Navigating High-Cost Medicines

Promoting consistent, evidence-based use of high-cost medicines in a fiscally and equitable responsible manner

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on behalf of CATAG

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WHAT CATAG DOES

1. Expert, consensus-based and focused collaboration with new and existing strategic partners across Australia to influence clinical practice to ensure a quality use of medicines approach is considered in both policy and practice.

2. Resources to guide decision-making processes at the local and jurisdictional levels to facilitate prescribing for cost effective, quality use of medicines across the health care continuum and fostering equity of patient access to safe, cost-effective and affordable medicines nationally.

3. Effective communication and information sharing through the network of CATAG members, to ensure a strategic, high-level, cohesive approach to therapeutic issues of national importance to support

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WHO WE ARE

A collaborative of all Australian state and territory therapeutic or medicines advisory groups

GOALS

Optimising medicines use in Australia's public hospitals and at transitions of care.

Find out more about CATAG activities and outcomes on www.catag.org.au

WHY CATAG MATTERS

1. Virtually all therapeutically complex and/or new drugs are first used in hospitals, with three quarters (73%) used in public hospitals.

2. Rapidly increasing medicines expenditure in hospitals. (20% of PBS spending was in hospitals in 2017, and this is growing rapidly.)

3. Specialist and hospital prescribing, are major predictors of subsequent prescribing by GPs and throughout the healthcare system

4. Australia's public hospitals provide the majority of training for the next generation of general practice and specialist prescribers.

WHY?

- High-cost medicines – significant, increasing impact on hospital medicines budgets
- Hospital decision makers frequently receive requests for new HCM, complex to review
- Variation in decision-making
  - no national framework
  - differing processes for assessment - within state variation, within hospital,
  - heterogeneous capacity and expertise of decision makers
  - Variation in outcomes

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Medicines funding in Australia

- Government, non-government organisations, private health insurers, individuals/patients
- Primary care - PBAC assessment and PBS subsidy (Cwlth)
- Public hospital medicines
  - PBS subsidy – opd, discharge, day chemo
  - Non-PBS - state government funded
    - All inpatient use, hospital only indications, rare/emerging conditions, off label
    - challenging evidence base, low volume, not cost effective pricing

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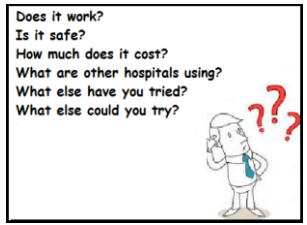
WHY?

- high-cost medicines use should be governed and managed with a fair, standardised evidence-based process
- Equity of access
- Clinical and cost effective
- standardised review process fosters high-quality care



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Method

- Literature review and survey of current practice
- Expert Advisory Group - expertise in quality use of medicines, evidence-based medicine, HTA and medicines governance.
- Draft guiding principles and consultation with stakeholders
- Collation and review of feedback to refine final content.

