

# Medical Services Advisory Committee (MSAC) Public Summary Document

## ***Application No. 1627.1 – Point-of-care testing for sexually transmitted infections provided by Aboriginal Medical Services or Aboriginal Community Controlled Health Services in rural or remote areas***

**Applicant:** The Kirby Institute, UNSW

**Date of MSAC consideration:** 23-24 November 2023

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

### **1. Purpose of application**

A resubmission requesting Medicare Benefits Schedule (MBS) listing of point of care testing (PoCT) for detection of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) was received from the Kirby Institute, UNSW, by the Department of Health and Aged Care.

### **2. MSAC's advice to the Minister**

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC supported the creation of a new MBS item for PoCT for detection of CT, NG, and TV provided by Aboriginal Medical Services or Aboriginal Community Controlled Health Services located within remote (Modified Monash [MM] category 6) and very remote (MM category 7) communities. MSAC again recognised that there is a clinical need for the proposed testing due to a high prevalence of sexually transmitted infections (STIs) and the serious consequences of untreated infections for the proposed population. In addition, laboratory testing for STIs (current alternative to PoCT) necessitates follow-up care several days after the test creating barriers to timely treatment. However, MSAC noted that no new clinical evidence was provided and therefore, while PoCT for STIs reduced the time from testing to treatment, the magnitude of the incremental benefit and impact on health outcomes remained highly uncertain. Further, the cost-effectiveness of PoCT for STIs compared to standard laboratory testing remained highly uncertain due to the reservations in relation to the modelled health benefits and the use of an overly complex and unreliable economic model. MSAC noted the applicant had reduced the fee for PoCT (i.e., total fee for combined CT/NG and TV PoCT of \$212.90 [85% rebate \$181]) and reduced the locations for the service to those in MM category 3 (large rural towns) to MM category 7 (very remote communities). MSAC considered that this population and fee was not supported due to the uncertainty that remained regarding the clinical and cost-effectiveness of PoCT for STIs. However, MSAC considered the high clinical need and value of PoCT for STIs in remote and very remote communities (i.e., MM categories 6 to 7), where PoCT for STIs could have the greatest potential benefit by improving timely access and reducing delays in receiving test results. Therefore, MSAC supported MBS listing of PoCT for STIs in this high need population (i.e., MM categories 6-7), at a total fee for combined CT/NG and TV PoCT of

\$117.65 (85% rebate \$100; comprising the equivalent to the fee for standard laboratory testing plus additional costs that MSAC considered were justified for provision of the service).

### **Consumer summary**

This is an application from The Kirby Institute requesting Medicare Benefits Schedule (MBS) listing of point of care testing (PoCT) for sexually transmitted infections (STIs) for people presenting to Aboriginal Medical Services or Aboriginal Community Controlled Health Organisations in rural and remote Australia. MSAC previously considered this application in November 2022.

STIs such as chlamydia, gonorrhoea and trichomonas are infections that are spread through sexual contact and are treated with antibiotics. Individuals with these STIs may not have any symptoms. The long-term effects of untreated STIs can be serious and can include premature birth and problems with fertility. People aged 16 to 29 years old are most at risk, and the rates of STIs in Aboriginal and Torres Strait Islander communities in rural and remote Australia are high. The application to MSAC also outlined the challenges to accessing timely treatment with the testing approaches that are currently funded.

Currently, people are tested for STIs by collecting a sample that is sent to a laboratory for testing. The results can sometimes take up to 14 days for the doctor and patient to receive in remote locations. The majority of patients with STIs don't have any symptoms and need to wait for the laboratory results to return, before they can be contacted to return to the clinic for treatment, if it is required. For those patients who have symptoms, they may be given antibiotics that may not be specifically targeting the correct bacteria and may need to be contacted to return for the right antibiotics. In both cases, the patient may pass on the infection while waiting for the laboratory results.

PoCT is a much quicker alternative to standard laboratory testing. The samples are tested by a machine at the clinic and it takes 60 to 90 minutes to deliver a result. This could lead to quicker treatment for patients, particularly those who are asymptomatic and aren't easily able to return to a medical centre on another day or be easily reached by phone, later. PoCT and the right treatment delivered on the same day can help to reduce the spread of infection and avoid serious short and long-term effects of untreated STIs. The evidence presented to MSAC also outlined ways that PoCT could contribute to a model of care that is more culturally safe and appropriate for Aboriginal and Torres Strait Islander people being tested for STIs presenting to Aboriginal Medical Services or Aboriginal Community Controlled Health Organisations in rural and remote Australia.

MSAC had previously concluded that PoCT was likely to be as accurate as standard laboratory testing and would enable most patients to receive their results the same day. However, the evidence previously presented did not show that PoCT leads to better health outcomes compared to standard laboratory testing. MSAC noted that no new clinical evidence was provided. Therefore, the magnitude of benefit to patients remained uncertain. MSAC noted that the applicant had reduced the proposed MBS fee but it was still much higher than standard laboratory testing. MSAC noted the applicant had proposed limiting the service to patients in large rural towns (Modified Monash [MM] category 3) to very remote communities (MM category 7). The Modified Monash Model is a system that gives different areas in Australia a category number based on whether they are metropolitan (MM category 1), regional (MM category 2), rural (MM categories 3, 4 & 5), remote (MM category 6) or very remote (MM category 7). However, MSAC was not convinced that PoCT (for the population and fee proposed by the applicant) improved patient outcomes enough to justify the very high cost (\$212.90) compared to standard laboratory testing (\$42.95). Further, MSAC considered that the potential overall costs to the health system remained very high and in reality, could be higher than expected.

## Consumer summary

MSAC acknowledged that people living in remote and very remote communities (i.e., MM categories 6-7) have a high clinical need due to their remoteness and would most benefit from PoCT for STIs, which could improve timely access and reduce delays in receiving test results. Therefore, MSAC supported MBS listing of PoCT for STIs in this high need population (i.e., MM categories 6-7), at a total fee of \$117.65 (85% rebate \$100). MSAC based this fee on the equivalent fee for standard laboratory testing plus additional costs that MSAC considered necessary for provision of the service.

### MSAC's advice to the Commonwealth Minister for Health and Aged Care

MSAC supported MBS listing of PoCT for STIs within remote and very remote communities (MM categories 6-7). MSAC considered that the test was safe, effective and would demonstrate value for those with the greatest potential benefit, that is those with a high need for access to a reliable and fast PoCT within remote and very remote communities.

## 3. Summary of consideration and rationale for MSAC's advice

MSAC noted that this resubmission requesting MBS listing of PoCT for the detection of CT, NG and TV provided by Aboriginal Medical Services or Aboriginal Community Controlled Health Services in rural or remote areas was received from the Kirby Institute, UNSW.

MSAC recalled that the original application, [MSAC application 1627](#), was initially considered by the MSAC Executive in October 2020. The MSAC Executive advised that if the applicant wished to pursue an MBS fee that is higher than the existing MBS fees for standard laboratory testing, the applicant would need to provide evidence that PoCT results in better health outcomes than standard laboratory testing, and this evidence would need to be supported with an appropriate economic analysis.

MSAC also recalled that it had considered and not supported the original application, [MSAC application 1627](#), at the November 2022 MSAC meeting. MSAC recalled that the committee had acknowledged there is a clinical need for the proposed testing due to a high prevalence of STIs and the serious consequences of untreated infections that represented a significant public health issue for the proposed population. At that time, MSAC had considered that the evidence demonstrated that PoCT for STIs reduced the time from testing to treatment and that the clinical benefits associated with this were clinically plausible. However, based on the evidence provided, the actual magnitude of the benefit and impact on health outcomes was highly uncertain. As a result of this, and also due to the economic model being overly complex and unreliable, MSAC had considered the cost-effectiveness of PoCT for STIs compared to standard laboratory testing to be highly uncertain. MSAC considered the proposed MBS fee was high and not sufficiently justified given the lack of objective data demonstrating improved health outcomes for patients compared to standard laboratory testing. MSAC also considered the financial estimates to be uncertain and likely underestimated.

MSAC recalled it had suggested a resubmission could consider restricting the population for PoCT to those who have very restricted access to standard laboratory testing (i.e., people in MM categories 6 to 7) or consider an alternative funding mechanism (i.e., non-MBS funding), along with revising and justifying the proposed fee. MSAC also noted, alternatively, if the applicant wished to pursue the proposed population (i.e., MM categories 2-7) then additional work, such as revising and respecifying the economic evaluation, was required.

