

## **KENT AND MEDWAY PRESCRIBING GUIDELINES FOR VITAMIN D IN ADULTS**

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### **DOCUMENT HISTORY:**

Version	Date Updated	Main Changes / Comments
1.0	January 2017	East Kent guidance ratified.
2.0	June 2020	Adjusted made to original guidance in light of new national guidance, and the formation of joint Kent and Medway Guidance
5.0	October 2020	Changes from prior JPC discussion
6.0	November 2020	Changes based on JPC comments

### **DOCUMENT DISTRIBUTION**

MOG/Clinical Group	Date discussed at MOG	Comments
Medway and Swale	6/8/2020	- Products not available for 50,000 strength Invita- updated with different product choices to provide a choice
West Kent	13/08/2020	- No comments received
East Kent	19/8/2020	- Units to be written as units rather than iu- changed - Clarification needed on prescribing in renal impairment and who initiates this. Updated within document - Where deficiency exists following compliant treatment who to refer to- addressed where possible within the paper. This will depend on comorbidities - Clarification on algorithm and NICE CKS criteria for testing, treatment duration and references updated. Cautions added for vitamin D prescribing
DGS		- Clarification on treatment duration, who this document applies to, treatment of insufficiency clarification. This has been updated within the document by updates to algorithm - Where self-care is indicated has been clarified. - Clarification needed throughout document around when self-care is needed. General comment around care home population and how this can be managed.
Kent and Medway JPC	16/9/2020	- Clarification on length of high dose treatment added - Treatment threshold for deficiency from MTW - Criteria for requesting vitamin D test at EKHUFT- removed NICE criteria from flow chart with link to local recommendations - Clarity on prevention and treatment especially for care home population

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**DO NOT ROUTINELY TEST FOR VITAMIN D DEFICIENCY**

Please refer to local trust criteria for when and what information is needed for a vitamin D assay.

YES

Test for vitamin D deficiency by measuring serum 25-hydroxyvitamin D (25[OH]D) levels To aid diagnosis and rule out other concerns consider arranging: eg Bone profile (calcium, phosphate, ALP), renal, liver and thyroid function tests, parathyroid hormone (PTH) level. Please refer to local trust criteria and NICE CKS for information

25(OH) Vitamin D level nmol/L >50:  
REPLETE

**DO NOT PRESCRIBE VITAMIN D**  
**See lifestyle advice- (appendix 1)PAGE 5**

NICE CKS guidance here  
Pregnant and breastfeeding women eligible for the NHS Healthy Start scheme can obtain free vitamin tablets by taking their coupons to a local distribution point. The daily dose of one tablet contains 400 units (IU) of vitamin D, 400 micrograms of folic acid, and 70 mg of vitamin C. The Healthy Start vitamin tablets are suitable for vegetarians; free from wheat, fish, egg, and salt; and have no colours, flavours, preservatives, or gluten-containing ingredients.

25(OH) Vitamin D level nmol/L= 25-50:  
insufficient

**If one or more of following applies:**

- Fragility fracture/osteoporosis/high fracture risk
- Drug treatment for bone disease
- Symptoms suggestive of vitamin D deficiency
- Increased risk of developing vitamin D deficiency e.g. Reduced UV exposure
- Raised PTH
- Treatment with anticonvulsants or glucocorticoids
- Malabsorption

NO

YES

25(OH) Vitamin D level nmol/L <25: deficient

**TREAT for deficiency (loading doses):** approximately 300,000 units given as a split dose over a period of weeks- see pages 2,3,4 and appendix 2 (page 6). Check for dietary calcium. Contact secondary care if hypercalcaemia exists. **This should be prescribed as an acute one off prescription and not placed on repeat.**

Following completion of loading dose

**Treat- Maintenance treatment**

Self-care for insufficiency. Advise patient to purchase this over the counter and lifestyle advice (appendix 1) see pages 2, 3, 4 and appendix 2 (page 6). Routine prescribing is not recommended for most patients

**PLEASE NOTE: if patient is taking Denosumab under shared care please refer to Kent and Medway shared care guidelines on managing vitamin D levels <50nmol/L. Loading doses may be indicated- self-care is not indicated for these patients.**

