

Are there valid alternative methods which might be used to achieve the same ends, in the short or the long term.

Role	Comments
NHS Professional	How does the mechanism cope with a reduction / increase in the price of the intervention?
Charity Chief Executive	alternative methods should be investigated and used if more cost effective but provide the same or very similar outcome
Chair of UK registered Charity	All methods should be put forward to the patient and his/her family for them to decide.
other	There should be far more emphasis placed on the evidence of the specialist oncologists who are far more qualified to judge a patients survival opportunities than non-specialist healthcare economists
NHS Professional	It seems unclear whether a quantitative approach to 'terminal' weighting of the QALY (and thus the ICER) is the most appropriate method of dealing with this issue especially given the polarisation of the debate, the ethical nature of the arguments, and the technical issues – as above. If a technical approach is taken to the 'terminal weighting' there should be a very clear, open and transparent (and peer reviewed by a wide range of independent economists) methodology – and robust elicitation of social preferences by the PUBLIC – but fully informed of any consequences. This is not a straightforward exercise. An alternative is a more qualitative approach. But again this needs to be robust and open / transparent with fuller participation from commissioners (who are responsible for – on behalf of the taxpaying public – allocation of all healthcare resources) than is currently the case. Seems like appraisal committees are weighted in favour of people who may have a bias towards an individual and not a population approach. This is a broader issue for NICE, but it IS of importance here.
Biostatistician	oddly, 3.2 allows that NICE-tx by NHS need NOT by pharma as NEW current best treatment (that is: control) in future RCTs.
Carer	let the clinicians be the judge of best patient care. They are the experts.
Patient	I would like to think that the appraisal committee undertook to look wider afield to drugs that are being used abroad with proven use, and clinical effectiveness. I would hope that as many trials of these drugs are carried out abroad ,the committee would look at the latest data here and abroad in constantly reviewing effectiveness, as patients in ENGAND may not have been on trials for a sufficient length of time.
Local government professional	Not having been part of the no doubt lengthy debates in achieving this document, I would not presume to make an uninformed snap "alternative" proposal.
Patient	There are no known valid alternative effective treatments.
Patient	Dont really know the answer to this one, as a lay person.
Consultant	If the Institute held its ground, downward pressure would be exerted on drug companies pricing policies, the NHS could secure better value for money, patients could obtain the drugs they seek and the Institutes reputation for independence from government interference could be strengthened rather than undermined.

Patient	Having undergone operations, radiotherapy and Interferon treatment without success, I dont think so!
NHS Professional	Specify the price at which the medicine would become cost-effective.
Patient	It is not just about money. Private Insurance would not cover you for this treatment for more than a year. People have been shown to still be surviving after years on trials. You just want to use the cheapest method to save money for the government. Up the ICER of Â£30,000 per QALY figure and then you will all sleep at night, and the public will start to have faith in you as an organisation. If we dont try new drugs then we will all stop where we are. And you might get the blame. The government will certainly pass it on to you. Alan Johnson has given you a way out, so take it.
other	As far as we all know there is no alternative methods.
Patient	There are currently no other alternative methods of effective treatment available to us. The NHS is awash with money taht it gets from our taxes (surplus Â£1.75 billion) by it seems to be a very ineffective organisation that is top heavy with expensive administrators. The expensive PCTs should be removed from the system, as the whole process could be managed by a handful of Area Health Authorities.
Carer	WITH KIDNEY CANCER PATIENTS,THERE IS NO ALTERNATIVE.INTERFERON IS MORE TOXIC AND LESS AFFECTIVE,THAN ANY OF THE KNEW DRUGS.
NHS Professional	Rare cancer commisioning across the UK
Healthcare Other	The drug companies should share the cost such that the ICER remains 30,000 pounds until efficacy has been proven.
NHS Professional	Im afraid I believe that once a drug has been approved on safety and efficacy criteria the NHS should provide it
Patient	Yes, but in many if not all cases, there is no other option for the patient other than palliative care and death
other	reduce the amount of emphasis placed on costs, see them in relation to the NHS expenditure on non-essential treatments for example!! Ensure that more emphasis is placed on CLINICAL effectiveness, and hear more real life stories. Bring the UK in line with the rest of Europe and North America for Cancer treatments especially. Renegotiate the pricing mechanism with big Pharma companies.
Public	If you take Kidney Cancer as an example, there are no alternative effective treatments at the moment.
Public	There are no other treatments for kidney cancer patients that work.
Carer	UK is lagging behind australia in cancer care. Â My father was given nurmerous treatments right up until his death with no outlay,sutent was given free at an extremely high cost to the govt, britain residents deserve the same care as in australia
Patient	My husband has Kidney Cancer he has no alternative effective treatments at the moment which makes the current situation intolerable. Â This should be taken into account with conditions where alternative treatments arent available. Â The local PCTs role needs reviewing which is expensive and outdated. Â Regional control would be prefable. Â In fact the whole decision making process needs to be made more efficient and up to date with changing requirements and technologies, we cannot consistantly lag behind the rest of Europe and North America in the treatment of Cancer care as is the case at present.
NHS Professional	See above.
Public	It is well-known that there are no other effective treatments for some cancers, for example, kidney cancer. Any

	suggestion that there are alternatives is playing into the hands of unscrupulous, unqualified practitioners peddling unproven alternative treatments
other	Not to my knowledge
Healthcare Other	Perhaps set a maximum budget spend per patient on expensive, last ditch attempt, treatments.
NHS Professional	I dont think that cost/QALY is a suitable tool for this type of scenario. What is wrong with a simple cost per month of expected life gain? The patient with the condition can then decide if their individual quality of life is such that they would wish to have treatment to extend it. I understand why NICE use cost/QALY and the pros and cons of this. In the context of end of life situation, particularly when there is a short time over which to accrue the quality it just does not feel right.
NHS Professional	this needs a robust longitudinal statistic assessment that is standard in its application and reliably so.
Pharmaceutical Industry	The alternatives risk all the anomalies of postcode prescribing and the inequalities of co-payment top up care.
other	I do not quite see the point of this question. Surely this proposal only concerns situations where effective alternatives are not currently available.
NHS Professional	i dont believe there are
other	We refer to our reply at 6.2.2, and would add that lower criteria to achieve a positive NICE recommendation should be used for patients with rare conditions and a rapid disease trajectory. If there are indications that the treatment is beneficial, it should receive NICE approval at that point, with feedback continuing to build up the evidence base.
NHS Professional	I have reservations to this. If the patient has had adverse side effects from the NHS available treatment then an alternative should be available
NHS Professional	The result in the long term of any terminal illness is death, sadly. It is the medium term which surely counts for these individuals. What is a short term valid alternative is again wide open to interpretation.
NHS Professional	There should be guidance for clinicians in this area with regard to realistic treatment aims so that terminally ill patients make informed choices. In general, the British public should be made aware of the cost of treatments provided on the NHS and cancer charities could play a part in supporting treatment funding outside of the NHS
Public	I do not know the answer to this question
Local government professional	There are no alternative methods of effective treatment available to renal cancer patients.
Public	In the case of Kidney Cancer there are no alternative effective treatments at the moment. - Review the expensive and outdated role of the local PCTs and instead move to more regional control. The whole decision making process needs to be made more efficient and up to date with changing requirements and technologies - we cannot consistently lag behind in the treatment of Cancer care
Patient	Not that have been suggested to me, but there seem to be other similar drugs giving real benefit in other types of cancer
other	NICE doesnt have expertise in drug development costs, so cannot validate arguments about drugs for uncommon conditions justifying higher prices. The new PPRS is the right place to deal with this, facilitating drugs affordable to the NHS whether for uncommon or common conditions. Cross-subsidy from other drugs from the same

