Northern Lincolnshire and Goole NHS Foundation Trust

Chief Operating Officer's Directorate
Pharmacy

GUIDANCE ON THE PREVENTION, DIAGNOSIS AND MANAGEMENT OF VITAMIN D DEFICIENCY

Reference:	DCM214
Version:	1.2
This version issued:	20/07/23
Result of last review:	Minor changes
Date approved by owner (if applicable):	
Date approved:	14/07/23
Approving body:	Medicine & Therapeutics Committee
Date for review:	July 2026
Owner:	Simon Priestley, Chief Pharmacist & Clinical Lead for Medicines Optimisation
Document type:	Miscellaneous
Number of pages:	15 (including front sheet)
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Contents

1.0 Guidance on the Prevention, Diagnosis and Management of Vitamin D Deficiency

1.1 The following guidance has been adapted in line with NICE CKS 2016 guidelines

1.2 Prevention: An estimated 60-70% of the UK population could be vitamin D insufficient.

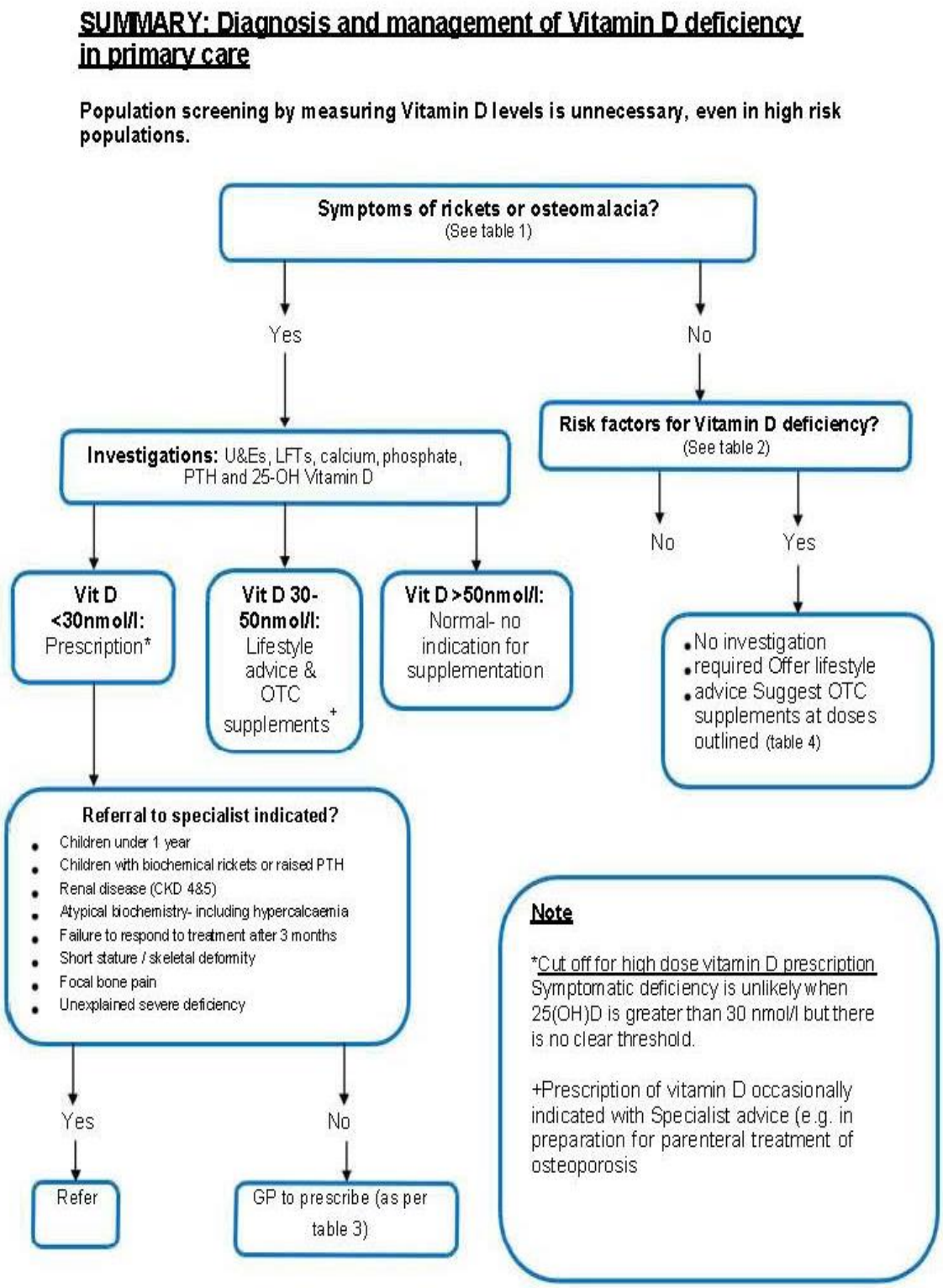
1.3 For this reason:

