IP ANTIVIRAL/nMAB SELF ASSESSMENT TOOL

(NON SEVERE ADULT COVID INPATIENTS ONLY)

COVID positive by PCR/lateral flow	YES / NO
Earliest positive within last 5-7 days	YES / NO
Symptoms not improving and initial symptom onset within last 5-7 days	YES / NO
Not on O2 therapy secondary to COVID pneumonitis?	YES / NO
High Risk patient category listed below? If not on this list then not considered high risk.	YES / NO
ELIGIBLE for Antiviral/nMAB therapy	**ONLY if ALL answers to above questions are** YES **See link here to select appropriate treatment**
NOT ELIGIBLE for Antiviral/nMAB therapy	**1 or more answers to above questions** NO

HIGHEST RISK ADULT PATIENTS

for assessment for Neutralising Monoclonal Antibody (nMAB) or Antiviral Treatments for COVID-19

Patient cohorts considered at highest risk from COVID-19 and to be prioritised for treatment with antivirals or nMABs. The following patient cohorts were determined by an independent advisory group commissioned by the Department of Health and Social Care (DHSC)

- Down's syndrome and other genetic disorders: All individuals with Down's syndrome or other chromosomal disorders known to affect immune competence (decision to treat to be at the discretion of the treating clinician).
- Solid cancer:
    - Metastatic or locally advanced inoperable cancer
    - Lung cancer (at any stage)
    - People receiving any chemotherapy (including antibody-drug conjugates), P13K inhibitors or radiotherapy within 12 months. (Patients with thyroid cancer who have undergone radio-iodine ablation will eligible for treatment)
    - People who have had cancer resected within 3 months and how received no adjuvant chemotherapy or radiotherapy. (Patients with basal cell carcinomas who have undergone local excision or topical treatment are not considered to be at sufficiently high risk to be eligible for treatment)
    - People who have had cancer resected within 3 to 12 months and receiving no adjuvant chemotherapy or radiotherapy are expected to be less risk (and thus less priority) but still at increased risk compared with the non-cancer populations
- Haematological diseases and recipients of haematological stem cell transplant (HSCT):
    - Allogeneic 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 people who do not fit the criteria above, and are diagnosed with:
        - Myeloma (excluding monoclonal gammopathy of undetermined significance (MGUS))
        - AL amyloidosis
        - Chronic B-cell lymphoproliferative disorders (chronic lymphocytic leukaemia, follicular lymphoma)
        - Myelodysplastic syndrome (MDS)
        - Chronic myelomonocytic leukaemia (CMML)
        - Myelofibrosis
    - All people with sickle cell disease
    - People with thalassaemia or rare inherited anaemia with any of the following (the decision to treat these patients will need to be at the individual patient level with input from the haematology consultant responsible for the management of the patient's haematological condition):
        - Severe cardiac iron overload (T2 *less than 10ms on magnetic resonance imaging)
        - Severe to moderate iron overload (T2 *greater than or equal to 10ms on magnetic resonance imaging) plus an additional co-morbidity of concern (for example, diabetes, chronic liver disease or severe hepatic iron load on MRI)

- Individuals with non-malignant haematological disorders (e.g. aplastic anaemia or paroxysmal nocturnal haemoglobinuria) receiving B-cell depleting systemic treatment (e.g. anti-CD20, antithymocyte globulin (ATG) and alemtuzumab) within the last 12 months

