NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

3 July 2015

Decision to amend access criteria for some vaccines

PHARMAC is pleased to announce the following changes to the funding access criteria for a number of vaccines. The changes in criteria follow consideration by PHARMAC of recommendations made by the Immunisation Subcommittee of PTAC during its September 2014 and February 2015 meetings. PHARMAC did not consult on these changes as they reflect current practice and/or aim to clarify the intent current funding criteria.

In summary the main effects of the decision area that from 1 July 2015:

- Influenza vaccine – access will be widened to include vaccination of people with cochlea implants, errors of metabolism at risk of major metabolic decomposition, Down syndrome and for people who are pre and post splenectomy .

- Diphtheria tetanus and pertussis vaccine, hexavalent vaccine (DTaP-IPV-HepB/Hib), haemophilus influenza type B and the meningococcal vaccines (monovalent and quadrivalent) – clarification of the access criteria for immunosuppressed patients.

- Hepatitis B vaccine – access will be widened to include vaccination following non-consensual sexual intercourse or needle stick injury.

- Pneumococcal (PCV13) vaccine – access will be clarified to include patients with complement deficiency (acquired or inherited), primary immunodeficiency and people with cochlear implants.

- Human papillomavirus (6, 11, 16 and 18) vaccine (HPV) and measles, mumps and rubella vaccines - minor changes to the access criteria including an additional dose being funded for patients under 26 years of age post chemotherapy.

Details of the decision are as follows:

Details of the decision

- Influenza vaccine will remain listed in Section I of the Pharmaceutical Schedule from 1 July 2015 with changes to the funding criteria as follows (deletions in strike through, additions in bold):

A) is available each year for patients who meet the following criteria, as set by PHARMAC:
a) all people 65 years of age and over; **or**
b) people under 65 years of age who:
i) have any of the following cardiovascular disease**s**:
a) ischaemic heart disease, **or**
b) congestive heart ~~disease~~ **failure**, **or**
c) rheumatic heart disease, **or**
d) congenital heart disease, or
e) cerebo-vascular disease; **or**
ii) have either of the following chronic respiratory disease**s**:
a) asthma, if on a regular preventative therapy, or
b) other chronic respiratory disease with impaired lung function; **or**
iii) have diabetes; **or**
iv) have chronic renal disease; **or**

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v) have any cancer, excluding basal and squamous skin cancers if not invasive; **or**
vi) have any of the following other conditions:
a) autoimmune disease, **or**
b) immune suppression **or immune deficiency**, **or**
c) HIV, **or**
d) transplant recipients, **or**
e) neuromuscular and CNS diseases**/disorders**, **or**
f) haemoglobinopathies, **or**
g) are children on long term aspirin, **or**
h) have a cochlear implant, or
(i) errors of metabolism at risk of major metabolic decomposition, or
(j) pre and post splenectomy, or
(k) down syndrome; or
vii) are pregnant; **or**
c) children aged four **years** and under who have been hospitalised for respiratory illness or have a history of significant respiratory illness.

Unless meeting the criteria set out above, the following conditions are excluded from funding:
a) asthma not requiring regular preventative therapy.
b) hypertension and/or dyslipidaemia without evidence of end-organ disease.

B) Doctors are the only Contractors entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

C) Individual DHBs may fund patients over and above the above criteria. The claiming process for these additional patients should be determined between the DHB and Contractor, **or**

D) Stock of the seasonal influenza vaccine is typically available from February until late July with suppliers being required to ensure supply until at least 30 June. Exact start and end dates for each season will be notified each year.

