

## Integrated Impact Assessment Report for Service Specifications

<b>Service Specification Reference Number</b>	1648		
<b>Service Specification Title</b>	DNA Nucleotide Excision Repair Disorders Service (all ages) Proposal <u>for routine commission</u> (source A3.1)		
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### Integrated Impact Assessment – Index

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#### About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes.
- Each theme sets out a number of questions.
- All questions are answered by selecting a drop down option or including free text.
- Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.
- Data in this document is either drawn from one of the relevant service specification documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.

## Section A - Activity Impact

### A1 Current Patient Population & Demography / Growth

A1.1 Prevalence of the disease/condition.	<p>NHS England currently commissions a service for Xeroderma Pigmentosa (XP), which is a disorder of DNA repair. This service specification proposes to expand the current XP service specification and encompass two other conditions of DNA disorders:</p> <ol style="list-style-type: none"> <li>1. DNA re Cockayne syndrome (CS) is a, rare inherited (autosomal recessive) disorder with an estimated prevalence of ~1 in 500,000; and</li> <li>2. Trichothiodystrophy(TTD) is a rare inherited (autosomal recessive) disorders with an estimated prevalence of 1 in a million in Europe pair disorders for which there is currently no recognised centre of expertise.</li> </ol> <p><i>Source: Service Specification Proposition section 3.1</i></p>
A1.2 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.	<p>The number of patients is estimated to be 132 in year of implementation (i.e. year 2 in the finance model).</p> <p><i>Source: Clinical intelligence/ diagnostic lab data</i></p>
A1.3 Age group for which the service is proposed according to the service specification commissioning criteria.	<p><b><u>All ages</u></b></p> <p>Please specify</p> <p>Treatment is indicated for all patients with a DNA repair disorder. Typically this would be the following age groups:</p> <p><b>XP</b> – Patients from birth through to mid/ late adulthood,</p> <p><b>CS</b> – Predominately paediatric patients, with potentially a few young adults, <b>TTD</b> –</p>

	Predominately paediatric patients, with potentially a few young adults.								
A1.4 Age distribution of the patient population eligible according to the proposed service specification commissioning criteria	<p>The average age of survival in affected children with Cockayne syndrome is 12 years, with some surviving into the second decade. The clinical picture in CS can be extremely variable, from a congenital onset at birth to a later onset, which makes the diagnosis and an accurate prognosis difficult. Age distribution in TTD patients ranges from diagnosis close to birth, with some young adults and a small number of older patients.</p> <p><i>Source: Service specification section 3.4 evidence base</i></p> <p>Please specify</p> <p><a href="#">Click here to enter text.</a></p>								
A1.5 How is the population currently distributed geographically?	<p><b><u>Evenly</u></b></p> <p>If unevenly, estimate regional distribution by %:</p> <table border="1"> <tr> <td>North</td><td>enter %</td></tr> <tr> <td>Midlands &amp; East</td><td>enter %</td></tr> <tr> <td>London</td><td>enter %</td></tr> <tr> <td>South</td><td>enter %</td></tr> </table> <p><i>Source: Service specification proposition section 6</i></p> <p>Please specify</p>	North	enter %	Midlands & East	enter %	London	enter %	South	enter %
North	enter %								
Midlands & East	enter %								
London	enter %								
South	enter %								

A2 Future Patient Population & Demography												
A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new service specification) in 2, 5, and 10 years?	<p><b><u>Increasing</u></b></p> <p>If other, Numbers are small and significant growth is not expected  <i>Source: Service specification proposition section 3.1</i></p>											
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	<p><b><u>No</u></b></p> <p>Please specify</p> <p>In the coming years we expect to see a steady growth of service activity due to a greater awareness, recognition of milder forms of the condition and improved diagnosis/far reach of the service in time rather than increase in prevalence.  <i>Source: Service specification proposition section 6/other</i></p>											
A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?	<table border="1"> <tbody> <tr> <td>YR2 +/-</td> <td>20</td> </tr> <tr> <td>YR3 +/-</td> <td>30</td> </tr> <tr> <td>YR4 +/-</td> <td>40</td> </tr> <tr> <td>YR5 +/-</td> <td>50</td> </tr> <tr> <td>YR10 +/-</td> <td>90</td> </tr> </tbody> </table> <p><i>Source: Service specification proposition section 3.1</i></p>	YR2 +/-	20	YR3 +/-	30	YR4 +/-	40	YR5 +/-	50	YR10 +/-	90	<p><b><u>No</u></b></p> <p>The patient numbers are anticipated to be higher than the ONS growth assumptions. For CS, the growth in patient numbers has been estimated to be 10 per annum and for TTD an estimate of 2 per annum.</p>
YR2 +/-	20											
YR3 +/-	30											
YR4 +/-	40											
YR5 +/-	50											
YR10 +/-	90											
Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.												

