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SCHEDULE 2 – THE SERVICES

A. Service Specifications

1. Service name	Specialist immunology services for adults with deficient immune systems
2. Service specification number	B09/S/a – 241219S
3. Date published	19/12/2024
4. Accountable Commissioner	NHS commissioning » Blood and infectionBlood and Infection Programme of Care england.npoc-bloodandinfection@nhs.net

5.	**Population and/or geography to be served**
5.1	**Population covered** This service specification relates to adults aged 18 years and over. Young people aged 16 and 17 years old may be treated in an adult specialist immunology service and will be considered on a case-by-case basis.
5.2	**Minimum population size** Specialist immunology services would normally be expected to serve a population size of at least 1.5 million. In specific circumstances, for example when populations are spread across wide geographical areas, specialist immunology services may serve a smaller population, however under these circumstances they must be networked with other specialist immunology services to ensure breadth of experience.
6.	**Service aims and outcomes**
6.1	**Service aims** Specialist immunology services, which include inborn and acquired errors of immunity (excluding HIV), aim to: • Improve life expectancy and health-related quality of life (QoL) of service users through the diagnosis and management of immune deficiency/dysregulation disorders and implementing treatment to improve short and long term outcomes; • Minimise the time taken to diagnosis to avoid unnecessary long-term complications;

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- Deliver multidisciplinary specialist care, ensuring access to advanced therapies such as gene therapies, HSCT and novel agents, through referral to and in collaboration with other specialist services according to best practice guidelines e.g. those defined by the British Society for Immunology Clinical Immunology Professional Network (BSI-CPIN) and European Society for Immunodeficiencies (ESID);
- Develop approaches to service user management, based on individual needs, for the replacement of immunoglobulin and other therapies for service users with immunodeficiency, Hereditary Angioedema (HAE), acquired C1 inhibitor deficiency, complex autoimmunity and autoinflammatory syndromes, including self-administration of treatment / home therapy;
- Ensure equity of access to specialist care and outcomes for service users.

6.2 Outcomes

NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	P
Domain 2	Enhancing quality of life for people with long-term conditions	P
Domain 3	Helping people to recover from episodes of ill-health or following injury	P
Domain 4	Ensuring people have a positive experience of care	P
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	P

Service defined outcomes/outputs

Reference	Domain	Rationale	Indicator
N/A	2	Disease control is an important outcome for service users	Proportion of service users with stable or improved disease control
N/A	2	Service aims to reduce impact of condition on health-related QoL of the service user	Proportion of service users with stable or improved health-related QoL 12 months after treatment

All centres must be registered and actively working towards or have achieved Quality in Primary Immunodeficiency Services (QPIDS) accreditation. Centres that are not yet accredited must have a Trust action plan demonstrating progress towards accreditation. Accreditation involves evaluating a service against a set of standards to promote a culture of continuous improvement, thereby providing assurance to service users, referrers and commissioners about the quality of the service provided.

All centres are expected to participate in the United Kingdom Primary Immunodeficiency (UKPID) registry data collection. The UKPID registry is the UK

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	version of the ESID. This registry collects data on service users with inborn errors of immunity (IEI) across Europe and, for the UK, service users with secondary antibody deficiencies. The registry allows the collation of datasets on clinical diagnosis and outcomes for these rare disorders. These data are made available to research collaborators to improve service user outcomes. Service users with a known or suspected IEI, and service users with secondary antibody deficiencies, should be approached at the earliest available opportunity to consent for inclusion onto the registry. Their clinical data should be uploaded to the registry and updated on an annual basis. The full definition of the quality outcomes and metrics together with their descriptions including the numerators, denominators and all relevant guidance will be accessible at NHS commissioning » Specialised services quality dashboards following the next scheduled quarterly refresh of the dashboard metadata document.
7.	**Service description**
7.1	**Service model** Specialist immunology services for adults include the diagnosis and management of people suspected or confirmed to have one of the following diagnoses: • IEI in keeping with the latest International Union of Immunological Societies (IUIS) classification; • Clinically significant immunodeficiencies (excluding HIV) e.g. with recurrent infections; • Hereditary and acquired angioedema; • Complex autoimmune and vasculitic conditions as shared care. The rarity, wide spectrum, severity of complications and associated mortality and complexity of treatments require that these conditions should generally be managed by immunology specialists. All specialist immunology services should be working regionally in networks to enable shared expertise such as through the production of regional protocols. Services may also use local infrastructure to deliver care e.g. satellite infusion units for immunoglobulin replacement.
7.2	**Pathways** Overall patient pathway Referrals may be made from primary, secondary or tertiary care. Specialist immunology services will be expected to support the management of service users receiving complex/novel therapies which cause impairment of immunity. All referrals should be triaged by a member of the specialist team to ensure the referral requires specialist input. If referrals are not accepted advice/guidance must be provided to the referring professional.

