# WG23-40

# THE NATIONAL HEALTH SERVICE (WALES) ACT 2006

Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 3) Directions 2023

Made 03 August 2023

Coming into force 1 September 2023

The Welsh Ministers, in exercise of the powers conferred on them by sections, 45, 203(9) and (10) and 204(1) of the National Health Service (Wales) Act 2006(a) and after consulting in accordance with section 45(4) of that Act with the bodies appearing to them to be representative of persons to whose remuneration these Directions relate, give the following Directions.

#### Title, application and commencement

- **1.**—(1) The title of these Directions is the Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 3) Directions 2023.
- (2) These Directions are given to Local Health Boards. They relate to the payments to be made by Local Health Boards to a GMS contractor under a GMS contract.
  - (3) These Directions are made on 03 August 2023 and come into force on 1 September 2023.

#### **Amendment to the Statement of Financial Entitlements**

**2.** The Directions to Local Health Boards as to the Statement of Financial Entitlements Directions 2013(**b**) which came into force on 11 June 2013, as amended by Directions listed in Annex J of the Schedule to these Directions, are further amended as follows.

#### **Amendment to the TABLE OF CONTENTS**

**3.** In the TABLE OF CONTENTS in PART 4 PAYMENTS FOR SPECIFIC PURPOSES for "10. SHINGLES IMMUNISATION PROGRAMME" substitute—

# "10. SHINGLES IMMUNISATION PROGRAMME IMMUNOCOMPROMISED

General

Payment for administration of the Shingles vaccine

Eligibility for payment

Claims for payment

**Conditions attached to payment** 

<sup>(</sup>a) 2006 c. 42.

**<sup>(</sup>b)** 2013 No. 8.

#### 10A. SHINGLES IMMUNISATION PROGRAMME IMMUNOCOMPETENT

General

Administration of the Shingrix® vaccine
Payment for administration of the Shingrix® vaccine
Eligibility for payment
Claims for payment".

#### Amendment of PART 4 – PAYMENTS FOR SPECIFIC PURPOSES

**4.**—(1) For *Section 10: SHINGLES IMMUNISATION PROGRAMME - ZOSTAVAX*® substitute—

"Section 10: SHINGLES IMMUNISATION PROGRAMME IMMUNOCOMPROMISED

#### General

**10.1.** Section 10 makes provision in respect of payments to be made in respect of the administration by a contractor to provide the Shingrix® vaccines as part of the Shingles Immunisation Programme to immunocompromised individuals as defined by the Greenbook chapter 28a, aged 50 years and over (with no upper age limit), including those anticipating immunosuppressive therapy. Further details on the Shingles Immunisation Programmes can be found in WHC (2023) 024.

# Administration of the Shingrix® vaccine

- **10.2.** Contractors must offer two doses of Shingrix® vaccine to immunocompromised eligible patients who are 50 years and over, including those anticipating immunosuppressive therapy, from 1 September 2023.
- **10.3.** The second dose should be administered eight weeks to 6 months after the first dose.
- **10.4.** Rollout to immunocompromised individuals who are aged over 50 years should take place in the first year beginning with 1 September 2023 and concluding by 1 September 2024.
- **10.5.** Beginning with the 1 September 2024 immunocompromised individuals who turn 50 years old should be offered vaccination within 12 weeks of reaching their invitation age.
- **10.6.** Contractors should also opportunistically vaccinate those individuals aged 50 or over from 1 September 2023 who missed their original appointment.
- **10.7.** Newly diagnosed unvaccinated immunocompromised individuals already over 50 years old should be vaccinated within 12 weeks of immunocompromised diagnosis.

# Payment for administration of the Shingrix® vaccine

**10.8.** A contractor may claim a payment of £10.03 in respect of each dose given to immunocompromised registered patients who are aged 50 or over beginning with 1 September 2023.

# Eligibility for payment

- **10.9.** A contractor is only eligible to make a claim for a payment under this Section in circumstances where the following conditions are met—
  - (i) the patient in respect of whom the payment is claimed was on the contractor's list of registered patients at the time the vaccine was administered;

- (ii) the contractor administers the vaccine to the patient in respect of whom the payment is claimed;
- (iii) the patient in respect of whom the payment is claimed falls within the groups referred to in paragraph 10.2 to 10.7 when the vaccine is administered;
- (iv) the contractor does not receive any payment from any other source in respect of the vaccine (if the contractor does receive any such payment in respect of any patient from any other source, the LHB must give serious consideration to recovering any payment made under this Section in respect of that patient pursuant to paragraphs 19.1 and 19.2 (overpayments and withheld amounts); and
- (v) the contractor submits the claim within 6 months of administering the vaccine.
- **10.10.** The LHB may set aside the requirement that the contractor submit the claim within 6 months of administering the vaccine if it considers it is reasonable to do so.

