Progress Update - Access to newly licensed medicines

Beatson West of Scotland Cancer Centre

From Robert J Jones, Professor of Clinical Cancer Research and honorary consultant in medical oncology.

I am grateful to the committee for seeking further views on this important matter. On this occasion, my colleagues and I have elected to send a consensus response focusing the specific areas raised in the Call for Written Views. Whilst I have attempted to derive a consensus, there will be some individual areas of disagreement. Please note that this response includes only the views of the Beatson consultants who treat people with solid tumours.

Scottish medicine consortium decision making

By and large, the sense of our group is that the 'threshold' for SMC acceptance of cancer drugs (most of which are considered for 'rare diseases or end of life medicines') has lowered since July 2013. This is probably the most important barometer of success for cancer patients. Another source of previous anger from patients was the fact that many cancer drugs were available within NHS England but not Scotland. These cross-border differences are fewer now than in early 2013 – indeed there are some drugs which are accepted for use in NHS Scotland which are not accessible in NHS England (including on the Cancer Drugs Fund).

Whilst the SMC decision making process is more transparent (particularly with the opening of the meetings to public observers), we have noted concerns that some SMC decisions do not seem to fully reflect the flavour of the discussions at the meetings, with minority (negative) clinical views seemingly having undue influence on the final decision on some occasions. In addition, our group has not noticed the process becoming any quicker – indeed several appraisals have been significantly delayed due to a backlog in the SMC system caused by a wave of company resubmissions in light of the changed criteria.

PACE groups

Our group is warmly supportive of this new part of the SMC process. Many have taken part in PACE groups. All who have were pleased to have been involved and the SMC should be complemented in the organizational aspects of this new process. However, whilst there is a general feeling that PACE groups do allow clinicians and patient groups to voice issues that may not be obvious from the written evidence, there is significant doubt about the extent to which the views of the PACE group actually affect the final decision by the SMC. Whilst there is a general feeling that PACE groups are a good thing, and should remain, we would like to see a stronger mandate on the SMC to demonstrate their considerations of the opinion of the PACE group in their final decision – particularly where they choose not to accept it.
Access to medicines in the absence of SMC acceptance

Individual patient treatment requests (IPTRs)

Opinions are divided among our group regarding the extent to which the ‘threshold for acceptance’ has changed since early July 2013. Some clinicians note a clear improvement in access by this route (where previously it was a ‘no’ unless there was compelling reason to say ‘yes’, now it is ‘yes’ unless there is compelling reason to say ‘no’), but others report no change. This difference in experience probably reflects differences in access to small numbers of key drugs in specific diseases and the ‘superspecialisation’ of oncologists within our group.

Some of our group question the validity of the process by which IPTR decisions are made, although the transparent involvement of disease-specialist oncologists is welcomed.

Whilst there was a previous clear instruction from the Scottish Government to redefine the criteria by which an IPTR should be assessed, most clinicians at the Beatson feel that the revised criteria remain poorly defined. It is, therefore, difficult to know which individual patient factors are likely to result in a successful IPTR.

There is also some evidence that the IPTR decision making criteria are now quite different between the regions of Scotland and that these differences have resulted in some patients being able to access drugs in one part of Scotland where access would have been denied had they lived in another. This has resulted in some low-level ‘postcode prescribing’ within Scotland, a practice which none of us support. We believe that it is now timely to consider mechanisms by which these inter-regional variations in access could be reduced. The development of national PACS may be one such mechanism.

It is notable that individual applications are now very difficult to make in NHS England, and our group consider it vital that a process remain in place by which individual patients’ needs can be addressed.

Peer Approved Clinical Systems (PACS)

This process, understood to be one by which clinicians might identify specific subgroups of patients to whom access could be granted despite the absence of SMC acceptance, was part of the original recommendation. None of our group has come across a PACS in any shape or form. There is some appetite for this among the group, although it is not entirely clear how this system would work. We would welcome an update on the plans to introduce PACS and would encourage consideration to be given to making these systems work on a national basis in order to reduce inter-regional inequalities in access.
Effectiveness of monitoring of the NHS boards Area drug and Therapeutic Committees

The group had few views on this matter. In general, the harmonization of advice given to the health boards within the West of Scotland Managed Clinical Network results in relatively rapid translation of SMC acceptance into routine practice, even if the ‘paperwork’ sometimes lags behind actual patient access to medicines. The group do not believe patients have been delayed access to SMC accepted medicines due to delays in the processes of formulary adoption within the West of Scotland Network of Health Boards.

The New Medicines Fund and access to new medicines for those with rare conditions

No one in the group was aware of any instance in which this fund had been used to access a medicine for a patient with a solid tumour. This is despite many such cancers being categorized as ‘rare conditions’. The group would be interested to learn more about which medicines have been financed by this fund and how much of the fund has been used to help gain access to medicines for patients with solid tumours.

Summary

Overall, the clinical and medical oncologists at the Beatson West of Scotland Cancer Centre have observed some improvement in access to medicines for rare diseases and for patients at the end of life since July 2013. Whilst the changes in SMC processes are welcomed, there is concern that clinician and patient opinions are not being appropriately heeded by the SMC in their final decisions. In particular, the views of PACE groups do not always seem to have obvious influence on these decisions, and the justifications for finding against PACE group advice are rarely given. IPTRs continue to be an important component of access to medicines, although greater clarity of the criteria by which they are judged would be welcomed by clinicians. The PAC system (or something similar) needs to be developed and might help to reduce the current variation in IPTR approvals across the country.

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