

# New Pathology MBS items for Cervical and Vaginal Tests

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From 1 December 2017, a new Cervical Screening Test every five years will replace the existing two yearly Pap test.

To align pathology MBS items for cervical screening will change from December 1 2017. This will have practical implications for healthcare providers, clinicians, and consumers alike.

## What do the changes involve?

There will be new pathology MBS items for cervical and vaginal screening tests, to reflect changes to the National Cervical Screening Program (NCSP), aligning with clinical best practice. The previously used MBS cervical screening items will be deleted.

Pap tests will no longer be eligible for Medicare rebates, meaning that patients may be charged if this test is requested.

Pathology laboratories will assign the pathology MBS item number based on the information provided on the pathology request form.

There are new naming conventions to write on the pathology request forms these are in the last column of the Pathology Test Guide for Cervical and Vaginal Testing.

You may also need to include some additional information that supports the screening or test type written on the pathology request form this may include age, presentation and clinical history.

Appropriate assignment of pathology MBS numbers by pathology labs is important in ensuring that patients avoid unnecessary out-of-pocket expenses for testing. It also enables laboratories to provide the correct clinical management recommendations, and accurate and timely reports on testing rates. This will in turn support the ongoing monitoring and evaluation of the new NCSP

Healthcare providers will still perform a vaginal speculum examination and take a cervical sample, but the sample medium is liquid-based and will be tested for the presence of HPV. If HPV is detected the laboratory will automatically conduct a cytology test.

## Why is the Government making this change?

The new Cervical Screening Test is expected to protect up to 30% more people from cervical cancer.

The new test is more effective because it detects the human papillomavirus (HPV). Human papillomavirus, also known as HPV, is a common virus that can cause cervical cell abnormalities that in rare cases may develop into cervical cancer.

The new Cervical Screening Test and pathway is a risk-based approach to the management of patients. Patients are managed according to their risk of developing cervical abnormalities



and that is determined by their Cervical Screening Test result, namely the HPV result and reflex liquid based cytology (LBC) if indicated.

The Medicare Benefits Schedule (MBS) items for cervical and vaginal pathology testing for cervical pre-cancer and cancer have been updated to support the revised clinical management pathway and renewed National Cervical Screening Program (NCSP). There will be seven new MBS item numbers, and the currently used item numbers will be deleted.

The new Cervical Screening Test and pathway will better identify patients at risk of precancerous abnormalities and cervical cancer.

## What are the changes?

There are several major changes to cervical screening practice in the renewed NCSP.

Five-yearly routine Cervical Screening Tests (CSTs) are recommended for asymptomatic patients from 25 up to 74 years of age, with a previously normal screening history. Where HPV is not detected, patients aged 70–74 years are eligible to exit the program.

Testing methodology and pathology MBS item numbers have changed. This means that pathology request forms need to be filled in differently from previously, and it is important that the appropriate test name and supporting patient information is written on the request form.

The renewed NCSP will be supported by the new National Cancer Screening Register (NCSR), and there are new 'opt out' procedures for patients.

Self -collection will not be immediately offered with the renewed program on 1 December 2017.

## What do screening providers need to do?

Healthcare service providers need to become familiar with the changes to the NCSP, and how these changes will affect their patients and practice.

For the pathology laboratory to correctly test your patient's sample you need to provide the patient's presentation, age and screening history on the pathology request form, as detailed in the Pathology Tests for Cervical and Vaginal Testing Quick Guide.

Self-collection will be available to encourage women who are under screened or never screened and have refused to have a healthcare provider collected sample. Women must be 30 years of age or older and overdue for cervical screening by two years or more to be eligible for an MBS funded test. A self-collect sample contains vaginal cells only (not cells from the cervix) and can be tested for HPV only.

Self-collection will not be offered with the renewal program on 1 December 2017 but it is expected that it will be offered later in 2018. More information about self-collection will be available when it becomes available at www.cancerscreening.gov.au/cervical

The Australian Government Department of Health's National Cervical Screening Program website has a range of practical resources for clinicians and consumers regarding the new NCSP and should be consulted for further information about screening, follow-up and clinical management for cervical cancers and pre-cancerous abnormalities.



