VSL#3®
For ileoanal pouchitis

Commissioning Statement

Fylde and Wyre Clinical Commissioning Group has agreed to fund the prescribing of VSL#3® for the maintenance of remission of ileoanal pouchitis induced by antibacterials in adults only if:

- Pouchitis has been diagnosed by a gastrointestinal specialist and treatment is initiated or recommended in secondary care and it is used under the supervision of a physician specialising in gastroenterology AND
- All other standard pharmacological treatments have been tried AND
- It is taken in accordance with the product literature

This is in line with the Advisory Committee on Borderline Substances (ACBS) approved indication.

Fylde and Wyre CCG does not commission any other probiotic supplement for this indication nor does it commission VSL#3® or other probiotics for any other indication.

This Food additive is classified as AMBER 0 for this indication

Background and summary of the evidence

- Some people with ulcerative colitis need to have part of their bowel removed and a loop of bowel constructed in its place. This loop, or pouch, can become inflamed (possibly due to an imbalance of bacteria), leading to diarrhoea and other problems. This inflammation is known as "pouchitis".
- Prescribing only includes those who have had the surgical intervention described above and does not include those who have lactose intolerance, IBS, Crohn's Disease or Ulcerative Colitis.
- Probiotics, as defined by WHO in 2002, are 'live micro-organisms that, when administered in adequate amounts, confer a health benefit on the host'. They are available most commonly in yoghurts at the supermarket and in dried form in capsules from health-food shops and pharmacies.
- The micro-organisms are generally from the Lactobacillus and Bifidobacterium groups, which are important in maintaining the gut's ability to prevent invading pathogens from establishing in the bowel and causing disease.
- Their principal claims to benefit health, centre around strengthening the immune system (usually Lactobacilli) and improving digestive function (Bifidobacteria).
- VSL#3 is classified as a food supplement sold in sachet form and contains eight different strains of bacteria (Streptococcus thermophilus, Bifidobacterium breve, Bifidobacterium longum, Bifidobacterium infantis, Lactobacillus acidophilus, Lactobacillus plantarum, Lactobacillus paracasei, Lactobacillus delbrueckii subsp. Bulgaricus).
• Trial data for evidence for VSL#3 in pouchitis is limited and is from trials conducted in very small numbers of people.

• Sinagra et al reviewed the current literature for probiotics, prebiotics and symbiotics in inflammatory bowel diseases (IBD). The benefit of probiotics remains unproven in Crohn’s disease and ulcerative colitis.

• A Cochrane summary, published in 2010, looked at eleven RCTs. The efficacy of 10 different pharmacologic agents was assessed. For the treatment of acute pouchitis (4 RCTS, 5 agents), ciprofloxacin was more effective at inducing remission than metronidazole. Neither rifaximin nor lactobacillus GG were more effective than placebo, while budesonide enemas and metronidazole were similarly effective, for inducing remission of acute pouchitis. For the treatment and maintenance of remission of chronic pouchitis (4 RCTs, 4 agents), glutamine suppositories were not more effective than butyrate suppositories, and bismuth carbomer foam enemas were not more effective than placebo, while VSL#3 was more effective than placebo in maintaining remission of chronic pouchitis in patients with chronic pouchitis who achieved remission with antibiotics. For the prevention of pouchitis (3 RCTs, 2 agents), in one study VSL#3 was more effective than placebo while in another study VSL#3 was not more effective than no treatment. 

Estimated Costs

• VSL#3 cost is £32.98 for 30 sachets

• The usual recommendation is for 1-4 sachets daily.

• Cost per patient per year could be up to £1583

References


11. Holubar SD, Cima RR, Sandborn WJ, Pardi DS. Several antibiotic agents, including metronidazole, ciprofloxacin, and rifaximin, as well as oral probiotics, may be effective treatments for pouchitis. Cochrane Summary, published online 16 June 2010.

For details around the the colour classification system please refer to the website of the Lancashire Medicines Management Group at: http://www.lancsmmg.nhs.uk/