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1. Directors of Pharmacy
2. Medical Directors NHS Boards

1 February 2021

Dear Healthcare Professional,

COVID-19 THERAPEUTIC ALERT – INTERLEUKIN-6 INHIBITORS (TOCILIZUMAB OR SARILUMAB) FOR PATIENTS ADMITTED TO ICU WITH COVID-19 PNUEMONIA (ADULTS)

Please see the attached letter about UK Interim Clinical Commissioning Policies which have now been published, recommending that two Interleukin-6 (IL-6) inhibitors – tocilizumab and sarilumab - are made available as a treatment option for critically ill adult patients (aged 18 years and over) hospitalised with COVID-19 in accordance with the agreed criteria. I would be grateful if you could cascade this information to relevant colleagues.

Could all Directors of Pharmacy please forward this alert to:-

- Hospital Pharmacists
- Community Pharmacists

Please could Medical Directors forward this alert to:-

- Accident & Emergency Departments
- Directors of Public Health
- Consultants in Communicable Diseases
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy and Medicines Division

Department of Health & Social Care

NHS

COVID-19 Therapeutic Alert

CEM/CMO/2021/004 01 February 2021

Interleukin-6 inhibitors (tocilizumab or sarilumab) for critically ill patients with COVID-19 pneumonia (adults)

Summary

UK Interim Clinical Commissioning Policies have now been published, recommending that two Interleukin-6 (IL-6) inhibitors - tocilizumab and sarilumab - are made available as a treatment option for critically ill adult patients (aged 18 years and older) hospitalised with COVID-19 in accordance with the agreed criteria.

The REMAP-CAP trial has reported a finding of survival and time to recovery benefits for tocilizumab or sarilumab, over and above current standard of care (including corticosteroids), in the immune modulation therapy domain of the REMAP-CAP platform trial. Mortality was reported as 35.8% in the standard of care group, compared to 27.3% in the treatment group, an overall reduction in the relative risk of death of 24%. The treatment also reduced the time patients spent in the intensive care unit (ICU) by more than a week on average.

Rapid evidence reviews were subsequently published by the National Institute for Health and Care Excellence (NICE) for tocilizumab (15th January), and sarilumab (20th January), respectively. These reviews suggested that any mortality or recovery benefit from tocilizumab or sarilumab is seen only in the most severely ill patients who are given these agents soon after organ support is started, when any developing organ dysfunction may be more reversible.

Recruitment has now closed to the tocilizumab arm of the RECOVERY trial and the results are currently awaited. The policies will be further updated as required, once further data are available.

Please note that in addition to the tocilizumab supply arrangements put in place to support access under the previously published interim position statement, sarilumab supply will now also be available from early February.

Action

NHS acute trusts / health boards are asked to take the following immediate steps to support treatment of critically ill patients with COVID-19:

1. **Organisations are recommended to consider prescribing either tocilizumab or sarilumab to hospitalised patients with COVID-19 pneumonia being treated with non-invasive ventilation (including high-flow nasal oxygen therapy or continuous positive airway pressure ventilation) or invasive mechanical ventilation.** Any organisation treating patients with either IL-6 inhibitor, as off-label products, will be required to assure itself that the necessary internal governance arrangements have been completed before the medicine is prescribed. These arrangements may be through the health board / trust drugs and therapeutics committee, or equivalent.

2. Ensure that the criteria described in the published Interim Clinical Commissioning Policies are used to identify patients with COVID-19 related pneumonia who may be suitable for treatment with tocilizumab or sarilumab. In the absence of a confirmed virological diagnosis, tocilizumab or sarilumab should only be used when a multidisciplinary team has a high level of confidence that the clinical and radiological features suggest that COVID-19 is the most likely diagnosis.

