Decision Algorithm for evaluation of medicines for formulary listing in public hospitals

Is this drug approved by TGA for the requested indication?

YES

Is it PBS funded?

NO

See Note 1

YES

Has it been rejected by the PBAC?

YES

NO

Is the request for the same population?

YES

NO

REJECT

Define population

Are there advantages over current therapy in specified population?

• Safety: Yes: (Minor / Significant) No (Equivalent)
• Efficacy: Yes: (Minor / Significant) No (Equivalent)

Level of Evidence: I II III IV

Is there a clinician-led guideline/protocol for use?

YES

NO

Is the cost > existing therapy?

YES

NO

APPROVE

REJECT

Consider pharmacoeconomic evaluation

Evidence of cost-effectiveness?

YES

NO

Is exceptional use justified in an individual patient? *

YES

NO

Net cost per annum:

> $10,000 / patient / treatment course: Yes / No
> $50,000 / year total expenditure: Yes / No

(Consider level of confidence in cost estimate)

Note 1: Where a PBAC evaluation has been undertaken, the DTC may choose to accept the PBAC decision without further evaluation

Note 2: Adequacy of evidence for comparative safety and efficacy should be assessed by the DTC in light of the clinical circumstances. The need for a defined guideline/protocol for use should be determined on a case by case basis.

* For further guidance see IPU Decision Algorithm

# Level of Evidence

Level I Evidence from one or more systematic reviews of randomised controlled trials
Level II Evidence from one or more well-designed, randomised controlled trials
Level III Evidence from well-designed, non-randomised controlled trials; cohort, case control or interrupted time series studies
Level IV Case series with either post-test or pre-test/post-test outcomes

(From NHMRC interim levels of evidence 2005: www.nhmrc.gov.au/publications/_files/levels_grades05.pdf)