Health Technology Assessment Review
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Dear Review Team

Health Technology Assessment Review

Public Pathology Australia (PPA) welcomes the opportunity to contribute towards the Health Technology Assessment (HTA) Policy and Methods Review. We provide the following response to the Consultation Survey 1 questions.

Background

Seventy per cent of medical decisions rely on pathology, and pathology is required to diagnose one hundred per cent of cancers. Pathology tests and clinical consultative services facilitate diagnoses, assist in determining appropriate treatments and managing health conditions.

PPA is the national peak body for government owned and operated pathology services in Australia. Our members service all State and Territory jurisdictions. In addition to diagnostic and clinical consultation services, our members conduct research into new pathology tests and translation of these tests into diagnostic and clinical practice. Our members are funded principally from the National Health Reform Agreement and the Medicare Benefits Schedule (MBS). For more about PPA, go to: www.publicpathology.org.au.

We provide this submission from the lens of public pathology services who have been involved in applications to the Medical Services Advisory Committee (MSAC) and who provide diagnostic tests for items on the Medicare Benefit Schedule (MBS). This includes genetic tests required to access certain pharmaceuticals on the Pharmaceutical Benefits Scheme (PBS) following Pharmaceutical Benefits Advisory Committee (PBAC) processes (known as precision medicine or pharmacogenomics). Pathology tests are specifically referenced in the HTA Review Terms of Reference. This submission refers to technologies as being inclusive of pathology tests.

Key Points

PPA recommends to:

- Streamline MSAC processes, particularly for genomic items.
- Improve alignment of MSAC and PBAC processes, particularly for pharmacogenomic applications.
- Ensure new items are agnostic in terms of testing platforms.
- Seek advice from relevant peak bodies on fees as well as descriptors as Australian comparators may not be available or appropriate.
- Introduce specialist HTA groups (e.g. for genomics).
- Accept international and real world evidence where appropriate.
- Introduce an accepted methodology to assess the downstream cost savings to the broader health system, patients, community and the economy.
- Reduce incentives to cost shift between NHRA and MBS funded services by setting the same MBS fees for all pathology providers, expediting NHRA provided tests onto the MBS, and providing alternate funding options for applicants.

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Response to Survey Questions

1.0 Are there any elements and features of HTA policy and methods in Australia that are working effectively?

1.1 Are you able to provide detail of any elements and features of HTA policy and methods that are working effectively? Please use specific details where possible.

The HTA processes aim to ensure the quality, safety, efficacy, effectiveness and cost effectiveness of health technologies.

Over recent years, there has been greater consultation with relevant national peak bodies such as PPA in HTAs. This engagement has led to better informed decision making about introducing new technologies, and it should continue.

1.2 Are you able to provide details of positive outcomes resulting from Australia's HTA policies and methods? Please use specific examples where possible.

There are many positive outcomes resulting from approving funding for new or improved diagnostic tests. In recent times, there has been an increased listing of genomic tests and personalised medicines which have significantly improved patient outcomes and value for in new tests and therapies. There has also been shorter HTA approval turnaround times but the HTA process still lags behind the technology and MBS and PBS applications are not in sync for new pharmacogenomics.

2.0 Elements and features of HTA policy and methods in Australia acting as a current or future barrier to earliest possible access.

2.1 What are the elements and features of HTA policy and methods that are acting as a current barrier to earliest possible access?

Where possible, please detail:

- Specific examples or experiences
- The specific policy, method and/or mechanism that is causing the barrier
- The group/s being impacted
- The magnitude of the impact
- The group/s in the HTA approval pathway contributing to these issues.

While HTA processes must be robust, they also must be fit for purpose. Australian HTAs do not keep pace with developments in new technologies. Specifically, the MSAC HTA process is burdensome and therefore time consuming and expensive. Recent applications by the Royal College of Pathologists of Australasia have taken around two years to be approved.

In the case of genomic applications, these must be submitted variant-by-variant or indication-by-indication which is extremely time consuming. In genomics there is a rapid emergence of variants combined with evolving methodologies for the detection of variants and rapidly changing fees.

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Applications should not be specific as to particular pathology platforms/analysers as this locks pathology providers into contracting with certain suppliers with whom they may have little control over platform and consumable costs. It can also mean that laboratories need multiple platforms for similar tests (e.g. immunotherapy assay PBL1 - testing many antibodies on specific platforms). The capital intensive requirement for specific equipment is a disincentive to provide these items. It also increases workload and risk of errors. Laboratories need flexibility to choose the appropriate platforms for their services.