3. In England, trusts who have not yet done so should register (by site) to participate in COVID-19 specific tocilizumab and sarilumab supply arrangements, respectively, via Blueteq™. Blueteq should also then be used to confirm pre-authorisation for individual patients. Blueteq forms are now also available for post pubescent children under NHS England's Medicines for Children Policy. HSC Trusts in Northern Ireland should liaise with the Regional Pharmaceutical Procurement Service to register interest. In Scotland, Health Board Directors of Pharmacy should notify NHS National Procurement if they wish to participate. Health Boards in Wales should notify the All Wales Specialist Procurement Pharmacist of their intention to participate.

4. Order tocilizumab and sarilumab supply through existing (business as usual) routes. Arrangements have been made with Roche CHUGAI and Sanofi to secure initial supply to the UK to meet potential COVID-19 treatment requirements, alongside existing (licensed) clinical indications. For those organisations who have formally confirmed they wish to participate, the additional supply will be managed by providing an indicative maximum order 'cap' by hospital / trust (based on modelled intensive care activity). Retrospective reimbursement of medicines costs will continue to be managed as usual through the excluded drugs funding route in England. Further advice on this will follow for Northern Ireland, Scotland and Wales.

5. Maintain access to intravenous tocilizumab for existing (non COVID-19) indications including rheumatoid arthritis (where appropriate), paediatric indications and treatment of cytokine storm (CRS) following CAR-T therapy.

6. Maintain access to subcutaneous sarilumab for existing rheumatoid arthritis patients.

7. Provide regular updates on the stock position to trust / hospital and regional pharmacy procurement lead / chief pharmacists.

Product Details

Tocilizumab (RoActemra®) is supplied to the UK by Roche CHUGAI. It is a humanised monoclonal antibody against the interleukin-6 (IL-6) receptor.

Tocilizumab for intravenous use has a marketing authorisation for adults in the treatment of moderate to severe rheumatoid arthritis. Tocilizumab for intravenous use has marketing

authorisations for children 2 years and over in the treatment of active systemic juvenile idiopathic arthritis, juvenile idiopathic polyarthritis and CAR-T induced cytokine release syndrome (CRS).

Sarilumab (Kevzara®) is supplied to the UK by Sanofi (Aventis Pharma Ltd). It is a human monoclonal antibody that specifically binds to interleukin-6 receptors and blocks the activity of pro-inflammatory cytokines.

Sarilumab for subcutaneous use has a marketing authorisation for adults with moderate to severe rheumatoid arthritis.

The published Interim Clinical Commissioning Policies cover off-label use of tocilizumab or sarilumab in adults as an intravenous infusion.

Prescribing

Tocilizumab and sarilumab are not licensed for use in COVID-19. As such, clinicians prescribing either tocilizumab or sarilumab for this indication should follow trust / hospital governance procedures in relation to the prescribing of off-label medicines.

Further guidance on the prescribing of off-label medicines can be found below:

- https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities
- https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines#paragraph-71

Administration

Tocilizumab should be administered as an intravenous infusion at a dose of 8mg per kg, up to a maximum dose of 800mg.

A single dose is to be administered. A second dose should not be considered, given the uncertainty over evidence of additional benefit as well as the need to maximise available supply.

Sarilumab should be administered as a single dose of 400mg (using 2 x 200mg pre-filled syringes) as an intravenous infusion.

The Medusa monograph is available here (registration / log-on required).

Neither tocilizumab nor sarilumab should be infused concomitantly in the same IV line with other medications.

Co-Administration

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. Updated WHO guidance on the use of systemic corticosteroids in the management of COVID-19 can be found here. There is no interaction of tocilizumab or sarilumab with either dexamethasone or hydrocortisone expected.

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 either tocilizumab, or sarilumab, with remdesivir expected.

For further information please visit the University of Liverpool COVID-19 Drug Interactions website (https://www.covid19-druginteractions.org/checker).

Monitoring, tracking and follow-up

IL-6 inhibitors are immunosuppresants which can suppress C-Reactive Protein (CRP) response for up to 3 months after administration. Monitoring of longer-term progress is recommended via recruitment of patients receiving these agents to the ISARIC-CCP study. All handovers of clinical care (including between hospitals if patients are transferred, between levels of care and clinical teams within hospitals, and between hospitals and primary care) should explicitly mention that an IL-6 inhibitor has been given and the date of administration.

