

GUIDELINE FOR VITAMIN D: SUPPLEMENTATION, MEASUREMENT AND TREATMENT FOR ADULTS, CHILDREN AND YOUNG PEOPLE

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	treatment in primary and secondary care		
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1. INTRODUCTION

1.1 Purpose

Manx Care has reviewed the use of Vitamin D supplementation, taking into account relevant guidance published by NICE and other specialist sources. Vitamin D testing and supplementation will not be routinely funded by Manx Care unless they are at high risk of deficiency.

Higher risk of vitamin D deficiency in adults includes:

- Those with limited sun exposure and who spend very little time outdoors (those who are housebound, in a care home or an institution, for example those in prison)
- People with dark skin (African, African-Caribbean, Asian or Middle-Eastern ethnic origin)
- Those who have an adverse effect or symptom of a more complex illness (such as a malabsorption syndrome) or who are taking certain medications (such as Phenytoin, Carbamazepine, Tamoxifen, Clotrimazole, Rifampicin, Dexamethasone, Nifedipine and Spironolactone) or herbal medications such as St Johns-Wort, that may increase the risk of vitamin D deficiency.
- All patients initiated on anti-resorptives (e.g. Zolendronic acid, denosumab or oral bisphosphonates) who need to maintain vitamin D levels at > 50nmol/L.
- Those with bone diseases that may improve with Vitamin D treatment.

1.2 Scope

All primary and secondary care prescribers

2. GUIDELINE

2.1 Background Information

Vitamin D is a fat soluble vitamin that regulates Calcium and Phosphate homeostasis and is therefore vital for musculoskeletal health. There are two forms: Vitamin D3 (Colecalciferol) which is synthesised in the skin by the action of sunlight and in foods (natural, fortified and supplements), and D2 (Ergocalciferol) which can be found in natural foods, fortified foods and food supplements.

However, dietary sources of Vitamin D are limited with oily fish being the only significant source. Small amounts can be found in egg yolk, red meat and fortified foods (formula milks, breakfast cereal and margarine)

The major natural source is from skin synthesis following exposure to sunlight. From October to the beginning of April in the Isle of Man there is no ambient ultraviolet sunlight of the appropriate wavelength for skin synthesis of Vitamin D. It is estimated that 23% of children and 8% of adults may have low Vitamin D status.

UK NHS guidance suggests that during the autumn and winter months everyone within the UK should take an average of 10mcg Vitamin D supplement every day to support general health, bone and muscle health. This is especially important for those who have limited exposure to sunlight during the spring and summer, such as those in residential homes, nursing homes and those in prison.

2.2 Measurement

- 2.2.1 Vitamin D measurement will not be routinely funded for asymptomatic individuals except in those who belong to an at risk group. As per recommendations from the Royal Osteoporosis Society (ROS), testing for Vitamin D deficiency will be funded for the following:
 - Patients with musculoskeletal symptoms that could be attributed to Vitamin D
 deficiency. Symptoms may include bone discomfort or pain in lower back, pelvis and
 lower extremities, symmetric lower back pain or chronic widespread pain. Muscle
 aches and weakness which may be marked and most noticeable in the quadriceps and
 glutei, resulting in difficulty rising from a seating position, or a waddling gait.
 Impaired physical function or fragility fracture.
 - Patients suspected of having bone diseases that may be improved with Vitamin D treatment. This request may come from secondary care.
 - Patients with bone diseases, prior to specific treatment where correcting Vitamin D deficiency may be necessary. This request may come from secondary care.
- **2.2.2** The ROS guidelines for children and young people advises that routine Vitamin D testing is not recommended in children and young people unless there is a clear indication including:

- Symptoms or signs of rickets (progressive bowing legs and knock knees, wrist swelling, rachitic rosary, craniotabes, delayed tooth eruption and enamel hypoplasia)
- Other symptoms or conditions associated with Vitamin D deficiency (unexplained bone pain for over three months, muscular weakness, tetany (involuntary muscle contractions), seizures and cardiomyopathy.
- Abnormal investigations (low plasma calcium or phosphate, high alkaline phosphatase) radiographs showing osteopenia, rickets or pathological fractures.
- Chronic disease that may increase risk of deficiency (chronic renal and/or liver disease) malabsorption syndromes e.g Coeliac disease, Crohn's disease or Cystic fibrosis)
- Treatment with bone targeted drugs that require Vitamin D sufficiency (bisphosphonates)

