

Overview – Crohn’s disease: infliximab and adalimumab

Issue date: August 2008

Errata

After issuing the overview to the Appraisal Committee a number of textual errors were identified.

- In table 3 on page 10 the length in weeks of the Present trial was 18 (not 14 as stated).
- In table 5 on page 12 the difference in remission rates between the intervention and placebo arms of the GAIN trial was 18% (not 14% as stated).
- In section 3.2.3 the Assessment report page reference to PCDAI scores associated with Baldassano is table 37 on page 116 (not table 38 on page 119 as stated).
- In section 3.3.3 the Assessment report page reference to CDAI and PCDAI scores associated with the REACH trial was table 38 on page 119 (not table 37 on page 116 as stated).

The following items replace sections of the overview, as indicated:

Table 3 on page 10

Table 3 Summary of trials of induction therapy in people with Crohn's disease

Drug	Trial	Population (size)	Length (weeks)	Withdrawal rate (%)	Dosage	Severity
Adalimumab	CLASSIC I	Active severe n = 299	4	5	Placebo 40 mg/ 20 mg 80 mg/ 40 mg 160 mg/ 80 mg	CDAI 220–450
	GAIN	Active severe n = 325	4	4	Placebo 160 mg/ 80 mg	
Infliximab	D'Haens et al. (1999)	Active severe n = 30	4	–	Placebo 5 mg/kg 10 mg/kg 20 mg/kg	CDAI 220–400
	Targan et al. (1997)	Active severe n = 108	4	0		CDAI 220–450
	Present et al. (1999)	Fistulising n = 94	<u>18</u>	6	5 mg/kg 10 mg/kg	Mean PDAI 9 Mean CDAI 192.9
	Baldassano et al. (2003)	Paediatric n = 21	12	10	1 mg/kg 5 mg/kg 10 mg/kg	PCDAI > 30 or modified CDAI > 200
CDAI, Crohn's disease activity index; PCDAI, paediatric Crohn's disease activity index; PDAI, perianal disease activity index.						

Table 5 on page 12

Table 5 Proportion of patients achieving remission

Trial	Intervention remission (%)	Placebo remission (%)	Difference
CLASSIC I	24	12	12
GAIN	52	34	<u>18</u>
Targan et al. (1997)	48	4	44

Section 3.2.3 (second paragraph, sixth sentence)

For remission, no clear pattern relating to dose or length of follow-up was apparent. The results presented demonstrated that PCDAI decreased and response to treatment improved with infliximab. Please see table 37 on page 116 of the assessment report for more information.

Section 3.3.3 (third paragraph, third sentence)

The results presented demonstrated that CDAI and PCDAI scores both decreased and response improved. Please see table 38 on page 119 of the assessment report for more details.