

# **Directed Enhanced Service Specification**

**Seasonal influenza and pneumococcal  
polysaccharide vaccination programme 2020/21**

# Directed Enhanced Service (DES) Specification

## Seasonal flu and pneumococcal vaccination programme

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Updated: September 2020. The seasonal influenza DES specification (Part 2) has been updated to reflect the changes to the national flu immunisation programme – including the additional eligible cohorts - as outlined at [www.gov.uk/government/publications/national-flu-immunisation-programme-plan](http://www.gov.uk/government/publications/national-flu-immunisation-programme-plan)

Prepared by NHS England and NHS Improvement

### **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."

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Please be aware that all aspects of this service specification outline the requirements for this programme. As such, commissioners and GP practices should ensure they have read and understood all sections of this document as part of the implementation of this programme.

Practices are advised that to ensure they receive payment, particular attention should be paid to the payment and validation terms. Practices will need to ensure they understand and use the designated clinical codes as required to ensure payment.

Other formats of this document are available on request. Please send your request to: [england.gpcontracts@nhs.net](mailto:england.gpcontracts@nhs.net)

## 1 Introduction

- 1.1 All GP practices must provide essential and those additional services they are contracted to provide to all their patients. This directed enhanced service (DES) 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 DES<sup>1</sup> is directed at GP practices<sup>2</sup> delivering vaccination and immunisation services in England.
- 1.3 This DES is agreed between NHS England and NHS Improvement, the British Medical Association (BMA) General Practitioners Committee (GPC) England.
- 1.4 The aim of the seasonal influenza and pneumococcal polysaccharide immunisation DES is to protect those who are most at risk of serious illness or death should they develop influenza or pneumococcal disease, by offering protection against the most prevalent strains of influenza virus and against 23 serotypes of *Streptococcus pneumoniae*.
- 1.5 Where a practice agrees to participate in this DES, they will be expected to deliver vaccinations to eligible patients for both the seasonal influenza and pneumococcal vaccination programmes. The arrangements to deliver this DES supersede any previous local agreements.

## Part one – pneumococcal polysaccharide vaccination (PPV) programme

### 2 Background (pneumococcal)

- 2.1 Pneumococcal infection is caused by *Streptococcus pneumoniae* – a common cause of pneumonia which can also lead to invasive disease including meningitis and septicaemia. Invasive disease is common in young children, who are offered protection against 13 serotypes of *S. pneumoniae* through the pneumococcal conjugate vaccination (PCV13) programme. Children under two

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<sup>1</sup> Section 7a functions are described as 'reserved functions' which are not covered by the 'directed 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.

<sup>2</sup> Reference to 'GP practice' in this specification refers to a provider of essential primary medical services to a registered list of patients under a GMS, PMS or APMS contract.

years are covered by the Statement of Financial Entitlements (SFE)<sup>3</sup>. In older children and adults, severe pneumococcal infection predominantly affects those with underlying conditions and the elderly.

- 2.2 This specification for commissioners is to commission routine seasonal influenza and pneumococcal polysaccharide vaccinations (PPV). The pneumococcal element of this DES is effective from 1 April 2020 to 31 March 2021. The patients eligible for pneumococcal vaccination under this DES are those who are previously unvaccinated with PPV23 since aged two, who are:
- a. aged 65 and over
  - b. aged two to 64 years and defined as at-risk in the Green Book<sup>4</sup>
- Patients eligible for vaccination under this DES are also outlined at annex A.
- 2.3 The vaccine used against pneumococcal disease in those aged two and over is the 23-valent plain pneumococcal polysaccharide vaccine – PPV23. Adults previously unvaccinated with PPV23 aged 65 and over should be offered a single dose of PPV23 (except where booster doses are being given, see annex A). Children aged two and over but only adults in a clinical risk group who have not previously received a PPV23 vaccination should also be offered a single dose of PPV23 (some groups require booster doses, see annex A).
- 2.4 Due to vaccine supply constraints, practices are requested to vaccinate eligible patients throughout the year rather than in line with the seasonal influenza vaccination programme to ensure a consistent flow of vaccine availability throughout the year. Practices are advised to vaccinate on this basis until further notice<sup>5</sup>.
- 2.5 PPV23 is not repeated annually, therefore only one dose is required, except for individuals with no spleen, splenic dysfunction or chronic renal disease who will require boosters at five year intervals. Practices should contact their commissioner to reach local agreement on the re-vaccination of these patients. Where local agreement has been reached, commissioners can manually adjust achievement on the Calculating Quality Reporting Service (CQRS) to facilitate payment.
- 2.6 Further details on the background, dosage, timings and administration of the

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<sup>3</sup> SFE. <https://www.gov.uk/government/publications/nhs-primary-medical-services-directions-2013>

<sup>4</sup> This is also included as Annex B of this service specification.

<sup>5</sup> <https://www.gov.uk/government/publications/vaccine-update-issue-300-october-2019-bug-special-edition>

vaccination can be found in the Green Book<sup>6</sup>.

### 3 Aims (pneumococcal)

- 3.1 The aim of this DES is to support commissioners in commissioning pneumococcal polysaccharide vaccination services from GP practices to protect patients who are at increased risk of severe complications of pneumococcal diseases.

