MSAC application 1747 – Permanent Medicare Benefits Schedule (MBS) items for COVID-19 nucleic acid testing

There are three permanent MBS items for detection of a virus or microbial antigen or microbial nucleic acid that do not specifically include testing for SARS-CoV-2. Five temporary MBS items for laboratory-based SARS-CoV-2 nucleic acid testing were implemented in October 2022. The temporary MBS items will cease on 31 December 2023. In the absence of a decision of Government to embed new, permanent items in the MBS; the testing for SARS-CoV-2 will revert to the existing, permanent generic nucleic acid amplification test (NAAT) MBS item 69494 and combined testing for SARS-CoV-2 and other respiratory pathogens claimed under MBS items 69495 and 69496.

The Government has asked the Minister for Health and Aged Care to seek the Medical Services Advisory Committee (MSAC)'s advice on the appropriate use and public funding of laboratory-based testing for SARS-CoV-2 nucleic acids, including the use and utility of multiplex testing for SARS-CoV-2 and other respiratory pathogens, publicly funded under the MBS. The Department of Health and Aged Care has therefore requested advice from MSAC on permanent MBS items for COVID-19 nucleic acid testing. This assessment is to inform MSAC's consideration and advice to the Minister.

Table 1 Parameters for assessing permanent MBS items for COVID-19 testing

Component	Description
Population	Individuals who require testing for the diagnosis of SARS-CoV-2 and/or other respiratory viral illness - split into testing performed in outpatient settings and inpatient settings. The assessment should examine the clinical place of singleplex and multiplex SARS-CoV-2 testing, including differences by clinical setting (e.g., test sequencing in primary care versus admitted hospital patient, and test purpose in confirming or refuting a diagnosis of SARS-CoV-2 and/or other respiratory viral infections) and in the context of other respiratory viral testing.
Intervention	Permanent MBS items for testing for SARS-CoV-2 and/or other respiratory virus nucleic acids (any method, though recognising advice from laboratory providers indicates that current testing in Australia uses polymerase chain reaction (PCR) methods). The proposed permanent items could use the same structure and item descriptors as the temporary SARS-CoV-2 test MBS items (full schedule fees, laboratory-based): 69511 one test $68.85 69512 two to four tests $74.75 69513 five to eight tests $80.65 69514 nine to twelve tests $86.55 69515 thirteen or more tests $92.45 *See Appendix A for MBS item descriptors.* Noting that the current temporary MBS items for the detection of SARS-CoV-2 include a fee differential between public and private pathology providers to align with the fifty-fifty cost-sharing agreements between the Commonwealth and states and territories. The assessment is to use the fees for private providers. The assessment is to include justification for the proposed cost of testing. This should include more granular cost inputs if possible, as well as comparing the fees sought against those from current and recent MSAC assessments relevant to pathogen molecular testing (e.g. 1627 and 1646), and existing similar MBS items. Rapid PCR testing of nucleic acids (e.g. Cepheid GeneXpert®) conducted in an accredited pathology laboratory is also to be assessed (scope of platform tests, fees and turnaround time to be included). Compare the available technologies (e.g. GeneXpert®) and service delivery models for singleplex and multiplex laboratory-based PCR testing, and their associated costs and turnaround times.

Component	Description
Comparator	SARS-CoV-2 testing if the temporary items cease on 31 December 2023; i.e., testing for suspected SARS-CoV-2, and/or other respiratory viral pathogens using the generic permanent MBS items for nucleic acid testing (full schedule fees): 69494 – one test $28.65 69495 – two tests $35.85 69496 – three or more tests $43.05 *See Appendix B for MBS item descriptors.* The intervention is proposed to be listed on the MBS in addition to (rather than replacing) these permanent MBS items.
Reference standard	Assessing the comparative analytical validity of different SARS-CoV-2 testing strategies comprised of the same tests is not required. The assessment of the effectiveness of the intervention should include the analytical validity of the in-scope test methods (e.g. sensitivity, specificity, false positive rate, false negative rate, positive predictive value, negative predictive value). For this comparison the reference standard is laboratory-based PCR testing.
Outcomes	The assessment should examine outcomes that could potentially differ between the intervention and comparator. This includes at least: • Diagnostic yield of SARS-CoV-2 testing and other relevant viruses, including in different settings with varying incidence, and according to testing strategy • Test turnaround time • Analytical validity of the in-scope test methods • Any changes in management following a positive SARS-CoV-2 result that may differ between the intervention and comparator, including in different settings • Cost of testing strategy and test sequence
Economic evaluation	Cost consequences analysis (CCA)
Utilisation & financial implications	• Review patterns of utilisation of the current respiratory viral testing MBS items. • Estimate the utilisation of permanent MBS items, including the proportions of singleplex versus multiple testing, and across different clinical settings. • Estimate the resulting financial impact, including for both singleplex and multiplex testing. Based on the utilisation of current permanent test items and the temporary SARS-CoV-2 items compare the total cost of single and multiplex tests for a standardised population: (i) for inpatient and outpatient tests combined and (ii) separated according to inpatient and outpatient-based testing. Consider the proposed fee structure for SARS-CoV-2 testing with other MBS-reimbursed respiratory viral tests.
Other relevant considerations	There may be a personal and/or public health benefit from e.g. patient cohorting and/or quarantining based on SARS-CoV-2 test results – where this could differ between the intervention and comparator, the evidence should be examined.

Appendix A: Item descriptors for the intervention – current temporary items 69511-69515

Category 6 – Pathology Services
Group P3 - Microbiology
69511 Detection of SARS-CoV-2 nucleic acid if: a. the person is a private patient in a hospital other than a recognised hospital; or b. the person receives a bulk-billed service not covered by item 69506 MBS Fee: $68.85 Benefit: 75% = $51.65 85% = $58.55
69512 Detection of a viral, fungal, atypical pneumonia pathogen or Bordetella species nucleic acid from a nasal swab, throat swab, nasopharyngeal aspirate and/or lower respiratory tract sample, and a service described in 69511, if: a. the person is a private patient in a hospital other than a recognised hospital; or b. the person receives a bulk-billed service not covered by item 69507 2 to 4 tests MBS Fee: $74.75 Benefit: 75% = $56.10 85% = $63.55
69513 5 to 8 tests described in 69512. MBS Fee: $80.65 Benefit: 75% = $60.50 85% = $68.60
69514 9 to 12 tests described in 69512. MBS Fee: $86.55 Benefit: 75% = $64.95 85% = $73.60
69515 13 or more tests described in 69512. MBS Fee: $92.45 Benefit: 75% = $69.35 85% = $78.60

Appendix B: Item descriptors for the comparator – current permanent generic nucleic acid amplification test (NAAT) items 69494-69496

Category 6 – Pathology Services
Group P3 - Microbiology
69494 Detection of a virus or microbial antigen or microbial nucleic acid (not elsewhere specified). 1 test MBS Fee: $28.65 Benefit: 75% = $21.50 85% = $24.40
69495 2 tests described in 69494 MBS fee: $35.85 Benefit: 75% = $26.90 85% = $30.50
69496 3 or more tests described in 69494 MBS Fee: $43.05 Benefit: 75% = $32.30 85% = $36.60