

Leukemia and head and neck cancer drugs not approved for NHS England

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People with head and neck cancer or leukemia in England are set to miss out on access to two new cancer drugs, after the National Institute for Health and Care Excellence (NICE) said it couldn't recommend

pembrolizumab (Keytruda) or gilteritinib (Xospata) for NHS use.

Both decisions will be reviewed later this year, after the drugs' manufacturers have had the opportunity to provide additional data on the drug's benefits or offer a new price.

For pembrolizumab, NICE have requested extra information from the manufacturer to help them interpret clinical trial data, before making a follow-up decision.

Rose Gray, policy manager at Cancer Research UK, said the initial decisions would be "disappointing" for people affected by these [cancer](#) types.

Clinical trial "uncertainties" for head and neck cancer treatment

Pembrolizumab is an immunotherapy that aims to boost the immune system's ability to recognize and kill cancer cells. It works by blocking a molecule often found on [cancer cells](#)—PD-L1—from talking to immune cells.

Currently, treatment for head and neck cancer in the NHS in England will depend on where the cancer started growing:

- If the cancer started inside the mouth, it's typically treated with a combination of a targeted cancer drug (cetuximab) and chemotherapy drugs.
- If the cancer started outside the mouth, treatment usually includes a combination of chemotherapy drugs

But pembrolizumab could provide a new treatment option for adults whose cancer has spread to other parts of the body and have not received

any treatment, or whose cancer has returned and cannot be removed surgically. It would only be an option for patients whose tumors test positive for PD-L1.

How do you know if a tumor is PD-L1 positive?

For head and neck cancer, researchers can calculate the percentage of PD-L1 positive cells (including immune cells) within the tumor, which is reported as a combined positive score (CPS). A tumor that has a CPS of more than one is considered to be PD-L1 positive.

Results from a clinical trial showed that patients lived longer if they were treated with pembrolizumab, either on its own or in combination with chemotherapy, compared with those taking cetuximab and chemotherapy. Patients taking pembrolizumab survived for around 13 months on average.

"Clinicians told NICE [pembrolizumab](#) could cause less [severe side effects](#) for many head and [neck cancer](#) patients than current treatments, and clinical trial evidence suggests it could help some patients live longer," says Gray.

But NICE flagged some uncertainties with the clinical trial data.

Pembrolizumab was only compared to a combination of cetuximab and chemotherapy, regardless of where the tumor started growing. But this doesn't reflect how patients are currently treated in the NHS.

This has made it difficult to determine if the drug would be [cost effective](#) on the NHS, so NICE has requested more evidence on the drug's benefits before the committee make a recommendation on its value for money.

leukemia drug not recommended

A second drug also received an initial 'no' from NICE last week. Gilteritinib is a targeted cancer drug, which works to block chemical signals that would otherwise help a cancer grow.

It would have been a new treatment option for adults with acute myeloid leukemia (AML), if their cancer tests positive for a particular DNA error in the FLT3 gene, where the disease has returned or is not responding to treatment. This DNA error is linked to aggressive leukemia that's more likely to return after treatment.

Currently, the majority of adults with this type of leukemia are treated with chemotherapy once all other options have been exhausted.

"Gilteritinib would have provided a new treatment option to people with few existing alternatives," adds Gray.

In a clinical trial involving 371 patients, gilteritinib was found to increase survival. People taking gilteritinib lived for 9.3 months on average, compared with 5.6 months for those taking chemotherapy.

And patients told NICE that gilteritinib could improve people's quality of life, as the [drug](#) can be taken at home.

But uncertainties over the long-term benefits of the treatment—in particular whether it helps patients who are able to receive a stem cell transplant after initial treatment to live longer—meant NICE couldn't be confident it would offer the NHS value for money.

NICE will review both decisions later this year. NICE decisions are usually adopted in Wales and Northern Ireland as well as England, so the decision is likely to affect patients in all three nations. Scotland has a

separate process for reviewing drugs.

More information: NICE (2020) Pembrolizumab for untreated metastatic or unresectable recurrent squamous cell head and neck cancer [www.nice.org.uk/guidance/index ... id-ta10181/documents](http://www.nice.org.uk/guidance/index...id-ta10181/documents)

NICE (2020) Gilteritinib for treating relapsed or refractory acute myeloid leukaemia [www.nice.org.uk/guidance/index ... id-ta10460/documents](http://www.nice.org.uk/guidance/index...id-ta10460/documents)

Provided by Cancer Research UK

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