2.3 Treatment

- **2.3.1** The Royal Osteoporosis Society guidance, following a review of the Scientific Advisory Committee on Nutrition and the Institute of Medicine, proposes the following Vitamin D thresholds in respect of bone health:
 - Plasma 25(OH)D <25nmol/L = **Deficient**
 - Plasma 25(OH)D 25-50nmol/L = Inadequate/Insufficient in some people
 - Plasma 25(OH)D >50nmol/L = **Sufficient in most of the population**
- **2.3.2** For patients with **insufficient** levels, treatment is recommended in patients with the following:
 - Fragility fracture, documented osteoporosis or high fracture risk
 - Treatment with antiresorptive medication (Zoledronic acid)
 - Symptoms suggestive of Vitamin D deficiency
 - Increased risk of developing deficiency in the future due to reduced exposure to sunlight, religious/cultural dress code, skin colour etc.
 - Raised parathyroid hormone
 - Medication with antiepileptic drugs or oral glucocorticoids
- **2.3.2** Loading regimens are recommended for the treatment of deficiency in adults up to a total of approximately 300,000 IU of Colecalciferol, given either as weekly or daily split doses. The exact regimen will depend on patient choice but may include:
 - 50,000 IU (tablets, capsules or liquid) given once weekly for six weeks (300,000 IU)
 - 40,000 IU given once weekly for seven weeks (280,000 IU)
 - 20,000 IU Two each week for seven weeks (280,00 IU)
 - 1,000 IU tablets, four a day for 10 weeks (280,000 IU)
 - 800 IU capsules, five a day given for 10 weeks (280,000 IU)

Maintenance regimens should generally be started one month after loading with doses equivalent to 800 to 2,000 IU daily (up to a maximum of 4,000 IU daily), given either daily or intermittently at a higher equivalent dose. Prescribing of maintenance doses is not recommended for the majority of the general Manx population and should instead be purchased over the counter unless the patient fits into the categories listed above.

Maintenance for Care Home or Housebound Patients

The CQC advises that providers (nursing homes, prison healthcare etc) should support people's full nutritional needs which includes Vitamin D supplementation throughout the year.

We advise that the GP or healthcare provider are contacted to check if Vitamin D is safe for residents before starting. A maintenance dose of between 800 and 1,000 units is recommended.

Each nursing home or facility will need to have a policy in place for the provision of Vitamin D, this may also be included in the homely remedies policy.

Residents should be supported to self-administer Vitamin D supplements if they chose to and if it safe for them to do so.

However, where clinically indicated, prescriptions for maintenance dose will be provided by the GP.

2.4 Vitamin D and COVID 19

Evidence of a link between Vitamin D and COVID 19 is still being researched with larger trials needed. The NICE rapid evidence summary concluded that there is no evidence to support taking Vitamin D supplements to specifically prevent or treat COVID 19. However, all people should continue to follow the advice on daily Vitamin D supplementation to maintain bone and muscle health during the COVID 19 pandemic.

2.5 Monitoring

All patients receiving loading doses of Vitamin D should have their plasma-calcium concentration checked at intervals initially once a month.

During long term treatment, serum calcium, urinary calcium excretion and renal function should be monitored by measuring the serum creatinine level. Monitoring is especially important for elderly patients who concomitantly take cardiac glycosides or diuretics. Routine monitoring of serum 25(OH)D is unnecessary but may be appropriate in patients with symptomatic Vitamin D deficiency or malabsorption and where poor compliance with medication is suspected. If the patient is still symptomatic after treatment, wait at least three months, preferably six months, before retesting 25(OH)D.

2.6 Toxicity

Excessive intake of Vitamin D can lead to toxic effects. Overt Vitamin D toxicity manifests itself through chronic hypercalcaemia (elevated plasma calcium). It is rarely seen unless the Vitamin D dose is very high, either through inappropriate high dose treatment or accidental overdosing. Less severe symptoms of Vitamin D toxicity include prolonged hypercalciuria, which potentially increases the risk of renal stones.