There is a disconnect between the HTA PBAC and MSAC processes. Sometimes pharmaceuticals are listed on the PBS without their co-dependent pathology test being listed on the Medicare Benefits Schedule (MBS). This creates cost barriers to testing as without the MBS item, ether the test is not conducted or there is an out of pocket charge associated with the test. This leads to delayed diagnoses and inability to access certain PBS treatments.

The preference for randomised controlled trial (RCT) data and unwillingness to accept indirect comparison methodology often sets an unattainable evidence threshold in HTAs. Australian health outcomes and economics studies may not exist, however international evidence may be available.

Another barrier is the way comparators are used in HTAs. Comparators are the benchmark upon which comparative efficacy, safety and cost-effectiveness analyses are conducted. Comparators are instrumental in fee-setting. Typically in a MSAC application, a similar MBS item is chosen as the comparator. Sometimes an MBS Item for a pathology test such as a new genomic test doesn't exist, and sometimes the fee of an existing similar test does not reflect the cost of the test.

A common feature of approved applications in recent years has been the lack of alignment between the fees proposed, the fees for similar items in the MBS and the actual cost of the tests. This may be due to siloed applications and the fact that the technology has rapidly evolved.

The Pathology Services Table of the MBS (PST) has not been updated to reflect contemporary clinical practice nor the current cost of pathology tests. Unlike other medical specialties, the Pathology MBS Review recommendations have not been implemented. The MBS Review Pathology Clinical Committee Recommendations were sensible and should be adopted in a scheduled way. As a result of inaction on these measures, the PST has items that are overfunded and underfunded. Therefore, when these items are used as a comparator for fees, the fees set for new items do not reflect costs. Where the fees are underfunded, this precludes pathology providers from providing the tests even when they are listed on the MBS.

It is not only comparator issues that lead to issues in fee-setting but also lack of real world diagnostic service provision and understanding of actual laboratory and specimen collection costs. When applications for pathology tests are made by organisations that are not directly involved in mainstream pathology provision, they make inaccurate assumptions about the cost of the tests. By way of recent example, the newly listed Item 73420 for non-invasive prenatal testing of blood from a RhD negative pregnant patient for the detection of the RhD gene from fetal DNA reflects clinical guidelines and would save time and money but the $56 fee does not reflect test costs which are around $150.

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2.2 What are the elements and features of HTA policy and methods that may act as a future barrier to earliest possible access? Where possible, please detail:

- Specific examples or experiences
- The specific policy, method and/or mechanism that will cause the barrier
- The group/s impacted
- The magnitude of the impact
- The group/s in the HTA approval pathway contributing to these issues.

Full HTA processes have to be followed despite similar technologies being introduced albeit for different applications.

2.3 Would you like to provide feasible options or suggestions you have to improve elements of HTA policy and methods that are acting as a current or future barrier to earliest possible access?

Where possible, please detail:

- Specific examples or experiences
- The specific policy, method and/or mechanism being suggested
- The group/s in the HTA approval pathway that will need to contribute to the solution
- The outcome the suggestion is expected to achieve
- Any foreseeable risks or negative impacts the suggested change may have and possible ways to mitigate them.

There needs to be more efficient HTA processes, including greater synergy between MSAC and PBAC processes for pharmacogenomic applications. The following recommendation of the Standing Committee should be adopted:

"The Australian Government ensure the membership of the MBAC and MSAC provides the appropriate expertise…This should include … enhanced cross-membership between the two committees."

Where a previously approved technology is sought to be introduced for a different application, there should be a streamlined version of the application process to avoid the requirement to duplicate elements of the previous application.

Assessors should be selected on the basis of their knowledge of the subject matter of the application. For instance, there should be genomic subject matter experts involved in the HTA for new genomic test applications.

While peak bodies such as Public Pathology Australia are consulted with respect to advice on descriptors after in principal approval by MSAC, Public Pathology Australia should be able to provide submissions relating to the cost of the test and proposed fees. If the proposed fees do not reflect test costs, then the tests may not be provided despite being listed on the MBS.

Assessors should accept evidence where there is a reasonable evidence base for safety, efficacy and cost effectiveness from other countries. Clinical and cost effectiveness data from studies performed in comparable health jurisdictions should be given weight in the application process. For example, where the FDA has approved an application, it may not be necessary to replicate a clinical trial in Australia should not be required. Where data does not exist in Australia and international data is relevant but not directly compatible, there should be an established methodology for adapting overseas data for the purpose of making an application. Real world evidence should also be considered.

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3.0 Elements and features of HTA policy and methods in Australia that are acting as a current or future barrier to equitable access.

