



**CLINICAL PRIORITIES ADVISORY GROUP
18 07 2022**

Agenda Item No	3.2
National Programme	Trauma
Clinical Reference Group	Specialised Orthopaedics
URN	2007

Title
Fresh osteochondral allograft (OCA) for osteochondral lesions of the knee in adults and post-pubescent children

Actions Requested	1. Support the adoption of the policy proposition
	2. Recommend its relative prioritisation

Proposition
<p>This policy proposition proposes fresh osteochondral allografts (OCA) be made available as a treatment option to adults and post-pubescent children who have osteochondral lesions greater than 2cm² in size.</p> <p>Osteochondral lesions are combined lesions of cartilage and bone, usually within the knee. The main symptoms involve pain, swelling, instability (giving way) and locking (when the knee becomes fixed in one position). As a consequence, patients are unable to stand for long periods, walk significant distances or undertake manual work. Without treatment these lesions progress, become larger and result in osteoarthritis. The condition also impacts negatively on patients' co-morbidities and mental health due to their pain and inability to function.</p> <p>Fresh OCA is a surgical procedure where healthy bone and cartilage obtained from young, recently deceased donors, is implanted to repair the cartilage and bone damage in a single surgery. The purpose of OCA is to improve pain and function in patients with osteochondral lesions and to delay the need for artificial joint replacement e.g. total knee replacement (TKR).</p>

Clinical Panel recommendation
The Clinical Panel recommended that the policy proposition progress as a routine commissioning policy.

The committee is asked to receive the following assurance:	
1.	The Head of Clinical Effectiveness confirms the proposal has completed the appropriate sequence of governance steps and includes an: Evidence Review; Clinical Panel Report.
2.	The Head of Acute Programmes Programme confirms the proposition is supported by an: Impact Assessment; Engagement Report; Equality and Health Inequalities Impact Assessment; Clinical Policy Proposition. The relevant National Programme of Care has approved these reports.
3.	The Director of Finance (Specialised Commissioning) confirms that the impact assessment has reasonably estimated a) the incremental cost and b) the budget impact of the proposal.
4.	The Clinical Programmes Director (Specialised Commissioning) confirms that the service and operational impacts have been completed.

The following documents are included (others available on request):	
1.	Clinical Policy Proposition
2.	Engagement Report
3.	Evidence Summary
4.	Clinical Panel Report
5.	Equality and Health Inequalities Impact Assessment

In the Population what is the clinical effectiveness and safety of the Intervention compared with Comparator?

Outcome	Evidence statement
Clinical effectiveness	
Critical outcomes	
Knee specific score	Knee specific scores are important to patients because they measure pain, symptoms, function in daily living, function in sport and quality of life, all of which can have a significant impact on patients.
Certainty of evidence: Very low	In total, seven case series (one prospective and six retrospective) reported non-comparative evidence for a range of knee specific outcome scores with mean follow-up ranging from 67 months to 15.5 years for people treated with OCA f or large osteochondral defects. The scores used varied between studies and included the Knee Injury and Osteoarthritis Outcome Scores (KOOS), the International Knee documentation Committee (IKDC) scores, the Knee Society – function (KS-F) and Knee Society – knee (KS-K) scores, the Western Ontario and McMaster Universities Osteoarthritis

