Factsheet: Eligible patient groups for the LFD service

The National Institute for Health and Care Excellence (NICE) has published guidance which lists the risk factors for progression to severe COVID-19 in young people aged between 12 and 17 years and adults. These patients are therefore potentially eligible for COVID-19 treatments should they catch COVID-19 and are eligible to access free LFD test kits from community pharmacies under the NHS Lateral Flow Device tests supply service for patients potentially eligible for COVID-19 treatments (Advanced service) (the LFD service).

A copy of the risk factors from the NICE guidance has been included below; pharmacy owners can choose to print this as a reference to assist with checking a patient's eligibility for the service.

Risk factors for progression to severe COVID-19 in adults defined by the independent advisory group commissioned by the Department of Health and Social Care (June 2023)

Down's syndrome and other genetic disorders

All individuals with Down's syndrome or other chromosomal disorders known to affect immune competence

Solid cancer

- metastatic or locally advanced inoperable cancer
- lung cancer (at any stage)
- people receiving any chemotherapy (including antibody-drug conjugates), PI3K inhibitors or radiotherapy within 12 months
- people who have had cancer resected within 3 months and who received no adjuvant chemotherapy or radiotherapy
- people who have had cancer resected within 3 to 12 months and receiving no adjuvant chemotherapy or radiotherapy are expected to be at 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 versus 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 CAR-T cell therapy in the last 24 months, or until the lymphocyte count is within the 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, 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
  - any mature T-cell malignancy
- all people with sickle cell disease
- people with thalassaemia or rare inherited anaemia with any of the following:
  - severe cardiac iron overload (T2 * less than 10 ms)
  - severe to moderate iron overload (T2 * greater than or equal to 10 ms) plus an additional comorbidity of concern (for example, diabetes, chronic liver disease or severe hepatic iron load on MRI)
- individuals with non-malignant haematological disorders (for example, aplastic anaemia or paroxysmal nocturnal haemoglobinuria) receiving B-cell depleting systemic treatment (for example, anti-CD20, anti-thymocyte 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], ATG)
  - an additional substantial risk factor which would in isolation make them eligible for monoclonals or oral antivirals
- non-transplant renal patients who have received a comparable level of immunosuppression
- patients with chronic kidney disease (CKD) stage 4 or 5 (an estimated glomerular filtration rate [eGFR] less than 30 ml per min per 1.73 m^2) without immunosuppression

Liver diseases

- people with cirrhosis Child-Pugh (CP) class A, B and C, whether receiving immune suppressive therapy or not. Those with decompensated liver disease (CP 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 cirrhosis)

Solid organ transplant recipients

Solid organ transplant recipients not in any of the above categories

Immune-mediated inflammatory disorders (diseases in which autoimmune or autoinflammation-based pathways are implicated in disease, for example, inflammatory arthritis, connective tissue diseases, inflammatory skin diseases, inflammatory gastrointestinal disease)

- people who have received a B-cell depleting therapy (anti-CD20 drug, for example, rituximab, ocrelizumab, ofatumab, obinutuzumab) in the last 12 months
- people who have been treated with cyclophosphamide (IV or oral) in the 6 months prior to positive PCR or relevant COVID test
- people who are on corticosteroids (equivalent to or greater than 10 mg per day of prednisolone) for at least the 28 days prior to positive PCR
- people who are on biologics or small molecule JAK inhibitors
- people who are on current treatment with mycophenolate mofetil, oral tacrolimus, azathioprine, mercaptopurine, or similar agents (for major organ involvement such as kidney, gastro-intestinal tract, liver, lung, brain), methotrexate (for interstitial lung disease or asthma only) and/or ciclosporin. No minimum dose threshold is suggested
- 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
- 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) other high risk

comorbidities (for example, body mass index [BMI] greater than 30, diabetes mellitus, hypertension, major organ involvement such as significant kidney, liver, nervous system or lung inflammation or significantly impaired renal, liver, nervous system and/or lung function)