### 4 Process (pneumococcal)

- 4.1 The pneumococcal element of this DES begins on 1 April 2020 until 31 March 2021.
- 4.2 Commissioners will invite GP practices to participate in this DES before 30 April 2020. All practices who participate in this DES must respond to the commissioners' offer no later than 30 June 2020. This agreement should be recorded in writing with their commissioner
- 4.3 Payment and activity recording will be managed by the CQRS and all practices must sign-up to CQRS – no later than 30 June 2020<sup>7</sup> whether or not they intend to deliver the ES to ensure that they can claim payment once this becomes an essential service.
- 4.4 Where a practice agrees to participate in this DES, they will be expected to deliver vaccinations to eligible patients for both the seasonal influenza and PPV programmes.

### 5 Service specification (pneumococcal)<sup>8</sup>

- 5.1 **Provide pneumococcal polysaccharide vaccination** to all eligible patients
- 5.2 registered at the GP practice; unless contra-indicated.
- a. Eligible patients are those who are previously unvaccinated with PPV23 since aged two, registered with the practice, who are:
- i. aged 65 and over.
  - ii. aged two years and over but adults aged up to 64 years defined as

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<sup>6</sup> Green Book. Chapter 25. <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

<sup>7</sup> Practices will be required to sign-up to CQRS in order for payment to be calculated and processed.

<sup>8</sup> Commissioners and practices should ensure they have read and understood all sections of this document as part of the implementation of this programme and to ensure accurate payment.

at-risk in the Green Book<sup>9</sup>.

- b. Patients should be vaccinated on either:
  - i. a proactive call and recall basis, if considered at-risk, or
  - ii. a proactive call basis, if not considered at-risk.
- c. 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.
- d. Vaccination must be delivered during the period of this DES, between 1 April 2020 and 31 March 2021.
- e. Vaccination is with a single dose of the vaccine. Boosters are required at five yearly intervals in individuals with no spleen, splenic dysfunction or chronic renal disease as outlined in Green Book. Practices should contact their commissioner to reach local agreement on the re-vaccination of these patients. Where local agreement has been reached, the commissioner can manually adjust achievement on CQRS to facilitate payment.

**5.3 Take all reasonable steps to adhere to defined standards of record keeping ensuring that the medical records of patients receiving the pneumococcal vaccination 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<sup>10</sup>.

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

- a. referred to the clinical guidance available.
- b. the necessary experience, skills and training, including training with

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<sup>9</sup> This is also included as Annex B of this service specification.

<sup>10</sup> This should be reported via the yellow card scheme. <https://yellowcard.mhra.gov.uk/>

regard to the recognition and initial treatment of anaphylaxis.

- 5.5 **GP practices are required to ensure all locally procured orders of vaccine are in line with national guidance, including adherence to any limits on stocks to be held at any one time.** The recommended pneumococcal vaccine for patients aged 65 and over and for children and adults in the clinical risk groups aged two to 64, administered as a single dose is confirmed in the Green Book.
- 5.6 **Ensure that all vaccines are stored in accordance with the manufacturer's and Public Health England (PHE)<sup>11</sup> 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 and that appropriate action is taken when readings are outside the recommended temperature.
- 5.7 **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 DES due to a protected characteristic, as outlined in the Equality Act (2010) – this includes Age, Disability, Gender Reassignment, Marriage and Civil Partnership, Pregnancy and Maternity, Race, Religion or Belief, Sex or Sexual Orientation.
- 5.8 **Practices will monitor and report all activity information via ImmForm on a monthly basis** as per the national uptake surveys for influenza and PPV uptake. This information will be used by NHS England and NHS Improvement and PHE for monitoring coverage, payment purposes, population coverage, uptake achievement and national reporting.
- 5.9 **Practices who agree to participate in this DES must indicate acceptance on CQRS** to enable CQRS to calculate the monthly payment achievement data Practice must input data manually into CQRS, until GPES is available.
- 5.10 **Practices that do not intend to deliver the DES must still indicate acceptance on CQRS by 31 July 2020 to ensure payment once this becomes an essential service.**
- 5.11 **Where the patient 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.

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<sup>11</sup> PHE's ordering, storing and handling protocol  
<https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>



## 6 Monitoring (pneumococcal)

- 6.1 Commissioners will monitor services and calculate payments under this DES using CQRS<sup>12</sup>, wherever possible. GPES will provide information, using the defined clinical codes, on the number of patients on the practices registered list, who are aged 65 and over, or aged two to 64 years and defined as at-risk in the Green Book and who are recorded as being vaccinated against PPV during the period 1 April 2020 to 31 March 2021.
- 6.2 If the automated collection via GPES is not available for any reason, Practices must manually input data into CQRS, until such time as GPES<sup>13</sup> is available again. For information on how to manually enter data into CQRS, see the NHS Digital website<sup>14</sup>. Alternatively, Practices may choose to wait until the automated collection is available again and claim payment later.
- 6.3 When GPES is available, each GPES data collection will capture data for all payment and management information counts and report on activities from the start of the reporting period, eg 1 April to the end of the relevant reporting month. The reporting month will be the month prior to the month in which the collection is run, eg if the collection month is May, the reporting month will be April.
- 6.4 When collections begin, GPES will provide to CQRS the monthly counts.
- 6.5 The Practices should ensure that they use the relevant clinical codes included in the supporting Business Rules (<http://content.digital.nhs.uk/qofesextractspecs>) and practices should also re-code patients where necessary. This will allow CQRS to calculate achievement and payment and for commissioners to audit payment and service delivery. Commissioners and practices should refer to the supporting Business Rules to ensure that they have the most up-to-date information on management counts and clinical codes. .
- 6.6 Practices should maintain clear records of how they have 'called' and recalled all eligible patients.

