Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	D10X03		
Policy Title	Autologous chondrocyte implantation for osteochondral lesions of the talus (adults)		
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Section K - Activity Impact			
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)	
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	K1.1 This policy proposes to **not routinely commission** autologous chondrocyte implantation (ACI) in patients with Osteochondral Lesions (OCLs)[i] also known as osteochondritis dissecans (OCD), of the talus. OCD is rare, with an estimated incidence of 15-30 persons per 100,000 of the population in the UK.[ii] This corresponds to c. 8,150 to 16,300 new people affected in England in 2014/15.[iii] Moreover, lesions of the talus account for 4% of all osteochondral lesions in the body.[iv]	

		Therefore, in 2014/15 in England, around 325 to 650 persons are estimated to present with OCL of the talus. *It is recognised that the incidence of damage to the talar joint surface could be higher than this but the majority of these would heal without intervention.*[v]
	K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K1.2 Patients eligible for treatment with ACI are those who failed a first line treatment such as surgical debridement or bone grafting.[vi] An estimated 10%-15%[vii] of patients with OCL of the talus do not respond to primary surgery. This therefore results in c. 35-100[viii] patients currently eligible under the proposed policy, and it is expected that this would be closer to the higher estimate.
	K1.3 What age group is the treatment indicated for?	K1.3 This treatment is indicated for adults (18 years or older).
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 The average age of patients with an OCL is 20-30 years. Moreover, around 70% of the patient population is male.[ix] This is reflective of the sporting population and is therefore likely to vary over time.[x]
	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 The number of ACI for OCL of the talus is small and currently funded through individual funding requests (IFRs)[xi]. In 2014/15, there were 2 IFRs received for this procedure by NHS England but the number of IFRs that have been approved is not known.[xii] This low level of activity of at most 2 procedures per year reflect the ongoing change to current practice.[xiii]

	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	K1.6 It is assumed that incidence of OCL of the talus grows in line with demographic growth for the relevant population.[xiv] In future the number of patients with OCL is estimated in the region of:[xv] • ~ 330 - 655 people in 2016/17 (year 1) • ~ 330 - 660 people in 2017/18 (year 2) • ~ 325 - 655 people in 2020/21 (year 5)
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2, 5 and 10 years?	K1.7 The number of ACI for OCL of the talus undertaken in future is not expected to change from current levels. Therefore, it is assumed that there will be an average of 2 procedures per year in the 'do nothing' scenario, as identified in K1.5.
	K1.8 How is the population currently distributed geographically?	K1.8 Across England, no evidence of geographic variation has been identified in this review.
K2 Future Patient Population & Demography	K2.1 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?	K2.1 The policy moves to a 'non-routine commissioning' position.
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	K2.2 Many patients with osteochondral lesions have experienced previous ankle trauma or injury.[xvi] As such, changes in the overall level of physical activity in the population might affect the risk of trauma. Apart from this, no factors were identified that might affect growth other than demographic factors.

	K 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.	K2.3 None identified.
	K2.4 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?	K2.4 The proposed policy establishes a 'not routinely commissioned' position for the relevant population (the specific cohort set out in K1.2).The number of patients who fall outside this cohort covered by the proposed policy, or for whom exceptionality is demonstrated is likely to be small. As compared to the 'do nothing' case, there would be a net decrease of c. 2 patients accessing ACI every year. These patients would instead either[xvii]: • Repeat primary treatments such as surgical debridement, alone or in combination with Kirschner-wire drilling or microfracture of the subchondral bone, or bone grafting; or • Undergo a newer resurfacing approach, which include one step approaches, such as bone marrow harvesting, concentration and implantation during surgery.
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.	K3.1 The current activity is as described in K1.5.
	K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide	K3.2 Should the policy be implemented, i.e. ACI for OCL in the talus is not routinely commissioned; ACI would no longer be undertaken except as described in K2.4.

