Enhanced Service Specification

Meningococcal B (MenB) infant vaccination programme 2015/16
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All GMS practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This Enhanced Service (ES) specification outlines more specialised services to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

This Enhanced Service is directed at GP practices delivering vaccination and immunisation services in England.

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Meningococcal B (MenB) infant vaccination programme

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The National Health Service Commissioning Board was established on 1 October 2012 as an executive non-departmental public body. Since 1 April 2013, the National Health Service Commissioning Board has used the name NHS England for operational purposes

Equalities and Health Inequalities Statement:

"Promoting equality and addressing health inequalities are at the heart of NHS England’s values. Throughout the development of the policies and processes cited in this document, we have

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities.”
Contents

Meningococcal B (Men) infant vaccination programme ........................................... 1
Contents .................................................................................................................. 4

1 Introduction ......................................................................................................... 5
2 Background ........................................................................................................ 5
3 Aims. ..................................................................................................................... 6
4 Process ................................................................................................................ 6
5 Service specification ............................................................................................ 7
6 Monitoring. .......................................................................................................... 9
7 Payment and validation. ....................................................................................... 10

Annex: Administrative provisions relating to payments ...................................... 12
1 Introduction

1.1 All GMS practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This Enhanced Service (ES) specification outlines more specialised services to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

1.2 This ES\(^1\) is directed at GP practices\(^2\) delivering vaccination and immunisation services in England.

1.3 This ES is agreed between NHS Employers (on behalf of NHS England) and the British Medical Association (BMA) General Practitioners Committee (GPC).

2 Background

2.1 In March 2014 the Joint Committee on Vaccination and Immunisation (JCVI) recommended the vaccination of infants against meningococcal group B infection (MenB) to protect them from this strain of meningococcal bacteria.

2.2 There are 12 types of Meningococci (A, B, C, E, H, I, K, L, W, X, Y and Z). B, C, Y and W are the most common types in the UK. Since the introduction of the routine MenC programme in November 1999 the number of cases of MenC have greatly reduced. Currently, MenB accounts for 80% of cases of invasive meningococcal disease.

2.3 Meningococcal disease is more common in children under five years, with a higher number of cases in babies under 12 months of age and peak incidence at five months of age.

2.4 This new routine programme is a three dose programme for babies aged two, four and 12 to 13 months of age. The two doses at two and four months

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\(^1\) Section 7a functions are described as ‘reserved functions’ which are not covered by the ‘enhanced services delegated to CCG’ category in the delegation agreement. NHS England remains responsible and accountable for the discharge of all the Section 7a functions. As this vaccination is defined as a Section 7a function, this agreement cannot be changed or varied locally.

\(^2\) Reference to ‘GP practice’ in this specification refers to a provider of essential primary medical services to a registered list of patients under a General Medical Services, Personal Medical Services or Alternative Provider Medical Services contract.
constitute the “primary course” required to ensure optimum protection for babies ahead of peak incidence at five months. The third dose at 12 to 13 months provides longer term protection. A short-term catch-up element is included under this ES.

2.5 The vaccine will be centrally supplied through ImmForm for use for all patients eligible for vaccination under this ES. A single dose of prophylactic paracetamol will also be supplied for first doses only (at either two, three or four months old). Further details on the background, dosage, timings and administration of the vaccination can be found in the Green Book\(^3\) and supporting guidance\(^4\).

3 Aims

3.1 The aim of this ES is to support commissioners in establishing a MenB infant vaccination service with GP practices in order to prevent cases of the disease, deaths and long-term physical, cognitive and psychological effects. The most severe long-term complications include hearing loss, visual impairment, communication problems, limb amputations, seizures and brain damage.

4 Process

4.1 This ES commences on 1 September and runs to 31 March 2016.

4.2 Commissioners will seek to invite GP practices to participate in this ES before 1 July 2015. Practices who participate in this ES should respond to the commissioner’s offer within 30 days. The agreement should be recorded in writing with their commissioner no later than 31 July 2015.

4.3 Participating practices are also required to sign up to the Calculating Quality Reporting Service (CQRS)\(^5\). Commissioners will record GP practices' participation on CQRS by 31 August 2015.