### A3 Activity

A3.1 What is the purpose of new service specification?

**Provide service specification document for a service already commissioned by NHS England in accordance with 'The Manual' but without a published specification**

Please specify

The aim of this service is to provide a nationally integrated multidisciplinary clinical and molecular diagnostic service to co-ordinate care and management of patients with DNA nucleotide excision repair disorders. This service will expand the current XP service to include patients with additional diagnoses of DNA repair including Cockayne Syndrome (Q87.1) and Trichothiodystrophy (L67.8).

A3.2 What is the annual activity associated with the existing pathway for the eligible population?

- 86 Cockayne syndrome (CS). See A2.3 above
- 16 cases of Trichothiodystrophy (TTD). See A2.3 above

Currently there is no unified service for CS/TTD patients and patients are currently seen largely by local paediatric or support services

*Source: required*

Please specify

[Click here to enter text.](#)

A3.3 What is the estimated annual activity associated with the proposed service specification proposition pathway for the eligible population?

The estimated activity associated with the service specification proposal relates to the number of patients listed below.

YR1	112 patients
YR2	122 patients
YR3	132 patients

	YR4	142 patients	
	YR5	152 patients	
	Source: <i>Financial Model</i>		
A4 Patient Pathway			
A4.1 Patient pathway Describe the current patient pathway and service.	Patients with CS & TTD rarely receive specialist management currently and are usually seen in a variety of different services e.g. paediatric neurology to manage the symptoms of the condition. Their care and clinic attendance is poorly co-ordinated with multiple clinic attendances for different problems. Without genetics input and diagnosis this can lead to unnecessary investigations, more complications and poor prognosis if the associated co-morbidities are not actively managed. Source: <i>SWG clinical and patient group advice</i>		
A4.2. What are the current service access and stopping criteria?	Click here to enter text. <i>Service not currently commissioned</i> Source: Click here to enter text.		
A4.3 What percentage of the total eligible population are: a) Referred b) Meet any existing criteria for care c) Considered to meet any existing exclusion criteria	If not known, please specify This service is not currently commissioned as a HSS. Some patients have been identified through data collection based on patient numbers. a) 100% b) 0% c) 100% Source: <i>required</i>		

<p>A4.4 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> <li>a) Be referred to the proposed service</li> <li>b) Be eligible for care according to the proposed criteria for the service</li> <li>c) Take up care according to the proposed criteria for the service</li> <li>d) Continue care according to the proposed criteria for the service?</li> </ul>	<p>If not known, please specify Numbers of patients are small but planning has been done on the basis of all patients accessing the service in some way plus new births.</p> <ul style="list-style-type: none"> <li>a) 100%</li> <li>b) 100 %</li> <li>c) 100%</li> <li>d) 100%</li> </ul> <p>Source: <i>required</i></p>														
<p>A4.5 Specify the nature and duration of the proposed new service or intervention.</p>	<p><b><u>Life long</u></b></p> <p>For time limited services, specify frequency and/or duration.</p> <p><a href="#">Click here to enter text.</a></p> <p>Source: <i>required</i></p>														
<p><b>A5 Service Setting</b></p>															
<p>A5.1 How is this service delivered to the patient?</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Emergency/Urgent care attendance</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Acute Trust: inpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Acute Trust: day patient</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Acute Trust: outpatient</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Mental Health provider: inpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Mental Health provider: outpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Community setting</td> <td><input type="checkbox"/></td> </tr> </table>	Emergency/Urgent care attendance	<input type="checkbox"/>	Acute Trust: inpatient	<input type="checkbox"/>	Acute Trust: day patient	<input checked="" type="checkbox"/>	Acute Trust: outpatient	<input checked="" type="checkbox"/>	Mental Health provider: inpatient	<input type="checkbox"/>	Mental Health provider: outpatient	<input type="checkbox"/>	Community setting	<input type="checkbox"/>
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Homecare	<input type="checkbox"/>									
Other	<input type="checkbox"/>									
<p>A5.2 What is the current number of contracted providers for the eligible population by region?</p>	<table border="1"> <tr> <td>NORTH</td> <td>0</td> </tr> <tr> <td>MIDLANDS &amp; EAST</td> <td>0</td> </tr> <tr> <td>LONDON</td> <td>0</td> </tr> <tr> <td>SOUTH</td> <td>0</td> </tr> </table>	NORTH	0	MIDLANDS & EAST	0	LONDON	0	SOUTH	0	
NORTH	0									
MIDLANDS & EAST	0									
LONDON	0									
SOUTH	0									
<p>A5.3 Does the proposition require a change of delivery setting or capacity requirements?</p>	<p><b><u>yes</u></b>          Please specify:          Additional outpatient capacity requirements.  <i>Source: Provider discussion</i></p>									
<p><b>A6 Coding</b></p>										