## Change to item description / fees:

Following a period of extensive stakeholder consultation, the Department is pleased to provide the National Cervical Screening Program Renewal MBS item descriptors, associated fees and explanatory statement, which will come into effect from 1 December, 2017.

Item	Item descriptor
73070	A test, including partial genotyping, for oncogenic human papillomavirus that may be associated with cervical pre-cancer or cancer:
	performed on a liquid based cervical specimen; and
	for an asymptomatic patient who is at least 24 years and 9 months of age
	For any particular patient, once only in a 57 month period
	Fee: \$35.00 75%= \$26.25 85%= \$29.75
73071	A test, including partial genotyping, for oncogenic human papillomavirus that may be associated with cervical pre cancer or cancer:
	performed on a Self-collected vaginal specimen; and
	for an asymptomatic patient who is at least 30 years of age
	For any particular patient, once only in a 7 year period
	Fee: \$35.00 75%= \$26.25 85%= \$29.75
73072	A test, including partial genotyping, for oncogenic human papillomavirus, performed on a liquid based cervical specimen:
	for the investigation of a patient in a specific population that appears to have a higher risk of cervical pre cancer or cancer; or
	for the follow up management of a patient with a previously detected oncogenic human papillomavirus infection or cervical pre cancer or cancer; or
	for the investigation of a patient with symptoms suggestive of cervical cancer; or
	for the follow up management of a patient after treatment of high grade squamous intraepithelial lesions or adenocarcinoma in situ of the cervix;



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for the follow up management of a patient with glandular abnormalities; or

for the follow up management of a patient exposed to diethylstilboestrol in utero

Fee: \$35.00 75%= \$26.25 85%= \$29.75

A test, including partial genotyping, for oncogenic human papillomavirus:

performed on a self-collected vaginal specimen; and

for the follow-up management of a patient with oncogenic human papillomavirus infection or cervical pre-cancer or cancer that was detected by a test to which item 73071 applies

For any particular patient, once only in a 21 month period

Fee: \$35.00 75%= \$26.25 85%= \$29.75

73074 A test, including partial genotyping, for oncogenic human papillomavirus: performed on a liquid based vaginal vault specimen; and for the investigation of a patient following a total hysterectomy

Fee: \$35.00 75%= \$26.25 85%= \$29.75

73075 A test, including partial genotyping, for oncogenic human papillomavirus, if:

the test is a repeat of a test to which item 73070, 73071, 73072, 73073, 73074 or this item applies; and

the specimen collected for the previous test is unsatisfactory

Fee: \$35.00 75%= \$26.25 85%= \$29.75

73076 Cytology of a liquid-based cervical or vaginal vault specimen, where the stained cells are examined microscopically or by automated image analysis by or on behalf of a pathologist, if:

the cytology is associated with the detection of oncogenic human papillomavirus infection by:

a test to which item 73070, 73071, 73073, 73074 or 73075 applies; or

a test to which item 73072 applies for a patient mentioned in



paragraph (a) or (b) of that item; or

the cytology is associated with a test to which item 73072 applies for a patient mentioned in paragraph (c), (d), (e) or (f) of that item; or

the cytology is associated with a test to which item 73074 applies; or

the test is a repeat of a test to which this item applies, if the specimen collected for the previous test is unsatisfactory; or

the cytology is for the follow-up management of a patient treated for endometrial adenocarcinoma

Fee: \$46.00 Benefit: 75% = \$34.50 85%= \$39.10

#### Explanatory notes

It is the responsibility of the treating healthcare practitioner to determine if the sample is being collected as part of the routine screening program under 73070 or 73071 or represents a sample falling under 73072 or 73073 or 73074 or 73075 or 73076, and to indicate this on the request form. Unless a co-test is specifically requested, requiring the pathology laboratory to perform both a human papillomavirus (HPV) test and a liquid based cytology (LBC) test on the same specimen, the pathology laboratory will by default perform an HPV test and then only undertake reflex LBC testing if oncogenic HPV (any type) is detected. The pathology laboratory will issue the HPV test result, the LBC test result and overall screening risk rating as a combined report as prescribed by the National Pathology Accreditation Advisory Council (NPAAC) Requirements for Laboratories reporting tests for the National Cervical Screening Program (NPAAC Requirements).

