What does the new personalized cancer medicine approved in England mean for patients?

April 22 2020, by Duncan Sim

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Today, a new personalized cancer treatment was approved for NHS use in England.

But this was no ordinary drug approval. Larotrectinib (Vitrakvi) is a highly innovative new treatment that, unlike most cancer drugs, is designed to target specific changes in cancer cells' DNA rather than where the cancer is growing in the body.

This means patients with various types of cancer may be able to benefit.

It's the first drug licensed in Europe that works in this way. And it's been called "revolutionary" by the head of NHS England, Simon Stevens.

But drugs like larotrectinib also pose unique and complex challenges for the NHS, which have been exacerbated by the COVID-19 pandemic.

The latest decision

Larotrectinib was originally rejected for funding on the NHS in England back in January. Since then, the manufacturer and NHS England have negotiated a new price for the drug, which has made it possible for it to go into the Cancer Drugs Fund (CDF).

Because the drug is so innovative, it's been more challenging than usual for NICE (the body that recommends whether the NHS should pay for new medicines in England) to answer key questions about how the treatment should be used and how effective it is.

This uncertainty is why the drug was initially rejected. It's taken a lot of work from all sides—the NHS, NICE and the drug's manufacturer—to overcome these challenges.

But now the drug's been approved for the Cancer Drugs Fund, the NHS will pay for it for a time-limited period, while more data is collected—including from NHS patients—to help resolve these questions. And if this data shows the drug is cost effective for the NHS,

it will become available on a permanent basis.

Meindert Boysen, deputy chief executive and director of the Centre for Health Technology Evaluation at NICE, said: "These cutting-edge therapies can be used to treat tumors with often rare genetic mutations regardless of where in the body the tumor originated.

"The clinical evidence is usually based on extremely small sample sizes, requiring novel approaches to testing them in clinical trials and translation into models of assessment for potential value in NHS practice."

Drugs in the CDF are also usually made available to patients in Wales and Northern Ireland, through bespoke funding routes in those nations. Scotland has a separate system for appraising new drugs and larotrectinib hasn't been considered there yet.

Why it matters

Larotrectinib will be used to treat people whose tumors test positive for a particular genetic change, called an NTRK fusion, and who have run out of other treatment options.

This is hugely significant for these patients, but according to Professor Peter Johnson, national clinical director for cancer at NHS England, it's also a great example of how the NHS can "bring to bear" its recent investment in genomic (genetic) testing in England to improve cancer treatment.

Johnson says work in this area has been building at a national level, ever since Cancer Research UK started our Stratified Medicine programme in 2010.

And while the NHS has offered genomic tests to help guide decisions on patients' treatment for many years, NHS England has been working to coordinate and expand genomic testing services in seven hubs in England. This aims to make access to these tests more consistent across the country and help to speed up the introduction of new targeted drugs like larotrectinib in the future.

According to Johnson, "what's come together are the development of the genomic laboratory hubs across England, and the first targeted drugs coming through from research that are effective across multiple tumor types. This is an exciting convergence of these two strands of work."

Testing challenges in rollout

But despite this convergence, there are still challenges to overcome before larotrectinib will be available to patients. And as we've previously explained, chief among these is making sure the NHS can test patients appropriately to see who might benefit from the drug.

The NHS intends to test up to 100,000 patients a year for this genetic change eventually. But it's not in a position to make the test that widely available yet.

To balance this, it's going to stagger the roll out of larotrectinib, beginning with people with rare cancers where the genetic change is most common, and children and young people.

According to NICE, between 600–700 people in England have solid tumors with NTRK gene fusions. And a proportion of these people with no satisfactory treatment options will be eligible for treatment within the first year that it's available on the CDF.

The impact of coronavirus

Rolling out a treatment like larotrectinib would be challenging at the best of times, but the COVID-19 pandemic makes things even more complicated and means it will take longer to scale up testing to the wider population.

"Because of the crisis equipment and people have been diverted from Genomic Laboratory Hubs to support testing for coronavirus," says Johnson.

"As soon as we can, we will introduce the capacity to continue rolling this out in a phased way to a much wider population of people for whom conventional treatment has not been successful."

And while the NHS is under a huge amount of strain with COVID-19, Johnson believes it's vital that the NHS continues to assess and introduce new treatments.

"We will get through the coronavirus crisis and are planning to put cancer services back on a firm footing in the future. Having new therapies coming through and the diagnostics to find out who could benefit is as important as it has ever been."

Provided by Cancer Research UK

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