- Population screening of vitamin D blood levels is not recommended
- Lifestyle advice and use of over the counter vitamin D preparations are recommended for prevention. Patient information resources are included in this guideline
- The government Healthy Start Scheme offers free vitamin supplements (containing vitamin D) to eligible patients. They can also be purchased cheaply by those not eligible for free supplies
- Prescriptions of vitamin D preparations should be reserved for treatment of patients with **symptoms AND low vitamin D** levels and those patients who have an indication for supplementation but are unable to access non-prescription vitamin D supplementation such as the elderly and infirm

1.4 Pharmacy keep the following strengths of Vitamin D (prescribed as colecalciferol):

- 50,000 units, 20,000 units and 10,000 units for high dose treatment
  1000 units, 800 units and 400 units for maintenance treatment

2.0 SUMMARY: Diagnosis and management of Vitamin D deficiency in primary care



3.0 Introduction

3.1 Vitamin D deficiency is an important public health issue concerning infants, young children, adults & elderly people. Recent evidence estimates that 60-70% of population could be vitamin D insufficient, particularly ethnic minority and the immigrant population.

3.2 This guideline has been revised for 2013 following the publication of the National Osteoporosis Society "Vitamin D and Bone Health" document and new developments in the commercial field of vitamin D supplements. The document provides information on vitamin D, diagnosis and management of deficiency and advice for patients with insufficiency.

4.0 Vitamin D Physiology

4.1 What is Vitamin D?

4.1.1 Vitamin D is a group of fat soluble vitamins that is essential for bone formation in all age groups. The 2 main forms are D2 (ergocalciferol), predominantly from plants and D3 (colecalciferol), mainly from animal sources. Both have similar actions. Vitamin D is activated in the liver to 25- hydroxycolecalciferol and then in the kidney to 1,25- dihydroxycolecalciferol (active vitamin D). The most well established action of vitamin D is to promote calcium absorption by the GI tract.

4.1.2 90% of our daily vitamin requirement is obtained by the action of UVB sunlight on the skin (only during April to September in the United Kingdom).

4.1.3 10% is obtained through diet such as oily fish (sardines, salmon), liver, egg yolks, fortified margarine and fortified breakfast cereals).

4.2 Does Vitamin D have other functions?

Research has identified epidemiological links between vitamin D levels and various disease states. It remains unclear whether vitamin D could offer pharmacological benefit for any of these conditions. At the present time the indications for vitamin D treatment relate to maintenance of calcium homeostasis and bone health via the primary mode of action to aid absorption of calcium at the gut.

5.0 Prevention of Vitamin D Deficiency

5.1 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) or units for short, of vitamin D throughout the year, including in the winter months.

5.2 Advise that:

- 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 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

- All other people can purchase multivitamin preparations (tablets, capsules, and liquids) containing 400 units of vitamin D from pharmacies. Allergies and dietary restrictions should be considered before buying these preparations to ensure that their content is safe and appropriate

6.0 Diagnosis

6.1 Vitamin D deficiency is best assessed by measurement of serum 25-OH vitamin D. Measurement of other vitamin D metabolites or sub-fractions adds nothing further and is not recommended.

6.2 Population screening is NOT recommended. Vitamin D deficiency should be suspected in patients presenting with clinical features as detailed in table 1 below and the general principle is to test only those individuals who have symptoms or features suggestive of vitamin D deficiency or osteomalacia.

6.3 Clinical features of Vitamin D deficiency (Table 1)

Children	Adults
Poor growth, delayed fontanelle closure Delayed walking or a waddling gait Tender or swollen joints, classically the wrists or costochondral junctions Deformed bones (bow legs or knock knees) Bone pain or tenderness Muscle pain or proximal myopathy Delayed eruption of teeth, or enamel hypoplasia Carpopedal spasm, tetany, seizures or irritability due to hypocalcaemia & requiring urgent treatment	Gradual onset & persistent bone pain without preceding mechanical injury (frequently in back, ribs or lower limb) Fragility fracture Proximal muscle weakness (difficulty with stairs, getting up off the floor or standing after sitting in a low chair, waddling gait) or muscle pain Carpopedal spasm, tetany, seizures or irritability due to hypocalcaemia & requiring urgent treatment

6.4 Risk factors for Vitamin D deficiency (Table 2)

Age Groups	Poor exposure to UVB light	Poor dietary intake	Metabolic risk
≥65years <5 years Pregnant women Breastfeeding women	Pigmented skin Occlusive garments Housebound Use of sun blocking creams	Vegetarian (or fish-free diet) Malabsorption, including bariatric surgery patients Cholestatic liver disease Breast fed infants	Reduced synthesis Liver disease (reduced stores) Renal disease (reduced synthesis of active vitamin D) Obese people (excess storage in fat) Drugs: Rifampicin, Antiretroviral drugs, anticonvulsants, cholestyramine, glucocorticoids.