## 7 Payment and validation (pneumococcal)

- 7.1 Payment is available to participating GP practices under this DES as an item

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<sup>12</sup> Although the seasonal influenza and pneumococcal vaccination programmes are mutually dependent, they are separate services on CQRS and GPES.

<sup>13</sup> When GPES becomes available it will be communicated via NHS Digital.

<sup>14</sup> NHS Digital. <https://digital.nhs.uk/article/279/General-Practice-GP-collections>

of service payment of £10.06 per dose to eligible patients.

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

- a. The GP practice is contracted to provide vaccine and immunisations as part of additional services.
- b. All patients in respect of whom payments are being claimed were on the GP practices 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 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.
  - iii. The GP practice did not receive any payment from any other source in respect of the vaccine (should this be the case, then the commissioner may reclaim any payments as set out in annex D).
  - iv. The GP practice submits the claim within six months<sup>15</sup> of administering the vaccine (commissioners may set aside this requirement if it considers it reasonable to do so<sup>16</sup>).

7.3 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 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.

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

7.5 Payments will begin provided that the GP practice has manually entered and declared achievement, or GPES<sup>17</sup> has collected the data and the practice has

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<sup>15</sup> Consistent with payment claims for other vaccination programmes which are covered by the SFE I

<sup>16</sup> By exception only, for example where payment processes are made manually without CQRS and take longer to complete.

<sup>17</sup> See 'Process' section for information relating to sign-up and automated collection.

declared such data<sup>18</sup>. The first payment processed will include payment for the same period.

- 7.6 Commissioners are responsible for post payment verification. This may include auditing claims of practices to ensure that they meet the requirements of this DES.

## Part two – seasonal influenza vaccination programme

### 8 Background (influenza)

- 8.1 This DES covers those patients most at risk from influenza aged six months and older. Children aged two and three years are not included in this DES as these patients are covered by the childhood seasonal influenza vaccination programme<sup>19</sup>.
- 8.2 This specification is for commissioners to commission routine seasonal influenza vaccinations and PPV. The seasonal influenza element of this DES is effective from 1 September 2020 to 31 March 2021. The patients eligible for seasonal influenza vaccination under this DES are those patients:
- a. aged 65 and over on 31 March 2021,
  - b. diagnosed as pregnant,
  - c. aged six months to 64 years (excluding patients aged two and three on 31 August 2020) defined as at-risk in annex B<sup>20</sup>;
  - d. locum GPs;
  - e. health and social care staff employed by a registered residential care/nursing home or registered domiciliary care provider and;
  - f. health and care staff employed by a voluntary managed hospice provider
  - g. health and social care workers employed through Direct Payments and/or Personal Health Budgets (such as personal assistants) to deliver domiciliary care to patients and service users
  - h. household contacts of an individual on the Shielded Patient List

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<sup>18</sup> Practices are reminded that they are responsible for checking their 'achievement' is accurate before they 'declare' it on CQRS.

<sup>19</sup> NHS England. Childhood influenza vaccination programme specification.  
<http://www.england.nhs.uk/commissioning/gp-contract/>

<sup>20</sup> Green Book. Chapter 19. <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

- i. household contacts of immunocompromised individuals
- j. living in long-stay residential or nursing homes or other long-stay health or social care facilities
- k. Carers

**Please see Annex B for further information on cohort definitions.**

- 8.3 The live attenuated influenza vaccine (LAIV), administered as a nasal spray, is recommended for patients, aged two years and over but not yet 18 years of age, without a clinical contra-indication. LAIV is centrally procured and supplied by Public Health England through ImmForm.
- 8.4 For children aged six months to two years and other at-risk children, less than 9 years of age where LAIV is contraindicated, a suitable egg-grown quadrivalent inactivated influenza vaccine (QIVe), will be centrally supplied via ImmForm.
- 8.5 For children aged 9 years and over where LAIV is contraindicated, practices are required to offer a cell-based quadrivalent influenza vaccine (QIVc) from their locally procured stock which will be reimbursed by NHS England and NHS Improvement. Where QIVc is unavailable, practices can either offer QIVe which can be either ordered through ImmForm from centrally purchased supplies, or use their own locally procured QIVe which will be reimbursed by NHS England and NHS Improvement
- 8.6 For patients aged 18 years to under 65 years defined as at-risk in the Green Book. NHS England and NHS Improvement will reimburse the vaccines outlined below following the advice on the recommended vaccines for 2020/21 from the Joint Committee on Vaccination and Immunisation (JCVI):
- Cell-based quadrivalent influenza vaccine (QIVc)<sup>1</sup>
  - Egg-grown quadrivalent influenza vaccine (QIVe) ( as an alternative to QIVc subject to the JCVI considerations outlined below).

