



Pierre Fabre

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████████████████████
Chair, Appeal Committee
National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London WC1V 6NA

Dear ██████████

Re: Initial Scrutiny Letter – Vinflunine for the treatment of advanced or metastatic transitional cell carcinoma of the urothelial tract.

Thank you for taking the time to review the second application to Appeal on this latest version of the FAD for the above Single Technology Appraisal.

The arrival of Vinflunine and this Single Technology Appraisal process has helped to highlight the unacceptable trends in bladder cancer survival. The next logical step is to review the entire patient pathway and make sure the management is consistent with the evidence and joined-up across the specialties involved. NICE have already published the Final Scope for a Clinical Guideline and included a wider look at chemotherapy at all stages of management.

It is clear that the original Scope for this STA has already been overtaken by changing practice in bladder cancer. We feel this STA process is not flexible enough to cope with the change and by pushing through this FAD, the institute has acted unfairly.

We are concerned that this injustice will be carried forward to the Clinical Guideline process and seek an opportunity to discuss our concerns with those involved.



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1.1 In formulating Guidance, the Institute has been unfair by not responding to the findings of the previous Appeal Hearing and has continued to apply inconsistent data quality standards.

The Committee has accepted the clinical opinion that 2nd line chemotherapy is routinely used in clinical practice and there is a clinical need. In rejecting Vinflunine, the inherent assumption is that this clinical need will continue to be met with the existing, alternative technologies. The evidence base to support other drugs is too weak to pull patients through and get them in front of the oncologists in a timely way.

A median survival of 4.3 months in a control group that is *younger, fitter and had better renal function than the general population of UK patients* is a poor reflection on current UK practice.

Medical practice changes when new treatment tools become available. Access to new treatment has been a remarkably effective way to stimulate earlier diagnosis and referral in other tumour types – renal, lung, colo-rectal and bladder cancer is in desperate need of new treatments. All that we want is the opportunity to place the data sets for other drugs alongside Vinflunine so that we can understand the quality and magnitude of the respective evidence base to properly inform our decision making.

We submitted this Appeal because we feel that this guidance has detrimental consequences for the overall management of bladder cancer and research in the UK.

1.2 The Institute has been unfair in the economic evaluation of vinflunine for patients with urothelial cancer that relapse after prior chemotherapy.

The clinical opinion is that chemotherapy at this stage is increasingly being used and the clinical element of the Scope has been overtaken by events. We seek only to assess the economic impact of Vinflunine against existing treatment and if this is no longer BSC, we would like the opportunity to compare against the other drugs being used.



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I do not think that this is unreasonable.

3.1 The Institute has exceeded its powers by reviewing decisions made by the EMEA and MHRA and drawing different conclusions despite not having the data available or the qualifications to so do.

You make the point that the institute is interested in the whole NHS population and has a concern that a licence granted for “fit” patients and projected down onto “less fit” patients will reduce the net benefit of this new technology. The institute has tended to discount the gains demonstrated in this phase III study.

However, this is not the situation we have here. Patients with a 12 week expected survival are not “fit” but represent the last possible opportunity to deploy radical treatment and test efficacy. The Competent Authority demanded a 50% improvement in median survival in patients with an overwhelming burden of disease. When this was delivered – and it should be emphasised that this is a remarkable achievement, they confidently licence it for use in the gap between this “Worst Case” patient UP to the point when existing treatment runs out. The outcomes with Vinflunine should not fall below that seen in the trial but will improve if we diagnose and refer patients to the relevant oncologists earlier. Rather than discounting the impact of Vinflunine in routine practice, we feel that the institute should supplement the value.

We are frustrated that the Committee did not recognised this “bottom-up” development strategy adopted by the Competent Authority and have reached inappropriate conclusions.

This is the point we are trying to make in item 3.1.

Summary

This STA has drawn attention to the management of bladder cancer but has been overtaken by increased awareness of the magnitude of the problem in bladder cancer.

There is a desperate need for a wider, evidence based approach to the management of



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this disease. The most appropriate mechanism to achieve this is a Clinical Guideline and it is very important that NICE have now published the Final Scope for this programme.

Unfortunately this STA process has been overtaken by events and the original Scope is no longer fit for purpose but the process is not flexible enough to allow consensus on key topics. The result is that we feel that we have been treated unfairly and our concern is that this bias will carry forward into the Clinical Guideline process.

Our only mechanism to highlight these concerns is an Appeal and we would still welcome an opportunity to discuss a more constructive way forwards.

I would finally like to express my sincere respect for Peter Clark and the Appraisal team. Peter did more than most to address similar issues in the management of lung cancer and has significant experience in solving similarly tough problems. As we noted in our Appeal, there is nothing wrong with our skill sets, we just need new tools.

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Managing Director