HI Kate.

Apologies for this coming in at the last minute, and apologies too for submitting through the incorrect medium.

Firstly, I as a formal consultee I agree with the comments made by CSAS in relation to the evaluation of the evidence. My comments however were in relation to how this service might be commissioned and delivered and to raise the potential additional costs that might impact on cost effectiveness.

Fulvestrant in its licensed indications will if approved by NICE potentially be used in patients under specialist cancer care.

Fulvestrant is not cytotoxic chemotherapy and therefore isn't specifically excluded from PbR Tariff, however as the costs are greater than 1.5 times the tariff income, Acute Trust providers may seek to negotiate PCO's funding as if it were excluded. There is therefore potential for fragmentation and guidance on the funding arrangements would be welcome to ensure consistency.

If the drug is approved and provided via an Acute Trust Cancer service, and agreed as a PbR exclusion, the drug cost will be subject to VAT, increasing the cost by 20% for the commissioner. This cost should in our opinion be included in the cost-effectiveness analysis as this is what we will be expected to pay.

In addition consideration needs to be given as to where ongoing doses will be given. If patients are receiving other chemotherapy, it may be cost-effective for this to be given in the clinic as part of the same day-case or outpatient appointment. If dedicated outpatient appointments are needed for this the cost will be around £1500 for the first year and £1200 thereafter. This too needs to be factored in to the cost-effectiveness analysis.

Patient experience also needs to be taken into account and it may be undesirable or impractical for some patients in rural settings to travel to hospital on a monthly basis.

Some GPs may be prepared to prescribe and administer but others won't. If prescribed by a GP on an FP10, the VAT will be zero rated and represent 20% saving to the commissioner, but there may be a demand for the GP to be paid under a local enhanced service to administer it. Nonetheless this is likely to be less expensive than a hospital outpatient appointment. Services may be fragmented however as some GP;s will do this whilst others won't. (such is the nature of LES's)

Whilst NICE do not routinely consider commissioning arrangements, consideration perhaps should be given to the "Homecare Sector", through a competitive tendering procurement exercise it may be possible for this to be provided to patients in their own homes, zero rated for VAT , and at a cost again lower than an out patient setting.

I hope that's helpful- apologies for the rather rushed response but it is now 4.55, so please excuse a lack of spell checking

regards