	<p>Index (WOMAC), the modified Hospital for Special Surgery score (mHSS), and the modified Merle d'Aubigné-Postel (MAPS) score. The scores measure pain and various aspects of function and activities (see end of table for more details).</p> <p>At up to two years and mean 7.29 +/- 3.30 years follow-up:</p> <ul style="list-style-type: none"> • Two case series (Brown et al 2011, Cotter et al 2018) (n range = 24 to 38 knees) reported the KOOS pain, symptoms and sport scores. • Brown et al 2011 reported mean +/- standard deviation (SD) scores at baseline, 6 months, 1 year and 2 years, with a p value comparing baseline vs 2 years. The scores at these time points for pain were 59 +/- 17; 79 +/-17; 77 +/-18; 74 +/-22; p=0.028; for symptoms were 58 +/-16; 69 +/-20; 69 +/-21; 70 +/-20; p=0.172; and for sports were 37 +/-26; 65 +/-27; 59 +/-23; 57 +/-30; p=0.005. The scores for pain and sports showed statistically significant improvements between baseline and 2 years. The improvement in the symptoms score was not statistically significant. The score improvements for pain at 6 months and 1 year, and for sport at 6 months exceeded the minimum clinically important difference (MCID) defined in the PICO, but declined thereafter. (VERY LOW) • Cotter et al 2018 found mean improvements in score between pre-op and latest follow-up of 20.8 (pain), 14.8 (symptoms) and 25.96 (sport) (all statistically significant improvements, p<0.001) at mean 7.29 +/- 3.30 years follow-up. The score improvements for pain and sport exceeded the MCID defined in the PICO. Cotter et al 2018 reported that the improvement in symptoms score exceeded the MCID but did not provide the MCID definition. (VERY LOW) <p>At mean from 6 months to 11.0 (range 2.9 to 29) years follow-up:</p> <ul style="list-style-type: none"> • Six case series (Brown et al 2011, Cotter et al 2018, Early et al 2018, Gortz et al 2010, Gracitelli et al 2017, Sadr et al 2016) (n range= 23 to 137 knees) reported IKDC scores. • Four case series (Brown et al 2011, Cotter et al 2018, Gracitelli et al 2017, Sadr et al 2016) reported IKDC total score and all reported statistically significant improvements. Brown et al 2011 reported mean +/- SD scores at baseline of 45 +/-11, 6 months of 57 +/-14, 1 year of 59 +/- 15 and 2 years of 62 +/-20; p<0.001 (comparing baseline vs 2 years). Cotter et al 2018 found a mean improvement at follow-up of 25.54 (p<0.0001); Gracitelli et al 2017 found a mean pre-op score of 32.9 and mean follow-up score of 54.3 (p=0.012) and Sadr et al 2016 found a mean (+/- SD) pre-op score of 44.2 +/- 17.5 and follow-up score of 82.3 +/- 15.8 (p<0.001).
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	<p>Cotter et al 2018 reported that the improvement exceeded the MCID but did not provide the MCID definition. (VERY LOW)</p> <ul style="list-style-type: none"> • Four case series (Early et al 2018; Gortz et al 2010; Gracitelli et al 2017; Sadr et al 2016) reported IKDC pain score and all but one reported statistically significant improvements. Early et al 2018 found a mean pre- op score of 7.2 and mean follow-up score of 2.8 (p<0.001); Gortz et al 2010 found a mean pre-op score of 7.1 and mean follow-up score of 2.0 (p<0.001); Gracitelli et al 2017 found a mean pre-op score of 6.4 and mean follow-up score of 4.5 (p=0.055) and Sadr et al 2016 found a mean (+/- SD) pre-op score of 5.3 +/- 2.5 and follow-up score of 2.1 +/- 2.2 (p< 0.001). (VERY LOW) • Four case series (Early et al 2018, Gortz et al 2010, Gracitelli et al 2017, Sadr et al 2016) reported IKDC function score and all reported statistically significant improvements. Early et al 2018 found a mean pre- op score of 3.3 and mean follow-up score of 6.5 (p=0.005); Gortz et al 2010 found a mean pre-op score of 3.5 and mean follow-up score of 8.3 (p=0.002); Gracitelli et al 2017 found a mean pre-op score of 2.8 and mean follow-up score of 6.0 (p=0.001) and Sadr et al 2016 found a mean (+/- SD) pre-op score of 3.5 +/- 1.8 and follow-up score of 8.1 +/- 2.0 (p<0.001). (VERY LOW) <p>At mean from 67 months to 11.0 (range 2.9 to 29) years follow-up:</p> <ul style="list-style-type: none"> • Three case series (Early et al 2018, Gortz et al 2010, Sadr et al 2016) (n range=23 to 137 knees) reported the Knee Society-function score and all reported statistically significant improvements. Early et al 2018 found a mean pre-op score of 61.7 and mean follow-up score of 87.5 (p=0.0030); Gortz et al 2010 found a mean pre-op score of 60.0 and mean follow-up score of 85.7 (p=0.005), and Sadr et al 2016 found a mean (+/- SD) pre- op score of 72.3 +/- 18.6 and follow-up score of 95.7 +/- 9.6 (p<0.001). (VERY LOW) • One case series (Sadr et al 2016) (n=137 knees) reported the Knee Society-knee score with a mean (+/- SD) pre-op score of 81.1 +/- 14.8 and mean follow-up score of 94.3 +/- 8.8 (p<0.001), a statistically significant improvement. (VERY LOW) <p>At mean 7.29 +/- 3.30 years follow-up:</p> <ul style="list-style-type: none"> • One case series (Cotter et al 2018) (n=38 knees) reported a statistically significant improvement in the WOMAC pain score and WOMAC stiffness score (both p<0.0001); actual scores or change in scores were not reported. Cotter et al
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	<p>2018 reported that the improvement in both scores did not exceed the MCID but did not provide the MCID definition. (VERY LOW)</p> <p>At mean from 67 (range 25 to 235) months to 6.3 (range 1.9 to 16.8) years follow-up:</p> <ul style="list-style-type: none"> Two case series (Gortz et al 2010; Sadr et al 2016) (n range = 25 to 137 knees) reported the MAPS scores and both reported statistically significant improvements. Gortz et al 2010 found a mean pre-op score of 11.3 and mean follow-up score of 15.8 (p<0.001) and Sadr et al 2016 found a mean (+/- SD) pre-op score of 13.6 +/- 2.0 and mean follow-up score of 16.8 +/- 1.5 (p<0.001). (VERY LOW) <p>At mean 15.5 (range 4.3 to 31.7) years follow-up:</p> <ul style="list-style-type: none"> One case series (Abolghasemian et al 2019) (n=60 knees) reported the mHSS score and found a statistically significant improvement. They found a mean pre-op score of 69 (range 48 to 85) and mean follow-up score of 85.5 (range 56 to 100), p < 0.001. (VERY LOW) <p>These studies provided very low certainty evidence that there is a statistically significant improvement in knee specific scores in patients undergoing OCA at between 2 years and mean 15.5 years follow-up after surgery.</p> <p>They do not provide any evidence about changes in knee specific scores for patients undergoing OCA compared to ACI with bone graft, ACI alone or no surgical treatment. Two studies provided very low certainty evidence that the improvement in two scores (KOOS pain and KOOS sport) exceeded the predefined MCID.</p>
<p>Quality of life score</p> <p>Certainty of evidence: Very low</p>	<p>Quality of life (QOL) score is important to patients because osteochondral defects may be associated with a significant reduction in quality of life. This measure helps inform patient-centred shared decision making and health policy. Disease specific quality of life questionnaires can provide information regarding improvement in symptoms.</p> <p>In total, two case series (one prospective and one retrospective) reported non-comparative results for quality of life in people treated with OCA for large osteochondral defects. Quality of life was measured using the SF12 and the KOOS QOL score.</p> <p>At up to two years and mean 7.29 +/- 3.30 years follow-up:</p> <ul style="list-style-type: none"> Two case series (Brown et al 2011, Cotter et al 2018) (n range= 24 to 38 knees) reported the KOOS knee-related QOL score. Brown et al 2011 reported a mean +/- SD score at baseline of 23 +/-17, at 6 months of 47 +/-21, at 1 year of

