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Proposed price capping scheme for lenalidomide for the treatment of patients with multiple myeloma who have received at least two prior therapies

Further to my conversation this morning with your colleague Matthew Harpur, we are pleased to enclose details of our proposed price capping scheme for lenalidomide. We would be happy to meet with you to discuss our proposal at your earliest convenience.

Background:

- Lenalidomide for the treatment of multiple myeloma in people who have received at least one priory therapy is currently the subject of a NICE Single Technology Appraisal (STA)
- The appraisal has reached the stage of stakeholder consultation
- The appraisal consultation document (ACD) was circulated to consultees and commentators on 18th October. The deadline for comments on the ACD is 18th November
- The appraisal committee have acknowledged the significant improvements in clinical outcomes associated with lenalidomide in terms of improved response rates, time to progression and overall survival. However, they concluded that the use of lenalidomide was not a cost-effective use of NHS resources. Therefore, the appraisal committees preliminary recommendation is that lenalidomide in combination with dexamethasone is not recommended for the treatment of multiple myeloma in people who have received at least one prior therapy
- There has been significant media coverage subsequent to the publication of the ACD, which has included a coalition of patient groups (including Myeloma UK, MacMillan Cancer Support and Leukaemia CARE) calling on the Department of Health, NICE and Celgene to work in partnership to overturn this preliminary negative recommendation for those seriously ill patients who could benefit from lenalidomide through improvements in their life-expectancy and quality of life

Rationale:

- Lenalidomide is a unique treatment for multiple myeloma in that it is an oral therapy and (as noted in the ACD) it is associated with a more favourable adverse effect profile compared with other regimens used in the management of multiple myeloma
- The combination of the oral administration and the favourable adverse effect profile enable patients to remain on long-term treatment and continue to benefit from the treatment until their disease progresses
- It is this ability for patients to remain on treatment and continue to receive long-term benefits that is a key driver in the cost-effectiveness of lenalidomide because costs continue to accrue as patients continue to benefit from the treatment. This has led the appraisal committee to conclude in their preliminary recommendation that lenalidomide is not a cost-effective use of NHS resources
- In response to the call from the coalition of patient groups to work with the Department of Health and NICE, we would like to propose a price capping scheme that will enable patients who have received at least two prior therapies to continue to enjoy the benefits of long-term treatment with lenalidomide
- Specifically, we propose a scheme that will cap the maximum cost to the NHS for an individual patient at two years of treatment (26 cycles each of 28 days). The cost of lenalidomide for those patients who remain on treatment beyond two years will be met by Celgene
- We believe that this scheme will benefit both patients and the NHS as it would improve the cost-effectiveness of lenalidomide and thus enable the NICE appraisal committee to recommend lenalidomide for the treatment of patients with multiple myeloma who have received at least two prior therapies

Implementation:

- Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide cannot be ruled out in humans, and for these reasons a risk minimisation plan was mandated and approved by the EMEA and MHRA during the licensing process to ensure that there is no foetal exposure to lenalidomide
- The main objective of the plan is to inform of the potential teratogenic risk of lenalidomide and to restrict use in women of childbearing potential, unless the Pregnancy Prevention Programme (PPP) is followed. Details of the PPP are provided in the lenalidomide SmPC.
- The core PPP consists of the following four elements:

1. An educational programme
2. Therapy management advice
3. A system to ensure that all appropriate measures have been performed prior to the drug being dispensed
4. Follow-up of the effectiveness of the PPP

- Element 3 of the PPP is implemented through a Prescription Authorization Form (PAF), which must be completed by the prescribing physician and checked by the dispensing pharmacist every time a prescription for lenalidomide is dispensed for a cycle of treatment
- Currently, the PAF is a paper document that is retained by the dispensing pharmacist and the follow-up of the effectiveness of the PPP (element 4) is conducted by the pharmacist through an annual audit
- We propose to introduce a secure web hosted database to capture and track individual PAFs. Such a database would enable element 4 of the PPP to be implemented with less burden on pharmacists and enable initiation of anonymised individual patient dispenses to be recorded and subsequently tracked over time. Consequently once an individual anonymised patient has received two years (26 cycles) of treatment with lenalidomide it would be possible to automate the process by which Celgene would bear the cost of the anonymised patients continued treatment with lenalidomide
- This approach, incorporating the implementation of the price capping scheme within the PPP, would have neutral burden or arguably reduce the burden on the NHS as dispensing pharmacists would have the added value of a database of PAFs ready for audit. We anticipate this approach would be preferred by NHS pharmacists to a scheme that would require two separate systems with associated complexity and burden

Yours sincerely