



DIACEUTICS GROUP

Xalkori/ALK

The co-development of Xalkori and the ALK test led to the inclusion of an FDA-approved ALK test in the indications and usage and, ultimately, a successful launch and fast adoption.

Case Summary

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This case will help you understand:

- That co-development of the anaplastic lymphoma kinase (ALK) test was pivotal for a successful launch of Xalkori by Pfizer.
- How the cost of a test can be a major issue for payers and patients.
- How test technology can influence a test's adoption and prescribing rates.
- How, during the six months in the market since receiving FDA approval, the ALK mutation test enjoyed a fast adoption.

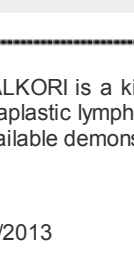
Key messages:

- The co-development of Xalkori and the ALK test led to the inclusion of an FDA-approved ALK test in the indications and usage.
- The cost of the test should always be considered as this may lead to issues for payers and patients.
- Any confusion and/or debates around quality of testing may have an impact on adoption and prescription rates.
- Post launch, oncologists are becoming more comfortable with personalizing treatment, but true adoption will only be seen with time.

Key actions:

- Understand diagnostic test implications in payer discussions and for patients.
- Know the key health economic experts in your field and work with them.
- Investigate where diagnostics can offer health care savings and communicate that effectively with payers.

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Xalkori is a Kinase Inhibitor Indicated for the Treatment of Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)

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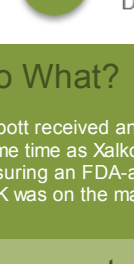
INDICATIONS AND USAGE

XALKORI is a kinase inhibitor indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved test. This indication is based on response rate. There are no data available demonstrating improvement in patient-reported outcomes or survival with XALKORI.

02/2013

Source: <http://www.pfizer.com>

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Co-Developed Companion Diagnostic Test was Available at the Xalkori Launch

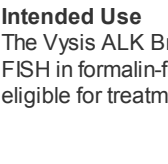
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So What?

Abbott received an FDA PMA at the same time as Xalkori was approved, ensuring an FDA-approved test for ALK was on the market.

Commentary

Aligned with the FDA's latest guidance on targeted therapies and companion diagnostics, Pfizer worked closely with the FDA and partnered with Abbott Molecular's business in clinical studies. This was to ensure the simultaneous review and approval of Xalkori along with a diagnostic test (Abbott Molecular's Vysis ALK Break Apart FISH Probe Kit) to identify the presence of the ALK fusion gene. The simultaneous approval of Xalkori in parallel with Abbott Molecular's ALK FISH test marks the first time a Pfizer oncology drug, or any lung cancer medication, was developed and approved in parallel with a diagnostic test.



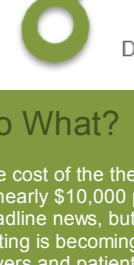
Vysis ALK Break Apart FISH Probe Kit

Intended Use

The Vysis ALK Break Apart FISH Probe Kit is a qualitative test to detect rearrangements involving the ALK gene via FISH in formalin-fixed paraffin-embedded (FFPE) NSCLC tissue specimens to aid in identifying those patients eligible for treatment with Xalkori.

Source: <http://www.abbottmolecular.com>

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\$1,500 ALK Test Adds to the High Price Already Charged for Xalkori 4/10

The cost of the therapy, announced at nearly \$10,000 per month was headline news, but the cost of testing is becoming a major issue for payers and patients.

Commentary

Because ALK mutation is present in only 5 per cent of NSCLC patients, about 20 patients have to be tested to identify one ALK-positive patient eligible for Xalkori at a cost of \$1,500 per result, the price to identify one patient is \$30,000. Even if the price to payers per test is lower than \$1,500, the overall cost to identify such a small population is substantial. As Pfizer's experience with Selzentry confirms, the costs of the test and drug can be viewed together.



Gene Test For Pfizer Cancer Drug To Cost \$1,500 Per Patient

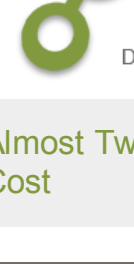
An ALK test, including the pathology service, will be approximately \$1,500 (a one time cost). The price we charge for the test kit itself is less than \$250, which is similar to other FISH tests.

- Abbott Laboratories spokesman



Source: <http://www.forbes.com>

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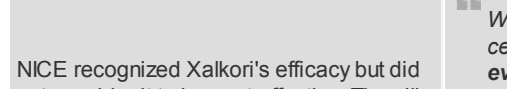
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Almost Two Years after Approval, Xalkori is Still Not Reimbursed in the UK due to High Cost

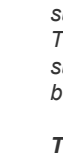
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NICE consults on new draft recommendations for lung cancer drug

NICE recognized Xalkori's efficacy but did not consider it to be cost-effective. The pill costs £4,689 (about \$7,079) for a 30-day supply, with a course of treatment costing up to £51,579 per patient (about \$77,000).

However, in its announcement of draft guidance, the NICE seemed ready to change its mind if the price was right.



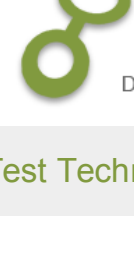
"We have already recommended a number of treatments for the various stages of non-small-cell lung cancer. However, although the independent committee that considered the evidence found crizotinib to be clinically effective treatment for ALK-positive non-small-cell lung cancer, even if the supplementary advice to the committee for life-extending treatments had applied, crizotinib could not be considered a cost-effective use of NHS funds."

