Cervical Cancer Screening Update

The Cancer Council of Australia has recommended significant changes to the National Cervical Screening Program. The new 2016 Guidelines will replace the current 2005 NHMRC Guidelines. This program “Renewal” was planned for May 1, however has been delayed until December 1.

As part of the transition program between May and December, liquid based cytology (LBC), covering both ThinPrep and SurePath, was added to the Medicare Benefits Schedule (MBS) from May 1, item number 73069.

This allows you to choose either conventional glass slides or a LBC sample for performing a pap smear. We recommend that you send a ThinPrep sample, for improved methodology. Please do not send in LBC and a slide on a single patient, as both are not covered under the MBS thus it may result in your patient being billed.

HPV testing is also performed on ThinPrep and SurePath mediums.

Currently

✓ The association of high risk human papillomavirus (HPV) and cervical cancer has been well established.

✓ Currently HPV vaccinations do not protect against all high risk HPV infections. The vaccination program which commenced in 2007 for girls and 2013 for boys, has aided in the reducing the prevalence of HPV within the community.

✓ Unfortunately in Australia 80% of women with cervical cancer have never been screened or have not had regular pap smears

Starting from 1 December, 2017:

✓ Women over the age of 25 will be invited by the National Cervical Screening Register to participate in the new National Cervical Cancer Screening Program.

✓ The recommended time between cervical screening tests will change from two to five years.

✓ The cervical smear will be replaced by a more sensitive cervical screening test, detecting HPV.

✓ The cervical cells will be collected in the same way as previously collected for Pap smears. The only difference is that the cells will be placed in a vial with liquid media for processing rather than smeared.

✓ Cervical screening requests that follow the national prescribed laboratory process will be completely covered by the Medicare Schedule. However if the patient wants additional cervical cytology smears that don’t fit the MBS criteria these tests cannot be rebated to Medicare.

✓ The cervical screening program will be available to women between the ages of 25 and 74 years.

✓ Women of any age who have symptoms such as unusual bleeding, discharge and pain should see their Health Care Professional immediately.
Women positive for HPV16/18 will be referred straight to colposcopy irrespective of the reflex LBC test result.

Women positive for all other genotypes will use the reflex LBC result to determine referral to colposcopy or other follow-up.

If the HPV test result is positive, the pathology laboratory will automatically arrange the reflex cytology testing on the same sample.

Dorevitch Pathology will use the latest HPV technology for the detection of the 14 HPV genotypes known to be associated with cervical cancer. The test specifically detects HPV 16 and 18 (which cause 75% of cervical cancers) while simultaneously detecting the 12 other oncogenic genotypes. There is an internal control which minimises the risk of false negative results for each patient. As per NPAAC guidelines, a negative patient result must be accompanied by an internal control result.
Managing the risks
The new clinical screening methods use a risk based approach, which is based on the woman's risk of cervical cancer. This is determined by their clinical history, their HPV test result and additional reflex testing.

There are three Risk Categories.
- **Low Risk** – Women will be invited to rescreen in 5 years as long as she is asymptomatic and has no evidence of HPV in the sample.
- **Intermediate Risk** – Women will be invited to have another HPV test in 12 months as they have tested positive for one of the oncogenic HPV types but not for HPV 16 and 18. After 12 months they will be retested to see if the HPV infection is cleared.
- **High Risk** – Women who test positive for either or both HPV 16 and 18, will be placed in this higher risk category. The sample will also be tested with reflex liquid based (LBC) cytology screening. A combined report will be issued with a recommendation to be referred to a Specialist for further investigation.

Reported Results:
Pathology Laboratories will follow the mandated NPAAC (National Pathology Accreditation Advisory Council) guidelines.

Request Form
Pertinent clinical details are essential for reliable cervical screening, as there are changes in the expected cell patterns in various clinical states. The laboratory testing of the sample and the clinical recommendations given in the pathology report are heavily reliant on the details provided on the request form.

State the reason for cervical screening:
- Primary Screening
- Follow-up test

Other important information required on the request form:
- Date of last menstrual period
- Pregnant or Postnatal
- Postmenopausal
- Hormone therapy including Tamoxifen
- IUDS (Intrauterine conception devices)
- Immune deficient
- DES exposure history
- Pap smear history
- Previous Radiotherapy
- Cervix
  - Suspicious
  - Normal
- Bleeding
  - Post Coital
  - Post-Menopausal
  - Other

Funding and Billing Changes
From the December 1 the pap smear will be known as the Medicare-Funded Cervical Screening Test. Until December 1 the current MBS schedule will exist, with the recent addition of LBC.

<table>
<thead>
<tr>
<th>Referral May 1 to November 30, 2017</th>
<th>Charges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional smear only</td>
<td>Bulkbill</td>
</tr>
<tr>
<td>Liquid based cytology only (ThinPrep or SurePath)</td>
<td>Bulkbill</td>
</tr>
<tr>
<td>Conventional smear AND liquid based cytology</td>
<td>$40 out of pocket fee</td>
</tr>
<tr>
<td>HPV screening</td>
<td>$40 out of pocket fee</td>
</tr>
<tr>
<td>HPV test of cure</td>
<td>Bulkbill if criteria met</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Referral December 1, 2017 (anticipated)</th>
<th>Charges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional smear</td>
<td>TBA – non Medicare rebatable</td>
</tr>
<tr>
<td>Liquid based cytology (ThinPrep or SurePath)</td>
<td>Non Medicare Rebatable if Doctor or patient initiated. Bulkbilled only if performed as a Reflex Test by the laboratory</td>
</tr>
<tr>
<td>HPV screening</td>
<td>Bulkbill</td>
</tr>
<tr>
<td>HPV test of cure</td>
<td>Bulkbill</td>
</tr>
</tbody>
</table>

References:
2. MSAC Outcomes, Application number 1276. Accessible from msac.gov.au
3. Sample collection information from www.thinprep.com
4. NPAAC: National Pathology Accreditation Advisory Council
Specimen Collection

How to take a specimen

The collection of cervical cells from the cervix is the same way a usual pap smear is collected. The only difference is that instead of smearing the cervical cells on a slide, the cells are placed in a specific liquid in a vial. The steps below describe how the cervical cells are placed in this vial.

1. **LABEL SPECIMENS** - Samples should be labelled prior to sampling and include the following as a minimum: Given Name, Surname and Date of birth.

2. **INSERT** the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently and rotate the broom in a clockwise direction five times.

3. **RINSE** the broom as quickly as possible into the ThinPrep solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. **Discard the collection device.**

4. **TIGHTEN** the cap so that the torque line on the cap passes the torque line on the vial. Do not over-tighten.

5. **PLACE** the vial and request form in a specimen bag for transport to the laboratory.

**Note:**
- HPV testing is NOT validated for non-gynaecological sites, male patients or histology samples.
- In addition, it should be noted that the test ONLY detects the oncogenic HPV types.
- The test is not to be used for the non-oncogenic types of HPV that cause common verrucae.
- A self-collected HPV sample is possible but only recommended for certain patient groups.

For more information please contact:
A/Prof Afaf Haddad | P 03 9244 0441 | M 0434 604 443 | E afaf.haddad@dorevitch.com.au