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	Services should provide an advice and guidance service using existing NHS platforms. <u>Specialised patient pathway</u> Specialist immunology services incorporate the investigation, clinical assessment, treatment and holistic management of service users. **Diagnosis** The Provider must deliver a diagnostic package of tests for the investigation of the conditions listed in 7.1 above, including initial consultation and follow-up in a dedicated clinic, specialist immunopathological tests, test immunisations, specialist genetic and radiology studies. **Treatment and monitoring** The management of service users under the care of specialist immunology services requires lifelong therapy and regular monitoring to assess response to treatment and to identify complications. Treatment decisions to start high-cost therapies (e.g. immunoglobulin and HAE prophylaxis) must be agreed and documented at a multi-disciplinary team meeting with a minimum of two Consultant Clinical Immunologists and specialist nursing representation. The Provider must deliver hospital-based outpatient and day-care with access to inpatient facilities. Outpatient care must be provided with sufficient clinic numbers and staff to accommodate the service user cohort within clinically appropriate timeframes and maintain QPIDS accreditation. As a minimum this will comprise: • Adequate staffing and clinic space for regular face-to-face and remote outpatient clinics for assessment and follow-up. The service must have the capacity to review service users in clinic face-to-face when clinically indicated; • Access to appropriate organ-based specialists to manage complex muti-organ disease, ideally within an in-person or virtual multi-disciplinary setting; • Access to an appropriately staffed designated day case unit that can provide intravenous or subcutaneous immunoglobulin infusions and novel therapies. Staff within the unit should be working to the BSI-CIPN competency framework for immunology nursing or overseen by specialist nurses working to these standards; • Adequate space and staffing to deliver home therapy training effectively in accordance with QPIDS standards; • Advice from specialist nursing and medical staff with expertise in specialist immunology must be available to service users and other health care providers during office hours; • Service users will be provided with a documented personal management package with a plan for acute and long-term treatment (including home therapy where appropriate) and prophylaxis (including high cost specialised and novel therapies) and regular follow up including monitoring, bloods, lung function testing and radiology;

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	• The Provider must ensure that pathways for out of hours access to appropriate emergency care are locally agreed and that service users are aware of the arrangements. Policies must be in place for access to antibiotics for infections, treatment for angioedema attacks and admission if indicated; • Services should have processes in place to identify service users who require specialist protocols for out of hours or urgent care; • Services should liaise with urgent care services to utilise local systems for early identification of service users under the care of the specialist immunology service (e.g. using Emergency Department alert systems); • Services should work collaboratively with urgent care services to guide the management of users of the immunology service should they present acutely; Services must work with other specialist teams to appropriately manage service users requiring new treatments. This needs multi-disciplinary oversight, ensuring robust governance and interaction with appropriate specialist networks; • Where service users transfer to a new specialist immunology service, the transferring service must ensure that a formal transfer of care is undertaken to ensure continuity of care, including medication. The Provider must offer service users home therapy when clinically appropriate as an option in their management based on the service user's wishes, abilities and circumstances, to include: • Provision of information about when to seek advice from the centre about obtaining or taking antibiotics and training for the administration of blood products at home; • Training and assessment of competency (for example for self-administration of injected/infused treatments at home); • Provision of home therapy as a package of care on a named service user basis including nursing supervision for C1 inhibitor, replacement immunoglobulin or other novel therapies as appropriate (intravenous or subcutaneous). Provision of infusion sets, pumps for subcutaneous delivery, and deliveries of consumables to service users' homes. Arrangements for regular outpatient consultations with monitoring of antibody levels, blood counts, lung function and liver function tests; • The Provider must ensure that all home care programmes are working to QPIDS home therapy standards. <u>Shared care arrangements</u> Service users will often have shared care with other organ-based medical specialties, other units and/or primary care. Depending on the nature of the immune disease, services are involved in shared care in relation to general medical needs, delivery of antibiotics and, for some service users, immunoglobulin therapy. There should be regular communication with prescribing teams at other hospitals and with the service user's primary care team, including copies of clinical correspondence and clear communication of treatment plans.