6.4.1 Investigations (to be arranged by primary care):

- U&Es, LFTs, calcium, phosphate and 25-OH Vitamin D
- PTH (parathyroid hormone) should be measured when the adjusted calcium is significantly low (<2.15)
- Children: In addition, albumin & PTH should be measured routinely in children (refer if PTH high)
- The findings in osteomalacia are a low/normal calcium, low/normal phosphate, raised alkaline phosphatase, low vitamin D and raised PTH (secondary hyperparathyroidism)

6.4.2 **Vitamin D levels** are expressed as nmol/L (nanogram/ml x 2.5 = nmol/L). The definition of vitamin D deficiency and insufficiency is based on blood measurements of 25-hydroxyvitamin D (25-OH vitamin D):

- >50 nmol/l Satisfactory Vitamin D levels
- 30-50 nmol/l Vitamin D insufficiency
- <30 nmol/l Vitamin D deficiency

Note: In patients with a Vitamin D level >30 nmol/l, symptoms are unlikely to be due to Vitamin D deficiency. However, clinicians should use clinical judgment when considering the diagnosis and treatment plan for an individual patient.

7.0 Management of Vitamin D Deficiency (i.e. Vitamin D level <30nmol/l)

7.1 Patients meeting the above criteria should be managed according to the following principles:

- **Treat for vitamin D deficiency if serum 25-hydroxyvitamin D (25-OH vitamin D) levels are** less than 30 nmol/L
- **Treat for vitamin D insufficiency if serum 25-OH vitamin D levels are** in the range of 30–50 nmol/L and the person:
  - Has a fragility fracture, documented osteoporosis, or high fracture risk
  - Is being treated with an antiresorptive drug for bone disease
  - Has symptoms suggestive of vitamin D deficiency
  - Is at increased risk of developing vitamin D deficiency in the future, for example because of reduced sunlight exposure
  - Has raised parathyroid hormone levels
  - Is taking an antiepileptic drug or an oral corticosteroid, or is on long-term treatment with other drugs known to cause vitamin D deficiency, such as colestyramine
  - Has a malabsorption disorder (for example Crohn's disease) or other condition known to cause vitamin D deficiency, such as chronic kidney disease

- Available evidence suggests that oral colecalciferol offers greater improvements in serum 25-OH Vitamin D compared with oral ergocalciferol or intramuscular preparations at equivalent doses. As such, oral colecalciferol is the first line treatment option

- Alfacalcidol and calcitriol are completely inappropriate for treatment of vitamin D deficiency outside of CKD 4-5, due to high risk of toxicity

Table 3	ADULTS	CHILDREN (>6 months)
Drug	Colecalciferol	Colecalciferol
Dose	20,000 units daily orally x 15 days or 50,000 units weekly x 6 weeks Standard course 300,000 units total dose. (Consider increase total dose to 400,000 - 600,000 units if very low baseline or poor absorption anticipated).	**6 months – 12 years** 6000 units daily orally **for 4 – 8 weeks**** **12 – 18 years 10,000 units daily orally for 4 – 8 weeks**** Ensure dietary factors improved. Check PTH normalised – indicating deficiency Has resolved
Monitoring	6 weeks; Calcium, phosphate, ALP. Repeat vitamin D levels only if symptoms persist.	1 month (or 1 week if symptomatic hypocalcaemia): calcium, phosphate, ALP and PTH. Repeat 3 monthly until treatment stopped. If ALP does not improve, check compliance. Where treatment continues >6 months, check early morning urine calcium:creatinine.
Follow Up	No further monitoring or follow up needed.	Review and investigate family members. Give prevention advice

		as a minimum.
Maintenance Therapy (This can be used as initial treatment in asymptomatic individuals)	800 units daily. To be continued long term. Higher doses up to 2400 units daily may be needed in some patients (e.g. malabsorption).	400 – 800 units daily. To be continued long term. Healthy Start vitamins, Abidec or Dalivit vitamin Drops are recommended.
Long term monitoring	No routine monitoring or rechecking of serum 25OHD levels is needed whilst on maintenance therapy. Recheck biochemistry if symptoms return or malabsortion/poor compliance suspected.	