- influenza vaccine will remain listed in Part II of Section H of the Pharmaceutical Schedule from 1 July 2015 with changes to the restriction as follows (deletions in strike through, additions in bold):

Any of the following:
1 All people 65 years of age and over; or
2 People under 65 years of age who:
2.1 Have any of the following cardiovascular diseases:
2.1.1 Ischaemic heart disease; or
2.1.2 Congestive heart ~~disease~~ **failure**; or
2.1.3 Rheumatic heart disease; or
2.1.4 Congenital heart disease; or
2.1.5 Cerebro-vascular disease; or
2.2 Have any of the following chronic respiratory diseases:
2.2.1 Asthma, if on a regular preventative therapy; or
2.2.2 Other chronic respiratory disease with impaired lung function; or
2.3 Have diabetes; **or**
2.4 Have chronic renal disease; **or**
2.5 Have any cancer, excluding basal and squamous skin cancers if not invasive; **or**
2.6 Have any of the following other conditions:
2.6.1 Autoimmune disease; **or**
2.6.2 Immune suppression **or immune deficiency**; **or**
2.6.3 HIV; **or**
2.6.4 Transplant recipients; **or**
2.6.5 Neuromuscular and CNS diseases**/disorders**; **or**
2.6.6 Haemoglobinopathies; **or**
2.6.7 Are children on long term aspirin; **or**
2.6.8 Have a cochlear implant, or
2.6.9 Errors of metabolism at risk of major metabolic decomposition, or
2.6.10 Pre and post splenectomy, or
2.6.11 Down syndrome; or
2.7 Are pregnant, or
2.8 Are children aged four and under who have been hospitalised for respiratory illness or have a history of significant respiratory illness; or
3 Patients who are compulsorily detained long-term in a forensic unit within a DHB hospital in the 2015 season.

Note: The following conditions are excluded from funding:
- asthma not requiring regular preventative therapy; and

- hypertension and/or dyslipidaemia without evidence of end-organ disease.

- Diphtheria, tetanus and pertussis vaccine (Boostrix) will remain listed in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2015 as follows (deletions in strike through, additions in bold):

  Funded for any of the following criteria:
  1) A single vaccine for pregnant woman between gestational weeks 28 and 38 during epidemics; or
  2) A course of up to four vaccines is funded for children from age 7 **up to the age of 18** inclusive to complete full primary immunisation; or
  ~~3) A course of up to four vaccines is funded for children from age 7 to 17 years inclusive for reimmunisation following immunosuppression.~~
  3) An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens.
  Notes: Tdap is not registered for patients aged less than 10 years. Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

- Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae Type B vaccine (Infanrix-hexa) will remain listed in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2015 as follows (deletions in strike through, additions in bold):

  Funded for patients meeting any of the following criteria:
  1) Up to four doses for children up to **and under** the age of 10 for primary immunisation; or
  ~~2) Up to four doses (as appropriate) for children **individuals** are funded for (re)immunisation for patients post HSCT, or chemotherapy; pre- or post splenectomy; renal dialysis and other severely immunosuppressive regimens; or~~
  2) An additional four doses (as appropriate) are funded for (re-)immunisation for children up to and under the age of 10 who are patients post haematopoietic stem cell transplantation, or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
  3) Up to five doses for children up to **and under** the age of 10 receiving solid organ transplantation.
  Note: A course of up-to four vaccines is funded for catch up programmes for children (up to **and under** the age of 10 years) to complete full primary immunisation. Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

- Haemophilus influenzae Type B vaccine (Act-HIB) will remain listed in Section I and Part II of Section H of the Pharmaceutical Schedule effective from 1 July 2015 as follows (deletions in strike through, additions in bold):

  One dose for patients meeting any of the following:
  1) For primary vaccination in children; or
  ~~2) For revaccination of children following immunosuppression; or~~
  ~~3) For children aged 0-18 years with functional asplenia; or~~
  ~~4) For patients pre- and post splenectomy; or~~
  2) An additional dose (as appropriate) is funded for (re-)immunisation for patients post haematopoietic stem cell transplantation, or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, pre- or post cochlear implants, renal dialysis and other severely immunosuppressive regimens; or
  3 ~~5~~) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

- Hepatitis B vaccine (HBvaxPRO) inj 5 mcg per 0.5 ml vial and inj 10 mcg per 1 ml vial will remain listed in Section I and Part II of Section H of the

Pharmaceutical Schedule effective from 1 July 2015 as follows (deletions in strike through, additions in bold):

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
4) for HIV positive patients; or
5) for hepatitis C positive patients; or
6) for patients following non-consensual sexual intercourse; or
7 ~~6~~) for patients following immunosuppression; or
8 ~~7~~) for transplant patients; or
9) following needle stick injury.

