**Casirivimab and imdevimab in the treatment of COVID-19 in hospitalised adults**

**Product**

Casirivimab and imdevimab is a neutralising monoclonal antibody combination that binds to 2 different sites on the spike protein of the SARS-CoV-2 virus blocking its entry into the host cell. This combination has been approved for use in 2 patients cohorts: patients hospitalised with acute COVID-19 (2.4g) and patient s with hospital-onset COVID-19 (1.2g)

**Criteria for Use**

1. Adult patients (≥16) hospitalised with COVID-19 pneumonia (total dose 2.4g)

All must apply

* Patients who are hospitalised specifically for the management of acute COVID infection.

AND

* SARS-CoV-2 infection confirmed by PCR or when an MDT has a high clinical suspicion that COVID-19 is the most likely diagnosis

AND

* Negative for baseline anti-spike antibodies against SARS-CoV-2.\* (Intermediate result – consider giving if benefit outweighs risks, MDT discussion required). Request ‘COVID antibody for NMAB use’ and contact laboratory on 4099 (Mon-Fri 9-5 and Saturday 9-2)
	+ \*Spike protein interpretation
		- Reported as SARS-CoV-2 IgG Spike AU/mL
		- <50: negative
		- 50-200: intermediate
		- >200: positive

2. Adult patients (≥16) with hospital-onset COVID-19 (total dose 1.2g)

* SARS-CoV-2 infection confirmed by PCR within the preceding 72 hours or when an MDT has a high clinical suspicion that COVID-19 is the most likely diagnosis
* Hospitalised for indication other than the management of severe COVID-19

AND

* At high risk of progression to severe COVID-19

OR

* COVID-19 presents a risk of destabilising a pre-existing condition or compromising recovery from a procedure (as determined by MDT assessment)

AND

* A baseline serum anti-spike (anti-S) test has been taken prior to administration (result does not need to be known)

**Exclusion**

* Under 16 years (see Paediatric protocol)
* Hypersensitivity to active products
* Weight under 40kg
* Repeat doses should not be administered if the patient has previously received the higher dose

**Pregnancy**

Limited or no data is available. Casirivimab and imdevamib should be used in pregnancy only if the potential benefit justifies the potential risk for the mother and foetus. A discussion between Respiratory and Obstetrics is suggested

**Authorisation to supply**

1. Decision to give casirivimab and imdevamib must be authorised by a Consultant – discuss with Respiratory Consultant (Mon-Fri 9-5) or on-call Consultant out of hours
2. Blueteq form must be completed (see appendices 1 and 2/Microguide) [COVID-19 Related Guidelines (microguide.global)](https://viewer.microguide.global/guide/1000000300#content,1c20107a-765d-4ae6-b754-4dd6b2c3548a). The Blueteq forms differ depending on whether patients fall into cohort 1 or 2 and the correct form must be completed.

Once all criteria have been met, call Ward Pharmacist or on-call Pharmacist to supply.

**Administration**

* Cohort 1: 2.4g (1.2g casirivimab and 1.2g imdevimab) in 250ml of 0.9% sodium chloride to be made up in Pharmacy and delivered to the ward or made up on the ward under supervision by a Pharmacist
* Cohort 2: 1.2g (600mg casirivimab and 600mg imdevimab) in 250ml of 0.9% sodium chloride to be made up in Pharmacy and delivered to the ward or made up on the ward under supervision by a Pharmacist
* To be administered as a single IV infusion over 30 minutes
* Do not infuse concomitantly with other IV medications

**Monitoring**

Observations to be taken:

* Before infusion is administered (within 60 minutes)
* 15 minutes after the start of infusion
* At the end of the infusion (usually 30 minutes)
* 60 and 90 minutes after the infusion has finished

**Risks**

Hypersensitivity reactions including anaphylaxis – immediately discontinue infusion and initiate treatment for anaphylaxis.

Infusion related reactions (IRRs) are mostly mild-moderate and include chills, dizziness, nausea, flushing, rash, urticarial. If clinically significant reaction occurs during infusion consider stopping/slowing infusion and provide appropriate supportive care.

**Co-administration**

There are no interactions with steroids, Remdesivir or Tocilizumab.

**Follow up and monitoring**

All patients who are given casirivimab and imdevamib should have the date of administration recorded on their discharge summary.

Repeat doses should not be administered if the patient has previously received the 2.4g dose

Patients who have received the 1.2g dose may be eligible for a 2.4g repeat dose if they continue to deteriorate such that their acute COVID-19 illness requires hospital-based care and the patient fulfils  the eligibility criteria for patients hospitalised with COVID-19

Routine PCR testing should be undertaken weekly during the patient’s admission and if/when any follow up is performed.