	<p>49 +/-24, and at 2 years of 48 +/-22 (statistical test only reported between baseline vs 2 years; p<0.001, a statistically significant improvement). Cotter et al 2018 reported a statistically significant improvement in mean score of 20.88 (p<0.0001) at mean 7.29 years follow-up but actual scores were not reported. Cotter et al 2018 reported that the improvement in QOL score exceeded the MCID but did not provide the MCID definition. (VERY LOW)</p> <p>At mean 7.29 +/- 3.30 years follow-up:</p> <ul style="list-style-type: none"> • One case series (Cotter et al 2018) (n=38 knees) reported the SF12- mental and SF12-physical scores. They found a statistically significant improvement in the SF12-physical score (p=0.002; actual scores and change in scores not reported) but no statistically significant change in the SF12-mental score (p=0.910). (VERY LOW) <p>These studies provided very low certainty evidence that there is a statistically significant improvement in the KOOS QOL score in patients with large osteochondral defects undergoing OCA at 2 years and at 7.29 years after surgery.</p> <p>They also provided very low certainty evidence that there is a statistically significant improvement in SF12-physical score, but no significant change in SF12-mental score in patients undergoing OCA for osteochondritis dissecans (OCD) at a mean of 7.29 years after surgery.</p> <p>They did not provide any evidence about quality of life for patients undergoing OCA compared to ACI with bone graft, ACI alone or no surgical treatment.</p>
<p>Activities of daily living Score</p> <p>Certainty of evidence: Very low</p>	<p>Activities of daily living (ADL) score is important to patients because it grades mobility, work and sports activities and therefore impacts on their daily function and ability. Activities of daily living refer to the basic skills needed to properly care for oneself and meet one's physical needs.</p> <p>In total, two case series (one prospective and one retrospective) reported non-comparative results for ADL in people treated with OCA for large osteochondral defects. ADL subscores, each consisting of 17 items, were reported from two knee specific scores.</p> <p>At up to two years and mean 7.29 +/- 3.30 years follow-up</p> <ul style="list-style-type: none"> • Two case series (Brown et al 2011, Cotter et al 2018) (n range= 24 to 38 knees) reported the KOOS (ADL) score. Brown et al 2011 reported a mean +/- SD score at baseline of 69 +/-21, at 6 months, of 85 +/-16, at 1 year of 84 +/-16, and at 2 years of 83 +/-23 (statistical test only reported