	company or other mechanisms in PPRS would enable NICE to operate a more consistent ICER threshold
NHS Professional	I disagree with the ends therefore do not have ideas for achieving them
Patient	Yes, as outlined above survival and health outcomes should be the leading criterion. Other EU countries, USA and Japan should be consulted on their use of the new treatment and their outcome data. NICE tends to ignore what other countries do and their better survival rates. All costs should be considered - to patients and their families, their employers, social costs and to the economy as a whole. If a treatment, although expensive can keep a patient healthier for longer versus early longer hospital/terminal care that is a real cost benefit for everyone. There should be no artificial ceiling at £30k. All clinical evidence should be considered not just cross-over studies, which are ethically questionable. Evidence should be sought from other countries. The main aim should be outcome and survival on a par with the best in the world.
Patient	I do not have the skill set to determine alternative models however i believe in the importance of individualised models of care which engages the patient carer and clinician. This is a very small patient population and therefore the costs are relatively low against the whole budget. I am mindful that the drugs industry will try and get the most money out of the NHS as it can however the trick is not to penalise the patient for corporate greed but as decision makers engage in dialogue about what can be afforded.
Public	If you take Kidney Cancer as an example, there are no alternative effective treatments at the moment. - Review the expensive and outdated role of the local PCTs and instead move to more regional control. The whole decision making process needs to be made more efficient and up to date with changing requirements and technologies - we cannot consistently lag behind the rest of Europe and North America in the treatment of Cancer care
NHS Professional	Carry on with a case-by-case assessment. If a company thinks it genuinely has a good case, it can make it. But you wont feel obliged to work within new arbitrary "rules". Already companies....are creative with the truth...because they think they know what we want and tailor the truth to fit that (e.g. calculating QALYs when they are impossible to calculate but THATs WHAT WELL WANT...)
Carer	It has to be presumed that end of life means just that. All other treatments tried and failed and no other alternative available. I know of very few clinicians who recommend treatments where there are alternative, more cost-effective and established treatments available.
NHS Professional	Apply cost per additional life year analysis rather than cost per QALY for treatments considered under this guidance. In this way any period of increased survival would be valued equally, rather than valuing a higher quality of life at a higher level.
NHS Professional	Not that we are aware of
NHS Professional	The "ends" have not been defined. NICE should provide guidance which helps the NHS to maximise health gain with the inevitably limited funds. This proposal would not do that.
Carer	- If you take Kidney Cancer as an example, there are no alternative effective treatments at the moment. - Review the expensive and outdated role of the local PCTs and instead move to more regional control. The whole decision making process needs to be made more efficient and up to date with changing requirements and technologies - we cannot

	consistently lag behind the rest of Europe and North America in the treatment of Cancer care
NHS Professional	Section 2.1.1 There is a need to clarify how the criteria defining the maximum patients' population was reached. i.e. maximum of 7,000 new cases per annum. Â Also for a great number of conditions, we simply do not have population estimates of their incidence/ prevalence and often there is a continuum of severity. Section 2.2.3 The fact that there is no alternative treatment is not grounds for agreeing to higher cost treatments. Â One does not agree to poor value medicines just because they are the only option available.
Other	I think if this were to be applied, then there should be consideration of severity rather than end of life. For people with some severe chronic diseases death in six months time might look quite pleasant when you are faced with being bed ridden and dependent on a carer for 20 years or so
NHS Professional	A comprehensive debate on the rationing of all healthcare resources would have made this rear-guard action unnecessary, as the allocation of appropriate funds to rare diseases would logically have followed in many cases. This debate still needs to take place.
NHS Professional	not aware of any
NHS Professional	Should we be looking at what is offered in other EEC countries? as a professional I get 1 or 2 patients complaining that the Rx they request is on offer abroad (usually Spain as the age group concerned not infrequently have properties there)
Local government professional	No, in our opinion the NHS should not compromise patient care in other areas by being forced to fund treatments with marginal benefits at high cost simply because the treatment is for a Â life limiting and rare condition. This will compromise our duties to patients with less emotive conditions who cannot garner public support.
NHS Professional	The ends are questionable ones- reached without full consideration- we need a proper debate.
Public	None Known
NHS Professional	In my view alternative methods are not required as they are already allowed for within the current methodology of the Institute.
Public	This remains under constant review The difference between palliative care and end of life treatment is not clear one is where patients can be made more comfortable for the time, Â and the other where a good quality of life is expected, as well as more time.
Public	It is a little awkward to attempt to "come up with" a valid alternative method, of establishing what, or which treatments can be assessed as beneficial, or how to arrive at formulae to decide what basis should be the "yardstick" for innovative, or indeed, any course of treatment, except to rely upon the considered and experience based opinion of medically qualified consultants, or consultant groups in their particular fields
Other	Decisions should be made using discretion to recommend certain treatments despite limited cost-effectiveness on a case by case basis. However, there should not be a general change in approach signalling that (very near) end of life treatments will be looked upon more favourably.
other	The Royal College of Radiologists does not have an alternative model.
NHS Professional	PCTs strive to, through evidence-based prioritisation, achieve the best health gain for their whole population from the

	resources available for commissioning. That being the case, working to a higher ICER for a category of patients (albeit deserving of compassionate treatment) may make it more difficult to achieve this goal: resources are likely to be diverted from more effective health technologies to less effective end of life drugs. It is even possible that such shifts can cost lives. An alternative is for PCTs to ring-fence a proportion of their budget for end-of-life medicines. That way, end-of-life medicines will not compete with other health technologies, and the transparency of the priorities agenda can be preserved. Besides, it will obviate discussions around justification for exceptionality of this group of patients, and the affordability of the higher ICER threshold.
Carer	Currently there are no alternative treatments, besides these drugs, for kidney cancer patients and so by not allowing them access to them then people will surely die. To aid the money currently available could not the PCTs be run regionally and not locally. This would then release money into the system to fund drugs for patients. This would also make the whole decision making process more efficient in the long run and also ensure that the NHS can be up to date with changing requirements and technologies. As a result this will drastically reduce our lag behind the rest of Europe and North America in the treatment of cancer care.
Other	We do not have any alternative methods to suggest
NHS Professional	As above the 'ends' are not clearly stated. I am not aware of a readily implementable technical solution (such as weighting QALYs). It may be that it is a philosophical issue rather than a technical one.
Public	If a drug has been proven in other countries to be effective against specific cancers then there should be no issue in recommending this for approval to the PCTs. The world is awash with so called palliatives and quack medicines sold to sufferers as miracle cures. The issue of a recognised and effective treatment cuts out this sort of mis-selling and gives credibility to the recognised drug companies who have the wherewithall to offer robust solutions.
other	We are pleased that the Government and the pharmaceutical industry is now reaching agreement on pricing of treatments, including flexible pricing. We hope that NICE and the pharmaceutical industry can reach similar agreements, so that NICE is able to make its decisions earlier, without compromising its access to the data it needs to make this decision. We hope that NICE, in conjunction with clinicians and the pharmaceutical industry, bases its decisions more upon the criteria used in clinical trials to evaluate the efficacy of treatments. We also hope that NICE listens more closely to the views of expert clinicians, including those who design and run trials, before making its decisions, as it is these experts who are best placed to tell NICE the true efficacy of a drug and which group(s) of patients it is best placed to benefit.
NHS Professional	These aims are not reasonable and should not be supported. Treatments should be funded if they improve quality of life to the extent that justifies the diversion of funds from other parts of the health care system. Such quality improvement would be legitimately assessed by QALY or other similar calculations. It is not reasonable to give higher

