This is an "as amended" version prepared by the Welsh Government, it incorporates the amendments made by The Primary Care (Contracted Services: Immunisations) (Amendment) Directions 2022 to assist readers, it is not an official version of the Subordinate Legislation.

S U B O R D I N A T E L E G I S L A T I O N

WG No. 21-97

THE NATIONAL HEALTH SERVICE (WALES) ACT 2006

The Primary Care (Contracted Services: Immunisations) (Amendment) Directions 2021

Made	3 December 2021
Coming into force	4 December 2021

The Welsh Ministers, in exercise of the powers conferred on them by sections 10, 12(3) and 203(9) and (10) of the National Health Service (Wales) Act $2006(\mathbf{a})$, make the following Directions.

Title, application and commencement

1.—(1) The title of these Directions is the Primary Care (Contracted Services: Immunisations) (Amendment) Directions 2021.

- (2) These Directions are given to Local Health Boards.
- (3) These Directions come into force on 4 December 2021.

Amendment of the Primary Care (Contracted Services: Immunisations) Directions 2021

2.—(1) The Primary Care (Contracted Services: Immunisations) Directions 2021(**b**) are amended as follows.

(2) In Direction 4(4), in subparagraph (e)—

- (a) in paragraph (i) omit "and",
- (b) in paragraph (ii) for "." substitute ", and", and
- (c) after paragraph (ii) insert—
 - "(iii) in addition to the fee specified in sub-paragraph (i) and for the period beginning with 4 December 2021 and ending with 31 March 2022—
 - (aa) £2.42 per Covid-19 vaccine administered on a working day or a Saturday,
 - (bb) £7.42 per Covid-19 vaccine administered on a Sunday, and
 - (cc) $\pounds 17.42$ per Covid-19 vaccine administered at the location where the patient normally resides but which is not a care home(c).".

⁽**a**) 2006 c. 42.

⁽**b**) WG No. 21-70.

⁽c) 'care home' means a place in Wales at which accommodation, together with nursing or care, is provided to persons because of their vulnerability or need.

(3) In Schedule 1 (Primary Care Contracted Services: Immunisations (Covid-19 vaccines) Specification)—

- (a) in section 7., after paragraph a. insert—
 - "b. In addition to the payments specified in paragraph a., for the period beginning with 4 December 2021 and ending with 31 March 2022, the Local Health Board must pay to an engaged provider who qualifies for payment in accordance with Directions 5 to 7 a payment of
 - i £2.42 per Covid-19 vaccine administered on a working day or a Saturday under this PCCS:I,
 - ii £7.42 per Covid-19 vaccine administered on a Sunday under this PCCS:I, and
 - iii £17.42 per Covid-19 vaccine administered under this PCCS:I at the location where the patient normally resides, but which is not a care home.".
- (b) in Appendix A, in the list of eligible cohorts for entry 14 substitute "14.children and young people aged 12 to 15 years (see Appendix B for further information)";
- (c) for Appendix B substitute

"Appendix B

This appendix provides a summary of the information on vaccinating children and young people aged 12-17 years with the Pfizer BioNTech (Comirnaty) Covid-19 vaccine.

The information contained in this Appendix is correct at the time the Directions that establish or amend this PCCS:I come into force. Engaged providers must read the current and any future advice from the JCVI and Welsh Government's Chief Medical Officer in this regard.

Summary of JCVI advice – JCVI advice on the UK vaccine response to the Omicron variant - GOV.UK (www.gov.uk), 29 November 2021

1. All children and young people aged 12 to 15 years should be offered a second dose (30-micrograms) of the Pfizer-BioNTech COVID-19 vaccine at a minimum of 12 weeks from the first dose.

Summary of JCVI advice - Joint Committee on Vaccination and Immunisation (JCVI) advice on COVID-19 vaccination in people aged 16 to 17 years: 15 November 2021 -GOV.UK (www.gov.uk)

1. JCVI advises that young people aged 16 to 17 years who are not in an at risk group should be offered a second dose of Pfizer-BioNTech (Comirnaty) COVID-19 vaccine. See the Summary of JCVI advice of 4 August 2021 below for further information on the at-risk groups for young people aged 16 to 17 years.

2. The second vaccine dose should be given 12 weeks or more following the first vaccine dose.

3. For persons who have had proven SARS CoV-2 infection and a first dose of vaccine, the second vaccine dose should be given 12 weeks or more following the first vaccine dose, or 12 weeks following SARS-CoV-2 infection, whichever is later.

Summary of UK Chief Medical Officers' advice — (Written Statement: COVID-19 Vaccination — JCVI & Chief Medical Officers' advice on vaccinating 12-15 year olds (14 September 2021) | GOV.WALES)

1. The UK CMOs recommend that all children and young people aged 12-15 years not already covered by existing JCVI advice should be offered a first dose of Pfizer-BioNTech (Comirnaty) COVID-19 vaccine.