MSAC noted that the applicant's resubmission proposed changing the eligible population to those living in MM category 3 (large rural towns) to MM category 7 (very remote communities) and had proposed a lower total combined fee for CT/NG and TV PoCT \$212.90 (\$181 at 85% rebate). MSAC noted this proposed fee was lower than the combined \$265 fee considered in November 2022. MSAC also noted the resubmission proposed three MBS items that were different to that previously presented to MSAC. The resubmission proposed two separate MBS items for CT/NG (item XXX) and TV (item YYY) PoCT, which covered the cost of the test cartridge and transport. In addition, a "miscellaneous" item (item ZZZ) was proposed for the purposes of a "service fee", which covered staff time/costs for performing the test. It was noted that the staff member may not necessarily be a clinician. It was noted other pathology testing does not have a separate administration fee, and that to split the fee in this way was not the department's preferred position and that there would be concerns about the precedent this would set. MSAC noted the department had also proposed alternative fees for MSAC's consideration (see Table 4, in section 6).

MSAC noted the revised population was similar to the previously proposed population (i.e., MM categories 2-7). MSAC noted that the applicant had proposed limiting the PoCT to MM categories 3-7, not to MM categories 6-7 as previously suggested by MSAC, based on consultation with the National Aboriginal Community Controlled Health Organisation. The applicant stated that restricting the population to those living in MM category 6-7 communities would lead to major inequities in other areas where there is restricted access to centralised pathology services. MSAC noted that under the current program, 13% are in MM categories 3-5 and 81% in MM categories 6-7. These are sites that have been selected on basis of need, existing prevalence of STIs, distance from routine pathology services, difficulty in clients accessing care and recalling clients for treatment.

MSAC noted that the comparator was unchanged from the original application, which is standard laboratory testing, the current standard of care. However, MSAC noted that in reality for those living in remote and very remote communities there are access barriers (locality, delays in results and possible treatment) that result in patients not accessing standard laboratory STI testing. MSAC considered that for this subset of the proposed population, a comparator of "no testing" could potentially have been appropriate but this subpopulation had not been considered and no evidence had been presented to support it.

MSAC noted that additional qualitative research had been presented on how PoCT can address some barriers to STI testing and follow up. However, no new quantitative clinical evidence was presented and therefore, MSAC considered its previous conclusions regarding the comparative safety and effectiveness of PoCT remained unchanged. That is, PoCT had noninferior safety compared with standard laboratory testing for CT/NG and TV and that the reliability and validity (i.e., sensitivity and specificity) of the PoCT was non-inferior to standard laboratory testing. Further, while it is clinically plausible that the reduced time from test to treatment with PoCT could lead to improved health outcomes, the available evidence did not demonstrate that PoCT improved health outcomes compared to standard laboratory testing. Therefore, MSAC concluded that PoCT had noninferior clinical effectiveness compared to standard laboratory testing CT/NG and TV. However, MSAC acknowledged that, while no longer-term evidence regarding change in management or impact on patient outcomes was provided in the applicant's response, it is unlikely that this will become available in the near future due to the length of studies that would be required.

MSAC noted that the resubmission presented a revised economic analysis using the same complex economic model previously presented to MSAC. MSAC noted the revisions included applying the revised target population, the revised PoCT fees and retesting of patients. MSAC noted that the model still relied on modelling health benefits that MSAC considered may be

plausible but had not been demonstrated by the clinical evidence, creating high uncertainty in the ICER. MSAC noted that as no new evidence was provided, the revised ICER presented by the applicant is unlikely to be useful for decision making due to the continued high uncertainty. MSAC also recalled that it had previously highlighted a number of issues with the model and had advised that the model should be respecified to address these concerns. MSAC noted the applicant's pre-MSAC response asserted that the model aligns with the PICO and was complex as it required multiple pathways for different subgroups and for three different infections, all of which have different sequelae. While MSAC agreed the model aligned with the PICO, MSAC still considered the economic analysis and the ICER generated was not useful for decision making given it modelled health outcomes that were not demonstrated by the clinical evidence and the model was not respecified to address the fundamental concerns previously raised by MSAC.

MSAC recalled it had previously concluded that financial estimates were uncertain and likely to be underestimated. MSAC noted the resubmission presented revised financial estimates based on the same market-based approach that estimated the net cost to MBS over 5 years (2024–2028) would be \$24.1 million. MSAC noted the estimated net cost to the MBS decreased if the alternative fees proposed by the department were applied (see Table 8). However, MSAC considered the predicted utilisation of the PoCT was underestimated.

Overall, MSAC did not support funding PoCT for STIs for the proposed population (i.e., MM category 3 large rural towns to MM category 7 very remote communities) at the proposed total fee for combined CT/NG and TV PoCT of \$212.90 [85% rebate \$181] due to the continued uncertainty regarding the clinical effectiveness and cost-effectiveness of PoCT for STIs that was unchanged from MSAC's previous consideration.

As per MSAC's previous consideration, MSAC again reiterated that remote and very remote communities (i.e., MM categories 6-7) represented the areas of Australia that would have the greatest clinical need and who would currently face restricted timely access and significant delays to test results from standard laboratory testing. Therefore, MSAC was supportive of funding PoCT for STIs in remote and very remote communities where PoCT could have the greatest potential benefit by improving timely access and reducing delays in receiving test results.

However, MSAC considered the applicant's proposed fee of \$212.90 (\$181 85% rebate) was not justified even in remote and very remote communities (i.e., MM categories 6-7) with high clinical need. Further, MSAC did not agree that the fee should be separated out into items for the microbiology (test kit and transport costs) and miscellaneous (staff time/costs to perform the test) components. MSAC also did not agree that the proposed total fee with 40 minutes of staff time to perform the CT/NG and TV PoC tests was reasonable. MSAC noted that the department had proposed an alternative total fee where the staff time (miscellaneous fee component) was reduced to 20min for the combined CT/NG and TV PoC tests (Alternative fee 1 in Table 4) and that the applicant's pre-MSAC response had proposed a compromise of 30mins. However, MSAC noted the proposed miscellaneous service fee (\$65.85 for 20min of staff time) was significantly more expensive than other similar MBS services with comparable procedures and tasks.

Regarding the test component fee, MSAC noted the applicant's justification that this reflects the cost of purchasing the testing kit and transport. MSAC considered the attempt to build in transport costs into the cost of the PoCT was fraught as there is huge variation in distances across MM category 3 to MM category 7 and it would be difficult to land on a value that is equitable. However, if restricted to MM categories 6-7, then it would be reasonable to include transport costs.

MSAC noted that the department had also proposed an alternative fee based on a fee equivalent to MBS item 69319 (comparator laboratory test item) plus additional costs for the test cartridges

(Alternative fee 2 in Table 4). MSAC considered this approach to be reasonable but suggested some revisions. MSAC considered the fee for combined CT/NG and TV PoCT should be set at \$117.65 (85% rebate \$100) so that the 85% rebate encompasses costs for the professional service (equivalent to MBS item 69319) plus costs for cartridges and transport (see MSAC supported fee in Table 4).

MSAC highlighted that it still considered another funding mechanism would be more appropriate but also acknowledged the reasons the applicant has continued to pursue MBS listing. Therefore, based on the significant unmet need for PoCT for STIs in remote and very remote communities, MSAC supported MBS listing of PoCT for CT/NG and TV in remote and very remote areas (i.e., MM categories 6-7) at a fee of \$117.65 (85% rebate \$100). MSAC considered that if the applicant wished to pursue MBS listing of PoCT for STIs in a broader population or at a higher fee then the applicant would need to address all of the concerns raised by MSAC at its November 2022 consideration as outlined in the Public Summary Document for MSAC application 1627.