There is a potential advantage to using cell-based influenza vaccines compared with egg-culture influenza vaccines, due to the possible impact of “egg-adaption” on the effectiveness of influenza vaccines, particularly against A(H3N2) strains. The evidence on additional benefit is reasonably consistent, but available for only very few seasons. The available limited evidence supports a slight preference for QIVc over QIVe, although any impact will likely be limited to seasons in which the influenza season is dominated by well-matched H3N2 strains.

- 8.7 For all adults over 65 years adjuvanted trivalent influenza (aTIV) and where aTIV is not available, the QIVc should be offered.
- 8.8 Details of this programme and the wider seasonal influenza programme can be found in the annual flu letter <sup>21</sup>.
- 8.9 Further details on the background, dosage, timings and administration of the vaccination can be found in the Green Book<sup>22</sup>.

## 9 Aims (influenza)

- 9.1 The aim of this DES is to support commissioners in commissioning seasonal influenza vaccination services from GP practices to protect patients who are most at risk of serious illness or death should they develop influenza and to reduce transmission of the infection. Practices will be expected to meet the national ambitions for all patient cohorts as given in the annual flu letter.
- 9.2 Vaccination should be given in sufficient time to ensure patients are protected before the virus starts circulating. Practices should aim to schedule their immunisation services to match vaccine supply and complete vaccination by the end of November, where possible. However, influenza can circulate considerably later than this and clinicians should apply clinical judgement to assess the needs of the individual patients for immunisation beyond this point.

## 10 Process (influenza)

- 10.1 The 2020-2021 seasonal influenza element of this DES (“20/21 Influenza DES”) begins on 1 September 2020 until 31 March 2021. The 20/21 Influenza DES automatically replaces the seasonal influenza element in all previous versions of this Specification.
- 10.2 Commissioners will invite GP practices to participate in the 20/21 Influenza DES before 7 September 2020. All practices who participate in this DES must respond to the commissioners no later than 14 September 2020. The agreement should be recorded in writing with their commissioner.
- 10.3 Payment and activity recording will be managed by the Calculating Quality Reporting Service (CQRS) <sup>23</sup> and all practices must sign-up to CQRS – no

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<sup>21</sup> PHE. Seasonal influenza. <https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan>

<sup>22</sup> Green Book. Chapter 19 <https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19>

<sup>23</sup> Further guidance relating to CQRS and GPES will be provided by NHS Digital when services are updated.

later than 31 July 2020<sup>24</sup> whether or not they intend to deliver the ES to ensure that they can claim payment once this becomes an essential service.

## 11 Service specification (influenza)<sup>25</sup>

11.1 **Provide seasonal influenza vaccination** to all eligible patients registered at the GP practice; unless contra-indicated.

- a. Eligible patients are those who are registered at the practice, who are:
  - i. aged 65 and over
  - ii. Diagnosed as pregnant
  - iii. aged six months to 64 years (inclusive)<sup>26</sup> and defined as at-risk in annex B<sup>27</sup>
  - iv. locum GPs (to be vaccinated by the GP practice where they are registered as a patient)
  - v. carers
  - vi. household contacts of an individual on the Shielded Patient List
  - vii. household contacts of immunocompromised individuals
  - viii. those in long-stay in residential or nursing homes or other long-stay health or social care facility
  - ix. health and social care staff employed by a registered residential care/nursing home or registered domiciliary care provider (to be vaccinated by the GP practice where they are registered as a patient) and;
  - x. health and care staff employed by a voluntary managed hospice provider (to be vaccinated by the GP practice where they are registered as a patient).
  - xi. health and social care workers employed through Direct Payments and/or Personal Health Budgets (such as personal assistant) to deliver domiciliary care to patients and service users (to be vaccinated by the GP practice where they are registered as a patient).

The programme may be further extended in November and December to include those in the 50-64 year old age group subject to vaccine supply and after existing eligible groups have been prioritised. Notification of the phased eligibility of

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<sup>24</sup> Practices will be required to sign-up to CQRS in order for payment to be calculated and processed.

<sup>25</sup> Commissioners and practices should ensure they have read and understood all sections of this document as part of the implementation of this programme and to ensure accurate payment.

<sup>26</sup> Patients aged two and three are not included in this DES. These patients are covered by the childhood influenza vaccination programme.

<sup>27</sup> This is also included as Annex A of this DES specification.

individuals in this cohort will be formally announced later in the flu season. Each year group will be considered separately, but an announcement of an extension may relate to just one year group or more than one year group. Decisions to extend to a specified year group or groups will have followed normal authorisation process for these decisions (reflecting the authorisation process for PGDs), and will then be published, together with the start date for the extension, and communicated to GP practices via the Primary Care Bulletin. The General Practitioners Committee of the BMA will be informed ahead of an announcement, and a copy of the announcement will be available at: <https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan>

These patients are not eligible to be vaccinated under this service until that announcement has been made, unless they also fall in to one of the eligible cohorts listed at paragraph 8.2.