- Renal disease:
  - Renal transplant recipients (including those with failed transplants within the past 12 months), particularly those who have:
    - received B cell depleting therapy within the past 12 months (including alemtuzumab, rituximab [anti-CD20], anti-thymocyte globulin)
    - an additional substantial risk factor which would in isolation make them eligible for nMABs or antivirals
    - not been vaccinated prior to transplantation
  - Non-transplant renal patients who have received a comparable level of immunosuppression. Please refer to section on 'Immune-mediated inflammatory diseases' below for a list of qualifying immunosuppressive therapies
  - Patients with chronic kidney stage (CKD) 4 or 5 (an eGFR less than 30 ml/min/1.73m^2) without immunosuppression
- Liver disease:
  - people with cirrhosis Child-Pugh class A, B and C, whether receiving immune suppressive therapy or not. Those with decompensated liver disease (Child-Pugh B and C) are at greatest risk
  - people with a liver transplant
  - people with liver disease on immune suppressive therapy (including people with and without liver cirrhosis) – please refer to the section on 'Immune-mediated inflammatory diseases' below for a list of qualifying immunosuppressive therapies
- Patients with immune-mediated inflammatory disorders (IMID):
  - People who have received a B cell depleting therapy in the last 12 months (anti-CD20 drug for example rituximab, ocrelizumab, ofatumab, obinutuzumab)
  - People who have been treated with cyclophosphamide (IV or oral) in the 6 months prior to positive PCR
  - People who are on biologics or small molecule JAK-inhibitors (except anti-CD20 depleting monoclonal antibodies) or who have received these therapies within the last 6 months. (people on monotherapy with biologics as maintenance therapy in IMIDs (including anti-IL17A, anti-IL-6R, anti-BLyS, anti-TNF, anti-IL12/23, vedolizumab and abatacept) appear not to be at significantly increased risk of severe COVID-19 on available evidence but may have variable responses to currently available vaccines; physician discretion is advised in the context of patients in receipt of combination immune modification)
  - People who are on corticosteroids (equivalent to greater than 10mg per day of prednisolone) for at least the 28 days prior to positive PCR
  - People who are on 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) and/or ciclosporin
  - 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)

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 or autoimmune polyendocrinopathy, candidiasis, ectodermal dystrophy (APECED syndrome)
  - Primary immunodeficiency associated with impaired type I interferon signalling
  - X-linked agammaglobulinaemia (and other primary agammaglobulinaemias)
  - Any patient with a secondary immunodeficiency receiving, or eligible for, immunoglobulin replacement therapy
- HIV/AIDS
  - people with high levels of immune suppression, have uncontrolled or untreated HIV (high viral load) or present acutely with an AIDS defining diagnosis
  - people on treatment for HIV with CD4 <350 cells/mm3 and stable on HIV treatment or CD4 >350 cells/mm3 and additional risk factors (e.g. age, diabetes, obesity, cardiovascular, liver or renal disease, homeless, alcohol-dependency). The use of CD4 counts to assess eligibility for treatment applies only to those patients for whom CD4 counts are used to monitor for treatment compliance and/or levels of immune compromise. Where CD4 coutns are not known, but concerns remain around potential immune compromise, discussion with the patient's HIV team is advised.
    - On 191221 *British HIV Association (BHIVA) suggested the following be considered additional risk factors: age 55 years or older, diabetes requiring treatment (i.e. not just diet-controlled), BMI >30, chronic kidney disease (eGFR <60ml/min), liver cirrhosis, congestive heart failure (New York Heart Association class II, III or IV), moderate to severe asthma - more info here*
- Solid organ transplant recipients: solid organ transplant recipients not in any of the above categories
- Rare neurological and severe complex life-limiting neurodisability conditions: An NHS England and Improvement (NHSEI) expert group has identified the key conditions are:
  - Multiple sclerosis (many of the immune modifying therapeutics used in MS are already covered in the other recommendations under the wider category of IMIDs)
  - Motor neurone disease
  - Myasthenia gravis
  - Huntington's disease

Updated: 130622
Full guidance: https://www.gov.uk/government/publications/higher-risk-patients-eligible-for-covid-19-treatments-independent-advisory-group-report/defining-the-highest-risk-clinical-subgroups-upon-community-infection-with-sars-cov-2-when-considering-the-use-of-neutralising-monoclonal-antibodies

British HIV Association additional guidance: https://www.bhiva.org/update-on-COVID-treatments-for-people-with-HIV