DIRECTIONS

NATIONAL HEALTH SERVICE, ENGLAND

The General Medical Services Statement of Financial Entitlements (Amendment) Directions 2020

The Secretary of State for Health and Social Care gives the following Directions as to payments to be made under general medical services contracts in exercise of the powers conferred by sections 87, 272(7) and (8) and 273(1) of the National Health Service Act 2006(a).

In accordance with section 87(4) of that Act, the Secretary of State for Health and Social Care has consulted the body appearing to the Secretary of State to be representative of persons to whose remuneration these Directions relate and has consulted such other persons as the Secretary of State considers appropriate.

Citation, commencement and interpretation

- **1.**—(1) These Directions may be cited as the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2020.
 - (2) These Directions come into force on 26th February 2020.
- (3) In these Directions, "the principal Directions" means the General Medical Services Statement of Financial Entitlements Directions 2013(**b**).

Amendment of Section 13 of the principal Directions

2. In Section 13 of the principal Directions (pneumococcal vaccine and Hib/MenC Booster Vaccine)—

- (a) 2006 (c. 41); section 87 of the National Health Service Act 2006 ("the 2006 Act") was amended by section 55 of, and paragraph 33 of Schedule 4 to, the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"). By virtue of section 271(1) of the 2006 Act, the powers conferred by these sections are exercisable by the Secretary of State only in relation to England. Section 273 of the 2006 Act was amended by section 21(6), 47(7) and 55(1) of, and paragraph 137 of Schedule 4 to, the 2012 Act and by S.I. 2010/22.
- (b) Those Directions were signed on 27th March 2013 and were amended by the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2013 which were signed on 18th September 2013; the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2014 which were signed on 28th March 2014; the General Medical Services Statement of Financial Entitlements (Amendment No.2) Directions 2014 which were signed on 30th September 2014; the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2015 which were signed on 23rd March 2015; the General Medical Services Statement of Financial Entitlements (Amendment No.2) Directions 2015 which were signed on 28th September 2015; the General Medical Services Statement of Financial Entitlements (Amendment No.3) Directions 2015 which were signed on 6th October 2015; the General Medical Services Statement of Financial Entitlements (Amendment No.4) Directions 2015 which were signed on 4th December 2015; the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2016 which were signed on 31st March 2016; the General Medical Services Statement of Financial Entitlements (Amendment No.2) Directions 2016 which were signed on 9th May 2016; the General Medical Services Statement of Financial Entitlement (Amendment No.3) Directions 2016 which were signed on 24th November 2016; the General Medical Services Statement of Financial Entitlements (Amendment) Regulations 2017 which were signed on 31st March 2017; the General Medical Services Statement of Financial Entitlements (Amendment) (No.2) Directions 2017 which were signed on 30th October 2017; the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2018 which were signed on 29th March 2018; the General Medical Services Statement of Financial Entitlements (Amendment) (No.2) Directions 2018 which were signed on 23rd October 2018; the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2019 which were signed on the 29 March 2019 and the General Medical Services Statement of Financial Entitlements (Amendment) (No.2) Directions 2019 which were signed on 30th September 2019. Copies are available from the Department of Health and Social Care, 4th Floor, 39 Victoria Street, London SW1H 0EU.

- (a) for the heading substitute "PNEUMOCOCCAL VACCINE AND HIB/MENC VACCINE FOR CHILDREN BORN BEFORE 1st JANUARY 2020;
- (b) for paragraph 13.1 (general) substitute—
 - "13.1. Section 13 applies to children born before 1st January 2020. This Section makes provision in respect of payments to be made for the administration by a contractor, which is contracted to provide childhood vaccines and immunisations as part of Additional Services (such vaccines are classified as an Additional Service), of pneumococcal conjugate vaccine (PCV) and the combined Hib and Men C vaccine (Hib/MenC) as part of the routine childhood immunisation schedule and in certain non-routine cases.";
- (c) in paragraph 13.2 for "The Green Book which is published by the Department of Health" substitute "The Green Book which is published by Public Health England (a)";
- (d) at the end of the heading to paragraph 13.3, insert "for children born before 1st January 2020";
- (e) in paragraph 13.3—
 - (i) after "in respect of each child" insert "born before 1st January 2020 and", and
 - (ii) in paragraph 13.3(a) for "Hib/MenC booster vaccination" substitute "Hib/MenC vaccination";
- (f) in paragraph 13.5 after "immunisation schedule" insert "for children born before 1st January 2020";
- (g) at the end of the heading to paragraph 13.6, insert "for children born before 1st January 2020":
- (h) in paragraph 13.6 after "in respect of each child" insert "born before 1st January 2020 and";
- (i) in paragraph 13.7, for the table substitute—