3.1 What are the elements and features of HTA policy and methods that are acting as a current or future barrier to equitable access?

Where possible, please detail:

- Specific examples or experiences
- The specific policy, method and/or mechanism that is causing the barrier
- The group/s being impacted
- The magnitude of the impact
- The group/s in the HTA approval pathway contributing to these issues.

There does not seem to be appropriate weight assigned to the impact of technologies on the health system, and patients and society beyond the clinical outcomes associated with the technology that is the subject of the application.

3.2 Are you able to provide details of feasible options / suggestions to improve elements of HTA policy and methods that are acting as a current or future barrier to equitable access?

Where possible, please detail:

- Specific examples or experiences
- The specific policy, method and/or mechanism being suggested
- The group/s in the HTA approval pathway that will need to contribute to the solution
- The outcome the suggestion is expected to achieve
- Any foreseeable risks or negative impacts the suggested change may have and possible ways to mitigate them.

In addition to metrics such as increased quality of life years, there must be an agreed methodology to assess the broader benefits to the patients, community and economy and downstream savings to the health system by adopting the technology that is the subject of the application.

Beyond the cost of test (to patients if it were privately charged or to Government if it was funded), the following factors could be considered:

- Convenience of access to specimen collection centres and testing laboratories
- Reduced number of touchpoints with healthcare providers
- Societal, workforce and economic benefits from faster diagnosis, treatment and return to productive life (e.g. in reduced bed days, improved patient flow, savings in patient transport, less days off work, childcare or carer costs).

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4.0 Elements and features of HTA policy and methods in Australia that may be detracting from person-centeredness.

4.1 Are you able to provide details of any elements and features of HTA policy and methods that may be detracting from person-centeredness?
Where possible, please detail:

- Specific examples or experiences
- The specific policy, method and/or mechanism that is detracting from person-centeredness
- The group/s being impacted
- Details of the impact this is having
- The group/s in the HTA approval pathway contributing to these issues.

The patient experience is largely missing from HTAs.

4.2 Are you able to provide details of feasible options / suggestions to improve elements of HTA policy and methods that are detracting from person-centeredness?

Where possible, please detail:

- Specific examples or experiences
- The specific policy, method and/or mechanism being suggested
- The group/s in the HTA approval pathway that will need to contribute to the solution
- The outcome the suggestion is expected to achieve
- Any foreseeable risks or negative impacts the suggested change may have and possible ways to mitigate them.

The patient experience could be captured when considering evidence, such as real world evidence as part of the HTA. In this context real world evidence consists of information from electronic health records, hospital episode data, claims data, chart reviews, clinical audits and trials. This information is largely unavailable in the public realm but may be accessible by particular applicants involved in research projects or clinical trials.

5.0 Elements or features of HTA policy and methods in Australia that are causing or could cause unintended consequence or perverse incentives.

5.1 Are you able to provide details of elements of features of HTA policy and methods that are causing or could cause unintended consequence or perverse incentives?

Where possible, please detail:

- Specific examples or experiences
- The specific policy, method and/or mechanism creating the perverse incentive
- Details of the unintended outcome occurring or that could occur
- The group/s contributing to these issues.

There is potential to cost shift between National Health Reform Agreement funded services and MBS funded services depending on whether technologies are listed on the MBS and given differing payment rates for providers under the MBS (e.g. higher MBS fees to private pathology providers compared to public pathology providers for every pathology episode.

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5.2 Are you able to provide details of feasible options / suggestions to improve elements of HTA policy and methods that are creating unintended outcomes or perverse incentives either currently or in the future?

Where possible, please detail:

- Specific examples or experiences
- The specific policy, method and/or mechanism being suggested
- The outcome the suggestion is expected to achieve
- The group/s that will need to contribute to the solution.
- Any foreseeable risks or negative impacts the suggested change may have and possible ways to mitigate them?

The following would reduce perverse incentives to cost shift:

- Ensuring the MBS pays the same fees irrespective of provider type (i.e. instituting funding parity between public and private pathology providers);

- Expediting applications where tests are being provided in the NHRA funded sector but not the MBS funded sector; and

- Providing a list of alternate funding arrangements that could potentially be used other than via the NHRA or MBS when applications are made.

6.0 Areas for further investigation or analysis – examples from other countries
No comment.

7.0 Noting the objectives of the review set out in the Terms of Reference, is there any other information relevant to the Review not provided above that you would like to add?
No comment.

Please contact Public Pathology Australia CEO Jenny Sikorski on ceo@publicpathology.org.au, 0466 576 221 should you require any further information.

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