The cost-effectiveness of imlifidase (IDEFIRIX®) for desensitisation treatment of highly sensitised adult kidney transplant patients in Ireland

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Introduction

- End-stage renal disease (ESRD) occurs when kidney function is <10% of capacity and is treated with kidney transplant (gold-standard) or dialysis.[1-3]
- There is a group of ESRD patients that are "highly sensitised“, meaning that their immune system is likely to reject most donor kidneys. There is a relevant and real unmet need for these patients that are unlikely to ever find a compatible organ and therefore face a very long time on dialysis.[4]
- Dialysis is associated with several comorbidities leading to poorer QoL[3] and survival[5] outcomes than a kidney transplant and is more costly to the health system over a patient’s lifetime.[6]
- Imlifidase is currently the only desensitisation treatment (conditionally) approved by the European Medicines Agency (EMA) in Europe to enable kidney transplantation in highly sensitised adult patients who have a positive crossmatch against an available deceased donor kidney.[7]
- Imlifidase clinical trial data highlights that imlifidase successfully enables kidney transplant in eligible patients and that imlifidase-enabled transplants are associated with high five-year graft survival (85%) and patient survival (92%).[7,8]
- While imlifidase is reimbursed in several countries, the cost-effectiveness of imlifidase to the healthcare system in Ireland is not yet known.

Objective

A cost-effectiveness model (CEM) was developed from the Irish healthcare perspective to determine whether imlifidase-enabled kidney transplantation is a cost-effective use of Irish healthcare resources compared to current standard of care (SoC; defined as lifelong dialysis, with a small proportion of patients receiving a kidney transplant).

Methods

Model overview

- A Markov model was developed to evaluate the cost-effectiveness of imlifidase to the Irish healthcare system (Health Services Executive; HSE).
- The model includes three health states: (1) Dialysis (hospital haemodialysis [HD], Home HD, or peritoneal dialysis [PD]); (2) Functioning graft; and (3) Death (see Figure 1). Patients accrue costs, life years (LYs) and quality-adjusted life years (QALYs) in the dialysis and functioning graft health states, while death is an absorbing health state.[9]
- The model structure is matched to the clinical pathway of care in Ireland, where dialysis and kidney transplant are the two renal replacement therapy options available for highly sensitised ESRD patients.[5]

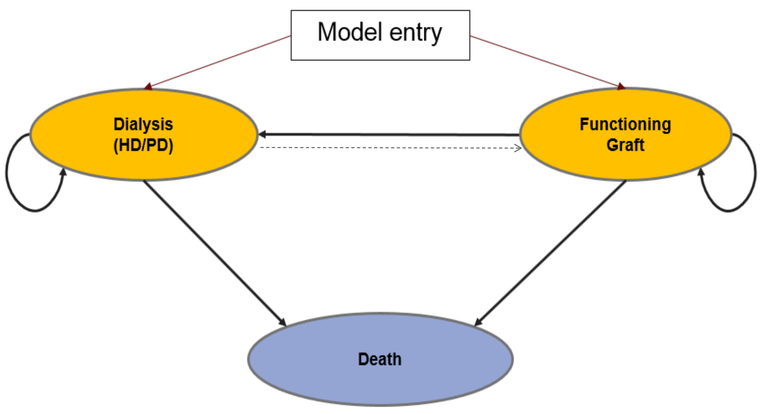

Figure 1. Imlifidase cost-effectiveness model structure.

- The use of imlifidase “should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients”.[4,7] The eligible population for imlifidase in Ireland was therefore defined, in collaboration with clinical experts from the Irish National Kidney Transplant Service (NKTS), as those with:
  - PGen ≥98% i.e., the patient is sensitised to ≥98% of potential donor kidneys.[9]
  - Cumulative mean fluorescence intensity score <5,000 in <2% of available deceased donor kidneys.[9]
  - ≥38 months on the transplant waiting list (twice the median waiting list time).[9]
- Costs and health outcomes were discounted annually at 4%, in line with the NCPE reference case.[10]

Inputs

- Clinical data for imlifidase, including graft and patient survival, were sourced from four clinical trials conducted as part of the imlifidase clinical development programme.[8]
- Clinical data to inform patient survival on dialysis were sourced from clinicians at Beaumont hospital, the centre which oversees all kidney transplants in Ireland.
- Quality of life data were sourced from Cooper et al. 2020.[3] Disutilities for dialysis and functioning graft were applied to general population utility.
- Costs were sourced from Ireland cost databases, UK cost databases (with costs converted to Euros), and published literature.
- The model approach and key inputs and assumptions were validated with clinical experts from the NKTS.

