

Response to the revised Appraisal Consultation Document on lenalidomide for the treatment of multiple myeloma in people who have received at least one prior therapy

1. Do you consider that all of the relevant evidence has been taken into account?

1.1 We are satisfied that all evidence has been taken into account and we are happy with the outcome. We are pleased that the price capping scheme offered by the manufacturer and the application of the supplementary end of life guidance means that myeloma patients who have received two or more prior therapies and are suitable for lenalidomide will now get access to this clinically effective treatment.

1.2 Whilst we are pleased that this draft recommendation is positive, we remain concerned and surprised about the magnitude of difference between the manufacturer's base case QALY and the ERG's, and that there was such a marked divergence of opinion as to whether mean or median should have been used in the economic model.

1.3 To reiterate a point made in our response to the negative ACD: given the increasing frequency of crossover trials and the likely consequences that crossover has on the validity of data, we recommend the Institute establishes a standard method to assess treatments which are penalised by the current appraisal process for being the focus of trials unblinded early because of their superior clinical effectiveness.

2. Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence, and that the preliminary views on the resource impact and implications for the NHS are appropriate?

2.1 We feel the recommendation is a fair reflection of the evidence and represents a good deal for both patients and the NHS.

2.2 We applaud the willingness and commitment of the Institute, the Department of Health and the manufacturer to making lenalidomide available on the NHS and for creating an innovative solution to ensure that this important drug can be accessed by patients.

3. Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

3.1 As the recommendation stands, we consider it a sound and suitable basis for guidance to the NHS. We urge the Institute to convert this draft guidance into final guidance as soon as possible.

4. Are there any equality related issues that need special consideration that are not covered in the ACD?

4.1 We do not know of any equality related issues not addressed in the ACD.