PHARMAC
TE PĀTAKA WHAIORANGA

Proposal to fund meningococcal B vaccine for close contacts of cases and people at higher risk of meningococcal disease

3 MAY 2021

Medicines

Consultation Closes 21 May

We are seeking feedback on a proposal to fund meningococcal B vaccine (Bexsero).

What we're proposing

We are proposing to fund meningococcal B vaccine (Bexsero) for people who are close contacts of meningococcal cases or are at higher risk of meningococcal disease, from 1 July 2021.

Vaccination would be funded for people who are close contacts of meningococcal cases of any meningococcal group (e.g. A, C, W, Y or B), or are at higher risk of meningococcal B disease because they are pre- or post-splenectomy, have functional or anatomic asplenia, HIV, complement deficiency, are pre- or post-solid organ transplant, following bone marrow transplant or following immunosuppression.

Our clinical advisors have reviewed and recommended several options for funding access to meningococcal vaccines. This proposal is to progress funding for the groups outlined above; other options for widening funded access to the meningococcal B and meningococcal ACWY vaccines remain under consideration.

Feedback to this consultation will help us decide if this proposal should be approved. Consultation closes at **5 pm on Friday, 21 May 2021** and feedback can be emailed to vaccines@pharmac.govt.nz *[mailto:vaccines@pharmac.govt.nz?subject=Consultation%20feedback%20-%20MeNZB%20vaccine]*.

What would the effect be?

From 1 July 2021, people who are close contacts of meningococcal cases, or are at higher risk of meningococcal B disease, would be eligible to receive funded meningococcal B vaccine from general practice.

We estimate that approximately 1,500 people would be eligible for vaccination each year.

Vaccination of eligible people would reduce their risk of meningococcal disease. Another meningococcal vaccine, Menactra, is already funded for these people and provides protection against meningococcal groups A, C, W and Y.

Meningococcal infection rates are typically higher in Māori and Pacific peoples compared to the total population. This proposal would improve access to meningococcal vaccination for Māori and Pacific peoples in the groups proposed for funding.

For funders and service providers

From 1 July 2021, PHARMAC expects there would be a small increase in eligible people accessing funded vaccination in primary care. We acknowledge that primary care has a high vaccination workload in 2021 with influenza and COVID-19 vaccination programmes, but do not anticipate the additional 1,500 eligible people would have a significant impact. The Ministry of Health is responsible for supporting the implementation of changes to the National Immunisation Schedule and would lead communications with service providers about the vaccination programme.

Funded vaccine supply would be available through ProPharma as with other funded vaccines. As with most other funded vaccines (apart from influenza vaccine), pharmacist vaccinators would not be able to administer this funded vaccine at this time. Significant changes would be required to the current funding process to allow pharmacists to administer funded vaccines. We continue to consider options for changes to the funding process that would allow pharmacists to administer funded vaccines in the future.

Who we think will be interested

- People with reduced immune function due to certain conditions, who may be at higher risk of meningococcal disease, close contacts of confirmed meningococcal cases, and their whānau
- Doctors in general practice, other primary care prescribers, nurses and vaccinators
- DHBs
- Suppliers and wholesalers
- Organisations with an interest in immunisation

About meningococcal disease and meningococcal B vaccine

Meningococcal disease is caused by the *Neisseria meningitidis* bacterium. Meningococcal bacteria are commonly carried in the nose and throat, and do not usually cause disease. Carriage rates are highest in teenagers and young adults. The bacterium can be spread from carriers or people with meningitis to other people by coughing, sneezing or contact with saliva. Occasionally a person who is carrying the bacterium may develop severe disease such as meningitis (inflammation of the membranes around the brain), septicaemia (blood infection) or pneumonia (lung infection). On average in New Zealand, meningococcal group B causes around two-thirds of meningococcal disease each year.

People who survive meningococcal disease may have long term consequences, including skin scarring, amputation of limbs and extremities, hearing loss, seizures or brain injury. Even when meningococcal disease is diagnosed and treated early, 10% to 20% of affected people may die.

The Bexsero brand of meningococcal vaccine is approved for immunisation for the prevention of invasive meningococcal disease caused by meningococcal group B strains. Each 0.5 ml dose of Bexsero meningococcal group B vaccine contains multiple components and is administered by deep intramuscular injection. Infants under one year of age require three doses, older children and adults require two doses.

Further information regarding Bexsero dosing and administration can be found in the product datasheet on the Medsafe website.(external link) *[https://www.medsafe.govt.nz/profs/Datasheet/b/bexseroinj.pdf]*

Why we're proposing this

In recent years there has been an increasing trend of meningococcal disease cases being notified in New Zealand, with 62 cases notified and 5 deaths in 2019 that were caused by meningococcal group B (the group covered by vaccination with Bexsero).