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	Transition All healthcare services are required to deliver developmentally appropriate healthcare to service users and families. Children and young people with ongoing healthcare needs may be required to transition into adult services from children's services. Transition is defined as a 'purposeful and planned process of supporting young people to move from children's to adults' services'. Poor planning of transition and transfer can result in a loss in continuity of treatment, service users being lost to follow up, service user disengagement, poor self-management and inequitable health outcomes for young people. It is therefore crucial that adult and children's NHS services, in line with what they are responsible for, plan, organise and implement transition support and care (for example, holding joint annual review meetings with the child/young person, their family/carers, the children's and adult service). This should ensure that young people are equal partners in planning and decision making and that their preferences and wishes are central throughout transition and transfer. NICE guidelines recommend that planning for transition into adult services should start by age 13-14 years at the latest, or as developmentally appropriate and continue until the young person is embedded in adult services. Centres should refer to the Paediatric Medicine Immunology and Infectious Diseases Service Specification.
7.3	**Clinical networks** The Provider is required to participate in a networked model of care with other specialist immunology centres to enable services to be delivered as part of a co-ordinated, combined whole system approach.
7.4	**Essential staff groups** Specialist immunology services will be delivered by a multi-disciplinary team due to the complex nature of the conditions (see section 7.6 below). This must include: • At least two Consultant Clinical Immunologists with experience in the management of service users with the conditions listed in 7.1 above and who maintain up to date Continuing Professional Development (CPD) in their area of practice (single handed practice can occur within a managed clinical network with evidence of MDT working, meeting QPIDS standards and all other requirements outlined here); • Senior Specialist Nurses with immunology experience and training to provide nursing care, training and run home treatment programmes in accordance with QPIDS standards. The Provider should also ensure access to psychologists, genetic counsellors, dieticians and social workers for service users as required. The Provider should ensure access to clinical pharmacists with expertise in immunology and pharmacy support staff to assist in medicines optimisation and

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	safety, cost-effective prescribing, service user training and education in relation to prescribed treatments, medication access, and management of homecare services. There should also be pharmacy support for the maintenance of the MDSAS National Immunoglobulin Database.
7.5	**Essential equipment and/or facilities** The Provider must provide outpatient and day case facilities for the review and treatment of service users. Facilities for home therapy training must also be available. The Provider should meet the relevant minimum standards for facilities outlined in the QPIDS standards. The Provider must have appropriate pharmacy facilities including: • Appropriate storage and dispensing facilities for drugs and immunoglobulin products; • Pharmacy storage facilities for immunological therapies and good documentation of dispensing to individual service users. The Provider must have access to a specialist immunology laboratory service with United Kingdom Accreditation Service (UKAS) accreditation or equivalent.
7.6	**Interdependent service components – links with other NHS services** Clinical immunologists must liaise with other specialties as clinically appropriate. They should also engage in national MDTs for complex decision making. The Provider must work with specialist paediatric services to provide robust referral pathways for young people transitioning into adult immunology services. The Provider must have access to advice and an agreed referral pathway or joint working for other organ based specialists. The Provider should ensure close input from respiratory clinicians including access to respiratory physiotherapy. Service users with respiratory disease should be managed in a joint clinic/MDT with a consultant respiratory physician. The Provider should ensure close input from gastroenterology and hepatology teams, with access to joint clinics/MDTs for service users with gastrointestinal/hepatological complications of their underlying immunological disorder. The Provider should have access to and work with clinical genetic services.
7.7	**Additional requirements** None
7.8	**Commissioned providers** The list of commissioned Providers for the services covered by this specification will be published in due course.

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7.9	**Links to other key documents** Please *refer to the Prescribed Specialised Services Manual for* information on how the services covered by this specification are commissioned and contracted for. Please refer to the Identification Rules tool for information on how the activity associated with the service is identified and paid for. Please refer to the relevant Clinical Reference Group webpages for NHS England Commissioning Policies which define access to a service for a particular group of service users. The specific clinical policies that relate to the services covered by this service specification include: • Allogeneic haematopoietic stem cell transplant for primary immunodeficiencies (all ages) • Anakinra to treat periodic fevers and autoinflammatory diseases (all ages) • Baricitinib for use in monogenic interferonopathies (adults and children 2 years and over) • Canakinumab for treating periodic fever syndromes: TRAPS, HIDS/MKD and FMF (ages 2 years and older) • Plasma-derived C1-esterase inhibitor for Prophylactic treatment of hereditary angioedema (HAE) types I and II • Rituximab for cytopaenia complicating primary immunodeficiency • Use of therapeutic immunoglobulin in England • Tocilizumab for the treatment of adult-onset Still's disease refractory to second-line therapy (adults) • Treatment of acute attacks in hereditary angioedema (adult) Other key documents are as follows: QPIDS publicly available accreditation standards December 2019.pdf British Society for Immunology and United Kingdom Primary Immunodeficiency Network (UKPIN) consensus guideline for the management of immunoglobulin replacement therapy | Clinical and Experimental Immunology | Oxford Academic (oup.com) National genomic test directory

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Change form for published Specifications and Products developed by Clinical Reference Group (CRGs)

Product name: Specialist immunology services for adults with deficient immune systems

Publication number: B09/S/a – 241219S

CRG Lead: Immunology and allergy CRG Lead / National Programme of Care Senior Manager