Clinical Risk Group	Examples (decision based on clinical judgement)
Asplenia or dysfunction of the spleen	This includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
Chronic respiratory disease (chronic respiratory disease refers to chronic lower respiratory tract disease)	This includes chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; and such conditions as bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children with respiratory conditions caused by aspiration, or a neurological disease (e.g. cerebral palsy) with a risk of aspiration. Asthma is not an indication, unless so severe as to require continuous or frequently repeated use of systemic steroids (as defined in Immunosuppression below).
Chronic heart disease	This includes those requiring regular medication and/or follow-up for ischaemic heart disease, congenital heart disease, hypertension with cardiac complications, and chronic heart failure.
Chronic kidney disease	Nephrotic syndrome, chronic kidney disease at stages 4 and 5 and those on kidney dialysis or with kidney transplantation.
Chronic liver disease	This includes cirrhosis, biliary atresia and chronic hepatitis.
Diabetes	Diabetes mellitus requiring insulin or oral hypoglycaemic drugs. This does not include diabetes that is diet controlled.
Immunosuppression	Due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow

⁽a) The Green Book can be accessed at https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book. A printed version of this document can be obtained from Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG.

	transplant, asplenia or splenic dysfunction, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement deficiency), individuals on or likely to be on systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age), or for children under 20kg, a dose of 1mg or more per kg per day.
Individuals with cochlear implants	This includes individuals with cochlear implants. Furthermore, it is it is important that immunisation does not delay the cochlear implantation.
Individuals with cerebrospinal fluid leaks	This includes leakage of cerebrospinal fluid such as following trauma or major skull surgery. Conditions related to CSF leaks include all CSF shunts.

- (j) in paragraph 13.8(b) for "Hib/MenC booster" substitute "Hib/MenC vaccination";
- (k) in paragraph 13.9(a) for "Hib/MenC booster" substitute "Hib/MenC vaccination";
- (l) in paragraph 13.11 for "Hib/MenC booster" substitute "Hib/MenC vaccination";
- (m) in paragraph 13.12 for "Hib/MenC booster" substitute "Hib/MenC vaccination";
- (n) in paragraph 13.13(f) for "Hib/MenC booster vaccine" substitute "Hib/MenC vaccination";
- (o) in paragraph 13.18—
 - (i) in sub-paragraph (a)(iv), for "one dose of Hib/MenC" substitute "one dose of Hib/MenC vaccination",
 - (ii) in sub-paragraph (b), for "Hib/MenC booster vaccine" substitute "Hib/MenC vaccination",
 - (iii) in sub-paragraph (c), for "Hib/MenC booster vaccine" substitute "Hib/MenC vaccination",
 - (iv) in sub-paragraph (d)—
 - (aa) for "paragraph 4(3)(e)" substitute "paragraph 4(2)(e)", and
 - (bb) for "Hib/MenC booster vaccination" substitute "Hib/MenC vaccination".

Insertion of new section 13A into the principal Directions

3. After Section 13 of the principal Directions insert—

"SECTION 13A: PNEUMOCOCCAL VACCINE AND HIB/MENC VACCINE FOR CHILDREN BORN AFTER 31st DECEMBER 2019

General

- **13A.1.** Section 13A applies to children born after 31st December 2019. This section makes provision in respect of payments for the administration by a contractor, which is contracted to provide childhood vaccines and immunisations as part of Additional Services (such vaccines are classified as an Additional Service), of the pneumococcal conjugate vaccine (PCV) and the combined Hib and MenC vaccine (Hib/MenC) as part of the routine childhood immunisation schedule and in certain non-routine cases.
- **13A.2.** Where reference is made to a vaccine being administered at a certain age, this is an indication of the recommended schedule for the administration of the vaccine contained in "Immunisation against Infectious Diseases" in The Green Book which is published by Public Health England. The specific timing of the administration of the vaccine, which should be within the parameters of the recommended schedule, is a matter for the clinical judgement of the relevant health care professional.