	preference to the last few months/years unless one is also prepared to give preference to older patients rather than younger in terms of valuing their remaining time.
NHS Professional	The committee should consider alternative proven methods that can achieve the same end if they are available.
NHS Professional	There has been no mention of clinical trials. This is a potentially important means of accessing these treatment, with free access to drugs. This could at least partly offset the increased costs to the NHS.
NHS Professional	This looks reasonable-not expert enough to make judgements on what cancers have an incidence of 7,000 per.annum or 24 month survival
NHS Professional	The alternative is, presumably, to weight QALYs gained differently if they are gained at the end of life. We are not sure that there is any reason to support this but not, for example, weight QALYs gained in children, or those gained by prevention etc etc. It seems a very awkward precedent to set for NICE that will leave the Institute vulnerable to lobbying from special interest groups.
Pharmaceutical Industry	3.1 Â Does the 2 year time period suggested for reviews refer to the start of the review (i.e at the point NICE considers whether it is appropriate to do a re-review) or does it refer to completion of the review? Â This has substantial impact on timings – if the 2 years dates from the initiation of the re-review, it could be another 2 years before completion i.e. 4 years from initial decision. 5.2. Â£100,000 seems a figure that is far too low to collect sufficiently robust data to demonstrate survival benefits and provide information to support economic modelling for re-review purposes. Â Clinical trials powered to detect survival, in cancer for example, cost tens of millions of pounds, not thousands. Â In addition, it would be particularly slow and difficult to recruit sufficient patient numbers from England and Wales when the process relates to rare diseases or those with from small populations in the UK. Â Therefore, international data would probably be required which would greatly increase the resource required to conduct appropriately designed research.
Other	Beating Bowel Cancer believes there are valid alternative methods which might be used to achieve the same ends, the short or the long term. Firstly, the cost-per-QALY ‘threshold’ of Â£30,000 requires urgent review. The range NICE uses currently to assess ‘cost effectiveness’ is Â£20,000 to Â£30,000 - the same as it was in 1999. This figure has not kept pace with NHS-specific inflation and is subsequently no longer an appropriate figure to use when calculating healthcare costs. Secondly, as new treatments are being appraised by NICE which are ‘additive’ treatments to existing regimes (e.g. addition of a monoclonal antibody treatment to an approved chemotherapy regime) it is becoming increasingly difficult to demonstrate cost-effectiveness due to the number of different drugs being prescribed simultaneously. Beating Bowel Cancer requests that the methodology of appraising ‘additive’ treatments is urgently reassessed. Finally, Beating Bowel Cancer requests that greater consideration is given to quality of life when deciding whether a drug is to

	<p>receive a positive appraisal from NICE. People affected by metastatic colorectal cancer consider any additional life, whether it is weeks, months or years, to be of enormous value it is time to take this into account.</p>
other	<p>We welcome the introduction of this scheme as an important step towards ensuring that Health Technology Assessment processes reflect the value that society places on the last few months and years of life. The additional flexibility given to Appraisal Committees in interpreting a QALY is an important step forward. However, we believe that further refinement in the methodology used for calculating a QALY will also contribute to ensuring that Health Technology Assessment processes are more reflective of the challenges faced in improving treatment near the end of life.</p> <p>If refinements to the guide to methods are being considered on the principle that the current reference case methodology may not reflect society's value of end of life medicines, we would like to highlight other potential methodological issues worthy of consideration and consistent with this direction of travel.</p>
other	<p>It is not clear from Section 1 exactly what the objectives of the exercise are. A cynical view would be that this is directed at finding a convenient 'technical fix' to a short-term political embarrassment, generated by commercial vested interests to circumvent the current NICE system. To the extent that this view has any substance, it should be firmly resisted, since the desire for enhanced profit is never satisfied and every concession is quickly followed by more extreme demands. However, other commentators have asked legitimate questions as to the inadequacy of the current NICE decision criteria to reflect population preferences that go beyond a purely utilitarian perspective. This debate has never been actively pursued in a systematic manner, and this may be the time to initiate research and informed debate to consider alternative social paradigms, which could lead to a richer and more humanitarian framework for investment decisions. Nonetheless, this proposal does not do that, and may serve to frustrate any attempt at rational development, since it effectively pre-empts a major aspect of the debate and makes a comprehensive solution more difficult to achieve and implement. Furthermore, it sets up a conflict between one part of the population (cancer sufferers) and various other equally 'deserving' candidates for special treatment such as young children, the severely disabled, those with severe learning difficulties, the frail vulnerable elderly, etc. Therefore, the proposal should be resisted. If NICE considers it appropriate to address alternative decision criteria, it should announce a programme of research, funded from national resources, to gather evidence on population 'special' priorities leading to a structured debate and consultation on competing alternative schemes.</p>
NHS Professional	<p>The ends appear to be increasing access to drugs that are considered unaffordable or not cost-effective at the end-of-life. Essentially no drug is inherently not cost-effective, what makes it not cost-effective is the price charged, consideration therefore needs to be given to centrally negotiated pricing for these drugs. Accepting that differential pricing in a global market might be difficult, innovative solutions to guarantee value for money need to be agreed. The scheme recently announced whereby prices would start low at introduction, and increase subject to outcomes, should</p>

