Prescribing for vitamin D deficiency/insufficiency in adults.

Please note, this advice is a summary of Royal Osteoporosis Society[1] and NICE CKS[2] guidance.

It is a prescriber's responsibility to make appropriate decisions for their patients and they may need to refer to additional reference sources or specialist advice to make that choice.

This guidance does not cover the management of vitamin D deficiency or insufficiency in patients with an eGFR<30ml/min; patients with CKD stage 4 or 5 are likely to need management of their vitamin D and calcium levels by specialist renal services.

Typical symptoms/signs of vitamin D deficiency

- Pain and proximal muscle weakness.
    - Rib, hip, pelvis, thigh and foot pain are typical.
- Hypocalcaemia (a late effect) which might result in seizures or tetany.

Frequent risk factors for vitamin D deficiency[2]

- Age ≥ 65 years.
- Low or no exposure to the sun, for example those who cover their skin for cultural, religious, or health reasons; who are housebound; or who are confined indoors for long periods.
- Darker skin pigmentation, for example people of African, African-Caribbean, or South Asian origin.
- Gastrointestinal or malabsorption disorder, or following weight loss surgery, resulting in a reduced ability to absorb fat-soluble vitamin D.
- Low dietary intake of vitamin D such as a vegan, vegetarian, or fish free diet.
- Severe liver disease or end-stage chronic kidney disease.
- Pregnant or breastfeeding.
- Multiple short interval pregnancies.
- Obesity - vitamin D may be sequestered into adipose tissue reducing bioavailability.
- Seasonal insufficient sunlight exposure - Welsh Government recommends that everyone should consider taking dietary supplement of vitamin D a day between the months of October and March[3]. Self-care is preferred but NHS prescribing may be appropriate if a person has no access/ability to self-purchase.
- Taking certain drugs that can increase the risk of vitamin D deficiency (*this is not a complete list*).
    - Rifampicin
    - Antiepileptics
    - Colestyramine
    - Digoxin
    - Antacids
    - Antiretroviral drugs
    - Glucocorticoids
    - Thiazides
    - Calcium channel blockers

Adapted from ABUHB vitamin D guidance Sep '21.
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Recommended investigations if vitamin D deficiency is suspected

- U&Es, Bone, GGT & FBC (to identify hypocalcaemia and provide a baseline for monitoring)
- Renal function (to exclude renal cause)
- FBC (iron deficiency commonly co-exists)
- 25-hydroxyvitamin D levels (see below for information on when to test and result interpretation)

Testing of vitamin D levels (plasma 25(OH)D)

DO TEST:

☑ Patients with bone disease that may be improved with vitamin D treatment, e.g. osteomalacia or osteoporosis.

☑ Patients with bone disease who are starting treatment that requires correction of vitamin D levels (e.g. zoledronate, denosumab, or teriparatide, **but not** oral bisphosphonates).

☑ Patients with musculoskeletal symptoms that could be attributed to vitamin D deficiency.

☑ It is not ALWAYS necessary to check levels in individuals starting treatment for osteoporosis with oral bisphosphonates who are going to be prescribed vitamin D as part of their treatment anyway BUT do consider if vitamin D deficiency could be the cause of their fractures.

☑ Patients with signs and symptoms of a vitamin D deficiency AND risk factors warrant further investigations (if not already carried out). Provide lifestyle advice and consider measurement of vitamin D levels.

Signs/symptoms of vitamin D deficiency	**Risk factors for vitamin D deficiency**	**Abnormal biochemistry** (e.g. raised Alk Phos or low calcium)	**Measure 25(OH)D level?**
✓	✓	✓	**NO** (unless uncertain diagnosis). **TREAT AS DEFICIENT**.
✓	✓	✘	**CONSIDER**.

DO NOT TEST:

☒ Asymptomatic high-risk individuals. They should be advised to use supplements as "maintenance" as indicated in the treatment table below and given lifestyle advice.

☒ Asymptomatic population-risk individuals. They should be offered lifestyle advice about sun exposure, diet and over-the-counter supplements. Population screening by measuring vitamin D blood levels is not recommended.