A6.1 Specify the datasets used to record the new patient pathway activity.

\*expected to be populated for all commissioned activity

*Select all that apply:*

Aggregate Contract Monitoring *	<input checked="" type="checkbox"/>
Patient level contract monitoring	<input checked="" type="checkbox"/>
Patient level drugs dataset	<input type="checkbox"/>
Patient level devices dataset	<input type="checkbox"/>
Devices supply chain reconciliation dataset	<input type="checkbox"/>
Secondary Usage Service (SUS+)	<input checked="" type="checkbox"/>
Mental Health Services DataSet (MHSDS)	<input type="checkbox"/>
National Return**	<input type="checkbox"/>
Clinical Database**	<input type="checkbox"/>
Other**	<input checked="" type="checkbox"/>

\*\*If National Return, Clinical database or other selected, please specify: Data will be reported directly through the Highly Specialised reporting mechanism.

A6.2 Specify how the activity related to the new patient pathway will be identified.

*Select all that apply:*

OPCS v4.8	<input checked="" type="checkbox"/>
ICD10	<input checked="" type="checkbox"/>
Service function code	<input checked="" type="checkbox"/>
Main Speciality code	<input checked="" type="checkbox"/>
HRG	<input checked="" type="checkbox"/>
SNOMED	<input type="checkbox"/>

	<div> <div>Clinical coding / terming methodology used by clinical profession</div> <div><input type="checkbox"/></div> </div>
<b>A6.3 Identification Rules for Drugs:</b> How are any drug costs captured?	<p><b><u>Not applicable</u></b></p> <p>If already specified in the current NHS England Drug / Devices List, please specify drug name and indication for all that apply:  <a href="#">Click here to enter text.</a></p> <p>If drug(s) NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead:  <a href="#">Click here to enter text.</a></p>
<b>A6.4 Identification Rules for Devices:</b> How are device costs captured?	<p><b><u>Not applicable</u></b></p> <p>If device(s) covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance) for all that apply:  <a href="#">Click here to enter text.</a></p> <p>If device(s) not excluded from Tariff <b>nor</b> covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team.  <a href="#">Click here to enter text.</a></p>
<b>A6.5 Identification Rules for Activity:</b> How are activity costs captured?	<p><b><u>Not captured by an existing specialised service line</u></b></p> <p>If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).          NCBPS24Z– NEUROLOGY          NCBPS08O - SPECIALISED DERMATOLOGY</p>

	<p><a href="#">Click here to enter text.</a></p> <p>If activity costs are already captured please specify whether this service needs a separate code. <a href="#">Choose an item.</a></p> <p>If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team.</p> <p><a href="#">Click here to enter text.</a></p> <p>If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team.</p> <p><a href="#">Choose an item.</a></p>
<b>A7 Monitoring</b>	
<p><b>A7.1 Contracts</b></p> <p>Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</p> <p>Please identify any excluded drugs or devices relevant to the service and their current status with regard to NHS England specialised services commissioning.</p>	<p><b><u>Yes - other</u></b></p> <p>Please specify</p> <p>DNA repair including Cockayne Syndrome (Q87.1) and Trichothiodystrophy (L67.8) activity will be reported against either:</p> <p>NCBPS24Z – Specialised Dermatology (non-admitted care)</p> <p>NCBPS24Z – Specialised Dermatology (admitted care)</p>
<p><b>A7.2 Business intelligence</b></p> <p>Is there potential for duplicate reporting?</p>	<p><b><u>Yes</u></b></p> <p>If yes, please specify mitigation:</p> <p>Monitoring via the established processes for Highly Specialised Services via the HSS Informatics lead.</p>
<b>A7.3 Contract monitoring</b>	<b><u>No</u></b>