	<p>between baseline vs 2 years; not statistically significant, $p=0.058$). Cotter et al 2018 reported a statistically significant improvement in score of 20.88 ($p<0.0001$) at mean 7.29 years follow-up but actual scores were not reported. Cotter et al 2018 reported that the improvement in ADL score exceeded the MCID but did not provide the MCID definition. (VERY LOW)</p> <p>At mean 7.29 +/- 3.30 years follow-up:</p> <ul style="list-style-type: none"> • One case series (Cotter et al 2018) (n=38 knees) reported the WOMAC (function) score. They reported a statistically significant improvement in score ($p<0.0001$) but actual scores and changes in scores were not reported. (VERY LOW) <p>These studies provided very low certainty evidence that there is not a statistically significant improvement in ADL scores in patients with large osteochondral defects undergoing OCA at 2 years, but there is a statistically significant improvement in ADL scores in patients undergoing OCA at a mean of 7.29 years after surgery.</p> <p>They do not provide any evidence about ADL for patients undergoing OCA compared to ACI with bone graft, ACI alone or no surgical treatment.</p>
Important outcomes	
<p>Allograft survival rate at 5, 10, 15 and 20 years</p> <p>Certainty of evidence: Very low</p>	<p>Allograft survival rate is important to patients because longevity of the treatment will affect patient satisfaction as well as reduce the need for further intervention which may have negative outcomes and increased risks.</p> <p>In total, six retrospective case series reported non-comparative results for allograft survival rate in people treated with OCA for large osteochondral defects at various intervals between five and 20 years after surgery.</p> <p>Allograft survival rate at five years:</p> <ul style="list-style-type: none"> • Six case series (Abolghasemian et al 2019, Cotter et al 2018, Early et al 2018, Gortz et al 2010, Gracitelli et al 2017, Sadr et al 2016) (n range=28 to 149 knees) reported allograft survival rate at 5 years. They found survival rates of 90% (95% confidence interval (CI) 83% to 94%), 97%, 90%, 89%, 82.6% and 95% respectively (CI reported where available). (VERY LOW) <p>Allograft survival rate at 10 years:</p> <ul style="list-style-type: none"> • Five case series (Abolghasemian et al 2019, Early et al 2018, Gracitelli et al 2017, Raz et al 2014, Sadr et al 2016) (n range=33 to 149 knees) reported allograft survival rate at