Description of changes required

Describe what was stated in original document	Describe new text in the document	Section/Paragraph to which changes apply	Describe why document change required	Changes made by	Date change made
Format change: the content of the original service specification has been transferred into the updated NHS England Specialised Service Specification Template. As a result, some sections have been removed in line with guidance to make service specifications shorter, more precise and therefore more accessible.	Formatting changes throughout the document	Throughout	A new service specification template was published in 2022	SWG	May 2023
Terminology updated to refer to Inborn Errors of Immunity (IEI)	Term “Inborn Errors of Immunity (IEI)” used throughout the document	Throughout	Terminology widely used amongst the clinical community in line with the International Union of Immunological Societies (2022)	SWG	Jan 2024

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Service: Specialised Immunology (All Ages)	Service name: Specialist immunology services for adults with deficient immune systems	Service / Service name	Service name updated to reflect the Prescribed Specialised Services Manual	SWG	May 2023
National/local context and evidence base	None	1.1 National/local context and evidence base	National/local context and evidence base section not required in new template	SWG	May 2023
1.1 National/local context and evidence base All centres are expected to participate in national registry data collection 3.1 Applicable national standards The provider shall deliver a means for populating national and international disease registries including the UK PID Registry	All centres are expected to participate in the United Kingdom Primary Immunodeficiency (UKPID) registry data collection. The UKPID registry is the UK version of the European Society for Immunodeficiencies Registry (ESID). This registry collects data on service users with inborn errors of immunity (IEI) across Europe and, for the UK, service users with secondary antibody deficiencies. The registry allows the collation of datasets on clinical diagnosis and outcomes for these rare disorders. These data are	1.1 National/local context and evidence base & 3.1 Applicable national standards / 6.2 Outcomes	To reflect update to national registry	SWG	Aug 2024

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	made available to research collaborators to improve service user outcomes. Service users with a known or suspected IEI, and service users with secondary antibody deficiencies, should be approached at the earliest available opportunity to consent for inclusion onto the registry. Their clinical data should be uploaded to the registry and updated on an annual basis.				
The provider shall ensure that Specialist Immunology centres will provide: • A high quality, accessible and sustainable service that meets the needs of the local population and reflects effective resource use and incorporates the views of patients. • Excellent, holistic, multidisciplinary care for patients with immunodeficiency, complex autoimmunity and auto-inflammatory syndromes according to best practice guidelines defined by UKPIN,	Specialist immunology services, which include inborn and acquired errors of immunity (excluding HIV), aim to: • Improve life expectancy and health-related quality of life (QoL) of service users through the diagnosis and management of immune deficiency/dysregulation disorders and implementing treatment to improve short and long term outcomes;	2.1 Aims and objectives of service / 6.1 Service aims	Amended to make more succinct and reflect feedback from clinicians and service users on key aims	SWG	Oct 2024

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ESID and other authoritative bodies. • The expertise and facilities required for the investigation, clinical assessment, treatment and holistic management of patients with suspected and established primary immunodeficiencies, autoimmune diseases associated with primary immunodeficiencies and autoinflammatory syndromes. • Equity of access to best practice standards, based on current guidelines for diagnosis and management for patients with PID and related complications. Integrated care with primary, secondary and other care providers and ensure close links and collaboration with other expert centres at national and international levels. Train future specialists to maintain service continuity. The service will deliver the aim to improve both life expectancy and quality of life for adults with immunodeficiencies by:	• Minimise the time taken to diagnosis to avoid unnecessary long-term complications; • Deliver multidisciplinary specialist care, ensuring access to advanced therapies such as gene therapies, HSCT and novel agents, through referral to and in collaboration with other specialist services according to best practice guidelines e.g. those defined by the British Society for Immunology Clinical Immunology Professional Network (BSI-CPIN) and European Society for Immunodeficiencies (ESID); • Develop approaches to service user management, based on individual needs, for the replacement of immunoglobulin and other therapies for service users with immunodeficiency,				

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• Preventing acute infections or attacks caused by immunodeficiency disorders. • Halting the progress of complications if present and where possible. • Reversing previous psychological damage and disability when possible. • Recognising further complications early and managing them optimally, particularly those not amenable to replacement immunoglobulin therapy. • Avoiding complications of replacement immunoglobulin therapy. • Developing approaches to management, based on individual needs, for the lifelong replacement of immunoglobulin, including self administration/home therapy when possible.	Hereditary Angioedema (HAE), acquired C1 inhibitor deficiency, complex autoimmunity and autoinflammatory syndromes, including self-administration of treatment / home therapy; • Ensure equity of access to specialist care and outcomes for service users.				
• Regular outpatient clinics for assessment and follow-up.	Outpatient care must be provided with sufficient clinic numbers and staff to accommodate the service user cohort within clinically appropriate timeframes and	2.2 Service description/care pathway / 7.2 Pathways	Specify importance of waiting times and meeting accreditation standards	SWG	Apr 2024

