please see below

Do not leave the test longer than the waiting time specified in the test kit instructions as this may affect the result.

Dispose of the Kit and PPE in the Clinical waste stream.

Remove your PPE and wash your hands

Reporting the result

The result **MUST** be documented on Sunrise, whether it is positive, negative, or void.

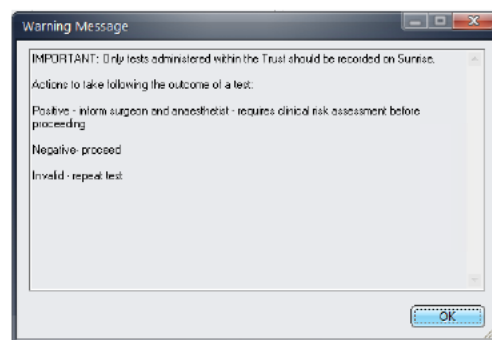
All positive results must be wither telephoned to the IPC office on ext. 2174 or the result emailed on dqft.infection.control@nhs.net

APPENDIX 2

Uploading patients details to Sunrise.

REPORTING LATERAL FLOW DEVICE RESULTS ON SUNRISE USER GUIDE

1. Login to Sunrise, navigate to the appropriate ward tracking board and select the required patient
2. Select 'Enter Order' and search for 'LFD'
3. Double click on the '**COVID Lateral Flow Device Self-Reported Result**' order. Read and acknowledge the warning message



4. Complete the mandatory fields on the order form (marked with a red star ★)
 - a. Enter the time the LFD test was taken

Test time
Time Critical [dropdown] [red star] [red star] [red star]

- b. Enter the result

Result
[red star] [dropdown]
Negative SARS-CoV-2 CORONAVIRUS
Positive SARS-CoV-2 CORONAVIRUS
Invalid result

- c. Confirm the specimen type

Specimen Type
[dropdown]
Naso-Pharyngeal - NSW
Throat swab - THS
Nose Swab - NOS
Naso-Pharyngeal - NSW

- d. Record if the patient is asymptomatic or symptomatic

Is Patient Asymptomatic or Symptomatic
[red star] [dropdown]
Asymptomatic
Symptomatic

- e. Add any further relevant clinical details

Clinical Details
[red star] [text area]

5. Click OK
6. Submit the order
7. The result will be added to the 'Results' tab

ALLSCRIPTS Gateway | My Applications | Acute Care

My Applications Acute Care

File Registration View GoTo Preferences Tools

DOE, John Born 15-Oct-1942 (79y) Gender Male

Address Unknown Phone and Email Unknown MRN 00123456 Location zzz Dummy Ward - RM 1 - Bed 8

Order Entry Worksheet - Doe, John

DOE, John Born 15-Oct-1942 (79y) Gender Male NHS No: Unknown

Address Unknown Phone and Email Unknown MRN 00123456 Location zzz Dummy Ward - RM 1 - ... Known allergies

Requested By: Me Other: Source: Allergy Details

Session Type: Standard Reason: Manual Entry Searching for...

Id Order LED (COVID Lateral Flow Device Self Reported Result) .

START

DOE, John

zzztest, config

ZZZTEST, Test Meows P

ZZZTEST, Test Tablet Pa

Test date: 30-Aug-2022 Test time: Time Critical 09:20 Sample collection: Patient assayed Foreign Travel: Collection Container: Specimen Type: Naso-Pharyngeal - NSW Patient Category: Patient Specimen Collection Instructions: Clinical Details: Decision made to proceed

COVID Lateral Flow Device Self Reported Result - Test Date: 30-Aug-2022 Test time: 09:20 Specimen Type: Naso-Pharyngeal - NSW Result: Negative SARS-CoV-2 CORONAVIRUS 30-Aug-2022 09:20 Pending

Submit Order(s) for Doe, John Hide Worksheet Cancel Help

DOE, John Born 15-Oct-1942 (79y)

Address Unknown Phone and Email Unknown MRN 00123456

Previous Next Refresh Enter Find Find Show Visits Health Enter Clinical Allergies Signature Worksheet Task Flowchart User Print Add Care Patient Patient Screen Order Patient View /Referrals Issues Document Path Mgr. Summary Manager Viewer Manager Alerts Reports Prov...

