RACGP
Royal Australian College of General Practitioners

Healthy Profession.
Healthy Australia.

23 February 2024

HTA Review Secretariat

Via email: htareviewconsult@health.gov.au

Dear HTA Review Secretariat,

Re: Health Technology Assessment Policy and Methods Review - Consultation 2

The Royal Australian College of General Practitioners (RACGP) thanks the Reference Committee for the opportunity to provide feedback on the Health Technology Assessment (HTA) Policy and Methods Review – Consultation 2.

GPs are the first point of contact for most Australians seeking healthcare, with almost 90% of the population seeing a GP at least once each year.[1] According to Australian Institute of Health and Welfare (AIHW) data, GPs prescribed the most Pharmaceutical Benefit Scheme (PBS) and Repatriation Pharmaceutical Benefit Scheme (RPBS) medicines in Australia, accounting for approximately 87% of all prescriptions dispensed in 2020-21.[2] While GPs play an important role in the prescribing and administering medications, they also educate and counsel their patients regarding medication usage, undertake medication reviews, and deprescribe where necessary.

Following a review of the options paper, we provide the following comments for consideration.

1. **Impact of the fundamental questions on decision making**

The three fundamental questions asked when deciding if a health technology should be funded or subsidised in the document have been paraphrased as: Does it work? Is it better or equal to existing options? Should it be funded? These questions do not enable adequate attention to issues such as equity of access and environmental consequences of decisions.

Recommendation: Review the fundamental questions to include equity of access and environmental consequences so the Quintuple aims[3,4] are addressed within the HTA decision making process.

2. **Rapid introduction of new treatments**

The findings presented in the consultation paper emphasise the need for quicker access to funded items. The rapid introduction of new treatments should be done cautiously. It could result in limited real-world experiences observed for the new treatment.

Recommendation: Consider robust, comprehensive, planned and funded after-market evaluation and surveillance leveraging primary care data linkage and electronic registers.

3. **Approve funding on a case-by-case basis**

HTA decisions to fund items currently depend on clearly articulated ‘appropriate use’ criteria. This often involves finding a compromise between adhering to the strict criteria used in clinical trials and ensuring access for everyone who can potentially benefit from access to a particular health technology.

The Royal Australian College of General Practitioners Ltd
100 Wellington Parade, East Melbourne VIC 3002
Tel **1800 4RACGP** | 1800 472 247 Fax (03) 8699 0400 Email racgp@racgp.org.au
racgp.org.au ACN 000 223 807 ABN 34 000 223 807

Recommendation: There should be a standing committee with authority to approve funding on a case-by-case basis for patients who are likely to benefit from access but fall outside the strict criteria requirements.

4. Importance of an evidence-based approach to support decision-making

Significant expertise is required to develop high quality evidence tables (which ideally meet the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework, as detailed in our previous submission). Evidence-to-decision frameworks should be transparent and based on the quintuple aim as we have indicated in our first recommendation above. The use of GRADE tables offers a consistent approach, allowing various jurisdictions or funders to rely on shared evidence synthesis while retaining the flexibility to make diverse funding decisions based on local context and priorities.

For example, the National COVID-19 Clinical Evidence taskforce demonstrated an effective decision-making process through its living guideline approach. This involved weekly discussions and consensus recommendations agreed on from committees representing various peak bodies and consumer groups. These living guidelines became a trusted source of information in Australia and beyond, influencing decisions for antiviral treatments for Covid-19.

Recommendation: Use GRADE tables for presentation of evidence of effectiveness, preferably independently developed by evidence synthesis experts.

5. Utilise information from registered clinical trials

To prevent sponsors from selectively choosing trials with favourable outcomes, it's important that all trial information is obtained from registered trials. This ensures a comprehensive and unbiased assessment of the evidence.

Recommendation: All trial information be critically appraised according to the Enhancing the QUAlity and Transparency of health Research (EQUATOR) recommended checklists.

6. Importance of consulting with and considering impact on health providers

In cases where funding for a previously supported product is restricted or removed, GPs should be provided with advance notice, a clear explanation, and an opportunity to contribute to the decision-making process. This not only ensures transparency but also allows GPs to provide valuable input and make necessary prescribing changes, especially considering that some GP prescribing occurs at intervals of 6-12 months for patients whose condition is stable.

Including input from GPs, as specialist generalists, into evidence-to-decision frameworks helps prevent an excessive focus on a single organ system and narrow outcomes. GPs provide a holistic perspective to care and this broader perspective enhances the comprehensiveness of decision-making processes.

Recommendation: Health providers are consulted and their experience in delivering healthcare should be considered as part of the decision-making process.

7. Role of committees and sponsors on decision making

There seems to be some overlap in the roles of the Therapeutic Goods Administration (TGA) (safety, effectiveness, marketing approval) and the Pharmaceutical Benefits Advisory Committee (PBAC) (PBS funding decisions based on price and effectiveness and predicted extent of use).

Recommendation: Consider approaches which include implementing parallel process with interactions between committees, along with a triage process for low-risk applications and pre-decision collaboration with the sponsor to confirm an application has the necessary ingredients. The options related to these are outlined in section 2.

8. **Pricing**

Recommendation: Certainty of benefit is an important consideration and pricing should be lower where there is greater uncertainty of benefit. For example, by taking the bottom of the range of uncertain effectiveness when conducting Quality-Adjusted Life Year (QALY) calculations to reflect the risk and encourage responsible pricing in healthcare.

General comments

- The options described in 1.1 seem appropriate.
- The options described in 1.2 seem appropriate. Consumer engagement beyond expert committees is important for decisions that involve balancing of rights, responsibilities, and priorities. Methods of engagement with consumers could include citizen juries in which a broad group of individuals collectively seek to become informed of the facts and make a collected recommendation that is made public.
- The RACGP welcomes the recommendation to engage with stakeholders such as the RACGP, regarding implementation of disruptive technologies and products as described in 1.4.6 option.
- The RACGP welcomes the recognition of the complexity of new antimicrobial research, development, and release in the context of antimicrobial resistance.
- The RACGP welcomes the attention to increase early stakeholder input into choice of PICO (Population, Intervention, Comparison and Outcomes), as it helps prevent a product sponsor from selecting irrelevant comparators or outcome measures.
- The RACGP welcomes the proactive identification of unmet clinical need and horizon scanning international use of new technologies.

Thank you again for the opportunity to provide feedback. For any enquiries regarding this letter, please contact Stephan Groombridge, National Manager, Practice management, Standards and Quality Care on (03) 8699 0544 or stephan.groombridge@racgp.org.au.

Yours sincerely

Dr Nicole Higgins
President

References

1. Department of Health. Annual Medicare statistics: Financial year 1984–85 to 2019–20. Canberra: DoH, 2020
2. Australian Institute of Health and Welfare. Medicines in the health system. Canberra: Australian Institute of Health and Welfare, 2022. Available from: https://www.aihw.gov.au/reports/medicines/medicines-in-the-health-system [accessed 8 February 2024].
3. Itchhaporia D. The Evolution of the Quintuple Aim Health Equity, Health Outcomes, and the Economy. J Am Coll Cardiol. 2021; 78(22): 2262–2264.
4. Bodenheimer T & Sinsky C. From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider. Ann Fam Med. 2014, 12 (6): 573-576