N.B. *Loading regimens for treatment of deficiency up to a total of approximately 300,000 units given either as weekly or daily split doses. The exact regimen will depend on the local availability of vitamin D.

N.B. **The same effect may be achieved by multiplying the dose by seven and giving it weekly if compliance is a concern.

N.B. Where poor compliance is suspected give supervised stat oral doses (100,000 units colecalciferol for adults) at weekly intervals.

N.B. Liquid “specials” of vitamin D (unlicensed) should NOT be routinely prescribed. Cost effective alternatives are available.

N.B. Most vitamin D preparations contain gelatin. Hux D3 & Pro D3 are vegetarian and Halal products.

N.B. In patients where Fultium D3® is intolerable, or an alternative is required for maintenance.

8.0 Management of Vitamin D Insufficiency (i.e. Vitamin D level 30-50nmol/l AND risk factors for Vitamin D deficiency)

8.1 Patients should be offered lifestyle advice and advised to purchase supplements over the counter (OTC) at doses outlined above for maintenance therapy. Healthy start vitamins are available for children <5years.

8.2 Lifestyle advice for Vitamin D insufficiency (and deficiency)

8.2.1 **Sun exposure:** Sun exposure is the main source of vitamin D and should be exploited! However, this should be balanced with the risks of excessive exposure. Time required in the sun to make sufficient vitamin D is generally short and less than the time needed for skin to burn. This should be adjusted on an individual basis and safe practices adopted. Little and often is best. The following advice was given in the New England Journal of Medicine (2007): "Exposure of arms and legs for 5 to 30 minutes (depending on time of day, season, latitude, and skin pigmentation) between the hours of 10 a.m. and 3 p.m. twice a week is often adequate".

Note: Use of creams containing sun protection factors reduces vitamin D synthesis by >95%.

8.2.2 **Diet:** Dietary sources of Vitamin D include:

- Oily Fish – Salmon, Mackerel, Sardines, Herring, Pilchards, Fresh Tuna etc. Cod liver oil & other fish oils
- Red meat & Eggs yolk
- Infant formula milk, powdered milk Fortified breakfast cereals
- Soya products, fortified margarines, low fat spreads

8.3 It is difficult to obtain enough vitamin D from usual diet alone. The average daily intake from a normal diet is just 80-160 units/day (2 - 4 micrograms). Where supplementation is indicated, the following doses are recommended (Table 4):

Age and Risk Group	Daily Requirement
Newborn up to 1 month	300 – 400 units /day (7.5-10 microgram)
1 month – 18 years	400 – 1000 units/day (10-25 microgram)
Pregnant and breastfeeding women	400 units/day (10 microgram)
Adults	400 units/day (10 microgram)
Adults not exposed to much sunlight	400 units/day (10 microgram)

9.0 Special Circumstances

9.1 Primary hyperparathyroidism / Hypercalcaemia

9.1.1 Patients with Primary Hyperparathyroidism frequently have vitamin D deficiency Vitamin D deficiency in primary hyperparathyroidism may exacerbate bone loss in this condition.

9.1.2 Treatment with vitamin D has the potential to exacerbate hypercalcaemia and hypercalciuria. **Specialist advice (Endocrinology) is recommended prior to vitamin D treatment in this context.** Prescription supplements (e.g. Fultium D3) are likely to be warranted to ensure accuracy of dosing and avoid toxicity.

9.2 Development of New Hypercalcaemia during Vitamin D Replacement

Patients may develop hypercalcaemia during correction of vitamin D deficiency. This can indicate vitamin D toxicity although this would not be expected when using recommended doses. Most other cases are due to underlying and previously undiagnosed Primary Hyperparathyroidism although granulomatous conditions are also relevant (e.g. Sarcoidosis). The diagnosis can be aided by measurement of Parathyroid Hormone (PTH) - and such cases should be referred to Endocrinology for assessment.

9.3 Elderly Patients

9.3.1 The majority of elderly patients are ambulant and community dwelling. Many will still be at risk of vitamin D deficiency but the principles of management are not different to that presented in the rest of this document. Dual supplementation with calcium and low dose vitamin D (as in numerous commercially available preparations) is more likely to be appropriate in the elderly and infirm where sun exposure is likely to be poor and gastrointestinal calcium absorption reduced.