Tracking Board Clinical Summary

Patient Info Documents Flowcharts Orders Results Visit Record Review Referral List Refer

Display Display Reset Order Order Set View Annotation Modify Reorder Print Results Forward Results Refe Format View Details Details Details Time Scale for Order for Order Pat

END

✓ All results for all available charts for performed dates from 30-May-2022; Display Format: Results Tab D

30Aug22 09:20

Microbiology

COVID Lateral Flow Device Self Reported Result Negative SARS-CoV-2 CORONAVIRUS

TOCILIZUMAB AND SARILUMAB FOR PATIENTS WITH COVID-19 PNEUMONIA (ADULTS) GUIDELINE	DOCUMENT TITLE:		PATIENTS WITH COVID-19 PNEUMONIA (ADULTS) GUIDELINE
	Name of Originator/Author /Designation & Specialty:		
	Local / Trust-wide	Trust-Wide	
	Statement of Intent:	To outline the use of Tocilizumab and Sarilumab in patients with covid-19	
	Target Audience:	To be referred by all medical staff considering the use of Tocilizumab or Sarilumab to treat a patient with COVID-19 and by all nursing staff involved in the administration of Tocilizumab or Sarilumab to treat a patient with COVID-19	
	Version:	5.0	
	Name of Group and Date when Recommended for Ratification	Drug & Therapeutics Group GRIP	Date: 18/01/2023 01/03/2023
	Name of Division and Date of Final Ratification:	Community with Core Clinical Services (CCCS) Div Meeting	Date: 18/04/2023
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	Contributors:	Designation: 	
The electronic version of this document is the definitive version			

CHANGE HISTORY

Version	Date	Reason
1.0	December 2020	This is a new document
1.1	January 2021	Renamed to remove 'admitted to ICU' from title. 2.1 Eligibility - remove admitted 'to ICU'. 2.7 Added 'clinician' - <i>The 'clinician' or pharmacist will complete the Blueteq form retrospectively.</i> Appendix 2 – amended title to remove 'ICU'. Appendix 1 – amendments to dose banding
2.0	February 2021	Renamed to include Sarilumab. Each section update to include reference to Sarilumab
3.0	February 2021	Major revisions since publication of new commissioning policies