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Interpretation of plasma 25(OH)D results

< 25nmol/l	**DEFICIENT: High dose treatment initially, then long term maintenance treatment required.**
25-50 nmol/l	**INSUFFICIENT: Long term maintenance treatment required** if one or more risk factors present: • 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 sunlight exposure • Raised parathyroid hormone • Treatment with anticonvulsants or oral glucocorticoids • Malabsorption
> 50 nmol/l	**SUFFICIENT.**

Seek specialist advice or arrange referral before starting vitamin D treatment in cases of:

- **Conditions that predispose to hypercalcaemia**, e.g. sarcoidosis or other granulomatous disease, metastatic bone disease, focal bone pain, lymphoma, or parathyroid disorder (increased risk of vitamin D toxicity).
- **Known or suspected gastrointestinal or malabsorption disorder**. Intensive high-dose replacement or maintenance treatment may be needed under specialist supervision.
- **Renal stones (or history of).** Risk of vitamin D toxicity causing hypercalciuria and renal stone disease.
- **Severe liver disease**. Specialist treatment with activated vitamin D metabolites may be needed.
- **Renal disease** - eGFR<30ml/min. Specialist treatment with activated vitamin D metabolites may be needed.
- **Pregnancy**.
- **Atypical biochemistry or atypical clinical manifestations**.
- **Tuberculosis** (increased risk of hypercalcaemia and vitamin D toxicity).
- **Unexplained deficiency**.
- **Unexplained weight loss**.

Potential for toxicity

- A daily dose of less than 10,000 units is not usually associated with toxicity[1].
- The UK Scientific Advisory Committee on Nutrition considers that an upper limit of 4,000 units per day is safe for adults[1].
- Provided basic investigations are undertaken before treatment and renal disease, liver disease, primary hyperparathyroidism and inflammatory conditions have been excluded, then vitamin D toxicity is very rare.
- Early symptoms of toxicity include symptoms of hypercalcaemia such as thirst, polyuria and constipation.
- See also - Specialist Pharmacy Service, Safety considerations when using Vitamin D - https://www.sps.nhs.uk/articles/safety-considerations-when-using-vitamin-d/

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Monitoring

All patients receiving therapy for vitamin D **DEFICIENCY** should be monitored as follows[2]:

- Check adjusted serum calcium level within 1 month after the last loading dose, or after starting lower dose maintenance treatment with vitamin D, to detect calcium deficiency or unmasked primary hyperparathyroidism.
- If hypercalcaemia is detected, advise to stop vitamin D (and calcium, if taking) supplements and arrange ongoing investigation and management.
    - People with increased sensitivity to vitamin D, such as those with CKD, sarcoidosis, tuberculosis, or hyperparathyroidism may need lower subsequent dosing. Seek specialist advice if there is any uncertainty.
- If hypocalcaemia is detected, assess dietary calcium intake and advise to increase dietary calcium and/or on the need for calcium supplements if this is inadequate.
    - If the person is already taking a calcium supplement, arrange referral to an endocrinologist for further investigation and management.
- **Routine monitoring of serum 25[OH]D levels is not routinely needed however, consider checking the serum 25(OH)D level 3–6 months after starting vitamin D treatment in people:**
    - With symptoms of vitamin D deficiency.
    - With a malabsorption disorder.
    - Where poor compliance with medication is suspected.
    - Prescribed antiresorptive therapy who have extremely low levels of vitamin D at baseline assessment.
    - Needing sequential doses of a potent antiresorptive agent (zoledronate, denosumab, or teriparatide).
    - If the serum 25(OH)D level is < 50 nmol/l, assess adherence to treatment and arrange referral to an appropriate specialist for investigation of an underlying cause, depending on clinical judgement.
    - If the serum 25(OH)D level is > 50 nmol/l, advise on the use of lower dose maintenance treatment with vitamin D.
- Refer for specialist assessment if insufficient response to treatment after 3 months.