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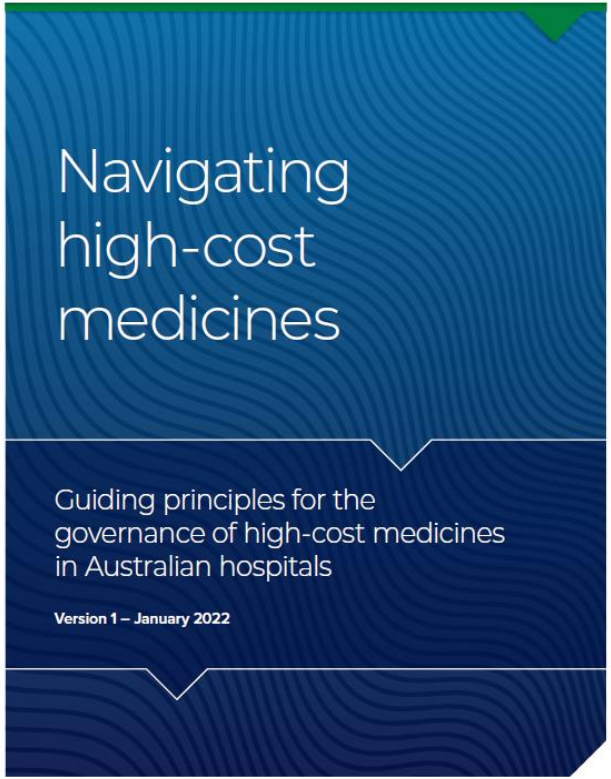
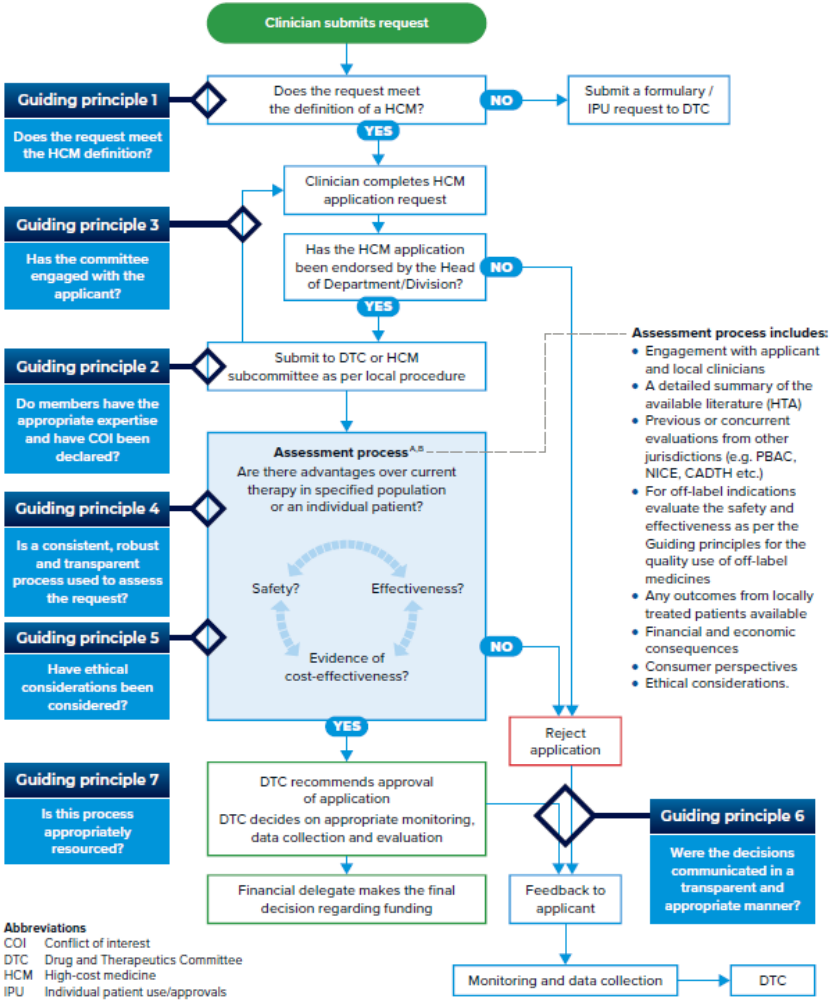


- A definition of HCM should be determined and clearly articulated for use by each medicines governance committee.
- Review of HCM requires members with relevant expertise to facilitate good and effective decision making.
- The committee should engage directly with the applicant prior to review to ensure a full understanding of the rationale for the request.
- A consistent, robust and transparent procedure for the assessment of HCM applications should be defined and implemented for use by each medicines governance committee to ensure fair process.
- Ethical considerations fundamentally underpin deliberations around HCM.
- The decisions and outcomes of the decision making should be transparent and appropriately communicated to the various audiences.
- The high-quality assessment of high-cost medicines requires appropriate training and resourcing.



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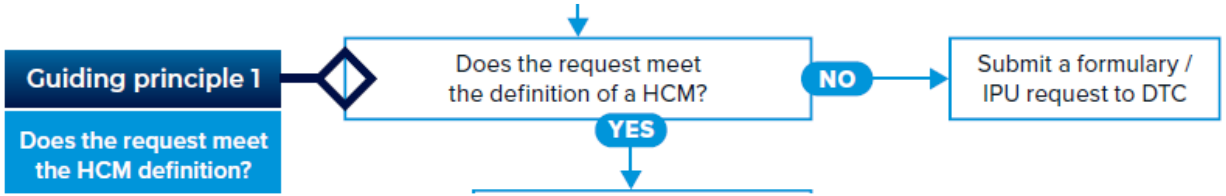
1. A definition of high-cost medicines should be determined and clearly articulated for use by each medicines governance committee.