9.3.2 Occasionally lone vitamin D supplementation may be needed (e.g. concurrent primary hyperparathyroidism) Meta-analysis suggests that Vitamin D supplementation may prevent falls, although this is controversial. Vitamin D supplementation (with or without calcium) will invariably be appropriate in recurrent fallers. In some cases high dose supplementation will be recommended in this context on a case by case basis by the Falls Clinic team (Vitamin D deficiency has been shown by local Audit to be almost ubiquitous in the Falls clinic population so testing of deficiency prior to treatment will not always be needed). Older people with falls should be assessed for their falls risk factors and referred as per local guidelines.

9.4 Asian Population

9.4.1 A combination of skin type and cultural factors which reduce sun exposure and limit dietary and supplement choices mean that Asian patients or patients with pigmented skin are at particular risk of Vitamin D deficiency and have particular barriers to effective treatment.

9.4.2 In fact vitamin D insufficiency is almost ubiquitous in this group and virtually all patients will be appropriate for supplementation. It is known that take up of "Over the Counter" options is low in this group.

9.5 Parenteral Osteoporosis Treatments

Parenteral treatments for osteoporosis require adequate vitamin D levels in order to be safe and effective. The osteoporosis team will be involved with the care of these patients and will optimise vitamin D prior to initiation of treatment. It is vital that vitamin D levels are adequate prior to each injection to minimise the risk of severe hypocalcaemia. Vitamin D levels should be checked in patients who are not on regular supplements or in those whose compliance is suspected to be poor. The aim is to ensure 25-OH Vitamin D levels are greater than 50 nmol/l prior to treatment.

10.0 Referral

The following patients should be referred to secondary care for further investigation:

- Children under 1 year
- Children with biochemical rickets or raised PTH Renal disease (CKD 4&5)
- Atypical biochemistry- including hypercalcaemia or failure to respond to treatment after 3 months or short stature/skeletal deformity
- Focal bone pain
- Unexplained severe deficiency or unexplained weight loss

11.0 References

11.1 Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management. National Osteoporosis Society. April 2013.

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11.3 Primary vitamin D deficiency in adults. Drug & Therapeutics Bulletin. 2006; 44(4): 25-29.

11.4 Vitamin D – Advice on supplements for at risk groups. CMO CAS letter 2012. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_132509

11.5 Vitamin D Deficiency. Holick MF. New England Journal of Medicine 2007;357:266-81. Vitamin D for the treatment of chronic painful conditions in adults (review). The Cochrane Collaboration. 2010. Available from: http://onlinelibrary.wiley.com/o/cochrane/clsysrev/articles/CD007771/pdf_fs.html

11.6 Guide for Vitamin D in Childhood. Royal College of Paediatrics and Child Health. October 2013: http://www.rcpch.ac.uk/system/files/protected/page/vitdguidancedraftspreads%20FINAL%2 0for%20website.pdf

11.7 Vitamin D deficiency in adults - treatment and prevention. Available from: NICE CKS 2016 November reference

11.8 Quick Reference Guide for Healthcare Professionals: https://www.england.nhs.uk/publication/quick-reference-guide-for-healthcare-professionals-conditions-for-which-over-the-counter-items-should-not-routinely-be-prescribed-in-primary-care/

12.0 Equality Act (2010)

12.1 Northern Lincolnshire and Goole NHS Foundation Trust is committed to promoting a pro-active and inclusive approach to equality which supports and encourages an inclusive culture which values diversity.

12.2 The Trust is committed to building a workforce which is valued and whose diversity reflects the community it serves, allowing the Trust to deliver the best possible healthcare service to the community. In doing so, the Trust will enable all staff to achieve their full potential in an environment characterised by dignity and mutual respect.

12.3 The Trust aims to design and provide services, implement policies and make decisions that meet the diverse needs of our patients and their carers the

general population we serve and our workforce, ensuring that none are placed at a disadvantage.

12.4 We therefore strive to ensure that in both employment and service provision no individual is discriminated against or treated less favourably by reason of age, disability, gender, pregnancy or maternity, marital status or civil partnership, race, religion or belief, sexual orientation or transgender (Equality Act 2010).

13.0 Freedom to Speak Up

Where a member of staff has a safety or other concern about any arrangements or practices undertaken in accordance with this document, please speak in the first instance to your line manager. Guidance on raising concerns is also available by referring to the Freedom to Speak Up Policy for the NHS (DCP126) which has been adopted by the Trust in line with national guidance. Staff can raise concerns verbally, by letter, email or by completing an incident form. Staff can also contact the Trust's Freedom to Speak Up Guardian in confidence by email to nlg-tr.ftsuguardian@nhs.net or telephone 07892764607. More details about how to raise concerns with the Trust's Freedom to Speak Up Guardian can be found on the Trust's intranet site.

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