4.0	September 2021	Sarilumab elig in line with upo
5.0	April 2023	Updated to inc update to eligibility criteria

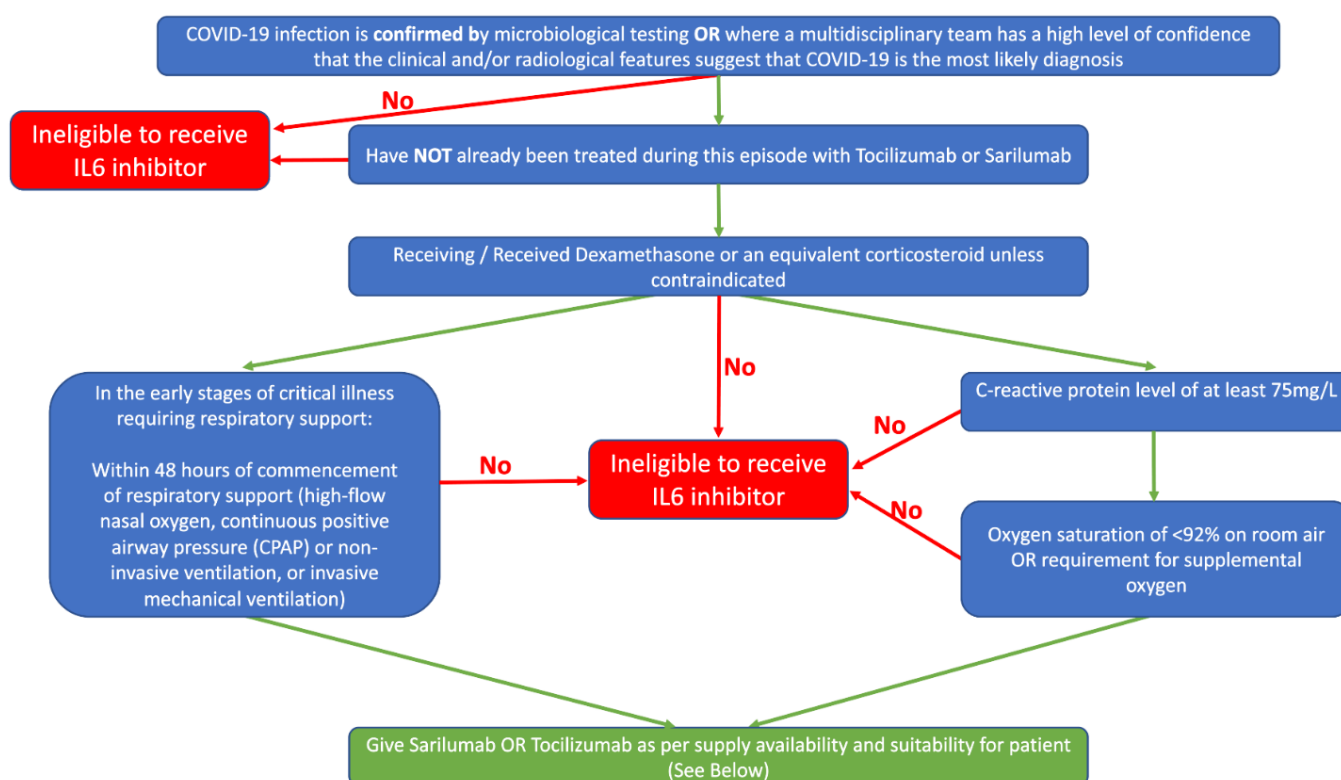
A translation service is available for this document. The Interpretation/Translation Policy, Guidance for Staff is located on the intranet under Trust-wide Policies.

THE DUDLEY GROUP NHS FOUNDATION TRUST

TOCILIZUMAB AND SARILUMAB FOR COVID-19 PNEUMONIA (ADULTS) GUIDELINE

1. GUIDELINE SUMMARY

This guideline provides a guide to the eligibility, prescribing, and administration of IV Tocilizumab and Sarilumab to Covid-19 patients at the Dudley Group in response to NHS England's Interim Clinical Commissioning Policies^{1,2}.



Exclusion Criteria (Tocilizumab):

1. Known hypersensitivity to tocilizumab
2. Pregnancy unless clear necessary and after multidisciplinary team discussion and agreement

Cautions:

1. Co-existing infection that might be worsened by tocilizumab
2. A baseline alanine aminotransferase (ALT) or aspartate aminotransferase (AST) more than 10 times the upper limit of normal (caution is recommended if hepatic enzymes are more 1.5 times the upper limit of normal)
3. A pre-existing condition or treatment resulting in ongoing immunosuppression
4. Neutropoenia and thrombocytopenia
5. Women of child-bearing potential should use effective contraception for up to 3 months after treatment

Exclusion Criteria (Sarilumab):

1. Known hypersensitivity to sarilumab
2. Co-existing infection that might be worsened by sarilumab
3. A baseline alanine aminotransferase (ALT) or aspartate aminotransferase (AST) more than 5 times the upper limit of normal (caution is recommended if hepatic enzymes are more 1.5 times the upper limit of normal)
4. A baseline platelet count of less than 150 x 10⁹/L
5. A pre-existing condition or treatment resulting in ongoing immunosuppression
6. Pregnancy unless clear necessary and after multidisciplinary team discussion and agreement

Cautions:

1. Neutropoenia
2. Women of child-bearing potential should use effective contraception for up to 3 months after treatment

	<u>Tocilizumab</u>	<u>Sarilumab</u>
Recommended dose	8mg/kg (max 800mg) as a once-only intravenous infusion	400mg as a once-only intravenous infusion. NB. The use of Sarilumab intravenously in COVID-19 is off label.
Repeat doses	A second dose should not be considered , given the uncertainty over evidence of additional benefit as well as the need to maximise available supply.	
Dilution	Dilute in 100mL bag of 0.9% sodium chloride, after removing an equivalent volume of saline (total volume 100mL) and given over 1 hour.	Sarilumab is available as a pre-filled syringe. Two 200mg doses should be used to make up the total 400mg dose. 400mg of Sarilumab should be diluted in a 100mL bag of 0.9% sodium chloride, after removing an equivalent volume of saline (total volume 100mL) and given over 1 hour.
Administration	The recommended infusion rate is: 10ml/hour for first 15 minutes then 130ml/hour for the remaining 45 minutes followed by a 20ml normal saline flush.	

