HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
AND
NATIONAL COMMITTEE FOR THE EVALUATION OF MEDICAL DEVICES AND HEALTH TECHNOLOGIES

having met in application of article L. 161-41 of the French Social Security Code

SUMMARY

30 JUNE 2020

The legally binding text is the original French opinion version

spheroids of human autologous matrix-associated chondrocytes
SPHEROX 10-70 spheroids/cm² implantation suspension

First assessment

Key points

Unfavourable opinion for reimbursement in the repair of symptomatic cartilage defects of the knee (International Cartilage Repair Society classification grade III or IV) with defect sizes up to 10 cm² in adults (for more details, see MA).

Role in the care pathway?

The therapeutic objectives are repair of damaged cartilage, improvement of functional performance and the patient's quality of life, as well as prevention of osteoarthritis of the knee.

Medical treatment firstly includes adaptation of physical activities, weight loss if necessary, joint immobilisation, treatment of pain and rehabilitation.

Surgical treatment is only envisaged for symptomatic, grade III or IV knee cartilage defects in young patients, without ligament lesions or knee malalignment.

The choice of method depends on the size of the defect, the condition of the cartilage and the patient (age, weight, history, functional demand).

In France, the most commonly used methods are mosaicoplasty, microfractures (alone or with membrane cover) and osteochondral allograft. Mosaicoplasty is the reference technique for defects < 2 cm^2. For these non-extensive defects, microfractures alone can also be used. The microfractures "plus" technique (combined with insertion of a membrane) is used for defects > 2 cm^2 whereas the osteochondral allograft technique is reserved for very extensive (> 4 cm^2) and deep defects.

Role of the medicinal product in the care pathway

On the basis of currently available data, SPHEROX has no role in the repair of cartilage defects of the knee with defect sizes up to 10 cm^2 in adults.

JOINT COMMITTEE CONCLUSIONS

Clinical benefit

◗ Symptomatic, deep cartilage defects of the knee (grade III and IV of the ICRS classification) can cause pain and loss of joint function, leading to disability and a marked deterioration in quality of life. In the longer term, these defects can progress to osteoarthritis.
◗ SPHEROX is a curative treatment to relieve pain and improve functional capacities and patients' quality of life. SPHEROX may represent a preventive treatment by avoiding the development of osteoarthritis.
◗ The efficacy/adverse effects ratio of SPHEROX has not currently been adequately established.
◗ There are surgical alternatives for defects up to 10 cm^2. The most commonly used methods in France are the microfractures (with or without membrane cover), osteochondral graft (mosaicoplasty) and osteochondral allograft techniques.
◗ SPHEROX has no role in the repair of symptomatic articular cartilage defects of the femoral condyle and the patella of the knee with defect sizes up to 10 cm^2 in adults (see section 09 of this opinion).

Public health impact:

Considering:

- the impact of symptomatic, deep cartilage defects on patients' quality of life,
- the medical need to have access to more effective surgical alternatives, particularly with respect to the development of osteoarthritis,
- methodological limitations meaning that the data assessing the impact of SPHEROX on morbidity cannot be considered to be robust,
- the absence of a demonstrated impact on patients' quality of life,
- the potentially negative impact on the organisation of care of the autologous chondrocyte implantation (ACI) technique, conducted in two surgical stages, compared to the microfractures and mosaicoplasty techniques, which require only one hospitalisation,
- the lack of additional response to the identified partially met medical need,

SPHEROX is unlikely to have an additional impact on public health.

Considering all these elements, the Joint Committee deems that the clinical benefit of SPHEROX is insufficient in view of the available alternatives to justify its funding by the French national health insurance system in the MA indication.

The Joint Committee issues an unfavourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and dosages.

Clinical Added Value

Not applicable