Neutralising monoclonal antibodies or antivirals for non-hospitalised patients with COVID-19

The following patient cohorts below were determined by an independent advisory group commissioned by the Department of Health and Social Care (DHSC). Please refer to the most recent Interim Commissioning Policy for an up to date list of the patient cohorts. They are considered to be at the highest risk from COVID-19 to develop severe illness. The Interim Commissioning Policy focuses on prioritising these patients for treatment. Changes from previous version are highlighted in red.

Appendix C: Eligible patients

The following patient cohorts were determined by an independent advisory group commissioned by the Department of Health and Social Care (DHSC)

Cohort	Description
Down's syndrome and other genetic disorders	• All patients with Down's syndrome • Patients with chromosomal disorders known to affect immune competence[1]
Patients with a solid cancer	• Active metastatic cancer and active solid cancers (at any stage) • Locally advanced inoperable cancer • Lung cancer (at any stage) • All patients receiving **any** chemotherapy within the last 12 months (including antibody-drug conjugates and PI3K inhibitors) • Patients receiving radiotherapy within the last 12 months • Cancer resection within the previous 12 months, who received no adjuvant chemotherapy or radiotherapy

Patients with a haematological disease and stem cell transplant recipients
 	
(continued over page)
	• Allogeneic haematopoietic stem cell transplant (HSCT) recipients in the last 12 months or active graft vs host disease (GVHD) regardless of time from transplant (including HSCT for non-malignant diseases)
	• Autologous HSCT recipients in the last 12 months (including HSCT for non-malignant diseases)
	• Individuals with haematological malignancies who have
	  ○ received chimaeric antigen receptor (CAR)-T cell therapy in the last 24 months, or
	  ○ radiotherapy in the last 12 months
	• Individuals with haematological malignancies receiving systemic anti-cancer treatment (SACT) within the last 12 months
	• All patients who do not fit the criteria above, who are diagnosed with:
	  ○ myeloma (excluding MGUS)
	  ○ AL amyloidosis

Cohort	Description
Patients with a haematological disease and stem cell transplant recipients (continued)	○ chronic B-cell lymphoproliferative disorders (e.g. chronic lymphocytic leukaemia, follicular lymphoma) ○ myelodysplastic syndrome (MDS) ○ chronic myelomonocytic leukaemia (CMML) ○ myelofibrosis • All patients with sickle cell disease • Thalassaemia or rare inherited anaemia with any of the following: ○ Severe cardiac iron overload (T2* < 10ms)[2] ○ Severe to moderate iron overload (T2* ≥ 10ms) PLUS an additional co-morbidity of concern (e.g. diabetes, chronic liver disease or severe hepatic iron load on MRI) • Individuals with non-malignant haematological disorder (e.g. aplastic anaemia or paroxysmal nocturnal haemoglobinuria) receiving B-cell depleting systemic treatment (e.g. anti-CD20, anti-thymocyte globulin [ATG] and alemtuzumab) within the last 12 months
Patients with renal disease	• All renal transplant recipients (including those with failed transplants within the past 12 months), particularly those who: ○ Received B-cell depleting therapy within the past 12 months (including alemtuzumab, rituximab, ocrelizumab, ofatumab, obinutuzumab [anti-CD20], anti-thymocyte globulin) ○ Have an additional substantial risk factor which would in isolation make them eligible for nMABs or oral antivirals ○ Not been vaccinated prior to transplantation • Non-transplant patients who have received a comparable level of immunosuppression • Patients with chronic kidney stage (CKD) 4 or 5 (an eGFR less than 30 mL/min/1.73m^2) without immunosuppression
Patients with liver disease	• Patients with cirrhosis Child's-Pugh class B and C (decompensated liver disease) • All liver transplant recipients • Liver patients on immune suppressive therapy (including patients with and without liver cirrhosis) • Patients with cirrhosis Child's-Pugh class A who are not on immune suppressive therapy (compensated liver disease)
Solid organ transplant recipients	• All recipients of solid organ transplants not otherwise specified above
Patients with immune-mediated inflammatory disorders (IMID) (continued over page)	• IMID treated with rituximab or other B-cell depleting therapy[3] in the last 12 months • Currently treated with/have been treated within the past 6 months with: ○ Cyclophosphamide (IV or oral) ○ Biologics or small molecule JAK-inhibitors[4]

Cohort	Description
Patients with immune-mediated inflammatory disorders (IMID) (continued)	• Current treatment with mycophenolate mofetil, oral tacrolimus, azathioprine/mercaptopurine (for major organ involvement such as kidney, liver and/or interstitial lung disease), methotrexate (for interstitial lung disease only) and/or ciclosporin • Taking equivalent or greater than prednisolone 10mg per day (including budesonide) for at least 28 days prior to positive test • IMID patients with active/unstable[5] disease including those on biological monotherapy and on combination biologicals with thiopurine or methotrexate
Immune deficiencies	• Common variable immunodeficiency (CVID) • Undefined primary antibody deficiency on immunoglobulin (or eligible for Ig) • Hyper-IgM syndromes • Good's syndrome (thymoma plus B-cell deficiency) • Severe Combined Immunodeficiency (SCID) • Autoimmune polyglandular syndromes/autoimmune polyendocrinopathy, candidiasis, ectodermal dystrophy (APECED syndrome) • Primary immunodeficiency associated with impaired type I interferon signalling • X-linked agammaglobulinaemia (and other primary agammaglobulinaemias)
HIV/AIDS	• Patients with high levels of immune suppression, have uncontrolled/untreated HIV (high viral load) or present acutely with an AIDS defining diagnosis • On treatment for HIV with CD4 <350 cells/mm^3 and stable on HIV treatment or CD4>350 cells/mm^3 and additional risk factors (e.g. age, diabetes, obesity, cardiovascular, liver or renal disease, homeless, those with alcohol-dependence)
Rare neurological conditions	• Multiple sclerosis • Motor neurone disease • Myasthenia gravis • Huntington's disease

[1] Examples of chromosomal disorders know to affect immune competence: DiGeorge syndrome (22q11.2 deletion), CHARGE syndrome (CHD7 mutation), Corneal de Lange syndrome, Chromosome 8 or 18 abnormalities, Primary immunodeficiency syndromes, including: X-linked agammaglobinaemia, X-linked lymphoproliferative syndrome

[2] T2* is referring to the MRI T2 weighted image to make the diagnosis. If this information is not available, the patient may be asked questions such as whether they have haemochromatosis (a disease of increased iron storage) or any condition requiring recurrent blood or iron transfusions

[3] Local additional information: B-cell depleting therapies used in the treatment of immune-mediated inflammatory disorders include: alemtuzumab, belimumab, natalizumab, ocrelizumab, ofatumumab, rituximab, obinutuzumab
See MiDatabank Enq. No:353373

[4] Examples of small molecule JAK-inhibitors may include: abrocitinib, baricitinib, fedratinib, filgotinib, peficitinib, ruxolitinib, tofacitinib, upadacitinib.

[5] Definition of active/uncontrolled IMID: people who exhibit at least one of: (a) uncontrolled or clinically active disease (that is required recent increase in dose or initiation of new immunosuppressive drug or IM steroid injection or course of oral steroids within the 3 months prior to positive PCR); and/or (b) major organ involvement such as significant kidney, liver or lung inflammation or significantly impaired renal, liver and/or lung function)