	also be considered in a retrospective way for drugs currently not approved.
NHS Professional	The ICER value of £30,000 for NICE's threshold has not been revised since the Institute was established nearly 10 years ago. It has to be more appropriate and equitable to revise the ICER for all appraisals rather than make special rules for certain medications which only happen to be used at the end of life.
NHS Professional	A suggestion for alternative methods would involve a process to disinvest in existing treatments that were not as cost or clinically effective as newer therapies. In connection with this, it was noted that a good approach to improving access to end of life medicines would be to implement the recommendation in 'Guidance on NHS patients who wish to pay for additional private care – A consultation' which relates to the pricing and availability of new medicines. If manufacturers can supply the treatment at the same cost as an alternative NHS funded treatment, this would provide an acceptable mechanism to redirect existing resources from the current treatment into the new treatment being assessed
Patient	In terms of workload and cost saving it would be sensible for diseases with very small numbers of patients (tens to very few hundreds) to be approved on the basis of clinical evidence alone if the estimated total cost burden for the NHS was within a stated limit.
NHS Professional	Don't know. Important to look at quality of life as well as duration. Important to continue audit outcomes of patients beyond NICE approval to see how patients fare (in the real world). Encourage registration schemes (?funded by but independent of) drug companies to look at patient outcomes.
Pharmaceutical Industry	comments 6.2.1 continued - the outcomes of their appraisals of Orphan Medicines. Recent research by the OHE has revealed that orphan medicines appear to fair less well in terms of positive NICE recommendations when compared with NICE appraisal of non-orphan medicines. Orphan Medicines are relevant to this consultation because by definition they are for treatment of serious life-threatening conditions affecting small number of patients (< 5 per 10,000). The purpose of European legislation on orphan medicinal products (No 141/2000 & No 847/2000) was to encourage the development of medicines for rare, severe and debilitating diseases, often where there is low commercial viability. Despite the legislation patients in the UK still have limited access to the innovative treatments as demonstrated by the OHE. The costs of orphan medicines are higher per patient than medicines for more prevalent disease as there are fewer patients to recover the costs of research and development. It is therefore not surprising that many orphan medicines will not achieve a cost per QALY below £30,000. Therefore, we welcome the Institutes intension to supplement the advice it gives to its appraisal committ
Pharmaceutical Industry	With clarity re the above and addressing the point below, we believe this proposal should achieve its proposed aims.
NHS Professional	<ul style="list-style-type: none"> It is important that NICE takes into account affordability and estimates the likely cost of any recommended treatment to the NHS
Pharmaceutical Industry	We believe that the proposed scheme, subject to the minor clarifications suggested in response to 6.2.1 and 6.2.2, offers the most appropriate short term option for applying greater flexibility to the appraisal for treatments used for relatively rare, end of life, conditions. We hope that the result of the scheme will be to reduce the emerging gap between NICE's recommendations and accepted good clinical practice throughout Europe. In the medium term, we believe that revisions to the methodology for calculating the cost effectiveness of treatments used near the ends of life

	should also be considered. This should include reassessing how quality of life gains are measured, as well as better reflecting the cost of - and value delivered by - innovation.
Pharmaceutical Industry	<ul style="list-style-type: none"> • In the context of the proposed process, as above, MSD believes the suggested criteria should not be all or nothing and that a means should be found for these to be applied more flexibly.
Public	Why are some cancer treatments available elsewhere in Europe and the rest of the world that are not available in the UK? It suggests we are being far too rigid in our assessment.
Pharmaceutical Industry	The US has some different approaches to collect real-world data through episode of care administrative data sets / demonstration projects which can be set-up to provide long-term answers. In terms of the cost-effectiveness methodology, we are aware of an Office of Health Economics report commissioned by the Pharmaceutical Oncology Initiative that examines in detail the current standard methodology for calculating QALYs and presents various suggestions for methodological improvements.
NHS Professional	Alternative methods are not necessary as NICE has developed considerably experience and expertise in appraising new drugs. If NICE wishes to alter the ICER level then it can do so within the methodology that already exists but it will cause problems if the proposal introduces inequity for other patients with non-terminal illnesses.
other	The 2008 guide to the methods of technology appraisal already covers in principle what the proposal suggests. However, asking the Committee to be flexible with the upper end of the cost-per-QALY range does not provide a transparent and explicit decision making process. It would be methodologically more robust, and more in line with the guide, to ask for a sensitivity/scenario analysis, which shows how much more the benefit needs to be weighted in order for the cost-per-QALY fall under £30,000. It is important for the Committee to know if a more favourable decision for an end-of-life intervention would be based on rating the benefits 30% higher or 20 times higher than for all other people in the NHS.
Other	Whatever alternative methods might be used to achieve the same ends in the short or the long term must be fair, flexible, transparent and take into account a range of issues (as mentioned elsewhere in this response) so that patients who desperately need treatments can access them.
Other	<ul style="list-style-type: none"> • Adjusting the QALY threshold to reflect increased health costs. The overall QALY 'threshold' should be subject to regular review. This would impact upon the 'base' QALY at which the proposed scheme would operate. • Reviewing the methodology used to calculate QALYs – generating a QALY is not an exact science and, in the light of experience, we would urge NICE to review whether the current methodology is sufficiently sensitive to the benefits that new treatments can bring to patients nearing the end of life. Factors which could be assessed include how best to measure quality of life and how treatments which are used in addition to existing interventions should be costed. • Flexible pricing – we welcome the recent announcement of the new Pharmaceutical Price Regulation Scheme

	<p>which acted on the recommendation made in the Richards Review to introduce greater flexibility into treatment pricing, both by allowing the price to be varied after licence and by encouraging access schemes to be put in place. We urge NICE to do everything it can to facilitate such approaches.</p> <ul style="list-style-type: none"> • Promoting greater patient involvement – as a patient-led organisation, we believe it is imperative that NICE considers how its processes could be adjusted to bolster the confidence of patients who make considerable effort to contribute their experiences to the appraisal process. We would welcome an opportunity to work with NICE in this respect.
Other	Continue to use existing methods that are available to the Committee – high quality economic models with extensive critique and sensitivity analysis. Incremental improvement as better evidence of utilities in specific health states emerges
Other	<p>Bayer believe that the Appraisal Committees should base their decisions on multiple criteria across all technologies, rather than their apparent preference to rely on the ICER, particularly when the estimated ICER is over £30,000 per QALY. We acknowledge that in rare instances, the Committee has accepted ICERs greater than £30,000, taking other factors into consideration.</p> <p>We believe the proposed supplemental advice provides the Appraisal Committee with clearer guidance on when to explicitly consider other benefits and adopt a multiple criteria decision process. Therefore, we do not feel that there is an alternative method that could achieve a similar aim in the short term. In line with the procedural justice principles outlined in NICE's Social Value Judgement report, Bayer would like to see the relative weighting given to each criteria by the Committee explicitly stated in each guidance issued by NICE. Not only would this improve the transparency of how decisions are made, it will also provide an opportunity for any proposed independent evaluation to assess the relevance and impact of the supplementary advice.</p>
NHS Professional	This is probably as good as can be given the environment. A Prospective studies needed measuring Quality of Life as well as longevity
NHS Professional	This raises the question of what are these ends? Current guidance is more than adequate for drug appraisal. The aim should be for a package of care for patients with terminal illness, with a positive end of life plan and a choice of places to die with dignity. If faster-track appraisal of new cancer drugs is needed (debatable as the data are often insufficiently mature) then the Scottish Medicines Consortium approach could be adopted - "where the economic case has been demonstrated". Improving communication between oncologists and patients in discussing palliative care also needs to be addressed.
other	No comment available to be given, not expert on appraisal process♣
Pharmaceutical Industry	Quality of life at the end of life might be poorer, but the individual may value more the extension of life at the terminal health state. Indeed there is a large body of evidence that demonstrates significant differences between