Table 1 New MBS item supported by MSAC (Group P9 – simple basic pathology tests)

Category 6 –PATHOLOGY SERVICES Group P9–Simple Basic Pathology Tests
MBS [Item number YYY] Detection of: (a) CT ( <i>Chlamydia trachomatis</i> ) and NG ( <i>Neisseria gonorrhoeae</i> ) via molecular point-of-care testing for the diagnosis of CT or NG infection, <b>and</b> , (b) Detection of TV ( <i>Trichomonas vaginalis</i> ) via molecular point-of-care testing for the diagnosis of TV infection. (Item is subject to restrictions in rule PR.9.x of explanatory notes to this category) Fee: \$117.65 Benefit: 85% \$100

Pathology Rule - PR.9.x

Item numbers YYY can only be performed in the following circumstances:

- (a) by or on behalf of a medical practitioner who has determined the service to be necessary for the patient under their care
- (b) the service is rendered at, of from, a practice location in:
  - i. a Modified Monash 6 area, or
  - ii. a Modified Monash 7 area.
- (c) organisation for which the practitioner works is delivering health services and is part of the Aboriginal Medical Services or the Aboriginal Community Controlled Health Organisations
- (d) the practitioner referred to in paragraph (a), or the organisation for which the practitioner works, is participating in the First Nations Molecular PoC Testing Program
- (e) the service is provided in accordance with the Program referred to in paragraph (d).
- (f) The service is conducted by a medical practitioner, nurse, Aboriginal health practitioner/worker or other staff member designated by the health service who holds current certification as a competent POC operator by the First Nations Molecular PoC Testing Program for the test(s) performed; and
- (g) The items can only be claimed for a PoC test(s) that gives valid patient result(s) (i.e., not device errors)

## Other discussion

MSAC noted that the Department commissioned a report on the appropriateness, implementation and effectiveness of the Aboriginal and Torres Strait Islander COVID-19 Point-of-Care Testing Program, which was implemented in remote First Nations communities in 2020 to 2022 in response to the COVID-19 pandemic. The COVID-19 PoCT uses the same GeneXpert system that the PoCT for CT/NG and TV used in the clinical evidence presented for MSAC application 1627.1. Further, the COVID-19 PoC Testing Program was delivered by the Kirby Institute, who is also the applicant for MSAC application 1627.1. The findings showed that staff

training on PoCT was effective, the First Nation population is likely to use PoCT for STI and PoCT has the potential to avoid negative health outcomes and costs.

## 4. Background

MSAC application 1627 was initially considered by the MSAC Executive in October 2020. The MSAC Executive noted that the evidence presented indicated that the sensitivity and specificity of the PoC tests was comparable to standard laboratory testing and provided sufficient evidence to confirm the validity of using PoCT as a diagnostic test for CT, NG and TV. The MSAC Executive considered that if the applicant wished to pursue an MBS fee that is higher than the existing MBS standard laboratory testing fees, the applicant would need to provide evidence that PoCT results in better health outcomes than standard laboratory testing, and this evidence would need to be supported with an appropriate economic analysis.

The applicant subsequently submitted an Applicant Developed Assessment Report (ADAR) for consideration at the November 2022 MSAC meeting. After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC did not support funding PoCT for STIs provided by Aboriginal Medical Services or Aboriginal Community Controlled Health Services in rural and remote areas. MSAC recognised that there is a clinical need for the proposed testing due to a high prevalence of STIs and the serious consequences of untreated infections representing a significant public health issue for the proposed population. MSAC considered the evidence provided demonstrated that PoCT for STIs reduced the time from testing to treatment and that the clinical benefits associated with this were clinically plausible. However, based on the evidence provided, the magnitude of the benefit and impact on health outcomes was highly uncertain. As a result of this, and also due to the economic model being overly complex and unreliable, MSAC considered the cost-effectiveness of PoCT for STIs compared to standard laboratory testing to be highly uncertain. MSAC considered the proposed MBS fee was very high and the costings should be re-examined. MSAC considered that the fee was not sufficiently justified given the lack of objective data demonstrating improved health outcomes for patients. MSAC also considered the financial estimates to be uncertain and likely underestimated (see [MSAC 1627 Public Summary Document](#) [PSD]).

In July 2023, the applicant submitted a document responding to the MSAC 1627 PSD.

**Table 1 Summary of key matters of concern**

Component	Matter of concern	How the Applicant's response addresses it
Options for resubmission	<p>MSAC did not support public funding of PoCT for STIs (due to concerns listed in this table below).</p> <p>MSAC suggested options for resubmission:</p> <ul style="list-style-type: none"> <li>- targeting PoCT for STIs to people living in remote and very remote areas</li> <li>- alternative funding models to the MBS for services provided by Aboriginal Medical Services or Aboriginal Community Controlled Health Services in rural or remote areas.</li> </ul> <p>Alternatively, should a resubmission continue to pursue the proposed population considered in this application (i.e. MM categories 2 to 7) then the errors and significant concerns highlighted with the economic model would have to be fully addressed and the model would need to be re-specified (pg 7, MSAC 1627 PSD).</p>	<p>Responded to in point 2 and 7 of the applicant's response. Under point 2, in consultation with NACCHO, applicant has proposed limiting the PoCT to MM3-MM7 (rural and remote), but not to MM6-MM7. A rationale for this was provided (see pg 2, Applicant response). The applicant asserted that restriction to MM6-MM7 would lead to major inequities in areas where there is restricted access to centralised pathology services.</p> <p>Under point 7, the applicant provided a justification for why the applicant considers block-funding is not a sustainable funding solution.</p> <p>Partially addresses MSAC's concern – proposes refining the population to MM3-7 (instead of MM6-7 suggested by MSAC) and provides a justification.</p> <p>Response to revised economics below.</p>
Qualitative evidence on cultural perspectives or additional benefits of cultural importance of PoCT over standard laboratory testing.	<p>MSAC noted that whilst research and consultation outcomes presented spoke to the feasibility, safety and acceptability of PoCT in Aboriginal and Torres Strait Islander communities, cultural perspectives or additional benefits of cultural importance of PoCT over standard laboratory testing were not specifically presented. MSAC noted that patients with direct lived experience of the POC testing, communities, community organisations and the Indigenous PoCT Leaders Group referenced in the applicant's pre-MSAC response may be able to provide this lived experience expertise or community knowledge about important non-health benefits. MSAC agreed with ESC that presenting such additional qualitative evidence, including from community members who chose not to have the PoCT and those outside of the health sector, would have been informative (pg 3, MSAC 1627 PSD).</p>	<p>Responded to in point 8 of the applicant's response. Reiterated qualitative evidence that was presented in MSAC 1627 ADAR and briefly presented new unpublished research - a secondary analysis of data from the interviews with the 18 health care providers, who were PoC test operators, in rural and remote clinics.</p> <p>The applicant response claimed that this research showed how PoCT can overcome barriers to STI testing and follow up.</p> <p>This additional information does not appear to specifically address the evidence that MSAC suggested would have been beneficial (e.g., qualitative evidence from community members who chose not to have PoCT) but would likely be welcomed by MSAC.</p>



Component	Matter of concern	How the Applicant's response addresses it
Evidence to demonstrate PoCT improved health outcomes compared to standard laboratory testing	MSAC considered that it was clinically plausible that the reduced time from test to treatment with PoCT could lead to quicker resolution of infection which could reduce the chances of onward transmission and could reduce serious downstream sequelae. However, the evidence presented did not demonstrate that PoCT actually improve health outcomes beyond what standard laboratory testing could provide. Therefore, MSAC concluded that PoCT had noninferior clinical effectiveness compared to standard laboratory testing for chlamydia, gonorrhoea and trichomonas (pg 5, MSAC 1627 PSD).	Not addressed. No new clinical evidence presented. Application continues to be based on clinical evidence presented in MSAC 1627.
Cost-effectiveness of PoCT for STIs compared to standard laboratory testing was considered highly uncertain	<p>MSAC considered the cost-effectiveness of PoCT compared with standard laboratory testing was highly uncertain due to the uncertainty in the magnitude of benefit modelled, use of an overly complex microsimulation model without incorporating changes to reflect population behaviour changes over time, errors in the model along with the lack of transparency and inability to verify updates prior to MSAC (pg 5, MSAC 1627 PSD).</p> <p>The errors and significant concerns highlighted with the economic model would have to be fully addressed and the model would need to be re-specified. The resubmitted model should be based on the trial data and present a stepped analysis with the incremental cost per person tested. Any reduction in time to treatment and sequelae avoided and how these transform into QALYs should be clearly presented in accordance with the Technical Guidelines (pg 7, MSAC 1627 PSD).</p>	<p>Responded to in point 4 of the applicant's response. Incorporates the reduced cost of the test and updated the model to include re-testing of people with a positive result and annual infection risk based on mathematical models of CT and NG transmission in remote Aboriginal and Torres Strait Islander communities as recommended in the public summary document.</p> <p>The economic model is assumed to still rely on modelling health benefits, that MSAC considered may be plausible but were not demonstrated by the clinical evidence. MSAC previously noted this created high uncertainty in the ICER. As no new clinical evidence was provided, it is likely that this issue continues to create uncertainty in the ICERs.</p>
Proposed MBS fee was very high and not sufficiently justified.	<p>The proposed MBS fee was very high and the costings should be re-examined (pg 4, MSAC 1627 PSD).</p> <p>The fee was not sufficiently justified given the lack of objective data demonstrating improved health outcomes for patients (pg 6, MSAC 1627 PSD).</p>	<p>Responded to in point 3 of the applicant response. The total cost of the test kit and the staff time to conduct the test has been reduced and the total proposed fee \$106.45 each for CT/NG and TV tests; compared to previous proposed fee of \$150 and \$115 respectively.</p> <p>The applicant response has also proposed separating the MBS items for each test into a P9 pathology MBS service (for the cost of the test) and a miscellaneous MBS service item (cost of the staff time [Aboriginal Health Worker/Practitioner, nurses] to conduct the test).</p>