#### Claims for payment

- 10.11. The contractor must submit claims after administering each dose of the Shingrix® vaccine at a frequency to be agreed between the LHB and the contractor (which must be a frequency which provides for the claim to be submitted within 6 months of administering the vaccination), or if agreement cannot be reached, within 14 days of the end of the month during which the vaccine 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.
- **10.12.** The LHB must ensure that the receipt and payment in respect of any claims are properly recorded and that each claim has a clear audit trail.

#### Conditions attached to payment

- **10.13.** A claim for payment under the provisions of this Section is only payable by the LHB if the contractor satisfies the following conditions—
  - (a) the contractor must supply the LHB with the following information in respect of each patient for which a payment is claimed—
    - (i) the name of the patient;
    - (ii) the date of birth of the patient;
    - (iii) the NHS number, where known, of the patient;
    - (iv) confirmation that the patient has received the vaccine in accordance with paragraph 10.2;
    - (v) the date on which the vaccine was administered by the contractor,

but where the patient objects to details of that patient's name or date of birth being supplied to the LHB, the contractor need not supply such information to the LHB but must supply the patient's NHS number;

- (b) the contractor must—
  - (i) develop a proactive and preventative approach to offering immunisation by adopting robust call and reminder systems to contact patients, with the aims of—
    - (aa) maximising uptake in the interests of patients, and
    - (bb) meeting any public health targets in respect of such immunisations;
  - (ii) make up to three attempts to contact eligible individuals within 12 weeks of reaching their invitation age. At least one of these contacts must be a written invitation.

- (c) a requirement that the engaged GMS contractor takes all reasonable steps to ensure that the lifelong medical records held by an at-risk patient's general practitioner are kept up to date with regard to their immunisation status and, in particular, to include—
  - (i) any refusal of an offer of vaccination, or
  - (ii) where an offer of vaccination was accepted—
    - (aa) details of the consent to the vaccination or immunisation (where a person has consented on an at-risk patient's behalf, that person's relationship to the at-risk patient must also be recorded),
    - (bb) the batch number, expiry date and title of the vaccine,
    - (cc) dose administered,
    - (dd) the date of the administration of the vaccine,
    - (ee) where 2 vaccines are administered, the route of administration and the injection site of each vaccine,
    - (ff) any contraindication to the vaccination or immunisation,
    - (gg) any adverse reaction to the vaccination or immunisation;
- (d) a requirement that the engaged GMS contractor ensures that it adheres to the current guidance in chapter 3 (Storage, distribution and disposal of vaccines) of the latest edition of the Green Book(a);
- (e) a requirement that the engaged GMS contractor supplies Public Health Wales with information on patients, via automated data extraction, for the purposes of monitoring local and national uptake;
- (f) the contractor must provide appropriate information and advice to the patient about the vaccine and immunisation;
- (g) 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 are 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;
- (h) the contractor must make available to the LHB any information which the LHB does not have but needs, and the contractor either has or could be reasonably expected to obtain, in order to form its opinion on whether the contractor is eligible for payment under the provisions of this Section;
- (i) all information provided pursuant to or in accordance with this paragraph must be accurate.
- **10.14.** If the contractor breaches any of these conditions, the LHB may, in appropriate circumstances, withhold payment of all or any part of any payment due under this Section."

(2) For *Section 10A: SHINGLES IMMUNISATION PROGRAMME - SHINGRIX*® substitute—

"Section 10A: SHINGLES IMMUNISATION PROGRAMME IMMUNOCOMPETENT

#### General

**10A.1.** Section 10A makes provision in respect of payments to be made in respect of the administration by a contractor to provide the Shingrix® vaccine as part of the Shingles

<sup>(</sup>a) https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3

Immunisation Programme to immunocompetent individuals. Further details on the Shingles Immunisation Programmes can be found in WHC (2023) 024(a).

#### Administration of the Shingrix® vaccine

Phase 1

- **10A.2.** From 1 September 2023 to 31 August 2028, those individuals who reach age 65 or 70 years during this period should be called in on/after their 65<sup>th</sup> or 70<sup>th</sup> birthday for their first dose of Shingrix®.
- **10A.3.** The second dose of Shingrix® should be administered 6 to 12 months after the first dose.
- **10A.4.** Those cohorts previously eligible for Zostavax® prior to 1 September 2023 remain eligible until their 80<sup>th</sup> birthday. Those individuals who are under 80 years of age, should continue to be offered Zostavax® (unless contraindicated) until central stocks deplete when they should be offered Shingrix®.
- **10A.5.** Where an individual has turned 80 years of age following their first dose of Shingrix®, a second dose should be provided before the individual's 81st birthday to complete the course.
- **10A.6.** If the individual received Zostavax® there is no need for a second dose as Zostavax is a one dose schedule.