Dietary and lifestyle advice[2]

- Most people make sufficient vitamin D by going out for short periods in strong sunlight and leaving only areas of skin that are often exposed uncovered.
- Longer periods of sun exposure may be needed for people with dark pigmented skin.
- Prolonged exposure to strong sunlight e.g. leading to burning or tanning, is unlikely to provide additional benefit and should be avoided.
- Sunbed use is ineffective for vitamin D synthesis, is potentially harmful, and should be avoided.
- It is difficult to obtain sufficient vitamin D from food alone. The BDA vitamin D fact sheet https://www.bda.uk.com/resource/vitamin-d.html may be helpful.
- If dietary calcium intake is inadequate these calcium rich food resources may be helpful

  BDA - https://www.bda.uk.com/resource/calcium.html

  ROS - https://theros.org.uk/information-and-support/bone-health/nutrition-for-bones/calcium/calcium-rich-food-chooser/

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- Colecalciferol (vitamin D3) is usually synthetically produced using lanolin (wool fat)[4]. Products originating from wool fat may be unacceptable to vegans. Vitamin D2 (ergocalciferol) can be used in people who cannot take vitamin D3 for cultural, dietary, or religious reasons because of the animal sourcing of vitamin D3[2] but there are currently no *licensed* vitamin D2 preparations.
- Information sources on product choice in patients with dietary restrictions:
    - **Vegan diet:** Information is available from the SPS - https://www.sps.nhs.uk/articles/choosing-an-oral-vitamin-d-preparation-for-vegetarians-or-vegans/
    - **Peanut or soya allergy:** Information is available from the SPS - https://www.sps.nhs.uk/articles/is-there-a-suitable-vitamin-d-product-for-a-patient-with-a-peanut-or-soya-allergy/
    - **Halal or Kosher diet:** Information is available in the South West London CCG Local Prescribing Guideline for the Management of Vitamin D Deficiency in Adults - https://swlimo.southwestlondon.icb.nhs.uk/wp-content/uploads/SWL-Vitamin-D-Guidelines-for-Adults-and-Children.pdf

Vitamin D level < 25nmol/l - Deficiency treatment/loading regimen

For patients identified as vitamin D deficient, the **Royal Osteoporosis Society recommends approx. 300,000 units vitamin D3 orally given over 6-10 weeks**[1]. In the absence of patient-specific information precluding its use, **WEEKLY** dosing is preferred as the most cost-effective option.

To ensure that high dose treatment is continued for no longer than is needed.

- **DO NOT** add initial deficiency treatment to repeat medication.
- **DO** add a deficiency treatment stop date to the patient's record.

Suggested vitamin D3 loading doses[2]

WEEKLY DOSING - 50,000 units once a week for 6 weeks **OR** **DAILY DOSING** - 4,000 units once daily for 10 weeks.

If there are no changes in the patient's lifestyle/diet after completing loading regimen - start maintenance treatment **4 weeks AFTER loading** as for insufficiency[1].

Formulary advice	Strength	Preferred deficiency/loading cost-effective product	Cost per course
1st-line	50,000units (weekly loading)	Colecalciferol 50,000unit capsules‡	£9.90
2nd-line	50,000units (weekly loading)	Colecalciferol 50,000units/1ml oral solution unit dose ampoules sugar free‡	£12.50
	4,000units (daily loading)	Colecalciferol 4,000unit tablets‡	£15.90
Vegetarian diet	50,000units (weekly loading)	InVita D3 50,000units/1ml oral solution*	£12.50
	4,000units (daily loading)	Desunin 4,000unit tablets*	£15.90

‡ Generically prescribed products *MAY* contain animal derivatives, depending on the preparation dispensed.

* When prescribing vitamin D for patients with dietary requirements, branded prescribing is necessary to ensure that the diet-compatible product is dispensed.

Calcium

- Assess calcium intake for all patients - consider using an online calcium calculator.
  - UK Centre for Genomic and Experimental Medicine[2] https://webapps.igc.ed.ac.uk/world/research/rheumatological/calcium-calculator/
  - International Osteoporosis Foundation https://www.osteoporosis.foundation/educational-hub/topic/calcium-calculator
- If calcium intake is inadequate - < 700 mg a day (< 1000 mg a day in osteoporosis) - advise to increase dietary calcium intake. Promote the relevance of adequate dietary calcium intake. If patient is unable or unwilling to increase dietary calcium intake, consider the need for calcium supplements.
- **Combined vitamin D3/calcium preparations are not suitable for vitamin D loading**. Consider need for separate calcium supplementation.

500mg calcium equivalent per tablet
Calcium carbonate 1.25g chewable tablets sugar free.
Calcium carbonate 1.25g effervescent tablets sugar free.