Is this part of routine contract monitoring?	<p>If no, please specify contract monitoring requirement:</p> <p>Inclusion in NHS Standard Contract Information Schedule and service lines monitored. Data will be provided to supplier managers via the HSS informatics lead.</p>
<p><b>A7.4 Dashboard reporting</b></p> <p>Specify whether a dashboard exists for the proposed service?</p>	<p><b>No</b></p> <p>If yes, specify how routine performance monitoring data will be used for dashboard reporting.</p> <p><a href="#">Click here to enter text.</a></p> <p>If no, will one be developed?</p> <p>Monitoring of the agreed outcomes will be via the HSS team, no plans to develop a dashboard</p>
<p><b>A7.5 NICE reporting</b></p> <p>Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new service specification?</p>	<p><b>No</b></p> <p>If yes, specify how performance monitoring data will be used for this purpose.</p> <p><a href="#">Click here to enter text.</a></p>
<p><b>Section B - Service Impact</b></p>	
<p><b>B1 Service Organisation</b></p>	
<p>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</p>	<p>The XP service is currently a commissioned HSS service from a single provider. A service for CS and TTD patients is not currently commissioned.</p> <p><i>Source: required</i></p>
<p>B1.2 Will the specification change the way the commissioned service is organised?</p>	<p><b>Yes</b></p> <p>Please specify:</p>

	<p>Centralised expertise with development of a national clinical network to provide outreach support for patients at their local hospitals and in their home, school and work environments. The service will be expected to establish a clinical network to support the patient pathway, improve awareness of DNA repair disorders amongst referrers and help develop equitable access for patients.</p> <p><i>Source: service spec page 5</i></p>
B1.3 Will the specification require a new approach to the organisation of care?	<p><b><u>Implement a new model of care</u></b></p> <p>Please specify:</p> <p>Patients seen in the service will have laboratory proven diagnosis of a DNA nucleotide excision repair disorder or, if laboratory data is not available, a referral from a hospital consultant where the clinical diagnosis of a DNA nucleotide excision repair disorder needs to be excluded. Standard international diagnostic clinical criteria will apply. Stopping points would be a diagnosis confirming an alternate condition or death.</p> <p>One-stop multidisciplinary clinics will take place over a one or two day period. Patients will be offered an annual review, tailored to their diagnosis and specific needs. Care will be delivered in partnership with the patient support groups (e.g. Amy and Friends for CS, and the XP Support Group for XP patients).</p> <p>A national clinical network for this service will be developed to provide outreach support for patients at their local hospitals and in their home, school and work environments. The clinical nurse specialists will play a key role in managing the network and smoothing the transition between local and specialist care. This is the basis on which the current HSS XP service is delivered.</p>
<b>B2 Geography &amp; Access</b>	
B2.1 Where do current referrals come from?	<p><u>Select all that apply: Not currently commissioned, future referrals would</u></p>

	<p>be:</p> <table border="1"> <tr> <td>GP</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Secondary care</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Tertiary care</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Other</td><td><input checked="" type="checkbox"/></td></tr> </table> <p>Please specify: Paediatricians, paediatric neurologists, GPs, patient support group.</p>	GP	<input checked="" type="checkbox"/>	Secondary care	<input checked="" type="checkbox"/>	Tertiary care	<input checked="" type="checkbox"/>	Other	<input checked="" type="checkbox"/>
GP	<input checked="" type="checkbox"/>								
Secondary care	<input checked="" type="checkbox"/>								
Tertiary care	<input checked="" type="checkbox"/>								
Other	<input checked="" type="checkbox"/>								
B2.2 What impact will the new service specification have on the sources of referral?	<p><b><u>No impact</u></b></p> <p>Please specify:</p>								
B2.3 Is the new service specification likely to improve equity of access?	<p><b><u>Increase</u></b></p> <p>Please specify:</p> <p>Most of forms of CS/TTD affect multiple systems and lead to complex management needs and life-limiting disorders.</p> <p>It is expected that a specialist service would significantly improve equity of access to specialised care, enhance patient care, streamline management and ensure appropriate surveillance and anticipatory monitoring for recognised complications are put in place.</p> <p><i>Source: Equalities Impact Assessment</i></p>								
B2.4 Is the new service specification likely to improve equality of access and/or outcomes?	<p><b><u>Increase</u></b></p> <p>Please specify:</p> <ul style="list-style-type: none"> <li>Colleagues from around the country will be informed of the new model of care through dissemination of the information to Royal College of Physicians and professional groups as well as patient support groups and</li> </ul>								

