## APPENDIX A

**SERVICE SPECIFICATION**

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| Service Specification No. |  |
| Service | **Vitamin D vouchers for Winter Well packs** |
| Authority Lead | **St Helens Council, Public Health** |
| Provider Lead | **Community Pharmacy** |
| Period | 11th Nov 2024 – 31st March 2025 |
| Date of Review | **Annual** |

|  |
| --- |
| 1. Population Needs |
| * 1. **National/local context and evidence base**   **National Context:** Vitamin D is important as it helps regulate the amount of calcium and phosphate in the body, which is needed for healthy bones and muscles, and for supporting immunity. Too little vitamin D can lead to bone problems such as rickets in children, and bone pain and muscle weakness in adults; this may also increase the risk of falls in older people. While we do get some vitamin D from our diet, the main source is sunlight exposure on the skin. During autumn and winter in the UK, UV levels from the sun are not sufficient making vitamin D in this way.  [According to NICE](https://cks.nice.org.uk/topics/vitamin-d-deficiency-in-adults/background-information/prevalence/), nearly a quarter of people aged 19 to 64 years and 21% aged 65 years and over are vitamin D deficient. In the winter, this increases to 29.3% of those 65 years and over, and 40% 19–64 years. NICE therefore recommends that all adults should consider taking a daily vitamin D supplement, particularly in the autumn and winter months. A survey commissioned by the [British Nutrition Foundation](https://www.nutrition.org.uk/news/2021/british-nutrition-foundation-survey-reveals-49-adults-unaware-of-uk-government-guidelines-for-vitamin-d/#:~:text=The%20National%20Diet%20and%20Nutrition,vitamin%20D%20in%20their%20blood.) revealed that almost half of British adults (49%)are not aware of this advice.  **Local Context:** During the winter, St Helens has provided vouchers, as part of the winter well packs, for free vitamin D supplements for residents who are most vulnerable. Over the last couple of years that this has run, uptake has increased, which is positive, and something that we would like to build upon. We are not aware of other areas that have supplied vitamin D vouchers outside the healthy start programme, while other local authority areas have expressed an interest in learning from our experiences. Vitamin D is fat soluble and there is the potential to overdose or have side effects which means that the benefits can outweigh the risks. Pharmacy staff will have a conversation with recipients of the free vitamin D to ensure people understand how to take vitamins safely and provide the service locally in a safe manner. |
| 2. Key Service Outcomes |
| * + Increased access to vitamin D for some of the most vulnerable people in St Helens   + Increased numbers of people taking vitamin D in St Helens.   + Improving winter wellbeing of people in St Helens   + Advocating for all people to take vitamin D if it is safe for them to do so |
| 3. Scope |
| **3.1 Aims and Objectives of the Service**  The aim of the service is to promote the uptake for vitamin D in winter  **3.2.1 Services, Care and Interventions Provided:**     * 6000 vulnerable adults in the borough will be provided with vitamin D vouchers this winter included in the winter well pack provided to the target residents. The voucher is for suitable licensed vitamin D, which can be exchanged for 4 months’ supply of vitamin D tablets, to last them until end of March 2025. * The client attends the pharmacy and exchanges voucher for a maximum of 150 vitamin D tablets. The staff member will supply the product with supporting information verbally. * The pharmacy must supply tablets after checking the necessary contraindications as described in the protocol (Appendix O). Overall responsibility for ensuring the suitability of the selected therapy product supplied to the client lies with the pharmacist. * The St Helens Public Health team and the pharmacist will be responsible for ensuring the completion and accuracy of recorded client data and service documentation.   **3.2.2 Service Standards**   * The pharmacy has a duty to ensure that pharmacists and other staff involved in the provision of this service have the relevant knowledge, skills and have read about this service and are aware of and act in accordance with local protocols and national guidance, specified in Appendix O. * The pharmacist should consider communicating this information to the client’s GP with the client’s consent and always where medicines need dose adjustment if vitamin D is being taken * A GP notification will be included in the PharmOutcomes module * The pharmacy must endorse all vouchers for audit and payment purposes and input into PharmOutcomes for each voucher exchanged. The details in the form (Appendix P) should be kept for 6 months, until the audit process is complete. * Clients can present with further vouchers in accordance with local protocols.   **3.2.3** **Information provided to clients in the Winter Well pack**  Vitamin D is important for building immunity against infections, and keeping bones, teeth and muscles healthy.   * Take vitamin D supplements during the winter months when you are less likely to get it directly from sunlight. * Some people have medical conditions that mean they may not be able to safely take as much. If in doubt, you should consult your doctor * If you can take vitamin D supplements, 10 micrograms a day will be enough for most people. * Do not take more than 100 micrograms (4,000 IU) of vitamin D a day as it could be harmful. This applies to adults, including pregnant and breastfeeding women and the elderly, and children aged 11 to 17 years * Children aged 1 to 10 years should not have more than 50 micrograms (2,000 IU) a day. Infants under 12 months should not have more than 25 micrograms (1,000 IU) a day. * If your doctor has recommended you take a different amount of vitamin D, you should follow their advice. Check with your GP or pharmacist whether you are unable to take vitamin D supplement for any reason. If this is the case, vitamin D is also found in a small number of foods. * Eat food rich in vitamin D including oily fish (salmon, sardines, herring, and mackerel), red meat, liver, egg yolks and fortified foods (some fat spreads and breakfast cereals) * Taking a Vitamin D supplement as well as eating foods rich in vitamin D and spending a lot of time outside in sunshine is not a problem.   They will also receive useful information on how to access practical support such as food and fuel to keep people healthy this winter with the rising cost of living, as well as information on common winter illnesses and how to prevent them.   * 1. **Population Covered**   People who are resident, working or studying in St Helens who have been provided with the vitamin D vouchers as part of their Winter Well packs are covered in the programme. These will be targeted towards people who are considered to be more likely to experience serious illness over winter, including those aged 65 and over who are living alone.   * 1. **Any Acceptance and Exclusion Criteria and Thresholds**   **Acceptance:**  See Above.  **Exclusion:**  People who do not reside, work, or study in St Helens, and have not received the Winter Well pack.  Patients with hypercalcaemia (high levels of calcium in the blood) or metastatic calcification (deposits of calcium in otherwise normal tissue).  Caution must also be taken if the patient has a diagnosis of sarcoidosis.  If the patient is already taking vitamin D in any other form (e.g., certain Calcium preparations contain vitamin D)  Patients with Chronic kidney disease should have their native Vitamin D replaced following advice from a renal consultant regarding replacement and monitoring requirements. Check if a renal patient and if so, do not supply via this scheme.  Long-term use of anti-epileptic drugs (in particular carbamazepine, phenytoin, phenobarbital, primidone and sodium valproate) is associated with decreased bone mineral density that may lead to osteopenia, osteoporosis, and increased fractures in at-risk patients. Vitamin D status should be assessed by their usual doctor and not be supplied via this scheme.  **3.5 Interdependencies with Other Services**  The pharmacy will work closely with the St Helens Council in delivering their services. The obligations of each service are outlined below.  **Obligations of the Pharmacy**   * + The pharmacy must supply Vitamin D in exchange for the voucher in accordance with the protocol. Vitamin D must be supplied when the voucher is presented   + Pharmacy staff responsible for the service must read all the information in Appendix O, including the links to BNF and NICE guidelines.   + The pharmacy will co-operate with any locally agreed audits and assessment of service user experience.   + The pharmacy will co-operate with any audit of the voucher service.   **Obligations** **of the Council**   * + All materials required including leaflets and protocols will be supplied free of charge to the pharmacy by St Helens Council   + The Council will reimburse the pharmacy for the total cost of vitamin D including VAT plus a supply fee for each voucher processed (see Appendix E).   + The Council will provide a form (Appendix P) for recording relevant service information for the purposes of audit and claiming payment via PharmOutcomes.   + The St Helens Public Health team will be responsible for the promotion of the service locally including the development of publicity materials.   1. **Any Activity Planning Assumptions**     There are no fixed targets for the contract, however, each contracted pharmacy should actively promote and signpost people to taking vitamin D in the winter as opportunities arise. |
| 4. Applicable Service Standards |
| **4.1 Applicable National Standards e.g. NICE**  The service will be compliant with NICE and UK Office for Health Improvement and Disparities (previously Public Health England) guidance of vitamin D supplementation.  **4.2 Applicable Local Standards**  The service will follow the local **treatment protocol** as shown in Appendix O.  **4.3 Standards – Patient Group Directions**  There are no PGDs for this service however **t**he pharmacy / pharmacist will follow the local **treatment protocol** as shown in Appendix O. All supplies of therapies must be recorded on the PharmOutcomes system. |
| 5. Location of Provider Premises |
| **The Provider’s Premises are located at:**  Named community pharmacies within the Borough of St Helens at locations to be agreed with St Helens Council, Public Health. |
| 6. Required Insurances |
| The Provider must satisfy required insurances detailed in the St Helens Council PQQ Stage/PQQ Accreditation Questionnaire and must notify their professional indemnity insurers |

