23 May 2017

Changes to the National Immunisation Schedule

PHARMAC is pleased to announce decisions related to the National Immunisation Schedule (NIS) that will take effect from 1 July 2017. The decisions have been made following a Request for Proposals (RFP) for the supply of various vaccines, issued on 15 February 2016, and were the subject of a consultation letter dated 9 December 2016.

The decisions are as consulted on with the exception of changes to access criteria for pneumococcal conjugate vaccines PCV10 and PCV13 and Hepatitis B recombinant vaccine. The decisions will result in the following:

From 1 July 2017

- **Pneumococcal conjugate (PCV13) vaccine**
  - High-risk children aged less than 5 years will be eligible for vaccination with the PCV13 vaccine rather than PCV10.
  - PCV13 vaccine will remain funded for use in diagnostic testing for primary immunodeficiency diseases. This follows consultation feedback that moving this indication to PCV10 was not appropriate.

- **Pneumococcal conjugate (PCV10) vaccine**
  - As above, the PCV10 vaccine will not be funded for use in testing for primary immunodeficiency diseases.

- **Varicella vaccine**
  - The primary vaccination eligibility criteria for varicella vaccine for infants and 11-year old children will include a birth date cut off to clarify who is eligible.

- **Brand switch transition periods introduced**
  - All GlaxoSmithKline (GSK) vaccines will have Sole Supply Status from 1 September 2017 until 30 June 2020. This is a change from 1 July 2017, and will provide a transition period in the distribution chain between 1 July and 31 August 2017 for the introduction of the following vaccines:
    - Pneumococcal (PCV10) vaccine (Synflorix);
    - Measles, mumps and rubella vaccine (Priorix);
    - *Haemophilus influenzae* type B vaccine (Hiberix); and
    - Rotavirus vaccine (Rotarix).

- **Hepatitis A vaccine**
  - GSK’s hepatitis A vaccine (Havrix/Havrix Junior) will remain listed. Sole Supply Status will apply in the community and DHB hospitals from 1 September 2017 until 30 June 2020.

- **Hepatitis B vaccine and pneumococcal polyvalent vaccine (Pneumovax 23)**
  - Merck Sharp & Dohme’s (MSD’s) hepatitis B recombinant vaccine (HBvaxPRO – 5 mcg, 10 mcg & 40 mcg) and pneumococcal polyvalent vaccine (Pneumovax 23) will remain listed. Sole Supply Status will apply in the community and DHB hospitals from 1 July 2017 until 30 June 2020.
  - Eligibility criteria for the hepatitis B vaccine has been clarified to include patients who have received a solid organ transplant or haematopoietic stem cell transplant, and children who have not received a primary course of vaccination.
Eligibility criteria for the pneumococcal (PPV23) polysaccharide vaccine for high risk patients has been amended to align with high risk criteria for other pneumococcal vaccines.

- **Meningococcal conjugate vaccine, Poliomyelitis vaccine, and Tuberculin purified protein derivative (Mantoux) test**
  - The following Sanofi-Aventis New Zealand Limited (Sanofi) vaccines will be listed:
    - Meningococcal A, C, Y and W135 conjugate vaccine (Menactra);
    - Poliomyelitis vaccine (IPOL);
    - Tuberculin PPD (mantoux) test (Tubersol).
  - Sole Supply Status will apply in the Community and Hospital settings from 1 July 2017 until 30 June 2020.

Further details of the decisions are set out below as follows:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Page</th>
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<tr>
<td>Pneumococcal conjugated (PCV13) vaccine</td>
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<td>Pneumococcal conjugated (PCV10) vaccine</td>
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<td>Varicella vaccine</td>
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<tr>
<td>Poliomyelitis vaccine</td>
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<td>11</td>
</tr>
</tbody>
</table>

The listings and amendments to the National Immunisation Schedule in this notification complete the majority items from the RFP process.
Pneumococcal (PCV13) conjugate vaccine

From 1 July 2017, the following chemical name, presentation details and restrictions will apply to the listing of Pneumococcal conjugate (PCV13) vaccine in Section I (National Immunisation Schedule) of the Pharmaceutical Schedule, with similar restrictions in DHB Hospitals (deletions shown by strikethrough and additions shown in bold):