Results

- At list price, imlifidase is associated with €783,731 total costs and 10.71 total quality-adjusted life years (QALYs) over a patient’s lifetime. In comparison, SoC (dialysis) is associated with €1,078,662 total costs and 8.16 total QALYs.[9]
- This means that an imlifidase-enabled transplant is associated with greater total QALY gains and lower total costs compared to SoC in Ireland, resulting in a dominant incremental cost-effectiveness ratio (ICER).

Sensitivity analyses

- One-way sensitivity analyses showed that imlifidase remained dominant compared with dialysis in all analyses except when age at model entry was increased from 45 years to 69 years. In this analysis, imlifidase (list price) was associated with an ICER of €38,111 per QALY, which remains within the threshold considered to be cost-effective in Ireland.[10]
- Probabilistic sensitivity analyses (PSA) demonstrated that imlifidase-enabled kidney transplants are dominant versus SoC in 94.5% of model simulations, shown by most iterations being in the south-eastern quadrant of the incremental cost-effectiveness plane (Figure 2).
- Imlifidase was also dominant in all scenario analyses, including scenarios in which different model time horizons, discount rates, and literature sources were used.
- The sensitivity analyses show that model results are robust to uncertainty.

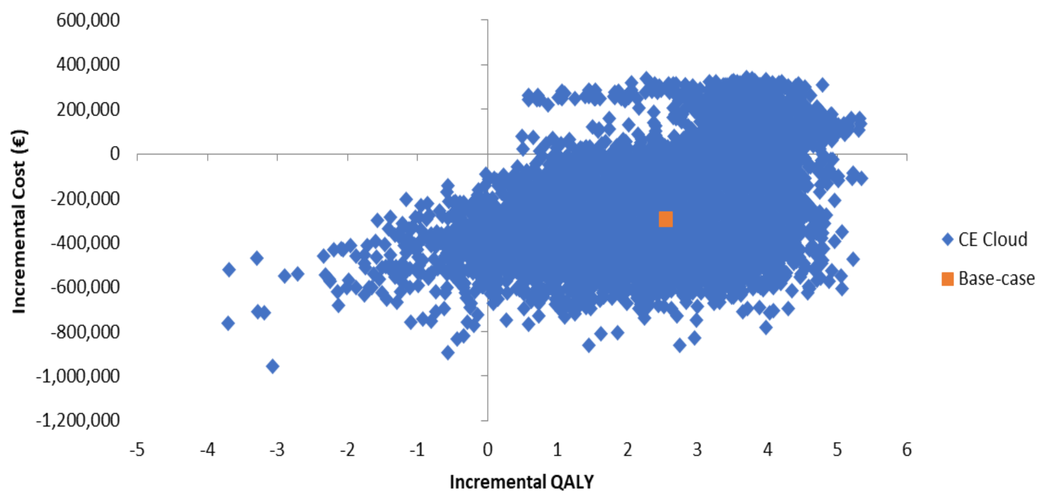

Figure 2. Probabilistic sensitivity analysis scatter plot of imlifidase (list price) vs dialysis.

Limitations

- Clinical studies supporting imlifidase have small sample sizes given the small population size of highly sensitised ESRD patients, the limited supply of deceased donor kidneys.
- To overcome this limitation, the model had the flexibility to either use the imlifidase clinical development program data from all patients who received an imlifidase-enabled transplant or from only those patients who met the Irish eligibility criteria. In both scenarios, imlifidase was dominant versus SoC (dialysis).
- Another limitation is that utility data specific to highly sensitised ESRD patients were not available. The model therefore used published utility data from a general ESRD population. The underlying assumption is that highly sensitised patients with a functioning graft have the same quality of life as non-highly sensitised patients with a functioning graft.

Conclusions

- Most highly sensitised ESRD patients face a lifetime on dialysis, which is burdensome to patients and to healthcare systems. There is an unmet need for treatments that enable kidney transplant in highly sensitised ESRD patients.
- Imlifidase meets this unmet need as the only desensitisation treatment with EMA approval (conditional) to enable kidney transplantation in highly sensitised adult kidney transplant patients who have a positive crossmatch against an available deceased donor kidney. The use of imlifidase should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients.[7]
- This analysis demonstrates that imlifidase is a cost-effective use of healthcare resources in Ireland – patients receiving an imlifidase-enabled transplant are associated with higher QALYs and lower costs over a lifetime than patients remaining on dialysis, resulting in a dominant ICER.[4]

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