NHS STANDARD CONTRACT
FOR PAEDIATRIC MEDICINE: SPECIALISED ALLERGY SERVICES

SCHEDULE 2 – THE SERVICES A. SERVICE SPECIFICATIONS

<table>
<thead>
<tr>
<th>Service Specification No.</th>
<th>E03/S/j</th>
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<tbody>
<tr>
<td>Service</td>
<td>Paediatric Medicine: Specialised Allergy services</td>
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<td>Period</td>
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1. Population Needs

1.1 National/local context and evidence base

Allergic diseases are amongst the most common in Western society affecting up to 30% of the UK population (20 million) at some time in their lives. The prevalence of allergic diseases including eczema, asthma, allergic rhinitis and food allergy has risen dramatically over the past 30 years and recent primary care data suggests almost 40% of children have an allergic diagnosis. The majority of patients with allergic disease could be managed by competent primary care or non-specialist allergy services, using allergy testing, routine therapies (e.g. topical or nasal steroids, and antihistamines), provision of emergency adrenaline autoinjectors, advice regarding natural history and allergen avoidance and provision of allergy management plans. However, the burden of allergic disease is extensive, with significant co-morbidity (different expressions of allergy in the same individual), complexity and increasing severity of allergy. Disease-modifying therapy is available in specialist centres for severe aeroallergen, venom and food allergy. Specialised allergy services provide diagnosis and care for the more severe and complex cases, or where allergic aetiology is suspected or needs to be excluded.

Several reports indicate that severe, multi-system and complex allergy requires management in specialised allergy centres:
• Allergy: the unmet need. Royal College of Physicians, 2003
• Allergy. Report of the House of Lords Science and Technology Committee 2007
• Allergy Services; Still not meeting the Unmet Need. Royal College of Physicians. 2010

1.2 RCPCH Allergy Care Pathways

National care pathways for the management of children with allergic disease have been described. The Allergy Care Pathways; Royal College of Paediatrics and Child Health. 2011 define the competences needed to deliver specialist allergy services for children. Care Pathways have been documented for the following conditions:
1. Anaphylaxis
2. Food allergy
3. Asthma / rhinitis
4. Eczema
5. Urticaria/mastocytosis/angioedema
6. Drug allergy
7. Venom allergy
8. Latex allergy

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

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

2.1.1 General outcomes
Domain 1
- To minimise mortality by providing the most appropriate care for children with allergic disease.

Domain 2
- To minimise morbidity by providing the most appropriate care for children with allergic disease.
- To work with secondary care network providers to ensure high quality allergy services at secondary care level.

Domain 5
- To ensure there is sufficient, skilled and competent multi-disciplinary workforce to manage children with allergic disease.
- To ensure that children with allergic disease are treated in line with national guidelines and agreed local pathways.

2.1.2 Specific outcomes

Domain 2
- A reduction in time away from school due to ill health, by improved management of allergic conditions.
- Improvement in quality of life for children receiving pollen immunotherapy as measured by the Paediatric Quality of Life Inventory (PADQLQ).
- Improvement in food allergy specific quality of life, as measured by the FAQLQ, in children with food allergy, following immunotherapy
- Fewer allergic reactions and unscheduled healthcare service visits through appropriate management of children with complex allergic disease
- A reduction in unscheduled healthcare visits and improvement in quality of life as measured by IDQOL and CDQOL through appropriate management of children with severe eczema.

Domain 3
- Documented improvement in symptoms and reduction in medication use for children receiving immunotherapy with inhalant allergens.

Domain 4
- Deficiencies identified through the use of Patient Related Experience Measure (PREM) surveys for patients (including children) and on an annual basis, using the allergy specific instrument developed by the RCPCH care pathways project, will be acted on and that will be documented.
- Minimise the potential disruption of care and stress for older children and their parents / carers through the provision of organised transition to an adult allergy service

Domain 5
- To minimise the risks to children by providing immunotherapy, immunomodulatory treatments and high risk challenges in a safe environment in accordance with national and international best practice
3. Scope

3.1 Aims and objectives of service

The Paediatric allergy service will provide diagnosis and care for children with severe or complex allergic disease, or where an allergic aetiology is suspected.

