Breast Cancer Network Australia

22 February 2024

Breast Cancer Network Australia feedback on Consultation Two of the Health Technology Assessment Review

Thank you for the opportunity to provide feedback on Phase 2 of the Health Technology Assessment (HTA) review. Breast Cancer Network Australia (BCNA) supports in principle the options and recommendations put forth as part of the Options Paper as a meaningful, comprehensive, and holistic approach to reforming Australia's HTA systems and processes.

In addition to the specific feedback that BCNA has provided to individual options via the online survey, we wish to put forward the following general feedback regarding the Options Paper and the HTA review thus far. This feedback is made in consultation with Consumer Representatives and on behalf of our wider network of 180,000 Australians with a lived experience of breast cancer.

BCNA was pleased to see that consumers and patient groups have been well represented in the Options Paper. We assert that consumers are not solely inputs into HTA processes, but partners in this decision making as well.

The Options Paper also makes significant progress in describing ways that Australia's HTA processes could better deliver on the objectives and mandate of the National Medicines Policy, of which we believe our HTA is not currently adherent to, specifically in the areas of equity of access to medicines.

Taking into account the overarching goals of the HTA Review – that all features are ensuring early and equitable access that is person-centered and free from perverse incentives, the following feedback represents the areas that BCNA believes would have the most impact on a meaningful reform of the HTA.

Data and evidence – BCNA is encouraged to see approaches in the Options Paper that seek to diversify the types of evidence valued by the HTA to consider and make decisions. BCNA supports the use of Real-World Data (RWD) (including patient-reported outcomes (PROMS)) where traditional data, such as that gathered through Randomized Control Trials (RCT), may not be relevant or sufficiently available such as for rare diseases or medicine repurposing where there is little or no commercial incentive to run RCTs. The options could be further strengthened by exploring the matrix of data considered by the HTA and recommending the development of a framework that assists in determining where value and weighting is best placed to assess a new health technology.

BCNA particularly supports one of the options presented to allow fast-tracked Pharmaceutical Benefits Scheme (PBS) subsidies for new therapies with high unmet clinical need (HUCN) that may not have adequate RCT evidence, for a fixed time period within which RWD can be gathered and reevaluated as to the cost-effectiveness of these therapies. BCNA notes there

would need to be consideration given to navigating the event in which a therapy is removed from the PBS after this time period due to insufficient evidence.

Strengthened data is a key enabler spanning a number of the options described in the Options Paper. Whilst outside of the scope of the HTA Review, BCNA notes the importance of parallel pieces of work such as the development of Cancer Data Frameworks currently underway by Cancer Australia to make improvements to Australia's cancer data ecosystem including minimum datasets and data linkages. The HTA Review could leverage work such as this by highlighting data improvements that would see strengthened HTA e.g. Medicare data linkage with state/territory hospital datasets, cancer registries, etc.

Strengthened overall health data would have the added benefit of incentivizing industry to establish clinical trail sites in Australia, allowing for improves domestic RCT data to be collected to inform further HTA.

Triaging and tailored assessment – One of the greatest concerns held by BCNA regarding current HTA processes that negatively impact on equity of access is the time it takes for new treatments to be subsidized on the PBS. BCNA frequently engages in advocacy to expedite HTA processes and see new treatments for breast cancer available as soon as possible without the significant financial burden of privately funding these treatments.

BCNA supports the extensive reimagining of HTA processes contained in the Options Paper, particularly the proposed new step of 'triaging' that would see new applications appropriately risk-assessed with streamlined and expedited pathways for medicines that are low-risk and target diseases with HUCN. In oncology, this could include drugs to treat triple-negative breast cancer, metastatic breast cancer, and new and emerging breast cancer subtypes such as HER2-low.

