Response ID ANON-YGVX-SRZB-F

Submitted to MSAC Consultation Survey - Application 1782
Submitted on 2024-07-11 16:21:16

Privacy and Consent

Consent

I have read the above text on how the department will handle personal information included in my response to this MSAC consultation survey. I consent to the department collecting, using, and disclosing my personal information, including any sensitive information, as described above.:
Yes

Contact details

1 What is your name?

Name:
Michael Quinn

2 What is your email address?

Email:
michael.quinn3@health.qld.gov.au

3 What is your phone number?

Phone number:
0736461256

4 What is your postcode?

Postcode:
4029

5 Providing Input

I am providing input on behalf of a medical, health, or other (non-consumer) organisation. For example, input on behalf of a group of clinicians, research organisation, professional college, or from an organisation that produces a similar service or technology.

6 If you are providing input on behalf of a group or organisation, what is the name of the group or organisation and what is your role with the organisation?

Name:
Australian Genomics

Questions for Medical, Health and Other Organisations (non-consumer)

1 What is the organisation’s experience with the proposed health service or technology, or with the related health condition?

Write your answer below.:

Australian Genomics is an Australian Government initiative supporting genomic research and its translation into clinical practice. Through broad engagement and a national collaborative approach, it achieves two key objectives: to improve efficiency, reach and timeliness of genomic research projects, and to support Commonwealth, State and Territory health departments in the implementation of genomics research outcomes by refining and communicating evidence to inform policy development.

Australian Genomics engages with current and emerging government policy and priorities to identify gaps and opportunities, to support policy and action for integrating genomic technologies into the health system. By interfacing with consumers, government, industry and global genomics initiatives, Australian Genomics drives change and growth in the sector.

Australian Genomics has investigated clinical implementation of genomic testing into a range of rare disease and cancer diseases. This had included a somatic cancer flagship, that investigated clinically actionable variants in a range of cancer types using the Comprehensive Cancer Panel at the Peter MacCallum Cancer Centre. A familial cancer genomics flagship on rare inherited cancers (ICCon), collaborated with familial cancer centres across Australia. Additionally, a lung cancer diagnosis flagship (EBUS-TBNA) has investigated the methodology of endobronchial ultrasound lymph node aspirates for nucleotide extraction and whole genome / whole exome sequencing technologies, to guide lung cancer treatment.

Australian Genomics has an established Community Advisory Group which includes members who have personal experience with disease types including cancer. Australian Genomics also engages with patient advocacy organizations, including the Breast Cancer Network Australia through the Genomics in

the Community Project (https://www.australiangenomics.org.au/genomics-in-the-community/).

2 Is the proposed population(s) for the health service or technology appropriate?

Write your answer below.:

The population for this intervention is well defined and appropriate.

Breast cancer patients may present with advanced or metastatic disease (5-10%) with 20 to 30% of breast cancer patients progressing to locally advanced/metastatic disease (Redig & McAllister 2013). The population in the current application is patients who have estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced (node positive) or metastatic breast cancer who have had disease progression after at least one line of endocrine therapy. ER-positive HER2-negative breast cancer patients are a well characterised subtype classified by histology or cytology. The subtype accounts for up to 70% of breast cancer and has poor treatment outcomes. Advanced/metastatic disease is incurable with a median survival of three years (five-year survival for metastatic breast cancer is 26% (Peart (2017)). Estrogen receptor 1 gene (ESR1) mutations are a cause of acquired resistance that affects 40-50% of patients after initial endocrine therapy in the metastatic setting and are associated with a poorer prognosis (Brett et al., 2021).

The proposed test (ESR1 mutation detection) from circulating tumour DNA (ctDNA) in blood plasma, will subsequently be used to determine eligibility for elacestrant (Orserdu®) treatment (health technology relies on a new listing on the Pharmaceutical Benefits Scheme (PBS). Elacestrant is a novel, nonsteroidal, oral selective ER degrader. Testing of circulating DNA from blood plasma will potentially be conducted multiple times in this patient group, as the ESR1 mutation is an acquired mutation.
The detection of ESR1 activating mutations is a predictive biomarker for treatment with elacestrant, and longer endocrine therapy treatments can lead to resistance and poorer outcomes. The EMERALD trial was the key study which indicated tailored treatment options for patients in terms of the clinical utility of ESR1 mutation testing.