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Presentation</th>
<th>Brand</th>
<th>Pack size</th>
<th>Subsidy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal (PCV13) conjugate vaccine</td>
<td>Inj 30.8 mcg of pneumococcal polysaccharide serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in 0.5 ml syringe</td>
<td>Prevenar 13</td>
<td>10</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

Following consultation feedback, the eligibility criteria for use in testing for primary immunodeficiency diseases will be reinstated for PCV13 (additions in bold and deletions in strikethrough):

**Pneumococcal (PCV13) vaccine**

Any of the following:

1. A primary course of four doses for previously unvaccinated individuals up to the age of 59 months inclusive; or
2. Up to three doses as appropriate to complete the primary course of immunisation for individuals under the age of 59 months who have received one to three doses of PCV10; or
3. One dose is funded for high risk children (over the age of 17 months and up to the age of under 18 years) who have previously received four doses of PCV10; or
4. Up to an additional four doses (as appropriate) are funded for high risk children aged under 5 years for (re-)immunisation of patients:
   
   2.1 on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
   2.2 with primary immune deficiencies; or
   2.3 with HIV infection; or
   2.4 with renal failure, or nephrotic syndrome; or
   2.5 who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
   2.6 with cochlear implants or intracranial shunts; or
   2.7 with cerebrospinal fluid leaks; or
   2.8 receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
   2.9 with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
   2.10 pre term infants, born before 28 weeks gestation; or
   2.11 with cardiac disease, with cyanosis or failure; or
   2.12 with diabetes; or
   2.13 with Down syndrome; or
   2.14 who are pre-or post-splenectomy, or with functional asplenia; or

43. Up to an additional four doses (as appropriate) are funded for (re-)immunisation of patients 5 years and over with HIV, for patients pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or

54. For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.
In DHB hospitals, the restrictions will be as follows (additions in bold and deletions in strikethrough):

Restricted

Initiation – High risk children who have received PCV10

**Therapy limited to 1 dose**

Any of the following:

1. A primary course of four doses for previously unvaccinated individuals up to the age of 59 months inclusive; or
2. Up to three doses as appropriate to complete the primary course of immunisation for individuals under the age of 59 months who have received one to three doses of PCV10; or
3. One dose is funded for high risk children (over the age of 17 months and up to the age of under 18 years) who have previously received four doses of PCV10.

Initiation – High risk children aged under 5 years

**Therapy limited to 4 doses**

Both:

1. Up to an additional four doses (as appropriate) are funded for children aged under 5 years for (re-)immunisation; and
2. Any of the following:
   2.1 on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
   2.2 with primary immune deficiencies; or
   2.3 with HIV infection; or
   2.4 with renal failure, or nephrotic syndrome; or
   2.5 who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
   2.6 with cochlear implants or intracranial shunts; or
   2.7 with cerebrospinal fluid leaks; or
   2.8 receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
   2.9 with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
   2.10 pre term infants, born before 28 weeks gestation; or
   2.11 with cardiac disease, with cyanosis or failure; or
   2.12 with diabetes; or
   2.13 with Down syndrome; or
   2.14 who are pre-or post-splenectomy, or with functional asplenia.

Initiation – High risk adults and children 5 years and over

**Therapy limited to 4 doses**

4. Up to an additional four doses (as appropriate) are funded for (re-)immunisation of patients 5 years and over with HIV, for patients pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency.

Initiation – Testing for primary immunodeficiency diseases

5. For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes
Pneumococcal (PCV10) conjugate vaccine

Synflorix will be listed from 1 July 2017 and have Sole Supply Status in both the community and DHB hospital settings, with a 0% DV Limit, for pneumococcal (PCV10) conjugate vaccine from 1 September 2017 until 30 June 2020.

Changes following consultation

From 1 July 2017, the previously notified pneumococcal (PCV10) conjugate vaccine will be replaced with the following restrictions in Section I (National Immunisation Schedule) of the Pharmaceutical Schedule, with equivalent restrictions applicable in DHB Hospitals (deletions shown by strikethrough and additions shown in bold):

Either Any of the following:

1. A primary course of four doses for previously unvaccinated individuals up to the age of 59 months inclusive; or
2. Up to three doses as appropriate to complete the primary course of immunisation for individuals under the age of 59 months who have received one to three doses of PCV13; or
3. For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

Varicella vaccine

Varilrix will have Sole Supply Status in both the community and DHB hospital settings, with a 0% DV Limit, for varicella vaccine [chickenpox vaccine] from 1 September 2017 until 30 June 2020.