Phase 2

- **10A.7.** From 1 September 2028 to 31 August 2033, those individuals who reach age 60 or 65 years during this period should be called in on/after their 60<sup>th</sup> or 65<sup>th</sup> birthday for their first dose of Shingrix®.
  - **10A.8.** The second dose should be administered 6 to 12 months after the first dose.

#### **Ongoing routine offer**

- **10A.9.** From 1 September 2033 onwards, those individuals turning 60 years of age should be called in on/after their 60<sup>th</sup> birthday. Those who have been previously eligible will remain eligible until their 80<sup>th</sup> birthday.
  - **10A.10.** The second dose should be administered 6 to 12 months after the first dose.

# **Opportunistic Vaccination**

- **10A.11.** In instances where an individual has already attained or passed the age of 65 but not yet 80 for phase one, or 60 but not yet 80 in phase two, then contractors can accommodate opportunistic vaccination if operationally possible.
  - **10A.12.** The second dose should be administered 6 to 12 months after the first dose.

#### Eligibility for payment

- **10A.13.** A contractor is only eligible to make a claim for a payment under this Section in circumstances where the following conditions are met—
  - (i) the patient in respect of whom the payment is claimed was on the contractor's list of registered patients at the time the vaccine was administered;
  - (ii) the contractor administers the vaccine to the patient in respect of whom the payment is claimed;

<sup>(</sup>a) https://www.gov.wales/changes-shingles-vaccinations-september-2023-whc2023024

- (iii) the patient in respect of whom the payment is claimed falls within the age group referred to in paragraph 10A.2 to 10A.5 and 10A.7 to 10A.12 when the vaccine is administered;
- (iv) the contractor does not receive any payment from any other source in respect of the vaccine (if the contractor does receive any such payment in respect of any patient from any other source, the LHB must give serious consideration to recovering any payment made under this Section in respect of that patient pursuant to paragraphs 19.1 and 19.2 (overpayments and withheld amounts); and
- (v) the contractor submits the claim within 6 months of administering the vaccine.
- **10A.14.** The LHB may set aside the requirement that the contractor submit the claim within 6 months of administering the vaccine if it considers it is reasonable to do so.

#### Claims for payment

**10A.15.** The contractor must submit claims after administering each dose of the Shingrix® vaccine at a frequency to be agreed between the LHB and the contractor (which must be a frequency which provides for the claim to be submitted within 6 months of administering the vaccination), or if agreement cannot be reached, within 14 days of the end of the month during which the vaccine 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.

**10A.16.** The LHB must ensure that the receipt and payment in respect of any claims are properly recorded and that each claim has a clear audit trail.

#### Conditions attached to payment

- **10A.17.** A claim for payment under the provisions of this Section is only payable by the LHB if the contractor satisfies the following conditions—
  - (a) the contractor must supply the LHB with the following information in respect of each patient for which a payment is claimed—
    - (i) the name of the patient;
    - (ii) the date of birth of the patient;
    - (iii) the NHS number, where known, of the patient;
    - (iv) confirmation that the patient has received the vaccine in accordance with paragraph 10A.2 to 10A.8;
    - (v) the date on which the vaccine was administered by the contractor,

but where the patient objects to details of that patient's name or date of birth being supplied to the LHB, the contractor need not supply such information to the LHB but must supply the patient's NHS number;

- (b) the contractor must -
  - (i) develop a proactive and preventative approach to offering immunisation by adopting robust call and reminder systems to contact patients, with the aims of—
    - (aa) maximising uptake in the interests of patients, and
    - (bb) meeting any public health targets in respect of such immunisations;
    - (cc) make up to three attempts to contact eligible individuals within 12 weeks of reaching their invitation age. At least one of these contacts must be a written invitation.
- (c) a requirement that the engaged GMS contractor takes all reasonable steps to ensure that the lifelong medical records held by an at-risk patient's general practitioner are

kept up to date with regard to their immunisation status and, in particular, to include—