Distribution

NHS Trusts (NHS boards in Scotland and Wales)
Regional Medical Directors
Regional Chief Pharmacists
Lead/Senior Pharmacists and Regional Procurement Pharmacy Leads
Trust/Hospital Medical Directors to circulate to medical and nursing staff managing COVID-19 patients

Enquiries

England

Enquiries from NHS trusts in England should in the first instance be directed to your trust pharmacy team who will escalate issues to the Regional Chief Pharmacist and national teams if required. Further information can be requested from the dedicated email address: england.spoc-c19therapeutics@nhs.net.

Northern Ireland

Enquiries from hospitals in Northern Ireland should in the first instance be directed to your hospital pharmacy team who will escalate issues to the Regional Pharmaceutical Procurement Service or Pharmaceutical Directorate at the Department of Health if required Further information can be obtained by contacting RPHPS.Admin@northerntrust.hscni.net

Scotland

Enquiries from hospitals in Scotland should in the first instance be directed to your hospital pharmacy team who will escalate issues to either NHS National Procurement or the Scottish Government's Medicines Policy Team if required. Contact should be made using the following emails: nss.nhssmedicineshortages@nhs.scot or medicines.policy@gov.scot

Wales

Enquiries from hospitals in Wales should in the first instance be directed to the health board's Chief Pharmacist who will escalate issues to the Pharmacy and Prescribing Team at Welsh Government if required. Enquiries to the Welsh Government should be directed to: COVID-19.Pharmacy.Prescribing@gov.wales.

Department of Health & Social Care

The Scottish Government
Riaghaltas na h-Alba

Llywodraeth Cymru
Welsh Government

Department of Health
An Roinn Sláinte
Männystrie O Poustie

NHS

Rapid Policy Statement

Interim Clinical Commissioning Policy: Sarilumab for critically ill patients with COVID-19 pneumonia (adults)

04 February 2021

Commissioning position

The proposal is: sarilumab is recommended to be available as a treatment option through routine commissioning for adult patients (aged 18 years and older) hospitalised with COVID-19 in accordance with the criteria set out in this document.

Evidence summary

A rapid evidence review published by the National Institute for Health and Care Excellence (NICE) on 20 January 2021 suggested that any mortality or recovery benefit from sarilumab is seen only in the most severely ill patients given sarilumab soon after organ support is started, when any developing organ dysfunction may be more reversible.

https://www.nice.org.uk/advice/es34/chapter/Product-overview

Implementation

Eligibility criteria

Patients must meet all of the eligibility criteria and none of the exclusion criteria. Hospitalised patients are eligible to be considered for 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/or radiological features suggest that COVID-19 is the most likely diagnosis; and
- Treated with respiratory support (high-flow nasal oxygen, continuous positive airway pressure (CPAP) or non-invasive ventilation, or invasive mechanical ventilation);[1, 2] and

[1] In the context of the COVID-19 pandemic, treatment of patients critically unwell with COVID-19 can be in the following (critical care equivalent) settings: designated intensive care unit (ICU); surge ICU; or other hospital settings delivering an equivalent level of respiratory care (such as respiratory ward, infectious disease ward).
[2] The decision to treat with sarilumab should be made by two consultants, of whom one should be experienced in respiratory support (as defined above).

- Less than 24 hours[3] have elapsed since commencement of respiratory support (high-flow nasal oxygen, continuous positive airway pressure (CPAP) or non-invasive ventilation, or invasive mechanical ventilation).

Exclusion criteria

Sarilumab should not be administered in the following circumstances:

- Known hypersensitivity to sarilumab
- Co-existing infection[4] that might be worsened by sarilumab
- 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 than 1.5 times the upper limit of normal)
- A baseline platelet count of less than 150 x 10^9/L
- A pre-existing condition or treatment resulting in ongoing immunosuppression

Please refer to the Summary of Product Characteristics (SmPC) for sarilumab for contraindications and cautions for use.

