

## Tertiary/Quaternary Level Essential Drug List Medication Review Summary

**Medication Name:** Basiliximab

**Date:** 11 April 2017

**Indication:**

Induction therapy for prophylaxis against acute rejection in renal transplant recipients.

**Context:**

Induction therapy in the transplant setting is an intense prophylactic treatment strategy intended to lower the risk of acute rejection in the early post-transplant period. Current treatment protocols consist of lymphocyte depleting agents, including anti-thymocyte globulin (ATG) and interleukin 2 receptor antagonists (IL2-RAs).

Basiliximab is a monoclonal antibody directed at the interleukin-2 receptor and inhibits the proliferation of T-cells resulting from allograft antigen stimulation but does not affect resting T-lymphocytes. When compared with ATG, IL2-RAs are thought to offer more selective immunosuppression, while ATG, when compared with no induction, has been reported to be associated with higher risks of opportunistic infections and lymphoproliferative disorders.

**Quality of evidence:**

No new randomized controlled trials, systematic review or meta-analyses were identified after the 2010 Cochrane review by Webster and colleagues.

**Clinical efficacy:**

Webster *et al*<sup>i</sup> reported that when compared with placebo, IL2-RAs reduced graft loss, including death with a functioning graft, by 25% at 6 months (RR 0.75, 95% CI 0.58 to 0.98) and at one year (24 studies: RR 0.75, 95% CI 0.62 to 0.90). At one-year, biopsy-proven acute rejection was reduced by 28% (14 studies: RR 0.72, 95% CI 0.64 to 0.81). When compared with ATG, there was no difference in graft loss at any time point, or for acute rejection diagnosed clinically. However, ATG therapy reduced biopsy-proven acute rejection at one year (8 studies: RR 1.30 95% CI 1.01 to 1.67).

When compared with no treatment, the NNT for IL2-RA was calculated as 9 to prevent one recipient having rejection, 42 to prevent one graft loss, and 38 to prevent one incidence of CMV disease over the first year post-transplantation.

**Safety concerns:**

Nil

**Further considerations:**

COST	Strength	Dose*	Cost	Total dose	Cost per course
<b>Basiliximab</b>	20mg/vial	20mg IV on day 0 and day 4	R 10 397.11**	40mg	R 20 794.22
<b>ATG (Equine)</b>	100mg/vial	Total dose 9mg/kg	R 3 671.00**	630mg (700mg)	R 25 697.00

\*Dose based on GSH dosing protocols (based on 70kg)

\*\*Cost based on GSH buy out price March 2017

**Recommendation:**

Basiliximab should be included on the Tertiary/Quaternary Essential Medicines List as induction therapy in low risk patients renal transplantation recipients.

<sup>i</sup> Webster et al. Interleukin 2 receptor antagonists for kidney transplant recipients (Review). The Cochrane Library. 2010, issue 3.