	details in accompanying excel sheet.	
	K3.3 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.	K3.3 The 'do nothing' case would be the same as the position set out in K1.7
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.	K4.1 Patients are first treated with either: • Surgical debridement, alone or in combination with Kirschner-wire drilling or microfracture of the subchondral bone • Bone grafting If the first surgery does not resolve the symptoms, patients may receive a repeat primary treatment, or be referred to specialist orthopaedic centres for a resurfacing approach. Alternative resurfacing techniques include one step approaches, such as bone marrow harvesting, concentration and implantation during surgery. Although these are not explicitly routinely commissioned, they are considered standard clinical practice.
	K4.2. What are the current treatment access criteria?	K4.2 Patients presenting with symptomatic osteochondral defects that have not been resolved by first line surgery
	K4.3 What are the current treatment stopping points?	K4.3 Not applicable

K5 Comparator (next best alternative treatment) Patient Pathway	K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity. K5.2 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.	K5.1 and K5.2 See K.4
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy. K6.2 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	K6.1 Not applicable – no new pathway proposed K6.2 Not applicable – no new pathway proposed

	indicate likely outcome for patient at each stopping point.	
K7 Treatment Setting	K7.1 How is this treatment delivered to the patient? ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	K7.1 ACIs are two-stage procedures. The first stage involves harvesting the patient's own chondrocytes from the joint during an arthroscopy, this is typically performed as a day case procedure.[xviii] Chondrocytes are then cultured in a laboratory to increase their number. In a second stage, the chondrocytes are implanted into the area of damaged cartilage, and this is typically performed as a day case, but could involve an inpatient stay depending on the patient.[xix] K7.2 No
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded? K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	K8.1 Not applicable as the position is to not routinely commission. K8.2 Not applicable
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information	K9.1 Not applicable

	Schedule?	
	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	K9.2 Not applicable
	K9.3 What analytical information /monitoring/ reporting is required?	K9.3 Not applicable
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	K9.4 Not applicable
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 Not applicable
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	K9.6 Not applicable
	K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See*	K9.7 Not applicable

	also linked question in M1 below	
Section L - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	L1.1 There are 25-30 Adult Specialist Orthopaedic Centres. Some provide outreach clinics as part of a provider network.
	L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.2 No change
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 Patients with symptomatic osteochondral defects treated in Specialist Orthopaedic Centres under circumstances where they have had a primary treatment.
	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 No
	L2.3 Is the new policy likely to improve equity of access?	L2.3 Yes, through a consistent commissioning position across country
	L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.4 No

L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	L3.1 No
	L3.2 Is there a change in provider physical infrastructure required?	L3.2 No change required
	L3.3 Is there a change in provider staffing required?	L3.3 No new requirements
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4 No change required
	L3.5 Are there changes in the support services that need to be in place?	L3.5 No change required
	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	L3.6 No change required
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.7 No change in the number of providers anticipated

	L3.8 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)	L3.8 Not applicable
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	L4.1 Not applicable
Section M - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which? M1.2 Is this treatment excluded from national prices? M1.3 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?	M1.1 No. M1.2 Yes. M1.3 Yes. ACI is a 2 step procedure and is estimated to cost[xx]: a) c. £2,400 for the cell harvesting; and b) c. £6,900 for the procedure of cell implantation (including the cost for cells). This gives a total cost of c. £9,300 per procedure. As prices are

		negotiated locally, there may be some variability in costs.
	M1.4 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?	M1.4 Not applicable.
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 VAT would be recoverable under certain specific conditions[xxi]. It is assumed here that VAT would not be recoverable.
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	M1.6 No.
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 As the policy proposes a not-routinely commission position, the cost per patient for ACI would be nil. For reference, however, the costs per patient would be expected to comprise:[xxii] • Before undergoing surgery, a minimum of one outpatient attendance would be required. This has an estimated cost of £129[xxiii]. • Fewer than 50% of patients present with other ongoing pathologies and require an additional outpatient appointment[xxiv]

