Evidence Review for Area Prescribing Committee

Treatment: Renavit

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Summary page

- How strong is the evidence for claimed efficacy?
  (Grade A = > 1 RCT or meta-analysis; Grade B = 1 RCT or descriptive study; Grade C = expert committee report/opinion)

This is not a submission for a new therapy but a replacement for an existing one which is an established part of dialysis therapy. Initial recommendations come from national guidelines (European Best Practice)[1] and Renal Association recommendations.[2]

- Potential advantages in terms of: efficacy, compliance, pharmacokinetics, drug interactions and adverse effects?

Renavit, would meet the EBPG at a dose of one tablet daily, it also contains folic acid (which we supplement separately) and is less expensive than Ketovite. In addition Ketovite requires cold storage and renavit does not.

- Is there a clear place in therapy / treatment pathway?
  (E.g. patient type / characteristics, and relationship to other therapies)

Recommended for all dialysis patient (as Ketovite is currently).

- Is the drug licensed / licensed for this indication in the United Kingdom?

Yes

- Is monitoring for efficacy required?

No

- Is monitoring for toxicity required?

No

- Is dose titration required?

No

- Recommended traffic light status (i.e. who will prescribe the drug and any restrictions required)?

Mostly primary care as current therapy

- Role of the specialist (if applicable)?

Recommendation of initiation

- Role of GP (if applicable)?

Prescribing

- Financial implications/ Budget impact? (including estimated cost of pathway and costs/opportunities for the local health economy if possible)

Represents a cost saving

Estimated cost or saving per 100 000 population:

Cost saving of £60.52 per patient per year.

- Other issues

Advantages for storage and reduced tablet burden for patients.

- National Guidance available

Water soluable vitamin supplementation recommended by EBPG [1] and Renal Association.[2]

Recommendations:

Switch patients from Ketovite to Renavit tablets 1 OD

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment

1. Purpose of the Review

New product on market

2. Appropriateness

2.1 The patient: Renal dialysis patients

2.2 The problem: Vitamin supplementation

Definition: Vitamin supplementation in dialysis patients.

Effects and prognosis:

Patients with chronic kidney disease (CKD) undergoing dialysis are at risk of lower serum levels of water soluble vitamins caused by abnormal renal metabolism, dietary restriction, poor gastrointestinal absorption and dialysate losses. The European Best Practice Guidelines[1] (EBPG) and Renal Association Clinical Practice Guidelines for Nutrition in CKD[2] recommend dialysis patients are prescribed water soluble vitamin supplements. It is difficult for clinicians and patients to meet the increased requirements for water-soluble vitamins as the majority of these patients are on restrictive low potassium diets, limiting their intake of fruit and vegetables. The Dialysis Outcomes and Practice Patterns Study (DOPPS)[3] has suggested dialysis patients receiving water soluble vitamin supplements have a lower mortality risk compared to patients not receiving supplements. Vitamin supplements containing fat soluble vitamins (A, D, E and K) are not recommended due to reduced renal losses and risk of hypervitaminosis, hence standard multivitamin preparations are not suitable. Previous research has shown that the provision of water-soluble vitamins for haemodialysis patients varies across the UK, with only 58% of renal units providing routine replacement Therapy.[4] Despite the lack of robust evidence, guidance acknowledges vitamin provision as a low cost, low risk practice which may reduce morbidity and mortality.[3]

Etiology: See above

Diagnosis: N/A

2.3 The Intervention: Vitamin supplementation, Renavit 1 OD

How does it work:
Vitamin supplementation as dietary restriction make dietary sources difficult and dialysis removes water soluble vitamins.

Care setting: Where is the intervention given?
Outpatient Setting

Frequency: How often is the intervention given?

1 tablet OD

2.4 Alternative treatments:
Alternatives are the current therapy Ketovite at a recommended dose of three tablets daily, which is more expensive and requires refrigeration, or the unlicensed product Dialyvit.


req vits.rtf

St George's policy is attached

3. Effectiveness

3.1 Expected benefits
The Dialysis Outcomes and Practice Patterns Study (DOPPS)[3] has suggested dialysis patients receiving water soluble vitamin supplements have a lower mortality risk compared to patients not receiving supplements.

3.2 Is there a plausible biological basis for effectiveness?
Yes, as previously stated.

3.3 Side-effects/complications
Vitamin provision is a low cost, low risk practice which may reduce morbidity and mortality.[3]

3.4 Review of evidence
There is national guidance for the intervention, application is for a switch in product.

East Kent Prescribing Group have also reviewed this with a recommendation to switch to renavit


Water_soluble_vitam in_deficiency_in_patie


New drug evaluation form renavit.doc

ESHUT considered the attached paper at their NDAIG in Feb 2014

4. Summary of Key Points for Consideration

4.1 National guidance: Renal Association guidance [2]

4.2 Efficacy The Dialysis Outcomes and Practice Patterns Study (DOPPS)[3] has suggested dialysis patients receiving water soluble vitamin supplements have a lower mortality risk compared to patients not receiving supplements.

