

Natalizumab for multiple sclerosis

Case study

Two groups of patients

- Rapidly evolving severe (RES) relapsing-remitting multiple sclerosis defined by
 - Two or more disabling relapses in one year
 - One or more lesions on MRI
 - ‘increase in T2 lesion load’
- Failed response to beta interferon (‘suboptimal therapy’)

Natalizumab

- Annual cost about £14 730 per year
- Increased risk of progressive multifocal leuko-encephalopathy

Comparators

- Beta interferon
- Glatiramer acetate
- ‘Supportive care’

Outcomes

- Progression of disability (EDSS) at two years
- Relapse rate (annualised)

Two studies

- AFFIRM
 - RCT
 - Comparator = placebo
 - N = 942
 - Of which RES = 209
- SENTINEL
 - Natalizumab + interferon vs interferon alone
 - 'Suboptimal therapy group'



Effectiveness

- Reduces EDSS vs placebo
- Reduces relapse rate vs placebo

For both patient groups

Comparator

- No direct study natalizumab vs interferon
- No direct study natalizumab vs glatiramer
- Indirect comparison
- Natalizumab vs systematic reviews

Published reviews

- No separate study for RES or suboptimal therapy groups
- Indirect comparison:
- Reduction in relapse rate vs interferon and glatiramer

Markov model

- Used the same model from previous NICE appraisal (of interferon and glatiramer)
- 20 year time horizon
- Health service costs plus carer disutility
- $EDSS > EQ5D > \text{utility}$

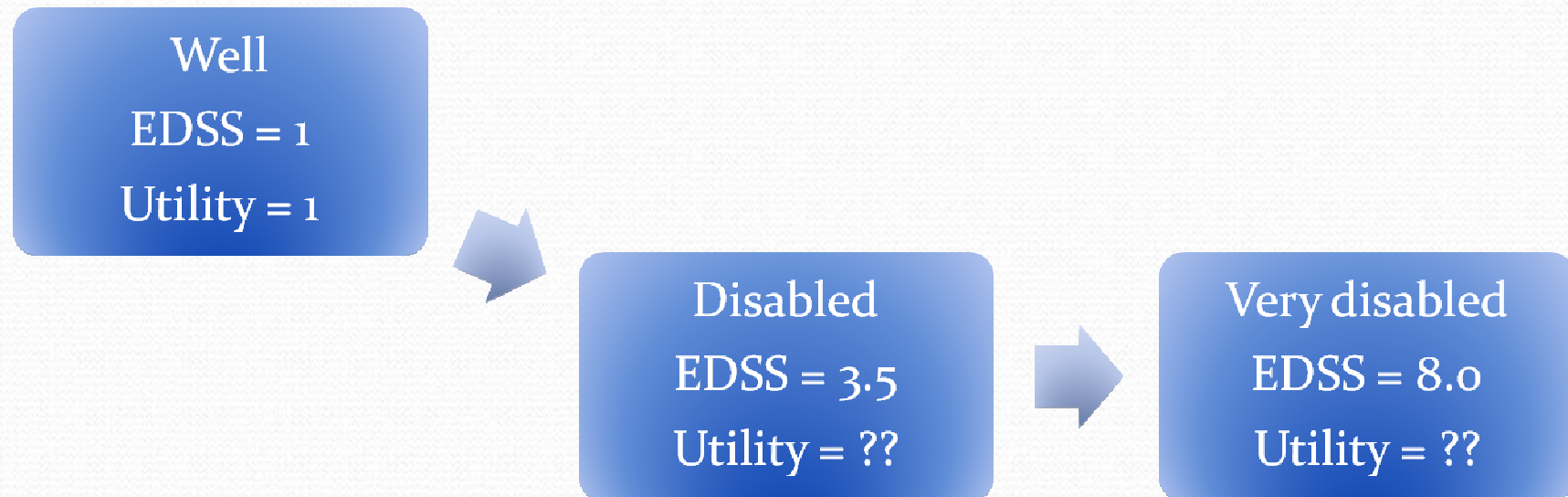
Disease states



Disease states



Disease states



Two issues

- Disability progression
 - AFFIRM – two years
 - ‘London Ontario’ 25 years
 - Model different from AFFIRM at 2 years
- EDSS states
 - The UK MS survey – not all highly active MS

ICERs

Natalizumab versus:	RES group	Suboptimal therapy group
No treatment	44 600	56 100
Interferon	32 000	43 400
Glatiramer	34 600	44 300

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