### **Prescribing points for treatment therapy for above algorithm**

- Oral vitamin D3 (Cholecalciferol) is the treatment of choice in vitamin D deficiency. Colecalciferol is considered preferable to ergocalciferol (vitamin D2) because the former raises vitamin D levels more effectively and has a longer duration of action.
- Ergocalciferol should not be prescribed, in primary care.
- Short-acting, potent vitamin D analogues (such as alfacalcidol and calcitriol), are not recommended for routine prescribing, and should only be prescribed in people with renal impairment that is severe enough to impair the hydroxylation of vitamin D to its active metabolite (specialist initiation only).
- Patients are considered to have a deficiency and require treatment when their 25-Hydroxyvitamin D (25(OH)D) level is <25 nmol/L.
- Where rapid correction of vitamin D deficiency is required, the recommended treatment regimen is based on fixed loading doses followed by regular maintenance therapy. Where deficiency requires a prescription licensed preparations should be prescribed.
- Due to the short treatment time period loading Vitamin D courses should not be put on repeat prescriptions.
- Vitamin D maintenance therapy should not be routinely prescribed as per NHSE guidance.<sup>(12)</sup>

### ***The below relates to prevention only rather than the above algorithm:***

- Adults with no risk of vitamin D deficiency should not be prescribed vitamin D products.
- **Advise that all adults living in the UK, including people at increased risk of vitamin D deficiency, should take a daily supplement containing 400 international units (IU [10 micrograms]) of vitamin D throughout the year<sup>(2)</sup>**
  - Patient's in at risk groups should not be prescribed vitamin D product but should be given appropriate lifestyle advice (Appendix 3).
  - All care home and housebound patients should be advised to purchase Vitamin D supplementation, of at least 400 units per day. This should be documented as part of the care home's medication policy.
  - Patients with darker skin should be advised to purchase Vitamin D supplementation, of at least 400 units per day throughout the year alongside lifestyle advice

**This should be bought OTC AND NOT PRESCRIBED**

**Do not prescribe vitamin D preparations to people with<sup>[2]</sup>:**

- Hypercalcaemia or hypercalciuria (or diseases or conditions which can cause these problems).
- Metastatic calcification.
- Hypervitaminosis D.
- Nephrolithiasis.
- Severe renal impairment — vitamin D<sub>3</sub> and D<sub>2</sub> are not metabolized normally; other forms of vitamin D should be used (as per above advice from renal team for these patients)

Cautions to vitamin D prescribing please see [NICE CKS](#) here and individual SPCs

**Patients at higher risk of Vitamin D deficiency (25(OH) Vitamin D level <25nmol/L)<sup>(2)</sup>**

- Are at increased risk of nutritional deficiency, for example vegans (Appendix 3) and those who do not eat fish, or generally have a poor diet.
- Are pregnant or breastfeeding.
- Are elderly (65 years and older)
- Are institutionalised ie in care home setting or housebound.(See Appendix 3)
- With darker skin (for example those of African, African- Caribbean or Asian or Middle-Eastern origin) (See Appendix 3)
- Have certain conditions (such as a malabsorption syndrome) or are taking certain drugs (such as some antiepileptic drugs) that may increase the risk of vitamin D deficiency.
- Are obese (body mass index greater than 30 kg/m<sup>2</sup>) or have had gastric bypass surgery.
- Have a family history of vitamin D deficiency.
- Pregnant and breast feeding ladies: Those women eligible, should be directed to the NHS Healthy Start scheme where they can obtain free vitamin tablets by taking their coupons to a local distribution point. The daily dose of one tablet contains 400 IU of vitamin D, 400 micrograms of folic acid, and 70 mg of vitamin C. The Healthy Start vitamin tablets are suitable for vegetarians; free from wheat, fish, egg, and salt; and have no colours, flavours, preservatives, or gluten-containing ingredients.

### Treatment of Vitamin D DEFICIENCY (Loading doses)

A loading regimen up to a total of approximately 300,000 units given as a split dose over a period of weeks. There are numerous options depending upon the product for how many weeks this period covers. Please see appendix 2 for high dose replacement regimens. ***Prescriptions for loading doses should be a single prescription issued on an acute basis and should not be placed on repeat.***

Higher doses are required in malabsorption states, liver disease or treatment of hypocalcaemia. See above algorithm for where a referral to secondary care may be considered. (Appendix 2 product choices). When prescribing a loading dose, those patients who were already receiving Calcium and Vitamin D supplementation, should STOP this supplement during the loading dose phase. This can be re-started, if appropriate, following loading dose completion.

### Maintenance following treatment for vitamin D DEFICIENCY

Following on from loading dose (rapid dose correction): Lifelong maintenance treatment of 800 units daily (higher doses of up to 2000 units a day, occasionally up to 4000 units a day may be used for certain groups of people (e.g. those with malabsorption syndromes)<sup>2</sup>. Check adequacy of calcium intake also. **Calcium replete patients should purchase over the counter vitamin D supplements as part of self-care<sup>[12]</sup>.**

Patients who were previously prescribed an oral calcium and vitamin D preparation can continue to be prescribed treatment with this preparation where appropriate. Lifestyle advice should also be provided. (Appendix 1)

### Treatment of Vitamin D INSUFFICIENCY<sup>(1,2)</sup>

Provide lifestyle advice (Appendix 1) and encourage **self-treatment with 'over the counter' vitamin D supplements** at a dose of 800 units daily (higher doses of up to 2000 units a day).

