NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

ChondroCelect for repairing articular cartilage defects of the knee

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of ChondroCelect within its licensed indication for repairing articular cartilage defects of the knee.

Background

Articular cartilage damage in the knee can be caused directly from injury, often as a result of sporting activity, or spontaneously (a condition called osteochondritis dissecans). Articular cartilage refers to hyaline cartilage on the articular surfaces of the bone. Damage of the articular cartilage does not heal on its own and can be associated with symptoms such as knee pain, knee swelling, knee locking and giving way of the knee joint. Ultimately, mechanical damage to the joint surface can lead to osteoarthritis. The International Cartilage Repair Society has a grading system by which cartilage defects can be ranked (grade 0-IV), where grade III indicates lesions having deep crevices in more than 50% of the cartilage layer, and grade IV is where the cartilage tear exposes the underlying bone.

There are no reliable estimates of the prevalence of full thickness cartilage defects of the knee, although it is estimated that every year in the UK, around 10,000 people have cartilage damage serious enough to require treatment.

Current treatment options include symptomatic relief, knee lavage with or without debridement (removal of damaged cartilage) and procedures to re-establish the articular surface. Interventions that aim to re-establish the articular surface include marrow stimulation techniques (such as microfracture), mosaicplasty (also known as osteochondral transplantation), biodegradable scaffolds and implantation of healthy cartilage cells (chondrocytes), a technique known as autologous chondrocyte implantation.

NICE technology appraisal 89 does not recommend autologous chondrocyte implantation for the treatment of articular cartilage defects of the knee except in the context of ongoing or new clinical studies. NICE guidance recommends that mosaicplasty (NICE Interventional Procedure Guidance 162) should only be used with special arrangements for clinical governance, consent and audit or research. Another type of treatment which involves partial replacement of the meniscus of the knee using a biodegradable scaffold (NICE Interventional Procedures Guidance 430) should also only be used with special arrangements for clinical governance, consent and audit or research.

The technology

ChondroCelect (TiGenix) is used as part of an autologous chondrocyte implantation (ACI) procedure. The combination of ChondroCelect (the product) and ACI (the procedure) is called Characterised Chondrocyte Implantation. The active substance in ChondroCelect is the patient's own cartilage cells. A biopsy (a small sample) is taken from the patient's cartilage in the knee, the cartilage cells (chondrocytes) are then grown and expanded in the laboratory to provide enough cells to make up a suspension of cells that can be used to treat the cartilage defect. Open knee surgery is performed, where a biodegradable cover is sutured over the cartilage defect, under which the cells are injected.

ChondroCelect has a UK marketing authorisation for the "repair of single symptomatic cartilage defects of the femoral condyle of the knee (International Cartilage Repair Society [ICRS] grade III or IV) in adults". The randomised controlled trial that supported the marketing authorisation for Chondrocelect included patients with lesions between 1-5cm^2.

Intervention(s)	ChondroCelect
Population(s)	Adults with a single symptomatic defect in the cartilage of the femoral condyle of the knee
Comparators	• Microfracture (marrow stimulation) • Mosaicplasty • Biodegradable scaffolds
Outcomes	The outcome measures to be considered include: • pain • knee function including long-term function • rates of retreatment • adverse effects of treatment • health-related quality of life.

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation.
Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No. 89, May 2005, 'Autologous chondrocyte implantation (ACI) for the treatment of cartilage injury (review of Technology Appraisal16). Review Proposal deferred to 2013. Related Interventional Procedures: Interventional Procedure No.430, Jul 2012, 'Partial replacement of the meniscus of the knee using a biodegradable scaffold'. Interventional Procedure No.162, Mar 2006, 'Mosaicplasty for knee cartilage defects'.

Questions for consultation

Have the most appropriate comparators for ChondroCelect for treating articular cartilage defects of the knee been included in the scope?

- Should biodegradable scaffolds be considered as a comparator?
- Are the other comparators listed routinely used in clinical practice?

Are there any subgroups of people in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which ChondroCelect is licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)