Respiratory

- asthma in people on oral corticosteroids (defined above). Any asthma patient taking immunosuppressants for their asthma including but not exclusively methotrexate, ciclosporin
- COPD on long term home non-invasive ventilation (NIV). Patients on long term oxygen therapy. People with moderate or severe disease (FEV1 less than or equal to 50% predicted) who have required 4 or more courses of prednisolone 30 mg for 5 days or greater in last 12 months
- interstitial lung disease (ILD) – all patients with idiopathic pulmonary fibrosis
- sub-types of ILD, for example, connective tissue disease related, sarcoidosis, hypersensitivity pneumonitis, NSIP (non-specific interstitial pneumonia) who have received a B-cell depleting therapy in last 12 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, cyclosporin or methotrexate. No minimum dose criteria
- any people 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 and tracheostomy ventilated – all patients requiring this type of support regardless of the underlying disorder (which might include COPD, obesity hypoventilation syndrome, scoliosis, bronchiectasis, neurodisability and genetic muscular diseases [refer to neurology section]).
- lung cancer patients, refer to 'Solid cancer' section above
- lung transplant patients (refer to solid organ transplant section)
- pulmonary hypertension (PH): groups 1 and 4 from PH classification

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 1 interferon signalling
- X-linked agammaglobulinaemia (and other primary agammaglobulinaemias)
- any person with 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 less than 350 cells per mm^3 and stable on HIV treatment or CD4 greater than 350 cells per mm^3 and additional risk factors (for example, age, diabetes, obesity, cardiovascular, liver or renal disease, homeless, alcoholic dependency)

Neurological disorders

- 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, neurodegenerative and neuroimmune disorders when associated with severe frailty (for example, levels 7 or 8 on Clinical Frailty Scale, as part of a personalised care plan):
  - 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

Risk factors for progression to severe COVID-19 in young people aged 12 to 17 years

Pathway for PCR positive symptomatic cases aged older than 12 and younger than 18 years, greater than 40 kg weight, and clinical concern: defined by the independent advisory group commissioned by the Department of Health and Social Care (March 2023)

Non-hospitalised individuals in the older than 12 and younger than 18 years age range considered at high risk from COVID-19 and to be prioritised for consideration of treatment with neutralising monoclonal antibodies when symptomatic and SARS-CoV-2 PCR positive. Concerned clinicians should refer for regional multidisciplinary team (MDT) case discussion through local established pathways, who will confirm eligibility and consider risk benefit and whether to proceed with offer of treatment.

Children and young people (CYP) at substantial risk

Complex life-limiting neurodisability with recurrent respiratory infections or compromise.

CYP at significant risk if 2 or more of these risk factors are present

Primary immunodeficiency:

- common variable immunodeficiency (CVID)
- primary antibody deficiency on immunoglobulin (or eligible for immunoglobulin replacement)
- 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 1 interferon signalling
- X-linked agammaglobulinaemia (and other primary agammaglobulinaemias)

Secondary immunodeficiency:

- HIV CD4 count less than 200 cells per mm^3
- solid organ transplant
- haematological stem cell transplant (HSCT) within 12 months, or with graft versus host disease (GVHD)
- CAR-T cell therapy in last 24 months
- induction chemotherapy for acute lymphoblastic leukaemia (ALL), non-Hodgkin's lymphoma, chemotherapy for acute myeloid leukaemia (AML), relapsed and/or refractory leukaemia or lymphoma

Immunosuppressive treatment:

- chemotherapy within the last 3 months
- cyclophosphamide within the last 3 months
- corticosteroids greater than 2 mg per kg per day for 28 days in last 4 weeks
- B-cell depleting treatment in the last 12 months

Other conditions:

- high body mass index (BMI; greater than 95th centile)
- severe respiratory disease (for example, cystic fibrosis or bronchiectasis with FEV1 less than 60%)
- tracheostomy or long-term ventilation
- severe asthma (paediatric intensive care unit [PICU] admission in 12 months)
- neurodisability and/or neurodevelopmental disorders
- severe cardiac disease
- severe chronic kidney disease
- severe liver disease
- sickle cell disease or other severe haemoglobinopathy
- trisomy 21
- complex or chromosomal genetic or metabolic conditions associated with significant comorbidity
- multiple congenital anomalies associated with significant comorbidity
- bronchopulmonary dysplasia – decisions should be made taking into account degree of prematurity at birth and chronological age
- infants less than 1 year with congenital heart disease (CHD):
    - cyanotic CHD
    - haemodynamically significant acyanotic CHD and history of prematurity
    - those due for corrective surgery, to avoid complications or delay due to SARS-CoV-2 infection