Component	Matter of concern	How the Applicant's response addresses it
Financial estimates were uncertain and likely underestimated	<p>MSAC considered that the estimates were likely to be underestimated. That is, the estimated number of people tested per year using PoCT would be higher if the estimates had been based on pre-COVID testing data.</p> <p>MSAC also queried whether the assumption of a maximum 300 tests/site per year also underestimates the likely utilisations of PoCT. MSAC noted the ADAR assumed that POC testing would substitute standard laboratory testing one-to-one (i.e., assumed that the overall number of people tested would not increase with PoCT) which MSAC considered is unlikely to be appropriate. MSAC considered it plausible that more people would be willing to undertake a test with same-day results (i.e., PoCT) than a test where results might not be available for up to 14 days (i.e., standard laboratory testing). MSAC also noted the financial estimates had costed the PoC test using 100% of the proposed MBS fee rather than applying the 85% rebate. MSAC also highlighted that the estimates did not include the cost of re-testing 3 months post treatment (per the clinical guidelines) and cost offsets for the downstream sequelae were based on 2016-17 costs, creating further uncertainty (potentially underestimating) the financial impact of listing PoCT on the MBS (pg 6, MSAC 1627 PSD).</p> <p>MSAC advised that the estimates around uptake of the testing and financial impact would need to be revised and clearly described in accordance with the approach taken in the resubmission with uptake based on extrapolation of pre-COVID testing rates (pg 7, MSAC 1627 PSD).</p>	<p>Responded to in point 5 and 6 of the applicant response. Revised financial analysis using post-COVID PoCT numbers as a new baseline (2022-2023).</p> <p>Average annual site testing numbers</p> <ul style="list-style-type: none"> <li>- May 2019 to April 2020 (pre-COVID) = 187 for CT/NG and 152 for TV (339 combined)</li> <li>- May 2022-April 2023 (post-COVID) = 99 for CT/NG and 71 TV (170 tests combined).</li> </ul> <p>The applicant expects recovery to pre-COVID levels over the subsequent 2-3 years. The estimates include re-testing at 3 months after a positive test.</p>

Source: compiled by the department based on MSAC 1627 PSD and applicant's response to MSAC 1627 PSD

Abbreviations: ADAR = Applicant Developed Assessment Report; CT = *Chlamydia trachomatis*; ICER = incremental cost-effectiveness ratio; MBS = Medicare Benefits Schedule; MSAC = Medical Services Advisory Committee; MM = Modified Monash category; NACCHO = National Aboriginal Community Controlled Health Organisation; NG = *Neisseria gonorrhoeae*; PoC = point of care; PoCT = point of care testing; PSD = Public Summary Document; TV = *Trichomonas vaginalis*

## 5. Prerequisites to implementation of any funding advice

Unchanged from MSAC 1627 PSD. Both the combined Xpert CT/NG PoC test and the Xpert TV PoC test are included on the Australian Register of Therapeutic Goods (ARTG; ARTG ID 207540 Cepheid GeneXpert (CT/NG) effective from 28/3/2013 and ARTG ID 290014 Cepheid GeneXpert (TV) from 9/6/2017).

A quality assurance program to support pathology testing is required. It is envisaged that the management of quality assurance for PoCT could be co-ordinated under a quality assurance program such as the Quality Assurance for Aboriginal and Torres Strait Islander Medical Services

(QAAMS) Program implemented by the Flinders University International Centre for Point of Care Testing (ICPOCT), which follows Australian guideline recommendations for PoCT.

The department noted the following PoCT STI Quality Assurance resources:

- An updated NPAAC Standard on Requirements for PoC came into effect on 1 January 2022. These guidelines - Requirements for point of care testing (Second Edition 2021) replaced the previous guidelines (Guidelines for Point of Care Testing (First Edition 2015).
- The Royal College of Pathologists Australia Quality Assurance Programs have developed a Molecular Sexually Transmitted Pathogens program and participants using PoCT devices such as the GeneXpert can enrol and use this QAP. It encompasses: Chlamydia trachomatis, Neisseria gonorrhoea, Trachomatis vaginalis, Mycoplasma genitalium including resistant strains and Herpes simplex virus.

## 6. Proposal for public funding

The applicant's response proposed three items. Two separate MBS items are proposed for the CT/NG (item XXX) and TV (item YYY) PoCT, which cover the cost of the test cartridge and transport. In addition, a 'miscellaneous' item is proposed for the purposes of a 'service fee' (item ZZZ), which covers staff time/costs for performing the test, who may not necessarily be a clinician (see Table 2).

The three items proposed in applicant's response are different to the proposed MBS items previously considered by MSAC in November 2022 (refer to Table 1 in [MSAC 1627 PSD](#)). The key differences are:

- The costs for the PoCT nucleic acid amplification techniques (NAAT) have been split out into two components:
  - Pathology P9 – simple basic pathology item(s) (item XXX for NG/CT and item YYY for TV) for the cost of the test cartridge and transport,
  - Miscellaneous MBS item accounting for 20 minutes staff time for the health worker to conduct the test (item ZZZ).
- The proposed price for PoCT testing has been reduced (total proposed fee \$106.45 each for CT/NG and TV tests); compared to previous proposed fee of \$150 and \$115, respectively; see Table 3.
- Limiting the PoCT to MM category 3 to MM category 7 (in clinics servicing rural and remote communities only) from MM category 2 to MM category 7 in the original submission.

**Table 2 New MBS items proposed by the applicant (two Group P9 – simple basic pathology tests and one miscellaneous) with Department update in strikethrough**

Category 6 –PATHOLOGY SERVICES–Simple Basic Pathology Tests
MBS [Item number XXX] <del>Microbiology</del> Detection of CT ( <i>Chlamydia trachomatis</i> ) and/or NG ( <i>Neisseria gonorrhoeae</i> ) via molecular point-of-care testing for the diagnosis of CT or NG infection. Fee: \$40.60 Benefit: 85% \$34.50(Item is subject to restrictions in rule PR.9.x of explanatory notes to this category)
Category 6 –PATHOLOGY SERVICES Group P9–Simple Basic Pathology Tests
MBS [Item number YYY] <del>Microbiology</del> Detection of TV ( <i>Trichomonas vaginalis</i> ) via molecular point-of-care testing for the diagnosis of TV infection. Fee: \$40.60 Benefit: 85% \$34.50(Item is subject to restrictions in rule PR.9.x of explanatory notes to this category)
Category 8 MISCELLANEOUS SERVICES Category T1 –Service to conduct a Molecular PoCT
MBS [Item number ZZZ]* SERVICE for operator to conduct a molecular point-of-care test Fee: \$65.85 Benefit: 85% = \$56.00.(See explanatory notes to this Category)
Explanatory notes - PR.9.x
Item numbers XXX and YYY can only be performed in the following circumstances:
<ul style="list-style-type: none"> <li>a) The service is rendered by or on behalf of a medical practitioner who has deemed the services is required; and</li> <li>b) The organisation for which the practitioner works, is enrolled in the First Nations Molecular PoC Testing Program – a formal training and quality management provider; and</li> <li>c) The organisation for which the practitioner works is located in a rural or remote setting (MM3-7) and predominantly provides services to Aboriginal and Torres Strait Islander peoples; and</li> <li>d) The service is conducted by a medical practitioner, nurse, Aboriginal health practitioner/worker or other staff member designated by the health service who holds current certification as a competent POC operator by the First Nations Molecular PoC Testing Program for the test(s) performed; and</li> <li>e) The items can only be claimed for a PoC test(s) that gives valid patient result(s) (i.e., not device errors)</li> </ul>

Source: Pg 8 of MSAC 1627.1 Applicant response (Resubmission)

\*The applicant response stated that each test is run separately to maintain test quality as such, the Miscellaneous service is required for each microbiology item (XXX and YYY)

**Table 3 Applicant proposed revised Fee/Benefit associated with the proposed new pathology items, and the comparison in cost (percentage reduction) between original submission (1) and resubmission (2).**

Pathology items		CT/NG (\$)	TV (\$)
<b>Microbiology service (test cost)</b>	Fee	40.60*	40.60
	85% Benefit	34.50	34.50
<b>Miscellaneous service (staff time cost to conduct test)</b>	Fee	65.85	65.85
	85% Benefit	56.00	56.00
Previous – <b>Total requested Fee/Benefit# for CT/NG + TV PoCT</b> (Submission 1 – MSAC ADAR 1627)	Fee	150.00	115.00
Proposed new - <b>Total requested Fee for CT/NG + TV PoCT</b> (Submission 2 – Applicant response to 1627 PSD) (% decrease in proposed fees)	Fee	106.45 (29.4%)	106.45 (7.9%)
	85% Benefit	90.50	90.50
<b>Difference between Submissions 1 and 2 (% decrease in Benefit) –</b> reflects both decrease in proposed fee and decrease from 100% benefit to 85% benefit.		59.50 (65%)	24.50 (27%)

Source: Table 2, pg 4 of MSAC 1627.1 Applicant response (Resubmission) with department clarification/corrections

\*Service agreements and software licencing fees have been removed and will be managed by the training and quality management program that will receive block funding. Costs for these items were only included in the original CT/NG costing and not TV.

