Name	Dr Riyaz Shah
Role	NHS Professional
Location	England
Conflict	yes
Notes	I was nominated and acted as a clinical advisor on the appraisal committee meeting for this subject.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I do not feel that the provisional recommendations are sound or a suitable basis for guidance to the NHS. My main concern regards the conclusion that this indication could not be considered under the supplementary advice to the Committee on end of life treatments (4.26). The Committee calculated this population to be in excess of 8000, however my calculations suggest that this is a gross overestimate. I agree that the National Lung Cancer Audit 2012 (NLCA2012) provides the most robust database upon which to base population calculations. While not all lung patients are captured by this database, it does capture all patients discussed at MDM?s and therefore provides the most accurate estimation of the ?real? and ?treatable? population. My rationale is detailed in section 4.
Section 3 (The manufacturer's submission)	In para 4.23 there is significant consideration of the switch maintenance strategy. I feel that this is misleading. Assuming that a patient has Stage IIIb/IV non-squamous non small cell lung cancer and a PS of 0-1, the correct treatment would be cisplatin and pemetrexed. This is NICE approved. There may be some patients, in whom pemetrexed is contraindicated however, in my clinical experience that is a very rare phenomenon. It is important that the committee appreciate that switch and continuation maintenance are not applicable to separate subgroups of patients. These treatment strategies relate to potential pathways for the same subgroup of patients.
Section 4 (Consideration of the evidence)	NICE estimate 6698 patients with NSCLC stage IIIB or IV and a PS of 0-1. 68% are nonsquamous giving a population of 4555. NLCA2012 shows about 55% of these patients are treated with chemo, giving a population of 2500 who are actually eligible for cisplatin + PEM first line and 1500 may go on to maintenance PEM. The population eligible for first line + maintenance is 2500 + 1500 = 4000. Does the manufacturer have sales data that would help estimate the 1st line population size? Adding the group of patients eligible for second line PEM is misleading. The second line license is old and predates that data showing its benefit in the non-squamous subgroup. The trial (Hanna et al. J Clin Oncol 2004) is based on patients recruited between 2001 and 2002. This a historical trial. There is no evidence supporting the role of PEM second line in patients pretreated with first line PEM let alone those receiving

	maintenance PEM. Second line PEM is not cost effective, not NICE approved and has no defined commissioned pathway. My calculations suggest the total population size eligible for PEM is no more that 5600 (2500 first line + 1500 maintenance + 1600 meso). Or 7100 if including second PEM.
Section 5 (Implementation)	I feel that adequate importance was not given to the clinical experts opinions that maintenance chemotherapy is a highly effective strategy for a small subgroup of patients. The experience from the cancer drugs fund would indicate that only a small number of patients are being offered this treatment within regions where no financial barrier exists (i.e. the cancer drugs fund in that area have a blanket policy to approve all requests for maintenance chemotherapy). This suggests that even with no barrier to access, oncologists are being highly selective and offering this to the select subgroup of patients identified within the PARAMOUNT trial.
Section 7 (Related NICE guidance)	Pemerexed is coming close to the end of its patent. I don't know the exact dates however, the price of this drug is likely to drop substantially after that point. This will fundamentally alter all of the cost effectiveness calculations. It would be helpful if NICE could review their guidance on this drug in a timely manner after that point.
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