From 1 July 2017, the current restrictions to varicella vaccine [chickenpox vaccine] will be replaced with the following restrictions in Section I (National Immunisation Schedule) of the Pharmaceutical Schedule, with equivalent restrictions applicable in DHB Hospitals (deletions shown by strikethrough and additions shown in bold):

Varicella vaccine [chickenpox vaccine]

Either:

1. Maximum of one dose for primary vaccination for either:
   1.1 Children at 15 months Any infant born on or after 1 April 2016; or
   1.2 For previously unvaccinated children at turning 11 years old on or after 1 July 2017, who have not previously had a varicella infection (chickenpox), or

2. Maximum of two doses for any of the following:
   2.1 Any of the following for non-immune patients:
      2.1.1 with chronic liver disease who may in future be candidates for transplantation; or
      2.1.2 with deteriorating renal function before transplantation; or
      2.1.3 prior to solid organ transplant; or
      2.1.4 prior to any elective immunosuppression*, or
      2.1.5 for post exposure prophylaxis who are immune competent inpatients.; or
   2.2 For patients at least 2 years after bone marrow transplantation, on advice of their specialist, or
   2.3 For patients at least 6 months after completion of chemotherapy, on advice of their specialist, or
   2.4 For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist.
   2.5 For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella, or
2.6 For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella, or
2.7 For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.
* immunosuppression due to steroid or other immunosuppressive therapy must be for a treatment period of greater than 28 days

Brand switch transition periods

PHARMAC previously consulted on and notified of four brand switches involving new listings and Sole Supply Status for GlaxoSmithKline vaccines:

- Pneumococcal (PCV10) vaccine (Synflorix);
- Measles, mumps and rubella vaccine (Priorix);
- *Haemophilus influenzae* type B vaccine (Hiberix); and
- Rotavirus vaccine (Rotarix).

Our previously notified decision was that the vaccines will have Sole Supply Status in both the community and DHB hospital settings, with a 0% DV Limit from 1 July 2017 until 30 June 2020.

Changes

All GlaxoSmithKline’s vaccines will have their start date for Sole Supply Status delayed by two months to create a transition period for the distribution chain. All the vaccines will still be listed in Part II of Section H and Section I of the Pharmaceutical Schedule from 1 July 2017 (as notified previously) and will now have Sole Supply Status in both the community and DHB hospital settings, with a 0% DV Limit from 1 September 2017 until 30 June 2020.

The four other GlaxoSmithKline vaccines affected by the change in start date of Sole Supply Status are set out below. Please note that these vaccines are already listed in the Schedule, so the impact of the proposed change will be negligible for:

- Varicella vaccine [chicken pox vaccine] (Varilrix)
- Diphtheria, tetanus, pertussis and inactivated polio vaccine (Infanrix IPV);
- Diphtheria, tetanus and pertussis vaccine (Boostrix); and
- Diphtheria, tetanus, pertussis, polio, hepatitis B and *haemophilus influenzae* type B vaccine (Infanrix hexa).

Hepatitis A vaccine

From 1 July 2017, GlaxoSmithKline NZ Limited’s injection of hepatitis A vaccine (Havrix/Havrix Junior) will remain listed, with no change to the current funding restrictions, in Part II of Section H and Section I of the Pharmaceutical Schedule as follows:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Presentation</th>
<th>Brand</th>
<th>Pack size</th>
<th>Subsidy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis A vaccine</td>
<td>Inj 1440 ELISA units in 1 ml syringe</td>
<td>Havrix</td>
<td>1</td>
<td>$0.00</td>
</tr>
<tr>
<td>Hepatitis A vaccine</td>
<td>Inj 720 ELISA units in 0.5 ml syringe</td>
<td>Havrix Junior</td>
<td>1</td>
<td>$0.00</td>
</tr>
</tbody>
</table>
Havrix/Havrix Junior will have Sole Supply Status in both the Community and Hospital settings for hepatitis A vaccine from 1 September 2017 until 30 June 2020.

A confidential discount will apply, reducing the net price of the product to the Funder.