- a. GP practice should ensure they offer vaccination to all eligible patients.  
GP practices are required to ensure:
  - i. a proactive call and recall basis, if considered at-risk, or
  - ii. a proactive call basis, if not considered at-risk with the aim of maximising uptake
  - iii. reasonable co-operation with any national call and recall service.
- b. Practices must include within at least one written communication (including letters and SMS text messages) offering vaccination to eligible patients, a request that the patient advises the practice of their ethnicity status if they have not previously provided this information to the practice and where provided by the patient or their carer, the practice must record the ethnicity information in the patient record.
- c. 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.
- d. Vaccination must be delivered during the period of this DES, namely between 1 September 2020 and 31 March 2021.

The target timeframe for the influenza programme is three months from 1 September 2020 to 30 November 2020 where possible, in order to achieve maximum impact. Vaccination should be given in sufficient time to ensure patients are protected before flu starts circulating. Vaccination may continue until 31 March 2021 but where possible should be completed before influenza starts to circulate in the

community. However, influenza can circulate considerably later than this and clinicians should apply clinical judgement to assess the needs of individual patients for immunisation beyond this point. This should take into account the level of flu-like illness in the community and the fact that immune response following immunisation takes about two weeks to fully develop.

- e. Practices should ensure they order and are able to offer the most effective vaccine for each eligible group consistent with national guidance.
- f. Vaccination must be with the recommended vaccines as appropriate for patient cohorts as outlined in the JCVI advice. The NHS reimbursement for vaccine is outlined in the letter published in the Annual seasonal flu vaccination programme and reimbursement guidance for 2020/21<sup>28</sup>. During the influenza season there may be additional advice from Public Health England if there are issues with vaccine supply.<sup>29, 30</sup> Practices should ensure that the correct dosage is administered as clinically appropriate. Where two doses of vaccine are required a failure to do so may render vaccination ineffective. Conversely where only one vaccination is clinically appropriate payment should not be made for a second dose.
  - i. Egg-grown quadrivalent inactivated influenza vaccine (QIVe) (which will be centrally supplied), is required for patients defined as at-risk aged six months to under two years at the time of vaccination.
  - ii. LAIV (which will be centrally supplied), is required for patients aged two years and over but not 18 years or over at the time of vaccination who are not contra-indicated. Where LAIV is contraindicated, a suitable quadrivalent inactivated influenza vaccine (QIV) is required for patients defined as at-risk.

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<sup>28</sup> <https://www.england.nhs.uk/publication/annual-seasonal-flu-vaccination-programme-and-reimbursement-guidance-for-2020-21/>

<sup>29</sup> Further details on the background, dosage, timings and administration of the vaccination can be found in the annual flu letter.

<sup>30</sup> This is also included as Annex C of this DES specification.



- iii. Those aged 2 to less than 9 years should receive a suitable egg-grown vaccine (QIVe), which will be centrally supplied via ImmForm. Children aged 9 years and over who are contraindicated to receive LAIV should be offered QIVc from locally procured stock which will be reimbursed. Where QIVc vaccine is unavailable QIVe can be offered, which can be either ordered through ImmForm from centrally purchased supplies, or practices who use locally procured QIVe will be reimbursed by NHS England and NHS Improvement.
- iv. Patients aged six months to under nine years at the time of vaccination, defined as at-risk and who have not received influenza vaccination previously, will require a second dose of either LAIV or QIVe at least four weeks after the first dose.
- v. Practices will not be reimbursed for QIVe vaccine supplied by Public Health England free of charge via ImmForm.
- vi. For patients aged 18 years to 64 years eligible under the influenza DES it is recommended that one dose of QIVc is administered or QIVe as an alternative if QIVc is not available. For adults aged 65 years and over, aTIV should be administered, where aTIV is not available, QIVc may be used for this age group. All vaccines for patients aged 18 and over should be ordered direct from the manufacturers, as well as QIVc for at risk children aged 9 years and over.

**11.2 Take all reasonable steps to adhere to defined standards of record keeping ensuring that the medical records of patients receiving the influenza vaccination 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<sup>31</sup>
- vii. Practices should update patient records the same or next working day the vaccine is administered or that notification is received from another provider that a vaccine has been administered to one of the practice's registered patients.

**11.3 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.

**11.4 Ensure all orders of vaccine are in line with national guidance, including adherence to any limits on stocks to be held at any one time<sup>32</sup>.** The LAIV and QIVe vaccines for patients aged two to 17 years, aged six months to under 2 years and those aged four to less than 9 years of age defined as at-risk should be ordered online from ImmForm as per other centrally supplied vaccines. Practices are required to order the recommended QIV vaccines for all other patients eligible for vaccination under this DES direct from the manufacturers. Practices are expected to use QIVc from their own locally procured stock which will be reimbursed. Practices will not be reimbursed for QIVe vaccine supplied free of charge via ImmForm.