Caution is necessary when prescribing sarilumab to patients with neutropaenia. Please note that C-reactive protein (CRP) levels may be depressed for some time after treatment with sarilumab.

Pregnancy and women of childbearing potential

Sarilumab should not be used during pregnancy unless clinically necessary.

The SmPC for sarilumab currently states that: *"Women of childbearing potential should use effective contraception during and up to 3 months after treatment. There are no or limited amount of data from the use of sarilumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Kevzara should not be used during pregnancy unless the clinical condition of the woman requires treatment with sarilumab."*

The SmPC for sarilumab should be consulted if further information is required.

For women who are breast-feeding, the SmPC states "*It is unknown whether sarilumab is excreted in human milk or absorbed systemically after ingestion. The excretion of sarilumab in milk has not been studied in animals. Because IgG1 are excreted in human milk, a decision should be made whether to discontinue breast-feeding or to discontinue sarilumab therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman."*

Dose

The recommended dose of sarilumab is 400mg to be delivered as a once-only intravenous infusion. **Please note that the use of sarilumab intravenously in COVID-19 is off label.**

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

[3] This can be extended up to a maximum of 48 hours for relevant clinical reasons, such as transfer of patients. However, the principle is to treat patients as early as possible in their critical illness.
[4] Any active, severe infection other than COVID-19; caution is advised when considering the use of sarilumab in patients with a history of recurring or chronic infections or with underlying conditions which may predispose patients to infections.

chloride, after removing an equivalent volume of saline (total volume 100mL) and given over 1 hour[5].

Sarilumab should not be infused concomitantly in the same IV line with other medications**.**

Further information on the use of sarilumab intravenously is available here (registration may be required).

Co-administration

Corticosteroids

Administration of systemic dexamethasone or hydrocortisone (corticosteroid CAS alert) is recommended in the management of patients with severe or critical COVID-19. Corticosteroids are not suggested in non-severe COVID-19 disease. Updated WHO guidance on the use of systemic corticosteroids in the management of COVID-19 can be found here. Sarilumab should not be regarded as an alternative to corticosteroids.

There is no interaction of 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).

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 sarilumab with remdesivir expected. For further information please visit the University of Liverpool COVID-19 Drug Interactions website (https://www.covid19-druginteractions.org/checker).

Safety reporting

Any suspected adverse drug reactions (ADRs) for patients receiving sarilumab should be reported directly to the MHRA via the new dedicated COVID-19 Yellow Card reporting site at: https://coronavirus-yellowcard.mhra.gov.uk/

Marketing authorisation

Sarilumab has marketing authorisation for subcutaneous use in adults with moderate to severe active rheumatoid arthritis. **The use of sarilumab intravenously in COVID-19 is off label.**

Governance

Off-label use of medication

Any provider organisation treating patients with these interventions will be required to assure itself that the internal governance arrangements have been completed before the medicine is prescribed. These arrangements may be through the health board/hospital/trust's drugs and therapeutics committee, or equivalent.

Data collection requirement

Provider organisations in England should register all patients using prior approval software (alternative arrangements in Scotland, Wales and Northern Ireland will be communicated)

[5] The following infusion rate is recommended: 10ml/hour for first 15 minutes then 130ml/hour for the remaining 45 minutes followed by a 20ml normal saline flush

and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined.

Clinical outcome reporting

Hospitals managing COVID-19 patients are strongly encouraged to submit data through the ISARIC 4C Clinical Characterisation Protocol (CCP) case report forms (CRFs), as coordinated by the COVID-19 Clinical Information Network (CO-CIN) (https://isaric4c.net/protocols/).

Effective from

This policy will be in effect from the date of publication.

