Vedolizumab subcutaneous prescribing

Recommendations

- Review locally whether homecare capacity allows suitable patients to be switched from intravenous (i.v.) vedolizumab to subcutaneous (s.c.) vedolizumab.
- Switching suitable patients to the s.c. formulation could help reduce capacity problems at providers. As with all switches, these should be tailored to the individual patient and should take capacity of homecare providers into account.
- Ensure that prescribing is in line with its licence and relevant NICE guidance.
- A cost calculator is available here https://www.prescqipp.info/our-resources/bulletins/bulletin-274-subcutaneous-vedolizumab/ for local commissioners and providers to compare costs of different biologics used for the treatment of inflammatory bowel disease (IBD) using the tariffs charged locally. Where applicable, costs used in the calculator are split based on patient weight, where this affects dose and therefore costs.
- If more than one biologic is suitable to meet an individual patient's needs, the most cost effective first line options remain biosimilar adalimumab (s.c.) and infliximab (i.v.) based on current contract prices.

National Guidance

Vedolizumab (given i.v.) is one of several biologics licensed and recommended by NICE for the management of IBD. It is a second line treatment after an anti-TNF in Crohn's disease and one of the first line options for ulcerative colitis.[1-4] A subcutaneous formulation of vedolizumab has recently been licensed and is available in pre-filled pens and syringes.[5]

The choice of agent is generally guided by a combination of clinical factors which include patient choice, overall cost (taking into account administration costs, dosage and price per dose), likely adherence and local infusion capacity.[6] If more than one treatment is suitable, the least expensive option should be chosen to make the best use of NHS resources. On this basis, adalimumab and infliximab (both available as biosimilars) are currently the most cost effective first line choices of biologics for IBD based on current contract prices and administration costs.

Vedolizumab (given as an i.v. infusion) has demonstrated increased efficacy compared to adalimumab in a head-to-head trial (sponsored by the manufacturer of vedolizumab) in patients with ulcerative colitis.[7] It is therefore posed as an alternative first line biologic agent by the British Society of Gastroenterology (BSG)[6] in the treatment of ulcerative colitis after failure of conventional therapy. There is no data available to determine whether the same applies in Crohn's disease or to the s.c. preparation. It is also unclear whether the increased efficacy of i.v. vedolizumab is matched with a higher cost-effectiveness when factoring in the higher cost of vedolizumab to the NHS compared to adalimumab.

Clinical effectiveness and safety

Marketing authorisation for the s.c. formulation of vedolizumab was granted based on the data from two double-blind randomised phase three trials (VISIBLE 1 and VISIBLE 2),[8,9] and one open-label extension study (VISIBLE OLE).[10]

In both double-blinded trials, patients with moderate to severe active disease received two induction doses of vedolizumab 300mg i.v. at weeks zero and two after which clinical response was assessed. Only patients who achieved a clinical response at week six were then randomised to receive s.c. vedolizumab 108mg every two weeks, placebo or (for VISIBLE 1 only) i.v. vedolizumab 300mg every eight weeks. The total study period of both trials was 52 weeks.[8,9]

In VISIBLE 1[8] (ulcerative colitis), the primary efficacy endpoint (clinical remission at week 52) was met, with a rate of 14.3% for placebo compared with 46.2% and 42.6% for the s.c. vedolizumab and i.v. vedolizumab respectively ($p<0.001$).

In VISIBLE 2[9] (Crohn's disease), the primary endpoint was clinical remission (defined as Crohn's CDAI score ≤150 at week 52). At week 52, 48.0% of patients on vedolizumab versus 34.3% of patients with on placebo were in clinical remission ($p=0.008$).

Overall, 86.2% of ulcerative colitis patients and 82.6% of Crohn's Disease patients achieved a clinical response after two or three vedolizumab intravenous infusions.[10]

Switching options

The availability of s.c. vedolizumab gives patients the flexibility to inject at home. Switching from infusions to s.c. injections in patients responding well to vedolizumab and who are willing and able to self-administer, could generate cost savings and reduce the need to attend hospital thereby reducing risks to patients during the pandemic and increasing capacity in day units.

Guidelines for IBD[6] recommend switching to either a different class of biologic or alternative anti-TNF if there is an indication for discontinuing first-line treatment with adalimumab or infliximab. Whether it is clinically more appropriate to switch to an alternative anti-TNF or a different class of biologic depends on numerous factors, including whether the reason for discontinuation was intolerance, loss of efficacy (and after what time) and what the drug/antibody concentrations in the blood are.

References

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Additional resources available	Bulletin & Implementation resources	https://www.prescqipp.info/our-resources/bulletins/bulletin-274-subcutaneous-vedolizumab/

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