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	maintain QPIDS accreditation.				
• Adequate clinical space in relation to the number of patients being treated.	• Adequate staffing and clinic space for regular face-to-face and remote outpatient clinics for assessment and follow-up. The service must have the capacity to review service users in clinic face-to-face when clinically indicated	2.2 Service description/care pathway / 7.2 Pathways	Remote clinics now part of standard practice	SWG	Jan 2024
• Adequate space for patients receiving infusion or training.	• Adequate space and staffing to deliver home therapy training effectively in accordance with QPIDS standards	2.2 Service description/care pathway / 7.2 Pathways	Additional clarity and reference to accreditation standards	SWG	Jan 2024
• A safe working environment for staff.	None	2.2 Service description/care pathway	Removed as part of standard contract	SWG	Aug 2024
• Access to an appropriately staffed designated day case unit that can provide Biologic and Cytotoxic infusion facilities. This service should be supported by clear guidelines, protocols, and pathways for patient care, in which are embedded the key principles of Chemotherapy safety, As outlined in the document “Chemotherapy	• Access to an appropriately staffed designated day case unit that can provide intravenous or subcutaneous immunoglobulin infusions and novel therapies. Staff within the unit should be working to the BSI-CIPN competency framework	2.2 Service description/care pathway / 7.2 Pathways	Language updated to reflect current treatments and standards of care	SWG	Jan 2024

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Services in England: Ensuring quality and safety. A report from the National Chemotherapy Advisory Group August 2009" adopted where appropriate for use in non-cancer chemotherapy.	for immunology nursing or overseen by specialist nurses working to these standards				
The provider shall have access to support from other clinical specialties for complications of PID including: • Ear, Nose and Throat Medicine, Respiratory Medicine, Gastroenterology, Infectious Diseases, Haematology/ Oncology, Paediatrics, Clinical Genetics, Rheumatology	• Access to appropriate organ-based specialists to manage complex muti-organ disease, ideally within an in-person or virtual multi-disciplinary setting	2.2 Service description/care pathway / 7.2 Pathways	More concise and to specify importance of MDT	SWG	Jan 2024
• Specialised Immunology Laboratory services with CPA accreditation or equivalent. • Access to diagnostics for rare and emerging diseases through European/USA laboratories.	• The Provider must have access to a specialist immunology laboratory service with United Kingdom Accreditation Service (UKAS) accreditation or equivalent.	2.2 Service description/care pathway / 7.5 Essential equipment and/or facilities	To reflect updated standard	SWG	Feb 2024
The provider shall have appropriate pharmacy facilities including: • Pharmacy support for maintenance of the Immunoglobulin demand	• The Provider should ensure access to clinical pharmacists with expertise in immunology and pharmacy support staff to assist in medicines	2.2 Service description/care pathway / 7.4 Essential staff groups	Additional clarity	SWG	Jan 2024

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management programme database	optimisation and safety, cost-effective prescribing, service user training and education in relation to prescribed treatments, medication access, and management of homecare services. There should also be pharmacy support for the maintenance of the MDSAS National Immunoglobulin Database.				
• The provider shall provide patient self-care	• The Provider must offer service users home therapy when clinically appropriate	2.2 Service description/care pathway / 7.2 Pathways	Additional clarity	SWG	May 2024
• Competency testing (for example after home therapy training).	• Training and assessment of competency (for example for self-administration of injected/infused treatments at home)	2.2 Service description/care pathway / 7.2 Pathways	Additional clarity	SWG	Aug 2024
• The provider shall ensure that all home care programmes should be accredited through UKPIN	• The Provider must ensure that all home care programmes are working to QPIDS home therapy standards.	2.2 Service description/care pathway / 7.2 Pathways	To reflect updated standards	SWG	Feb 2024
Patients with confirmed PID requiring regular immunoglobulin replacement therapy will be	• Service users will be provided with a documented personal	2.2 Service description/care	Expanded to cover all service users, not just	SWG	Feb 2024

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provided with a management package comprising: • Day case attendance every 1-3 weeks, nursing supervision, drugs, intravenous (IVIG) or subcutaneous (SCIG) immunoglobulin, pumps for SCIG, monitoring by specialised immunopathological tests, radiological imaging, lung function tests, biochemical tests, medical follow-up, monitoring for efficacy and adverse effects and control of this expensive/scarce product. • Acute and long-term management for patients who require C1 esterase inhibitor (or other high cost parenteral drugs) for treatment or prophylaxis (e.g. surgical, dental or investigational procedures) including managing those patients on home therapy. • Management of those immunodeficiencies requiring other/new treatments (e.g. monoclonal antibodies or cytokines) on a named patient basis, where there is a suitable evidence base. This includes day case attendance, nursing	management package with a plan for acute and long-term treatment (including home therapy where appropriate) and prophylaxis (including high cost specialised and novel therapies) and regular follow up including monitoring, bloods, lung function testing and radiology	pathway / 7.2 Pathways	those on regular immunoglobulin replacement therapy. More concise.		