# Applicant previously proposed 100% rebate hence fee and benefit were the same in MSAC 1627 ADAR

As per the applicant's response, the applicant intends that if a patient received both the CT/NG and TV PoCTs, then the miscellaneous item, which accounts for 20 minutes of staff time to perform the test, would be claimed twice (i.e., once for each test). The applicant claimed each test is run separately, one at a time, to maintain test quality. This implied that 40 minutes of staff time is required to perform the CT/NG and TV PoCTs.

Existing consultation items and block funding arrangements are generally used to cover the proposed miscellaneous service.

If MSAC considered the inclusion of miscellaneous service appropriate, the department noted preference for the proposed Item ZZZ to be claimed only once per episode, irrespective of whether one or both of Item XXX and YYY are claimed in that episode under a single item fee (i.e. without splitting the service into separate testing and collection/processing fees) (see Alternative 1 fee in Table 4).

Further, the department noted the applicant's proposed fee could potentially be significantly reduced by removing costs that are not appropriate to include in an MBS item fee (software, cartridge transport, etc) or likely already funded via other sources (e.g. training, QC, QA funded via QAAMS) - see Alternative 2 fee in Table 4, which removes costs for miscellaneous service and proposes a service fee plus the additional cost elements.

The Department also noted another option is for the fee for PoCT testing and laboratory-based STI testing to be the same (i.e., equivalent to MBS item 69317 or 69319 depending on whether or not PoCT CT/NG testing is combined with PoCT TV testing) – see Alternative 3 fee in Table 4.

For MSAC's reference, the initial fee proposed by the applicant and considered by the MSAC Executive in October 2020, was \$86.44 per CT/NG and TV MBS item (combined \$172.88).

**Table 4 Summary of applicant proposed fees and alternative fee options to reflect different cost elements for funding**

<b>Pathology items</b>	<b>CT/NG PoCT Fee (85% benefit)</b>	<b>TV PoCT Fee (85% benefit)</b>	<b>Combined CT/NG and TV Fee (85% benefit)</b>
<b>Applicant proposed fee – October 2020</b>	\$86.44	\$86.44	\$172.88
<b>Applicant proposed fee in MSAC 1627 ADAR – considered by MSAC Nov 2022</b>	\$150.00	\$115.00	\$265.00
<b>Applicant proposed fee in MSAC 1627.1 Applicant response (resubmission)</b>	\$106.45	\$106.45	\$212.90
<b>Alternative 1 – MSAC 1627.1 applicant proposed items &amp; fees but single miscellaneous service item claimed per patient episode</b> <ul style="list-style-type: none"> <li>Single PoCT (CT/NG or TV) cost = microbiology service item (\$40.60) plus single miscellaneous item (\$65.85) = \$106.45</li> <li>Combined CT/NG and TV PoCT = CT/NG microbiology (\$40.60) + TV microbiology (\$40.60) + single miscellaneous item (65.85) = \$147.05</li> </ul>	\$106.45 (\$90.50)	\$106.45 (\$90.50)	\$147.05 (\$125.00)
<b>Alternative 2 – fee equivalent to the service fee (MBS item 69319) + additional cost elements</b> <ul style="list-style-type: none"> <li>Single PoCT (CT/NG or TV) item = cost for 1 test cartridge (\$29.01) + professional service (\$42.95) = \$71.96 (rounded to \$72.00)</li> <li>Combined CT/NG and TV PoCT item = cost for 2 test cartridges (\$29.01 x2) + professional service (\$42.95) = \$100.97 (rounded to \$101.00)</li> </ul>	\$72.00 (\$61.20)	\$72.00 (\$61.20)	\$101.00 (\$85.85)
<b>Alternative 3 – fee equivalent to laboratory-based testing</b> <ul style="list-style-type: none"> <li>Single PoCT (CT/NG or TV) item = equivalent to MBS item 69317 (\$35.85)</li> <li>Combined CT/NG and TV PoCT item = equivalent to MBS item 69319 (\$42.95)</li> </ul>	\$35.85 (\$30.50)	\$35.85 (\$30.50)	\$42.95 (\$36.55)
<b>Applicant Pre-MSAC Alternative fee – MSAC 1627.1 applicant proposed items &amp; fees but 1.5x miscellaneous service item claimed per patient episode</b> <ul style="list-style-type: none"> <li>Single PoCT (CT/NG or TV) cost = microbiology service item (\$40.60) plus single miscellaneous item (\$65.85) = \$106.45</li> <li>Combined CT/NG and TV PoCT = CT/NG microbiology (\$40.60) + TV microbiology (\$40.60) + single miscellaneous item (1.5 x 65.85) = \$180.00</li> </ul>	\$106.45 (\$90.50)	\$106.45 (\$90.50)	\$180.00 (\$153.00)
<b>MSAC supported fee for combined CT/NG and TV PoCT</b> <ul style="list-style-type: none"> <li>Combined CT/NG and TV PoCT = professional service + cost for 2 test cartridges + transport</li> </ul>	-	-	117.65 (\$100)

## 7. Population

The population as proposed by the applicant includes symptomatic individuals, or asymptomatic individuals (including those who do not disclose symptoms), at risk of sexually transmitted infections, attending Aboriginal Medical Services (AMS) or Aboriginal Community Controlled Health Organisations (ACCHOs) in regional and remote areas (equivalent to MM categories 3 to 7) as defined by the Australian Bureau of Statistics (ABS)<sup>1</sup>.

- Location of population

A key issue is whether the population should be further restricted to people attending AMS or ACCHOs in very remote and rural areas of Australia, as defined by the Modified Monash Model<sup>2</sup> as areas 6 and 7 and suggested as a pragmatic population by MSAC as they are most likely to benefit from the proposed intervention. People in these areas would likely have to wait the longest to obtain standard laboratory test results, are very mobile and could be difficult to locate for the purposes of providing test results and conducting contact tracing. This population could potentially have the most difficulty in accessing services to treat any serious consequences of ongoing STIs (leading to worse health outcomes and increased health system costs).

The applicant's response, developed in consultation with NACCHO, have advocated for the population to consist of people in MM categories 3 to 7 (rural and remote areas). The applicant response asserted that restricting the population to MM categories 6 to 7 would lead to major inequities in areas where there is restricted access to centralised pathology services. For example, the applicant stated that the median aerial distance from clinics in MM categories 3-5 to a major city with laboratory capacity is 785.2km [IQR: 442.6km – 1079.9km], and in MM categories 6-7 clinics it is 876.3km [IQR: 606km – 1361km]).

Further, the applicant notes that the current STI PoCT program includes 62 clinics of which 6% were in MM category 2; 13% were in MM categories 3-5 and 81% were in MM categories 6-7. The applicant stated that restricting access to the rebate to those in MM6-7 will “undermine the substantial benefit being derived from existing STI PoCT in almost 1 in 5 clinics”. The applicant's proposed approach of including MM categories 3 – 5 in addition to MSAC's suggested MM categories 6 -7 would mean that 94% of existing clinics would be included. Additionally, Aboriginal and Torres Strait Islander peoples living in MM categories 3-5 experience socio-economic disadvantage, similar to those living in very remote areas and are a highly mobile population, with a third or more away from their community at any point in time (with those aged 20 – 34 the most mobile) – making follow up and treatment based on standard laboratory testing challenging for this population.

