Comments on the ACD Received from the Public through the NICE Website

Name	[redacted]
Role	NHS Professional
Other role	Submitting on behalf of UKCPA - a clinical pharmacy membership association
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 3 (The manufacturer's submission)	"The evaluation of clinical effectiveness focuses mainly on the EDSS score which does not capture other symptoms such as fatigue, bladder symptoms, cognitive impairment and depression. We agree with the criticism of the ERG that trial data before 2000 was excluded in the base-case analysis. We are also in agreement with the concern regarding pooling of heterogenic analysed data. The safety concerns in terms of monitoring and the failure to include associated costs for severe adverse reactions into the economic analysis have been noted. The proposed frequency for monitoring may not be sufficient to detect some of the more serious adverse drug reactions and an increased frequency of blood tests should be taken into account in the cost analysis. The proposed arguments for these concerns appear correct and reasonable. After a careful risk-benefit assessment, Alemtuzumab may still need to be considered as a treatment option for patients with highly active MS (treatment failure, side effects) before supportive care."
Section 4 (Consideration of the evidence)	"Yes, the key studies of Alemtuzumab have been identified. The limitations of the available trials and related analysis have been identified and further information has been requested accordingly. A weakness of the evidence was using only Rebiff44 in the clinical trials. Long-term safety and efficacy beyond the follow-up period remain unclear. Appropriate consideration was given to evidence related to clinical effectiveness, quality of life and economical aspects as well as clinical experts and affected patients and their families. The reason for the provisional recommendations is clear and, in view of the calculated ICER range, understandable."

Name	[redacted]
Role	Patient
Other role	I also work as a clinical nurse specialist in the NHs
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	

Section 4 (Consideration of the evidence)	As a person living with MS the primary consideration is halting/slowing disability accumulation. The longer I can remain active, tax paying, etc the least burden. Alemtuzumab represents the greatest chance of halting the relentless, frightening progression of this disease. Many with MS are willing to risk the rare serious side effects. The current 1st line treatments are relatively ineffective with regular injections and many wearing side effects. Alemtuzumab represents real hope of a permanent change to the immune system. I know of many NHS treatments that have huge negative associated costs. For example a large proportion of in-vitro fertilisation (IVF) treatments result in multiple pregnancy. This results in admissions to special care baby units, life long disability, stillbirth etc. If the years of costs for this consequence of IVF were taken into consideration this effective life changing treatment for family formation would not be available. I do not feel that a very rare serious side effect of Alemtuzumab, eg renal failure, should prevent this possibly revolutionary drug being used to huge benefit for the majority, allowing us to remain active.

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	"There is lack of transparency in paragraph 4.9. (and in the ACD as a whole) on why the Committee was not convinced of the efficacy of alemtuzumab in these subgroups based on the MTC results. The results quoted in this paragraph relate to efficacy relative to fingolimod and natalizumab but it is not explained why these results leads to a conclusion that alemtuzumab is not efficacious in these subgroups.The impact of not being able to use this medication in the highly active/rapidly evolving group will ultimately result in inevitable cns damage which would have been prevented with alemtuzumab use. This medication has a place for patients who require substantial relapse reduction to avoid irretrievable disability. There is lack of transparency in paragraph 4.9. (and in the ACD as a whole) on why the Committee was not convinced of the efficacy of alemtuzumab in these subgroups based on the MTC results. The results quoted in this paragraph relate to efficacy relative to fingolimod and natalizumab but it is not explained why these results leads to a conclusion that alemtuzumab is not efficacious in these subgroups."
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	"The EMA did not identify any issues in relation to alemtuzumab efficacy varying between highly active and non-highly active patients

	The EMA did not identify any issues in relation to alemtuzumab efficacy varying between highly active and non-highly active patients"
Section 4 (Consideration of the evidence)	There is lack of transparency in paragraph 4.9. (and in the ACD as a whole) on why the Committee was not convinced of the efficacy of alemtuzumab in these subgroups based on the MTC results. The results quoted in this paragraph relate to efficacy relative to fingolimod and natalizumab but it is not explained why these results leads to a conclusion that alemtuzumab is not efficacious in these subgroups.

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	I am a Consultant Neurologist who has used Campath 1H in patients
Comments on individual sections of the ACD:	
Section 4 (Consideration of the evidence)	I do not agree with the duration of efficacy being limited to 5 years. My experience of patients is that the benefit is sustained for considerably longer. None of the patients I have treated has had a further relapse, nor progressed. Patients were included in a publication by Rice et al J Neurol 2008. It has thus proved cheaper than standard DMTs, Fingolimod or Tysabri all of which these patients would have been eligible for. There are little post treatment costs - blood testing for 5 years only, thyroxine replacement therapy for some. The infrequent infusions are much preferred by patients, whose lives are much less disrupted than the nearest equivalent available Tysabri

Name	[redacted]
Role	Patient
Other role	
Location	England
Conflict	no
Notes	"'NICE' should be SHOT..... Yes, my thyroid became 'under active' through being on the Phase 3 trial, BUT this is more than compensated for by my going from relapses every 3 - 6 months, to not having any relapse for over 4 & 1/2 years. NICE's decision really, really disappoints and disgusts me. This drug has been approved by the European Medical Agency. NICE is letting everyone with RRMS down severely... Obviously no one in NICE is trying to live with the severe difficulties of living with MS. I'm horrified....."