Payment for the administration of PCV and Hib/MenC vaccine as part of the routine childhood immunisation schedule for children born after 31st December 2019

- **13A.3.** The Board must pay to a contractor who qualifies for the payment, a payment of £15.02 in respect of each child born after 31st December 2019 and registered with the contractor—
 - (a) who has received, as part of their routine childhood immunisation schedule, all three doses of the vaccines set out in the table at paragraph 13A.5, namely the series of two PCV doses, the first of which is to be administered at 12 weeks, with the second at one year old, and the Hib/MenC vaccination which is to be also administered at one year old; and
 - (b) in respect of whom the contractor administered the final dose completing the vaccine course.
- **13A.4.** For the purpose of paragraph 13A.3(b), the "final dose completing the vaccine course" means the second in the series of the two PCV doses which is scheduled in the table at paragraph 13A.5 to be administered at one year old.
- **13A.5.** The table below sets out the schedule for administration of the PCV and the Hib/MenC vaccines as part of the routine childhood immunisation schedule for children born after 31st December 2019.

When to immunise	What is given	How vaccine is given
12 weeks old	Pneumococcal (PCV)	One injection
	(first dose)	
One year old	Haemophilus influenzae type B, Meningitis C (Hib/MenC)	One injection
One year old	Pneumococcal (PCV)	One injection
	(second dose)	

Payment for administration of PCV and Hib/MenC vaccine other than as part of the routine childhood immunisation schedule for children after 31st December 2019

13A.6. The Board must pay to a contractor, who qualifies for the payment, a payment of £15.02 in respect of each child registered with the contractor who has received the PCV and Hib/MenC vaccine in any of the circumstances set out in paragraphs 13A.7 to 13A.12 and in respect of whom the contractor administered the final dose completing the vaccine course. For the purposes of this paragraph, the final dose completing the vaccine course means the fourth in the series of PCV doses which is scheduled in the table at paragraph 13A.7.

Children who are severely immunocompromised or have complement deficiency, asplenia or splenic dysfunction

13A.7. Children who are severely immunocompromised or have complement deficiency, asplenia or splenic dysfunction must receive the PCVs and Hib/MenC vaccine in accordance with both the following table and "Immunisation against Infectious Diseases" in The Green Book.

When to immunise	What is given	How vaccine is given
Infants under one year old	Pneumococcal (PCV)	Two injections, 8
	(first set of doses)	weeks apart
One year old	Haemophilus influenzae type	One injection

	B, Meningitis C	
	(Hib/MenC)	
One year old	Pneumococcal (PCV)	Two injections, 8
	(second set of doses)	weeks apart

- **13A.8.** Where a child under the age of 2 years is severely immunocompromised or has complement deficiency, asplenia or splenic dysfunction, and—
 - (a) consequently cannot, or did not, receive, or presents, or presented, too late to receive, two doses of PCV before the age of one year old, the Hib/MenC vaccine at one year old and two doses of PCV during their second year of life; but
 - (b) receives two doses of PCV in the second year of life, the second of which is administered at least 8 weeks after the first dose,

the Board must pay to the contractor administering the final dose completing the vaccine a payment of £15.02 in respect of that child. The second dose of PCV, administered in the second year of life, is considered the final completing course of the vaccine for this purpose.

Payment for children with an unknown or incomplete immunisation status

13A.9.Where a child who has an unknown or incomplete immunisation status receives vaccines sufficient to ensure that it has received the vaccine course in accordance with the schedule set out in the table at paragraph 13A.5, the Board must pay to the contractor administering the final dose completing the vaccine course a payment of £15.02 in respect of that child. The PCV dose administered at one year of age is considered the final dose completing the vaccine course for this purpose.