**APPENDIX B**

**CONDITIONS PRECEDENT**

The service provider will be familiar with the local protocols (See Appendix O).

## APPENDIX C

**QUALITY OUTCOMES INDICATORS[[1]](#footnote-1)**

Quality measures will include the completeness of assessment and monitoring information and the clinical outcomes. This will form part of the training and review process undertaken by St Helens Public Health

|  |  |  |  |
| --- | --- | --- | --- |
| **Quality Outcomes Indicators** | **Threshold** | **Method of Measurement** | **Intervention type** |
| No of clients who exchanged vouchers for tablets | 6000 | Pharmacy taking note of number of vouchers presented | Vitamin D provided to vulnerable people in the community (those who are most vulnerable to serious illness including the elderly (over 65 years) and people who live alone. They will also receive useful information on how to access practical support such as food and fuel to keep people healthy this winter with the rising cost of living. |
| Promote vitamin D uptake in the winter months | Opportunistic | N/A | Brief discussions with clients from staff who have read and understood the protocol |

**APPENDIX D**

**SERVICE USER, CARER AND STAFF SURVEYS**

If service user, carer and staff surveys have been undertaken in relation to the service the results or reports should be sent to the commissioner.

We request that all practices involved in this service will co-operate with any surveys initiated by Public Health.

**APPENDIX E**

**CHARGES & PAYMENTS**

**Terms and Fees**

* + Reimbursement will be made for each voucher dispensed in accordance with the detail set out in the Vitamin D protocol. Each voucher should be marked to confirm and claim for:
* Product supplied with strength and quantity
* Cost price including VAT
* A supply fee of £5.00 for processing each voucher.

**Payment Method**

* + Payment will include a supply fee and the cost of product including VAT for the therapy product supplied.
  + Payment for the service will be made to the participating contractor.

**Payments**

* PharmOutcomes enables real time data (including claims) to be seen by both the Pharmacy and the Council.
* Payments will be made by the Council monthly in arrears by BACS.
* Payment is subject to adherence to the terms of the service specification.
* Pharmacies should ensure that all activity is uploaded onto PharmOutcomes by the 6th of each month to enable claims to be processed for payment by the Council from the 10th of each month.
* The Council will not reimburse claims for activity that is over 3 months old, so pharmacies need to ensure that activity is uploaded onto PharmOutcomes on a regular basis

**APPENDIX F**

**SAFEGUARDING POLICIES**

The Provider shall ensure all staff are aware of, trained to a level appropriate to their role and abide by guidance and legislation on Safeguarding (adults). The Service Provider should ensure that staff are aware of and abide by:

* St. Helens Safeguarding Adults Board’s Multi-Agency Safeguarding Policy, Procedures and Good Practice Guidance. A copy of the latest Edition is available on the Board’s website <https://www.sthelens.gov.uk/media/3514/1401235_st_helens_safeguarding_adults_edition_april_2015.pdf>).

This should include understanding safeguarding referral procedures and referral pathways to social care.

**APPENDIX G**

**INCIDENTS REQUIRING REPORTING PROCEDURE**

**Insert pursuant to clause B11 (Incidents Requiring Reporting) procedure for reporting,**

**Insert pursuant to clause B11 (Incidents Requiring Reporting) procedure for reporting, investigating*, and implementing and sharing Lessons Learned from: (1) Serious Incidents (2) reportable Patient Safety Incidents; and (3) Non-Service User incidents] – See main contract***

**Serious Untoward Incidents (SUIs)**

***\* Reporting of SUI will be in line with St Helens Council Public Health Contract requirements.***

The Service Provider must report all serious and untoward incidents, complaints and compliments to the commissioners. Whilst compliments and less serious complaints can be reported as part of monthly or quarterly routine data submissions, serious untoward incidents must be reported at the first available opportunity to the Local Authority Commissioner and within any case, within forty-eight hours.