	<p>via the NHS England website.</p> <ul style="list-style-type: none"> <li>Access to the service will be via referral from a local health professional. As part of a managed clinical network, the liaison nurses, in conjunction with the host team, will provide advice and guidance to clinicians at an individual patient level regarding referral queries, access criteria and patient management.</li> </ul> <p><i>Source: Equalities Impact Assessment</i></p>
<b>B3 Implementation</b>	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	<p><b><u>Procurement action</u></b></p> <p>Please specify:</p> <ul style="list-style-type: none"> <li><i>It is anticipated based on initial advice from the Commercial team that a formal procurement process will be required given the estimated value of the new service.</i></li> <li><i>It is proposed that that a Prior Information Notice could be run to ascertain market interest to provide a national DNA Repair service.</i></li> </ul>
<p><b>B3.2 Time to implementation:</b></p> <p>Is a lead-in time required prior to implementation?</p>	<p><b><u>Yes - go to B3.3</u></b></p> <p>If yes, specify the likely time to implementation: 6 months expected post procurement. The key factor influencing the lead in time would be consultant job planning to co-ordinate the involvement of multiple specialities.</p>
<p><b>B3.3 Time to implementation:</b></p> <p>If lead-in time is required prior to implementation, will an interim plan for implementation be required?</p>	<p><b><u>No - go to B3.4</u></b></p> <p>If yes, outline the plan:</p> <p><a href="#">Click here to enter text.</a></p>
B3.4 Is a change in provider physical infrastructure required?	<b><u>No</u></b>



	<p>Please specify:</p> <p>We would expect the service to be delivered within existing facilities.</p>
B3.5 Is a change in provider staffing required?	<p><b><u>Yes</u></b></p> <p>Please specify:</p> <p>Some reworking of job plans is expected to be required if the service is commissioned as an extension to the current HSS XP service</p>
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	<p><b><u>Yes</u></b></p> <p>Please specify:</p> <p>Patients with DNA Nucleotide Excision Repair disorders require input from many services including paediatrics, genetics, dermatology, ophthalmology (virtually all patients with CS have visual retinopathy and cataracts are present in 30% of patients), nephrology, neurology, audiology, endocrinology and paediatric dentistry. Experienced and specialised dermatology input is required to address the skin problems photosensitivity), which cause significant morbidity in these conditions. Inefficient (increased management of UV exposure protection from lack of expertise leads to unnecessary and avoidable complications. If skin and eye tumours are diagnosed late in XP the prognosis is worse and instigation of UV protection has a dramatic effect on reducing the incidence of tumours.</p>
B3.7 Are there changes in the support services that need to be in place?	<p><b><u>Yes</u></b></p> <p>Please specify:</p> <p>Some though limited, we would be a need to ensure support services were all in place prior to commencement of the service.</p>
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	<p><b><u>No</u></b></p> <p>Please specify:</p> <p><a href="#">Click here to enter text.</a></p>

B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region

**No change**

*Please complete the table:*

Region	Current no. of providers	Future State expected range	Provisional or confirmed
North	0	0	<u>P</u>
Midlands & East	0	0	<u>P</u>
London	1	1	<u>P</u>
South	0	0	<u>P</u>
Total	1	1	<u>C</u>

Please specify:

There is expected to be one national provider of the clinical service.

B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.