## 8. Comparator

Unchanged from MSAC 1627 PSD. The comparator is standard laboratory testing, which is the current standard of care (SOC). MBS items relevant to the comparator are shown in Table 5. Items 69316, 69317, 69319, and 69494 were added to the MBS on the 01 May 2007.

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<sup>1</sup> Australian Bureau of Statistics. Remoteness Structure Australian Statistical Geography Standard (ASGS) Edition 3. 20 July 2021. <https://www.abs.gov.au/statistics/standards/australian-statistical-geography-standard-asgs-edition-3/jul2021-jun2026/remoteness-structure> (accessed 1 December 2021).

<sup>2</sup> <https://www.health.gov.au/sites/default/files/documents/2020/07/modified-monash-model-fact-sheet.pdf>

**Table 5 MBS items claimed for the comparator service**

Category 6 – PATHOLOGY SERVICE
<p><b>69316</b>            Detection of <i>Chlamydia trachomatis</i> by any method - 1 test (Item is subject to rule 26) Fee: \$28.65 Benefit: 75% = \$21.50 85% = \$24.40</p>
<p><b>69317</b>            1 test described in item 69494 and a test described in 69316. (Item is subject to rule 26)            Fee: \$35.85 Benefit: 75% = \$26.90 85% = \$30.50</p>
<p><b>69319</b>            2 tests described in item 69494 and a test described in 69316. (Item is subject to rule 26)            Fee: \$42.95 Benefit: 75% = \$32.25 85% = \$36.55</p>
<p><b>69494</b>            Detection of a virus or microbial antigen or microbial nucleic acid (not elsewhere specified) 1 test            (Item is subject to rule 6 and 26)            Fee: \$28.65 <b>Benefit:</b> 75% = \$21.50 85% = \$24.40</p>
<p><b>73939</b>            Initiation of a patient episode by collection of a specimen for 1 or more services (other than those services described in items 73922, 73924 or 73926), if the specimen is collected by or on behalf of the treating practitioner and if:            () the service is performed in a prescribed laboratory or            () the person is a private patient in a recognised hospital            Fee: \$2.40 Benefit: 75% = \$1.80 85% = \$2.05</p>

Source: <http://www.mbsonline.gov.au/>

## 9. Summary of public consultation input

Unchanged from MSAC 1627 PSD.

## 10. Characteristics of the evidence base

Unchanged from MSAC 1627 PSD. MSAC previously noted that overall, there was relatively limited evidence for every component of the assessment report, except for test accuracy in detection of CT, NG and TV via PoCT in remote communities. For a summary of the key features of the evidence, which is unchanged from MSAC's previous consideration, please refer to Table 3, pg 12 of [MSAC 1627 PSD](#).

## 11. Comparative safety

Unchanged from MSAC 1627 PSD. As the same samples need to be taken for all NAAT tests, there are no additional safety concerns with PoC NAAT testing compared with standard laboratory NAAT testing.

## 12. Comparative effectiveness

Unchanged from the previous MSAC consideration (Refer to Section 12 of [MSAC 1627 PSD](#)). No new evidence regarding clinical effectiveness was presented in the applicant's response. However, the department noted that, while no longer-term evidence regarding change in management or impact on patient outcomes has been provided in the applicant's response, it is



unlikely that this will become available in the near future due to the length of studies that would be required.

The applicant's response did present some new unpublished qualitative research based on a secondary analysis of data from the interviews with 18 health care providers, who were PoC test operators, in rural and remote clinics (previously published by Lafferty et al. 2021<sup>3</sup>). The applicant stated the unpublished analysis found that PoCT can address some of the barriers to STI testing and follow-up by offering the PoCT opportunistically (when attending for other reasons), using language to normalise the experience, and discussing a confidential way to provide results to the patients when their results are available in 1-2 hours (rather than weeks), so others in their small community don't know the reason for their attendance at the clinic. Language used by healthcare providers to communicate follow up, and reconnecting in community later in the day, was viewed as a critical component to effective timely response afforded by PoC diagnostics.

The department noted that while this additional information would likely be welcomed by MSAC, this evidence does not appear to specifically address the evidence that MSAC suggested would have been beneficial (e.g., qualitative evidence from community members who chose not to have PoCT).

### 13. Economic evaluation

The applicant's response presented a revised economic analysis using the same economic model previously presented to MSAC with the following changes:

- Revised the target population to people attending clinics located in MM3-7 areas and justified retaining MM3-5 based on higher STI rates, large distance to laboratories, social disadvantage, and mobility.
- Reduced the test cost, specifically the Miscellaneous service item component (staff time to conduct the test).
- Included re-testing of people with a positive result and annual infection risk based on mathematical models of CT and NG transmission in remote Aboriginal and Torres Strait Islander communities.

The applicant's response stated that, based on these revisions and using a revised benefit of \$181 (Microbiology and Miscellaneous Service items), this produced an ICER of \$7,583 (see Table 6). For comparison, results previously considered by MSAC at the November 2022 meeting are also summarised in Table 6. In addition, the applicant response conducted 12 simulations of 25,000 iterations, which reported the ICER ranged between \$3,823-\$10,958 (Figure 1).

The department noted that the applicant used the 85% benefit (\$181) rather than the proposed fee (total \$211.90) in the economic analysis and that due to the complexity of the model, the amended model inputs and ICER reported would need to be verified by an assessment group. However, the department also noted that the model still relies on modelling health benefits that MSAC considered may be plausible but have not been demonstrated by the clinical evidence. MSAC previously noted this created high uncertainty in the ICER. As no new clinical evidence was provided, this issue would continue to create high uncertainty in the ICER. Therefore, even if the validation was undertaken, the revised ICER presented by the applicant is unlikely to be useful for decision making due to the continued high uncertainty.

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<sup>3</sup> Lafferty L, Smith K, Causer L, et al. (2021) Scaling up sexually transmissible infections point-of-care testing in remote Aboriginal and Torres Strait Islander communities: healthcare workers' perceptions of the barriers and facilitators. *Implement Sci Commun* 2(1):127. doi: 10.1186/s43058-021-00232-8 [published Online First: 2021/11/09]

**Table 6 Applicant's revised base case results over ten years and previous ICERS considered by MSAC**

	PoC	SOC	Increment
<b>Applicant's revised base case results over ten years</b>			
Cost	\$5,503	\$5,338	\$164
QALYs	7.93	7.91	0.02
<b>ICER</b>			<b>\$7,583</b>
<b>Previous ICERs considered by MSAC at November 2022 meeting</b>			
<b>1627 ADAR base case [10,000 trials; seed 1]</b>			
Cost	\$3,763.55	\$3,516.70	\$246.85
QALYs	8.4654	8.4581	0.0073
<b>ICER</b>			<b>\$34,010</b>
<b>1627 ADAR base case with corrections [10,000 trials; seed 1]<sup>a</sup></b>			
Cost	\$4,256.06	\$4,068.06	\$188.00
QALYs	7.9595	7.9496	0.0100
<b>ICER</b>			<b>\$18,876</b>
<b>1627 Adjusted for single episode of testing [10,000 trials; seed 1]<sup>b</sup></b>			
Cost	\$514.83	\$460.21	\$54.62
QALYs	8.0445	8.0435	0.0010
<b>ICER</b>			<b>\$55,084</b>
<b>1627 Expected cohort value (Commentary revised base case)</b>			
Cost	\$569.08	\$541.23	\$27.86
QALYs	8.0454	8.0440	0.0014
<b>ICER</b>			<b>\$20,453</b>
<b>1627 Excluding indirect health care costs (Commentary alternate scenario)</b>			
Cost	\$396.29	\$324.04	\$72.26
QALYs	8.0454	8.0440	0.0014
<b>ICER</b>			<b>\$53,049</b>
<b>Pre-ESC response</b>			
Cost	\$4,590.27	\$4,218.42	\$371.85
QALYs	8.29	8.28	0.01
<b>ICER</b>			<b>\$37,185</b>
<b>1627 Pre-MSAC response</b>			
Cost	\$5,352	\$4,754	\$598
QALYs	8.292	8.274	0.018
<b>ICER</b>			<b>\$33,287</b>

