ancer Network Pharmacists Group and BOPA stripped 070807 sh

From: O'Sullivan, Brendan []

Sent: 19 June 2007 17:28

To: Reetan Patel

Cc:

Subject: bortezomib consultation

Dear Reetan,

I am replying to the consultation of behalf of the Cancer Network Pharmacists Group and BOPA.

I have two main comments to make.

1. Administration of the VRS within the NHS -Simon Reeve's comments of the 25th April are noted in particular "We ... believe that it will not impose a disproportionate organisational burden on NHS organisations.."

I agree with his comments within the context of this scheme but warn that schemes such as this may be the thin end of the wedge. The VRS will have an impact as Janssen-Cilag will, presumably, want a level of detail to clarify the circumstances under which a claim is made. This will mean someone sitting down and going through the notes and the lab results for the patient. At a rough guess 2 or 3 hours work. Whether building in a cost for this would alter the economics of the scheme I could not say.

Most Pharmacy systems work on an average pricing system so any "refund" could not be attributable to an individual patient (or their commissioning PCT).

This is not a "show stopper" for bortezomib but we are aware of other similar proposals being considered by DoH ( such as sunitinib (Sutent)) which will also require considerable input to manage them.

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2. On a clinical / statistical note, I would expect that most clinicians would use bortezomib in combination with another agent, most likely dexamethasone. If one accepts that the response rate from a combination is better than bortezomib monotherapy, the cost / benefit equation of the VRS would be skewed such that Janssen-Cilag will be refunding fewer non-responders. This is quite likely to occur, dexamethasone as a single agent produces a good response rate. The problem with it is that the responses become less and less durable. I am aware that the trial data are not there to calculate an effect exactly but this should be borne in mind in any negotiations.

Regards,
Brendan O'Sullivan

Delivered via MessageLabs

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22<sup>nd</sup> June 2007

Reetan Patel
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Dear Reetan,

We write with regards to the current Appraisal Consultation Document entitled Bortezomib monotherapy for relapsed multiple myeloma and would like to express our concern over particular statements in the "Department of Health summary of the responder scheme" regarding the Velcade Response Scheme (VRS).

The British Oncology Pharmacists Association (BOPA) represents 500 individual members across the UK, the majority of whom are oncology pharmacists and the Cancer Network Pharmacists Forum (CNPF) represents Network Pharmacists from all NHS England Cancer Networks which have established a Lead Pharmacist post. In addition BOPA is also listed as one of the consultees for this appraisal.

As chairs of these groups we are surprised to hear "The company has consulted with a number of Senior..... pharmacists", that these individuals were "positive towards such a scheme" and that they felt this scheme could be "implemented with no incremental cost to the NHS". We have not had a chance to consult BOPA members, in particular Chief Pharmacists, but early communication from members and discussion at a recent meeting of the CNPF would suggest that this is not the case. Discussion at the last business meeting of the CNPF highlighted that the Network pharmacists are certainly not yet "positive towards such a scheme" and remain to be convinced that "this scheme could be implemented with no incremental cost to the NHS".

As senior pharmacists within their Networks the view held so far, and laid out previously by Brendan O'Sullivan on our behalf, is that the VRS will have an impact, which remains to be quantified, for already stretched pharmacy departments as Janssen-Cilag will, presumably, want a level of detail to clarify the circumstances under which a claim is made. We know, from experience, that the role of collating this data is likely to fall to oncology pharmacists in Acute or Foundation Trusts and is likely to be time and resource intensive.

We agree with Brendans' assertion that this is not necessarily a "show stopper" for bortezomib alone but we are aware of other similar proposals being considered by DoH (such as sunitinib (Sutent)) which will also require considerable input to manage them, and that this support will more than likely have to come from pharmacy departments. We have already had, informally, early indications from industry that if the VRS is accepted by NICE and the DoH other companies will not be slow in attempting to follow suit and if accepted the situation would quickly become unmanageable.

Finally we are also concerned that as part of the VRS scheme "the company will only provide replacement stock or credit for those patients at first relapse who fail to respond to Velcade" rather than "cash-back". We are certain that in the new financial flows of the NHS a PCT would want a refund for their own non-responding patients - if the Trust gets refunded replacement stock or credit that "refund" may not (or certainly won't easily) get back to the original PCT as the vials will almost certainly have to be used in whichever PCT's patients turn up next to avoid wastage. There may be ways around this but again this adds to the complexity on the ground and may further slow down the uptake of any NICE guidance by Trusts and PCT's.

We would like to finish by stating that we fully support any attempt to reduce the price of a therapy to allow it to be used in the relevant patient population but our concern is that the VRS as it stands may slow down uptake of any positive NICE guidance whilst the issues highlighted above are sorted out at a local level. We would also suggest that if the VRS is approved and followed by the proposal and approval of other similar systems for other therapies the situation would quickly become unworkable across the NHS.

We would be more than happy to work with the company to find solutions to some of the potential problems with the system as it is currently proposed,

Yours sincerely,

David Thomson, Chair, Cancer Network Pharmacists Forum.

And on behalf of

Geoff Saunders, Chair, British Oncology Pharmacy Association.

cc. Brendan O'Sullivan, Lead Pharmacist, West Anglia Cancer Network.
Professor Mike Richards, National Cancer Director, Department of Health.
Mr Simon Reeve, Head of Clinical and Cost Effectiveness, Medicines, Pharmacy and Industry Group, Department of Health.
Mr Tim Root, Specialist Pharmacist, Clinical Governance & Technical Services, East & South East England Specialist Pharmacy Services.

Mr Peter Sharott, Pharmaceutical Adviser (Secondary Care)
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England Specialist Pharmacy Services.
Mrs Jane Whittome, Associate Director – Hospital Services, National
Cancer Action Team.