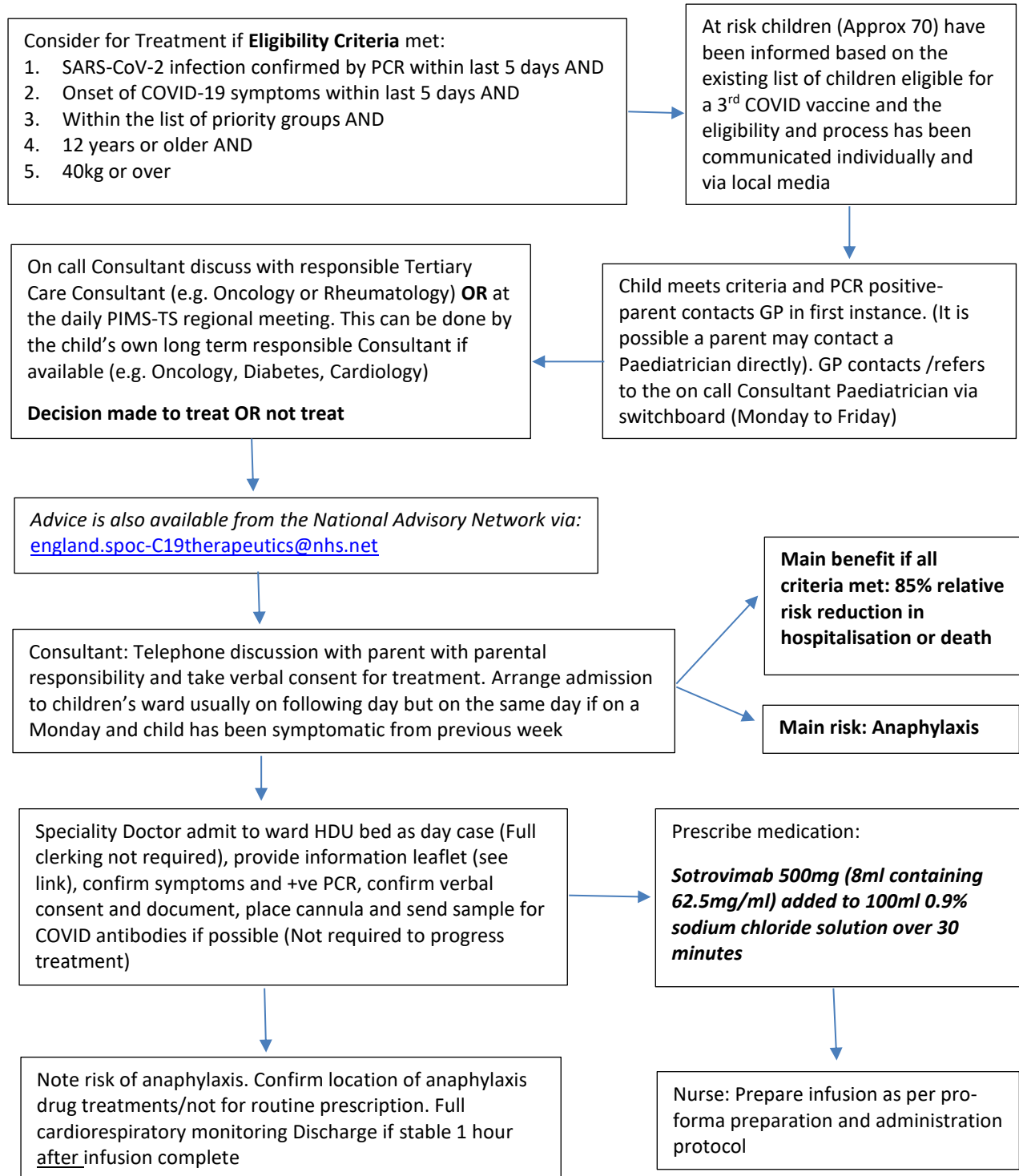


Standard Operating Procedure (SOP) for the provision of Sotrovimab (Xevudy) in the management of non-hospitalised CHILDREN with COVID-19 Infection and eligible for treatment

For the purpose of this SOP children are defined as: up to the 16th birthday AND children from the 16 birthday to 18th birthday who remain **within the active caseload of a Consultant Paediatrician**
Exclusions: Hypersensitivity to Sotrovimab or Excipients

NB: Treatment window is within 5 days of onset of symptoms



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Risk Groups (From RCPCH Guidance- see link in references)

Non-hospitalised patient cohorts in the 12-17 years age range considered at highest risk from COVID-19 and to be prioritised for consideration of treatment with neutralising monoclonal antibodies when symptomatic and SARS-CoV-2 PCR positive

CYP at significant risk
<p>Neuro-disability</p> <ul style="list-style-type: none"> • Complex life-limiting neuro-disability with recurrent respiratory infections/compromise
CYP at significant risk if 2 or more of these risk factors are present

<p>Primary immunodeficiency</p> <ul style="list-style-type: none"> • 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 /autoimmune polyendocrinopathy, candidiasis, ectodermal dystrophy (APECED syndrome) • Primary immunodeficiency associated with impaired type I interferon signalling • X-linked agammaglobulinaemia (and other primary agammaglobulinaemias)
<p>Secondary immunodeficiency</p> <ul style="list-style-type: none"> • HIV CD4 count <200 cells/mm³ • Solid organ transplant • HSCT within 12 months, or with GVHD • CAR-T 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
<p>Immunosuppressive treatment</p> <ul style="list-style-type: none"> • Chemotherapy within the last 3 months • Cyclophosphamide within the last 3 months • Corticosteroids >2mg/kg/day for 28 days in last 4 weeks • B cell depleting treatment in the last 12 months

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Other conditions

- High BMI (>95th Centile)
- Severe respiratory disease (e.g. CF or bronchiectasis with FEV1 <60%)
- Tracheostomy or long term ventilation
- Severe asthma (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 genetic or metabolic conditions associated with significant comorbidity
- Multiple congenital anomalies associated with significant comorbidity

References:

1. NHS Interim Clinical Commissioning Policy: nMABs or antivirals for non-hospitalised patients with COVID-19 (Published 16th December 2021, Effective from 20 December 2021
(https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103877)
2. EMC/medicines.org.uk **product information**
(<https://www.medicines.org.uk/emc/product/13097/smpc>)
3. EMC/medicines.org.uk **patient leaflet**
(<https://www.medicines.org.uk/emc/product/13097/pil>)
4. RCPCH guidance
<https://www.rcpch.ac.uk/resources/covid-19-management-children-hospital-and-non-hospitalised#treatment-criteria-for-covid-19-specific-therapy>