- Consistent and transparent cost triggers process
  - Cost per pt/treatment course or per year, cost to the system
  - Single time-limited course versus continuing therapy
- high budgetary impact medicines (cost vs volume)
- administration-related costs

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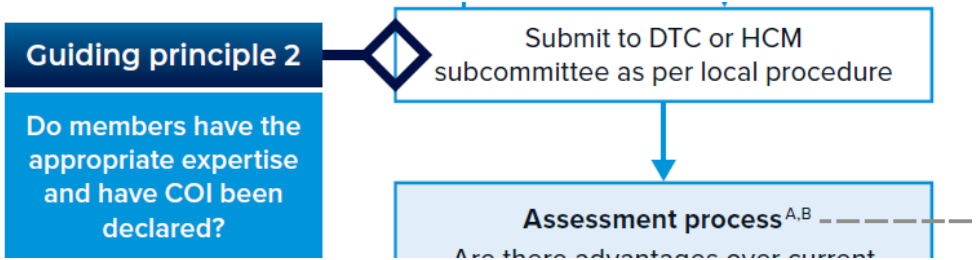
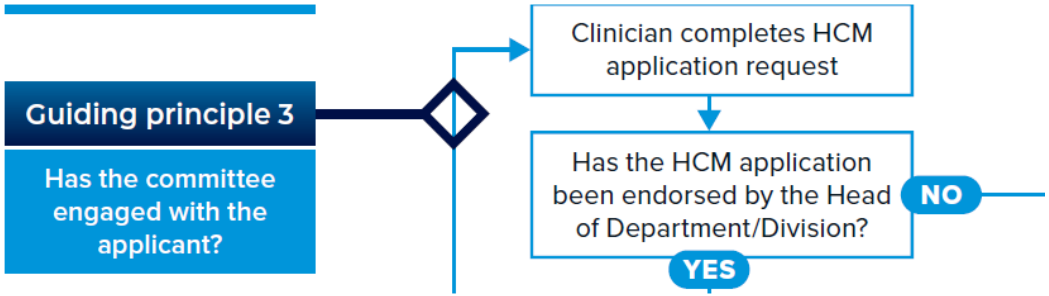
2. Review of high-cost medicines requires members with relevant expertise to facilitate good and effective decision-making.



A multidisciplinary group of individuals with skills and expertise including:

- Clinical specialties
- Medicine evaluation
- **Health technology assessment**
- Ethics
- Health economics
- Health finance
- **Consumers**

3. The committee should engage directly with the applicant prior to review to ensure a full understanding of the rationale for the request.



If the application is lacking in detail, the place in therapy is unclear, or other uncertainty, early **engagement** with **the applicant** is essential to ensure that the DTC reaches an appropriate decision.

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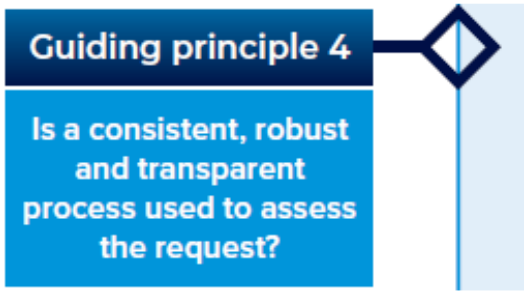
4. A consistent, robust and transparent procedure for the assessment of high-cost medicine applications should be defined and implemented for use by each medicines governance committee to ensure fair process.



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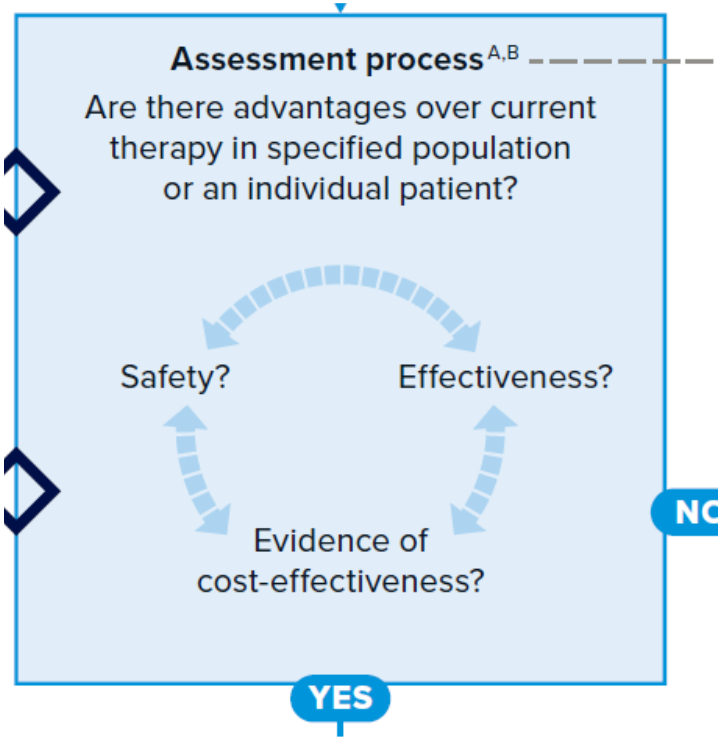