In addition it will:
- Improve and maintain quality of life of children with allergic disease
- Prevent acute and chronic allergic symptoms
- Prevent complications and progression of disease and reduce the development of allergic co-morbidities.
- Reverse psychological damage and disability
- Exclude allergic disease as a cause of illness
- Provide family-centred specialist care for children with allergic disease
- Minimise hospital attendance
- Deliver safe and effective allergen immunotherapy

The service will:
- Provide a high quality care allergy service for children, according to best practice guidelines defined by the RCPCH and BSACI.
- Provide a sustainable service for children with severe and complex allergies that meets the needs of the regional population, incorporates the views of patients and uses of resources effectively.
- Work with other tertiary paediatric services to provide a high quality allergy service for children with complex medical conditions.
- Provide integrated care with primary, secondary and other care providers and ensure close links with other expert centres at national and international levels.
- Provide training and expertise including the ability to communicate complex allergy issues for healthcare professionals as well as children and families, including safeguarding issues.
- Provide access to National Institute of Health Research (NIHR) portfolio clinical trials in allergy, leading to improvement in child health through underpinning research.
- Provide support, advice, expertise and training for the local/regional network.
- Work to support the development of allergy services in areas of the network which have poor provision.
- Integrate patient care between regional / national specialised centres and local services through the use of standardised shared-care protocols.
- Increase awareness of best practice in the diagnosis and management of uncommon conditions through active engagement and shared care with local providers.
- Employ consistent, evidence-based and equitable decision-making about use of off
license therapies in refractory or relapsing disease

3.2 Service description/care pathway

Paediatric Specialist Allergy services should be provided by a multi-disciplinary team that includes:

- At least two Consultant Paediatric Allergists with experience in the management of patients with complex/specialised allergy and who maintain up-to-date Allergy continuing professional development (CPD) in their area of practice.
- Physicians, dieticians and nurses trained in Paediatric Allergy or with specialist experience in the practice of paediatric allergy and who maintain up-to-date Allergy CPD.
- Links with dermatology, gastroenterology, respiratory, ENT, ophthalmology, general paediatrics, child psychology / CAHMS and community paediatric services.
- An advisory service including allergen avoidance, primary and secondary allergy prevention, co-ordination with community paediatric teams for the management of children at risk of anaphylaxis, specialist dietetic service, education, teaching and a resource for other consultants throughout the region.

The specialist allergy centre will have access to the following investigations and services:

- Complex skin testing using drugs/food/venom/latex (skin prick/intradermal).
- A full range of in-vitro allergy diagnostic testing including component-resolved diagnostics.
- A day ward for food challenges, drug provocation testing, administration of subcutaneous, sublingual and oral immunotherapy and Omalizumab.
- In-patient beds with PICU on site to support high-risk challenges.
- Paediatric radiology services.
- Specialised Immunology Laboratory services with Clinical Pathology Accreditation (CPA) for allergy testing.
- Paediatric pulmonary function testing including computerised spirometry and exhaled nitric oxide (NO).
- Paediatric bronchoscopy service for investigation of resistant asthma.
- Paediatric endoscopy service for children with eosinophilic G-I disease.
- Appropriate storage and dispensing facilities for drugs and immunotherapeutic products.
- Specialist adult allergy service and a seamless transition programme.

There will be timely and appropriate communications with services who are expected to provide other parts of the patients pathway.

Patient organisations provide invaluable additional information and ongoing support for those caring for children with allergic disease. The service will support such organisations.

3.2.1 Care Pathway Overall:

- Referral from secondary or tertiary care
• Complex referrals from primary care which fulfil the requirements for specialist allergy are accepted
• Initial outpatient assessment, including diagnostic tests
• Further diagnostic tests or day case allergen challenges as indicated
• Specific allergen immunotherapy as indicated
• Development of a long term management plan
• Review, ongoing monitoring and further management, either solely in tertiary care or as part of a shared care pathway with secondary care
• Eventual outcome: either discharge to secondary / primary care or transition to adult service

3.2.2 Specific pathways of care

Pathways for the management of allergic disease in children, and the competences required to deliver them, have been documented by the RCPCH National Allergy Care pathways Project 2011. Specialist paediatric allergy centres provide care for children who are not effectively managed in primary or secondary care settings. In addition, rare conditions will be managed by a specialist allergy service.

