01/02/12
The British Association Skin Cancer Specialist Nurses (BASCSN's) feedback re-

Vemurafenib for the treatment of unrespectable locally advanced or metastatic BRAFV600 mutation-positive malignant melanoma.

Format of feedback:
The BASCSN's overall views following reviewing written evidence.
Individual evidence / experience in the care of people affected by this stage of disease.
Individual evidence / experience in the care of people who have received Vemurafenib as part of their treatment.

NICE have cited that:

"At presentation, 10% of cutaneous melanomas will have metastasised. (stage III, of which stage IIIc disease includes tumours of varying size with lymph node involvement [large enough to be visible on imaging tests or clinically palpable], but no metastases) or to other parts of the body (stage IV).

The incidence of malignant melanoma is increasing in England and Wales with rates doubling approximately every 10-20 years. There were 10297 new diagnoses of malignant melanoma and 1847 deaths registered in England and Wales in 2008. In the UK, melanoma is diagnosed at a mean age of around 50 years but approximately 20% of cases occur in young adults aged between 15 and 39 years old. Five-year survival rates are approximately 20-30% for stage IIIc disease and approximately 7-20% for stage IV disease.

Early recognition of malignant melanoma and accurate diagnosis presents the best opportunity for cure by surgical resection of the tumour. A very small minority of people with advanced disease can still have their tumour removed. People with unresectable stage III or IV (metastatic) disease are usually managed by a specialist oncologist and first-line standard care normally involves the administration of dacarbazine. Radiotherapy, immunotherapy and combination chemotherapy have also been studied in randomised clinical trials. The treatment options for second or subsequent line therapy are limited".

However, the BASCSN's feel that Vemurafenib is a step forward in the in the specific treatment of patients with unrespectable locally advanced or metastatic BRAFV600 mutation-positive malignant melanoma.

Moreover, present treatments options are not specific to BRAFV600 mutation-positive malignant melanoma.

CNS experience *experience in the care of people who have received Vemurafenib as part of their treatment:*

"The Cancer Centre at Singleton has been one of the centres that have been providing Vemurafenib in the UK and the only centre in Wales. It has been involved in the BRIM trials and is now providing the drug for those with a +ve BRAF mutation, on an 'open access' basis. Identification of those people with a mutation is failry rapid despite the tissue blocks having to be sent to Germany. The turnaround time for a report has been 7-10 days.
I can only say that while I feel that the number of people with the necessary mutation is lower than I would wish, the actual response has been (anecdotally) about 8 in 10 where they have the the mutation and receive the drug.
The responses have been quite remarkable, with a tumour load decrease by astonishing amounts. Quality of life is definitely improved for those who have received it and respond. I have seen some very sick people come fighting back for long periods of time. For our oncologist responsible, it is now regarded as the first line treatment for latter stage, unresectable metastatic malignant melanoma. I believe this is the same stance across the country. No-one knows the benefits over time and what if any survival advantage there is at this stage, (to my knowledge).
I feel the side effects on balance of what the drug does to the melanoma pale into insignificance I would say. It appears to be fairly well tolerated. Any side effects are well monitored by the research teams and usually easily dealt with ease. There is a risk of development of other skin cancers; however, I am reliably informed that they now know the mechanism of this".

"I have experience of caring for patients who have taken vemurafenib. I have found it to be a drug that is well tolerated by the majority of individuals, with the main side effects being manageable. This includes photosensitivity, managed by standard sun safety measures, arthralgia, managed by analgesia and dose modification and the development of skin lesions, managed by cryotherapy and surgery. Most patients are keen to continue treatment for as long as possible as the side effects do not impact greatly on their quality of life. The fact that it is an oral treatment is also beneficial to patients as hospital visits are limited to review appointments.
It represents a significant improvement in standard treatment options for patients with metastatic disease, (DTIC), with an improved response rate which can be measurable within a matter of days. It can make metastatic disease regress to an almost immeasurable level which allows patients to continue with their normal daily activities. Given that this population of patients can be young, this includes allowing patients to continue to work.
It is hard to define exactly what this drug has meant to patients, but the wife of one gentleman with teenage children told me it gave their family a summer together".

"Fully agree with that experience"

"Vemurafenib benefits can be seen relatively quickly when comparing benefits versus side effects. Arthralgia often being the greatest problem but administration of depot steroid injects can be useful".

Conclusion:

The BASCSN's *feels that* Vemurafenib represents a step change in treatment for unrespectable locally advanced or metastatic BRAFV600 mutation-positive malignant melanoma patients***.***

Being this is the first new treatment for this specific mutation that may offer significant palliation and possible survival gain for people with advance, form of unresectable disease that has progressed after first-line therapy.

Considering what NICE has already pointed out that, Malignant Melanoma has a disproportionate number of young adults & Young adults with young families, for an adult cancer. The impact of survival would be significant regarding return to:

- Normal life.
- Other activities.
- Work.

Therefore, we feel there is evidence to say that Vemurafenib will be the first specific treatment option to address & some way improve:

- Quality of life for patients and their families at this stage of decease.
- Financial impact on patients and their families at this stage of decease.
- Financial impact on society at this stage of decease.

In line with the:

DOH, Policy (2011). Improving Outcomes: A Strategy for Cancer. Gateway reference: 15108.

NICE (2004). Guidance on cancer services, Improving Supportive and Palliative Care for Adults with Cancer. London: National Institute of Clinical Excellence.