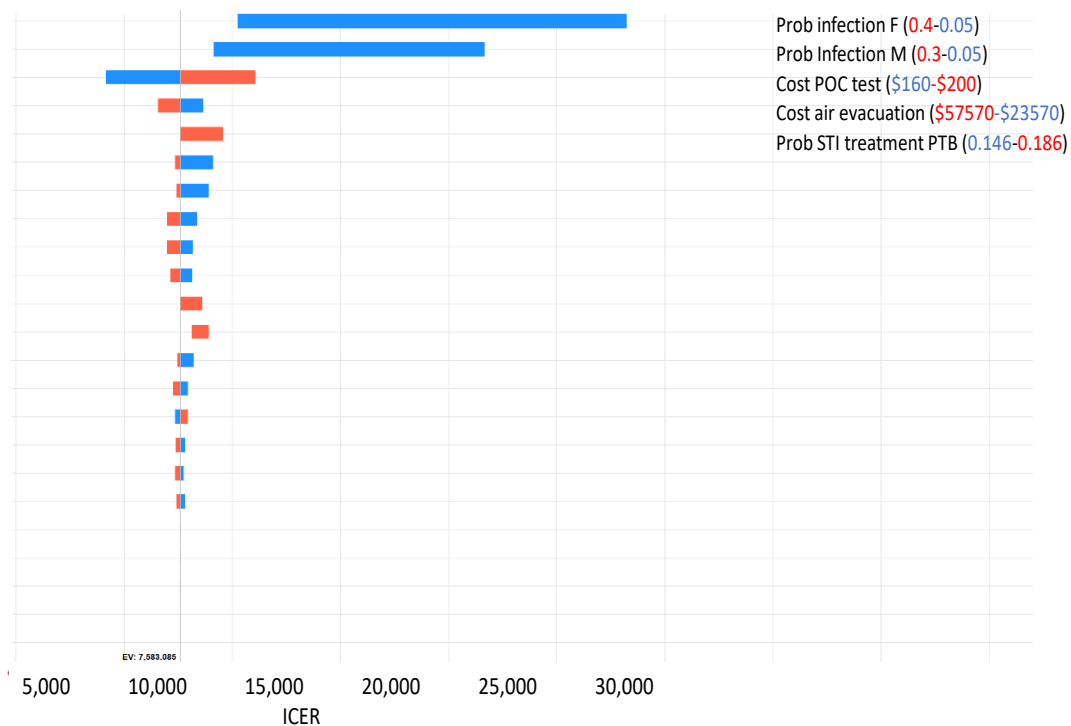
Source: Table 4, pg 9 of MSAC 1627.1 Applicant response (Resubmission); Table 11, pg24 of MSAC 1627 PSD, 1627 Applicant Pre-ESC response, 1627 Applicant Pre-MSAC response

ICER = incremental cost-effectiveness ratio; PoC = point of care; QALY = quality-adjusted life year; SOC = standard of care.

<sup>a</sup> This was corrected by the commentary, during the previous consideration of MSAC 1627, to account for errors identified through a model validation exercise that applied no discounting set with no utility decrements applied which observed >10 LYs being accrued. Other changes were made to correct for other inconsistencies identified during the evaluation (erroneous jump states or probabilities applied).

<sup>b</sup> No infections or testing in subsequent years. The probability of infertility and ectopic pregnancies was also increased to reflect the average incidence, rather than incidences by number of prior PID episodes.

**Figure 1 One way sensitivity analysis**



Source: Figure 2, pg 9 of MSAC 1627.1 Applicant response (Resubmission)

## 14. Financial/budgetary impacts

The applicant's response presented revised financial estimates (Table 8), based on the same market-based approach presented to MSAC in November 2022 with the following revisions:

- Applied May 2022 – April 2023 PoCT rates (99 CT/NG tests and 71 TV tests = 170 combined tests per site) as the baseline, assuming recovery to pre-COVID May 2019 – April 2020 testing rates (187 CT/NG tests and 152 TV tests = 339 tests per site) over the subsequent 2-3 years.
- Limiting PoCT to MM categories 3-7 (previously MM categories 2-7).
- Assumed 20% increase in the number of tests per site annually from 170 tests per site in Year 1 to 508 tests per site in Year 6 (previously 170 – 300 tests per site).
- Assume 15% increase in the number of sites that offer PoCT (previously 10%)
- Applied 85% MBS benefit (previously applied 100% MBS benefit) which equated to \$181 (refer to Table 3 discussed previously in Section 4).

The applicant response also clarified that the previous estimates and the revised estimates include retesting patients at 3 months.

The department noted the following issues:

- The baseline testing numbers used for scale-up in the financial analysis were based on post-COVID testing rates.

The applicant response stated that the average annual site testing numbers for CT/NG PoC tests in May 2019 to April 2020 (pre-COVID) was 187 for CT/NG and 152 for TV (339 combined). This is higher than the May 2022-April 2023 (post-COVID) average annual site testing numbers, which was 99 for CT/NG and 71 for TV (170 tests combined).

However, the department also noted that the way the annual testing numbers had been combined and costed in the financial analysis resulted in 340 tests being costed per site (170 CT/NG tests and 170 TV tests), which is higher than the 2022-2023 test numbers. As shown in Table 7, the estimated number of tests per site in Year 1 in the financial analysis appears to be similar to pre-COVID testing numbers.

**Table 7 Comparison of actual and estimated annual site testing numbers**

	2022-2023 Annual site testing numbers (post-COVID)	2019-2020 Annual site testing numbers (pre-COVID)	Costed Year 1 Annual site testing numbers in the financial analysis <sup>a</sup>
CT/NG tests	99	187	170
TV tests	71	152	170
Total	170*	339*	340 <sup>#</sup>

Source: compiled by the department based on Table 5 and 6 of MSAC 1627.1 Applicant response (Resubmission)

\* This is based on applicant adding the number of CT/NG and TV tests together.

# The financial estimate costed 170 CT/NG plus 170 TV PoCT per site to give 340 total tests per site – not to be mis-interpreted as costing 340 combined tests (i.e., 340 patients receiving both CT/NG and TV PoCT which would equate to 680 tests).

a Based on back-calculation of values in Table 9 (i.e., Estimated cost for CT/NG or TV tests / number of tests = tests per site)

- The financial analysis assumes a 1:1 substitution of standard laboratory STI testing when estimating the cost offsets from reduced use of standard laboratory STI testing.

The 1:1 substitution implies that each of the patients estimated to receive a PoCT test would have received a standard laboratory STI test in the absence of PoCT availability, which does not account for the potential that there may be patients who are not currently taking up standard laboratory STI testing (due to the barriers raised by the applicant) but who may utilise PoCT if funded. The department also notes that as additional laboratory testing would be required to determine the antibiotic sensitivity of the causative organism, there is the potential for PoCT testing to be performed in addition to standard laboratory testing. This has not been accounted for in the financial analysis.

- A minor change to the costing of the comparator - standard laboratory STI testing.

The applicant’s updated financial estimates have applied the 85% rebate (\$6.80) for MBS item 73938 for initiation of the patient episode when costing the comparator. Previously, MBS item 73939 (\$2.05 at 85% rebate) was used. The department notes MBS item 73938 would be appropriate for a private patient whereas MBS 73939 would be more appropriate for a public patient. PoCT for STIs is proposed for patients attending AMS and/or ACCHOs. The applicant has not justified why this change has been made and/or is more appropriate. However, the consequence of this change is minor. That is, reversing this change would increase the net cost to the MBS by ~3% to \$ \$2,382,067 in Year 1 and to \$11,782,406 in Year 6.

The department conducted additional sensitivity analyses using alternative fee 1 and 2 from Table 4.

- Alternative fee 1 - MSAC 1627.1 proposed items & fees but single miscellaneous service item claimed per patient episode.

As noted earlier, the applicant’s proposal is for the miscellaneous service item to be claimed twice if a patient received both the CT/NG and TV PoCTs, equating to 40min of staff time to perform the two PoC tests. Revising the financial analysis so that the miscellaneous service fee is only claimed once per episode for combined CT/NG and TV PoCT reduced the total cost to the MBS for the proposed PoCT from \$3,027,768 to \$2,091,000 in Year 1 and from \$14,976,233 to \$10,342,702 in Year 6 (as shown in Table 8).

- *Alternative fee 2 – PoCT fee equivalent to the service fee (MBS item 69319) + additional cost elements*

Alternative fee 2 proposed by the department provides for both single PoCT (CT/NG or TV) and combined CT/NG and TV PoCT items with a fee of \$64.85 and \$86.75, respectively. The 85% benefit would be \$55.10 for single PoCT (CT/NG or TV) and \$73.75 for combined CT/NG and TV PoCT. Revising the financial analysis to apply the 85% benefit (\$73.75) for the Alternative 2 - combined CT/NG and TV PoCT reduced the total cost to the MBS for the proposed PoCT from \$3,027,768 to \$1,233,690 in Year 1 and from \$14,976,233 to \$6,102,194 in Year 6 (as shown in Table 8).