Anaphylaxis
Idiopathic and complex anaphylaxis need specialist assessment. Accurate identification of the cause reduces stress and repeat emergency attendances. Facilities for challenge testing are required, multidisciplinary management and attention to co-morbidities such as asthma.

• Idiopathic anaphylaxis
• Children with recurrent episodes of anaphylaxis
• Previous anaphylaxis requiring PICU admission
• Previous anaphylaxis requiring HDU admission
• Food dependent exercise induced anaphylaxis

Food allergy and intolerance
Referral to a specialist paediatric allergy service is essential when there are several possible causes or a novel allergen whose natural history is unknown, when trigger avoidance adversely affects nutritional intake, when avoidance is complex, when symptoms are severe or the patient is at risk of anaphylaxis and where there are multiple co-morbidities. The range of foods causing allergy is changing. The implementation of protocols for desensitisation to foods (e.g. nuts, eggs and milk) is limited to specialist centres.

• Children with severe nutritional deficiencies e.g. rickets
• Children under 2 years of age with faltering growth due to severe food allergies
• Children with <80% school attendance due to significant allergy
• Children 5 years of age and over, with a history of severe reactions and impaired FAQLQ score requiring desensitisation to food
• Children with significant LTP allergy
• Children with severe food aversion requiring speech and language therapy or feeding clinic assessment and intervention
Gastrointestinal allergy
Food protein induced enteropathies can cause severe reactions as well as pain and psychological stress. Eosinophilic oesophagitis and enteropathies can cause failure to thrive in infants and debilitating vomiting, diarrhoea or constipation. The diagnosis is complex and often overlooked or not actively sought. Correct diagnosis requires expert assessment by a paediatric allergist working in collaboration with a paediatric gastroenterologist and specialist dieticians. Endoscopy and mucosal biopsy are often required for diagnosis and are managed in a specialist allergy centre.

- Eosinophilic gastrointestinal disease
- Food protein induced enterocolitis syndrome

Eczema
Infants and young children with moderate or severe atopic eczema that has not been controlled by optimal topical treatment are referred to an allergy service to identify possible food and other allergies (NICE QS44). Severe atopic dermatitis unresponsive to conventional therapy, with allergic triggers, requires specialist allergy referral.

- Children with severe eczema, treated with high potency topical steroids or calcineurin inhibitors.
- Children with severe eczema requiring treatment with systemic immunomodulators
- Children requiring house dust mite immunotherapy for treatment of eczema

Asthma
Referral to a specialist allergy service is necessary for children with severe atopic asthma, multisystem disease, when treatments are not effective or when allergy is suspected to precipitate the asthma attack, particularly if the asthma is unresponsive to conventional therapy. Children with asthma requiring treatment with anti IgE (Omalizumab) are sensitised to perennial allergens and should undergo specialist allergy assessment prior to starting treatment. Omalizumab for the treatment of severe asthma should be administered in conjunction with a specialist respiratory service. The management of asthma using a Temperature Controlled Laminar Airflow device (Airsonett) should be limited to specialist allergy centres, in conjunction with a specialist respiratory team.

- Children on BTS step 4 treatment for asthma
- Children requiring treatment with Omalizumab
- Children requiring treatment with Airsonett

Rhinitis and allergic conjunctivitis
Where symptoms are not controlled by first line treatment, immunotherapy can reduce symptoms by up to 50%. Specialist allergy services can confirm or refute allergic causes. Specific allergen immunotherapy using subcutaneous immunotherapy or non-licensed sublingual immunotherapy is only administered in specialist allergy centres.

