

NHS England confirms change to stopping/retreatment rules for anti PD-1 melanoma treatments: further information for clinicians and nurses

NHSE has agreed to revise its ruling covering the stopping and re-starting of treatment for patients with melanoma who are receiving pembrolizumab and nivolumab. This means clinicians will be able to halt treatment in responding patients after two years, with the assurance that funding for the drugs will be available if the disease progresses and treatment needs to be resumed.

As you will be aware, under the previous ruling – that once stopped, no further funding was available should treatment need to be re-started – clinicians and patients tended to adopt the understandably cautious approach of continuing treatment beyond the two-year point.

The decision is in response to an initiative by Melanoma Focus to persuade the NHS to alter its stance following the evidence from recent RCTs (notably Keynote 006, building on the findings of previous studies) showing that for many patients there is no additional gain in continuing the treatment for longer once a response has been confirmed. The advantages are obvious: significant cost savings and avoiding treatment regimes that can cause severe side-effects.

We expect NHSE to finalise the necessary procedures and documentation shortly. It has been agreed that there will be no limit to the duration of the re-started treatment and there are several conditions:

- All new first line anti PD-1 treatments will require a Bluteq form.
- The form will also need to be completed at the time of stopping treatment if future retreatment is a consideration. Data to be captured will include the duration of treatment and depth of response.
- There should be no other systemic therapy between stopping and re-starting anti PD-1 treatment.
- Special funding arrangements will be made in the case of trials looking at shorter treatment durations: for example DANTE, which randomises patients who are progression-free at 12 months to continue or stop treatment.

Professor Paul Lorigan, chairman of Melanoma Focus, comments: ‘NHS England has responded to the evidence presented in a very positive way, recognising the advantages for patients. Clinicians and patients are completely supportive and the collection of extra data will allow a better understanding of the benefits of retreatment.

‘This is a win-win situation. Patients won’t need to be treated for longer than is necessary, while they can be confident that the drugs will still be available if needed; and there will be substantial savings for the NHS by reducing unnecessary drug treatments as well as the costs of dealing with the side-effects’.

If you have any queries about this announcement please email rodwell@melanomafocus.com