Tocilizumab and Sarilumab supply arrangements are in place to support provision under the published policies and will continue to be carefully managed through weekly allocations at trust level. To ensure availability of Tocilizumab as standard of care in non-critically ill patients, those receiving respiratory support should receive Sarilumab where available.

2. GUIDELINE DETAIL

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus (SARS-Coronavirus 2) causes coronavirus disease COVID-19³.

The most common symptoms of COVID-19 are fever, dry cough, and tiredness. Other symptoms that are less common and may affect some patients include aches and pains, nasal congestion, headache, conjunctivitis, sore throat, diarrhoea, loss of taste or smell, or a rash on skin or discoloration of fingers or toes. These symptoms are usually mild and begin gradually. Some people become infected but only have very mild symptoms³.

Most people (about 80%) recover from the disease without needing hospital treatment. Around 1 out of every 5 people who get COVID-19 become seriously ill and develop difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart and lung problems, diabetes, or cancer, are at higher risk of developing serious illness. However, anyone can catch COVID-19 and become seriously ill³.

On 17th February 2021, NHS England published Interim Commissioning Policies on the use of Tocilizumab or Sarilumab for hospitalised patients with Covid-19 following the findings of the REMAP-CAP and RECOVERY trials^{1,2}. The Commissioning Policies provide eligibility and exclusion criteria for use of Tocilizumab or Sarilumab outside of the clinical trial setting.

On 11 February 2021 the RECOVERY trial announced the findings of Tocilizumab use in a broad hospitalised population, which indicated that Tocilizumab significantly improved survival and other clinical outcomes in patients with hypoxaemia and systemic inflammation. The commissioning policies were amended to take these results into account.

RECOVERY has now reported that in hospitalised COVID-19 patients with hypoxia and systemic inflammation, Tocilizumab improved both 28-day survival (a relative reduction in mortality of 14%) and other clinical outcomes. These benefits were seen regardless of the level of respiratory support and were additional to the benefits of systemic corticosteroids, such as dexamethasone.

New evidence and guidance have shown equivalence between the two IL-6 inhibitors. Further evidence from REMAP-CAP trial has demonstrated equivalent effects of both IL-6 inhibitors on survival and requirement for organ support (84.9% posterior probability of equivalence). These results have led to a strong recommendation to use both IL-6 inhibitors.

Tocilizumab and Sarilumab belong to a class of medicines known as Interleukin-6 Inhibitors (IL6 inhibitor). Tocilizumab has a marketing authorisation for the following indications; rheumatoid arthritis, juvenile idiopathic arthritis, temporal arteritis and for cytokine release syndrome as part of CAR-T therapy⁵. Sarilumab has a marketing authorisation for subcutaneous use in adults with severely active rheumatoid arthritis. The treatment of Covid-19 pneumonia with Tocilizumab and Sarilumab is “off-label” as this falls outside the marketing authorisation of the drugs. Prescribers should consider the greater level of responsibility involved with prescribing a medicine outside of the terms of its licence⁶.

On 29th November 2022, NHS England published Interim Commissioning Policies on the use of Tocilizumab or Sarilumab for hospitalised patients with Covid-19 based on the change in license of Tocilizumab. Tocilizumab is now authorised to be used as the **first line** IL-6 inhibitor for hospitalised patients in the treatment of COVID-19 adult patients who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation. Patients may continue to be considered for treatment with Sarilumab where Tocilizumab is unavailable for this indication or cannot be used.

