National Institute for Health and Care Excellence

IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)

IPAC dates: 13 May 2021 and 10 March 2022

There were 2 consultations for this guidance. The first ended in February 2021 and the second ran from 2 December 2021 to 13 January 2022.				
Consultation 1				
Com. no.	**Consultee name and organisation**	**Sec. no.**	**Comments**	**Response** Please respond to all comments
1	Consultee 1 NHS Professional - 1	**General**	As part of one of the initial sites for the principal trial, I am in a good position to comment on the use of Cartiva SCI. As an investigator, I do have a vested interest. The initial level I evidence paper by Baumhauer et al remains the best single piece of evidence for the surgical management of hallux rigidus. It contains the largest prospective study on arthrodesis of the 1MTPJ (the gold standard operation that has never had to undergo NIHCE scrutiny) and its results have been rigorously assessed by the FDA in the USA and found to be robust. There are other independent studies supporting its use (Brandao, Eble) using PROMs which also confirm not only, its efficacy, but also its safety for use in this indication. The only significant contrary study by Cassinelli from one surgeon who operated on 60 patients in a short 20-month period (all comers) and concludes the veracity in his patient selection criteria. Alternative joint procedures such as silastic implants and joint replacements have never been so rigorously scrutinised and, as a result, are not regarded as main stream treatment options.	Thank you for your comment. The study by Baumhauer is included in the key evidence summary, along with the studies by Brandao, Eble and Cassinelli.

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2	Consultee 1 NHS Professional - 1	**1.1**	If this product remained as a research objective (as it was in 2010, when I started using it), it would restrict its use and a significant group of patients would be denied a proven treatment option.	Thank you for your comment. The main recommendation was changed to special arrangements for people with advanced disease for whom arthrodesis is indicated.
3	Consultee 1 NHS Professional - 1	**General**	If NIHCE's response can be used internationally, I feel that it would be exposing itself to criticism from other regulatory authorities from not regarding the evidence for Cartiva in full.	Thank you for your comment. The process and methods used by the IP programme are designed to ensure that robust guidance is developed for the NHS in an open, transparent and timely way, with appropriate input from consultees and other stakeholders. Evidence from the rapid review and any additional evidence brought to the committee's attention during consultation were taken into account.

4	Consultee 2 British Orthopaedic Foot & Ankle Society	**1.1**	Re: Interventional Procedure Consultation Document for “Synthetic cartilage implant for first metatarsophalangeal joint osteoarthritis” The British Orthopaedic Foot and Ankle Society (BOFAS) is a body representing the interests of orthopaedic foot and ankle surgeons in delivering care to their patients. As part of the Society, the Scientific Committee, comprising 8 consultant surgeons, oversees research and audit projects from across the UK and has previously been consulted by NICE for its worthy opinion. Many of the BOFAS surgeons have either contributed to the literature supporting the use and/or regularly use the Cartiva SCI implant. The outcome of the recent IPC document regarding the Cartiva SCI concluded that the implant cannot be used other than in a research setting because of a lack of quality and quantity of clinical research supporting its use. This outcome has been communicated to the Scientific Committee from concerned members of BOFAS. The BOFAS Scientific Committee feel that, unlike other surgical treatment options for first metatarsophalangeal joint (1MTPJ) arthrosis (silastic replacement, total joint replacement, hemiarthroplasty and interpositional arthroplasty), the Cartiva SCI is supported by award-winning, robust, PROM-based studies (1-5). Indeed, the veracity of this quality of work is indicated by the fact that the index paper by Baumhauer et al (1), remains the most robust cohort of patients undergoing 1MTPJ fusion within the entire orthopaedic literature. BOFAS remains very keen to be involved more closely in such important decisions regarding foot and ankle surgery. The Society has previously worked effectively with NICE in the assessment of the management of other foot and ankle conditions and welcome continuing this collaborative.	Thank you for your comment. As part of the usual process, specialist societies were approached to nominate professional experts to comment on this procedure. NICE contacted 2 experts, 1 of whom did not respond and the other declined to take part. Advice was subsequently received from 12 professional experts and this was considered by the committee before the second consultation document was drafted. The cited references are all included in the key evidence summary.

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			References 1. Baumhauer, J.F., et al., Prospective, Randomized, Multi-centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus. Foot Ankle Int, 2016. 37(5): p. 457-69. 2. Goldberg, A., et al., Association Between Patient Factors and Outcome of Synthetic Cartilage Implant Hemiarthroplasty vs First Metatarsophalangeal Joint Arthrodesis in Advanced Hallux Rigidus. Foot Ankle Int, 2017. 38(11): p. 1199-1206. 3. Glazebrook, M., et al., Midterm Outcomes of a Synthetic Cartilage Implant for the First Metatarsophalangeal Joint in Advanced Hallux Rigidus. Foot Ankle Int, 2019. 40(4): p. 374-383. 4. Eble SK et al., Clinical outcomes of the polyvinyl alcohol (PVA) hydrogel for hallux rigidus. Foot Ankle Int, 2020. 41(9): 1031-40. 5. Brandao B et al. Cartiva case series: The efficacy of the Cartiva synthetic cartilage implant interpositional arthroplasty at one year. J Orthop, 2020. 20: 338-341.	