- Human papillomavirus (6, 11, 16 and 18) vaccine (Gardasil) will remain listed in Section I and Part II of Section H of the Pharmaceutical Schedule effective from 1 July 2015 as follows (deletions in strike through, additions in bold):

Maximum of three doses for patient meeting any of the following criteria:
1) Females aged under 20 years old; or
2) Patients aged under 26 years old with confirmed HIV infection; or
3) For use in transplant **(including stem cell)** patients; or
4) **An additional dose for patients under 26 years of age post chemotherapy**.

- Measles, mumps and rubella vaccine (M-M-R II) will remain listed in Section I and Part II of Section H of the Pharmaceutical Schedule effective from 1 July 2015 as follows (deletions in strike through, additions in bold):

A maximum of two doses for any patient meeting the following criteria:
1) For primary vaccination in children; or
2) For revaccination following immunosuppression; or
3) For any individual susceptible to measles, mumps or rubella**; or**
4) A maximum of three doses for children who have had their first dose prior to 12 months.
Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

- Meningococcal (groups A, C, Y, W-135) conjugate vaccine (Menactra) will remain listed in Section I and Part II of Section H of the Pharmaceutical Schedule effective from 1 July 2015 as follows (deletions in strike through, additions in bold):

Any of the following:
1) Up to three doses **and a booster every five years** for patients pre- and post splenectomy and for patients with functional or anatomic asplenia**, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant;** or
~~2) One dose every five years for patients with HIV, complement deficiency (acquired or inherited), functional or anatomic asplenia or pre or post solid organ transplant; or~~
2 ~~3~~) One dose for close contacts of meningococcal cases; or
3 4) A maximum of two doses for bone marrow transplant patients; or
4 ~~5~~) A maximum of two doses for patients following immunosuppression*.

Note: children under seven years of age require **two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly** ~~a second dose three years after the first and then five yearly.~~
*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

- Meningococcal C conjugated vaccine (Neisvac-C) will remain listed in Section I and Part II of Section H of the Pharmaceutical Schedule effective from 1 July 2015 as follows (deletions in strike through, additions in bold):

Any of the following:

1) Up to three doses **and a booster every five years** for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, **HIV, complement deficiency (acquired or inherited or pre or post solid organ transplant;** or

~~2) One dose every five years for patients with HIV, complement deficiency (acquired or inherited), functional or anatomic asplenia or pre or post solid organ transplant; or~~

2 ~~3~~) One dose for close contacts of meningococcal cases; or

3 ~~4~~) A maximum of two doses for bone marrow transplant patients; or

4 ~~5~~) A maximum of two doses for patients following immunosuppression*.

Note: children under seven years of age require **two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly** ~~a second dose three years after the first and then five yearly.~~

*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

- Pneumococcal (PCV13) vaccine (Prevenar 13) will remain listed in Section I and Part II of Section H of the Pharmaceutical Schedule effective from 1 July 2015 as follows (deletions in strike through, additions in bold):

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 18)** who have previously received four doses of PCV10; or

4) Up to an additional four doses (as appropriate) are funded for (re-)immunisation of patients with HIV, for patients post **haematopoietic stem cell transplantation**~~HSCT~~, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, **complement deficiency (acquired or inherited), cochlear implants**, **primary immunodeficiency** ~~and other severely immunosuppressive regimens up to~~ **under** ~~the age of 18~~; or

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

More information

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.