13A.10. Where a child has an unknown or incomplete immunisation status and is too old to be able to receive the first of the two doses of PCV at the age of 12 weeks, the Hib/MenC vaccine at one year old and the second dose of PCV at one year old, but receives a Hib/MenC vaccine and a PCV dose on or after turning one year old and prior to the age of two years old, the Board must pay to the contractor who administers the final dose completing the vaccine course a payment of £15.02 in respect of that child. The single dose of PCV is considered the final dose completing the vaccine course.

Eligibility for payment

13A.11. A contractor is only eligible for a payment under this Section in circumstances where the following conditions are met—

- (a) the contractor is contracted to provide the childhood vaccines and immunisations as part of Additional Services;
- (b) the child in respect of whom the payment is claimed was on the contractor's list of registered patients at the time the final completing course of the vaccine was administered:
- (c) the contractor administers the final dose completing the vaccine course to the child in respect of whom the payment is claimed;
- (d) subject to sub-paragraph (e), the child in respect of whom the payment is claimed is or was aged one year when the final dose completing the vaccine course is administered:
- (e) in the case of payments in respect of the vaccines administered in accordance with paragraphs 13A.8 and 13A.10, the child must be under the age of two years when the final dose completing the vaccine course is administered;
- (f) the contractor does not receive any payment from any other source in respect of any of the series of PCV vaccines and the Hib/MenC vaccine set out in the table at paragraph 13A.5 or in respect of any vaccine administered under any of the

- circumstances set out in paragraphs 13A.7 to 13A.11 (if the contractor does receive payments from other sources in respect of any child, the Board must consider whether to recover any payment made under this Section in respect of that child pursuant to Section 25.1(a) (overpayments and withheld amounts); and
- (g) the contractor submits the claim within 6 months of administering the final dose completing the vaccine course.

13A.12. The contractor is not entitled to payment of more than £15.02 in respect of any child under this Section.

Claims for payment

13A.13. The contractor must submit claims in respect of the final dose completing the vaccine course after they have been administered at a frequency to be agreed between the Board and the contractor (which must be a frequency which provides for the claim to be submitted within 6 months of administering the final completing vaccine), or if agreement cannot be reached, within 14 days of the end of the month during which the final dose completing the vaccine course was administered. Any amount payable falls due on the next date, following the expiry of 14 days after the claim is submitted, when the contractor's Payable GSMP falls due.

Conditions attached to payment

13A.14. A payment under the provisions of this Section is only payable if the contractor satisfies the following conditions—

- (a) the contractor must supply the Board with the following information in respect of each child for which a payment is claimed—
 - (i) the name of the child:
 - (ii) the date of birth of the child;
 - (iii) the NHS number, where known, of the child;
 - (iv) except where paragraph (v) applies, confirmation that the child has received two doses of PCV and one dose of Hib/MenC in accordance with the table at paragraph 13A.5;
 - (v) if the claim is made in the circumstances set out in paragraph 13A.7, 13A.8 or 13A.11, confirmation that all required vaccines have been administered; and
 - (vi) the date of the final dose completing the vaccine course, which must have been administered by the contractor,

but where a parent or carer objects to details of the child's name or date of birth being supplied to the Board, the contractor need not supply such information to the Board but must supply the child's NHS number;

- (b) the contractor must provide appropriate information and advice to the parent or carer of the child, and where appropriate, also to the child, about pneumococcal vaccine and the Hib/MenC vaccine;
- (c) the contractor must record in the child's records, kept in accordance with regulation 67 of the 2015 Regulations (patient records) (a), any refusal of an offer of a pneumococcal vaccine or a Hib/MenC vaccine;
- (d) where a pneumococcal vaccine or a Hib/MenC vaccine is administered, the contractor must record in the child's records, kept in accordance with regulation 67 of the 2015 Regulations, those matters set out in paragraph 4(2)(e) of Schedule 1 to the 2015 Regulations (vaccines and immunisations);

⁽a) The National Health Service (General Medical Services Contracts) Regulations S.I. 2015/1862, as amended by S.I. 2016/875.