5 Service specification

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\(^4\) NHS Employers. Vaccination and immunisation programmes 2015/16 guidance and audit requirements. [www.nhsemployers.org/vandi](http://www.nhsemployers.org/vandi)

\(^5\) Further guidance relating to CQRS will be provided by HSCIC when services are updated.
5.1 The requirements for GP practices participating in the ES are as follows in this section.

5.2 **Provide MenB vaccination** unless contra-indicated and **supply a single sachet of paracetamol**\(^6\) oral suspension 120 mg/5 mL **with the first dose**, to eligible patients.

a. Eligible patients are those who:

i. are registered at the practice,

ii. are born on or after 1 July 2015 and are aged two, four and 12 to 13 months\(^7\) (inclusive) at the time of vaccination,

iii. as part of the catch-up element are born between 1 May 2015 and 30 June 2015. These patients should be vaccinated on an opportunistic basis, however it is likely that catch-up doses would fall within the timings for the existing routine childhood immunisations schedule as follows. No first doses should be given on or after five months of age.

<table>
<thead>
<tr>
<th>Attending on or after 1 September for:</th>
<th>Recommended immunisation schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Third dose of DTaP-IPV-Hib and second dose of PCV13</td>
<td>Give MenB at same opportunity and booster at 12 to 13 months (1+1)</td>
</tr>
<tr>
<td>Second dose of DTaP-IPV-Hib and first dose MenC</td>
<td>Give MenB at same opportunity and further dose in one month and a booster at age 12 to 13 months (2+1)</td>
</tr>
<tr>
<td>First dose of DTaP-IPV-Hib and first dose PCV13</td>
<td>Give MenB at same opportunity and further dose in one month and a booster at age 12 to 13 months (2+1)</td>
</tr>
</tbody>
</table>

b. Immunisation is contra-indicated where the patient has previously had a confirmed anaphylactic reaction to a previous dose of the vaccine, or to any component of the vaccine.

c. As this programme will fit in with the existing routine childhood immunisations scheme there is no requirement for practices to operate additional call and recall specific to this vaccination.

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\(^6\) A single 5 ml sachet of prophylactic paracetamol will be supplied centrally and will available to order via ImImForm for the child’s first visit. Practices will able to supply one sachet per child and then advise parents to buy further supplies of paracetamol liquid suspension to administer at home.

\(^7\) Where the MenB programme refers to the dose at ‘12 to 13 months’, this means infants aged 12 months, up to the day before they become 14 months.
5.3 Take all reasonable steps to ensure that the medical records of patients receiving a MenB vaccine are kept up-to-date with regard to the immunisation status and in particular, include:

a. any refusal of an offer of immunisation.

b. where an offer of immunisation was accepted and:
   i. details of the informed consent to the immunisation,
   ii. the batch number, expiry date and title of the vaccine,
   iii. the date of administration,
   iv. when two or more vaccines are administered in close succession the route of administration and the injection site of each vaccine,
   v. any contra-indication to the vaccination or immunisation,
   vi. any adverse reactions to the vaccination or immunisation.

5.4 Ensure all doses of MenB vaccine administered are communicated to the local Child Health Informatics System (CHIS).

5.5 Ensure that all healthcare professionals who are involved in administering the vaccine have:

a. referred to the clinical guidance available; and

b. the necessary experience, skills and training, including training with regard to the recognition and initial treatment of anaphylaxis.

5.6 Ensure that all vaccine ordering is conducted in line with national guidance, including adherence to any limits on stocks to be held at any one time. Vaccines will be supplied centrally, ordered from ImmForm as per other centrally supplied vaccines.

5.7 Ensure that all vaccines are stored in accordance with the manufacturer's instructions and that all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that the readings are taken and recorded from that thermometer on all working days.

5.8 Services will be accessible, appropriate and sensitive to the needs of all service users. No eligible patient shall be excluded or experience particular difficulty in accessing and effectively using this ES due to their race, gender, disability, sexual orientation, religion and/or age.
5.9 Providers will monitor and report activity information via ImmForm on a monthly basis. The activity information shall include a monthly count of all eligible patients who received a vaccination in the relevant month.

5.10 Practices who agree to participate in this ES will be required to indicate acceptance on CQRS to enable CQRS to calculate the monthly payment achievement.

5.11 Practices will be required to input data manually into CQRS. The Read codes which must be used to record activity are available in the document “Technical requirements for 2015/16 GMS contract changes”.