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supervision, the drug, pumps for subcutaneous or intravenous use, monitoring by biochemical tests, specialised immunopathological tests and medical follow-up.					
• At least two Consultant Clinical Immunologists or equivalent with experience in management of patients with PID and who maintain up-to-date CPD in their area of practice (see comments above on single-handed practice).	• At least two Consultant Clinical Immunologists with experience in the management of service users with the conditions listed in 7.1 above and who maintain up to date Continuing Professional Development (CPD) in their area of practice (single handed practice can occur within a managed clinical network with evidence of MDT working, meeting QPIDS standards and all other requirements outlined here)	2.2 Service description/care pathway / 7.4 Essential staff groups	Original specification did not include comments on single-handed practice as stated	SWG	Apr 2024
The provider shall provide transition services: • For children with PID before referral to adult services based on the framework recommended by the Department of Health.www.dh.gov.uk/transition	Transition is defined as a 'purposeful and planned process of supporting young people to move from children's to adults' services'. Poor planning of transition and transfer can result in a	2.2 Service description/care pathway / 7.2 Pathways	Updated with generic wording on Transition	SWG	May 2023

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Children with PID are transferred to the adult service between the ages of 16 and 18 years. • Transfer arrangements and preferences should be discussed with the child and their family up to 12 months in advance. Shared protocols between child and adult services should be established, defining the roles and responsibilities of each member of the teams.	loss in continuity of treatment, service users being lost to follow up, service user disengagement, poor self-management and inequitable health outcomes for young people. It is therefore crucial that adult and children's NHS services, in line with what they are responsible for, plan, organise and implement transition support and care (for example, holding joint annual review meetings with the child/young person, their family/carers, the children's and adult service). This should ensure that young people are equal partners in planning and decision making and that their preferences and wishes are central throughout transition and transfer. NICE guidelines recommend that planning for transition into adult services should start by age 13-14 at the latest, or as developmentally appropriate and continue until the young				

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	person is embedded in adult services.				
The provider shall maintain the following links: Secondary care links • Depending on the nature of the immune disease, services are involved in shared care in relation to general medical needs, delivery of antibiotics and, for some patients, immunoglobulin therapy (small number of patients receive Ig therapy at peripheral hospitals) with: Primary care links • Care plans of PID patients are shared with primary care. • Antibiotic guidelines are shared with general practitioners. • Home therapy and management is arranged in liaison with CCGs. • Clinic letters are sent to GPs and other specialties involved in a patient's care.	• Service users will often have shared care with other organ-based medical specialties, other units and/or primary care. Depending on the nature of the immune disease, services are involved in shared care in relation to general medical needs, delivery of antibiotics and, for some service users, immunoglobulin therapy. There should be regular communication with prescribing teams at other hospitals and with the service user's primary care team, including copies of clinical correspondence and clear communication of treatment plans.	2.2 Service description/care pathway / 7.2 Pathways	Revised wording to fit with shared care arrangements section of new template	SWG	Oct 2024
Private sector and third sector links • The service shall maintain a strong liaison with Primary Immunodeficiency Patient Groups – including the Chronic	None	2.2 Service description/care pathway	Not required in new template	SWG	Nov 2023

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Granulomatous Disorder Society, Hereditary Angioedema UK, Genetic Disorders UK, Genetic Alliance, Wiscott Aldrich Society, Max Appeal (Di George Society), UK Primary Immunodeficiency Patient Society, etc) to provide further community support and continuity of care.					
The provider shall ensure Home therapy delivery services are available and may be contracted out to third party suppliers for delivery agency of immunoglobulin and C1 inhibitor concentrate products to patients' homes.	None	2.2 Service description/care pathway	Removed as home therapy covered included elsewhere in document	SWG	Nov 2023
Referrals can be made from both primary and secondary care as follows: • Due to the complex nature of PIDs, tertiary referrals into the immunology services come from Tier 2 (general physicians) or other Tier 3 tertiary or specialist physicians (particularly respiratory, ENT, gastroenterology and haematology). • Primary Care Physicians (Tier 1) may also refer patients directly to	Referrals may be made from primary, secondary or tertiary care. Specialist immunology services will be expected to support the management of service users receiving complex/novel therapies which cause impairment of immunity. All referrals should be triaged by a member of the specialist team to ensure the referral requires specialist input. If referrals are not accepted advice/guidance	2.2 Service description/care pathway / 7.2 Overall patient pathway	More concise	SWG	Jan 2024