	<p>10 years. They found survival rates of 79% (95%CI 70% to 86%), 82%, 69.6%, 91% (95%CI 80% to 96%), and 93% respectively (CI reported where available). (VERY LOW)</p> <p>Allograft survival rate at 15 years:</p> <ul style="list-style-type: none"> Two case series (Abolghasemian et al 2019, Raz et al 2014) (n range=58 to 113 knees) reported allograft survival rate at 15 years. They found survival rates of 64% (95%CI 53% to 73%) and 84% (95%CI 50% to 81%) respectively. (VERY LOW) <p>Allograft survival rate at 20 years:</p> <ul style="list-style-type: none"> Two case series (Abolghasemian et al 2019, Raz et al 2014) (n range=58 to 113 knees) reported allograft survival rate at 20 years. They found survival rates of 47% (95%CI 34% to 59%) and 69% (95%CI 50% to 81%) respectively. (VERY LOW) <p>These studies provided very low certainty evidence that allograft survival rate is around 82% to 97% at 5 years, around 70% to 93% at 10 years, around 64% to 84% at 15 years and around 47% to 69% at 20 years after OCA surgery in patients with large osteochondral defects.</p>
<p>Failure of transplantation</p> <p>Certainty of evidence: Very low</p>	<p>Failure of transplantation is important to patients because it can result in further treatment being required which will impact on patient satisfaction as well as recovery time.</p> <p>In total, eight retrospective case series reported non-comparative results for failure rates at between 46.2 months and 21.8 years after surgery for people treated with OCA for large osteochondral defects. While the details of definitions of failure varied across studies, most included revision or removal of the OCA, and/or conversion to total knee arthroplasty (TKA). The two studies reporting higher failure rates at shorter follow-up (Gracitelli et al 2017 and Gortz et al 2010) appeared to have used broader definitions of failure encompassing other types of surgery also.</p> <p>At mean 46.2 +/- 13.4 months follow-up:</p> <ul style="list-style-type: none"> One case series (Thomas et al 2013) (n=61 knees) reported a failure rate of 9.8%. (VERY LOW) <p>At mean 67 (range 25 to 235) months follow-up:</p> <ul style="list-style-type: none"> One case series (Gortz et al 2010) (n=28 knees) reported a failure rate of 18%. (VERY LOW) <p>At median 6.3 (range 1.9 to 16.8) years follow-up:</p> <ul style="list-style-type: none"> One case series (Sadr et al 2016) (n=149 knees) reported a failure rate of 8%. (VERY LOW)

	<p>At median 6.6 (range 2 to 23.6) years follow-up:</p> <ul style="list-style-type: none"> • One case series (Gracitelli et al 2017) (n=39 knees) reported a failure rate of 26%. (VERY LOW) <p>At mean 7.29 +/- 3.30 years follow-up:</p> <ul style="list-style-type: none"> • One case series (Cotter et al 2018) (n=39 knees) reported a failure rate of 5.1%. (VERY LOW) <p>At mean 11 (range 2.9 to 29) years follow-up:</p> <ul style="list-style-type: none"> • One case series (Early et al 2018) (n=33 knees) reported a failure rate of 27%. (VERY LOW) <p>At mean 13.8 (range 1.7 to 34) years follow-up:</p> <ul style="list-style-type: none"> • One case series (Abolghasemian et al 2019) (n=113 knees) reported a failure rate of 42%. (VERY LOW) <p>At mean 21.8 (range 15 to 42) years follow-up:</p> <ul style="list-style-type: none"> • One case series (Raz et al 2014) (n=58 knees) reported a failure rate of 22.4%. (VERY LOW) <p>These studies provided very low certainty evidence that failure rates ranged between 5.1% and 42% at time periods between 46.2 months and 21.8 years after OCA surgery in patients with large osteochondral defects.</p> <p>Definitions of failure rates varied and variations in failure rates across studies did not always appear to correspond with duration of follow-up.</p>
<p>Safety</p> <p>Adverse reactions</p> <p>Certainty of evidence:</p> <p>Very low</p>	<p>Adverse reactions are important to patients because they will impact on their treatment choices and recovery and could have long term sequelae.</p> <p>In total, three retrospective case series reported non-comparative results for rates of various complications after surgery in people treated with OCA for large osteochondral defects.</p> <p>The time points at which complications were reported were not stated.</p> <ul style="list-style-type: none"> • Three case series (Abolghasemian et al 2019, Cotter et al 2018, Thomas et al 2013) reported total complication rates of 2.7%, 10.3% and 8.2% respectively. The commonest complication was infection with rates of infection of 1.8%, 2.6% and 3.3% respectively. (VERY LOW) <p>These studies provided very low certainty evidence that complications occurred in between 2.7% to 10.3% of patients undergoing OCA for large osteochondral defects, and that the commonest complication was infection occurring in between 1.8% and 3.3% of patients.</p>