**Hepatitis B recombinant vaccine**

From 1 July 2017, MSD’s three strengths of hepatitis B recombinant vaccine (HBvaxPRO) will remain listed with a clarification to the current funding restrictions (see below with additions shown in bold), in Part II of Section H and Section I of the Pharmaceutical Schedule as follows:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Presentation</th>
<th>Brand</th>
<th>Pack size</th>
<th>Subsidy</th>
</tr>
</thead>
<tbody>
<tr>
<td>hepatitis B recombinant vaccine</td>
<td>Inj 5 mcg per 0.5 ml vial</td>
<td>HBvaxPRO 1</td>
<td>1</td>
<td>$0.00</td>
</tr>
<tr>
<td>hepatitis B recombinant vaccine</td>
<td>Inj 10 mcg per 1 ml vial</td>
<td>HBvaxPRO 1</td>
<td>1</td>
<td>$0.00</td>
</tr>
<tr>
<td>hepatitis B recombinant vaccine</td>
<td>Inj 40 mcg per 1 ml vial</td>
<td>HBvaxPRO 1</td>
<td>1</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

A confidential discount will apply, reducing the net price of the product to the Funder.

**Hepatitis B recombinant vaccine – HBvaxPRO (5 mcg & 10 mcg)**

Funded for patients meeting any of the following criteria:

1. for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or
2. for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or
3. for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination; or
4. for HIV positive patients; or
5. for hepatitis C positive patients; or
6. for patients following non-consensual sexual intercourse; or
7. for patients following immunosuppression; or
8. for solid organ transplant patients; or
9. for post-haematopoietic stem cell transplant (HSCT) patients; or
10. following needle stick injury.

**Hepatitis B recombinant vaccine – HBvaxPRO (40 mcg)**

Funded for any of the following criteria:

1. for dialysis patients; or
2. for liver or kidney transplant patient.

HBvaxPRO will have Sole Supply Status in both the Community and Hospital settings for hepatitis B vaccine from 1 July 2017 until 30 June 2020.
Pneumococcal (PPV23) polysaccharide vaccine

From 1 July 2017, MSD’s pneumococcal (PPV23) polysaccharide vaccine (Pneumovax 23) will remain listed with a clarification to the current funding restrictions (see below with additions shown in bold), Section I of the Pharmaceutical Schedule as follows:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Presentation</th>
<th>Brand</th>
<th>Pack size</th>
<th>Subsidy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal (PPV23) polysaccharide vaccine</td>
<td>Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)</td>
<td>Pneumovax 23</td>
<td>1</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

**Pneumococcal (PPV23) polysaccharide vaccine – Pneumovax 23**

Either:

1. Up to three doses (as appropriate) for patients with HIV, for patients post haematopoietic stem cell transplant, or chemotherapy; pre- or post-splenectomy, or with functional asplenia, pre- or post-solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or

2. Up to two doses are funded for high risk children to the age of 18 years for (re-)immunisation of patients:

   2.1 on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
   2.2 with primary immune deficiencies; or
   2.3 with HIV infection; or
   2.4 with renal failure, or nephrotic syndrome; or
   2.5 who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
   2.6 with cochlear implants or intracranial shunts; or
   2.7 with cerebrospinal fluid leaks; or
   2.8 receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
   2.9 with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
   2.10 pre term infants, born before 28 weeks gestation; or
   2.11 with cardiac disease, with cyanosis or failure; or
   2.12 with diabetes; or
   2.13 with Down syndrome; or
   2.14 who are pre- or post-splenectomy, or with functional asplenia.

Similar restrictions will apply in DHB Hospitals:

Initiation – High risk patients
Therapy limited to three doses
Any of the following:

1. Up to three doses (as appropriate) for patients with HIV, for patients post haematopoietic stem cell transplant, or chemotherapy; pre- or post-splenectomy, or with functional asplenia, pre- or post-solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency, or

Initiation – High risk children
Therapy limited to two doses
Both:

12. Up to two doses are funded for high risk children to the age of 18 years for (re-)immunisation; and

2 Any of the following:
2.1 on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
2.2 with primary immune deficiencies; or
2.3 with HIV infection; or
2.4 with renal failure, or nephrotic syndrome; or
2.5 who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
2.6 with cochlear implants or intracranial shunts; or
2.7 with cerebrospinal fluid leaks; or
2.8 receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
2.9 with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
2.10 pre term infants, born before 28 weeks gestation; or
2.11 with cardiac disease, with cyanosis or failure; or
2.12 with diabetes; or
2.13 with Down syndrome; or
2.14 who are pre-or post-splenectomy, or with functional asplenia.

