Pemetrexed Disodium for the Treatment of Malignant Pleural Mesothelioma

NICE Health Technology Appraisal: Consultee Submission from the June Hancock Mesothelioma Research Fund (JHMRF).

Mesothelioma is an incurable disease and its consequences are almost always fatal. For many patients the symptom burden is high. The JHMRF upholds the right for all patients diagnosed with mesothelioma to be given a full range of treatment options and to have appropriate explanation and information, given to them in a supportive environment, to enable them to decide which option is best for them and their families. In view of the relatively short life expectancy and sometimes rapid decline of patients, these treatment options should also include access to new or innovative therapies where these are known to be safe.

Modern day technology means that people now have access to a vast amount of information through the Internet, much of it from overseas particularly from the United States. However it can be difficult without specialist knowledge or help to critically appraise the information on offer. Pemetrexed Disodium (Alimta) in combination with cisplatin, a standard platinum compound, was approved in February 2004 by the U.S. Food and Drug Administration (FDA) to treat pleural mesothelioma. The new treatment has since been heralded by many as a breakthrough for mesothelioma patients. However, this conviction seems to be based on the results of a single trial [1] that compared two chemotherapy regimens in a randomised design but which did not include active symptom control (ASC) alone. Without evidence from randomised trials which include an ASC arm such as that currently being undertaken by the British Thoracic Society, [2] it is not known whether treatment with chemotherapy is better at prolonging life and reducing symptom burden than ASC alone, the currently recommended treatment.

Notwithstanding the lack of strong evidence for its clinical effectiveness, Alimta has penetrated public awareness to such a degree that recruitment to the BTS trial has reduced and there has been intense lobbying by the ARD victim support groups and politicians in the North-West. This has resulted in local Trusts in the Greater Manchester, Cheshire and Merseyside areas being obliged to offer Alimta to patients before its effectiveness is fully proven. Moreover, a recent newspaper report from Norwich suggested that mesothelioma patients in North Norfolk should seriously consider moving in order to obtain the treatment in an area of the country where it is freely available. Another article was published in Newcastle along similar lines. Both were very emotive pieces, quoting angry and worried sufferers, and other interested parties. JHMRF are thus concerned that Alimta is being hailed, by the media, as a "wonder drug" and that it is raising false hopes. There is, therefore, a danger that vulnerable patients could be exploited by persuasive promotion in a competitive market place.

Cost Effectiveness of Treatment

JHMRF fully appreciates the problems faced by the NHS in deciding how to allocate finite resources. The ever increasing range of interventions available and the high cost of hospital and community healthcare have sent costs spiralling in recent years. Nonetheless, from the perspective of patients suffering from mesothelioma, and other terminal diseases, the question of cost is less significant. The priorities for patients in desperate situations are to find treatments that will help them either by prolonging their survival or improving their quality of life. As a research fund committed to supporting high quality research, JHMRF would endorse the recommendation of treatments that above all were of proven benefit to patients with mesothelioma. The issue of cost effectiveness is secondary in our view because of the devastating nature of the disease and the relatively small numbers of patients concerned, although incidence of mesothelioma will continue to rise until the end of the next decade [3].

JHMRF therefore submit that:

1. There is currently insufficient evidence to determine the role of Alimta in mesothelioma, either alone or in combination with other chemotherapy drugs.

2. Estimates of the clinical effectiveness of Alimta (and other interventions) need to pay special attention to quality of life which is more important to patients than small physiological changes.

3. More research is needed to develop methodologies for measuring response in mesothelial tumours and to determine whether response has any relationship with survival.

Declaration of interest:

The JHMRF is a joint funder of the BTS Phase III feasibility study of active symptom control with or without chemotherapy in malignant pleural mesothelioma.

References

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