Name	[redacted]
Organisation	Calderdale & Huddersfield NHS Trust
Role	[redacted]
Job title	[redacted]
Location	England
Conflict	No
Disclosure	I have received a medical education grant to attend [redacted] in London in 2014 from [redacted]
Comments	«Comment_Id» 779 In section 3.29, the ACD refers to â€˜Watch and waitâ€™, or no treatment, as current practice where patients are no longer responding to first line therapy, currently ranibizumab. We feel that this is no longer clinical practice, and likely to be detrimental to good outcomes for patients. Specifically in patients with a pseudophakic lens, the comparator used in the analysis was ranibizumab. Clearly if such a patient is no longer sufficiently responding to 1st line treatment, TA301 states that ILUVIEN should be considered as an option. The choice of comparator therefore should be ILUVIEN
Submission date	12 March 2015

Name	[redacted]
Organisation	Bayer plc
Role	[redacted]
Job title	[redacted]
Location	England
Conflict	No
Disclosure	Bayer plc is currently undergoing a NICE STA for a similar indication
Comments	«Comment_Id» 780 The preliminary recommendations for dexamethasone intravitreal implant include a positive recommendation for people with diabetic macular oedema (DMO) if the implant is to be used in an eye with an intraocular (pseudophakic) lens and non-corticosteroid treatment is unsuitable for them: 1.1 Dexamethasone intravitreal implant is recommended as an option for treating people with diabetic macular oedema only if: â€¢ the implant is to be used in an eye with an intraocular(pseudophakic) lens and â€¢ their diabetic macular oedema does not respond to non-

	corticosteroid treatment or such treatment is unsuitable for them. It is unclear what is meant by â€˜unsuitableâ€™. Section 4.6 of the ACD states that the Appraisal Committee heard from clinical experts that there are no clinical criteria for determining whether a treatment is â€˜unsuitableâ€™ for a person with DMO. Nevertheless, the ACD clearly states in section 4.17 that dexamethasone intravitreal implant was not a cost-effective use of NHS resources compared with laser for treating DMO in people with a pseudophakic lens and a central retinal thickness (CRT) of less than 400 micrometres. This is not clearly reflected in the wording of the guidance and â€˜unsuitableâ€™ may be interpreted as not recommended by NICE guidance. We recommend that the definition of â€˜unsuitableâ€™ is clarified in the guidance in Section 1 and reflects the wording of Section 4 of the ACD with regard to the use of dexamethasone intravitreal implant in patients with DMO with a pseudophakic lens and a CRT of under 400 micrometres at baseline.
Submission date	12 March 2015