	<p>the values that an end of life patient may place upon particular health state, compared to the value estimated by the general public. In addition utility itself may be difficult to measure in an end of life disease within small patient populations. As such, an alternative approach could be to use a non utility linked measure of cost effectiveness such as cost per life year saved. Such an approach has been adopted as an option to manufacturers submitting to the SMC.</p>
NHS Professional	<p>We believe that the needs for patients approaching the end of their life will be best met through delivery of the national End of Life care Strategy, and appropriate local variations.</p>
other	<p>More research into robust evaluation of quality of life of people in the last year of life is needed to identify the other key effects which life-extending medicines should achieve in order to be considered of value.</p>
NHS Professional	<p>It is unclear what the short or long terms aims of this proposed change are. If the ultimate aim is to ensure that patients have appropriate access to new and affordable cost-effective drugs in a timely fashion, then the fast-track approach of the Scottish Medicines Consortium could be adopted. Drugs are appraised according to the evidence base and approved rapidly "where the economic case has been demonstrated". If on the other hand, the objective is every cancer (cancer bias from the population threshold and incidence estimates) sufferer has the opportunity to die with dignity and minimum of suffering in a place of their choosing – ie everyone gets a positive "end of life plan" the NHS should not spend disproportionate sums in high cost postponement of death. Alternative methods are not necessary as NICE has developed considerable experience and expertise in appraising new drugs. If NICE wishes to alter the ICER level then it can do so within the methodology that already exists.</p>
other	<p>Yes, an alternative is to negotiate harder on price. A medicine which extends life but is not acceptably cost-effective can become acceptably cost-effective when the price is sufficiently reduced. Recent developments indicates that this might be possible in the future. For example, the 20 November 2008 UK Financial Times reports that "a new process will also be introduced to streamline, accelerate and make systematic the process of renegotiating pricing for medicines initially rejected as not cost effective by [NICE]."</p>
other	<p>NICE should continue to offer its existing advice to Committees. This allows them to exercise discretion in interpreting the cost-effectiveness threshold. Thus, they may approve interventions with ICERs above £30,000 when there are special factors. In particular, one of the factors listed in the 'Guide to the methods of technology appraisal' document is the 'innovative nature of the technology'. This may apply to innovative medicines for rare conditions, for which there are currently no effective treatments and where R&D costs are high. Other 'supply-side' mechanisms, such as patent extensions, adjustments to the PPRS, or co-funding of research for important small indications, need to be developed if there is a real problem to be addressed. In addition, NICE should continue to support and actively engage with high-quality research on public preferences and social values and should consider whether there are important, consistently held differences in values that need to be reflected with differential QALY or utility weights, and if so these should be introduced in a systematic and consistent fashion across all NICE's considerations.</p>

Pharmaceutical Industry	<p>The proposed addendum to the NICE Methods of Technology Appraisal fails in its stated aim in a number of important ways which we feel could be addressed by taking the following actions: 1. Incorporate the points in the addendum to the HTA Methods Guide so they are considered early on in the process, thereby allowing appropriate technical reports to be prepared by manufacturers or by Technology Appraisal Groups. This would help to ensure that the Committees appraising “end of life” medicines are supplied with the evidence needed to back up their decisions. 2. Define clearly what is meant by "substantial" or "demonstrable" extensions to life. Surely what is "substantial" would vary depending on the life quality of the patient, the patient’s baseline life-expectancy, not to mention the perspective taken. 3. Remove or raise the "maximum life expectancy" cutoff. This cutoff limits the process to a particular population in a highly arbitrary way and presents the potential for severe complications when establishing comparator groups for future medicines.</p>
NHS Professional	<p><u>3. Recommendations for improvement of the proposal</u></p> <p>Our recommendation is that this proposal should not be implemented. However, we note that this policy, as announced in the ‘Improving access to medicines’ report, has been agreed by the Secretary of State prior to any announcement by the Institute and prior to the results of any consultation. Therefore, accepting this as a political decision initiated by interests outside the Institute, and without supporting evidence, we offer the following recommendations to improve the policy.</p> <p>a) Adjusting the threshold range or the measure of benefit</p> <p>As outlined above, we do not feel it is appropriate to amend the threshold range for cost-effectiveness. Adjustments of this type should be reflected in the measure of benefit and this would promote a consistent and transparent approach.</p> <p>There are two separate questions that need to be addressed:</p> <ul style="list-style-type: none"> i) do current QALY measures sufficiently capture the benefits of extending survival? ii) even when they do, should the health benefits in these groups be weighted more highly than other NHS patients who will bear the opportunity costs? <p>In the absence of empirical support, the proposal could be implemented in several ways as an interim approach whilst appropriate evidence is gathered:</p> <ul style="list-style-type: none"> i) Asking sponsors to submit additional non reference case analyses which might include the use of patient preferences rather than those of the general public, or other non reference case analyses of quality of life that would be given more consideration in these circumstances. ii) Where this is not available, extreme sensitivity analysis could be undertaken where survival is assigned the full age related QALY weight.

