

Comments from Wyeth on the ACD for the NICE appraisal of infliximab for the treatment of adults with psoriasis

Section No.	Section Title	Page Reference	Comments
1.2 2 nd bullet	Appraisal Committee's preliminary recommendations	3	The assessment report for etanercept and infliximab for rheumatoid arthritis (Table 23, March 2002) states for infliximab a cost per administration of £124.
3.1	The manufacturer's submission	5	<p>Wyeth concurs with the appraisal committee's view that etanercept used intermittently, in accordance with its licensed posology and NICE guidance, should be the principal comparator (Section 4.3). However we do not accept that etanercept is used continuously in routine UK clinical practice.</p> <p>The manufacturers assertion of continuous use is based on an audit of just two 'leading' dermatology clinics. It is likely these clinics are tertiary referral centres of the sort run by the clinical experts who attended the first appraisal committee meeting. Caution must be exercised when extrapolating the practice within specialist centres to the rest of the dermatology community.</p> <p>Indeed in a survey of UK Consultant Dermatologists a minority (approx. 25%) of the 55 respondents who reported using etanercept did so on a continuous basis¹.</p> <p>It would therefore seem inappropriate to consider etanercept used continuously as a valid comparator.</p>
3.9	The manufacturer's submission	9	This section should refer to the assumptions described in section 3.8 rather than 3.7

¹ Data on file Wyeth Pharmaceuticals. (Copy enclosed)

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4.6	Consideration of the evidence	11	<p>We are not aware of any clinical data to support the anecdotal claim of a longer-lasting response with infliximab compared with alternative therapies e.g. etanercept.</p> <p>Section 4.8 of the infliximab SPC identifies that 'In psoriasis patients treated with infliximab as a maintenance regimen in the absence of concomitant immunomodulators, approximately 28% developed antibodies to infliximab. Section 4.4 warns that 'An association between development of antibodies to infliximab and reduced duration of response has also been observed.</p>
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Research with UK Dermatologists regarding their use of Biological Therapies for Severe Plaque Psoriasis

Methodology and Sample

Consultant Dermatologists who are members of the Doctors.net.uk community were invited to participate in an online structured survey covering the following:

- The caseload of patient consultations in the previous 4 weeks for:
 - Psoriatic Arthritis
 - Severe Plaque Psoriasis
- The treatment modalities prescribed at these consultations
- The use of biological therapy for these conditions

Consultant Dermatologists are eligible to participate if they have prescribed biological therapy in the last 6 months.

The survey has been run monthly from February to June, achieving an average sample of 29 respondents per month (range 20 to 37).

Respondents who had prescribed etanercept/Enbrel for patients consulting in the previous 4 weeks were questioned as to their approach to the use of etanercept in patients who have responded to it.

The total sample and the respondents eligible to respond to the specific etanercept questions is given in the table below.

Month	Total Sample Size	Etanercept Prescribers in Severe Plaque Psoriasis (Base for q27a)
February	20	9
March	27	7
April	32	14
May	30	13
June	37	12
TOTAL	146	55

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Question Text

q27a - Enbrel treatment schedule

When prescribing Enbrel / etanercept for severe plaque psoriasis and thinking about patients who respond to treatment, which of the following best describes your treatment schedule?

- Treat continuously
- Treat for 12 weeks followed by a break in treatment
- Treat for 18 weeks followed by a break in treatment
- Treat for 24 weeks followed by a break in treatment
- Other (please specify)_____

If a break in therapy is used, respondents were then asked q28a

q28a - Length of treatment break with Enbrel / etanercept

For how long do you typically break treatment with Enbrel / etanercept?

Enter the number of weeks

Results

The moving quarterly results for q27a are shown in the table below. Only a quarter of Dermatologists treat continuously with etanercept.

	Qtr ending April		Qtr ending May		Qtr ending June	
Treat continuously	8	27 %	7	21 %	10	25 %
Treat for 12 weeks followed by a break in treatment	8	27 %	11	32 %	15	38 %
Treat for 18 weeks followed by a break in treatment	1	3 %	1	3 %	1	3 %
Treat for 24 weeks followed by a break in treatment	12	40 %	13	38 %	13	33 %
Other (please specify)	1	3 %	2	6 %	1	3 %
Total	30	100 %	34	100 %	40	100 %

The average break in therapy is between 9 and 11 weeks based on this data

Number of Weeks Break in Therapy	Qtr ending April		Qtr ending May		Qtr ending June	
0	0	0 %	0	0 %	0	0 %
1 - 3	3	14 %	5	19 %	6	20 %
4 - 6	5	23 %	6	22 %	7	23 %
7 - 9	2	9 %	2	7 %	4	13 %
10 - 12	6	27 %	10	37 %	10	33 %
13 - 15	1	5 %	1	4 %	1	3 %
16 - 18	0	0 %	0	0 %	0	0 %
>18	5	23 %	3	11 %	2	7 %
Total	22	100 %	27	100 %	30	100 %
AVG	11		10		9	