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NHS England

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Service specification No.[31]

Meningococcal group B (MenB) programme

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Meningococcal group B (MenB) programme

Prepared by Public Health England

Contents

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This service specification is to be applied by NHS England in accordance with the NHS public health functions agreement 2015-16 (the '2015-16 agreement') published in December 2014. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2015-16 agreement was made between the Secretary of State and NHS England Board. Any changes in other published documents or standards may have effect for the purposes of the 2015-16 agreement in accordance with the procedures described in Chapter 3 of the 2015-16 agreement.

Service specifications should be downloaded in order to ensure that commissioners and providers refer to the latest document that is in effect.

The 2015-16 agreement including all service specifications is available at www.gov.uk (search for 'commissioning public health').

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply. It must always be read in conjunction with the core service specification https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016 and the online version of the Green Book: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

1. Purpose of MenB immunisation programme (new schedule)

1.1. This document relates to immunisation to protect against invasive disease caused by capsular group B meningococcal (MenB) bacteria. For the purposes of brevity, this immunisation is henceforth referred to as “MenB immunisation”.

1.2. The purpose of this service specification is to enable NHS England to commission immunisation services to a standard that will minimise infections, outbreaks and associated morbidity and mortality due to MenB bacteria. This means achieving high levels of immunisation coverage across England as well as within upper tier local government areas and within the context of populations with protected characteristics as defined by the Equality Act 2010.

1.3. This specification provides a brief overview of the vaccine including the disease it protects against, the context, evidence base, and wider health outcomes. It should be read alongside the core service specification which underpins national and local commissioning practices and service delivery.

1.4. These arrangements underpin national and local commissioning practices and service delivery. This specification will also promote a consistent and equitable approach to the provision of the commissioning and delivery of the MenB immunisation programme across England. It is important to note that this programme can change and evolve in the light of emerging best practice and scientific evidence. NHS England and providers will be required to reflect these changes accordingly in a timely way as directed by the national schedule.

1.5. *Immunisation against infectious disease* (known as ‘the Green Book’), issued by Public Health England (PHE) is the main source of guidance for all immunisation programmes. This service specification must be read in conjunction with the core service specification, the online version of the Green Book, all current relevant official public health letters, and with additional evidence, advice and recommendations issued by the Joint Committee on Vaccination and Immunisation (JCVI).

1.6. This service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions that may apply, e.g. the Health and Social Care Act 2012. The specification will be reviewed annually and amended in line with any new recommendations or guidance, and in line with reviews of the Section 7A agreement.

2. Population needs

Background

2.1. *Neisseria meningitidis* (the meningococcus) is the bacterium responsible for invasive meningococcal disease, which is a major cause of bacterial meningitis and septicaemia in children and adolescents in Europe.

2.2. The meningococcus can be characterised into 12 different capsular groups, of which four are responsible for most invasive meningococcal infections: B, C, W and Y. Since the introduction of the MenC conjugate vaccine in 1999, the number of cases of MenC disease in the UK has reduced markedly. MenB is currently responsible for most meningococcal cases in children and adults.

2.3. Bexsero® is a novel multi-component, protein-based meningococcal vaccine that was licensed for use in Europe in January 2013 to protect against MenB disease. In the UK it is already available free of charge to children and adults who have problems with their immune system (including having no spleen, poorly functioning spleen or complement deficiency). It is also available for laboratory workers who are at occupational risk of exposure to MenB bacteria.

2.4. In March 2014, the Joint Committee on Vaccination and Immunisation (JCVI) recommended that the MenB vaccine should be introduced into the NHS's routine immunisation schedule for children, provided it could be obtained at a cost-effective price. The vaccine should be given at 2 and 4 months of age, with a booster at 12 months. There are no plans for a catch-up programme for older children because the main burden of the disease is in young babies. There will be a one-off limited catch-up programme for infants aged 3 or 4 months when the routine programme starts. The MenB vaccine will only be offered with the routine immunisation appointments.

2.5. Current estimates indicate that Bexsero® will prevent 73-88% of all MenB infections in infants and toddlers. Because this vaccine contains surface proteins that are present in all meningococci, it could also protect against other capsular groups such as MenC, MenW and MenY. However, because meningococcal disease is currently uncommon, the proportion of cases that will be prevented by vaccination will not be known until the vaccine is used routinely in a large population.

2.6. More than a million individuals worldwide have already received Bexsero® without any significant safety concerns. Clinical trials have shown that the vaccine can be administered at the same time as the routine infant vaccinations including diphtheria, tetanus, polio, pertussis, Hib and hepatitis B, without affecting immune responses to the individual vaccine antigens. However, higher rates of fever and local tenderness at the injection sites were noted when Bexsero® was given with the routine infant vaccines compared to when Bexsero® was administered alone.

Meningococcal disease

2.7. *Neisseria meningitidis* is the bacterium responsible for meningococcal disease, a serious, life-threatening infection characterised by meningitis (infection and inflammation of the lining of the brain), septicaemia (blood poisoning) or both.