	<p>iii) Threshold analysis of the relative weight that must be attached to this patient group relative to other NHS patients for the intervention to be considered cost- effective at the usual threshold range (£20,000 to £30,000). This would provide the Appraisal Committee with a starting point for deliberations e.g. a ratio 3 to 1 (we would need to be willing to give up 3 QALYs from other NHS patients to gain 1 QALY in this group).</p> <p>The Institute should commission research to address both questions about the measure of benefit. The research could review current work in this area and obtain potential weights from a sample of the UK general population. It could also examine whether patient preferences or the valuation of sequences/profiles gives higher quality of life weights at the end of life. This could also include examination of the impact on carers and families. This will provide an evidence base for the policy to better reflect the preferences of the population that the NHS serves. The policy could be developed in a similar way or along side/part of the methods as this work becomes available.</p> <p>We believe that a principled approach based on addressing legitimate concerns about measures of benefit would be more transparent and sustainable than the rather arbitrary rarity criteria in the current proposal which will inevitably be seen simply as a means of restricting when these considerations can be made. Therefore the combination of considering alternative measures of benefit now (but commissioning research to inform this)</p> <p>b) Additional concerns and clarification of the proposed criteria</p> <p>Innovation Clarification should be provided as to how “a sound case for the impact of innovating for a small patient population” will be assessed. Does innovation refer to the outcomes generated by the treatment (as is currently defined in the methods guide), or the mode of operation, etc? The OFT report as well as the NICE methods guide makes clear that there are no reasonable grounds to pay more for innovation simply for the sake of innovation itself. Is it envisaged that there could be cases where all other criteria are met but technologies are not recommended as they are not considered “innovative”? If so, is the aim of the proposition to promote research and development or health gain? If not, what is the purpose of this section?</p> <p>Use of prevalence and incidence The proposal is inconsistent in the use of prevalence versus incidence. 7,000 new cases per annum where average life expectancy is 24 months is considerably greater than 7,000 patients. Clarification needs to be provided as to which is meant.</p> <p>Life expectancy without treatment Clarification is needed regarding the 24 months life expectancy referred to in section 2.1.2. Does this refer to average life expectancy in the absence of treatment with the new technology eg Is this median or</p>
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	<p>mean survival? We recommend that it is stated that this applies to the (mean or median) average across all patients within the licensed indication. Otherwise it could be interpreted as referring to a subgroup of patients within the licensed indication. A rationale should be provided for the use of 24 months average life expectancy to define a terminal illness</p> <p>Substantial extension to life Some guidance as to what is meant by a 'substantial' extension to life is required to ensure consistency of application. It is recognised that the length in terms of time may vary depending upon the overall life expectancy, but some indication could be given as to what is meant.</p> <p>Robustness of data Clarification on what is meant by robustness is required. How, if at all, is "robust" to be defined to ensure consistency of application? If estimates are "robust" and "proven" then what is the purpose of "evidence development" as part of any recommendation for use in the NHS?</p> <p>Evidence development What type of evidence is to be collected as part of the "evidence development"? Is it accepted that robust estimates of relative survival benefits of treatment may not be feasible? If not please explain how these estimates will be made.</p> <p>Comparator How is a "comparable" alternative to be defined? Specifically, is this solely in terms of impact on life expectancy or are other health benefits valid in making this comparison? What are the criteria by which an intervention approved via this proposition is considered the relevant comparator in subsequent appraisals? while removing some of the criteria may carry some wider support and be more sustainable in the longer run. These proposals could be immediately and easily implemented.</p>
other	Breast Cancer Care believes the restrictions specified regarding patient population size and average life expectancy should be removed so that clinically effective end of life medicines are available to everyone who could benefit from them.
NHS Professional	other methods eg drugs will have been through NICEs existing processes so I am unclear what other methods are being suggested here.
Pharmaceutical Industry	It is NICE's over-reliance on the cost per QALY ratio which has led to treatments being denied to patients with terminal illness as well as other patient groups. It is our view that if the QALY was truly used as a 'tool not a rule' then these and other patients may have already been receiving life-saving and life-extending treatments. Â Examples include instances

	where the Appraisal Committee has deemed a product clinically effective, but not cost effective.
Pharmaceutical Industry	<p>The supplemental advice as currently outlined does not specify the approach through which the Appraisal Committee will attach more weight to health benefits of life extending medicines. If the cost per QALY threshold is to be raised, there is a need to specify the new benchmark and the empirical evidence underpinning this choice.</p> <p>This consultation is in part a recognition that the current methods used by NICE do not adequately reflect the value that society places on end of life treatments and treatments for rare conditions. It highlights the need for refinements in the way that HTA reflects societal and patient preference.</p> <p>For example, the QALY as currently utilised by NICE assumes that an individual's willingness to trade off quality and quantity of life is independent of their remaining life-expectancy, when there is good evidence that such a constant proportional trade-off may be invalid. The five domains of the EQ-5D often fail to adequately capture quality of life for patients and longer-term research into more effective instruments for eliciting patient reported generic quality of life is needed. Also evidence now exists that shows a discrepancy between the value that a patient at the end of life may place upon particular health states and the value estimated by the general public.</p> <p>Further research into the impact and merits of placing greater emphasis on patient valuation should improve the valuation methods. Industry is keen to play its part in this.</p>
NHS Professional	Alternative methods are not necessary, as NICE has developed considerably experience and expertise in appraising new drugs. If NICE wishes to alter the ICER level then it can do so within the methodology that already exists. It will cause problems if the proposal introduces inequity for other patients with non-terminal illnesses.
Other	<p>We welcome the recognition from NICE that the one size fits all approach is not always appropriate and that the cost per QALY should be considered alongside other factors rather than be the over-riding criterion for decision making.</p> <p>We are pleased to note that the proposed process is intended to include 'other uncommon conditions' as well as rare cancers. We are concerned however that there will still be a number of groups of patients who will not benefit from the new process because of the requirement to meet the full set of criteria listed. We believe that consideration should be given to how the criteria are applied to help to achieve the same ends but for a broader patient population.</p> <p>The consideration highlights the need for refinements in the way that HTA reflects societal and patient preference. Further research into how this might be achieved is necessary and the EMG is keen to work alongside other stakeholders to contribute to this.</p>
Pharmaceutical Industry	Pfizer believe that the fact of this consultation highlights some of the inevitable problems in undertaking Health Technology Appraisals – scarcity of data, lack of sensitive measurement tools, tendency towards over reliance on Cost per QALY etc.

	<p>In the long term we would hope to see the development of significantly improved tools and methodology – particularly in the area of utility measurement supplying a genuine alternative to the very blunt EQ-5D.</p> <p>In the shorter term we would contend the probability of rejecting valuable medicines in error is unacceptably high in the UK. This is evidenced by the considerably greater use of treatment for rare disease elsewhere. We would like to see less reliance on estimates of relative cost-effectiveness in appraisals and more consideration of the evidence of value provided by clinical and patient testimony. Following on from recommendations from groups such as the citizens council we would also like to see much greater weight applied to areas such as severity of disease, relative life expectancy and treatment equity.</p>
other	FPM understands that risk sharing agreements are happening and would recommend consideration of conditional approval whilst awaiting further data, including health-related quality of life. Indeed, where evidence of lack of benefit or increasing harm arise, consideration should be given to early termination of therapy.
Pharmaceutical Industry	Wyeth believes that the methods of appraising health technologies are ever evolving and there will be other methods that better encompass state-of-the art appraisal methodology within the remit of NICE. Multiple Criteria Decision Analysis (MCDA) is very similar to the existing decision making process used by NICE, however, it offers greater consistency and transparency and can be used across all health technologies without having to ‘adjust’ the ICERs due to specific considerations. Instead the ‘considerations’ are incorporated in the MCDA itself. See also: 1. Mussen F, Salek S & Walker S. A quantitative approach to benefit-risk assessment of medicines - part 1: the development of a new model using multi-criteria decision analysis. <i>Pharmacoepidemiology and Drug Safety</i> . 2007;16:S2-S15 2. Dowie J. The future of HTA is MCDA. Available at: http://knol.google.com/k/jack-dowie/the-future-of-hta-is-mcda/2rrcx2o0qipsa/14# Accessed on 3rd December 2008.
other	If we are to prioritise some patient groups over others then I think weighting of QALYs is the way to pursue this. However, more work would need to be done to derive these weights. So this is not a short-term solution.
NHS Professional	We have no alternative methods to suggest however these proposals should be implemented in parallel with the other changes proposed, both to the private drug access as well as a more speedy appraisal mechanism by NICE. We also suggest that NICE engage in a more public debate to outline and explain these issues to the public in general and patients and patient groups in particular.
NHS Professional	I think the use of life years gained would be an appropriate tool since the Committee is fundamentally stating that life extension is more important than the quality of that life. Ergo assuming LYG would be most appropriate with the same threshold.
NHS Professional	See above ie apply same criteria without the need for a condition to be terminal with short survival
NHS Professional	The measures proposed are appropriate but underlying funding and policy issues in the NHS need to be simultaneously reformed. For example, underpinning all considerations of the QALY and assessment of higher-cost treatments are issues of budgeting, affordability and whether the NHS is efficiently investing and disinvesting in medical