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5	Consultee 3 NHS Professional - 2	**General**	Thankyou for looking at this important treatment option for MTPJ arthritis. We use the CARTIVA synthetic joint replacement in select cases as part of the armamentarium for treatment of this condition. We support it's ongoing availability, but have experience revising (early) implants which have been inserted outside of the orthopaedic envelope. I would suggest it's ongoing use is sanctioned by BOA memebers only and that it is regarded as a prosthesis worthy on ongoing audit and PROMS data collection. I also recommend that the inclusion/exclusion criteria for its use are defined by a body of foot and ankle experts, without an interest in the product/company.	Thank you for your comment. The main recommendation was changed to special arrangements for people with advanced disease for whom arthrodesis is indicated.

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6	Consultee 4 NHS Professional - 3	**General**	Cartiva DOES have a place in the surgical management of hallux rigidus. In those patients who are willing to accept a circa 20% chance of failure to achieve a satisfactory outcome (same as cheilectomy), and who wish to have a chance of retaining motion at the 1st MTPJoint, it's results are no worse than cheilectomy, provided there is correct patient selection. Further, just like a cheilectomy, it can be salvaged easily with an arthrodesis. In my practice, if there is a pain free arc of midrange motion, then these patients should offered a cheilectomy. If the patient experiences pain throughout the residual range of motion, then Cartiva is an option, unless patient wants a 'one and done' procedure - in which case, they should be offered a arthrodesis. Males do better than post-menopausal females. If the joint is very stiff or there is evidence of metatarso-sesamoid degeneration, then Cartiva should not be offered. Provided these guidelines are adhered to, then Cartiva should be regarded as an addition to the surgical options available to manage hallux rigidus, and it should continue to be easily available on the NHS	Thank you for your comment. The main recommendation was changed to special arrangements for people with advanced disease for whom arthrodesis is indicated.

7	Consultee 5 NHS Professional - 4	**1.1**	I have a significant experience with Cartiva SCI and below is my contribution: I was involved in the clinical study to achieve FDA approval as an investigator and recruiting surgeon. I therefore experience of this device for nearly 10 years. The most appropriate design for a clinical study would be an RCT comparing Cheilectomy VS cheilectomy+Cartiva SCI. This design, although discussed, was NOT adopted by the company running the study, because it is likely that this would show no benefit of Cartiva over Cheilectomy alone. The study, referred to as a level I study (Baumhauer, et al. 2016) was a non-inferiority study with 2:1 randomisation of Cartiva + cheilectomy VS fusion of the joint. The raw data of the study demonstrated no superiority of Cartiva and in fact in almost all measures (aside from range of motion), the joint fusion group had better clinical outcome scores. Because the differences were small, the Cartiva was not considered inferior. I feel that the raw data however appears to have been articulated to the outside world as superiority data which is unfortunately somewhat misleading. I have treated more than 100 patients with Cartiva to date, and my practice has changed significantly over time. I don't believe the benefits suggested by the company funded studies are as large as claimed, and I now use it much more sparingly than I did 5 years ago. There are some indications where I feel Cartiva has a place. 1) Where there is patient demand (assuringly from marketing) usually by females wanting to wear high heels;	Thank you for your comment. The main recommendation was changed to special arrangements for people with advanced disease for whom arthrodesis is indicated.

			2) where the first metatarsal is short (and hence length is a good thing). Irrespective, I am now very honest with my patients explaining that some patients take a long time to "settle", and this can be 6-12 months, compared to Cheilectomy alone, which is a quicker recovery (usually 3 months). I also have an anecdotal series of patients with bilateral hallux rigidus, where I have operated on both sides at the same time. In some of these patients (n = 8) I placed a Cartiva into one side but on the contralateral side performed a cheilectomy alone. In almost all patients the outcome was superior on the Cheilectomy alone side. In other words, in my anecdotal series of patients with the study design that should have been done (Cheilectomy + Cartiva versus Cheilectomy alone) I believe the Cartiva would NOT show an advantage, even in patients with exposed bone changes (Grade 3/4). I should stress that my series is anecdotal and was not a formal study and was merely an unrandomised group treated on the basis of what I felt was right at the time (as part of clinical care) and hence may be subject to bias, but reinforces the committees point that the best study design would be Cheilectomy + Cartiva Vs Cheilectomy alone and that this study has NOT yet been funded nor run. The "Only in research designation" I believe is unfair because most clinicians are not in position to apply for ethics to run a clinical study, nor would they be in a position to obtain grant funding to run such a study. Responsible clinicians, like myself, only carry out Cartiva under strict audit principles, ensuring patients are fully and appropriately consented and where outcomes data are captured. Hence I would recommend that, like many NICE recommendations includes the ability for the product to be used only in organisations with appropriate clinical governance, consent and audit and not just research, as there are some limited indications where they believe	

