Myeloma UK response to appraisal consultation document on lenalidomide for treating multiple myeloma after 1 prior treatment with bortezomib (part-review of TA171) [ID667]

Introduction

Myeloma UK welcomes the opportunity to comment on the NICE appraisal consultation document (ACD) covering lenalidomide (Revlimid®) as a treatment for myeloma patients after one prior treatment with bortezomib (Velcade®).

We appreciate that NICE had issues with this appraisal, especially in regard to aspects of the modelling. However, and in spite of the very clear and compelling clinical case made, we are extremely disappointed by the draft decision.

As myeloma is a complex and individual cancer, clinicians need a range of treatments available at every stage of the disease, to ensure that they are able to treat their patients optimally. To this end, we do not agree that the draft negative decision is the correct one and strongly believe that if it remains negative, it will be to the detriment to the treatment and care of this group of myeloma patients.

In the first appraisal meeting, the clinical case for approving Revlimid as a second line treatment was put forward by both the clinical and patient experts. The clinical arguments appeared to be generally accepted by the committee, which is reflected in the ACD itself. The onus now appears to be on the manufacturer to either address the data uncertainties with new information or to put in place an appropriate PAS to address the issues.

To support this task we are happy to submit the following comments to assist NICE in taking forward the appraisal.

Importance of Revlimid in this setting

As outlined in the Myeloma UK patient expert submission and in the verbal evidence provided to the NICE appraisal committee, it is very important that Revlimid is approved in the setting covered by the appraisal.

The major argument in favour of approving Revlimid in the appraisal setting is to ensure that myeloma patients, where they have demonstrated in the past that they did not respond well to Velcade, do not have to go on to receive a below par treatment (i.e. retreatment with the same drug).

The approval of Velcade as an initial treatment (in patients who are intolerant or contraindicated to thalidomide) has opened up the clinical need to use Revlimid at first relapse – as it may not be clinically relevant for patients who relapsed quickly after receiving Velcade or for patients who experienced bad side-effects to receive Velcade retreatment at first relapse.

It is important that clinicians have the option of prescribing Velcade or Revlimid in patients at first relapse depending on the response to initial treatment with Velcade. We also consider it to be more cost-effective for patients to receive a treatment that they will respond to, rather than to retreat with a treatment that their clinician knows they will have a poor response to.

We also reiterate that the efficacy of Revlimid in first relapse and beyond is supported by a range of Phase III trials, so there is little controversy over the clinical effectiveness of the treatment.

Velcade retreatment

Having read through the draft NICE ACD, it is unclear why the committee is continuing to use standard chemotherapy regimens (such as melphalan and prednisolone [MP] and cyclophosphamide and dexamethasone [CD]) as comparators in the health economic analysis. These treatments are rarely, if ever, used in the setting covered by the appraisal (or indeed on their own at any stage of the disease) and do not add value to the NICE decision-making. Myeloma UK considers Velcade retreatment to be the only viable comparator in this appraisal.

Clinical practice in the UK dictates that myeloma patients would receive Velcade retreatment at first relapse, in line with current NICE guidance. Myeloma clinicians in England and Wales tell us that they use Velcade in this setting, as it is currently the only NICE approved novel agent at first relapse and is

preferable to using conventional chemotherapies (e.g. MP and CD) that do not have an equivalent impact on progression free and overall survival.

As Revlimid has been approved by the Cancer Drugs Fund (CDF) clinicians have recently become able to prescribe this in patients instead of Velcade, where appropriate. We know that myeloma clinicians in England value being able to access this for patients and have experience of using on the NHS. On this basis, at Myeloma UK we hope that Revlimid be approved in this setting for patients more widely.

Conclusions

As outlined above, Myeloma UK is disappointed with the negative recommendations. However, we are confident that with additional information supplied by the pharmaceutical company, further collaboration and more detailed consideration of how we can overcome the uncertainty associated with the modelling, we can find a way of making Revlimid available to myeloma patients in the UK to patients who need it at this point in their disease.

Please contact [redacted] or call [redacted] if we can provide any further information to support this appraisal.