	<p>technologies and treatments.</p> <p>We urge NICE to work with the Department of Health to continue to pursue wider assessments and reforms throughout the NHS budget to ensure efficiency and equality in the services it provides, rather than limit these to new technologies facing NICE scrutiny.</p> <p>With better investment and disinvestment within the entire NHS budget higher-cost treatments for rare and severe diseases could well be funded from within existing resources without the need for a scheme such as that being consulted on.</p> <p>In the longer term we anticipate that the new PPRS should work to promote better access to treatment in the NHS and incentivise better value for money. Further, we will look to future research to inform whether there is a way of optimising the QALY calculation to ensure appropriate costs, benefits and societal preferences are fully captured and accounted for.</p>
Other	<p>At a meeting with the Secretary of State and Professor Mike Richards, I did suggest recently ways of finding the money for an increased cost-effectiveness ratio from within existing NHS resources and I do hope that this will be seriously considered.</p>
NHS Professional	<p>Regardless of the method that is selected, it is essential that there is clarity concerning the rationale for its implementation, the details of the method and the criteria for receiving positive medicine recommendation. Transparency is a crucial component in all aspects of the process.</p>
NHS Professional	<p>From what I stated above I favor using the concepts of the current methods guide and for those situations in which the drug is for an EoL disorder quantify the benefits that have not been captured by the economic analysis. Once done one can make value judgments about the believability of the benefits missed. The only real reason we than have this EoL paper is to ensure that for those populations the calculations are done, although I would struggle not allowing such calculations for non EoL disorders where people suggest that benefits have been missed.</p> <p>In effect creating a situation where the exploration is done within the context of the prevailing economic model, the uncertainty pertinent to that model, and not as an extra 'bolt on' that simply raises the threshold of acceptance of certain</p>

	ICERs.
NHS Professional	In common with many other issues in children's medicine, the necessary requirement should be proof of effectiveness not artificial licencing requirements.
Other	We are not health economists so cannot provide alternative specific formulae. But it seems sensible to assume that in any one patient population in which it is possible to determine the number of patients likely to need access to a particular therapy, this could determine affordability. It is of course vital to have equity across an entire range of diseases but, as NICE has indicated earlier in the Summary Section of the document, other elements such as severity of disease should be taken into account as well as a therapy's positive effects on morbidity and/or quality of life. It goes without saying that any alternative methods which are applied to health technology assessments should be fair, flexible, transparent and take into account a range of issues not currently covered by the QALY, so that patients who desperately need vital treatments can access them.
Other	Whatever alternative methods might be used to achieve the same ends in the short or the long term must be fair, flexible, transparent and take into account a range of issues (as mentioned elsewhere in this response) so that patients with rare and less common cancers, who desperately need treatments, can access them.
Other	The way that the current NICE appraisal system interacts with the system of drug pricing acts to disproportionately disadvantage cancer patients and those patients with life threatening illnesses, in small patient populations, and in areas where there are few or no other comparator treatments. We welcome recent announcements by the Department of Health to change the way that the drug pricing system works to promote the use of patient access schemes and allow companies to set initially lower prices for treatments where effectiveness is likely to be easier to demonstrate in the clinical setting. In our opinion, these two proposals together are the best way to significantly impact on the number of drugs receiving favourable recommendations from NICE.

	<p>Tracking the impact of these proposals</p> <p>We welcome proposals to track the impact of treatments recommended under these new criteria. We would welcome more detail from NICE and the Department of Health on these plans.</p> <p>For cancer at least the National Cancer Intelligence Network (NCIN) is best placed to process and manage this data. The NCIN is already collecting data from the NHS to track services and outcomes. A parallel system established solely to track the implementation of NICE guidance would neglect the opportunity to exploit this well organised resource and likely lead to a massive duplication of effort.</p> <p>The expertise and experience of managing this type of information within the NCIN would be useful to support similar exercises in other disease areas.</p>
Other	<ul style="list-style-type: none"> • In the context of the proposed process, as above, MSD believes the suggested criteria should not be 'all or nothing' and that a means should be found for these to be applied more flexibly.
NHS Professional	<p>If by this, what is implied is that it should be possible to take into consideration other factors than cost-effectiveness; this is already stated in the Social Value Judgements document (see below). This is an acknowledgement that there are specific classes of technologies (palliative care interventions, so called 'orphan drugs') that may never be cost-effective using NICE methodology but should nevertheless be provided by the NHS.</p> <p>“Above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of the intervention as an effective use of NHS resources will specifically take account of the following factors. [...]</p> <p>When the intervention is an innovation that adds demonstrable and distinct substantial benefits that may not have been adequately captured in the measurement of health gain.” (pp 18-19)</p> <p>Any other 'alternative method' has the same risks as the current proposal in opening up the entire decision-making process to intense lobbying by the pharmaceutical industry and other interest groups (including patients and their carers) and could lead to possible class actions against NICE decisions.</p>
Other	<ol style="list-style-type: none"> 1. The Institute should consider using this opportunity to include new guidance on severe diseases. The NICE Board has accepted recommendations to include this in the next version of the Social Value Judgements guidance, however because of the time delay in this it would be helpful if severe diseases were included in these proposals.

	<p>2. As above, all orphan treatments should be considered within these new rules, so that patients with rarer cancers, even when they are not at end-of-life are able to access the clinically effective treatments which they need.</p>
Pharmaceutical	<p>Given the current experimental status of emerging methodologies we believe that the current proposal is a reasonable approach. It may also enable more transparent decision-making than would be afforded by adjusting individual and potentially multiple elements of the incremental cost per quality adjusted life year calculation.</p> <p>In the future, on the basis that the current framework for evaluating the value of a medicine does not fully reflect society's willingness to pay for end of life medicines (particularly that the QALY does not capture the benefits to carers and dependants, and the greater priority applied by society to more severe diseases with poor prognosis), NICE might consider the following when estimating value:</p> <ul style="list-style-type: none"> - Weighting QALYs to account for the apparent link between an individual's willingness to trade off quality and quantity of life, and the magnitude of a patient's remaining life-expectancy; - Development of generic health related quality of life instruments that fully account for the health benefits of end of life medicines, which is a known issue associated with the EQ-5D instrument currently in use; - Consideration of health state valuation by end of life patients, who are known to differ from the general public in their perceptions of value. <p>Consideration of how alternative methodologies could be utilised could be considered in future revisions of NICEs' methods guide.</p>
NHS Professional	<p>See response above.</p>
NHS Professional	<p>As this supplementary advice is most likely in practice to apply to cancers, should NICE be doing more to promote the development of better surgical techniques, early detection, diagnosis and intervention rather than using limited resources on end-stage treatment?</p>
TA Committee Member	<p>Essentially we are being asked to do 2 things – to look at the end of life situation and to look at a drug for a</p>

