Natalizumab for the treatment of adults with highly active relapsing remitting multiple sclerosis

Erratum to Premeeting briefing

After issuing the premeeting briefing to the Appraisal Committee a number of errors were identified. The following items replace sections of the premeeting briefing, as indicated:

Table on pg 7

Outcome	Group	Natalizumab (n = 627)	Placebo (n = 315)	Absolute risk reduction	Hazard ratio (95% CI)
Probability of sustained disability progression (defined as an increase in EDSS sustained for 12 weeks) at 2 years	ITT	0.17	0.29	0.12	0.58 (0.43 to 0.77)
	RES	0.14	0.29	0.15	0.47 (0.24 to 0.93)
Probability of sustained disability progression (defined as an increase in EDSS sustained for 24 weeks) at 2 years	ITT	0.11	0.23	0.12	0.46 (0.33 to 0.64)
	RES	0.10	0.26	0.16	0.36 (0.17 to 0.76)
Annualised relapse rate at 1 year	ITT	0.26	0.81	0.55	0.68 (0.59 to 0.74)
Annualised relapse rate at 2 years	ITT	0.24	0.73	0.50	0.68 (0.60 to 0.74)
	RES	0.28	1.46	1.17	0.81 (0.70 to 0.88)

2.1.3 (Second sentence)

In addition, a higher proportion of patients who received natalizumab remained disease free (natalizumab 28%, n = 177; placebo 6%, n = 18).

2.1.4. (Second sentence)

These were used to compare the relative efficacy and safety of the interventions.

2.1.6 (all)

The manufacturer presented safety results from AFFIRM that demonstrated that only fatigue and allergic reaction were statistically more common with natalizumab compared with placebo. Overall, the manufacturer concluded that natalizumab was not associated with higher incidence of adverse events compared with placebo.

2.2.4 (last sentence)

Natalizumab significantly improved disability progression at 24 weeks compared with glatiramer acetate if the Bornstein study was excluded (0.57 CI 0.33-0.99).

2.2.6

[delete last sentence]

3.1.5 (third sentence)

Disutilities from the administration of IFN-beta and glatiramer acetate were estimated from published studies; however the ERG noted that the manufacturer did not include the disutility from the adverse events.

3.1.8 (third last sentence)

In this analysis for the suboptimal therapy group the ICERs decreased to a range of £32,000 (vs IFN-beta), £35,000 (vs glatiramer acetate) and £44,600 (vs. BSC).

3.2.4 (last sentence)

The ERG noted that it is not clear if the drop-out rate included the patients developing anti-natalizumab antibodies.

3.2.8 (second sentence)

The only variable that had a noticeable effect was the price of natalizumab, which if lowered by 3-40% would result in ICERs below levels usually accepted as cost effective, depending on the comparator and group of interest.