The test used for detecting oncogenic HPV must allow partial HPV genotyping to identify HPV16, HPV18 with or without HPV45 as well as meet the criteria for a population based screening test as prescribed by the NPAAC Requirements.

When used together, the self-collection device and the HPV test must meet the NPAAC Requirements, including the HPV test must be a polymerase chain reaction (PCR) test.

73070 applies to an HPV test on a cervical specimen for primary screening purposes and collected by a healthcare practitioner (or an accredited test provider under the supervision of a healthcare practitioner) from an asymptomatic patient as part of routine five yearly screening recommended by the National Cervical Screening Program. The Health Insurance Act 1973 excludes payment of Medicare Benefits for health screening services except where Ministerial directions have been issued to enable benefits to be paid, this includes HPV testing that is performed in accordance with the policy of the National Cervical Screening Program (available at www.cancerscreening.gov.au). This policy provides for a screening interval of five years for an asymptomatic patient commencing at 24 years and 9 months of age and for a patient aged between 70 to 74 years of age to cease cervical screening if the last test result is normal (i.e. low risk). A patient aged 75 years of age or older who has never had a cervical screening test or has not had one in the previous five years, may request a cervical screening test and be screened.



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In accordance with the national policy for the National Cervical Screening Program, where oncogenic HPV (any type) is detected, the pathology laboratory will conduct reflex LBC automatically under 73076 (a) without requiring an additional request by the treating healthcare professional.

73071 only applies to HPV tests for primary screening purposes requested by a healthcare practitioner on a self-collected vaginal specimen if a specimen collected by a healthcare practitioner has been declined.

HPV testing on self collected vaginal specimens carried out under 73071 should be in accordance with the agreed National Cervical Screening Program Self Collection Policy. The Policy allows self collection where a patient is  $\geq$  30 years of age and has either never screened or is under screened (i.e. overdue for cervical screening by at least two years, being greater than 7 years since the patient's last HPV screening test). A patient aged 75 years of age or older who has never had a cervical screening test or has not had one in the previous seven years, may request a Self- collected vaginal sample and be screened.

During the early years of the transition, this may include a patient who is overdue since the patient's last conventional Pap test (i.e. greater than four years since last conventional Pap).

It is the intention of the National Cervical Screening Program where oncogenic HPV has previously been detected under this Item, the healthcare practitioner collected liquid based sample from the cervix that follows, can be claimed under 73076 (a) with a further request by the treating healthcare practitioner.

73072 applies to HPV tests where the specimen has been collected in accordance with the National Cervical Screening Program: Guidelines for the Management of Screen Detected Abnormalities, Screening in Specific Populations and Investigation of Abnormal Vaginal Bleeding (2016 Guidelines) which provides for:

(a) an HPV test (and reflex LBC) performed on a patient within a specific population suggestive of a higher risk of pre-cancerous or cancerous cervical changes. HPV tests carried out in specific populations under Item C should be in accordance with the 2016 Guidelines including:

(i) screening with an HPV test (and reflex LBC) every 3 years for an immune-deficient patient; or

(ii) a single HPV test between 20 and 24 years of age could be considered by healthcare practitioners on a case by case basis for a patient who experienced first sexual activity at a young age (less than 14 years of age) and who has not received the HPV vaccine before sexual debut; or

(b) an HPV test (and reflex LBC) performed for the follow up management of previously detected oncogenic HPV infection with a negative or possible/low grade squamous intraepithelial lesion (LSIL) cytology result; or

(c) a co-test (HPV+LBC) for the investigation of symptoms of cervical cancer, most commonly abnormal vaginal bleeding; or

(d) a co-test (HPV+LBC) for the management of a patient following treatment of high grade squamous intraepithelial lesions (HSIL) of the cervix as part of a 'test of cure' process



performed at 12 months after treatment and annually thereafter, until receiving a negative co-test on two separate consecutive occasions, then the patient can return to routine five yearly screening. In accordance with the 2016 Guidelines this also applies to a patient undergoing follow up or post-treatment for a glandular abnormality as part of annual surveillance performed indefinitely; or

(e) a co-test (HPV+LBC) for the follow up management of glandular abnormalities; or

(f) a co-test (HPV+LBC) for screening a patient exposed to diethylstilboestrol (DES) in utero and daughters of patients exposed to DES in utero, if requested.

