Antivirals and Neutralising monoclonal antibodies for non-hospitalised adult 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). Changes made in March 2023 are highlighted in green text. New additional eligibility criteria (July 2023) are highlighted in orange text.

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

Patients with a haematological disease and haematological stem cell transplant (HSCT) 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 until lymphocyte count is within normal range,
	• Individuals with haematological malignancies receiving systemic anti-cancer treatment (SACT) within the last 12 months or radiotherapy in the last 12 months
	• All people who do not fit the criteria above, who are diagnosed with:
	  ○ myeloma (excluding MGUS)
	  ○ AL amyloidosis
	  ○ chronic B-cell lymphoproliferative disorders (e.g. chronic lymphocytic leukaemia, follicular lymphoma)
	  ○ myelodysplastic syndrome (MDS)
	  ○ chronic myelomonocytic leukaemia (CMML)

Cohort	Description
Patients with a haematological disease and haematological stem cell transplant (HSCT) recipients (continued)	○ myelofibrosis ○ any mature T-cell malignancy • All people with sickle cell disease. • Thalassaemia or rare inherited anaemia with any of the following: ○ Severe cardiac iron overload (T2* < 10ms) ○ Severe to moderate iron overload (T2 * ≥ 10 ms) 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	• 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 [anti-CD20], anti-thymocyte globulin) ○ Have an additional substantial risk factor which would in isolation make them eligible for nMABs or oral antivirals • 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	• People with cirrhosis Child's-Pugh class A, B or C whether receiving immune suppressive therapy or not (those with decompensated liver disease (B and C) are most at risk). • People with a liver transplant • Liver patients on immune suppressive therapy (including patients with and without liver cirrhosis)
Solid organ transplant recipients	• All recipients of solid organ transplants not otherwise specified above
Patients with immune-mediated inflammatory disorders (IMID) - these might include any auto-immune or auto-inflammation based disorders for example inflammatory arthritis, connective tissue diseases, inflammatory skin diseases, inflammatory gastrointestinal disease (continued over page)	• IMID treated with rituximab or other B cell depleting therapy* in the last 12 months • Currently treated with/have been treated within the past 6 months with cyclophosphamide (IV or oral) • Taking corticosteroids equivalent or greater than prednisolone 10mg per day for at least 28 days prior to positive test. • People who are on biologics or small molecule JAK inhibitors • People who are on current treatment (or within the last 6 months) with S1P modulators (fingolimod, ponesimod or siponimod), or alemtuzumab or cladribine within the last 12 months

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, gastrointestinal tract, liver and/or interstitial lung disease), methotrexate (for interstitial lung disease or asthma) and/or ciclosporin. • IMID patients 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 test; and/or (b) other high-risk comorbidities (for example body mass index (BMI) greater than 30, diabetes mellitus, hypertension, major organ involvement such as significant kidney, liver or lung inflammation or significantly impaired renal, liver and/or lung function
Respiratory disorders	• Asthma in those taking oral corticosteroids (10mg per day for at least 28 days prior to positive test, or patients with frequent exacerbations requiring 4 or more courses of prednisolone per year at doses of 40mg per day for 5 days or more) • Any asthma patient taking immunosuppressants for their asthma but not exclusively methotrexate, ciclosporin • COPD on long term non-invasive ventilation (NIV). Patients on long term oxygen therapy. People with moderate or severe disease (FEV1 ≥50% predicted) who have required 4 or more courses of prednisolone 30mg for 5 days in last 12 months • Interstitial lung disease (ILD) -all patients with idiopathic pulmonary fibrosis • Sub-types of ILD for example connective tissue related, sarcoidosis, hypersensitivity pneumonitis, Non-specific interstitial pneumonia (NSIP) who have received a B-cell depleting therapy* in last 21 months, or IV or oral cyclophosphamide in the 6 months prior to testing positive for COVID-19. Any ILD patient on current treatment with corticosteroids, mycophenolate mofetil, azathioprine, tacrolimus, ciclosporin or methotrexate. • Any person with any type of ILD who may not be on treatment due to intolerance but has severe disease with an FVC predicted less than 60% • NIV- all patients requiring this type of support regardless of the underlying disorder (which might include COPD, obesity hypoventilation syndrome, scoliosis, bronchiectasis, genetic muscular diseases refer to neurology section) • Lung cancer patients (see solid cancer) • Lung transplant (see solid organ transplant) • Pulmonary hypertension (PH) groups 1 and 4 from PH classification
Immune deficiencies (continued over page)	• 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)

Cohort	Description
Immune deficiencies (continued)	• 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) • Any person with secondary immunodeficiency receiving, or eligible for immunoglobulin replacement therapy
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)

Neurological conditions	• Conditions associated with neuromuscular respiratory failure requiring chronic ventilatory support:
	  ○ motor neurone disease
	  ○ Duchenne muscular dystrophy
	• Conditions that require use of specific immunotherapies:
	  ○ multiple sclerosis (MS)
	  ○ myasthenia gravis (MG)
	  ○ other immune mediated disorders
	• Dementia and neurogenerative disorders when associated with severe frailty:
	  ○ Alzheimer's disease, vascular disease, Lewy body disease or frontotemporal atrophy
	  ○ Parkinson's disease
	  ○ Huntington's disease
	  ○ progressive supranuclear palsy and multiple system atrophy
	  ○ motor neurone disease
	  ○ multiple sclerosis and other immune-mediated neurological disorders

* 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	