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the service, though these cases will require screening to ensure the referral requires specialist input. A care pathway with referral guidance should be developed.	must be provided to the referring professional. Services should provide an advice and guidance service using existing NHS platforms.				
Equity of access to services No patient should have to travel excessively for access to local expert centres. Patients with rarer diseases requiring referral to a national specialist centre or centres should have equitable access and distance to travel wherever possible, taking account of geographical issues. Some centres provide specialist services to other health economies (Wales, Scotland, NI, Republic of Ireland).	None	2.2 Service description/care pathway	Not required in new template	SWG	Nov 2023
Location(s) of Service Delivery • All current centres in England as above	None	2.2 Service description/care pathway	Not required in new template	SWG	Nov 2023
The provider shall ensure that services are available during office hours.	None	2.2 Service description/care pathway	Removed as part of standard contract	SWG	Nov 2023

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• The provider shall ensure that there is a written agreed patient pathways for dealing with out of hours emergencies and a system for giving out-of-hours advice. These will include antibiotics for infections and C1 inhibitor or Icatibant for angioedema attacks in HAE and admission policies for PID.	• The Provider must ensure that pathways for out of hours access to appropriate emergency care are locally agreed and that service users are aware of the arrangements. Policies must be in place for access to antibiotics for infections, treatment for angioedema attacks and admission if indicated	2.2 Service description/care pathway / 7.2 Pathways	Specify importance of service users being aware of how to access care out of hours	SWG	Jan 2024
Response time & detail and prioritisation	None	2.2 Service description/care pathway	Not required in new template	SWG	Nov 2023
Service user/ carer information The provider shall ensure that centres will provide (in collaboration with patient organisations where they exist): • written disease-specific information leaflets. • periodic educational events for patients. • periodic educational events for GPs. • information to patients and staff about patient support organisations.	None	2.2 Service description/care pathway	Not required in new template	SWG	Nov 2023

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The provider shall ensure that Specialist Centre Staff support patient groups with membership of Medical Advisory panels.					
Entry Criterion Any patient suspected of having a PID or autoinflammatory condition as detailed above. Exit Criterion All patients in whom the above conditions have been excluded. All patients with PID and autoinflammatory conditions will require life-long specialist monitoring for recognition and management of complications of disease and therapy.	None	2.2 Service description/care pathway	Repetition with content in service model and pathways sections	SWG	Nov 2023
The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).	This service specification relates to adults aged 18 years and over. Young people aged 16 and 17 years old may be treated in an adult specialist immunology service and will be considered on a case-by-case basis.	2.3 / 5.1 Population covered	New template guidance and to provide clarity regarding treatment of 16 and 17 year olds.	SWG	Oct 2024

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*Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England. Specifically, this service is for adults with immunodeficiency syndromes requiring specialised intervention and management, as outlined within this specification.					
The provider will ensure that: • Each hub centre will operate in a network with approximately 250 PID patients to maintain sufficient expertise. Each centre develops a regional patient pathway for access to PID services which ensures that only patients with suspected immune deficiency or HAE or associated complications are referred. This can be supported with web-based referral decision tools such as the ESID/UKPIN diagnostic algorithm. http://www.ukpin.org.uk/home/ESID/index.htm	Specialist immunology services would normally be expected to serve a population size of at least 1.5 million. In specific circumstances, for example when populations are spread across wide geographical areas, specialist immunology services may serve a smaller population, however under these circumstances they must be networked with other specialist immunology services to ensure breadth of experience.	2.3 Population covered / 5.2 Minimum Population Size	Amended wording to reflect that the service specification covers other conditions. Repetition with referral information in pathways sections.	SWG	Jan 2024

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The following exclusion criteria shall apply: • Patients with HIV-associated immunodeficiency who will be cared for by physicians in Infectious Diseases and GU Medicine. • Symptoms such as Chronic fatigue syndrome without evidence of immune deficiency.	Specialist immunology services for adults include the diagnosis and management of people suspected or confirmed to have one of the following diagnoses: • IEI in keeping with the latest International Union of Immunological Societies (IUIS) classification; • Clinically significant immunodeficiencies (excluding HIV) e.g. with recurrent infections; • Hereditary and acquired angioedema; • Complex autoimmune and vasculitic conditions as shared care.	2.4 Any acceptance and exclusion criteria / 7.1 Service model	Additional clarity	SWG	Oct 2024
The provider shall have access to related services required for the optimal care of PID patients. Clinical immunologists must liaise closely with colleagues in a range of specialties, including respiratory medicine, ENT surgery, dermatology, haematology, oncology, infectious diseases,	Clinical immunologists must liaise with other specialties as clinically appropriate… The Provider should ensure close input from respiratory clinicians including access to respiratory physiotherapy. Service users with respiratory disease should be managed in a joint clinic/MDT with a	2.5 Interdependencies with other services / 7.6 Interdependent service components – links with other NHS services	Additional clarity	SWG	May 2024