**11.5 Ensure that all vaccines are stored in accordance with the manufacturer's and Public Health England <sup>33</sup>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 and that appropriate action is taken when readings are outside the recommended temperature.

**11.6 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 DES due to a protected characteristic, as outlined in the Equality Act (2010) – this includes Age,

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<sup>31</sup> This should be reported via the yellow card scheme. <https://yellowcard.mhra.gov.uk/>

<sup>32</sup> Further information can be found in the annual flu letter for 2020/21 and Vaccine Update.

<sup>33</sup> PHE's ordering, storing and handling protocol

<https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>

Disability, Gender Reassignment, Marriage and Civil Partnership, Pregnancy and Maternity, Race, Religion or Belief, Sex or Sexual Orientation.

- 11.7 **Practices will monitor and report all activity information via ImmForm on a monthly basis.** The activity information shall include a monthly count of all eligible patients who received a seasonal influenza vaccination in the relevant month. This information will be used by NHS England and NHS Improvement and PHE for monitoring uptake achievement and national reporting.
- 11.8 **Practices who agree to participate in this DES must indicate acceptance on CQRS to enable CQRS to calculate the monthly payment achievement.** Practices must input data manually into CQRS until GPES is available.
- 11.9 Practices who do not intend to deliver the 2020/21 Influenza DES should still have indicated acceptance on CQRS by 31 July 2020 in order to ensure payment once this becomes an essential service.
- 11.10 **Where the patient or parent/guardian where appropriate has indicated they/their child wish to receive the vaccination but it is physically unable to attend the practice** (for example is housebound) the practice must make all reasonable effort to ensure the patient is vaccinated.

## 12 Monitoring (influenza)

- 12.1 Commissioners will monitor services and calculate payments under this DES using CQRS, wherever possible<sup>34</sup>. GPES will provide information, using the defined clinical codes, on the number of patients on the practices registered list, who are defined as eligible in the service specification section and who are recorded as being vaccinated against influenza during the period 1 September 2020 to 31 March 2021.
- 12.2 If automated collection via GPES is not available for any reason, Practices must manually input data into CQRS, until such time as GPES<sup>35</sup> is available again. For information on how to manually enter data into CQRS, see the NHS Digital website<sup>36</sup>. Alternatively, Practices may choose to wait until the automated collection is available again and claim payment later.
- 12.3 When GPES is available, each GPES data collection will capture data for all payment and management information counts and report on activities from the

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<sup>34</sup> Although the seasonal influenza and pneumococcal vaccination programmes are mutually dependent, they are separate services on CQRS and GPES.

<sup>35</sup> When GPES becomes available it will be communicated via NHS Digital.

<sup>36</sup> NHS Digital. <https://digital.nhs.uk/article/279/General-Practice-GP-collections>

start of the reporting period, eg 1 September to the end of the relevant reporting month. The reporting month will be the month prior to the month in which the collection is run, eg if the collection month is October, the reporting month will be September.

- 12.4 When collections begin, GPES will provide to CQRS the monthly counts.
- 12.5 Practices should ensure that they only use the relevant clinical codes included in the supporting Business Rules (<http://content.digital.nhs.uk/gofesextractspecs>) and should also re-code patients where necessary. This will allow CQRS to calculate achievement and payment and for commissioners to audit payment and service delivery. Commissioners and practices should refer to the supporting Business Rules to ensure that they have the most up-to-date information on management counts and clinical codes.
- 12.6 Practices should maintain clear records of how they have 'called' and recalled all eligible patients.

## 13 Payment and validation (influenza)

- 13.1 Payment is available to participating GP practices under this DES as an item of service payment of £10.06 per dose to eligible patients.
- 13.2 Practices will only be eligible for payment for this DES in circumstances where all of the following requirements have been met:
- a. The GP practice is contracted to provide vaccine and immunisations as part of additional services.
  - b. All patients in respect of whom payments are being claimed were on the GP practices registered list at the time the vaccine was administered, and all of the following apply:
  - c. In order to receive payment for vaccination and reimbursement of vaccine. The GP practice will need to use the specified vaccines<sup>37</sup> recommended in the DES specification and NHS England guidance<sup>38</sup> :
    - i. The GP practice administered the vaccine to all eligible patients in respect of whom the payment is being claimed.
    - ii. All eligible patients in respect of whom payment is being claimed were within the cohort (as per the service specification section) at

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<sup>37</sup> NHS England letter. 'Implementing the Joint Committee on Vaccination and Immunisation advice on vaccines in the NHS annual seasonal flu vaccination programme and reimbursement guidance for 2020/21'. (20 December 2019). [www.england.nhs.uk/wp-content/uploads/2019/12/NHS-England-JCVI-advice-and-NHS-reimbursement-flu-vaccine-2020-21.pdf](http://www.england.nhs.uk/wp-content/uploads/2019/12/NHS-England-JCVI-advice-and-NHS-reimbursement-flu-vaccine-2020-21.pdf)

<sup>38</sup> NHS England Guidance 2020/21 <https://www.england.nhs.uk/gp/gpiv/investment/gp-contract/>

the time the vaccine was administered.