Serious Untoward Incidents include but are not restricted to:

* Incidents which in any way compromise the safety of service users or staff, including incidents of abuse/violence and how managed
* Emergencies leading to service restrictions or closures
* Staff vacancies causing service disruption (cover or minimum safety)

The Service Provider must deliver to the Commissioner a robust Management Board Action Plan detailing the response to the incident and steps that will be taken to remove or minimise future risk.

**Adverse Incident or Near Miss**

In the advent of any ‘adverse incident’ or ‘near miss’ the practice must complete the appropriate incident reporting form and demonstrate that the practice has learnt from the incident.

**APPENDIX H**

**DATA AND INFORMATION PROVISION**

Core Dataset – Requirements & Frequency:

Personal data:

• full name,

• full address,

• date of birth,

• contact number,

• health conditions,

• GP name and address.

No personal identifiable data to be sent to Commissioners.

Data Protection

a. Personal data must be protected in accordance with provisions and the principles of the Data Protection Act 1998.

b. Client data constitutes a medical record and must therefore be kept for eight years or until the client’s 25th birthday, whichever is the greater.

c. Records of clients who are pregnant or breastfeeding must be kept for 25 years.

**APPENDIX I**

**TRANSFER OF AND DISCHARGE FROM CARE PROTOCOLS**

[*Insert any locally agreed protocols including contents for discharge correspondence and relevant timescales for delivering such correspondence*]

**APPENDIX J**

**SERVICE QUALITY PERFORMANCE REPORT**

*[Insert format and manner of provision of the Service Quality Performance Report, together with the factors to be measured and reported on]*

**APPENDIX K**

**DETAILS OF REVIEW MEETINGS**

**Formal Contract Meetings**

The St Helens Public Health team will review the performance and quality of the voucher service each month until the end of the programme and will report their findings to Commissioners at the Local Authority.

**APPENDIX L**

**AGREED VARIATIONS**

**[*Insert agreed variations***

**APPENDIX M**

**DISPUTE RESOLUTION**

**Insert**

**APPENDIX N**

**SUCCESSION PLAN**

**Insert**

**APPENDIX O – Local treatment protocol**

**This protocol should be read by all staff who will be supplying vitamin D at the pharmacy setting.**

First, please read the BNF page on Colecalciferol (vitamin D3) here: [**https://bnf.nice.org.uk/drug/colecalciferol.html**](https://bnf.nice.org.uk/drug/colecalciferol.html)

The indication is **prevention** of vitamin D deficiency, and **not treatment** of vitamin D deficiency.

**Preparations**

The following preparations may be supplied. The following preparations provide supply for 1 month. Each voucher entitles supply for 4 months.

**SunVit-D3 400unit tablets (SunVit-D3 Ltd)**

| Active ingredients | Size | Unit | NHS indicative price |
| --- | --- | --- | --- |
| Colecalciferol 400 unit | 28 | tablet | £2.89 |

**ColeDose D3 400unit tablets (TriOn Pharma Ltd)**

| Active ingredients | Size | Unit | NHS indicative price |
| --- | --- | --- | --- |
| Colecalciferol 400 unit | 30 | tablet | £2.23 |

**ColeKal-D3 400unit tablets (Essential-Healthcare Ltd)**

| Active ingredients | Size | Unit | NHS indicative price |
| --- | --- | --- | --- |
| Colecalciferol 400 unit | 30 | tablet | £2.23 |

**Cubicole D3 400unit tablets (Cubic Pharmaceuticals Ltd)**

| **Active ingredients** | **Size** | **Unit** | **NHS indicative price** |
| --- | --- | --- | --- |
| Colecalciferol 400 unit | 30 | tablet | £3.55 |

**Check for contraindications for vitamin D**

Patients with hypercalcaemia (high levels of calcium in the blood) or metastatic calcification (deposits of calcium in otherwise normal tissue).