- Children with allergic rhinoconjunctivitis due to grass and tree pollen allergy requiring immunotherapy
Children with allergic rhinoconjunctivitis due to house dust mite allergy requiring immunotherapy
Children with allergic rhinoconjunctivitis due to allergy to animals requiring immunotherapy

**Multi-system allergic disease**
Children with multi-system allergic disease often have severe food allergy, which imposes considerable psychological stress due to the high burden of illness and risk of reactions. A comprehensive approach to management is required to treat the underlying components of allergy in each organ system
- Children with psychopathology related to allergic disease requiring specialist input
- Children with three or more systems involved with severe allergic disease requiring specialist multiprofessional / multidisciplinary care (e.g. eczema, asthma, multiple food allergies, gastrointestinal disease, ENT / eyes)

**Drug allergy**
Substantial NHS costs are incurred when patients are labelled drug allergic and prescribed alternative medication without proper testing. Accurate diagnosis is essential and usually involves a drug challenge. Specialist allergy services are able to diagnose causes of multiple or severe reactions e.g. to general anaesthetics or where choices of alternative drugs are limited or complex e.g. in cystic fibrosis.
- Children requiring investigation for anaphylaxis due to suspected drug allergy
- Children requiring investigation for non beta –lactam drug allergy
- Investigation of reactions to biological agents
- Children requiring investigation for allergy during anaesthesia
- Children requiring drug desensitisation

**Venom allergy**
Generalised reactions to bee and wasp stings are uncommon in children. All generalised reactions are referred to a specialist allergy service for consideration of immunotherapy. Treatment with Pharmalgen venom immunotherapy is initiated and monitored in a specialist allergy centre experienced in venom immunotherapy (NICE TA246).
- Systemic reaction to bee or wasp venom requiring immunotherapy
- Suspected systemic reaction to bee or wasp venom requiring assessment

**Latex allergy**
IgE mediated latex allergy in children is uncommon and potentially severe. In some cases there is cross reactivity with a range of fruits and vegetables mandating evaluation in a specialist service. All cases will be managed through a specialist allergy service.
- IgE mediated latex allergy

**Chronic urticaria**
The majority of childhood urticaria responds to treatment with antihistamines and
avoidance of triggers. Chronic urticaria which is unresponsive to high dose antihistamines and leukotriene receptor antagonists should be referred to a specialist centre for further assessment and management.

- Chronic urticaria unresponsive to high dose antihistamines and leukotriene receptor antagonists.

**Mastocytosis**

Prognosis is usually benign in childhood, but is associated with a risk of anaphylaxis and recurrent severe allergic-like reactions. Uncomplicated Urticaria pigmentosa and mastocytomas can be managed within a dermatology service. Specialised allergy services are required for more severe cases of urticaria pigmentosa with systemic symptoms, particularly gastrointestinal.

- Urticaria pigmentosa with gastrointestinal symptoms
- Mast cell activation syndrome

**Multiple non-specific symptoms**

Severe psychological stress because of difficulty in obtaining a diagnosis, patients often feel they are not taken seriously by doctors, allergy may be wrongly assumed as a result of alternative allergy testing leading to inappropriate dietary exclusion and other avoidances resulting in social isolation and family disruption. Allergy is rarely involved, but specialist expertise and competence in all aspects of allergy is required to over-turn a previous erroneous diagnosis. May require collaboration with CAMHS to ensure the child is re-directed to more appropriate therapy.

- Children with multiple non-specific symptoms, impacting severely on quality of life where allergy is suspected by parent/carer or doctor

3.2.3 Referral processes and sources

- Due to the complex nature of severe allergies, tertiary referrals come from secondary care or other specialist paediatricians (particularly dermatology, respiratory, ENT and gastroenterology).
- Primary Care Physicians may refer patients directly to the service if the patient meets specialist referral criteria.

3.2.4 Location(s) of Service Delivery

There are approximately 20 paediatric allergy centres in the UK, located within major teaching hospitals.

3.3 Population covered

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).

*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 children and young people up to 19 years of age with allergic disease requiring specialised intervention and management, as outlined within this specification.

Each tertiary service will provide support for the surrounding childhood population in partnership with their local secondary care services

3.4 Any acceptance and exclusion criteria and thresholds

3.4.1 Acceptance Criteria

The service will accept referrals for any of the conditions listed in the care pathways above.