- iii. The GP practice did not receive any payment from any other source in respect of the vaccine (should this be the case, then the commissioners may reclaim any payments as set out in the provisions annex.
- iv. The GP practice submits the claim within six months<sup>39</sup> of administering the vaccine (commissioners may set aside this requirement if it considers it reasonable to do so<sup>40</sup>).

- 13.3 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 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.
- 13.4 Payment will be made by the last day of the month following the month in which the practice validates and commissioners approve the payment.
- 13.5 Payments will begin provided that the GP practice has manually entered and declared achievement, or GPES<sup>41</sup> has collected the data and the practice has declared such data<sup>42</sup>. The first payment processed will include payment for the same period.
- 13.6 Practices should ensure that the correct dosage is administered as clinically appropriate. Where two doses are required, a failure to do so may render vaccination ineffective. Conversely where only one vaccination is clinically appropriate payment should not be made for a second dose within the period 1 September 2020 to 31 March 2021.
- 13.7 Payment under this DES, or any part thereof, will be made only if the GP practice satisfies the following conditions:
- a. the GP practice has participated in both the seasonal influenza and pneumococcal polysaccharide elements of this DES,
  - b. the GP practice must make available to commissioners any information

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<sup>39</sup> Consistent with payment claims for other vaccination programmes which are covered by the SFE

<sup>40</sup> By exception only, for example where payment processes are made manually without CQRS and take longer to complete.

<sup>41</sup> See 'Process' section for information relating to sign-up and automated collection.

<sup>42</sup> Practices are reminded that they are responsible for checking their 'achievement' is accurate before they 'declare' it on CQRS.

under this DES, which the commissioner needs and the GP practice either has or could be reasonably expected to obtain,

- c. the GP practice must make any returns reasonably required of it (whether computerised or otherwise) to the payment system or CQRS, and do so promptly and fully; and,
- d. all information supplied pursuant to or in accordance with this paragraph must be accurate.

13.8 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 DES that is otherwise payable.

13.9 If commissioners make a payment to a GP practice under this DES and:

- a. the commissioner 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);
- 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
- c. 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 DES that the contractor must pay to the commissioner that equivalent amount.

13.10 Where the commissioner is entitled under this DES 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 paragraphs 5 and 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.

13.11 Where the vaccine is centrally supplied for patients under 18 years except QIVc for those aged 9 years and over for whom LAIV is contraindicated, no claim for reimbursement of vaccine costs or personal administration fee apply to those vaccinations delivered to this cohort.

13.12 Commissioners are responsible for post payment verification. This may include auditing claims of practices to ensure that they meet the requirements

of this DES.

## Annex A: Groups included in this DES and included in the pneumococcal polysaccharide immunisation programme as defined in the Green Book

Eligible groups	Further details
Patients aged 65 years and over	“Sixty-five and over” is defined as those aged 65 years and over on 31 March 2021 (i.e. born on or before 31 March 1956).
Asplenia or dysfunction of the spleen	This also includes conditions that may lead to splenic dysfunction such as homozygous sickle cell disease and coeliac syndrome.
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 (such as 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 anti-diabetic medication. This does not include diabetes that is diet controlled.
Immunosuppression	Due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, asplenia or splenic dysfunction, complement disorder, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO). 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	It is important that immunisation does not delay the cochlear implantation.

Eligible groups	Further details
Individuals with cerebrospinal fluid leaks	This includes leakage of cerebrospinal fluid such as following trauma or major skull surgery (does not include CSF shunts).
Occupational risk	Please see page 9 of the Green Book

## Annex B: Groups included in this DES and included in the national influenza immunisation programme as defined in the annual flu letter and Green Book

Eligible groups	Further details
All patients aged 65 years and over	"Sixty-five and over" is defined as those aged 65 years and over on 31 March 2021 (i.e. born on or before 31 March 1956).
Chronic respiratory disease aged 6 months and over	Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children who have previously been admitted to hospital for lower respiratory tract disease.
Chronic heart disease aged six months and over	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
Chronic kidney disease aged six months and over	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease aged 6 months and over	Cirrhosis, biliary atresia, chronic hepatitis.



Eligible groups	Further details
Chronic neurological disease aged six months and over	<p>Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers).</p> <p>Clinicians should offer immunisation to all patients with a learning disability given their increased morbidity and mortality due to preventable pneumonia<sup>43</sup>.</p> <p>Clinicians should offer immunisation, based on individual assessment, to vulnerable individuals including those with cerebral palsy, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability.</p>
Diabetes aged 6 months and over	Type 1 diabetes, Type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet controlled diabetes.
Immunosuppression aged 6 months and over	<p>Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (eg IRAK-4, NEMO, complement deficiency).</p> <p>Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20 mg or more per day (any age), or for children under 20 kg, a dose of 1 mg or more per kg per day.</p> <p>It is difficult to define at what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered seasonal influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician.</p> <p>Some immune-compromised patients may have a suboptimal immunological response to the vaccine.</p>
Asplenia or dysfunction of the spleen aged six months and over	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
Pregnant women	Pregnant women at any stage of pregnancy (first, second or third trimesters).