"Appraisal committees will normally recommend treatments that cost around £20,000 to £30,000 per QALY or less. If a drug meets the criteria to be considered under NICE's supplementary advice for end of life treatments, then a higher cost per QALY may be accepted. There is no set threshold cost per QALY of drugs that meet the end of life criteria, but since the supplementary advice was introduced, the highest cost per QALY of a recommended drug has been around £50,000."

The Committee concluded that the most plausible cost per QALY would lie somewhere between £63,800 and £181,100 for crizotinib compared with docetaxel, and between £51,700 and £80,500 for crizotinib compared with best supportive care."

Source: <http://www.nice.org.uk/newsroom/pressreleases/CrizotinibACD.jsp>

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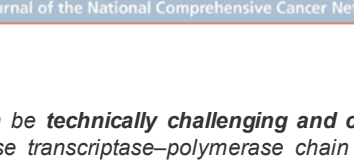
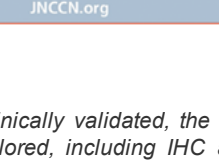
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Test Technology Quality is Questioned

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"Although ALK FISH is clinically validated, the assay can be technically challenging and costly. Therefore, other diagnostic modalities are being explored, including IHC and reverse transcriptase-polymerase chain reaction. This article provides an overview of the diagnostic assays available for detecting ALK rearrangement. Each assay, including ALK FISH, has its strengths and weaknesses."

Source: Shaw AT et al '11.

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Despite Cost and Test Technology Issues, ALK Mutation Testing for NSCLC is on the Rise

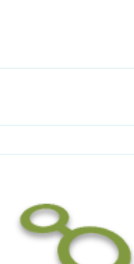
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"Oncologists are becoming increasingly comfortable personalizing treatment strategies."

Six months after the launch of Pfizer's NSCLC drug Xalkori with a companion ALK mutation test to gauge best responders, BioTrends Research Group surveyed 80 oncologists and found that 82% were offering genetic testing in this setting."

Source: <http://www.decisionresourcesgroup.com>

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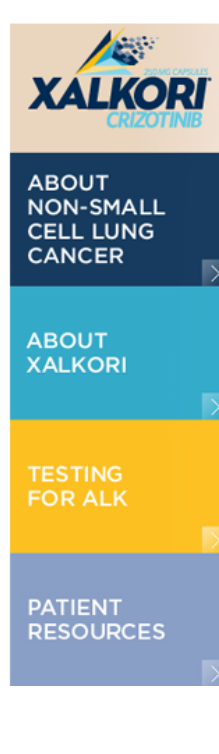
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The Xalkori Launch sees Pfizer Firmly Embrace a Personalized Medicine Approach

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Source: <http://www.xalkori.com/>

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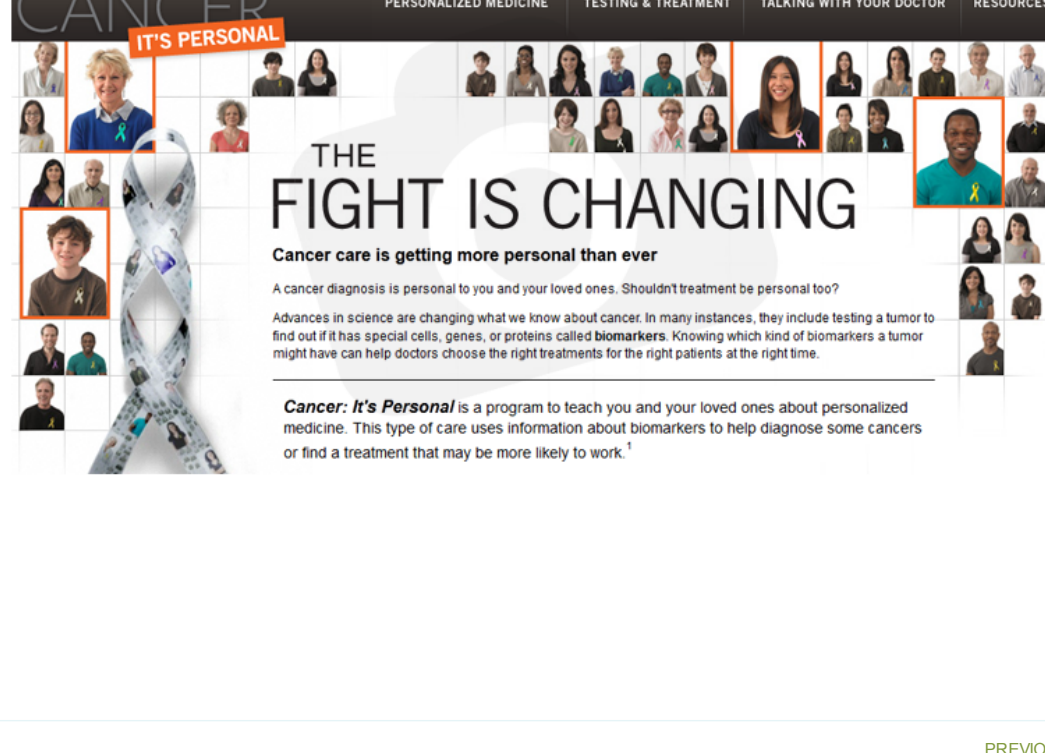
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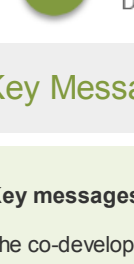
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For Xalkori, Pfizer Launched an Educational Website for Patients on Personalized Cancer Treatment

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Key Messages

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