Initiation – Testing for primary immunodeficiency diseases

3. For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Pneumovax 23 will have Sole Supply Status in both the Hospital and Community settings for pneumococcal (PPV23) polysaccharide vaccine from 1 July 2017 until 30 June 2020.

Meningococcal (Groups A, C, Y and W-135) conjugate vaccine

From 1 July 2017 Sanofi’s meningococcal (groups A, C, Y and W-135) conjugate vaccine will remain listed with no change to the current funding restrictions, in Part II of Section H and Section I of the Pharmaceutical Schedule as follows:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Presentation</th>
<th>Brand</th>
<th>Pack size</th>
<th>Subsidy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meningococcal (Groups A,C,Y and W-135) conjugate vaccine</td>
<td>Inj 4 μg of each meningococcal polysaccharide conjugated to a total of approximately 48 μg of diphtheria toxoid carrier per 0.5 mL dose</td>
<td>Menactra</td>
<td>1</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

Menactra will have Sole Supply Status for both the Community and Hospital settings for meningococcal (Groups A, C, Y and W-135) conjugate vaccine from 1 July 2017 until 30 June 2020.

A confidential discount will apply, reducing the net price of the product to the Funder.
Poliomyelitis vaccine

From 1 July 2017 Sanofi’s poliomyelitis vaccine (IPOL) will remain listed with no change to the current funding restrictions, in Part II of Section H and Section I of the Pharmaceutical Schedule as follows:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Presentation</th>
<th>Brand</th>
<th>Pack size</th>
<th>Subsidy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poliomyelitis vaccine</td>
<td>Inj 80D antigen units in 0.5 ml syringe</td>
<td>IPOL</td>
<td>1</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

IPOL will have Sole Supply Status in both the Community and Hospital settings for poliomyelitis vaccine from 1 July 2017 until 30 June 2020.

Tuberculin purified protein derivative (Mantoux) test

From 1 July 2017, Sanofi’s tuberculin purified protein derivative (Mantoux) test (Tubersol) will be listed on the Pharmaceutical Schedule with no restrictions in Part II of Section H and Section B of the Pharmaceutical Schedule as follows:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Presentation</th>
<th>Brand</th>
<th>Pack size</th>
<th>Subsidy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculin purified protein derivative (Mantoux) test</td>
<td>Inj 5 TU per 0.1 ml, 1 ml vial</td>
<td>Tubersol</td>
<td>1</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

Tubersol will have Sole Supply Status in both the Community and Hospital settings for tuberculin purified protein derivative (Mantoux) test, from 1 July 2017 until 30 June 2020.

Tuberculin purified protein derivative (Mantoux) test will be listed in Section B of the Pharmaceutical Schedule with the Xpharm restriction meaning that community pharmacy will not be able to dispense and claim for this product.

Distribution of vaccines and pricing

Vaccines (and Mantoux tests) are distributed differently to most other pharmaceuticals. The method for ordering vaccines by vaccinators will remain the same. The vaccines will be listed “Xpharm” with a $0.00 subsidy. An Xpharm listing means that pharmacies cannot claim subsidy because PHARMAC has made alternative distribution arrangements. Confidential net prices will apply to some vaccines listed.

Implementation of changes

The Ministry of Health will lead the implementation of these changes and PHARMAC will work closely with the Ministry.
Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 23 January 2017 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposals, and the following issues were raised in relation to specific aspects of the proposals:

