Thank you for giving the Welsh Assembly Government the opportunity to comment.

We have consulted Welsh stakeholders and the Minister would wish to pass on to NICE the views of the Welsh National Specialist Advisory Sub-committee in Rheumatological Medicine to the Welsh Medical Committee, these views were received from [redacted].

Efficacy

The evidence provided leads me to conclude that Golilumab is as effective as other Anti TNF inhibitors in treating patients who have failed standard disease modifying anti rheumatoid drug therapy (DMARD). I note that the ACR 70 Data is lacking but in clinical practice the ACR 20 and ACR 50 responses are the relevant outcomes for patients who have not responded to first line DMARD treatments. In clinical trials it is the ACR 20 and/or ACR 50 that are used as primary outcomes. The ACR 70 is never used as a primary outcome measure and it is therefore in my view not fair or appropriate to assess the efficacy of Golilumab on ACR 70 responses.

Safety

There is no significant difference in the safety data comparing Golilumab to other currently available anti TNF treatments or biologic agents.

Clinical Use

Golilumab has some clinical advantages for patients and implications for health resource use. The current approved anti TNF subcutaneous injections require weekly or fortnightly injections. Golilumab is given as a monthly injection. This means that patients who require the injection to be provided for them will need less access to health care resources to administer the injections and the longer half life of the preparation may also improve the quality of the response to the anti TNF treatment as some patients experience end of dose worsening of their symptoms with the shorter acting weekly or fortnightly preparations. Monthly injections will also be more convenient for patients who travel with their work or going on holiday, as the current anti TNF preparations need be kept refrigerated and this can be very difficult when travelling abroad.

The disadvantage of a monthly preparation is that the longer half life is undesirable in patients who stop treatment after the development of an infection, as the immunosuppressive effect of the Anti TNF treatment would persist for longer than the currently available preparations. This disadvantage could be minimised by clinicians excluding patients at high risk of infection.

Use after other Anti-TNF preparations

Golilumab is also the only Anti TNF treatment which has robust evidence that it is effective in patients who have had a previous Anti TNF treatment. The 'GO-AFTER' study shows response rates for Golilumab that are superior to placebo and at least equivalent to the response to Rituximab after a previous Anti TNF treatment. This data suggests that Golilumab should be recommended as a third line treatment for patients who have not tolerated or failed Rituximab after a first Anti TNF treatment. At present

the other Anti TNF treatments are already recommended for this indication and they have efficacy data which is less impressive than that of Golilumab.