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gastroenterology and ophthalmology and behavioural medicine. The provider shall deliver close input from physiotherapy - essential for the management of the respiratory complications associated with PID.	consultant respiratory physician. The Provider should ensure close input from gastroenterology and hepatology teams, with access to joint clinics/MDTs for service users with gastrointestinal/hepatological complications of their underlying immunological disorder. The Provider should have access to and work with clinical genetic services.				
The provider shall ensure access to social workers, psychologists and dieticians for selected patients completes the package of holistic care required for PID patients.	The Provider should also ensure access to psychologists, genetic counsellors, dieticians and social workers for service users as required.	2.5 Interdependencies with other services / 7.4 Essential staff groups	Updated to include genetic counsellors as part of wider MDT	SWG	Nov 2023
For centres without paediatric immunologists, the provider shall triage and identify patients requiring referral to highly specialised national services for immunodeficiency at GOS and Newcastle= and their collaboration Paediatric Immunology Specialist Services	The Provider must work with specialist paediatric services to provide robust referral pathways for young people transitioning into adult immunology services.	2.5 Interdependencies with other services / 7.6 Interdependent service components –	Updated to reflect current referral pathways	SWG	May 2024

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		links with other NHS services			
While most services do not have access to in-patient beds, admission pathways for PID patients should be established with individualized care plans where necessary.	None	2.5 Interdependencies with other services /	Removed as contradicts 2.2 which states “The provider shall provide hospital-based outpatient and day-care with access to in-patient facilities”	SWG	Nov 2023
3 Applicable Service Standards	7.9 Links to other key documents	3 Applicable Service Standards / 7.9 Links to other key documents	References updated	SWG	Apr 2024
3.1 Applicable national standards: The provider shall ensure that centres achieve UKPIN accreditation. Currently there are 5 fully accredited centres in England with the others registering or preparing for accreditation. This process shall eventually be mandatory for Specialist centres. and Accreditation and Quality Standards • All centres should participate and actively work towards	All centres must be registered and actively working towards or have achieved Quality in Primary Immunodeficiency Services (QPIDS) accreditation. Centres that are not yet accredited must have a Trust action plan demonstrating progress towards accreditation.	3.1 Applicable national standards & 4 Key Service Outcomes / 6.2 Outcomes	Updated to reflect current accreditation programme	SWG	Apr 2024

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UKPIN Accreditation and complete the UKPIN Accreditation Application Form					
Expected Outcomes – Adult Clinical	Service defined outcomes/outputs	4 Key Service Outcomes / 6.2 Outcomes	Updated in line with QNT approach to quality outcomes and metrics development	SWG	July 2024
Clinical governance	None	4 Key Service Outcomes	Not required in new template and network requirements outlined elsewhere in document	SWG	Nov 2023
Coding and Activity monitoring	None	4 Key Service Outcomes	Not required in new template	SWG	Nov 2023
Accreditation and Quality Standards – remaining content	None	4 Key Service Outcomes	Reference made to QPIDS standards throughout document	SWG	Nov 2023
Location of Provider Premises	None	5 Location of Provider Premises	Not required in new template	SWG	Nov 2023
None	The management of service users under the care of specialist immunology services requires lifelong therapy and regular monitoring to assess	7.2 Pathways	To reflect current practice	SWG	Oct 2024

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	response to treatment and to identify complications. Treatment decisions to start high-cost therapies (e.g. immunoglobulin and HAE prophylaxis) must be agreed and documented at a multi-disciplinary team meeting with a minimum of two Consultant Clinical Immunologists and specialist nursing representation.				
None	• Advice from specialist nursing and medical staff with expertise in specialist immunology must be available to service users and other health care providers during office hours	7.2 Pathways	To reflect current practice	SWG	Feb 2024
None	• Services should have processes in place to identify service users who require specialist protocols for out of hours or urgent care; • Services should liaise with urgent care services to utilise local systems for early identification of service users under the	7.2 Pathways	To provide additional clarity regarding management of service users out of hours	SWG	Feb 2024

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	care of the specialist immunology service (e.g. using Emergency Department alert systems); • Services should work collaboratively with urgent care services to guide the management of users of the immunology service should they present acutely				
None	• Where service users transfer to a new specialist immunology service, the transferring service must ensure that a formal transfer of care is undertaken to ensure continuity of care, including medication.	7.2 Pathways	Additional clarity	SWG	Oct 2024
None	7.3 Clinical networks The Provider is required to participate in a networked model of care with other specialist immunology centres to enable services to be delivered as part of a co-ordinated, combined whole system approach.	7.3 Clinical networks	New section in template with generic wording	SWG	May 2023

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None	• Clinical immunologists… should also engage in national MDTs for complex decision making.	7.6 Interdependent service components – links with other NHS services	To reflect current practice	SWG	Feb 2024