Individuals requiring specialist allergy services are also characterised by:
- Increased risk of death because of severity of the allergy (anaphylaxis, angioedema, drug allergy, brittle asthma).
- Persisting poor quality of life despite routine therapies with restrictions to daily activities at home, school or work (severe eczema / atopic dermatitis) with a major allergic component such as asthma, hay fever (allergic rhinoconjunctivitis) and chronic urticaria.
- Requirement for safe allergen immunotherapy: Subcutaneous immunotherapy should only be performed by experienced health care professionals in specialised centres with direct access to resuscitation facilities (CSM Update – desensitising vaccines, Br Med J, 1986).
- Rare diseases leading to allergic symptoms requiring complex investigations and therapies (mastocytosis, eosinophilic enteropathies).
- Diseases with allergic symptoms but where the cause in unclear and specialist input is required to make a specific diagnosis, identify triggers, optimise management and prevent further recurrences.
- Patients with complex medical and / or psycho-social problems, where allergy needs to be excluded as a cause

3.4.2 Exclusion Criteria

- Patients with less severe allergy who do not require specialist review
- Symptoms such as chronic fatigue syndrome without evidence of allergy

3.4.3 Exit Criteria

Patients will leave the service when:
- Their allergic disease is controlled and suitable for self-management or management
by non-specialised allergy services or primary care physicians.
- Their allergen immunotherapy course is completed and no further follow-up is indicated.
- Allergic disease has been excluded
- Transition to specialist adult services

3.5 Interdependencies with other services/providers

Links with other paediatric specialists include:
- Paediatric gastroenterology
- Paediatric respiratory medicine
- Paediatric dermatology
- Paediatric ENT
- Paediatric A&E
- Paediatric intensive care on site
- Immunology
- Paediatric ophthalmology
- Child Psychiatry / psychology
- General Paediatrics
- Community paediatrics
- School nursing teams
- Paediatric community nursing teams
- Community dietetics

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

4.1.1 BSACI Allergy service standards

Standards for the requirements of a specialist centre have been produced by the British Society for Allergy and Clinical Immunology (BSACI) and are detailed below.

(a) Offer services across the full range of allergic disease
(b) Offer a full-time service in allergy
(c) Have expertise in the diagnosis and management of specialist problems e.g. drug allergy (including anaphylaxis during general anaesthesia, local anaesthetic, antibiotic, aspirin and NSAID, opiate etc); latex allergy; food allergy; venom allergy and anaphylaxis and deal with severe or multi-system allergic disease
(d) Be provided by full-time specialist allergists with a minimum of two consultants per centre with trained support staff
(e) Have specialist facilities and be able to carry out the full range of diagnostic techniques including challenge testing and immunotherapy
(f) Have access to a laboratory service in clinical immunology
(g) Provide a full-time advisory service

4.1.2 NICE Clinical guidelines
National guidelines have been developed by National Institute for Health and Care Excellence (NICE) for allergic disorders and include the following:
- Food allergy in children and young people (CG116)
- Anaphylaxis (CG134)
- Atopic eczema in children (CG57)

4.1.3 NICE technology appraisals
- Omalizumab for treating severe persistent allergic asthma (TA278)
- Asthma (children under 5) – inhaler devices (TA10)
- Asthma (older children) – inhaler devices (TA38)
- Asthma (in children) – corticosteroids (TA131)
- Pharmalgen venom immunotherapy (TA246)

4.1.4 NICE Quality Standards
- Asthma (QS25)
- Atopic eczema in children (QS44)

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

4.2.1 BSACI Standards of care
National guidelines have been developed by the British Society for Allergy and Clinical Immunology (BSACI) for many allergic disorders and include the following:
- Guidelines for the management of chronic urticaria and angio-oedema. 2007
- Guidelines for the management of allergic and non-allergic rhinitis. 2008
- Guidelines for the management of rhinosinusitis and nasal polyposis. 2008
- Guidelines for the management of drug allergy.2009
- Guidelines for the investigation of suspected anaphylaxis during general anaesthesia. 2010
- Guidelines for the management of egg allergy. 2010
- Guidelines for the diagnosis and management of Hymenoptera venom allergy. 2011
- Guidelines for Immunotherapy for allergic rhinitis. 2011