### Follow up and monitoring

25- hydroxyvitamin D should be re-checked 3-6 months<sup>2</sup> after commencing high dose replacement treatment in order to assess response where patients are still symptomatic, have malabsorption, where poor concordance is suspected or are due to commence denosumab/zoledronic acid.

Patient should also be checked for signs of vitamin D toxicity and symptoms of hypercalcaemia following high dose replacement.

- **Within one month of completing high-dose vitamin D treatment**, check adjusted serum calcium levels.
- Consider checking adjusted serum calcium levels more regularly (for example every 1–2 weeks in the first months of treatment) in people receiving calcium supplements in addition to high-dose vitamin D treatment.
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- Calcium levels: Normal: stop calcium if pt is taking calcium Low↓: advise OTC calcium (1-2g). Refer to secondary care if pt already taking calcium High↑: stop calcium if pt is taking calcium, assess hydration, consider specialist advice as probable rare alternative diagnosis (e.g. parathyroid)
- In patients with stage 5 kidney disease, adjusted serum calcium should be checked regularly for a few weeks after starting treatment.
- Once vitamin D deficiency is corrected monitoring every 12 months may be advisable for patients still considered at risk.
- Patients who do not respond after 12 weeks of treatment may be considered for referral to secondary care. Referral is dependent upon possible alternative diagnosis as per NICE CKS and algorithm above.

### **Advise safe sun exposure**

- Exposing commonly uncovered areas of the skin (such as the forearms and hands) for short periods when in strong sunlight provides vitamin D.
- Longer periods of exposure may be needed for those with darker skin.
- Advise that skin that is not usually exposed to sunlight (for example the back, abdomen and shoulders) is particularly likely to burn, so extra care is needed.
- Prolonged exposure to strong sunlight (for example leading to burning or tanning) does not lead to excess production of vitamin D, as a regulation mechanism exists to destroy excess vitamin D, but increases the risk of skin cancer.
  - Between March and October in the UK, people should protect their skin from burning by covering up with suitable clothing (such as long-sleeved tops, a broad-brimmed hat, or long skirts and trousers); seeking shade (especially between 11am and 3pm); and applying sunscreen, which should meet minimum standards for UVA protection.
  - Provide at least sun protection factor (SPF) 15 to protect against UVB.
  - Be applied liberally and frequently, according to the manufacturer's instructions. If the sunscreen is applied too thinly, the amount of protection it gives is reduced.

NB: Sunbeds are not an effective method of protecting against vitamin D deficiency because they emit high levels of UVA, which do not contribute to vitamin D synthesis but increase the risk of skin cancer.

### **Provide advice regarding increasing dietary vitamin D**

It is important to maintain dietary intake of vitamin D by taking vitamin D supplements, especially during the winter months, as it is difficult to obtain sufficient vitamin D from food sources alone because they are limited. Rich sources include cod liver oil (this also contains vitamin A which can be harmful in high doses and should be avoided in pregnancy), oily fish (such as salmon, mackerel, and sardines). Egg yolk, meat, offal, milk, mushrooms, and fortified foods (such as fat spreads and some breakfast cereals and yoghurts) contain small amounts

## APPENDIX 2

### Product choices

#### High dose replacement therapy to correct Vitamin D deficiency:

**PRESCRIBE** a total dose of approximately 300,000 units in divided doses as per the table below. These are the current preferred preparations across Kent and Medway CCG. However, there are certain patient circumstances that may require alternative preparations and regimens to be prescribed- please refer to the summary product characteristics for this regimen for these preparations. For vegan and vegetarian suitable preparations please see the link below. For those suitable for peanut or soya allergy also please see below in appendix 3.

