



BRISTOL-MYERS SQUIBB PHARMACEUTICALS LTD

BELZER UW (VIASPAN®)  
COLD STORAGE SOLUTION:  
STORAGE OF DONATED KIDNEYS

MULTIPLE TECHNOLOGY APPRAISAL  
SUBMISSION TO THE NATIONAL  
INSTITUTE FOR HEALTH & CLINICAL EXCELLENCE

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This submission does not contain any commercial in confidence information.

## **Executive Summary**

End-stage renal disease (ESRD) is the irreversible decline in kidney function that is fatal in the absence of renal replacement therapy. Over the past three decades, renal transplantation has become the treatment of choice for ESRD patients, where it is possible. Currently the only alternative for these patients is life-time dialysis, which is expensive and associated with a series of complications, such as hypotension, hypoxemia, infection and others.

Although renal transplant is considered the best solution, demand for donated kidneys greatly exceeds their supply. According to UK Transplant statistics, on 31<sup>st</sup> January 2008, 6,697 individuals in the UK were registered for a kidney transplant; 1,826 kidney transplants were performed in 2007. Most kidneys for transplantation are obtained from cadaveric donors, including heart beating and, increasingly non-heart-beating and extended-criteria donors.

As the majority of kidney transplants involve grafts from deceased donors, organ preservation between retrieval and transplantation is one of the most important factors affecting the success of the transplant. The aim of preservation is to maintain kidney allografts in optimal condition from the time of explantation and return of all functions after transplantation. Two main methods of kidney preservation are in use today: cold (static) storage and machine perfusion. In the cold storage method, the kidney is flushed through with a preservation solution, and kept in this solution in a bag, on ice, whereas in the machine perfusion method, core cooling of the organ is achieved by active pumping cold preservation solution through it.

A systematic literature review was conducted to identify clinical evidence for the use of the two kidney preservation methods. The review was performed in line with the NICE-specified scope for this appraisal and focused on studies comparing the University of Wisconsin (UW, Viaspan®) solution with other cold storage solutions, and with the machine perfusion method. Of 52 potentially relevant publications, 14 were considered relevant to the scope of the appraisal and included in this review.

The included studies varied significantly in both design and type of outcomes assessed; therefore, a quantitative meta-analysis was not conducted. Qualitative comparison of results was difficult as the studies reported different outcomes. Recognizing these limitations, the data suggests that the University of Wisconsin storage solution appears to be associated with better outcomes (including delayed graft function, graft function and graft survival) than both Marshall and EuroCollins solutions and similar outcomes to HTK and Celsior solutions. The very limited data comparing UW solution with machine perfusion (Gambro preservation machine) suggests similar outcomes.

Cost-effectiveness analysis was not performed as part of this submission.