The pharmacist must check with the patient if they have these conditions. If the patient has either of these conditions, vitamin D must not be supplied. Caution must also be taken if the patient has a diagnosis of sarcoidosis. If the patient is already taking vitamin D in any other form (e.g., certain Calcium preparations contain vitamin D), further vitamin D should not be supplied via this scheme.

**Check if a renal patient**

Patients with Chronic kidney disease should have their native Vitamin D replaced following advice from a renal consultant regarding replacement and monitoring requirements. Check if a renal patient and if so, do not supply via this scheme.

**Check if on anti-epileptic medication**

Long-term use of anti-epileptic drugs (in particular carbamazepine, phenytoin, phenobarbital, primidone and sodium valproate) is associated with decreased bone mineral density that may lead to osteopenia, osteoporosis, and increased fractures in at-risk patients. Vitamin D status should be assessed by their usual doctor and not be supplied via this scheme.

**Further background to read**

The NICE guidelines for preventing vitamin D deficiency in the population can be found here. <https://www.nice.org.uk/guidance/ph56/resources/vitamin-d-supplement-use-in-specific-population-groups-pdf-1996421765317>

**Importance of vitamin D**

Colecalciferol (vitamin D3) is essential for skeletal growth and bone health. Around 20% of adults and 8 to 24% of children may have low vitamin D status. Severe deficiency can result in rickets in children and osteomalacia in adults. It is recommended that everyone over one year of age should consume 10 micrograms of vitamin D daily, especially in the winter months as it is derived from sunlight.

**Prevention of vitamin D deficiency and insufficiency**

It is important that people who find it hard to get enough vitamin D from the sun and their diet take a vitamin D supplement. Specific groups who may benefit from vitamin D supplementation are listed in the table below (Department of Health recommendations):

|  |  |
| --- | --- |
| **People at risk of vitamin D deficiency** | **Daily vitamin D supplement** |
| All pregnant and breastfeeding women | 400 International Units (10 micrograms) / day |
| People who are not exposed to much sun (e.g., people confined indoors for long periods and those who cover their skin for cultural reasons) | 400 International Units (10 micrograms) / day |
| People aged 65 years and over | 400 International Units (10 micrograms) / day |

Patients can be advised to buy over the counter vitamin D supplements or signposted to Healthy Start Clinics where Healthy Start Women’s vitamins are available beyond the winter months.

**Risk factors for vitamin D insufficiency and deficiency:**

· Infants and children under 5

· Pigmented skin (non-white ethnicity)

· Pregnant and breastfeeding women, particularly teenagers and young women

· Lack of sunlight exposure

· People over 65

· Skin concealing garments or strict sunscreen use

· Multiple, short interval pregnancies

· Elderly or housebound or confined indoors for long periods.

· Malabsorption (e.g., inflammatory bowel disease, coeliac disease, pancreatic insufficiency)

· Use of anticonvulsants, rifampicin, cholestyramine, anti-retrovirals, glucocorticoids

· Certain conditions e.g. liver or renal disease, cystic fibrosis

· Obesity (BMI > 30)

**CHECKLIST**

**APPENDIX P**

|  |  |  |  |
| --- | --- | --- | --- |
| Date: | | Time: | |
| Full name |  | | |
| Full address |  | | |
| Date of birth |  | | |
| Contact number |  | | |
| Health conditions |  | | |
| GP name and address |  | | |
| **CHECKLIST (tick as appropriate)** | | | |
| 1. **Check voucher** | | |  |
| 1. **Not already taking vitamin D in any form** | | |  |
| 1. **Check contraindications** | | | |
| 1. No hypercalcaemia | | |  |
| 1. No metastatic calcification | | |  |
| 1. No sarcoidosis | | |  |
| 1. Not a renal patient | | |  |
| 1. Not on anti-epileptic medication | | |  |
| **Explained dosage (one tablet per day)** | | |  |
| **Form fully completed** | | |  |
| **Supplied tablets for 4 months** | | |  |

1. These are suggested indicators based on evidence of good practice and national standards and guidance. Their inclusion is for local determination. [↑](#footnote-ref-1)