NHS
Yorkshire and Humber
Commissioning Support

NHS
Calderdale
Clinical Commissioning Group

Commissioning Statement

Treatment	Probiotics (including VSL#3®)
For the treatment of	Management of gastro-intestinal symptoms
Commissioning position	Calderdale CCG does not routinely commission or fund probiotic supplements ***Except:*** VSL#3® prescribed under the following criteria: • It is in line with the Advisory Committee on Borderline substances (ACBS) approved indication, i.e. for the maintenance of remission of ileo-anal pouchitis induced by antibacterials in adults (after an intense course of antibiotics has induced remission of pouchitis) **AND** • Treatment is initiated by a specialist in gastroenterology **AND** • Treatment is terminated on failure of remission of pouchitis At this time there is insufficient high quality evidence that demonstrates the clinical and cost effective use of probiotics except in the above circumstance. Patients not meeting the ACBS criteria may purchase a probiotic of their choice.
Date effective from	18 December 2014
Policy to be reviewed by	November 2017
Background information	Bacteria or yeast generally ingested orally as therapy are termed probiotics. They may be administered as a single organism or a defined mixture, aiming to beneficially alter the microbial ecology of the gut. Probiotic supplements are often taken with the view that they help manage gastro-intestinal disturbances. The nutritional supplement VSL#3®, is a powder containing 8 strains of live, freeze-dried, lactic acid bacteria. It is an ACBS approved product for one indication only - the maintenance of remission of ileo-anal pouchitis induced by antibacterials in adults. https://www.medicinescomplete.com/mc/bnf/current/PHP9039-vsl3.htm

	There is insufficient evidence to support the use of any probiotics for any other indication
Summary of evidence / rationale	**Clinical effectiveness:** In a small study partially supported by VSL Pharmaceuticals Inc., Mimura et al [1] evaluated the effectiveness of a single daily high dose probiotic in maintaining antibiotic-induced remission in patients with recurrent or refractory pouchitis. They randomised 20 patients to VSL#3® treatment and 16 to placebo. Remission was maintained at one year in 17 patients (85%) on VSL#3® and in one patient (6%) on placebo ($p<0.0001$). One patient withdrew from the trial due to abdominal cramps, vomiting and diarrhoea 10 days after starting the study medication. Three further attempts at taking the trial preparation resulted in the same symptoms. All patients in this study had previous recurrent or refractory pouchitis and had achieved remission after a four week course of intense antibiotic therapy. Antibiotic therapy would now appear to be the favoured form of treatment for active pouchitis. Although continuous antibiotics may be able to maintain remission induced by an acute course of antibiotics, this strategy has not formally been tested. The authors discuss that as an imbalanced or excessive response to intraluminal bacteria seems to be involved in the pathogenesis of inflammatory bowel disease, including pouchitis, probiotic therapy to modify the bacterial flora may be an attractive option. They conclude that VSL#3® is effective in maintaining antibiotic induced remission for at least a year. There is insufficient evidence to recommend it for other indications. A Cochrane review investigated use of probiotics to treat active ulcerative colitis. There is limited evidence that probiotics may reduce disease activity, but not enough to recommend them to treat active Ulcerative Colitis (UC). There is no clear evidence to support any role of probiotics in the maintenance of Crohn's disease after surgically or medically-induced remission. **Safety**: In the clinical situation, probiotic products are generally recognised as safe and reported problems are rare. There are some case reports of infection by probiotic organisms, but in nutritionally compromised patients. A systematic review cited 53 clinical trials in which 32 out of 4131 patients developed probiotic-related infection. Often these patients were acutely and severely ill [2]. Patients who do not meet ACBS criteria for VSL#3® prescribing who wish to continue to take probiotics should be asked to purchase OTC, and be made aware that efficacy is unproven in any other indications.

	Cost effectiveness/resource impact: In England over £872,500 was spent on all probiotics over the course of a year - VSL#3® is the most commonly prescribed costing 30 × 4.4-g sachets = £32.98 References 1. Mimura T, Rizello F, Helwig U et al. Once daily high dose probiotic therapy (VSL#3®) for maintaining remission in recurrent or refractory pouchitis. Gut 2004; 53: 108-114. 2. Cummings J. Probiotics and their role in AAD and CDAD. Prescriber supplement 2010 p9-2.www.prescriber.co.uk/SpringboardWebApp/userfiles/espres/file/cpd/probiotics.pdf
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