The Options Paper does not put forth a framework with which to determine HUCN need and low risk. Developing this further could strengthen the recommendations and ensure there are no perverse consequences (e.g. some medicines being considered faster than others despite the same level of need). One criterion that BCNA would support being included in a risk and HUCN framework is whether the drug or treatment is currently subsidized on the PBS for a different indication (e.g. pembrolizumab).

BCNA believes more could be done to create equal burden of responsibility between government and industry in enabling faster and more equitable access to new therapies. As an example, BCNA was disappointed to see there was no recommendation made to require sponsors to enact Patient Access Programs (PAP) for drugs with HUCN while awaiting HTA decision making. This could be incentivized in the form of waiving or reducing a submission fee and would help to alleviate waiting times for drug access without additional government spend.

BCNA also strongly advocates building better systems to evaluate whether subsidized treatments work as well as expected, or better, or not as well, in real world settings (as compared with trials). It is well recognised that trial populations and circumstances do not entirely reflect those of the real world, and it is important that there is routine and systematic

assessment of the performance of treatments and technologies in real world settings, both in terms of patient outcomes and patient experience.

Horizon scanning – A proactive and dedicated horizon scanning process was highlighted by BCNA as a key recommendation in our original Phase 1 HTA consultation response. Currently, the burden of horizon scanning is left to patients and patient groups in a majority of incidences, placing an unfair burden on smaller and less resourced disease types and meaning Australia's HTA is seldom prepared ahead of time for novel therapies and new types of treatment options. In oncology, these include precision medicines, genomics, antibody-drug conjugates, and drugs for newly defined breast cancer subtypes such as HER2-low.

BCNA was pleased to see dedicated horizon scanning processes recommended in the Options Paper but notes that only tentative language is used to suggest the involvement of patients and patient groups who are currently central to this process and must be involved in horizon scanning processes moving forward. BCNA also notes that this is a resource-intensive process and questions whether specific capacity-building for rarer disease types could be included as a recommendation, and that processes concerned with horizon scanning are established in partnership with those already doing this work across the NFP and research sectors.

Noting the interconnectedness of many of the recommendations in the Options Paper, BCNA encourages international harmonization to be part of horizon scanning activities to ensure consistency and equity with comparable jurisdictions overseas, as well as the potential to avoid overall duplication of work.

Equity – BCNA is pleased to see some elements of equity addressed in the Options Paper, specifically the attention given to areas of HUCN, but feels it could more strongly be a theme throughout all recommendations.

BCNA strongly supports the recommendation to establish a First Nations Advisory Committee, as well as to include First Nations representation on the PBAC and to include First Nations as a priority area of HUCN in horizon scanning. More engagement with the community and with Aboriginal Community Controlled Health Services is likely required at the implementation stage.

The recommendations could consider how other priority groups with poorer health outcomes might input into HTA processes to ensure greater access to treatments for conditions that disproportionately affect these groups, or in situations where it may be more difficult for members of specific groups to access treatments. This includes LGBTIQ+ and those living with disabilities.

Finally, one element affecting equity of access to health technologies that was not addressed in the recommendations is disparities caused at the state/territory level through disparities in public vs private healthcare. Examples that BCNA is particularly familiar with include breast implants, where products differ between public and private patients, access to non-subsidized privately funded drugs that are frequently unavailable at public hospitals, and secondary drugs such as filgrastim that are routinely prescribed in private hospitals but not in the public system. While greater equity between states/territories is somewhat addressed in the Options Paper, equity

within states and between public and private systems seems out of scope despite being a significant area of disparity in how HTA relates to Australian patients.

It is particularly important that treatments and tests subsidized through HTA processes are available on an equitable basis to all Australians according to their need and capacity to benefit, and not determined by where the patient lives or by which sector (public or private) they access for their healthcare.

Thank you again for the opportunity to contribute to this significant review of Australia's HTA. We hope to see as many of the recommendations put forth in the Options Paper implemented into meaningful policy reform.

BCNA is always ready to work with decision makers, at all stages of policy development, to ensure the lived experience of consumers is central to decision making.

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