Cartilage Repair Product

Genzyme Corporation announced that the US Food and Drug Administration (FDA) has approved a chondrocyte identity assay for Carticel® (autologous cultured chondrocytes). This is a unique and proprietary genetic assay that distinguishes chondrocyte cells, found in articular cartilage, from other cell types. The approval of this assay marks the fulfillment of the final postapproval commitment to the FDA for Carticel by Genzyme. Genzyme notes that this is the first and only assay of its kind to be developed by a commercial laboratory.

When a biopsy is taken from a patient it is possible that other cells, such as synovial cells, are included. This novel assay will provide treating surgeons and patients additional assurance that their Carticel implant is made up of positively identified chondrocyte cells—the only type of cell genetically predisposed to form hyaline-like cartilage, which has properties similar to native articular cartilage. By the end of the year, all Carticel implants will be tested with this assay.

The company points out that Carticel was the first cell therapy approved by the FDA. First introduced in March of 1995, it was approved by the FDA in August of 1997 after the FDA instituted specific cell therapy guidelines. Carticel employs a unique process to grow a patient's own cartilage cells for implantation to correct certain types of cartilage damage. The treatment starts when an orthopedic surgeon trained in the use of Carticel provides Genzyme with a biopsy of healthy cartilage taken from a patient's knee in an arthroscopic procedure. Technicians at Genzyme's cell culture laboratory in Cambridge, Massachusetts, use proprietary methods to grow millions of cells from this biopsy. The cells are then delivered to the hospital, where the surgeon implants them into the patient's knee defect in a surgical procedure.

Carticel is for autologous use and is indicated for the repair of symptomatic cartilage defects of the femoral condyle (medial, lateral, or trochlea) caused by acute or repetitive trauma in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure (eg, debridement, microfracture, drilling/abrasion arthroplasty, osteochondral allograft/autograft). Carticel should only be used in conjunction with debridement, placement of a periosteal flap, and rehabilitation. The independent contributions of the autologous cultured chondrocytes and other components of the therapy to outcome are unknown. It is not indicated for the treatment of cartilage damage associated with generalized osteoarthritis. It also is not recommended for patients whose knee meniscus has been surgically removed, unless the patient has undergone surgical reconstruction prior to or concurrent with Carticel implantation.

Pre-existing conditions, including meniscal tears, joint instability, or malalignment of the joint, should be corrected prior to or concurrent with Carticel implantation. It should not be used in patients with a known history of hypersensitivity to gentamicin, other aminoglycosides, or materials of bovine origin. Carticel is not routinely tested for transmissible infectious diseases and may transmit disease to the health care provider handling Carticel. In addition, it should not be used in patients who previously have had cancer in the bones, cartilage, fat, or muscle of the treated limb. Use in children, in patients over age 65 years, or in joints other than the knee has not yet been assessed.

The occurrence of subsequent surgical procedures (SSPs), primarily after arthroscopy, following Carticel implantation is common. In the Study of the Treatment of Articular Repair (STAR), 49% of patients underwent an SSP on the treated knee, irrespective of their relationship to Carticel, during the 4-year follow-up. The most common serious adverse events (≥ 5% of patients), derived from STAR, include arthrofibrosis/joint adhesions, graft overgrowth, chondromalacia or chondrosis, cartilage injury, graft complication, meniscal lesion, graft delamination, and osteoarthritis.

For more information about Carticel, visit www.Carticel.com or contact Genzyme, 500 Kendall Street, Cambridge, MA 02142; phone (617) 252-7500; fax (617) 252-7600; www.Genzyme.com.

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