5.12 Where the patient’s parent or legal guardian has indicated they wish to receive the vaccination but is physically unable to attend the practice (for example is housebound) the practice must make all reasonable effort to ensure the patient is vaccinated.

6 Monitoring

6.1 Commissioners will monitor services and calculate payments under this ES using CQRS, wherever possible.

6.2 Practices will be required to manually input data into CQRS. For information on how to manually enter data into CQRS, see the HSCIC website.

6.3 The ‘Technical Requirements document’ contains the payment counts and Read2 and CTV3 codes which are required for this service. Practices should use the relevant Read2 or CTV3 codes or re-code if necessary, only those included in this document will be acceptable. Practices will therefore need to ensure that they use the relevant codes from the commencement of this service and re-code patients where necessary.

7 Payment and validation

7.1 Claims for payments for this programme should be made monthly. Where claims are entered manually, this should be within 12 days of the end of the month when the dose was administered. Where there is an automated data

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8 NHS Employers. Technical requirements for 2015/16 GMS contract changes. www.nhsemployers.org/vandi
9 HSCIC. http://systems.hscic.gov.uk/cqrs/participation
collection, there is a five (working) day period following the month end to allow practices to record the previous month’s activity before the collection occurs. Activity recorded after the collection period is closed (five days), will not be collected and recorded on CQRS. Practices must ensure all activity is recorded by the cut-off date to ensure payment.

7.2 Payment will be made by the last day of the month following the month in which the practice validates and commissioners approve the payment.

7.3 Payments will commence provided that the GP practice has manually entered achievement, or GPES\textsuperscript{10} has collected the data.

7.4 Practices who wish to participate in this ES will be required to sign up to CQRS no later than 31 August 2015.

7.5 Payment is available to participating GP practices under this ES as an item of service payment of £7.64 per dose to eligible patients in accordance with the ‘Service specification section’ and provisions within this ES specification. GP practices will also receive an additional payment of £2.12 per dose to recognise the tight timeframe for implementation and delivery of the programme.

7.6 GP practices will only be eligible for payment for this ES in circumstances where all of the following requirements have been met:

a. The GP practice is contracted to provide vaccinations and immunisations as part of additional services.

b. All patients in respect of whom payments are being claimed were on the GP practice’s registered list at the time the vaccine was administered and all of the following apply:

i. The GP practice administered the vaccine to all patients in respect of whom the payment\textsuperscript{11} is being claimed.

ii. All patients in respect of whom payment is being claimed were within the cohort (as per the service specification section) at the time the vaccine was administered.

\textsuperscript{10} See ‘Process’ section for information relating to sign-up and automated collection.

\textsuperscript{11} Section 7a functions are described as ‘reserved functions’ which are not covered by the ‘enhanced services delegated to CCG’ category in the delegation agreement. NHS England remains responsible and accountable for the discharge of all the Section 7a functions. As this vaccination is defined as a Section 7a function, this agreement cannot be changed or varied locally.
iii. The GP practice did not receive any payment from any other source or under any other programme in respect of the vaccine (should this be the case, then the commissioners may reclaim any payments as set out in the annex).

iv. The GP practice submits the claim within six months\textsuperscript{12} of administering the vaccine (commissioners may set aside this requirement if it considers it reasonable to do so).

7.7 As the vaccine is centrally supplied, no claims for reimbursement of vaccine costs or personal administration fee apply.

7.8 Commissioners will be responsible for post payment verification. This may include auditing claims of practices to ensure that they meet the requirements of this ES.

7.9 Administrative provisions relating to payments under this ES are set out in the Annex.

\textsuperscript{12} In line with the SFE and only applicable if CQRS is not being used.
Annex. Administrative provisions relating to payments under the ES for meningococcal B (MenB) infant vaccination programme

1. Payments under this ES are to be treated for accounting and superannuation purposes as gross income of the GP practice in the financial year.

2. Claims for payments for this programme should be made monthly, after the final completing dose has been administered. Where claims are entered manually, this should be within 12 days of the end of the month when the completing dose was administered. Where there is an automated data collection, there is a five (working) day period following the month end to allow practices to record the previous month’s activity before the collection occurs. Activity recorded after the collection period is closed (five days), will not be collected and recorded on CQRS. Practices must ensure all activity is recorded by the cut-off date to ensure payment.