2.8. Meningococcal infection is spread by prolonged close contact. Around 5-10% of adults carry the bacteria harmlessly in their throats without any signs or symptoms of the disease. Carriage rates are very low in infants and young children but can be as high as 25% in teenagers. It is not fully understood why disease develops in some individuals but not in others.

2.9. Like most of Europe, the number of cases of meningococcal disease has been declining since the early 2000s, most likely because of natural secular trends. In England there were around 600 cases in 2014 in England and 400 were caused by MenB. Meningococcal disease peaks in winter. The highest incidence is in infants younger than 1 year, followed by toddlers (1-4 year-olds), with a secondary peak in incidence in young people aged 15 to 19 years.

2.10. Approximately one in ten people who develop meningococcal disease will die. With early diagnosis and treatment most people make a full recovery, but around a tenth of survivors of MenB disease may have major physical and/or neurological disabilities, including limb amputation, deafness, epilepsy and/or learning difficulties.

Men B immunisation – key details

2.11. The key details are that:

- MenB vaccine should be given to babies at two and four months of age, with a booster at 12-13 months.
- Immunisation will take place as part of the national schedule, and must be given at the same visit as the other scheduled vaccines.
- A 5ml sachet of liquid paracetamol will be offered to the parent / carer at the time of their first vaccination should they not already have any. A dose of 2.5ml should be administered from the sachet at the time of, or soon after, vaccination and the remaining paracetamol discarded. The parent / carer should be advised to purchase their own supply of liquid paracetamol for subsequent doses as two further 2.5ml doses of paracetamol are recommended to be given 4 to 6 hours apart, after both primary doses of MenB vaccination, but not the booster. N.B. three doses in total following vaccination.
- A one-off catch-up programme for 3 and 4 month-old infants at the start of the routine programme, with doses at 3, 4, 12-13 months for 3 month-old infants; and doses at 4 and 12-13 months for 4 month-old infants; will be implemented. Bexsero® should be offered when the children attend their routine 3 and 4 month vaccination visits.

3. Scope

Aims

3.1. The aim of the MenB immunisation programme is to protect infants and young children against MenB disease which can cause meningitis and septicaemia.

Objectives

3.2. The aim will be achieved by delivering an evidence-based immunisation programme that:

- identifies the eligible population and ensures effective timely delivery with optimal coverage
- is safe, effective, of a high quality and is independently monitored
- is delivered and supported by suitably trained, competent healthcare professionals who participate in recognised ongoing training and development in line with national standards
- delivers, manages and stores vaccine in accordance with national guidance
- is supported by regular and accurate data collection using the appropriate returns.

Direct health outcomes

3.3. In the context of health outcomes, the MenB immunisation programme aims to:

- Protect the health of individuals and the wider population
- Reduce the number of preventable infections and their onward transmission
- Achieve high coverage in the target cohort
- Minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).

Baseline vaccine coverage

3.4. Local services must aim to offer MenB vaccination to 100% of eligible individuals in accordance with the Green Book and other PHE, NHS England or Department of Health guidance. Local services should look to achieve at least 90% uptake as measured at two years of age.

4. Service description / care pathway

Local service delivery

4.1. The delivery of immunisation services at the local level is based on evolving best practice. This section of the document specifies the high-level operational elements of the national MenB immunisation programme, based on best practice that NHS England must use to inform local commissioning, contracts and service delivery. There is also scope to enable NHS England and providers to enhance and build on specifications to incorporate national or local service aspirations that may include increasing local innovation in service delivery. However, in order to promote a nationally aligned high-quality programme focusing on improved outcomes, increasing coverage and local take-up, it is essential that all the following elements are included in contracts and specifications.

Target population

4.2. Providers will be required to make the MenB vaccine available to:

- All eligible children both registered and unregistered with a GP, as part of the childhood immunisation programme's primary immunisation course. The first dose should be given to children at 2 months of age, the second dose at 4 months of age, and a third booster dose at 12-13 months.
- Immunisation will take place as part of the national schedule, and must be given at the same visit as other scheduled vaccines.

Vaccine schedule

- Routine schedule for all infants:

Cohort	**Date of Birth**	**Priming Dose**	**Priming Dose**	**Booster**
Routine	01/07/2015 onwards	2 months	4 months	12-13 months
Catch-up	01/05/2015 to 30/06/2015	3 months	4 months	12-13 months
		N/A	4 months	12-13 months

- Infants born before the 1st May 2015 will not be eligible for the MenB vaccination through the national MenB infant programme.
- For those born on or after the 1st May 2015 to the 30th June 2015, if their **third** routine primary immunisation appointment is due on or after 1st September 2015, they would follow the **1+1 schedule** at **4 and 12 months**, if their **second** routine

primary immunisation appointment is due on or after 1st September 2015 then they would follow the **2+1 schedule** at **3, 4 and 12 months**.

- In order to provide early protection, providers must aim to complete the schedule as near as possible to the recommended ages.
- Further information on scheduling is available in the relevant chapters of *Immunisation against infectious disease* (The Green Book) https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

Vaccine ordering

4.3. All centrally procured vaccines must be ordered via the ImmForm online ordering system (www.immform.dh.gov.uk), details of which are given in the core specification.