2.1 **Eligibility Criteria**

The decision to initiate treatment with Tocilizumab /Sarilumab should be made by the receiving consultant (registrar if overnight) and with the support from multi-disciplinary colleagues in cases of uncertainty. Patients must meet all eligibility criteria and none of the exclusion criteria to be considered for Tocilizumab /Sarilumab^{1,2}

Tocilizumab and Sarilumab

Eligibility for Tocilizumab has been expanded to include a wider group of hospitalised patients with Covid-19. A single dose of Tocilizumab or Sarilumab should be considered as adjuvant treatment to dexamethasone (standard of care).

Patients are eligible for Tocilizumab or Sarilumab if:

- COVID-19 infection is confirmed by microbiological testing or where a multidisciplinary team has a high level of confidence that the clinical and radiological features suggest that COVID-19 is the most likely diagnosis.

AND

- They are receiving (or have received) an equivalent corticosteroid up to 10mg prednisolone per day

AND

- With a C-reactive protein level of at least 75mg/L; AND an oxygen saturation of <92% on room air OR requirement for supplemental oxygen.

OR

- If an IL-6 inhibitor has not been already administered for COVID-19 during this admission and within 24-48 hours of commencement of respiratory support (high-flow nasal oxygen, continuous positive airway pressure (CPAP) or non-invasive ventilation, or invasive mechanical ventilation).

The checklist in ([Appendix 1](#)) must be completed for each patient prior to beginning the treatment.

2.2 Exclusion criteria

Tocilizumab should not be administered in the following circumstances:

- Known hypersensitivity to Tocilizumab.

Sarilumab should not be administered in the following circumstances:

- Known hypersensitivity to Sarilumab.
- A baseline platelet count of less than $150 \times 10^9/L$

Tocilizumab and Sarilumab should not be used during pregnancy unless clearly necessary and after multidisciplinary team discussion and agreement.

2.3 Cautions

Patients should be screened for risk of infection, tuberculosis and blood-borne viruses and have a baseline lipid profile checked⁵. The drug can be administered before results of viral screen are available.

Caution is necessary when prescribing Tocilizumab or Sarilumab to patients with neutropoenia or thrombocytopaenia. Please note that C-reactive protein (CRP) levels may be depressed for some time after treatment with IL6 inhibitors.

Women of childbearing potential should use effective contraception for up to 3 months after treatment.

Caution should be exercised when considering treatment with IL-6 inhibitors in the following circumstances:

- Co-existing infection that might be worsened by IL-6 inhibitor.

- A baseline alanine aminotransferase (AST) more than 5 times the upper limit
- A pre-existing condition or treatment

2.4 **Common Side Effects**

- Infections
- Hyperlipidaemia
- Abdominal pain
- Mouth ulcers
- Rash
- Neutropenia
- Raised liver function tests.
- Hypertension
- Cough, dyspnoea
- Conjunctivitis
- Dizziness
- Headaches
- Peripheral oedema

2.5 **Dose**

2.5.1 **Tocilizumab**

The recommended dose is 8mg/kg to be administered as an intravenous infusion. The total dose should not exceed 800mg.

Tocilizumab 20mg/ml solution for intravenous infusion is available in 3 different dosing volumes: 400mg (20ml 20mg/ml): 200mg (10ml 20mg/ml) 80mg (4ml, 20mg/ml). Dose banding should be used see [Appendix 2](#).

2.5.2 **Sarilumab**

The recommended dose of Sarilumab is 400mg to be delivered as a once-only intravenous infusion. Sarilumab is available as a pre-filled syringe. Sarilumab is licensed and labelled for “subcutaneous use” however should be given IV for Covid-19 in according with NHS England commissioning policy².

2.6 **Dose Adjustments Due to Laboratory Abnormalities**

2.6.1 **Liver Enzyme Abnormalities**

- Tocilizumab: ALT or AST must NOT exceed 10 x upper limit normal
- Sarilumab: ALT or AST must NOT exceed 5 x upper limit normal.

2.6.2 **Haematological Abnormalities**

Neutrophil count

- Neutrophils < 2 – caution

Low platelet count

- Tocilizumab: <50 do not give
- Sarilumab: <150 do not give.