Policy review date

This is an interim rapid clinical policy statement, which means that the full process of policy production has been abridged: public consultation has not been undertaken. This policy may need amendment and updating if, for instance, new trial data emerges, supply of the drug changes, or a new evidence review is required. A NICE Technology Appraisal or Scottish Medicines Consortium (SMC) Health Technology Assessment or All Wales Medicines Strategy Group (AWMSG) appraisal of sarilumab for COVID-19 would supersede this policy when completed.

Equality statement

Promoting equality and addressing health inequalities are at the heart of the four nations' values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010 or equivalent equality legislation) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Definitions

COVID-19	Refers to the disease caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) virus
High-flow nasal cannula	An oxygen supply system capable of delivering up to 100% humidified and heated oxygen at a flow rate of up to 60L/minute
Continuous positive airway pressure	A type of positive airway pressure in which air flow is introduced into the airways to maintain a continuous pressure that constantly keeps the airways open

Non-invasive ventilation	The administration of breathing support for those unable to breathe on their own without using an invasive artificial airway
Invasive mechanical ventilation	A life support treatment which helps people breathe using an invasive artificial airway when they are not able to breathe enough on their own

Rapid Policy Statement

Interim Clinical Commissioning Policy: Tocilizumab for critically ill patients with COVID-19 pneumonia (adults)

04 February 2021

Commissioning position

The proposal is: tocilizumab is recommended to be available as a treatment option through routine commissioning for adult patients (aged 18 years and older) hospitalised with COVID-19 in accordance with the criteria set out in this document.

Evidence summary

A rapid evidence review published by the National Institute for Health and Care Excellence (NICE) on 15 January 2021 suggested that any mortality or recovery benefit from tocilizumab is seen only in the most severely ill patients given tocilizumab soon after organ support is started, when any developing organ dysfunction may be more reversible.

https://www.nice.org.uk/advice/es33/chapter/Product-overview

Implementation

Eligibility criteria

Patients must meet all of the eligibility criteria and none of the exclusion criteria. Hospitalised patients are eligible to be considered for tocilizumab if:

- COVID-19 infection is confirmed by microbiological testing or where a multidisciplinary team has a high level of confidence that the clinical and/or radiological features suggest that COVID-19 is the most likely diagnosis; and
- Treated with respiratory support (high-flow nasal oxygen, continuous positive airway pressure (CPAP) or non-invasive ventilation, or invasive mechanical ventilation);[1, 2] and

[1] In the context of the COVID-19 pandemic, treatment of patients critically unwell with COVID-19 can be in the following (critical care equivalent) settings: designated intensive care unit (ICU); surge ICU; or other hospital settings delivering an equivalent level of respiratory care (such as respiratory ward, infectious disease ward).
[2] The decision to treat with tocilizumab should be made by two consultants, of whom one should be experienced in respiratory support (as defined above).

- Less than 24 hours[3] have elapsed since commencement of respiratory support (high-flow nasal oxygen, continuous positive airway pressure (CPAP) or non-invasive ventilation, or invasive mechanical ventilation).

Exclusion criteria

Tocilizumab should not be administered in the following circumstances:

- Known hypersensitivity to tocilizumab
- Co-existing infection[4] that might be worsened by tocilizumab
- 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 than 1.5 times the upper limit of normal)
- A pre-existing condition or treatment resulting in ongoing immunosuppression.

Please refer to the Summary of Product Characteristics (SmPC) for tocilizumab for contraindications and cautions for use.

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

Pregnancy and women of childbearing potential

Tocilizumab should not be used during pregnancy unless clinically necessary.

The SmPC for tocilizumab currently states that: "*Women of childbearing potential must use effective contraception during and up to 3 months after treatment. There are no adequate data from the use of tocilizumab in pregnant women. A study in animals has shown an increased risk of spontaneous abortion/embryo-foetal death at a high dose. The potential risk for humans is unknown. RoActemra should not be used during pregnancy unless clearly necessary.*"

The SmPC for tocilizumab should be consulted if further information is required.