The Resuscitation Council UK have worked in partnership with the BSACI to publish joint guidance on the emergency treatment of anaphylaxis:

4.2.2 EAACI position papers
The European Academy of Allergy and Clinical Immunology (EAACI) have developed the following position papers with relevance to paediatric allergy:
- International Consensus on (ICON) pediatric asthma 2012
4.2.3 WAO Guidelines
The World Allergy organisation have developed the following guideline with relevance to children:
Diagnosis and Rationale for Action against Cows Milk Allergy (DRACMA) Guidelines 2010

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)
These are in the process of being developed and will be inserted once agreed.

5.2 Applicable CQUIN goals (See Schedule 4 Part E)
These are in the process of being developed and will be inserted once agreed.

6. Location of Provider Premises

The Provider’s Premises are located at:

7. Individual Service User Placement
## Appendix

Quality standards specific to the service using the following template:

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<th>Threshold</th>
<th>Method of Measurement</th>
<th>Consequence of breach</th>
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<tr>
<td><strong>Domain 1: Preventing people dying prematurely</strong></td>
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<tr>
<td>Children with anaphylaxis requiring PICU / HDU admission should be reviewed by the allergy team before discharge from hospital</td>
<td>100% compliance</td>
<td>Number of children with anaphylaxis requiring PICU/HDU admission, who are reviewed by the allergy team before discharge home as a proportion of number of children with anaphylaxis requiring PICU/HDU admission</td>
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<td>Children with anaphylaxis requiring PICU / HDU admission should be reviewed in a specialist allergy clinic within 6 weeks of discharge</td>
<td>95% compliance</td>
<td>Number of children with anaphylaxis requiring PICU / HDU admission who are reviewed in a specialist allergy clinic within 6 weeks of discharge as a proportion of number of children with anaphylaxis requiring PICU/HDU admission</td>
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<td><strong>Domain 2: Enhancing the quality of life of people with long-term conditions</strong></td>
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<td>Children with systemic reactions to bee and wasp stings should be seen in the specialist allergy clinic within 6 weeks of the referral being received</td>
<td>100% compliance</td>
<td>Number of children with systemic reactions to bee or wasp stings seen within 6 weeks of the referral being received as a proportion of all those referred</td>
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<td><strong>Domain 3: Helping people to recover from episodes of ill-health or following injury</strong></td>
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<td>Percentage of admitted patients starting treatment within a maximum of 18 weeks from referral</td>
<td>Operating standard of 90%</td>
<td>Review of monthly Service Quality Performance Report</td>
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<td><strong>Domain 4: Ensuring that people have a positive experience of care</strong></td>
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<td>Referral time to dietetic review This is a marker of</td>
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<td>Time taken from diagnosis of food allergy in the allergy</td>
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<td>Quality Requirement</td>
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<td>adequacy of specialist dietetic support for the food allergy service</td>
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<td>Subcutaneous immunotherapy should only be performed by practitioners trained in the technique, where the centre maintains an appropriate caseload, in a unit with access to a PICU and with cover from a paediatric crash team</td>
<td>100% compliance</td>
<td>Number of subcutaneous immunotherapy injections performed by trained staff on a unit with access to PICU and cover from a paediatric crash team as a proportion of overall number performed.</td>
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<td>Sublingual immunotherapy should only be initiated by practitioners trained in the technique, where the centre maintains an appropriate caseload, a unit with access to a PICU and with cover from a paediatric crash team</td>
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<td>Children undergoing oral food challenges and drug provocation tests should be challenged by appropriately trained staff in a facility with access to PICU and cover from a paediatric crash team.</td>
<td>100% compliance</td>
<td>Total number of food challenges performed by trained staff on a unit with access to PICU and cover from a paediatric crash team as a proportion of overall number performed.</td>
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Change Notice for Published Specifications and Products
developed by Clinical Reference Groups (CRG)

Amendment to the Published Products

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Description of changes required

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