2.7 Prescribing

IV Tocilizumab or Sarilumab must be initiated by the receiving registrar or consultant and should be discussed with multidisciplinary colleagues in cases of uncertainty. Prescribers must be assured that patient meets all eligibility criteria through completion of ([Appendix 2](#)). The clinician or pharmacist will complete the Blueteq form retrospectively using the information contained in the checklist.

2.8 Drug Storage

- Please store in refrigerator (2-8 °C). DO NOT FREEZE
- Keep the vial/syringe in the outer carton in order to protect from light.
- After dilution the prepared solution is chemically stable for 24hrs at 2-8 °C, however from a microbiological point of view it should be used immediately.

2.9 Drug Preparation

- Preparation of drug infusions should be performed in a clinical/treatment room with no patient access during preparation.
- There should be adequate washing facilities i.e., sink with running water and an eye wash station.
- Work surfaces should be clean, smooth and impermeable.
- Prepare using aseptic technique utilising protective clothing (sterile gloves, safety glasses, mask, and apron).

2.10 Dilution

2.10.1 Tocilizumab

Tocilizumab should be diluted in a 100mL bag of 0.9% sodium chloride, after removing an equivalent volume of saline (total volume 100mL) and given over 1 hour. Tocilizumab should not be infused concomitantly in the same IV line with other medications.

2.10.2 Sarilumab

Two 200mg doses should be used to make up the total 400mg dose. 400mg of Sarilumab should be diluted in a 100mL bag of 0.9% sodium chloride, after removing an equivalent volume of saline (total volume 100mL) and given intravenously over 1 hour. (N.B. this product is licensed and labelled for subcutaneous use, however, it should be given IV for COVID-19, as per NHS England commissioning policy². Sarilumab should not be infused concomitantly in the same IV line with other medications.

Parenteral medicinal products should be inspected visually for any matter or discolouration prior to administration. The solution should be to opalescent, colourless to pale yellow when diluted.

2.11 **Infusion**

- The recommended infusion rate for both drugs is: 10ml/hour for first 15 minutes then 130ml/hour for the remaining 45 minutes followed by a 20ml normal saline flush.
- Use appropriate Infusion Set
- Sarilumab should be infused with a Sterile Non-Pyrogenic Low Protein 0.2micron filter (NHS supply order code FTC190)
- Tocilizumab and Sarilumab should be given through a fresh giving set, do not give through a line that has had other drugs administered through it.
- Blood pressure, temperature, pulse and respirations should be measured at beginning of administration of the infusion and at end of infusion.

2.12 **Monitoring of Infusion**

Nursing staff should complete the checklist in ([Appendix 3](#)) to ensure appropriate monitoring.

Tocilizumab has rarely been associated with acute infusion-related reactions, including anaphylactic shock and delayed hypersensitivity reactions.

Acute infusion reactions including anaphylactic reactions may develop within seconds or within a few hours following infusion. As this is rare, pre-treatment to prevent an infusion reaction is not required.

2.13 **Treatment of Infusion Reaction**

An infusion reaction is any reaction occurring during or within 1-2 hours of an infusion. This can be classified into mild, moderate and severe.

Mild/ Moderate Reactions: rash, urticaria, diarrhoea, epigastric discomfort, arthralgia and headache.

Severe Reactions: angioedema, significant hypo/hypertension, stridor, chest discomfort or shortness of breath, bronchospasm, angioedema of upper airway, elevated temperature

If a patient has any reaction:

- STOP infusion immediately.
- Obtain medical assistance.
- If a severe reaction or anaphylaxis is suspected treat as per anaphylaxis
- Protocol

- Contact the consultant responsible

2.14 Co-administration

2.14.1 Corticosteroids

Administration of systemic dexamethasone or hydrocortisone is recommended in the management of patients with severe or critical COVID-19. Corticosteroids are not suggested in non-severe COVID-19 disease. The Trust guideline on [Dexamethasone in Covid-19](#) can be accessed here. Tocilizumab and Sarilumab should not be regarded as an alternative to corticosteroids.