- **Assessment process includes:**
  - Engagement with applicant and local clinicians
  - A detailed summary of the available literature (HTA)
  - Previous or concurrent evaluations from other jurisdictions (e.g. PBAC, NICE, CADTH etc.)
  - For off-label indications evaluate the safety and effectiveness as per the Guiding principles for the quality use of off-label medicines
  - Any outcomes from locally treated patients available
  - Financial and economic consequences
  - Consumer perspectives
  - Ethical considerations.

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- Minimum criteria for approval should include safety, effectiveness, and cost effectiveness
- Explicit consideration of costs should include financial and economic impacts
- Monitoring criteria should be declared and approved
- The process should be open to appeal and there should be a documented, structured and formal process.

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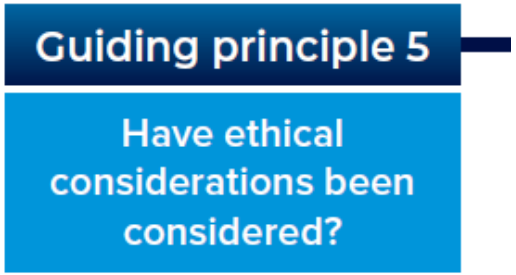
5. Ethical considerations fundamentally underpin deliberations around high-cost medicines.



The committee is charged with deliberating on the proposed '**value**' of the health outcome, and whether it is considered proportional to the cost.

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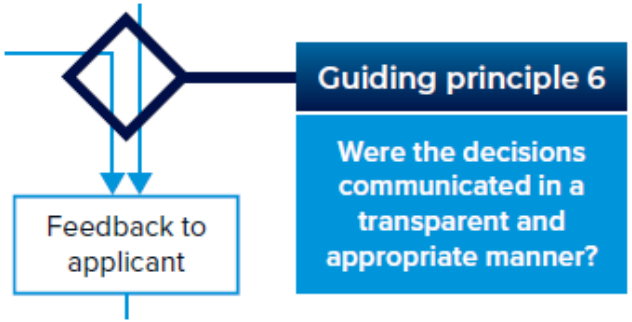
6. The decisions and outcomes of the decision making should be transparent and appropriately communicated to the various audiences.



The decision (whether for or against) and rationale should be communicated in a timely manner, by a clinician who can competently explain the complexities of the information in terms **the consumer or carer** can understand.

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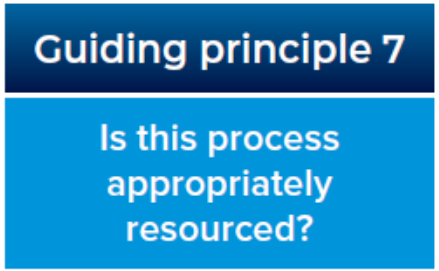
7. The high-quality assessment of high-cost medicines requires appropriate training and resourcing.



Assessment needs **investment** in capacity building and expertise by **training** those participating in these reviews.

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Impact

- 77% of surveyed DTCs considered the Guiding Principles useful and had implemented the principles

"Nationally endorsed guidance to help frame locally developed policy"

" We used the guiding principles for high-cost medicines to identify gaps between what is recommended and how we practice. "

"a useful resource to go back to when challenging requests for high-cost medicines are under review"

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Conclusion

- national guiding principles promote consistent, evidence-based use of high-cost medicines and provide a framework for Hospital DTCs to assess and achieve effective governance for the quality use of high-cost medicines.

https://catag.org.au/resource/navigating-high-cost-medicines/

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Acknowledgements

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