3. Payment will be made by the last day of the month following the month in which the practice validates and commissioners approve the payment.

4. Payment under this ES, or any part thereof, will be made only if the GP practice satisfies the following conditions:

   a. the GP practice must make available to commissioners information under this ES, which the commissioner reasonably requires and the GP practice either has or could be reasonably expected to obtain,

   b. the GP practice must make any returns reasonably required of it (whether computerised or otherwise) to the Exeter Registration System or CQRS, and do so promptly and fully; and,

   c. all information supplied pursuant to or in accordance with this paragraph must be accurate and up to date.

5. If the GP practice does not satisfy any of the above conditions, commissioners may, in appropriate circumstances, withhold payment of any, or any part of, an amount due under this ES that is otherwise payable.

6. If a commissioner makes a payment to a GP practice under this ES and:

   a. the GP practice was not entitled to receive all or part thereof, whether because it did not meet the entitlement conditions for the payment or because the payment was calculated incorrectly (including where a payment on account overestimates the amount that is to fall due); or
b. the commissioner was entitled to withhold all or part of the payment because of a breach of a condition attached to the payment, but is unable to do so because the money has already been paid; or

a. the commissioner is entitled to repayment of all or part of the money paid,

commissioners may recover the money paid by deducting an equivalent amount from any payment payable to the GP practice and where no such deduction can be made, it is a condition of the payments made under this ES that the contractor must pay to the commissioner that equivalent amount.

7. Where the commissioner is entitled under this ES to withhold all or part of a payment because of a breach of a payment condition and the commissioner does so or recovers the money by deducting an equivalent amount from another payment in accordance with paragraph 6 of this annex, it may, where it sees fit to do so, reimburse the contractor the amount withheld or recovered, if the breach is cured.

Provisions relating to GP practices that terminate or withdraw from this ES prior to 31 March 2016 (subject to the provisions below for termination attributable to a GP practice split or merger)

8. Where a GP practice has entered into this ES but its primary medical care contract subsequently terminates or the GP practice withdraws from the ES prior to 31 March 2016, the GP practice is entitled to a payment in respect of its participation if such a payment has not already been made, calculated in accordance with the provisions set out below. Any payment calculated will fall due on the last day of the month following the month during which the GP practice provides the information required.

9. In order to qualify for payment in respect of participation under this ES, the GP practice must provide the commissioner with the information in this ES specification or as agreed with commissioners before payment will be made. This information should be provided in writing, within 28 days following the termination of the contract or the withdrawal from the ES agreement.
10. The payment due to GP practices that terminate or withdraw from the ES agreement prior to 31 March 2016 will be based on the number of vaccinations given, prior to the termination or withdrawal.

**Provisions relating to GP practices who merge or split**

11. Where two or more GP practices merge or are formed following a contractual split of a single GP practice and as a result the registered population is combined or divided between new GP practice(s), the new GP practice(s) may enter into a new or varied agreement to provide this ES.

12. The ES agreements of the GP practices that formed following a contractual merger, or the GP practice prior to contractual split, will be treated as having terminated and the entitlement of those GP practice(s) to any payment will be assessed on the basis of the provisions of paragraph 8 of this annex.

13. The entitlement to any payment(s) of the GP practice(s), formed following a contractual merger or split, entering into the new or varied agreement for this ES, will be assessed and any new arrangements that may be agreed in writing with the commissioner, will commence at the time the GP practice(s) starts to provide such arrangements.

14. Where that new or varied agreement is entered into and the new arrangements commence within 28 days of the new GP practice(s) being formed, the new arrangements are deemed to have commenced on the date of the new GP practice(s) being formed. Payment will be assessed in line with this ES specification as of this commencement date.

**Provisions relating to non-standard splits and mergers**

15. Where the GP practice participating in the ES is subject to a split or a merger and:

   a. the application of the provisions set out above in respect of splits or mergers would, in the reasonable opinion of the commissioner, lead to an inequitable result; or,

   b. the circumstances of the split or merger are such that the provisions set out in this section cannot be applied,
commissioners may, in consultation with the GP practice or GP practices concerned, agree to such payments as in the commissioner’s opinion are reasonable in all circumstances.