Our clinical advisors, the Pharmacology and Therapeutics Advisory Committee (PTAC) and the Immunisation Subcommittee of PTAC, have recommended funding with a high priority for meningococcal B vaccine for a range of different patient groups, including:

- contacts of cases;
- high risk immunocompromised patients;
- entrants to close living situations (13 to 25 years of age) with catch-up;
- entrants to close living situations (13 to 25 years of age) with no catch-up;
- infant immunisation schedule.

PHARMAC has evaluated all of these recommendations using our Factors for Consideration *[/medicine-funding-and-supply/the-funding-process/policies-manuals-and-processes/factors-for-consideration/]*, and is currently in a position to progress a funding proposal for the close contacts and high risk groups, which are the subject of this proposal. The additional groups recommended by our clinical experts remain under active consideration by PHARMAC for future funding.

More information about the assessment of funding for the all of these groups, including links to the relevant clinical advice, can be found on the Application Tracker.(external link)
[https://connect.pharmac.govt.nz/apptracker/s/global-search/Meningococcal%20group%20B%20vaccine%20-%20Invasive%20meningococcal%20disease]

Details about our proposal

We are proposing to list meningococcal B vaccine in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2021 for people who are close contacts of meningococcal cases of any group, or are at higher risk of meningococcal B disease.

A confidential net price would apply to Bexsero.

The eligibility criteria for meningococcal B vaccine (Bexsero) would be listed in in Section I and Part II of Section H of the Pharmaceutical Schedule as follows:

Pharmaceutical	Brand Name	Form	Strength	Pack Size	Proposed Price
Multicomponent meningococcal group B vaccine	Bexsero	Injection	175 mcg per 0.5 ml	1	$0.00*

*Vaccine prices are listed with zero cost in the Pharmaceutical Schedule as PHARMAC distributes them free of charge to vaccinators. A confidential purchase price would apply to Bexsero.

Bexsero would be listed with "Xpharm" restriction. An Xpharm listing means that pharmacies cannot claim subsidy because PHARMAC has made alternate distribution arrangements.

Section I

[Xpharm]

Either:

A) Both:

a. Child is under one year of age; and
b. Any of the following:
    i. up to three doses 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
    ii. up to three doses for close contacts of meningococcal cases of any group; or
    iii. up to three doses for child who has previously had meningococcal disease of any group; or
    iv. up to three doses for bone marrow transplant patients; or
    v. up to three doses for child following immunosuppression*; or

B) Both:

a. Person is one year of age and over; and
b. Any of the following:
    i. up to two 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
    ii. up to two doses for close contacts of meningococcal cases of any group; or
    iii. up to two doses for person who has previously had meningococcal disease of any group; or
    iv. up to two doses for bone marrow transplant patients; or
    v. up to two doses for person following immunosuppression*

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

Section H

Restricted

Initiation – Infants under one year of age

Any of the following:

a. up to three doses 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
b. up to three doses for close contacts of meningococcal cases of any group; or
c. up to three doses for child who has previously had meningococcal disease of any group; or
d. up to three doses for bone marrow transplant patients; or
e. up to three doses for person following immunosuppression*

Initiation – Person is one year of age and over

Any of the following:

a. up to two 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
b. up to two doses for close contacts of meningococcal cases of any group; or
c. up to two doses for person who has previously had meningococcal disease of any group; or
d. up to two doses for bone marrow transplant patients; or
e. up to two doses for person following immunosuppression*

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

The Ministry of Health is responsible for supporting the implementation of changes to the Nati Immunisation Schedule.

The Ministry of Health's Immunisation Handbook would be updated to reflect the changes to eligibility for meningococcal B vaccine(external link)
[https://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/new-zealand-immunisation-schedule].

To provide feedback

Send us an email: vaccines@pharmac.govt.nz
[mailto:vaccines@pharmac.govt.nz?subject=Consultation%20feedback%20-%20MeNZB%20vaccine] by **5 pm on Friday 21 May 2021**.

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Your feedback may be shared

Feedback we receive is subject to the Official Information Act 1982 (OIA). Please be aware that we may need to share your feedback, including your identity, in response to an OIA request. This applies to anyone providing feedback, whether they are providing feedback themselves or for an organisation, in a personal or professional capacity.

We can only keep feedback confidential as allowed under the OIA and other related laws. If you want any part of your feedback treated as confidential, you need to tell us. Please let us know if you want to keep part of your feedback confidential, and why. Is it commercially sensitive, confidential or proprietary, or personal information? Clearly state this and tell us which parts of your feedback you want to keep confidential for these reasons. We will consider your request under our OIA requirements.