**Table 8 Annual (2023 – 2029) cost implications for PoC tests for CT/NG and TV to the MBS, including estimated 5-year budget cycle cost (2025 -2028).**

	2023	2024 (yr1)	2025 (yr2)	2026 (yr3)	2027 (yr4)	2028 (yr5)	2029 (yr6)	Cost over 5 yrs (2024-2028)*
<b>Number of sites</b> (15% increase per year)	62	82	94	108	124	142	163	
<b>Number of tests per site</b> (20% increase per year)	170	204	245	294	353	423	508	
Total number of tests	10,540	16,728	23,011	31,726	43,711	60,068	82,742	
Cost for PoCT CT/NG microbiology item <sup>a</sup>	\$363,630	\$577,116	\$793,886	\$1,094,550	1,508,046	\$2,072,348	\$2,854,586	\$6,045,946
Cost for PoCT CT/NG miscellaneous item <sup>a</sup>	\$590,240	\$936,768	\$1,288,627	\$1,776,660	2,447,843	\$3,363,811	\$4,633,531	\$9,813,710
Cost for PoCT TV microbiology item <sup>b</sup>	\$363,630	\$577,116	\$793,886	\$1,094,550	1,508,046	\$2,072,348	\$2,854,586	\$6,045,946
Cost for PoCT TV miscellaneous item <sup>b</sup>	\$590,240	\$936,768	\$1,288,627	\$1,776,660	2,447,843	\$3,363,811	\$4,633,531	\$9,813,710
<b>Total cost MBS proposed PoC tests</b>	<b>\$1,907,740</b>	<b>\$3,027,768</b>	<b>\$4,165,027</b>	<b>\$5,742,420</b>	<b>7,911,779</b>	<b>\$10,872,316</b>	<b>\$14,976,233</b>	<b>\$31,719,311</b>
Reduction in use of standard tests	10,540	16,728	23,011	31,726	43,711	60,068	82,742	
Reduction in cost to MBS for CT/NG/TV and Episode fee	\$456,909	\$725,159	\$997,536	\$1,375,326	1,894,893	\$2,603,950	\$3,586,849	\$7,596,864
<b>Net cost to MBS related to change in testing</b>	<b>\$1,450,831</b>	<b>\$2,302,609</b>	<b>\$3,167,492</b>	<b>\$4,367,095</b>	<b>\$6,016,886</b>	<b>\$8,268,366</b>	<b>\$11,389,384</b>	<b>\$24,122,448</b>
<b>Applicant Sensitivity analyses</b>								
<b>Change in cost to MBS if 10% increase in patients tested per site per year (base case: 20% increase)</b>								
Number of tests per site	170	187	206	226	249	274	301	
Total number of tests	10540	15334	19336	24437	30863	38878	49090	
Net cost if 10% increase in testing per year	\$1,450,831	\$2,110,725	\$2,661,573	\$3,363,775	\$4,248,323	\$5,351,517	\$6,757,232	\$17,735,913
<b>Net cost to MBS if 30% increase to patients tested per site per year (base case: 20% increase)</b>								
Number of tests per site	170	221	287	373	486	631	821	
Total number of tests	10540	18122	27006	40337	60207	89630	133751	
Net cost if 30% increase in testing per year	\$1,450,831	\$2,494,493	\$3,717,403	\$5,552,377	\$8,287,437	\$12,337,587	\$18,410,808	\$32,389,297
<b>Department Sensitivity Analysis</b>								
<b>Alternative 1 fee in Table 4 – Single 20min miscellaneous service item claimed for combined CT/NG and TV PoCT</b>								
Total number of tests	10,540	16,728	23,011	31,726	43,711	60,068	82,742	

Total cost MBS proposed PoC tests <sup>d</sup>	\$1,317,500	\$2,091,000	\$2,876,400	\$3,965,760	\$5,463,936	\$7,508,506	\$10,342,702	
Net cost to MBS related to change in testing	\$860,591	\$1,365,841	\$1,878,864	\$2,590,434	\$3,569,043	\$4,904,556	\$6,755,853	\$14,308,739
<b>Alternative 2 fee in Table 4 - Fee equivalent to the professional service fee + test cartridges</b>								
Total number of tests	10,540	16,728	23,011	31,726	43,711	60,068	82,742	
Total cost MBS proposed PoC tests <sup>e</sup>	\$904,859	\$1,436,099	\$1,975,512	\$2,723,684	\$3,752,631	\$5,156,842	\$7,103,368	
Net cost to MBS related to change in testing	\$447,950	\$710,940	\$977,976	\$1,348,358	\$1,857,738	\$2,552,892	\$3,516,519	\$7,447,905
<b>Applicant Pre-MSAC Alternative fee in Table 4 – 1.5 miscellaneous service item claimed for combined CT/NG and TV PoCT</b>								
Total number of tests	10,540	16,728	23,011	31,726	43,711	60,068	82,742	
Total cost MBS proposed PoC tests <sup>e</sup>	\$1,612,620	\$2,559,384	\$3,520,714	\$4,854,090	\$6,687,858	\$9,190,411	\$12,659,467	
Net cost to MBS related to change in testing	\$1,155,711	\$1,834,225	\$2,523,178	\$3,478,765	\$4,792,965	\$6,586,461	\$9,072,618	\$19,215,594

a Proposed Benefit for pathology Microbiology Service for CT/NG PoC test \$34.50 (Fee \$40.60), and Miscellaneous Service - for staff time conducting CT/NG PoC test \$56.00 (Fee \$65.85); Total Benefit for CT/NG PoC testing = \$90.50

b Proposed Benefit for pathology Microbiology Service for TV PoC test \$34.50 (Fee \$40.60), and Miscellaneous Service - for staff time conducting TV PoC test \$56.00 (Fee \$65.85); Total Benefit for TV PoC testing = \$90.50

c Benefit for laboratory test pathology service - MBS item 69319 (3 tests including test for chlamydia) and Item 73938- Episode fee for one or more services Combined Total Benefit \$43.35

d Sensitivity analysis uses 85% Benefit from Alternative 1 scenario in Table 4 – total combined 85% Benefit (\$125) for combined CT/NG, TV and single miscellaneous service item

e Sensitivity analysis uses 85% Benefit from Alternative 2 scenario in Table 4 – total combined 85% Benefit (\$73.75) for combined CT/NG, TV and single miscellaneous service item

\*5-year budget calculated from 2024 -2028, which aligns with a presumed availability of the approved items in 2024. An additional 6<sup>th</sup> year (2029) is provided [in the applicant response] but is not part of the 5-year budget estimate.

Note from the applicant response: The government will still be required to provide block funding to the First Nations Molecular Testing Program to conduct training, quality management and connectivity, consistent with national PoC testing guidelines, and the amount of funding provided to this Program provided will limit the total number of services able to conduct STI molecular PoCT.

## **15. Other relevant information**

Nil.

## **16. Applicant comments on MSAC's Public Summary Document**

The approval of the proposed rebate for STI POC testing is important, as it addresses a major inequity in health care access to timely diagnostics for infectious diseases in remote Aboriginal communities. The inclusion of funding to support the services to conduct the testing is also well received as it recognises this activity needs to be reimbursed like other clinical activities which have existing Medicare rebates. However, notably the amount provided accounts for less than half of the time required to conduct the testing and thus will not sufficiently cover the complete service. While a rebate supported for remote and very remote areas (MM6-7) will have significant benefits, the decision to not support regional areas (MM3-5) is a missed opportunity to lessen health inequity. The majority of Aboriginal and Torres Strait Islander peoples (43.8%) reside in regional areas, where notification rates for chlamydia and gonorrhoea are three and ten times higher in comparison to the non-Indigenous population, respectively, and regional clinical services are also significant distances away from centralised laboratory. The applicant notes that the basis for not funding the complete service and not approving the broader geographical scope was because MSAC considered there was insufficient clinical evidence to support the health economic evaluation. However, we provided the best available synthesized evidence from over 30 studies across the world (including data among Aboriginal women in Australia) which had already demonstrated the association between STIs and sequelae such as pelvic inflammatory disease. This evidence forms the basis of Australia clinical guidelines and the National STI Strategy, thus deemed sufficient. We also provided RCT and programmatic evidence from regional and remote Aboriginal communities, which showed STI POC testing significantly improved the uptake and timeliness of treatment, and in turn rapid cure from infection. Timely treatment and cure from STIs will reduce the risk of pelvic inflammatory disease and other reproductive morbidity, as well as onward transmission to sexual partners.

## **17. Further information on MSAC**

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)