The eligibility criteria for the proposed service are well aligned with the study population in the randomized phase III EMERALD trial (Bidard et al., 2022). This study had a patient cohort of ER-positive / HER2-negative advanced breast cancer who had one-two lines of endocrine therapy and one or less rounds of chemotherapy. In the study, 239 patients were randomly assigned to elacestrant and 238 received standard of care (SOC) treatment. Patients had histologically or cytologically proven ER-positive/HER2-negative breast adenocarcinoma with either regionally recurrent or metastatic disease. Disease progression must have occurred within 28 days of treatment wither one or two lines of endocrine therapy. One regimen of chemotherapy was permitted. SOC treatment ("investigators choice") included fulvestrant, anastrozole, letrozole or exemestane monotherapy. The study found a longer time period for progression free survival in the cohort receiving elacestrant and a significant reduction in the risk of progression or death (45%) compared with SOC, addressing an unmet clinical need to prolong progression free survival in these patients (Bidard et al., 2022).

In terms of translation to the Australian healthcare setting, we note the underrepresentation of Indigenous Peoples in clinical trials across various health systems including Australia, Canada, New Zealand and the United States (Umaefulam et al., 2022). It is crucial to address this issue as genetic variations can have an influence on drug response, therefore further work is required in this area to ensure accurate clinical trial data across all populations. This aligns with one of the strategic objectives of the Australian Cancer Plan, to achieve equity in cancer outcomes for Aboriginal and Torres Strait Islander People affected by cancer.

In terms of health inequities, the proposed service requires access to specialised medical service, for example medical oncologists for test specimen collection and test ordering, and often this will require in person attendance (with associated travel) at metro and regional health centre hubs across Australia. We note that the patient will often have their blood collected (for plasma and subsequent ctDNA extraction) at the same time as other treatments. However, we also note that these equity of access issues are not specific to the proposed service, but rather a concern to be addressed by health services to assess gaps across different levels in cancer screening and other specialised cancer treatment more generally (for example Frosch 2022 commentary). Some of these concerns regarding equity in cancer care are addressed at a policy level in the Australian Cancer Plan (https://www.australiancancerplan.gov.au/populations)

3 Is the proposed approach to delivery of the health service or technology appropriate?

Write your answer below.:

Proposed delivery: liquid biopsy. Possible sample source for the proposed service includes solid tissue biopsy, circulating tumour cells (e.g. from blood plasma), cell-free DNA and archival tumour material. The proposed service requires investigation of ESR1 mutation status at different time points due to the acquired nature of the mutation. A liquid biopsy, where circulating DNA is measured in blood plasma offers the advantage of being more efficient and less invasive than tissue biopsies. Archived material is not recommended for testing – due to subclonality, polyclonality and the distinctive effects of specific ESR1 mutations (Brett et al., 2022). However, Brett et al (2022) do note that different cell free DNA shedding rates and circulating tumour cell (CTC) release may differ depending on tumour microenvironment. In the Australian healthcare setting, request for sampling would be primarily organised by medical oncologists, at cancer care centres. The proposed approach of liquid biopsies from patient blood plasma would be feasible, noting the issues regarding specialised cancer care centres being more easily accessible in inner regional and metro areas.