<table>
<thead>
<tr>
<th>Theme</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hepatitis B recombinant vaccine</strong></td>
<td>PHARMAC agrees that the current criteria are unclear that children who have not received hepatitis B vaccine with their infant vaccines could receive hepatitis B vaccine to complete a primary course. We consider it is reasonable to allow vaccination in this small group, and in the majority of cases this would already occur. The following amendments to the criteria have been included: for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination:</td>
</tr>
<tr>
<td>One responder noted that there appeared to be currently no listing for children who require a primary immunisation course with a monovalent hepatitis B vaccine, needed for catch up programmes, for example with migrant children who may have received an infant vaccination combination that did not include hepatitis B. They requested an extra line in the funding criterion to include ‘For a primary immunisation course for children”.</td>
<td></td>
</tr>
<tr>
<td><strong>Pneumococcal conjugate (PCV13) vaccine</strong></td>
<td>PHARMAC notes the current PCV13 criteria that apply until 30 June 2017 allow for use in testing for primary immunodeficiency diseases, and with this proposal it was intended that this indication would transfer to PCV10. Following consideration of this feedback PHARMAC agrees it is reasonable to continue with this criterion for PCV13 once the change to PCV10 occurs for the infant schedule. We note this use is an unapproved indication for both PCV10 and PCV13.</td>
</tr>
<tr>
<td>One responder recommended PHARMAC continue the use of PCV13 for testing for immune deficiencies. They considered that this is numerically a small number of individuals, noting that this issue has been discussed in previous Subcommittee meetings, and that a conjugate vaccine is the preferable vaccine to use in testing, and PCV10 is not licensed in children &gt;5 years.</td>
<td></td>
</tr>
<tr>
<td><strong>Varicella vaccine</strong></td>
<td>PHARMAC has not previously considered this indication for funding.</td>
</tr>
<tr>
<td>One responder was concerned about children who have severe chronic skin conditions (e.g. eczema requiring specialist care) who have not had varicella infection or vaccination. They noted that people with eczema are particularly prone to severe infection and bacterial super infection. They recommended inclusion of children with severe skin conditions for funded varicella vaccine.</td>
<td>PHARMAC would welcome a funding application for varicella vaccine for groups not currently covered under the proposed criteria. PHARMAC staff will liaise with the responder to seek an application for children with severe skin conditions.</td>
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<td>Several respondents were unclear if the The intention of the funding criteria is to</td>
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catch-up dose of varicella vaccine only applied to 11 year olds, and questioned if an additional varicella vaccine dose would be funded for children over 13 years?

provide an opportunity for vaccination in children in their 11th year of age. This also means only one dose will be funded and only children who are age 11 will be eligible.

PHARMAC staff intend to work with the Immunisation team at the Ministry of Health to support its work in this area of implementation; in particular to ensure that clear information is provided to vaccinators and GPs so that their interpretation of this criteria is correct.

**Meningococcal (Groups A, C, Y and W-135) conjugate vaccine**

Two respondents noted that Menactra is currently available to close contacts of meningococcal cases and is funded regardless of serogroup. This means that families of people with serogroup B disease (for which there is no vaccine available in New Zealand) can receive a funded vaccine covering extra serogroups, but not the patient themselves.

The respondents recommend PHARMAC and the Immunisation Subcommittee undertake further enquiry around the extension of a funded dose of Menactra where appropriate.

PHARMAC intends to seek clinical advice from the Immunisation Subcommittee regarding this feedback at the Subcommittee’s next meeting.

**Pneumococcal (PPV23) polysaccharide vaccine**

One respondent requested that children aged over 5 years who are at high risk of pneumococcal disease should receive a single dose of PCV13 prior to receiving Pneumovax 23. They note that the proposed amendments are for two doses of PPV23 vaccine to be funded for the re-immunisation of patients with chronic conditions and/or are immunocompromised.

Another responder suggested that a single PCV13 dose is also appropriate for those aged over 5 years who are at high risk of pneumococcal disease prior to giving the 'Pneumovax 23valent' (eg. with CSF leaks over age 5, not just under 5 years as listed)

PHARMAC notes that children over 5 years of age with the following high risk conditions will be eligible for a PCV13 dose prior to PPV23 vaccination: patients with HIV, for patients pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, complemet deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency.

We also note that criteria 1 for PCV13 vaccine allows one dose of PCV13 for high risk children (over the age of 17 months and up to the age of under 18 years) who have previously received four doses of PCV10.

Therefore, patients over 5 years of age who have not received PCV13 primary vaccination and who do not have one of the specific high risk indications above will be
eligible for an additional PCV13 if needed, and this could be given prior to PPV23 vaccination.

PHARMAC notes that evidence suggests a minimum of 8 weeks between doses is required to use PCV13 vaccine as a primer for PPV23 vaccination. We are not aware of information suggesting a longer duration between doses is problematic. Therefore, we consider the criteria is sufficient to allow priming with PCV13 vaccine in all patients eligible for PPV23 vaccination.

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If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.