**Decision Algorithm for evaluation of medicines for individual patient use (IPU) approval**

**IPU Decision Algorithm: *Is exceptional use justified in an individual patient?***

Are there advantages over current therapy in this patient?
- Safety: Yes: (Minor / Significant) No (Equivalent)
- Efficacy: Yes: (Minor / Significant) No (Equivalent)

Level of evidence:^a I II III IV

Is there a clinician-led guideline/ protocol for use? Yes No

If there is no high quality evidence supporting use of a particular medicine*, and it is not suitable for ‘exceptional indications’ or for the purpose of research, use of the medicine is generally not recommended.

Is there justification for exceptional use?
- serious underlying disease or condition, and
- some evidence to support beneficial effect, and
- potential benefits outweigh potential risks, and
- standard therapy has been trialed or is inappropriate and
- there is written informed consent (for off label or unlicensed use)

YES NO

Is the cost > existing therapy? YES NO

Net cost per annum:
> $10,000 / patient / treatment course: Yes No

Approval from Head of Division / Executive?

YES NO

Have there been 3 or more IPU applications for this indication?

YES NO

Are there advantages over current therapy in this patient?

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

Complete Formulary Submission

**Approve**

Consider Pharmacoeconomic evaluation

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^a 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)

* Evaluation of evidence
For more detailed guidance on evaluation of evidence, see Gazarian et al. MJA 2006;185: 544-548.
In particular, refer page 545: Assessing appropriateness – evaluation of evidence