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15 July 2011

Dear [redacted]

Re: Bone metastases from solid tumours - denosumab

The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 25,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

Please see the attached submission from the NCRI/RCP/RCR/ACP/JCCO with regard to the above appraisal. These comments are specific to lung cancer.

Final scope

- Remit: fine
- Background: Comments from draft remit have been incorporated and this now reads better. There is no specific mention of lung cancer, perhaps because survival time is generally short so medium term bisphosphonate therapy has not been commonplace. However the high population incidence of lung cancer and the high incidence of bone metastases in this disease means that many patients might potentially benefit from this therapy and the added advantages of denosumab over intravenous bisphosphonates in terms of ease of administration might increase usage in this group of patients.
- Comparators: appropriate
- Outcomes: comprehensive list of outcomes though likely to be limited data on health-related quality of life. Also not sure how to assess or compare patient satisfaction/ease of access to treatment and whether there is some way of addressing this. The difference between a hospital visit for intravenous bisphosphonate which might take up to a whole day for patients travelling from a distance, compared to a four weekly subcut injection which might be done in the community is a significant factor in terms of patient satisfaction.
- Economic analysis: agree with comments and with need for long time horizon to assess fully.
- Other considerations: Agree that types of skeletal events should be reported to distinguish the more clinically significant (fractures/cord compression) from the less significant. Also that prior skeletal events should be taken into consideration, as well as primary diagnosis and ongoing other forms of management.
- Although licensing does not stipulate position of this treatment option relative to bisphosphonate (trials compared one to the other), it is possible than when available in clinical practice both treatment may get used along the way in an individual patient.

- Is it possible that denosumab might be added to formulary as sequential option to bisphosphonate (being used when patient becomes bisphonate resistant or disease progressing) or even in some cases considered for concurrent use with bisphosphonate, given that it is separate mechanism of action?

Yours sincerely

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