The Institute Of Medicines Report in 2011 set the upper limit (UL) for vitamin D at 4,000IU/day. They advise that acute toxicity would be caused by doses of vitamin D

probably in excess of 10,000 IU/day, which result in serum 25(OH)D concentrations >375 nmol/l. Potential chronic toxicity would result from administration of doses above 4,000 IU/day for extended periods, possibly for years, that cause serum 25(OH)D concentrations in the 125–375 nmol/l range.

2.7 Recommendations (Please see appendix 1)

- a) Do not routinely test for Vitamin D deficiency unless the patient is symptomatic, at very high risk of deficiency or there is a clinical reason to do so. When a Vitamin D test is indicated, use plasma 25-hydroxyvitamin D [25(OH)] to measure Vitamin D status.
- b) Self-care with over the counter (OTC) licensed Vitamin D supplements should be recommended, if appropriate; for those at risk of deficiency, patients that are insufficient and for the general Manx population as maintenance therapy, especially during the winter months. For the general population of the Isle of Man aged four years and above, a Reference Nutrient Intake (RNI) of 400IU (10mcg) a day is recommended, although this may need to be higher depending on patient circumstances.
- c) For the elderly the recommended daily dose would be higher, between 800IU and 1,000IU a day, due to poor absorption.
- d) A "Safe Intake" of 340-400IU (8.5mcg 10mcg) a day is recommended for ages 0 to one (including exclusively breast fed and partially breast fed infants, from birth) and 400IU (10mcg) for ages one to four years.
- e) Babies receiving more than 500ml of infant formula a day do not require Vitamin D supplements.
- f) For the treatment of Vitamin D deficiency (plasma 25(OH)D <25nmol/L) Vitamin D supplements should be prescribed by brand name as per the Manx Care formulary (please see appendix 2), at appropriate doses and duration of treatment to treat deficiency. Once the loading dose has been completed, maintenance therapy should be purchased over the counter one month after the loading dose.</p>
- g) When a treatment course is needed, this should be prescribed as an acute medication and not be placed on repeat.
- h) Care homes are responsible for the provision of Vitamin D as part of providing and meeting daily nutritional needs.
- i) Housebound patients should be encouraged to purchase Vitamin D supplements themselves, but if unable to do so the GP may prescribe.
- j) The Royal Osteoporosis Society (ROS) recommends oral Vitamin D3 as the treatment of choice for Vitamin D deficiency and therefore branded oral Colecalciferol should be prescribed.

3 REFERENCES AND/OR RESOURCES

- NICE PH56: Vitamin D supplement use is specific population groups https://www.nice.org.uk/guidance/ph56 (Last accessed 22/9/21)
- BNF online https://bnf.nice.org.uk/treatment-summary/vitamins.html (Last accessed 22/9/21)
- Prescqipp bulletin 275: Vitamin D https://www.prescqipp.info/our-resources/bulletins/bulletin-275-vitamin-d/ (Last accessed 22/9/21)

- Pan Mersey: Treatment of Vitamin deficiency in adults
 https://www.panmerseyapc.nhs.uk/media/2146/vitamind-adult.pdf (Last accessed 22/9/21)
- Royal Osteoporosis Society https://theros.org.uk/ (Last accessed 22/9/21)
- NCBI: Vitamin D Toxicity A Clinical Perspective https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6158375/#:~:text=The%20IOM%20cited%20several%20association,)%2C%20and%20falls%20and%20fractures.
- Care Quality Commission Vitamin D supplements, supporting people who receive adult social care. https://www.cqc.org.uk/guidance-providers/adult-social-care/vitamin-d-supplements-supporting-people-who-receive-adult

4 APPENDICES

 Appendix 1: Vitamin D and Bone Health – a Practical Clinical Guideline for Patient Manager (see page 6) https://theros.org.uk/media/5imnumtq/ros-vitamin-d-quick-guide-november-2018.pdf?UNLID=6983961762021419154626

(see next page)



Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management

The quick guide (for use in conjunction with full guideline)

