NICE National Institute for Health and Care Excellence

DIAGNOSTICS ASSESSMENT PROGRAMME

Therapeutic monitoring of TNF alpha inhibitors in Crohn's disease (LISA TRACKER ELISA kits, IDKmonitor ELISA kits, and Promonitor ELISA kits)

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 4 November 2015

Comment number	Name and organisation	Section number	Comment	NICE response
1	**Royal College of Nursing**	General	The Royal College of Nursing (RCN) welcomes the opportunity to contribute to this consultation. The RCN invited members of the Irritable Bowel Disease Special Interest Group to review this document on its behalf. The comments below reflect the views of our members.	Thank you for your comments.
2		1	We agree with the findings of the document in that there is insufficient evidence to recommend the routine adoption of the monitoring kits for the following reasons: • There needs to be ONE standard test adopted nationally for the purpose of standardisation and remove the variation that currently exists • Reference levels need to be established to give a national standard • There was no specific detail of turnaround times from sample submission to results being made available to clinicians. Our limited experience to date has been an average turnaround time of at least 4 weeks, which is unacceptably long when decisions about treatment escalation or change need to be made. The document goes some way to explain why this might be i.e. collecting enough samples to run a batch test but this inordinate	Thank you for your comments, which the Committee considered. The Committee decided to add an extra bullet point to the research recommendations in section 7.1 of the guidance document to recommend that primary reference standards are developed for use with the ELISA kits (LISA TRACKER, IDKmonitor and Promonitor).

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			length of time is unworkable in the clinical setting. Therefore, we conclude that monitoring would be useful if a universal test was adopted, reference ranges were determined and a national guideline was developed for the circumstances as to when the test should be done i.e. after induction doses, perceived loss of response.	
3	**British Society of Gastroenterology**	1.1	There is a pressing need for robust drug level test for TNF inhibitors, and antibodies to them, noting the growing evidence of their association with disease activity (eg Vande Casteele et al, Gut 2015;64:1539-45), and the potential for improving clinical outcomes, and maximising cost effectiveness of TNF inhibitor therapy	Thank you for your comment, which the Committee considered.
4		1.3	It is agreed that there is no clinical data on the use of the ELISA kits evaluated here, particularly with reference to appropriate drug level targets, and relevant antibody levels, and it is noted that current studies underway in the UK (eg the PANTS study) will provide useful data in use of these assays to guide clinicians in therapeutic decision-making in relation to TNF inhibitors	Thank you for your comment, which the Committee considered.
5		5.1	Error in table 4. In 1st column, rows 3 and 4, lower level of acceptable drug level should read 3ug/ml, not 0.3ug/ml	Thank you for your comment. This error has been changed in the

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				diagnostics guidance.
6	**MSD UK**		MSD welcomes the opportunity to consult on this draft NICE Diagnostics Guidance. We have no comments at this time.	Thank you for your comment.
7	**Department of Health**		Thank you for the opportunity to comment on the diagnostics consultation document for the above diagnostics assessment. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.
8	**Royal College of Physicians**		The RCP is grateful for the opportunity to respond to the above consultation. We would like to formally endorse the response submitted by the British Society of Gastroenterology.	Thank you for your comment.