



Resource impact statement

Resource impact

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NICE has recommended alpelisib with fulvestrant as an option for treating hormone receptor-positive, HER2-negative, PIK3CA-mutated, locally advanced or metastatic breast cancer in adults, only if:

- their cancer has progressed after a CDK4/6 inhibitor plus an aromatase inhibitor and
- the company provides alpelisib according to the commercial arrangement (see section 2 of guidance).

This recommendation is not intended to affect treatment with alpelisib plus fulvestrant that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

We expect the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £9,000 per 100,000 population, based on a population for England of 56.3m people).

This is because the technology is a further treatment option and the overall cost of treatment will be similar. The genetic testing is part of the National Genomic Test Directory for cancer and is funded by NHS England.

However the summary of product characteristics states that:

- all people having treatment with alpelisib should have their fasting plasma blood glucose and HbA1c monitored
- fasting glucose should be monitored at weeks 1,2,4,6 and 8 after treatment starts and then monthly for the remainder of the treatment
- HbA1c should be monitored after 4 weeks of treatment and every 4 weeks thereafter
- people with existing diabetes, pre-diabetes, BMI of 35 or higher or age 75 or older should have more frequent monitoring of fasting glucose.

This means that for the population who do not meet the requirements for increased frequency testing, the average number of fasting plasma glucose tests required for a course of treatment with alpelisib with fulvestrant is 14 and the average number of HbA1c tests would be 4. Fasting plasma glucose monitoring in people who meet the criteria for increased monitoring would be at least 28 tests, higher if required.

Feedback from experts has indicated that in some areas oncology teams will not have systems in place to set-up glucose monitoring for people having treatment with alpelisib with fulvestrant and there could be challenges in creating these links to diabetes services or primary care for HbA1c monitoring to be carried out.

This technology is commissioned by NHS England. Providers are NHS hospital trusts.

The payment mechanism for the technology is determined by the responsible commissioner and depends on the technology being classified as high cost.