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			that Cartiva has a benefit. I do agree however, that a full approval will potentially put patients at harm because it will be put into widespread use, often in indications unsupported by the clinical data.	
8	Consultee 6 NHS Professional - 5	**1.1**	NICE has recommended that this device is only used in the context of Research. There are good papers (Level 1 evidence) on use of the Cartiva. No other procedure in foot surgery has such good evidence for its use. Yet none of those procedures are limitedin this way by NICE	Thank you for your comment. The main recommendation was changed to special arrangements for people with advanced disease for whom arthrodesis is indicated.
9	Consultee 6 NHS Professional - 5	**1.1**	Some evidence has indeed shown sub-optimal results, though these papers have been criticised for poor technique and poor choice of patients. If NICE wish to put any restriction on the use of Cartiva then the more appropriate classification would be: "... raises no major safety concerns; however, current evidence on its efficacy is inconsistent. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research".	Thank you for your comment. The main recommendation was changed to special arrangements for people with advanced disease for whom arthrodesis is indicated.

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10	Consultee 6 NHS Professional - 5	**General**	One of the main advantages of the Cartiva implant is that if there is a poor outcome then the next step (fusion of the toe joint) can be achieved in a straightforward manner with no more difficulty than a primary fusion. This is in stark contrast to other commercially available joint replacements used for the big tie joint (none of which I use for precisely this reason - that salvage fusion later is complex requiring bone graft).	Thank you for your comment. The main recommendation was changed to special arrangements for people with advanced disease for whom arthrodesis is indicated.
11	Consultee 6 NHS Professional - 5	**General**	I have no disclosures with the company BUT I was a co-author on the Cartiva Motion Study from which the Level 1 evidence on the use of Cartiva was designed. This is not a COI but does mean that I have over 10 years experience of use of the Cartiva, and still use it to the benefit of carefully selected patients.	Thank you for your comment.

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12	Consultee 7 Company Stryker UK	**1.1**	Wright (now part of Stryker) respectfully disagrees with the draft designation in IP742 of 'Only in Research' because the "evidence on its efficacy is inadequate in quality and quantity". There is only one device relevant to this draft guidance, the CARTIVA SCI, the only implant in this class. CARTIVA SCI for the first metatarsophalangeal joint has been shown to be an effective, safe, motion-preserving, surgical treatment alternative to fusion for hallux rigidus, supported by substantial award-winning evidence with 12 publications (8 included in IP742 and 4 additional references provided in the Structured Information Request submitted by Wright (now part of Stryker)) including over 500 patients and Level I evidence. Wright (now part of Stryker) respectfully submits that the evidence supporting the efficacy of CARTIVA SCI is more than adequate in quality and quantity to support Standard Arrangement designation.	Thank you for your comment. The main recommendation was changed to special arrangements for people with advanced disease for whom arthrodesis is indicated.

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1	Consultee 1 The British Orthopaedic Association	General	The BOA have reviewed the interventional procedure consultation document on Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus). We note that BOFAS have responded to the Professional Exert questionnaire and overall consultation and we would support their comments. This procedure is reasonably widely used in the NHS and the guidelines as per the NICE recommendations for use under certain well defined restrictions are sensible. It is clearly not suited for all patient and all presentations of OA of the 1st MTPJ. We note that the CARTIVA implant can be considered for those patients who would otherwise have been offered an arthrodesis (fusion) as long as they are fully informed and their outcome entered onto the BOFAS data base. We would strongly support this requirement to add the patient to the BOFAS registry.	Thank you for your comment. Consultee agrees with main recommendation.

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2	Consultee 2 British Orthopaedic Foot and Ankle Society	1	The British Orthopaedic Foot and Ankle Society (BOFAS) has reviewed the draft recommendations from the review of the panel from the National Institute for Health and Care Excellence. BOFAS opines that, in cases of moderate to advanced osteoarthrosis of the first metatarsophalangeal joint, there is sufficient evidence to support using the Cartiva synthetic cartilage implant (SCI) as an alternative treatment option to arthrodesis (fusion) of the joint, especially in those patients keen to preserve joint motion. The Society supports the NICE view that a patient should be fully informed and consented about using this implant within established arrangements for clinical governance, audit or research such that patient outcomes are entered into a local or BOFAS outcome registry.	Thank you for your comment. The committee considered this comment but did not make any changes to the draft guidance. The committee considered that more evidence is needed on long term outcomes and patient selection, particularly about the stage of osteoarthritis in which the procedure should be used.

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