Proposed delivery: NGS vs ddPCR technology. Detection assays for ESR1 mutations include next generation sequencing (NGS) and droplet digital PCR (ddPCR). ddPCR is the most sensitive technique (Liao et al, 2020). NGS based assays offer the advantage of being able to assess multiple genes in parallel. In the future, this could allow for the assessment of other genes associated with cancer (e.g. PIK3CA as mentioned in the PICO set) to support a comprehensive cancer profiling approach. The EMERALD trial utilised NGS technology, specifically the Guardant360® CDx (Bidard et al., 2022). This assay allows for the detection of single nucleotide variants (SNVs), insertions and deletions (indels), copy number amplifications and fusions in a targeted panel of 55 genes. There is good coverage of the ESR1 gene, including the ligand-binding domain where all ESR1 mutations are located (Brett et al., 2022). This technique was proposed as the reference standard in the PICO set, however it was not available in Australia at the time of submission. Guardant360® CDx is currently available to patients in Australia by ordering and paying for the test privately through Guardant Health AMEA and arranging sample collection through the patient's local Sonic pathology practice (Sonic Genetics, 2024). The test report is subsequently issued by Guardant Health AMEA.

This assay has been approved for comprehensive genomic profiling for all solid tumours in the United States (US), Japan, Singapore, and Europe, with reimbursement available in Japan as well as the US (through Medicare and some private payers) (Guardant Health AMEA, 2023; Guardant Health AMEA, February 2024). Regulatory approvals for Guardant360® CDx in the US and Europe also include the assay as a companion diagnostic to identify advanced breast cancer patients with ESR1 mutations who may benefit from treatment elacestrant (Shah et al., 2024; Guardant Health AMEA, May 2024).

The panel of 55 genes used by this assay may allow for parallel assessment of relevant genes and pathways for targeted therapy in other cancer subtypes. The PICO notes that a ddPCR-based assay would have to be developed in-house by diagnostic laboratories, whereas NGS is an established technology in Australia. We encourage further guidelines by diagnostic laboratories and the Royal College of Pathologists Australasia (RCPA) around benchmarking between different techniques in the context of ESR1 mutations.

Equity of access issues: We have previously raised issues around access to specialised cancer care in Australia, which is a broader issue (see also strategic objective 5 of the Australian Cancer Plan (Cancer care workforce) rather than being specific to the proposed service. If diagnostic laboratories chose to use ddPCR technology, although there may be more sensitivity, there is not the same flexibility as NGS technology in terms of the ability to scale to other genes of interest in the future (e.g. PIK3CA).
Other health services involved: A specialist consultant (e.g. medical oncologist, breast surgeon, interventional radiologist) would be required to provide the specimen and a test request form. The PICO states that a registered molecular pathologist would be responsible for conducting detection, diagnosis and reporting. We note that it is unlikely this specific service would be organised by a clinical genetics service, with patient clinical care mainly being coordinated by medical oncology teams.

Possible barriers to access:
• As outlined previously, we raise the issues of access to specialised cancer services generally (required at the site where the liquid biopsy sample from blood plasma would be taken).
• Consistency of assay utilised by diagnostic laboratories. Laboratories would be required to have National Association of Testing Authorities (NATA) accreditation for NGS, and RCPA involvement in quality assurance programs.
• We also reconfirm the lack of clinical trial data generally for Aboriginal and Torres Strait Islander peoples in Australia and First Nation peoples in other countries. From the FDA multi-discipline review, the EMERALD trial included enrolment from the following regions: Asia (n=10), Australia (n=3), Europe (n=57), North America (n=27) and South America (n=3).

4 Does the comparator(s) set out in the application accurately reflect Australian clinical practice?

Write your answer below.:

The comparator of no service is appropriate – there is currently no funding available for testing of ESR1 mutations in the proposed population. In the absence of the proposed service, there would be difficulties in assessing the cohort of patients that would benefit most from the proposed tailored treatment of elacestrant.

SOC is described in the PICO as fulvestrant monotherapy, everolimus plus exemestane, switch endocrine therapy and chemotherapy. We note that the PICO indicates that the definition of SOC will be further refined based on local clinical practice. This reflects the variety of treatment options available, which may differ on a case-by-case basis. This is also captured in the clinical management algorithm from the PICO.

In the absence of public funding for ESR1 mutation testing or treatment, patients must pay for the test and associated treatment out-of-pocket. This is not a feasible strategy in the long-term and does not align with equity of access of healthcare services and treatments for all Australians.