4.3 Potential Benefits over existing therapy

The product is cheaper, does not require cold storage and offers a reduced tablet burden for patients. It is a licensed alternative in comparison to dialyvit.

4.4 Potential disadvantages
Workload of the change.

4.5 Budgetary Impact
As before, offers a cost reduction.

4.5.1 Cost: £12.50 for 100 tablets (3 months therapy).

4.5.2 Precedent setting:
N/A (cheaper than current therapy).

5. Conclusions and Recommendations

Suggest switch to Renavit .

Appendix 1: Evidence search

Search terms used:

Resource	Used in this review?
National Library for Health (NHL) http://www.library.nhs.uk/Default.aspx A gateway site with access to other resources such as Reviews (Bandolier, Cochrane, CRD etc), Guidelines (e.g. NICE), Clinical Knowledge Summaries (CKS) and Journals including AMED, British Nursing Index, CINAHL, E-books, EMBASE, HMIC, MEDLINE, My Journals, PsycINFO, PubMed, Databases from Dialog.	✓
National Institute of Health and Clinical Excellence (NICE) http://www.nice.org.uk/ NICE produces national guidance in three areas of health: 1. Public health - guidance on the promotion of good health and the prevention of ill health 2. Health technologies - guidance on the use of new and existing medicines, treatments and procedures within the NHS 3. Clinical practice - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.	✓ (through NHL)
Bandolier http://www.medicine.ox.ac.uk/bandolier/index.html Bandolier is a website about the use of evidence in health, healthcare, and medicine. Information comes from systematic reviews, meta-analyses, randomised trials, and from high quality observational studies.	✓(through NHL)
Centre for Reviews and Dissemination http://www.york.ac.uk/inst/crd/ CRD undertakes high quality systematic reviews that evaluate the effects of health and social care interventions and the delivery and organisation of health care. Databases maintained by CRD include Database of Abstracts of Reviews of Effects (DARE), NHS Economic Evaluation Database (NHS EED), Health Technology Assessment (HTA) Database	✓(through NHL)
Scottish Intercollegiate Guidelines Network (SIGN) http://www.sign.ac.uk/ Scottish equivalent of NICE	✓
Medical Services Advisory Committee (Australia)	✓

http://www.msac.gov.au/internet/msac/publishing.nsf/Content/home-1 The principal role of the Medical Services Advisory Committee (MSAC) is to advise the Australian Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures.	
Canadian Agency for Drugs and Technologies in Health (CADTH) http://www.cadth.ca/index.php/en/home The Canadian Agency for Drugs and Technologies in Health (CADTH) is a national body that provides Canada's federal, provincial and territorial health care decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies.	✓

Evidence retrieved

Guidelines
Brief description of any guidelines found

Reviews:
Brief description of any reviews found through Bandolier/Cochrane/CRD etc

Journals

Brief description of any further published studies found outside those already covered in any reviews described above. E.g. if a review only covered a certain time period, the journals could be searched to find studies published outside these dates. Briefly describe in table below.

Study	Design	Number of participants	Results
Title: **Citation:** **Author(s):**			

Appendix 2: Grading of evidence

- Ia: systematic review or meta-analysis of randomised controlled trials
- Ib: at least one randomised controlled trial
- IIa: at least one well-designed controlled study without randomisation
- IIb: at least one well-designed quasi-experimental study, such as a cohort study
- III: well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, case–control studies and case series
- IV: expert committee reports, opinions and/or clinical experience of respected authorities

Appendix 3: References

1.European Best Practice Guideline on Nutrition, Nephrol Dial Transplant (2007) 22 [Suppl 2]: ii45–ii87

2.Renal Association Guidelines http://www.renal.org/Clinical/GuidelinesSection/NutritionInCKD.aspx

3.Fissell RB, Bragg-Gresham JL et al. Dialysis Outcomes and Practice Patterns Study (DOPPS) Data on Medication in Hemodialysis Patients. Am J Kidney Dis 2004;44 [Suppl 2]: S61–S67

4.Hunt L**,** Royal Devon and Exeter Foundation Trust, British Renal Society Conference Poster 2011: Provision of water-soluble vitamin supplementation for haemodialysis patients.

5.http://www.medicinescomplete.com/mc/bnf/current/index.htm

6.Drug Tarriff accessed at: http://www/ppa.org.uk/ppa/edt_intro.htm

7.Manley HJ, Garvin CG, Drayer DK, Reid GM, Bender WL, Neufeld TK, Hebbar S, Muther RS Medication prescribing patterns in ambulatory haemodialysis patients: comparisons of USRDS to a large not-for-profit dialysis provider. Nephrol Dial Transplant. 2004 Jul; 19(7):1842-8