For women who are breast-feeding, the SmPC states *"It is unknown whether tocilizumab is excreted in human breast milk. The excretion of tocilizumab in milk has not been studied in animals. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with RoActemra should be made taking into account the benefit of breast-feeding to the child and the benefit of RoActemra therapy to the woman."*

Dose

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

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[5].

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[3] This can be extended up to a maximum of 48 hours for relevant clinical reasons, such as transfer of patients. However, the principle is to treat patients as early as possible in their critical illness.

[4] Any active, severe infection other than COVID-19; caution is advised when considering the use of tocilizumab in patients with a history of recurring or chronic infections or with underlying conditions which may predispose patients to infections.

[5] The following infusion rate is recommended: 10ml/hour for first 15 minutes then 130ml/hour for the remaining 45 minutes followed by a 20ml normal saline flush.

A single dose is to be administered. A second dose should not be considered, given the uncertainty over evidence of additional benefit as well as the need to maximise available supply.

Tocilizumab should not be infused concomitantly in the same IV line with other medications.

Co-administration

Corticosteroids

Administration of systemic dexamethasone or hydrocortisone (corticosteroid CAS alert) is recommended in the management of patients with severe or critical COVID-19. Corticosteroids are not suggested in non-severe COVID-19 disease. Updated WHO guidance on the use of systemic corticosteroids in the management of COVID-19 can be found here. Tocilizumab should not be regarded as an alternative to corticosteroids.

There is no interaction of tocilizumab 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).

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 with remdesivir expected. For further information please visit the University of Liverpool COVID-19 Drug Interactions website (https://www.covid19-druginteractions.org/checker).

Safety reporting

Any suspected adverse drug reactions (ADRs) for patients receiving tocilizumab should be reported directly to the MHRA via the new dedicated COVID-19 Yellow Card reporting site at: https://coronavirus-yellowcard.mhra.gov.uk/

Marketing authorisation

Tocilizumab delivered intravenously has marketing authorisation for use in moderate to severe active rheumatoid arthritis, some forms of juvenile idiopathic arthritis and for cytokine release syndrome as part of CAR-T therapy. NHS England also commissions off-label use of tocilizumab for Takayasu arteritis and Still's Disease. **The use of tocilizumab in COVID-19 is off-label.**

Governance

Off-label use of medication

Any provider organisation treating patients with these interventions will be required to assure itself that the internal governance arrangements have been completed before the medicine is prescribed. These arrangements may be through the health board/hospital/trust's drugs and therapeutics committee, or equivalent.

Data collection requirement

Provider organisations in England should register all patients using prior approval software (alternative arrangements in Scotland, Wales and Northern Ireland will be communicated) and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined.

Clinical outcome reporting

Hospitals managing COVID-19 patients are strongly encouraged to submit data through the ISARIC 4C Clinical Characterisation Protocol (CCP) case report forms (CRFs), as coordinated by the COVID-19 Clinical Information Network (CO-CIN) (https://isaric4c.net/protocols/).

Effective from

This policy will be in effect from the date of publication.

Policy review date

This is an interim rapid clinical policy statement, which means that the full process of policy production has been abridged: public consultation has not been undertaken. This policy may need amendment and updating if, for instance, new trial data emerges, supply of the drug changes, or a new evidence review is required. A NICE Technology Appraisal or Scottish Medicines Consortium (SMC) Health Technology Assessment or All Wales Medicines Strategy Group (AWMSG) appraisal of tocilizumab for COVID-19 would supersede this policy when completed.

Equality statement

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- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010 or equivalent equality legislation) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Definitions

COVID-19	Refers to the disease caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) virus
High-flow nasal cannula	An oxygen supply system capable of delivering up to 100% humidified and heated oxygen at a flow rate of up to 60L/minute
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Non-invasive ventilation	The administration of breathing support for those unable to breathe on their own without using an invasive artificial airway

Invasive mechanical ventilation	A life support treatment which helps people breathe using an invasive artificial airway when they are not able to breathe enough on their own