5 Does the organisation agree with the outcomes as set out in the PICO?

Write your answer below.:

We generally agree with the outcomes as set out in the PICO. We additionally make the following specific comments:

Certainty around proposed outcomes: The EMERALD randomised phase III trial demonstrated significant improvements in progression free survival in patients with ESR1 mutations who were administered elacestrant. Certainty around the proposed outcomes is strengthened by:

i) incorporation of ESR1 as a biomarker into cancer care treatment guidelines such as the European Society for Medical Oncology (ESMO) Clinical Practice Guidelines (Gennari et al., 2020); ASCO Burstein et al., 2021. The ESMO Metastatic Breast Cancer Living Guideline for ER-positive HER2-negative breast cancer also includes elacestrant if the patient is ESR1 mutation positive (ESMO, 2023). Elacestrant is also strongly recommended by the American Society of Clinical Oncology (ASCO) as an option for tumours with ESR1 mutations (Burstein et al., 2024). As noted in the application, the recently updated NCCN guidelines also include elacestrant as a new treatment option for postmenopausal females or adult males with ER-positive, HER2-negative, ESR1-mutated tumours after disease progression on 1 or 2 prior lines of ET, including one line containing a CDK4/6 inhibitor (Gradishar et al., 2023).

ii) adoption of service in other countries: elacestrant (Orserdu®) has been approved in Europe and the US for this indication with the Guardant360® CDx assay as a companion diagnostic (Shah et al., 2024; European Commission, 2024). Marketing authorisation for elacestrant has been granted in the UK and an evaluation by the National Institute for Health and Care Excellence (NICE) is currently in progress (Medicines and Healthcare products Regulatory Agency, 2023; NICE, 2024).

iii) approval of proposed NGS based assay Guardant360® CDx in the US (via the FDA) and similar approvals in Japan, Singapore, and Europe as previously mentioned.
Concerns about whether the proposed outcomes will be maintained over time: Some clarification required regarding repeated measures / treatment of drug. We anticipate this will be addressed by advice around delivery via the PBS.

Potential outcomes not mentioned in application: Patient expectations would have to be managed as different ESR1 mutations can relate to varying

degrees of drug effectiveness in different clinical presentations (Brett et al., 2021). The EMERALD trial also documented adverse side-effects of drug administration such as nausea and possible treatment discontinuation due to adverse effects (Bidard et al., 2022). Patients would be made aware of such side-effects as per routine practice. However, we note that as a result of the absence of alternative treatments, the potential for increased progression free survival may outweigh the risk of adverse effects in most cases.

6 Where the application is for an item on the Medicare Benefits Schedule, does the organisation want to comment on the proposed item descriptor(s)?

Write your answer below.:

MSAC Application 1782 Item descriptor comments:

• We generally agree with the patient access criteria, which is aligned with the patient cohort described in the randomized phase III EMERALD Trial and guidelines by ESMO and ASCO.

• We suggest providing clarity around the number of times the service can be accessed, given that blood plasma will be collected at multiple time points of treatment in order to detect the acquired ESR1 mutation.

• Although the methodology of testing is not described in the proposed item descriptor the PICO indicates that NGS based technology would be the preferred technique employed. This would potentially allow for other genes of interest (e.g. PIK3CA) to be tested in parallel to support a comprehensive profiling approach in other cancer subtype and treatment settings.

7 Where the application is for an item on the Medicare Benefits Schedule (MBS), does the organisation support the proposed fee for the health service or technology?

Write your answer below.:

The proposed MBS fee is currently unavailable and will be presented in the integrated co-dependent MSAC/PBAC submission, hence it is difficult to directly comment on this. We note that the cost of the Guardant360® CDx assay is reimbursed by Medicare in the US to the value of US$5000 (Guardant Health AMEA, February 2024). Other options for NGS assays could include the FoundationOne®Liquid CDx assay which is costed at US$3500 (Foundation Medicine).

8 If MSAC supported the proposed health service or technology, would the organisation want to see it implemented? If yes, what would have to happen for this to occur? If no, why not?