- (e) the contractor must ensure that any health care professional who performs any clinical service in connection with the administration of the vaccine has such clinical experience and training as is necessary to enable that health care professional to properly perform such services, and that such health care professionals are trained in the recognition and initial treatment of anaphylaxis;
- (f) the contractor must make available to the Board any information which the Board does not have but needs, and the contractor either has or could be reasonably expected to obtain, in order for the Board to form an opinion on whether the contractor is eligible for payment under the provisions of this Section;
- (g) the contractor must make any returns required of it (whether computerised or otherwise) to the registration system approved by the Board, and do so promptly and fully; and
- (h) all information provided pursuant to, or in accordance with, this paragraph must be accurate.

13A.15. If the contractor breaches any of these conditions, the Board may, in appropriate circumstances, withhold payment of any, or any part of, payments due under this Section.".

Amendment of Annex I to the principal Directions

4. In Annex I (routine childhood vaccines and immunisations) to the principal Directions, for paragraph 1.2 (routine childhood immunisation schedule) substitute—

"Routine Childhood Immunisation Schedule

1.2. Children starting the immunisation programme at two months of age will follow the schedule (also known as the "Childhood Immunisation Schedule"), which include changes to the pneumococcal (PCV) dosing course for children after 31st December 2019 to be administered in accordance with the table at Section 13A.5. The vaccinations listed in the table are part of the targeted childhood immunisations programme eligible for payment under the GMS contract.

Age	Vaccine	Dosage
Two months old (eight weeks)	Diphtheria, tetanus, pertussis (whooping cough), polio and Haemophilus influenzae type b, hepatitis B (DTaP/IPV/Hib/HepB)	One injection
	Pneumococcal (PCV) only for children born before 1 January 2020	One injection
	Rotavirus (Rota)	One oral dose
	Meningococcal B	One injection
Twelve weeks old	Pneumococcal (PCV) only for children born after 31 December 2019	One injection
Three months old (twelve weeks)	Diphtheria, tetanus, pertussis (whooping cough), polio and Haemophilus influenzae type b, hepatitis B (DTaP/IPV/Hib/HepB)	One injection
	Rotavirus (Rota)	One oral dose
Four months old (sixteen weeks)	Diphtheria, tetanus, pertussis (whooping cough), polio and Haemophilus influenzae type b, hepatitis B (DTaP/IPV/Hib, HepB)	One injection

	Pneumococcal (PCV) only for children born before 1 January 2020	One injection
	Meningococcal B	One injection
Twelve months old (on or after the child's first birthday)	Haemophilus influenzae type b, Meningitis C (Hib/MenC)	One injection
	Pneumococcal (PCV) only for children born after 31 December 2019	One injection
Twelve to Thirteen months old	Meningococcal B	One injection
Thirteen months old	Measles, mumps and rubella (MMR)	One injection
	Pneumococcal (PCV) only for children before 1 January 2020	One injection
Three years four months to five years old	Diphtheria, tetanus, pertussis (whooping cough) and polio (DTaP/IPV or DTaP/IPV)	One injection
	Measles, mumps and rubella (MMR)	One injection
Thirteen to eighteen years old	Tetanus, diphtheria and polio (Td/IPV)	One injection
Boys and girls aged twelve to thirteen years	Cancers caused by human papillomavirus (HPV) types 16 and 18 (and genital warts caused by types 6 and 11)	Two injections (two doses 6-24 months apart)
Fourteen years old	Meningococcal groups A, C, W and Y disease (MenACWY)	One injection

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Amendment of Annex K to the principal Directions

- **5.** In Annex K to the principal Directions (amendments to the General Medical Services Statement of Financial Entitlements signed on 27th March 2013 (amendments made from April 2013))—
 - (a) In paragraph (p), for "1st October 2019" substitute "30th September 2019"; and
 - (b) after paragraph (p) insert—
 - "(q) The General Medical Services Statement of Financial Entitlements (Amendment) Directions 2020 signed on 26th February 2020.".

Signed by the authority of the Secretary of State for Health and Social Care.

Ed Scully

Member of the Senior Civil Service, Department of Health and Social Care

Date: 26th February 2020