	less common disease. The first we were supposed to be achieving by in the short term giving “special attention” unspecified to such drugs and in the long term improving the QALY as a measure of effectiveness. The second looks much more like the orphan drug situation albeit with slightly more common disorders. Would orphan drug solutions not be better than distorting our cost-effectiveness approach which currently appears to be working well.
TA Committee Member	None come to mind at the present time.
TA Committee Member	Undertaking empirical work to establish decision making parameters.
TA Committee Member	<p>NICE should note, if they have not already done so, the paper by Camidge et al. (1) This paper discusses whether prognosis without treatment can be used as a modifying factor in health economic assessments and whether percentage increase in QALYs may be more suitable than life years gained. In general terms the paper supports the NICE proposal that a different approach is needed for life extending treatments. <i>“How long someone has to live intuitively seems important in rationing decisions. Incorporating it into economic assessments,... could make decisions fairer.”</i></p> <p>Ref (1) Prognosis without treatment as a modifier in health economic assessments. Camidge et al. BMJ 2005;330:1382-1384</p>
TA Committee Member	I have felt that too little qualitative and too much quantitative consideration is often given to our decision-making process, and I think that the public have picked up on this in some of the criticisms that we have received. Might this therefore now be an opportunity for us to lend perhaps more attention to qualitative issues than we might otherwise have done so in the past?
TA Committee Member	<p>Two options.</p> <ol style="list-style-type: none"> 1. Companies reduce the price 2. Government made to decide (as before NICE created). If a drug fails to meet our QALY threshold then back to DoH to decide whether to fund from their resources and negotiate with company eg cost sharing scheme (precedents exist I believe). The politicians have to be seen to either “assist” or “deny” in this situation – and take the praise or criticism
TA Committee Member	If “achieve the same ends” means finding ways of making expensive (and hitherto cost-ineffective)

	<p>treatments available on the NHS, then the only fair way forward is to have the necessary discussions with the DoH and be proactive in making risk sharing schemes more widespread and workable. i.e. find ways of reducing the cost of the drugs.</p> <p>I would be more sympathetic to give additional weight based on disease severity than I would on prevalence or life expectancy. This is also in accordance with the citizens council's report on severity of illness (but I would make this judgement based on baseline EQ-5D).</p>
TA Committee Member	<p>Tackling one of NICE's 'other considerations' by itself when there are many others listed in various places seems pretty silly to me even if may seem politically wise at the time (the two often go together). The long term answer is Multi-criteria Decision Analysis with all the 'other considerations' brought into the analysis and all the necessary value judgements/weightings made simultaneously and hence coherently and equitably. See my paper at http://knol.google.com/k/jack-dowie/the-future-of-hta-is-mcda/2rrcx2o0qipsa/14#</p>
TA Committee Member	<p>Research could be undertaken to estimate alternative utility weights for EoL and assess the degree to which the opportunity costs could be factored into the decision making process.</p> <p>If an upper threshold were specified then the impact of the proposals could be predicted more clearly in terms of the likely technologies that would 'pass' and the opportunity cost of existing technologies that need to be withdrawn. However, on what basis would this be based?</p>
TA Committee Member	<p>I don't believe in the objective (to promote un cost-effective technologies) therefore I do not believe in the methods.</p>
TA Committee Member	<p>The only 'fair' way I can see is to either raise the threshold for terminal cancer treatments to say 40k per QALY, or actually specifying average life years gained with an appropriate upper limit figure attached for all terminal/palliative cancer treatments- in fact possibly all (would need thinking through) cancer treatments could be dealt with in the same way and I think the public would understand that better.</p>
TA Committee Member	<p>I think the current methods are the best in the circumstances.</p>
TA Committee Member	<p>I am not aware of any alternative methods.</p>

	<p>I think there are three parts to this top down process. Policy, Procedure, Implementation. I agree with the Policy quoted in this consultation document. The outline Procedures in this document will be modified if necessary after consultation and presumably after the away day. They can be reviewed after the first appraisal meeting handling such a case.</p>
TA Committee Member	None that I can think of at the moment.
TA Committee Member	<p>If the objective is to improve access to these agents on grounds of clinical efficacy then nationally negotiated discounts for use in NHS in same population group—although am sure industry would argue that this is not possible if R&D costs to be recouped. However, I am not sure in my own mind that I buy into the argument that a life prolonging drug should have greater (or even equal) access than a life improving (or health promoting) intervention.</p> <p>Alternative would be to redefine the QALY (again as above I do not support this)</p>
TA Committee Member	<p>One of the major difficulties I find with STAs for novel agents (mainly, but not only, the various monoclonals) is the lack of evidence available to appraise their real clinical effectiveness. We are forced to rely heavily on modelling and mixed treatment comparisons which at times have felt very thin in terms of scientific robustness, but have been the best appraisal possible at the time NICE was asked to undertake it.</p> <p>I think it could be better, subject to individual approval under criteria perhaps similar to those proposed for this amendment and particularly with regard to novel agents, to grant a fixed term approval for such drugs at the time they are licensed, to be provided within a rigidly defined patient population and via specialist centres only and require that good quality prospective data is collected for all patients. Then, a “conventional” appraisal of the true cost / clinical effectiveness of the agent to the NHS could be carried out using properly informed data. This is effectively similar to the proposal in paragraph 1.7 of the consultation document but would leave out the initial appraisal. This would roll the drug out to the NHS faster and lead to good quality data to inform a definitive decision on its continued funding being available sooner. Overall, I think this approach could get us to the “right” answer sooner and (given the relatively small population groups targeted) without prohibitively higher costs overall.</p>
TA Committee Member	Where a treatment is clearly life prolonging and life improving then I think the standard ICER approach is

	<p>certainly valid. If a treatment is neither life prolonging nor life improving then such a treatment should never get through the first phase of the review process. However when a treatment is life prolonging but not life improving or life improving but not life prolonging there should be a new 'advanced ethical' appraisal committee to review in detail the value of such a treatment. Perhaps an ethicist should be appointed to this committee and alternative ethical approaches or frameworks considered to ensure ethical validity. Health economic studies at the end of life are perhaps particularly difficult and more consideration to the value that patients put on the treatment outside of the QALY measurement and proxy measures of carers utility are also important.</p>
TA Committee Member	<p>Have a fixed budget and allow the application of a defined higher QALY threshold, also consider the opportunity to apply budget impact to the decision making. In this way we would distinguish between the budget for end of life medicines and other needy disease areas. It would help offset some of the concerns regarding equity of access to new medicines and place a cap on how much the NHS is willing to pay for end of life medicines.</p>
TA Committee Member	<p>See comments on 'view of proposal'. Consider a specific method for assigning QALY rates at 1+ in the circumstances for which this guidance is designed.</p>
TA Committee Member	<p>Difficult to comment given my view to the other questions. There needs first to be evidence supporting the notion of a different utility for this patient population</p>
TA Committee Member	<p>This deserves to have some thorough research at a theoretical level, to see if there is a way of implementing this that does not destroy the credibility of NICE altogether. And is legal.</p> <p>There also needs to be empirical research to discover whether the public agrees with the proposition that certain groups should enjoy ICERs. The 7000 figure needs some kind of justification also.</p>