Product (with link to SPC)	Dose regime <i>Prescriptions for loading doses should be a single prescription issued on an acute basis and should not be placed on repeat.</i>	Place in therapy	Total dose	Cost of course (Drug tariff September 2020)
<a href="#">Invita D3 50.000 units soft capsules</a>	50,000 units capsule - 1 capsule a week for 6 weeks	1 <sup>st</sup> line	300,000 units	£9.90
<a href="#">Invita D3 50.000 units/ml</a>	50,000 unit (one single oral dose solution) once a week for 6 weeks. For those with swallowing difficulties	1 <sup>st</sup> line	300,000 units	£12.50
<a href="#">Stexerol 25.000 units tablets- one tablet twice a week (suitable for vegetarians, kosher and halal)</a>	50,000 units a week for 6 weeks	2 <sup>nd</sup> line	300,000 units	£17.00
<a href="#">Fultium 20.000 unit capsules</a>	20,000 units twice a week for 7 weeks	2 <sup>nd</sup> line	280,000 units	£15.90

### Maintenance treatment:

Self-care is recommended here. These products should not routinely be prescribed <sup>[12]</sup>. Where self-care is not possible the below may be prescribed. Use must be monitored along with NICE CKS guidelines for on-going suitability. For those patients with calcium and vitamin D (eg osteoporosis) please see preferred options for calcium and vitamin D products. Ensure dietary calcium is calculated. Online calculators example [here](#).

Product	Dose regime	Cost per month(Drug tariff September 2020)
Fultium 800 unit capsules (one to two capsules a day)	800-1600 units a day	£3.60 to £7.20
Stexerol 1000 unit tablets(one to two tablets a day)	1000units-2000units a day	£2.95 - £5.90

### Over the counter preparations:

This is not an exhaustive list. When advising patients to buy over the counter products there is a [MHRA warning](#) around certain brands of unlicensed imported products for those patients with soya or arachis oil allergies.

Dose	Product	Cost per month-1000units a day	Cost per month-2000units a day
1000 units	Valupak	£0.30	£0.59
1000 units	Tesco	£1.17	£2.34
1000 units	Boots	£1.50	£3.00
1000 units	Holland and Barrett	£2.73	£5.46



All prices correct as of June 2020, and many retailers will have special offers and multi-buy deals available.

## **APPENDIX 3**

### **Special populations- these recommendations do not apply where**

#### **Institutionalised patients (care homes and housebound)**

It is thought that 75% of institutionalised people are likely to be severely Vitamin D deficient<sup>(5,6)</sup>.

Although it has been difficult to assess the benefit of calcium supplements, vitamin D supplementation has shown a reduction in fragility fractures, and hip fractures, in care home patients. Not only is Vitamin D supplementation encouraged to improve outcomes related to falls in homes, but there has also been some published data linking Vitamin D levels with dementia and Alzheimer's risk. A Swedish study of 500+ care home residents, showed a possible link between predictors of dementia and Vitamin D levels. Another study of over 1600 patients, showed that 5 years or more Vitamin D deficiency increased the risk of developing dementia or Alzheimer's by 50%. Although causative effects are difficult to determine, the link is now well documented<sup>(7,8,9,10)</sup>.

**Recommendation: All care home and housebound patients should be advised to purchase Vitamin D supplementation, of at least 400units per day. This should be documented as part of the care home's medication policy.**

#### **Darker skin population**

Having darker skin — melanin, the pigment that gives skin its brown or black colour, absorbs a proportion of the UVB radiation needed for cutaneous synthesis of vitamin D. People with dark skin may therefore need more sunlight exposure to produce the same amount of vitamin D as people with lighter skin<sup>[2]</sup>.

**Recommendation: These patients should be advised to purchase Vitamin D supplementation, of at least 400units per day throughout the year alongside lifestyle advice**<sup>[2]</sup>

#### **What to do in a pandemic**<sup>(11,13,14,15,20)</sup>

During the COVID-19 pandemic emerging evidence has suggested that global populations with lower Vitamin D levels, such as the elderly and BAME populations have an increased risk of mortality, due to the virus. However, NICE rapid guidance, published in June 2020, have confirmed that there is no evidence to support taking

vitamin D supplements to specifically prevent or treat COVID-19. The pandemic has caused a higher proportion of the population to spend more time indoors, particularly those patients who have been instructed to shield. This may increase the risk of Vitamin D deficiency.

Our recommendation is that all patients should consider purchasing a daily supplement of 400units. To protect against musculoskeletal and bone problems. This should be taken during the pandemic and as above, the at risk populations should consider taking all year round.

### **Vegan and vegetarian patients**

Dietary choices in the vegan population, can increase the risk of Vitamin D deficiency. For supplementation guidance refer to:

<https://www.sps.nhs.uk/articles/which-vitamin-d-preparations-are-suitable-for-a-vegetarian-or-vegan-diet/>

NOTE: Stexerol tablets are NOT suitable for the vegan population, but ARE suitable for the vegetarian population. According to manufacturer's guidance both Stexerol is Halal and Kosher certified.

### **Peanut or soya allergy**

Please refer to: <https://www.sps.nhs.uk/articles/is-there-a-suitable-vitamin-d-product-for-a-patient-with-a-peanut-or-soya-allergy/>

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### **Acknowledgement**

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