- (i) any refusal of an offer of vaccination, or
- (ii) where an offer of vaccination was accepted—
  - (aa) details of the consent to the vaccination or immunisation (where a person has consented on an at-risk patient's behalf, that person's relationship to the at-risk patient must also be recorded).
  - (bb) the batch number, expiry date and title of the vaccine,
  - (cc) dose administered,
  - (dd) the date of the administration of the vaccine.
  - (ee) where 2 vaccines are administered, the route of administration and the injection site of each vaccine,
  - (ff) any contraindication to the vaccination or immunisation,
  - (gg) any adverse reaction to the vaccination or immunisation;
- (d) a requirement that the engaged GMS contractor ensures that it adheres to the current guidance in chapter 3 (Storage, distribution and disposal of vaccines) of the latest edition of the Green Book(a);
- (e) a requirement that the engaged GMS contractor supplies Public Health Wales with information on patients, via automated data extraction, for the purposes of monitoring local and national uptake;
- (f) the contractor must provide appropriate information and advice to the patient about the vaccine and immunisation;
- (g) 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 are 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;
- (h) the contractor must make available to the LHB any information which the LHB does not have but needs, and the contractor either has or could be reasonably expected to obtain, in order to form its opinion on whether the contractor is eligible for payment under the provisions of this Section;
- (i) all information provided pursuant to or in accordance with this paragraph must be accurate.

**10A.18.** If the contractor breaches any of these conditions, the LHB may, in appropriate circumstances, withhold payment of all or any part of any payment due under this Section.

# **Amendment of Annex J**

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**5.** For **ANNEX J - AMENDMENTS** substitute Annex J in the Schedule 1 to these Directions.

(a) https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3

Signed by Paul Casey, Deputy Director of Primary Care under the authority of the Minister for Health and Social Services, one of the Welsh Ministers

**Date: 03 August 2023** 

### SCHEDULE

Direction 5

#### "ANNEX J – AMENDMENTS

# Amendments to the Directions to the Local Health Boards as to the Statement of Financial Entitlements Directions 2013, which came into force on 11 June 2013

- (a) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2013 (2013 No.60), which were made on 30 September 2013;
- (b) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2014 (2014 No.3), which were made on 16 June 2014;
- (c) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 2) Directions 2014 (2014 No.17), which were made on 27 June 2014;
- (d) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 3) Directions 2014 (2014 No.24), which were made on 30 September 2014;
- (e) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2015 (2015 No.7), which were made on 31 March 2015;
- (f) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment No 2) Directions 2015 (2015 No.14), which were made on 01 April 2015;
- (g) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment No 3) Directions 2015 (2015 No.15), which were made on 20 April 2015;
- (h) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment No 4) Directions 2015 (2015 No.19), which were made on 25 June 2015;
- (i) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No.5) Directions 2015, which were made on 30 September 2015;
- (j) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2016, which were made on 30 March 2016;
- (k) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 2) Directions 2016, which were made on 11 April 2016:
- (I) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 3) Directions 2016, which were made on 13 July 2016;
- (m) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 4) Directions 2016 (2016 No.19), which were made on 16 August 2016;
- (n) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No.5) Directions 2016 which were made on 15 December 2016;

- (o) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 6) Directions 2017 which were made on 31 January 2017;
- (p) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2017 which were made on 27 April 2017;
- (q) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No.2) Directions 2017 which were made on 9 August 2017;
- (r) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No.3) Directions 2017 which were made on the 28 September 2017;
- (s) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2018 which were made on the 14 June 2018;
- (t) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 2) Directions 2018 which were made on 19 November 2018;
- (u) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2019 which were made on 29 March 2019;
- (v) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 2) Directions 2019 which were made on 28 June 2019;
- (w) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 3) Directions 2019 which were made on 29 August 2019;
- (x) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 4) Directions 2019 which were made on 30 September 2019;
- (y) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 5) Directions 2019 which were made on 14 October 2019:
- (z) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2020 which were made on 24 March 2020;
- (aa) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 2) Directions 2020 which were made on 22 June 2020;
- (bb) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 3) Directions 2020 which were made on 15 July 2020;
- (cc) Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 4) Directions 2020 which were made on 16 September 2020;
- (dd) Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 5) Directions 2020 which were made on 2 November 2020;
- (ee) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2021 which were made on 19 April 2021;
- (ff) The Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 2) Directions 2021 which were made on 31 August 2021;
- (gg) Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No.3) Directions 2021 which were made on 1 December 2021;

- (hh) Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2022 which were made on 29 March 2022;
- (ii) Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 2) Directions 2022 which were made on 8 June 2022;
- (jj) Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 3) Directions 2022 which were made on 4 November 2022;
- (kk) Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 4) Directions 2022 which were made on 29 November 2022;
- (II) Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) Directions 2023 which were made on 20 February 2023; and
- (mm) Directions to Local Health Boards as to the Statement of Financial Entitlements (Amendment) (No. 2) Directions 2023 which were made on 29 March 2023.