There is no interaction of Tocilizumab or Sarilumab with either dexamethasone or hydrocortisone expected. For further information please visit the University of Liverpool COVID-19 Drug Interactions website (<https://www.covid19-druginteractions.org/checker>).

2.14.2 Remdesivir

The Clinical Commissioning Policy for the use of remdesivir in hospitalised patients with COVID-19 who require supplemental oxygen can be found [here](#). There is no interaction of Tocilizumab or Sarilumab with remdesivir expected.

2.15 Monitoring of Patient Post Infusion

Tocilizumab and Sarilumab cause complete suppression of CRP, so this should not be used as a measure of response to treatment or as a sign of infection. Instead, other parameters such as a reduced requirement of respiratory support should be used to assess patient improvement. Consider use of pro calcitonin to monitor for signs of secondary bacterial infection. Suppression of CRP can occur for up to 3 months after administration, therefore any handover with primary care should explicitly mention that an IL-6 inhibitor has been given and the date of administration.

Any serious suspected adverse reactions should be reported immediately through the dedicated COVID-19 Yellow Card reporting site: <https://coronavirus-yellowcard.mhra.gov.uk/>.

3. Abbreviations

- **ALT:** Alanine Aminotransferase
- **ANC:** Absolute Neutrophil Count
- **AST:** Aspartate Aminotransferase
- **CPAP:** Continuous Positive Airway Pressure
- **CRP:** C-Reactive Protein
- **HFNO:** High Flow Nasal Oxygen

- **ICU:** Intensive Care Unit
- **IL6 inhibitor:** Interleukin-6 inhibitor
- **LFT:** Liver Function Test
- **NIV:** Non-Invasive Ventilation
- **SPC:** Summary-of Product Characteristics
- **ULN:** Upper Limit of Normal

4. Training/Support

All nursing staff administering Tocilizumab or Sarilumab will have attended trust training for IV medication administration. In addition, the nurse should be competent to administer as identified by the lead nurse for the area.

It is the responsibility of individual healthcare professionals to maintain and update their knowledge and skills and keep their own record of continuing professional development.

All prescribers are expected to keep themselves informed of changes to prescribing regulations and of developments in the management of conditions for which they prescribe.

5. References

1. European Medicines Agency (23rd July 2020) RoActemra 20mg/ml Concentrate for Solution for Infusion.
<https://www.medicines.org.uk/emc/product/6673/smpc#>
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3. Medicines and Healthcare products Regulatory Agency (2014) Off-label or unlicensed use of medicines: prescribers' responsibilities
<<https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities>> [Accessed 8th December 2020]
4. NHS England (2021) Interim Clinical Commissioning Policy: Sarilumab for critically ill patients with COVID-19 pneumonia (adults) <
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103774> | [Accessed 25th February 2021]
5. NHS England (2021) Interim Clinical Commissioning Policy: Tocilizumab for hospitalised patients with COVID-19 pneumonia (adults) <
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103773> [Accessed 25th February 2021]
6. Q&A on coronaviruses (COVID-19), World Health Organisation, 04/2020,
<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-coronaviruses> [Accessed 8th December 2020]

Patient sticker

Appendix 1

Date:.....

Intravenous Tocilizumab /Sarilumab use in COVID positive patients – Eligibility Checklist

Prescribing doctor to complete

If answer no to any of these questions then do not proceed with IV Tocilizumab /Sarilumab

Positive COVID-PCR or MDT decision that COVID is the likely diagnosis	YES	NO
Patient has yet to receive treatment with an IL-6 inhibitor (Tocilizumab or Sarilumab) on this admission for COVID-19	YES	NO
Severe pneumonia requiring respiratory support, such as high flow nasal oxygen, continuous positive airway pressure (CPAP) or non-invasive ventilation, or invasive mechanical ventilation started in last 24 hours	YES - Sarilumab OR Tocilizumab	NO – proceed with further questions
receiving (or have completed a course of) dexamethasone or an equivalent corticosteroid unless contraindicated	YES	NO
A C-reactive protein level of at least 75mg/L	YES	NO
Oxygen saturation of <92% on room air OR requirement for supplemental oxygen	YES	NO
Confirm the patient does not meet any exclusion criteria	YES	NO