*Select all that apply:*

Publication and notification of new service specification	<input checked="" type="checkbox"/>
Market intervention required	<input checked="" type="checkbox"/>
Competitive selection process to secure increase or decrease provider configuration	<input checked="" type="checkbox"/>
Price-based selection process to maximise cost effectiveness	<input type="checkbox"/>
Any qualified provider	<input type="checkbox"/>
National Commercial Agreements e.g. drugs, devices	<input type="checkbox"/>
Procurement	<input checked="" type="checkbox"/>

	<div>Other <input type="checkbox"/></div> <p>Please specify:</p> <p>Initially a PIN process to gauge interest in the market and subject to the level of interest received, a procurement process to select capable providers may need to be undertaken.</p>														
<b>B4 Place-based Commissioning</b>															
B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	<p><b>No</b></p> <p>Please specify:</p> <p><a href="#">Click here to enter text.</a></p>														
<b>Section C - Finance Impact</b>															
<b>C1 Tariff/Pricing</b>															
<p>C1.1 How is the service contracted and/or charged?</p> <p>Only specify for the relevant section of the patient pathway</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td rowspan="3"><b>Drugs</b></td><td>Not separately charged – part of local or national tariffs</td><td><input type="checkbox"/></td></tr> <tr> <td>Excluded from tariff – pass through</td><td><input type="checkbox"/></td></tr> <tr> <td>Excluded from tariff - other</td><td><input type="checkbox"/></td></tr> <tr> <td rowspan="3"><b>Devices</b></td><td>Not separately charged – part of local or national tariffs</td><td><input type="checkbox"/></td></tr> <tr> <td>Excluded from tariff (excluding ZCM) – pass through</td><td><input type="checkbox"/></td></tr> <tr> <td>Excluded from tariff (excluding ZCM) – other</td><td><input type="checkbox"/></td></tr> </table>	<b>Drugs</b>	Not separately charged – part of local or national tariffs	<input type="checkbox"/>	Excluded from tariff – pass through	<input type="checkbox"/>	Excluded from tariff - other	<input type="checkbox"/>	<b>Devices</b>	Not separately charged – part of local or national tariffs	<input type="checkbox"/>	Excluded from tariff (excluding ZCM) – pass through	<input type="checkbox"/>	Excluded from tariff (excluding ZCM) – other	<input type="checkbox"/>
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<p><b>C1.2 Drug Costs</b></p> <p>Where not included in national or local tariffs, list each drug or combination, dosage, quantity, <b>list</b> price including VAT if applicable and any other key information e.g. Chemotherapy Regime.</p> <p>NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	N/A																		
<p><b>C1.3 Device Costs</b></p> <p>Where not included in national or local tariff, list each element of the excluded device, quantity, <b>list or expected</b> price including VAT if applicable and any other key information.</p> <p>NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	N/A																		
<p><b>C1.4 Activity Costs covered by National Tariff</b></p> <p>List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</p>	The associated activity will be captured on hospital and national systems but excluded from chargeable activity under this arrangement.																		

<p><b>C1.5 Activity Costs covered by Local Tariff</b></p> <p>List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.</p>	<p>Not applicable.</p>		
<p><b>C1.6 Other Activity Costs not covered by National or Local Tariff</b></p> <p>Include descriptions and estimates of all key costs.</p>	<p>Currently there is a block contract for XP services of £625k at GSTT. As there are links between that service and the services in this service specification. The most likely contract mechanism would be that the block figures for CS\TTD be added to the current value of the XP contract if the service is awarded to GSTT and to establish a block contract for these services as a whole. The contract should include a volume adjustment based on activity.</p>		
<p><b>C1.7</b> Are there any prior approval mechanisms required either during implementation or permanently?</p>	<p><b>No</b></p> <p>Please specify: <a href="#">Click here to enter text.</a></p>		
<p><b>C2 Average Cost per Patient</b></p>			
<p><b>C2.1</b> What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?</p>     <p>Are there any changes expected in year 6-10 which would impact the model?</p>	YR1	£0	
	YR2	£14,237	
	YR3	£14,237	
	YR4	£14,237	
	YR5	£14,237	
	<p>If yes, please specify:</p>		

### C3 Overall Cost Impact of this Service specification to NHS England

C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.

#### **Cost pressure**

Please specify:

Year 1: £0

Year 2: £249.5k

Year 5: £180.9k

C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.

An assumption has been made, that CS/ TTD patients are receiving some form of care as this is a group of quite disabled patients, often children, in either a local/ specialist centre. In order to derive a benchmark comparison, a number of additional assumptions were made about the current pathway and then compared with the costs to set this service up on an ongoing basis.