		(with a cost of £76[xxv]) as well as an MRI scan (with an estimated cost of £173[xxvi]). • As identified in M1.3, the 2 step procedure costs around £9,300, or c. £10,050 including MFF and inflation and efficiency adjustments. • Follow-up costs are estimated in the region of £76 per attendance.[xxvii] Patients typically have follow-up appointments 6 weeks, 6 months and 1 year after surgery.[xxviii] This would therefore cost c. £230. This leads to an average total cost in year 1 of **c. £10,535[xxix].** Moreover, patients may also require physiotherapy[xxx], this could cost in the region of £50 per session.[xxxi] These are not included in the estimates, however, as the number of interactions will depend upon the individual patient. Under the policy to not routinely commission, patients would either undergo first-line treatments (at an estimated procedure cost of c. £470[xxxii]) or other resurfacing approaches as set out in K2.4 (these costs are not know, however are estimated to be significantly cheaper than ACI[xxxiii]). These are expected to have the same pre and post procedure costs as stated for ACI above. The total cost for the comparator treatment could therefore be c. £950.
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 Patients could have a yearly review appointment[xxxiv] at a cost of £76. [xxxv] Otherwise, no further costs in future years are anticipated.
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.	M3.1 There could be cost savings to NHS England if ACI is no longer undertaken and cheaper comparator (repeat first-line) treatments are performed instead. The savings relate solely to the reduction in ACI procedures, as first-line treatments are funded by CCGs[xxxvi]. The cost

		savings are estimated be around £0 to c. £21k per year, driven by the range in current activity from 0 to 2, as identified in K1.5.
	M3.2 Where this has not been identified, set out the reasons why this cannot be measured.	M3.2 Not applicable.
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).	M4.1 If first-line procedures (which do not fall under specialised commissioning and are funded by CCGs)[xxxvii] are repeated instead, this could lead to a cost pressure to CCGs in the region of £0 to c. £2k.
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.	M4.2 Either cost neutral or cost saving in the region of £19k per year based on the answers to questions M3.1 and M4.1.
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured.	M4.3 Not applicable.
	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. *e.g. decommissioning less clinically or cost-*	M5.1 Not applicable.

	effective services	
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy?	M6.1 Not applicable.
	M6.2 Can these be mitigated, if so how?	M6.2 Not applicable.
	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	M6.3 Not applicable.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*	M7.1 and M7.2 The review did not identify any relevant studies on cost effectiveness of ACI used in the treatment of osteochondral lesions of the talus compared to existing treatments. In some studies, authors have expressed opinion that ACI may not be more cost effective compared to other treatments (Zengerink et al., 2010, Apprich et al., 2012, Magnan et al., 2012). However, these views are yet to be substantiated with a robust, statistically-backed evidence base.
	M7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs*	M8.1 Not applicable.

	M8.2 If so, confirm the source of funds to meet these costs.	M8.2 Not applicable.

[i] OCLs are areas of joint damage involving the articular hyaline cartilage and the underlying subchondral bone.

[ii] Obedian RS, Grelsamer RP (1997). "Osteochondritis dissecans of the distal femur and patella." Clin Sports Med. 16(1):157-74.

[iii] Based on Annual Mid-Year Population Estimates for the UK, Office for National Statistics (ONS), 2015.

[iv] Alexander AH, Lichtman DM (1980)."Surgical treatment of transchondral talar-dome fractures (osteochondritis dissecans). Long-term follow-up." *J Bone Joint Surg Am*. 62(4):646-52.

[v] Based on discussions with the policy working group.

[vi] Based on discussions with the policy working group.

[vii] Based on discussions with the policy working group.

[viii] Based on the c. 325 to 650 patients identified in K1.1.

[ix] Based on Chew et al (2008). "Osteochondral Lesions of the Talus." *Ann Acad Med Singapore* ; 37:63-8; and OrthopaedicsOne (2012). *Ankle OCD*. [Online] Available from http://www.orthopaedicsone.com/display/MSKMed/Ankle+OCD: [Accessed: 05/01/2016]. It was noted by the policy working group that this might change as women are increasingly engaged in contact sporting activities and people are active at older ages.

[x] For example by age and gender. (Source: based on discussions with the policy working group).

[xi] Based on discussions with the policy working group.

[xii] Based on an extract from the national IFR database from 25/11/2015. From April 2015 to October 2015 (the end of the observation period), there have been no applications recorded.

[xiii] Based on discussions with the policy working group.

[xiv] More precisely, this is the population in England of the ages 20-30 (with a relative weight of men vs. women of 7:3, based on the response to K1.4) [based on ONS (2012). Population projections].

[xv] Based on the number of OCL in 2014/15 reported in K1.1 and the forecast demographic growth rate from ONS population projections (2012). Figures are rounded to the nearest 5.

[xvi] Zengerink et al. (2010). "Treatment of osteochondral lesions of the talus: a systematic review. Knee Surgery." *Sports Traumatology, Arthroscopy*. 18(2):238-246.