If answer yes to any of the following questions careful decision should be made as to whether to proceed with IV Tocilizumab or Sarilumab

History of recurrent infections?	YES	NO
Any recent exposure to tuberculosis/ chickenpox/ shingles?	YES	NO
History of hepatitis B, C or HIV	YES	NO
Does the patient have hepatic impairment?	YES	NO
Does the patient have haematological abnormalities?	YES	NO
If female, could the patient be pregnant? Contraception discussed	YES	NO
Is the patient breast feeding?	YES	NO

If previously infused with Tocilizumab /Sarilumab, any adverse reaction or delayed sensitivity to the infusion?

Patient sticker

Date:.....

IV Tocilizumab /Sarilumab use in COVID positive patients: Investigations Checklist

Prescribing doctor to complete

Blood tests required <24 hours from today's date should be documented below.

Blood tests (Normal range) Units	Date	Result	Signature
Hb (133-180) g/l			
WCC (4-11) x10 ⁹ /L			
Neutrophils (2-7.5) x10 ⁹ /L			
Plts (140-400) x10 ⁹ /L			
eGFR (seek advice if <50mL/min/1.73m ²)			
ALT (0-35) IU/L			
Alk Phos (30-130) IU/L			
Total cholesterol			
Patient Weight (kg)			
Urine dipstick			

Blood test abnormalities

Blood test parameter	Range		Tocilizumab Action if yes	Sarilumab Action if yes
Neutrophils	< 2	YES / NO	Caution	Caution
Platelets	<150	YES / NO	Proceed	Do not give
Platelets	<50	YES / NO	Caution	Caution
ALT	>52.5 (>1.5 x ULN)	YES / NO	Proceed	give cautiously and monitor LFTs
ALT	>175 (>5 x ULN)	YES / NO	give cautiously and monitor LFTs	Do not give

Appendix 2

Tocilizumab Dose Banding

Tocilizumab vials are supplied in three different strengths;

- 80 mg of Tocilizumab in 4 mL (20 mg/mL)
- 200 mg of Tocilizumab in 10 mL (20 mg/mL)
- 400 mg of Tocilizumab in 20 mL (20 mg/mL)

The dose of Tocilizumab is 8mg/kg, however a dose band has been created in order for the dose to be administered to the nearest appropriate vial size(s).

To dilute, withdraw a volume of sodium chloride 0.9% from a 100mL infusion bag equal to the volume of Tocilizumab required for the patient's dose. The required amount of Tocilizumab should be withdrawn from the vial and placed into the 100mL infusion bag. The final volume of the infusion should be 100mL. To mix the solution, gently invert the infusion bag to avoid foaming.

Weight (kg)	Dose Band	Vials to use. (mg)	Volume of Tocilizumab required for dose (20mg/ml)
< 41	8mg/kg rounded to nearest 20mg		
42 - 45	360mg	400	20mL
46 - 55	400mg	400	20mL
56 - 65	480mg	400 + 80	24mL
66 - 80	600mg	400 + 200	30mL
81 - 90	680mg	400 + 200 + 80	34mL
≥ 91	800mg	400 + 400	40mL

Patient sticker

Appendix 3

Date:.....

**Intravenous Tocilizumab /Sarilumab use in COVID positive patients –
Nurse Assessment Checklist**

Registered nurse to complete	
Tasks	Signature
Measure vital signs incl. temperature; withhold treatment until doctor has reviewed if patient is pyrexial	
Perform urinalysis; withhold treatment until doctor has reviewed if blood or protein is present. MSU SENT YES / NO	
Perform a pregnancy test on pre-menopausal female patients; must be negative	
Ensure that deteriorating patient trolley and anaphylaxis treatment is available, and anaphylaxis kit and resuscitation trolley are available on the ward	
Ensure patient has separate peripheral venous cannula that can be used only for Tocilizumab /Sarilumab infusion whilst it is running	
Administer infusion over 1 hour	
Observation's recorded; 30minute intervals for 1 hour. Hospital NEWS chart/ ICCA chart to be completed; appropriate action for any abnormal result.	