**Appendix 1**

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| **CASIM03\_ver1.1 Interim Clinical Commissioning Policy: Interim Clinical Commissioning Policy: Casirivimab and imdevimab in the treatment of COVID-19 in hospitalised patients – registration form for patients hospitalised due to COVID-19** |
| **Patient NHS No:** |   | **Trust:** |   |
| **Patient Hospital No:** |  \* | **Practice Code:** |   |
| **Patient's Initials and DoB:** |   | **GP Postcode:** |   |
| **Choose Consultant:** |     |
| **Consultant Name:** |   \* | **Other Contact Details:** |   \* |
| **Notification Email Address:**  (NHSE accredited domains ONLY)  |
| **Treatment Start Date:** |

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| **Please indicate whether patient meets the following criteria:** | **Please tick** |
| 1. I confirm that the patient is hospitalised with SARS-CoV-2 infection\*\* In the absence of a confirmed virological diagnosis, casirivimab and imdevimab should only be used when a multidisciplinary team have a high level of confidence that the clinical and radiological features suggest that COVID-19 is the most likely diagnosis |

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| Yes |
| No |

\* Required |
| 2. I confirm that **one** of the following apply(please select):

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| The patient had a negative test for baseline serum anti-spike (anti-S) antibodies against SARS-CoV-2 |
| The patient had a positive/marginal test (within the bottom 10% of the assay’s positive range) for baseline serum anti-spike (anti-S) antibodies against SARS-CoV-2 with a MDT determined treatment decision\*\* |
| The patient is immunodeficient and on replacement human immunoglobulin therapy\*\* |

  \*\*Refer to the interim clinical commissioning policy with respect to antibody testing and to use in patients on human immunoglobulin treatment   |

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| Yes |
| No |

\* Required |
| 3. I confirm the patient has been hospitalised specifically for the management of acute symptoms of COVID-19 |

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| Yes |
| No |

\* Required |
| 4. I confirm the patient does not meet any of the exclusion criteria listed in the interim clinical commissioning policy |

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| Yes |
| No |

\* Required |
| 5. I confirm that the patient will receive one dose of 2.4g (1.2g casirivimab and 1.2g imdevimab) as described in the Specialised Pharmacy Services institutional readiness document\*\*\***Note: This is an off-label dose and Trust policy regarding off-label use of medicines should apply**\*\*\* https://www.sps.nhs.uk/home/guidance/covid-19-treatments/neutralising-monoclonal-antibodies/casirivimab-and-imdevimab/ |

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| Yes |
| No |

\* Required |
| 6. I confirm that the patient will receive casirivimab and imdevimab according to the interim clinical commissioning policy\*\*\*\*\*\*\*\* As part of the policy sites 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) |

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| Yes |
| No |

\* Required |

**Appendix 2**

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| **CASIM04\_ver1.0 Interim Clinical Commissioning Policy: Interim Clinical Commissioning Policy: Casirivimab and imdevimab in the treatment of COVID-19 in hospitalised patients – registration form for patients with hospital onset COVID-19** |
| **Patient NHS No:** |   | **Trust:** |   |
| **Patient Hospital No:** |  \* | **Practice Code:** |   |
| **Patient's Initials and DoB:** |   | **GP Postcode:** |   |
| **Consultant Name:** |   \* | **Other Contact Details:** |   \* |
| **Notification Email Address:**  (NHSE accredited domains ONLY)  |
| **Treatment Start Date:** |

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| **Please indicate whether patient meets the following criteria:** | **Please tick** |
| 1. I confirm that the patient is in hospital with SARS-CoV-2 infection which has been confirmed by a polymerase chain reaction (PCR) test within the preceding 72 hours or where a multidisciplinary team (MDT) has a high level of confidence that the clinical and/or radiological features suggest that COVID-19 is the most likely diagnosis |

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| Yes |
| No |

\* Required |
| 2. I confirm the patient was hospitalised for indications other than for the management of acute symptoms of COVID-19 |

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| Yes |
| No |

\* Required |
| 3. I confirm **one** of the following apply (please select):

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| The patient is at high risk of progression to severe COVID-19 (see Appendix 1 of the interim clinical commissioning policy for list of qualifying conditions) |
| COVID-19 infection presents a material risk of destabilising a pre-existing condition or illness or compromising recovery from surgery or other hospital procedure (as determined by multidisciplinary team [MDT] assessment) |

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| Yes |
| No |

\* Required |
| 4. I confirm a baseline serum antibody test (anti-S) against SARS-CoV-2 has been taken prior to treatment administration\*\* All patients being considered for treatment with casirivimab and imdevimab for COVID-19 during their hospital stay should have their baseline serum antibody (anti-S) status measured prior to treatment, with appropriate patient consent, to support service evaluation and surveillance. |

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| Yes |
| No |

\* Required |
| 5. I confirm the patient does not meet any of the exclusion criteria listed in the interim clinical commissioning policy |

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| Yes |
| No |

\* Required |
| 6. I confirm that the patient will receive one dose of 1.2g (600mg casirivimab and 600mg imdevimab) as described in the Specialised Pharmacy Services institutional readiness document\*\*\*\* https://www.sps.nhs.uk/home/guidance/covid-19-treatments/neutralising-monoclonal-antibodies/casirivimab-and-imdevimab/ |

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| Yes |
| No |

\* Required |
| 7. I confirm that the patient will receive casirivimab and imdevimab according to the interim clinical commissioning policy\*\*\*\*\*\*\*\* As part of the policy sites 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) |

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| Yes |
| No |

\* Required |