Therefore, the estimate for the cost pressure is based on these assumptions made on the current patient pathway. However, as a proxy the average cost per patient for an XP patient is equal to c£6,250 per patient (£625k/100 patients).

The average cost per patient for the CS/ TTD cohort is estimated to be £4,435 in year 2 (implementation of service specification) and subsequently reduces each year to an average of £3,381 in year 5 per patient. Furthermore, the average reduces to £2,818 per patient in year 10.

C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?

Not applicable

### C4 Overall cost impact of this service specification to the NHS as a whole

C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: <u><b>Cost neutral</b></u> Budget impact for providers: <u><b>Cost neutral</b></u> Please specify:
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<u><b>Cost neutral</b></u> Please specify:
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	<u><b>No</b></u> Please specify:
<b>C5 Funding</b>	
C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	CPAG Prioritisation Reserve
<b>C6 Financial Risks Associated with Implementing this Service specification</b>	

C6.1 What are the material financial risks to implementing this service specification?	Risk associated with the financial impact include current currently poor data quality and coding. There are risks in a agreeing a block contract include a) the assumed patient cohort (86 – CS and 16 – TTD) do not materialise and the contract is overpaid by NHSE. Or conversely that b) the patient cohort is greater than the assumed patient cohort resulting in a contract underpayment on a per patient basis. This risk is shared equally between NHSE and the provider. Activity for this group of patients will be recorded against an established activity line if the service is procured from the existing XP provider. A contract model will need to be established which allows for the service to be set up but which also reflects some of the uncertainty over the time period to establish the service to the activity levels set out in the financial model. .
C6.2 How can these risks be mitigated?	Audit of data quality and commissioner responsibility. A flexible contract model will need to be agreed to allow for the likelihood of a longer lead in line to establish a service to steady state.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	In the absence of reliable and accurate data, a number of assumptions have been made with regard to the current pathway in order to derive a benchmark comparison that reasonably reflects the associated activity with this cohort of patients.
C6.4 What scenario has been approved and why?	The highest point of the expected cohort has been modelled as this is the most likely number of patients each year (excluding backlog).
<b>C7 Value for Money</b>	
C7.1 What published evidence is available that the service is cost effective as evidenced in the evidence review?	<b><u>Published evidence indicates service specification has the potential to be cost-effective</u></b>



	<p>Please specify:</p> <p>As set out in the evidence section of the service specification. Previous financial analysis of the cost effectiveness of the similar XP service has been completed.</p>														
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Available pricing data suggests the service is lower cost compared to current/comparator treatment</td><td><input type="checkbox"/></td></tr> <tr> <td>Available clinical practice data suggests the new service specification has the potential to improve value for money</td><td><input type="checkbox"/></td></tr> <tr> <td>Other data has been identified</td><td><input type="checkbox"/></td></tr> <tr> <td>No data has been identified</td><td><input type="checkbox"/></td></tr> <tr> <td>The data supports a high level of certainty about the impact on value</td><td><input type="checkbox"/></td></tr> <tr> <td>The data does not support a high level of certainty about the impact on value</td><td><input type="checkbox"/></td></tr> </table> <p>Please specify:</p> <p>Not applicable</p>	Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification	<input checked="" type="checkbox"/>	Available pricing data suggests the service is lower cost compared to current/comparator treatment	<input type="checkbox"/>	Available clinical practice data suggests the new service specification has the potential to improve value for money	<input type="checkbox"/>	Other data has been identified	<input type="checkbox"/>	No data has been identified	<input type="checkbox"/>	The data supports a high level of certainty about the impact on value	<input type="checkbox"/>	The data does not support a high level of certainty about the impact on value	<input type="checkbox"/>
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<b>C8 Non-Recurrent Costs</b>															
C8.1 Are there non-recurrent revenue costs associated with this service specification?	<p><b>No</b></p> <p>If yes, please specify and indicate whether these would be incurred or passed through to NHS England:</p> <p><a href="#">Click here to enter text.</a></p>														

	<p>If the costs are to be passed through to NHS England please indicate whether this has been taken into account in the budgetary impact.</p> <p>Choose an item.</p>
C8.2 Are there any non-recurrent provider capital costs associated with the service specification?	<p><b><u>No</u></b></p> <p>If yes, please specify and indicate with there is a separate source of funding identified (commissioners cannot reimburse capital costs).</p> <p><a href="#">Click here to enter text.</a></p>