<sup>43</sup> Practices are advised of the importance to ensure patients with a learning disability are vaccinated. Patients with a learning disability are included in the eligibility for payment under this DES. PHE understand the difficulty with vaccinating this group with injectable vaccines. PHE advises that LAIV is not licensed for adults so practice should attempt to vaccinate using an injectable vaccine. Previously, it has been found that LAIV is easier to use in similar patients and is less distressing. However, in the event that an injectable vaccine is not appropriate, GP's can use their clinical discretion to use the LAIV vaccine off license.

Eligible groups	Further details
Morbidly obese (class III obesity) <sup>44</sup>	Adults with a BMI $\geq 40$ kg/m <sup>2</sup> (adults aged 16+).
People in long-stay residential or homes	Vaccination is recommended for people living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions, or university halls of residence.
Household contacts of an individual on the shielded patient list aged 6 months and over	Specifically, individuals who share or expect to share living accommodation with a shielded person on most days over the winter (part of / all of September through to March) and therefore for whom continuing close contact is unavoidable.
Household contacts of immunocompromised individuals aged 6 months and over	Vaccines should be offered to household contacts of immunocompromised individuals, who share or expect to share living accommodation with on most days over the winter and therefore for whom continuing close contact is unavoidable.
Carers	Those who are in receipt of a carer's allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.
Locum GPs	Where locum GPs wish to be vaccinated, they should be vaccinated by their own GP ( <i>all other GP's and primary care staff are the responsibility of their employer as part of occupational health arrangements</i> ).
Health and social care workers	<p>In order to protect patients in a vulnerable care setting the following groups should be vaccinated by the GP practice where they are registered as a patient:</p> <p>Health and social care staff employed by a registered residential care/nursing home or registered domiciliary care provider and;</p> <p>Health care staff employed by a voluntary managed hospice provider</p>

<sup>44</sup> Many of this patient group will already be eligible for vaccination due to complications of obesity that place them in another risk category.

Eligible groups	Further details
Health and social care workers	Health and social care workers employed through Direct Payments and/or Personal Health Budgets (such as personal assistants) to delivery domiciliary care to patients and service users.

PHE states that this list is not exhaustive and the clinicians should apply clinical judgement to take into account the risk of influenza exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from influenza itself. Influenza vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above<sup>45</sup>.

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<sup>45</sup> Only those patients eligible for vaccination as defined in this DES specification will be paid for under this DES.

## Annex C: Vaccines and dosage

### PPV programme (as defined in the Green Book)

Eligible groups	Vaccine	Dosage
2 to 4 years in clinical risk groups	PPV23	1 single dose, after an age appropriate course of PCV13
5 to 64 years in clinical risk groups	PPV23	1 single dose (Individuals with CKD, asplenia or splenic dysfunction re-immunise every 5 years)
65 and over	PPV23	1 single dose (Individuals CKD, asplenia or splenic dysfunction re-immunise every 5 years)

### Seasonal influenza vaccination programme (as defined in the annual flu letter<sup>46</sup>)

Eligible groups	Vaccine	Dosage
At risk children aged from 6 months to less than 2 years	Offer standard egg-grown quadrivalent inactivated influenza vaccine (QIVe)	1 dose unless first influenza vaccination in which case a second dose is recommended at least 4 weeks after the first
At risk children aged 2 years to less than 9 years	LAIV unless contra-indicated, then offer QIVe	1 dose unless first influenza vaccination in which case a second dose is recommended at least 4 weeks after the first
At risk children aged 9 years to less than 18 years in clinical risk groups	LAIV unless contraindicated then QIVc is recommended. If QIVc is unavailable, QIVe should be offered as an alternative.	1 dose
At risk adults 18-64 years (including pregnant women)	QIVc or QIVe as an alternative to QIVc	1 dose
65 years and over	Adjuvanted trivalent influenza vaccine (aTIV) OR cell-grown quadrivalent influenza vaccine (QIVc) if aTIV is not available.	1 dose

For a list of the available inactivated vaccines, suppliers and the appropriate age indications see the 2020/21 annual flu letter.

<sup>46</sup> PHE. Seasonal influenza. <https://www.gov.uk/government/collections/annual-flu-programme>

## Provisions relating to GP practices that terminate or withdraw from this DES prior to 31 March 2021 (subject to the provisions below for termination attributable to a GP practice split or merger)

1. Where a GP practice has entered into this DES but its primary medical care contract subsequently terminates or the GP practice withdraws from the DES prior to 31 March 2021, 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.
2. In order to qualify for payment in respect of participation under this DES, the GP practice must provide the commissioner with the information in this DES 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 DES agreement.
3. The payment due to GP practices that terminate or withdraw from the DES agreement prior to 31 March 2021 will be based on the number of vaccinations given to eligible patients, prior to the termination or withdrawal.

## Provisions relating to GP practices who merge or split

4. 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 DES.
5. The DES 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 **Error! Reference source not found.** of this annex.
6. 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 DES, will be assessed and any new or varied arrangements that may be agreed in writing with the commissioner, will begin at the time the GP

practice(s) starts to provide such arrangements.

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

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

8. Where the GP practice participating in the DES 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 NHS England's opinion are reasonable in all circumstances.