A co-test requires both HPV and LBC tests to be performed irrespective of the HPV test result. A reflex LBC is only required if oncogenic HPV (any type) is detected; where oncogenic HPV (any type) has been detected in a liquid based sample from the cervix by a healthcare professional, the pathology laboratory will conduct LBC automatically without requiring an additional request. It is the intention of the National Cervical Screening Program where a co-test is requested or oncogenic HPV has previously been detected under this Item, the LBC can be claimed under 73076 without requiring an additional request by the treating healthcare professional.

73073 applies to the management of a patient with previously detected oncogenic HPV (any type) infection on a Self-collected vaginal sample if a specimen collected by a healthcare practitioner has been declined. It may only be claimed when the test is performed within in a 21 month period following detection of oncogenic HPV (any type) associated with 73071.

It is expected that most patients who are undergoing follow up, after detection of oncogenic HPV (any type) on a Self-collected vaginal sample, will agree to have a clinician collected cervical sample at the follow up visit. Some patients may decline and this Item applies to this group of patients.

It is the intention of the National Cervical Screening Program where oncogenic HPV has previously been detected under this Item, the healthcare practitioner collected liquid based sample from the cervix that follows, can be claimed under 73076 (a) with a further request by the treating healthcare practitioner.

73074 applies to an HPV test on a vaginal vault specimen collected by a healthcare practitioner (or an accredited test provider under the supervision of a healthcare practitioner) from a patient with past history of total hysterectomy, in accordance with the 2016 Guidelines which provides for:

(a) an HPV test for a patient who has no evidence of cervical pathology and the patient's screening history is not available, performed at 12 months following a total hysterectomy and annually thereafter until a patient has two negative HPV tests (i.e. oncogenic HPV detected) on two separate consecutive occasions and can be advised that no further testing is required; or

(b) a co-test (HPV+LBC) for a patient who has had a total hysterectomy, performed at 12 months following a total hysterectomy and annually thereafter until two consecutive co-tests are negative:

(i) if unexpected LSIL or HSIL is identified in the cervix at the time of total hysterectomy after completed 'test of cure' process; or

(ii) if the total hysterectomy was for treatment of high-grade cervical intraepithelial neoplasia in the presence of benign gynaecological disease; or



(iii) if the total hysterectomy was after histologically confirmed HSIL without Test of Cure and there is no cervical pathology; or

(c) indefinite co-testing (HPV+LBC) for a patient who has had a total hysterectomy, performed at 12 months after treatment and annually thereafter if the total hysterectomy was after adenocarcinoma in situ (AIS).

73075 applies to HPV tests repeated due to an unsatisfactory HPV test under 73070 or 73071 or 73072 or 73073 or 73074 or this item.

73076 applies to a LBC test on a cervical or vaginal vault specimen:

(a) as part of a reflex test following detection of oncogenic HPV (any type) described in the national policy and 2016 Guidelines associated with:

(i) items 73070 or 73071 or or 73073 or 73074 or 73075; or

(ii) item 73072 for a patient mentioned in paragraph (a) or (b);

(b) as part of a co-test (i.e. HPV+LBC) described in the national policy and 2016 Guidelines under 73072 for a patient mentioned in paragraph (c) or (d) or (e) of (f); or

(c) associated with a test to which item 73074 applies;

(d) if the test is a repeat of a test to which this item applies, if the specimen collected for the previous test is unsatisfactory; or

(d) for the follow up management of a patient with a past history of total hysterectomy for endometrial adenocarcinoma.