	<p>They do not provide any evidence about safety for patients undergoing OCA compared to ACI with bone graft, ACI alone or no surgical treatment</p>
<p>a. Summary of knee scores Higher score is better for all scores apart from the IKDC pain subscore, for which higher score is worse.</p> <ul style="list-style-type: none"> • IKDC (International Knee Documentation Committee): The full IKDC includes 10 questions measuring symptoms, including pain (6 questions), sports activities (3 questions), ADL (1 question). • KS (Knee Society Score): symptoms (3 items) (including pain (2 items)), functional activities (3 items - use of aids, standing, walking), standard activities (6 items), advanced activities (5 items), knee-related activities (3 items). • KOOS (Knee injury and Osteoarthritis Outcome Score): symptoms (5 items), stiffness (2 items), pain (9 items), sports/ recreation (5 items), each rated on a 5-point scale. • MAPS (modified Merle d'Aubigné-Postel): measures pain, gait and mobility, each on a 6-point scale. Minimum score 3, maximum score 18. • mHSS (modified Hospital for Special Surgery) score reports: Pain intensity (5-point scale); Instability (3-point scale); Use of walking aids; Walking distance; Knee extension; Knee flexion; Effusion. Maximum score 100. • WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index): pain (5 items), stiffness (2 items), each rated on a scale 0-4, max score 96. <p>b. QOL scores Higher score is better for all scores</p> <ul style="list-style-type: none"> • SF12: 12 questions taken from the SF-36 Health Survey which are combined and weighted to report on mental and physical functioning subscales. • KOOS QOL: 4 items on knee-related QOL: being aware of your knee, difficulty with your knee, lack of confidence in your knee, lifestyle modifications because of your knee. <p>c. ADL scores Higher score is better for all scores</p> <ul style="list-style-type: none"> • KOOS ADL: 17 items which cover a range of ADL activities (e.g. using stairs, sitting, standing, walking, getting dressed/ undressed, using bath/toilet, shopping, domestic tasks). • WOMAC function: 17 items which cover a range of ADL activities (e.g. using stairs, sitting, standing, walking, getting dressed/ undressed, using bath/toilet, shopping, domestic tasks). <p>Abbreviations:</p> <p>ACI: Autologous Chondrocyte Implantation ADL: Activities of Daily Living CI: Confidence interval IKDC: International Knee Documentation Committee score KS: Knee Society Score KOOS: Knee injury and Osteoarthritis Outcome Score MAPS: modified Merle d'Aubigné-Postel score</p>	

mHSS: modified Hospital for Special Surgery score
 MCID: Minimum clinically important difference
 OCA: Osteochondral allograft
 OCD: Osteochondritis Dissecans
 QOL: Quality of Life
 SD: Standard deviation
 TKA: Total knee arthroplasty
 WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

In the Population what is the cost effectiveness of the Intervention compared with Comparator?

Outcome	Evidence statement
Cost Effectiveness	No evidence was identified for cost effectiveness

From the evidence selected, are there any subgroups of patients that may benefit from the intervention more than the wider population of interest?

Outcome	Evidence statement
Subgroups	No evidence was identified regarding any subgroups of patients that would benefit more from treatment with OCA.

Patient Impact Summary

The condition has the following impacts on the patient's everyday life:

- **mobility:** Patients have severe problems in walking about or are unable to walk about.
- **ability to provide self-care:** Patients have moderate to severe problems in washing or dressing or are unable to wash or dress
- **undertaking usual activities:** Patients have severe problems in doing their usual activities or are unable to do their daily activities
- **experience of pain/discomfort:** Patients have severe pain
- **experience of anxiety/depression:** Patients are severely anxious or depressed.

Further details of impact upon patients:

Large osteochondral lesions are defects of the cartilage and bone, usually within the knee and measuring more than 2cm². The main symptoms involve pain, swelling, instability (giving way) and locking of the knee so that the knee becomes fixed in one position. As a consequence, patients are unable to stand for long periods, walk significant distances or undertake manual work. Younger patients may have difficulty getting to university/school/work and the pain medication may interfere with their cognition and consequently their ability to participate at work/school/university.

Without treatment, these lesions progress, become larger and patients may develop osteoarthritis (OA), eventually resulting in total knee replacement. The condition also impacts negatively on patients' mental health resulting in significant levels of depression and isolation.

Further details of impact upon carers:

The impact on carers is significant. Carers may have to spend time assisting the patient with mobility aids, transport, personal care and activities of daily living.

Carers may have to make sacrifices in their own lives to assist with the care and this, together with the burden of caring for the patient, may impact on their physical and mental wellbeing.

Considerations from review by Rare Disease Advisory Group

Not applicable

Pharmaceutical considerations

Not applicable

Considerations from review by National Programme of Care

1) The proposal received the full support of the Trauma PoC on the 8th June 2022