600mg calcium equivalent per tablet
Calcium carbonate 1.5g chewable tablets sugar free.

1000mg calcium equivalent per tablet
Calcium carbonate 2.5g chewable tablets sugar free.

- Adjusted serum calcium levels should be checked within 1 month after either last loading dose or starting maintenance treatment (to detect unmasked hyperparathyroidism).
- Assess need for ongoing calcium supplementation.

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Vitamin D level 25 – 50 nmol/l - Insufficiency treatment or post-loading maintenance regimen

- The Royal Osteoporosis Society[1] and NICE[2] recommend maintenance regimens with doses equivalent to **800 to 2,000 units of vitamin D daily.** There is little guidance available on dose choice within this range. For daily dosing, 1000unit tablets are currently slightly more cost-effective than 800unit capsules. Equivalent weekly (e.g. 5,600unit) or monthly (e.g. 25,000unit) dosing may be preferable for some patients.
- **There is no clear consensus on the duration of maintenance treatment**. Continue for as long as deemed clinically necessary, assessing whether lifestyle changes have been made and/or checking vitamin D levels[7].
- Consider **prescribing** for those patients with osteoporosis, other chronic condition, frailty, social isolation, or surgery that results in deficiency or malabsorption[2].
- Consider advising **over the counter** self-care for other patients. OTC vitamin D3 800 or 1,000unit products can be bought from approx. £1.30 per month. Add to medical record as an OTC product purchased by the patient.

Suggested vitamin D3 maintenance doses[2]

Formulary advice	Strength	Preferred deficiency/loading cost-effective product	Cost per month
1st-line *Minimal cost difference. Choose based on patient preference for dose frequency/formulation*	800units (daily maintenance)	Colecalciferol 800unit capsules‡	£3.60
	1,000units (daily maintenance)	Colecalciferol 1,000unit tablets‡	£2.95
	1,000units (daily maintenance)	Colecalciferol 10,000units/ml oral drops sugar free‡ **10ml = 3 months supply** (200units per drop)	£1.95
	5,600units (weekly maintenance)	Colecalciferol 5,600unit capsules‡	£2.50
	25,000units (monthly maintenance)	Colecalciferol 25,000unit capsules‡	£1.32
	25,000units (monthly maintenance)	Colecalciferol 25,000units/1ml oral solution unit dose ampoules sugar free‡	£1.48
Vegetarian diet	1,000units (daily maintenance)	Stexerol-D3 1,000unit tablets*	£2.95
	25,000units (monthly maintenance)	Stexerol-D3 25,000unit tablets*	£1.42

‡ Generically prescribed products *MAY* contain animal derivatives, depending on the preparation dispensed.

* When prescribing vitamin D for patients with dietary requirements, branded prescribing is necessary to ensure that the diet-compatible product is dispensed.

Calcium

- If not already carried out, e.g. starting maintenance vitamin D without a loading regimen - assess and advise on calcium intake as for deficiency.
- If prescribing vitamin D and calcium together as maintenance, combined products are generally more cost-effective e.g.

ONE tablet **TWICE** daily

Colecalciferol 400unit/calcium carbonate 1.5g **tablets**. (*600mg calcium per tab*).
Colecalciferol 400unit/calcium carbonate 1.25g **chewable tablets**. (*500mg calcium per tab*).
Colecalciferol 400unit / Calcium carbonate 1.5g **effervescent tablets**. (*600mg calcium per tab*).

ONE tablet **ONCE** daily

Colecalciferol 880unit/calcium carbonate 2.5g chewable tablets. (*1000mg calcium per tab*).
Colecalciferol 1,000unit/calcium carbonate 2.5g chewable tablets. (*1000mg calcium per tab*).

- Adjusted serum calcium levels should be checked within 1 month after either last loading dose or starting maintenance treatment (to detect unmasked hyperparathyroidism).
- Assess need for ongoing calcium supplementation.

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References:

1. Royal Osteoporosis Society (Dec 2018). Vitamin D and Bone Health, a Practical Clinical Guideline for Patient Management. V2. Available at: https://strwebprdmedia.blob.core.windows.net/media/ef2ideu2/ros-vitamin-d-and-bone-health-in-adults-february-2020.pdf
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