Summary of JCVI advice - 31 August 2021 (JCVI statement on COVID-19 vaccination of children aged 12 to 15 years: 3 September 2021 - GOV.UK (www.gov.uk))

1. A small number of children and young people with underlying chronic conditions are at increased risk of serious COVID-19 disease and therefore, children and young people aged 12 years and over with specific underlying health conditions should be offered a course of the Pfizer-BioNTech (Comirnaty) Covid-19 vaccination. This includes:

- (a) Children and young people aged 12 to 15 years with the following specific underlying health conditions that put them at risk of serious COVID 19; severe neuro-disabilities, Down's Syndrome, underlying conditions resulting in immunosuppression, those with profound and multiple learning disabilities, severe learning disabilities or who are on the learning disability register, haematological malignancy, sickle cell disease, type 1 diabetes, congenital heart disease and other health conditions as described with the JCVI advice under 'COVID 19 clinical risk groups for children aged 12 to 15 years'.
- (b) Children and young people with poorly controlled asthma are at higher risk from COVID-19. Those children and young people with poorly controlled asthma should be offered a course of COVID-19 vaccination.
- (c) A course of COVID-19 vaccination refers to a 2-dose primary schedule unless the individual is severely immunosuppressed when a 3-dose primary schedule is advised in accordance with the latest JCVI advice on third primary vaccine doses (see the Green Book, Chapter 14a).
- (d) Children and young people aged 12 years and over who are household contacts of persons (adults or children) who are immunosuppressed should be offered vaccination on the understanding that the main benefits from vaccination are related to the potential for indirect protection of their household contact who is immunosuppressed.

Summary of JCVI advice for young people aged 16 to 17 years — August 2021 (JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years: 4 August 2021 - GOV.UK (www.gov.uk)

1. JCVI advises that all young people aged 16 to 17 years, should be offered a first dose of Pfizer-BioNTech (Comirnaty) Covid-19 vaccine. This is in addition to the existing offer of 2 doses of vaccine to 16 to 17 year olds who are in 'at-risk' groups included in the Green Book.

2. Pending further evidence of effectiveness and safety in this age group, a second vaccine is anticipated to be offered later to increase the level of protection and to contribute towards longer term protection. Further data and the potential availability of alternative vaccine options will inform exact details which will be provided in a subsequent update of JCVI advice before second doses are due at approximately 12 weeks after the first dose.

3. It is considered operationally reasonable to allow a lead-in time to offer vaccination to those young people who are within three months of their 18th birthday to ensure good uptake of vaccine in newly-turned 18 year olds (2 doses).";

(d) for Appendix C substitute

"Appendix C

This appendix provides a summary of the information on the administration of booster doses.

The information contained in this Appendix is correct at the time the Directions that establish or amend this PCCS:I come into force. Engaged providers must read the current and any future JCVI advice in this regard.

JCVI advice on the UK vaccine response to the Omicron variant - GOV.UK (www.gov.uk), 29 November 2021

1. Booster vaccination eligibility should be expanded to include all adults aged 18 years to 39 years.

2. Booster vaccination should now be offered in order of descending age groups, with priority given to the vaccination of older adults and those in a COVID-19 at risk group. Booster vaccination should not be given within 3 months of completion of the primary course.

3. Severely immunosuppressed individuals who have completed their primary course (3 doses) should be offered a booster dose with a minimum of 3 months between the third primary and booster dose. Those who have not yet received their third dose may be given the third dose now to avoid further delay. A further booster dose can be given in 3 months, in line with the clinical advice on optimal timing.

4. Both the Moderna (50 microgram) and Pfizer-BioNTech (30 microgram) vaccines should be used with equal preference in the COVID-19 booster programme. Both vaccines have been shown to substantially increase antibody levels when offered as a booster dose.

Update to JCVI advice on booster vaccination in adults, 15 November 2021 - GOV.UK (www.gov.uk)

1. JCVI advises that all adults aged 40 to 49 years should be offered a booster vaccination with an mRNA COVID-19 vaccine, 6 months after their second dose, irrespective of the vaccines given for the first and second doses.

2. Booster vaccination should preferably be undertaken with either the Pfizer-BioNTech vaccine (BNT162b2/Comirnaty®), or a half dose of Moderna (mRNA-1273/Spikevax®) vaccine, as previously advised.

3. Future considerations include the need for booster vaccination (third dose) for 18 to 39 year olds who are not in an at-risk group, and whether additional booster vaccination (fourth dose) for more vulnerable adult groups may be required. At present, it is not known whether recurrent boosters will be required in the long term, and more data is required to inform these decisions as we move into 2022.

JCVI statement regarding a COVID-19 booster vaccine programme for winter 2021 to 2022 - GOV.UK (www.gov.uk) 14 September 2021

1. JCVI advises that for the 2021 COVID-19 booster vaccine programme individuals who received vaccination in Phase 1 of the COVID-19 vaccination programme (priority groups 1 to 9) should be offered a third dose COVID-19 booster vaccine. This includes:

- those living in residential care homes for older adults
- all adults aged 50 years or over
- frontline health and social care workers
- all those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19 (as set out in the green book), and adult carers
- adult household contacts (aged 16 or over) of immunosuppressed individuals

2. As most younger adults will only have received their second COVID-19 vaccine dose in late summer or early autumn, the benefits of booster vaccination in this group will be considered at a later time when more information is available. In general, younger, healthy individuals may be expected to generate stronger vaccine induced immune responses from primary course vaccination compared to older individuals. Pending further evidence otherwise, booster doses in this population may not be required in the near term.

3. JCVI will review data as they emerge and consider further advice at the appropriate time on booster vaccinations in younger adult age groups, children aged 12 to 16 years with underlying health conditions, and women who are pregnant.".

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

Lade

Date: 3 December 2021