# Integrated Impact Assessment Report for Clinical Commissioning Policies

| | | | |
|---|---|---|---|
| **Policy Reference Number** | A03/P(HSS)a | | |
| **Policy Title** | **Total Pancreatectomy with Islet Autotransplantation** | | |
| **Accountable Commissioner** | **Sarah Watson** | **Clinical Lead** | **Dr Edmund Jessop** |
| **Finance Lead** | **Craig Holmes** | **Analytical Lead** | **Jay Emin** |
| | | | |
| **Section A - Activity Impact** | | | |
| **Theme** | **Questions** | **Comments** (Include source of information and details of assumptions made and any issues with the data) | |
| A1 Current Patient Population & Demography / Growth | A1.1 What is the prevalence of the disease/condition? | A1. 1 The UK prevalence is 15.4-26.4/100 000 and the incidence is 6-7/100 000<br><br>Total pancreatectomy and islet autotransplantation (TPIAT) was carried out in the UK (Leicester) from 1994-2011 but is not currently provided by the NHS. 40 new patients in year 1 rising to a maximum of 80 new patients per year in year 5. | |
| | A1.2 What is the number of patients currently eligible for the treatment under the | A1.2 All adult patients will be eligible for treatment. In the Leicester series form 1994-2011 the median age of the treated population was 43 years and the | |

| | | |
|---|---|---|
| | proposed policy? | range was 21-65 years |
| | A1.3 What age group is the treatment indicated for? | A1.3 All adult patients will be eligible for treatment. In the Leicester series form 1994-2011 the median age of the treated population was 43 years and the range was 21-65 years |
| | A1.4 Describe the age distribution of the patient population taking up treatment? | A1.4 All adult patients will be eligible for treatment. |
| | A1.5 What is the current activity associated with currently routinely commissioned care for this group? | A1.5 In the Leicester series form 1994-2011 the median age of the treated population was 43 years and the range was 21-65 years |
| | A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years? | A1.6 Total pancreatectomy and islet autotransplantation (TPIAT) was carried out in the UK (Leicester) from 1994-2011 but is not currently provided by the NHS. |
| | A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years? | A1.7 The need for this service is expected to increase to year 5 to include existing patients and then no further growth in new patients. As the policy is a Not Routinely Commissioned policy there will be no activity implications. |

| | | |
|---|---|---|
| | | Year 2 - 50<br>Year 5 - 80<br>Year 10- 80 |
| | A1.8 How is the population currently distributed geographically? | A1.8 The population is evenly distributed throughout the UK. |
| A2 Future Patient Population & Demography | A2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other? | A2.1 This service is not currently commissioned and the policy is to not routinuely commission the service. Alternative treatments for this group of patients will be restricted. The alternative is not to do an islet autotransplant, in which case the patient will suffer from brittle diabetes. If TP is required the addition of an islet autotransplant is able to abrogate the majority of the symptoms and problems associated with total pancreatectomy alone. In addition since the funding for TPIAT ceased in 2011 there have been no total pancreatectomies performed in the UK in non-diabetic patients without islet autotransplantation as this is considered by the vast majority of units to be unethical. Indeed the resulting brittle diabetes if total pancreatectomy was performed in these patients would render a significant number candidates for a subsequent islet allotransplant, requiring lifelong immunosuppression, producing a significantly poorer outcome in the medium and long term and dramatically increasing the cost |

| | | |
|---|---|---|
| | A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival). | A2.2 The anticipated increase in the number of patients that could have been treated is related to the consolidation of referral patterns (the expert centres would be tertiary pancreatic units that receive complex patients with chronic pancreatitis but presently do not perform TPIAT) and an increase in confidence in the procedure as results are collected by the database and presented/published. |
| | A 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details. | A2.3 No – expected to be stable after 5 years |
| | A2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10? | A2.4 Policy is NRC – so no activity implications |
| A3 Activity | A3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet. | A3.1 There is no present activity |
| | A3.2 What will be the new activity should the new / revised policy be | A3.2 Not routinely commissioned. |

| | | |
|---|---|---|
| | implemented in the target population? Please provide details in accompanying excel sheet. | |
| | A3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet. | A3.3 The present "next best alternative" is at present best medical management. Previously total pancreatectomy without islet autotransplantation was considered an alternative treatment but with the advent of TPIAT and the published results demonstrating excellent outcomes and the avoidance of brittle diabetes this is no longer performed in non-insulin dependent patients. |
| A4 Existing Patient Pathway | A4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity. | A4.1 There is no existing comparative treatment |
| | A4.2. What are the current treatment access criteria? | A4.2 The treatment is not routinely commissioned and the policy is to not routinely commission the service. |
| | A4.3 What are the current treatment stopping points? | A4.3 The treatment is not routinely commissioned and the policy is to not routinely commission the service. |
| A5 Comparator (next best alternative | A5.1 If there is a 'next best' alternative | A5.1 There is no "next best" surgical procedure. The alternative |

| | | |
|---|---|---|
| treatment) Patient Pathway | routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity. | treatment at present is best medical management. Presently the only available alternative options to treat the pain from severe cases of chronic pancreatitis are medical. These include oral analgesics, regional and local pain blocks (Coeliac plexus/splanchnic and trigger point blocks). In a small number of cases where there is gross dilatation of the pancreatic duct or an inflammatory mass involving the head of the gland, drainage procedures are performed. These patients however are not the cohort who are candidates for total pancreatectomy and islet autotransplantation (TPIAT). TPIAT is indicated for patients with small duct disease or previously failed resectional/drainage procedures |
| | A5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point. | Chronic pancreatitis (CP) is an inflammatory disease causing progressive damage to the parenchyma with loss of exocrine and eventually endocrine function and consequent diabetes. Although conservative medical management can alleviate mild to moderate pain associated with CP, greater than 50% of patients will eventually require operative intervention for severe pain. A number of surgical approaches are possible including bypass procedures, duct decompression/drainage and partial or total resection.<br><br>The policy is to not routinuely commission TP IAT. The incidence of CP in the United Kingdom is estimated at 15.4 – 26.4/100 000 which gives an estimate of the number of affected individuals as |

| | | |
|---|---|---|
| | | 9,841 – 16 870. Very few of these patients require or are suitable for surgery and approximately 600 surgical procedures are carried out annually. The vast majority of these are relatively minor procedures do not aim to treat pain but specific complications such as pseudocysts, gastric outlet obstruction and biliary obstruction. Only a very small number of patients are undergoing resectional surgery and total pancreatectomy to treat intractable pain where all medical strategies have been exhausted is at present performed only under exceptional circumstances (and in insulin dependent patients) due to the non-availability of funding for islet autotransplantation (TPIAT). If TPIAT was available in the UK it is estimated that 40 – 80 patients would have been eligible annually. |
| A6 New Patient Pathway | A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.<br><br>A6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment | A6.1 Not routinely commissioned. |

| | | |
|---|---|---|
| | after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point. | |
| A7 Treatment Setting | A7.1 How is this treatment delivered to the patient?<br>○ Acute Trust: Inpatient/Daycase/ Outpatient<br>○ Mental Health Provider: Inpatient/Outpatient<br>○ Community setting<br>○ Homecare delivery<br><br>A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what?<br>*e.g. service capacity* | A7.1 Acute Trust: Inpatient<br>Diagnostic islet isolation facilities<br><br>A7.2 No |
| A8 Coding | A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?<br><br>A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure | A8.1 NRC<br><br>A8.2 NRC |

| | | |
|---|---|---|
| | codes) | |
| A9 Monitoring | A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?<br><br>A9.2 If this treatment is a drug, what pharmacy monitoring is required?<br><br>A9.3 What analytical information /monitoring/ reporting is required?<br><br>A9.4 What contract monitoring is required by supplier managers? What changes need to be in place?<br><br>A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?<br><br>A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy? | A9.1 – A9.7 NRC |

| | | |
|---|---|---|
| | A9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below* | |
| **Section B - Service Impact** | | |
| **Theme** | **Questions** | **Comments** (Include source of information and details of assumptions made and any issues with the data) |
| B1 Service Organisation | B1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)<br><br>B1.2 How will the proposed policy change the way the commissioned service is organised? | B1.1 Specialist Centre<br><br>B1.2 This service is currently not provided in England. |
| B2 Geography & Access | B2.1 Where do current referrals come from?<br><br>B2.2 Will the new policy change / restrict / expand the sources of referral?<br><br>B2.3 Is the new policy likely to improve equity of access?<br><br>B2.4 Is the new policy likely to improve equality of access / | B2.1 – B2.4 NRC |

| | | |
|---|---|---|
| | outcomes? | |
| B3 Implementation | B3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?<br><br>B3.2 Is there a change in provider physical infrastructure required?<br><br>B3.3 Is there a change in provider staffing required?<br><br>B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?<br><br>B3.5 Are there changes in the support services that need to be in place?<br><br>B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime | B3.1 There is some expertise in the country at present though all centres have stopped doing this procedure in the last 2 years. Service would need to be procured. If funding is agreed there would be a lead time of 12 – 16 weeks as some of the procedures required for islet autotransplantation differ slightly from those for allografting. In addition the workup of patients |

| | | |
|---|---|---|
| | contractor)<br><br>B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?<br><br>B3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration) | |
| B4 Collaborative Commissioning | B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements) | B4.1 No, this would have been a highly specialised service provided in a small number of centres commissioned nationally. |
| **Section C - Finance Impact** | | |
| **Theme** | **Questions** | **Comments** (Include source of information and details of assumptions made and any issues with the data) |
| C1 Tariff | C1.1 Is this treatment paid under a national prices*, and if so which? | C1.1 NRC |

| | | |
|---|---|---|
| | C1.2 Is this treatment excluded from national prices?<br><br>C1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?<br><br>C1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes?<br><br>C1.5 is VAT payable (Y/N) and if so has it been included in the costings?<br><br>C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy? | |
| C2 Average Cost per Patient | C2.1 What is the revenue cost per patient in year 1? | C2.1 If the service were commissioned the result of averaging the overall costs between units was a procedure cost of £88,088. Total first year costs of £91,578 including follow up and drugs costs. |

| | | |
|---|---|---|
| | C2.2 What is the revenue cost per patient in future years (including follow up)? | C2.2 Ongoing cost per patient is £3,490 per year. |
| C3 Overall Cost Impact of this Policy to NHS England | C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.<br><br>C3.2 Where this has not been identified, set out the reasons why this cannot be measured. | C3.1 In year 1 there would have been a cost increase of £1.4m compared with the do-nothing scenario for the initial cohort of patients. In following years there is a cost saving (Year 2 £0.3m, Year 3 £2.5m, Year 5 £8.5m, Year 10 £28.8m) where the high surgical cost is offset by the avoidance of ongoing annual drug costs. These savings can be seen as the difference between the total costs shown on table Q2 and Q3 on the finance tab on the spreadsheet model.<br><br>C3.2<br>n/a |
| C4 Overall cost impact of this policy to the NHS as a whole | C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).<br><br>C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole. | C4.1 NRC |

| | | |
|---|---|---|
| | C4.3 Where this has not been identified, set out the reasons why this cannot be measured.<br><br>C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders? | |
| C5 Funding | 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* | C5.1 *e.g. decommissioning less clinically or cost-effective services*<br>Specialised commissioning recurrent allocation envelope (CPAG growth) to cover year 1 cost pressure. Savings anticipated from year 2 onwards. |
| C6 Financial Risks Associated with Implementing this Policy | C6.1 What are the material financial risks to implementing this policy?<br><br>C6.2 Can these be mitigated, if so how?<br><br>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios? | C6.1 Other than activity variation compared with modelling assumptions, to maintain a NRC policy has been identified as an additional cost to NHS England.<br><br>C6.2 No<br><br>C6.3 Variation would depend on activity growth rates although in all scenarios there would have been savings post year 1 due to avoidance of alternative drugs costs |

| | | |
|---|---|---|
| C7 Value for Money | C7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*<br><br>C7.2 What issues or | C7.1 The Leicester series from 1994-2011 allowed the examination of a significant number of patients over a long period. TPIAT resulted in a reduction in the number and length of hospital admissions by 50 and 81.25% respectively. Post procedure the number of patients requiring opiates and the amount was significantly reduced; a total reduction of 95.5%. Despite these documented reductions it is difficult to calculate the cost per QALY due to the relatively low number of patients (60 in total) and the heterogeneity of the outcomes.<br><br>Approximately a third of patients will be insulin independent, a third will require minimal amounts and a third significant amounts. The reduction in hospital admissions and the requirements for opiates and outpatient support is also varied and dependent on the length of symptoms and opiate usage prior to referral for consideration of TPIAT. An attempt in 2014 using data from the Leicester series produced a figure of ~£12 000 per QALY and this is supported by an American study published in 2015 where results following TPIAT were compared to best medical management (Wilson GC et al J. Gastrointest Surg 2015;19(1):46-54). TPIAT cost $10 307/QALY and best medical management $17 047/QALY which is within NICE's normal limit of £20,000 per QALY. Long-term survival is expected to exceed 10 years and in the Leicester series a number of patients treated between 1994 and 2000 are alive between 15 and 20 years following their procedure. |

| | | |
|---|---|---|
| | risks are associated with this assessment? *e.g. quality or availability of evidence* | |
| C8 Cost Profile | C8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs*<br><br>C8.2 If so, confirm the source of funds to meet these costs. | C8.1 NRC policy |