[xvii] Based on discussions with the policy working group.

[xviii] Based on NHS Direct Wales. *Cartilage damage.* [Online] Available from: http://www.nhsdirect.wales.nhs.uk/encyclopaedia/c/article/cartilagedamage/ [Accessed: 06/01/2016]. However, depending on patient circumstances the procedure might be performed in an inpatient setting (based on discussions with the policy working group).

[xix] Based on discussions with the policy working group.

[xx] Based on NICE costing data for the knee obtained from NICE (2014). Knee cartilage defects - autologous chondrocyte implantation [ID686]: assessment report.

[xxi] Please refer to Section 3.2 of VAT Notice 701/557 (https://www.gov.uk/government/publications/vat-notice-70157-health-professionals-and-pharmaceutical-products/vat-notice-70157-health-professionals-and-pharmaceutical-products)

[xxii] The costs include a 10% uplift for MFF, and are corrected for efficiency gains of -3.5% and inflation of 1.9% [Based on discussions with NHS England Finance Lead and Monitor (2015). *Economic Assumptions 2015/16 to 2019/20*, [Online] Available from: https://www.gov.uk/government/publications/economic-assumptions-201516-to-201920/economic-assumptions-201516-to-201920 [Accessed: 06/01/2016]].

[xxiii] Based on the 2014/15 National Tarff costs of a single professional first outpatient attendance for 'Trauma & Orthopaedics' of £119. An MFF of 10% and the 2015/16 efficiency (-3.5%) and inflation (1.9%) are applied to determine 2015/16 prices. These are then assumed constant going forward.

[xxiv] Based on discussions with the policy working group.

[xxv] Based on the 2014/15 National Tarff costs of a single professional follow-up outpatient attendance for 'Trauma & Orthopaedics' of £70. An MFF of 10% and the 2015/16 efficiency (-3.5%) and inflation (1.9%) are applied to determine 2015/16 prices. These are then assumed constant going forward.

[xxvi] Based on the 2014/15 National Tarff costs of a 'Magnetic Resonance Imaging Scan, one area, no contrast' including the cost of reporting of £22. An MFF of 10% and the 2015/16 efficiency (-3.5%) and inflation (1.9%) are applied to determine 2015/16 prices. These are then assumed constant going forward.

[xxvii] Based on the 2014/15 National Tarff costs of a single professional follow-up outpatient attendance for 'Trauma & Orthopaedics' of £70. An MFF of 10% and the 2015/16 efficiency (-3.5%) and inflation (1.9%) are applied to determine 2015/16 prices. These are then assumed constant going forward.

[xxviii] Based on discussions with the policy working group.

[xxix] This assumes that 50% of patients would receive a second outpatient appointment and MRI scan, as mentioned in M2.1.

[xxx] Based on discussions with the policy working group.

[xxxi] Based on the unit cost of physiotherapy from the 2014/15 National Schedule of Reference Costs, Outpatient Tariff for service code 650: Physiotherapy of £46. A MFF uplift of 10% is applied, as well as the 2015/16 efficiency and inflation adjustment to determine 2015/16 prices. These are then assumed constant going forward.

[xxxii] Based on the cost of £432 for HRG code HA99Z – Other Procedures for Trauma listed the 2014/15 National Tariff. This HRG code was obtained from the 2014/15 HRG Grouper Tool in conjunction with the OPC code W808 - Other specified debridement and irrigation of joint. An MFF uplift of 10% and the 2015/16 efficiency (-3.5%) and inflation (1.9%) are applied to determine 2015/16 prices. These are then assumed constant going forward.

[xxxiii] Based on discussions with the policy working group.

[xxxiv] This would be recommended practice, however it was noted that not all patients would receive regular follow-ups (based on discussions with the policy working group).

[xxxv] Based on the 2014/15 National Tarff costs of a single professional follow-up outpatient attendance for 'Trauma & Orthopaedics' of £70. An MFF of 10% and the 2015/16 efficiency (-3.5%) and inflation (1.9%) are applied to determine 2015/16 prices. These are then assumed constant going forward.

[xxxvi] Based on discussions with the policy working group.

[xxxvii] Based on discussions with the policy working group.