## Pharmacotherapeutic report (ChondroCelect®) for the indication 'Simple cartilage defects of the femoral condyle of the knee in adults'

Medicine	ChondroCelect <sup>®</sup> contains characterised, viable, autologous cartilage
<u>ChondroCelect®</u>	cells, expanded <i>ex vivo</i> , expressing specific marker proteins.
Registered indication	Repair of single cartilage defects of the femoral condyle of the knee (ICRS grade III or IV) in adults. Concomitant asymptomatic cartilage defects (ICRS I and II) may be present.
Dose	The number of cells to be administered will depend on the size (surface area in cm <sup>2</sup> ) of the cartilage defect. Each product contains an individual treatment dose with a sufficiently large number of cells for treatment of the cartilage defect, the size of which will be determined in advance by means of arthroscopy.
Working mechanism Specific details	Cartilage expanding ( <i>ex vivo</i> ) expressing specific marker proteins. ChondroCelect <sup>®</sup> is the first cell therapy registered by the European Medicines Agency (EMA) on 5 <sup>th</sup> October 2009 as an Advanced Therapy Medicinal Product or ATMP – Regulation (EU) 1394/2007).
Favourable effects	Summary of therapeutic value The conclusion may be drawn that ChondroCelect® is effective for the treatment of cartilage defects of the femoral condyle where the defects measure between 1-4 cm <sup>2</sup> . Based on the available data, the conclusion
Unfavourable effects	may be drawn that the clinical efficacy of ChondroCelect <sup>®</sup> on cartilage defects between 1-4 cm <sup>2</sup> is comparable with that of microfracture treatment (MF). Its value is reduced for defects larger than 4 cm <sup>2</sup> because no research data are available in which ChondroCelect <sup>®</sup> was subjected to methodologically responsible research. There were no notable differences in side effects between ChondroCelect and microfracture treatment, except that joint swelling and influenza-like symptoms during the first four weeks after surgery occurred significantly more frequently in patients treated with ChondroCelect <sup>®</sup> .
Experience Applicability	Experience with ChondroCelect <sup>®</sup> is limited. ChondroCelect <sup>®</sup> can be widely used within the relevant indication field, as long as it is used as an autologous treatment.
Ease of use	Treatment with ChondroCelect® may require an arthrotomy as well as arthroscopy. This is unlike with MF, where arthroscopy is sufficient. This means a reduced ease of use.
Final conclusion	For the treatment of adults with single cartilage defects of the femoral condyle measuring between 1-4 cm <sup>2</sup> (ICRS III or IV), the therapeutic value of ChondroCelect <sup>®</sup> is equal to that of microfracture treatment. Its value is lower for defects larger than 4 cm <sup>2</sup> , because no research data are available in which ChondroCelect <sup>®</sup> was subjected to methodologically responsible research.