Write your answer below.:

Barriers to successful implementation:

• Access to specialised cancer care in outer regional, rural and remote communities. Liquid biopsy samples would be taken from blood plasma at the time of regular visits to specialised cancer care treatment centres.

• Costs of setting up either in-house ddPCR assays or NGS based diagnostic test. The PICO mentions engagement with local diagnostic laboratories and technical experts to further assess method utilisation as part of the co-dependent submission.

• Inclusion of standardisation of testing by regulatory bodies (e.g. benchmarking). Training and qualifications for laboratories and personnel would be under current cancer biomarker genomic testing guidelines. The PICO notes that the applicant has initiated contact with RCPA regarding a potential QAP in Australia.

• Inclusion and adoption of ESR1 mutation detection into relevant treatment Australian cancer care guidelines.

• Knowledge base of test ordering by health care professionals if assay involves a gene list beyond ESR1, for example the possibility of additional findings (Medford and Ellisen, 2024).

9 Does the organisation support public funding for the proposed health service or technology, as it is proposed to be delivered?

Support

Write your answer below.:

The proposed health service and technology is supported by Australian Genomics:

• The service would offer considerable improvements in quality of life (increased progression-free-survival) and offer a reduction in financial burden to the families of Australians with this disease.

• The liquid biopsy technique, isolating ctDNA from blood plasma is the preferred sample due to the benefits of longitudinal sample of the tumour microenvironment as ESR1 mutations are acquired during Endocrine Therapy. The test is also less invasive, more efficient and feasible compared to performing tissue biopsies at multiple time points.

• The population defined in the application is aligned to the Randomized Phase III EMERALD trial population, for standard endocrine therapy compared to

oral elacestrant in advanced or metastatic ER-positive, HER 2-negative breast cancer patients. The trial showed a significant increase in progression free survival.

• The determination of ESR1 mutation status via liquid biopsy would offer tailored treatment to patients at the optimal time, which does not have public funding available at this time.

• There is alignment of the service with current standard of care processes via cancer care services in Australian healthcare (noting points below).

• The service is potentially capable of being delivered by Australian diagnostic laboratories (noting points below).

• The service would bring Australia in line with standard of care practices and the implementation of comprehensive cancer profiling in other health systems internationally (e.g. US, Europe).

• The service would align with current cancer care guidelines including ESMO and ASCO.

Noting the support of the proposed service, we do suggest the following points of consideration in its implementation:

• Equity of access issues relating to access to specialist medical oncology and interventionalist radiologists required to aid in specimen request and test request.

• Issues regarding access to the likely private pathology services that would perform the test.

• Require clarification around the fee (understanding this will be included in the integrated co-dependent MSAC/PBAC).

• As noted by Brett et al., (2022), there is a lack of prospective studies which consider the effect of including ESR1 mutation status in clinical patient management. Although the EMERALD trial has been published in the interim, we encourage further review of published studies in this area.

• The relationship between ESR1 mutations and treatment resistance is complex across different mutation types and tumour scenarios. There are several ongoing trials (refer to Table 3 of Brett et al., 2022), for example investigations into treatment resistance and/or clinical outcomes for different ESR1 variants. Brett et al., (2022) hypothesize that mutation Y537S may drive resistance in ER therapies, based on PFS clinical trial data. Ongoing investigation into ESR1 mutation status and response to elacestrant are likely to address this issue. Additionally, ESR1 mutations occur in combination with other genomic alterations to confer resistance (Chandarlapaty et al., 2016; Fribbens et al., 2018). ESR1 mutation frequency also varies depending on the tumour microenvironment (Brett et al., 2022). We therefore recommend continued evolution around guidelines for ESR1 mutation positive guided treatment. For example, as suggested by Brett et al., 2022, novel oral SERDs should ultimately be developed for use in combination therapies.

Next Steps

For all respondents

1 Is there anything that you have not mentioned elsewhere that you would like to tell us about?

Additional comments:

Please also include email: australian.genomics@mcri.edu.au in future correspondence.

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Statement of interests

Declaration of Interest Statement

No interests

Description of interests: