Landmark cancer tumor drug Keytruda hampered by glitches

A landmark cancer drug approved last year seemed to herald a long-anticipated change in the treatment of some tumours: with medicines selected on the basis of molecular markers, rather than the tissue in which the cancer first took root. But clinicians and researchers are struggling to put that theory into practice. Although the drug itself works well in a variety of tumour types, some of the tests used to identify the molecular markers, it turns out, do not.

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The drug in question, pembrolizumab (Keytruda), works by firing up the body's immune responses against tumours.

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[T]he three kinds of tests commonly used to look for the DNA damage that arises from that defect can produce conflicting results, says Heather Hampel, a genetic counsellor at Ohio State University in Columbus. One relies on PCR, a process that amplifies specific regions of the genome; a second looks for certain proteins; and a third relies on DNA sequencing. "Which is the best? Is any positive on any test sufficient?" Hampel says. "Does that mean you should try them all? No one wants to miss a patient who might benefit from pembrolizumab."
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Eventually, some of these issues will be ironed out, says [oncologist] Michael Overman.

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[T]he FDA was wise to move forward with the approval rather than wait for more evidence to sort out the issues with the molecular marker tests, he says.
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