Anaplastic lymphoma kinase (ALK) gene rearrangement testing in non-small cell lung cancer (NSCLC)

Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors’ conclusions
Lung cancer is the leading cause of cancer-related death in the United States, constituting nearly 15% of all new cancer cases and 28% of all cancer-related deaths in American men and women in 2010. The 1-year survival rate for all lung cancer is approximately 43%; despite treatment, the 5-year survival rate drops to 16%. The two main categories of lung cancer are small cell (approximately 14% of cases) and non-small cell (approximately 85% of cases) lung cancer (NSCLC). Lung cancer treatment varies according to disease subtype and stage, and may include surgical resection, radiation, and/or chemotherapy. Recently, differences in tumor tissue type and genetics have been identified and used to differentiate treatment. An example of targeted treatment based on genetic differences is the use of specialized drugs such as erlotinib and gefitinib that act against tumors with variants in the epidermal growth factor receptor (EGFR) gene. In 2007, genetic rearrangements affecting the anaplastic lymphoma receptor tyrosine kinase (ALK) gene were identified in some NSCLC patients. Animal and cell studies suggest that these ALK rearrangements drive the cancer process, and that cancer cells containing ALK variants become dependent on the chimeric protein encoded by the rearranged gene. Drugs called ALK tyrosine kinase inhibitors (TKI), designed to inhibit the variant ALK gene product, are being investigated for treatment of the subset of NSCLC patients whose tumors harbor ALK rearrangements. Encouraging results from early clinical trials of crizotinib, an ALK TKI manufactured by Pfizer, led to accelerated Food and Drug Administration (FDA) approval of crizotinib in August 2011, with concurrent FDA approval of a fluorescence in situ hybridization (FISH) test designed to detect ALK rearrangements. Despite ongoing investigation of other ALK rearrangement testing methodologies, the FDA-approved test is required to be used in patients seeking qualification for crizotinib therapy. In addition to its use as a predictive biomarker for response to crizotinib therapy, ALK rearrangement is also being investigated in connection with other NSCLC therapies, with regards to its relationship to prognosis in NSCLC, and its relationship to clinical characteristics of NSCLC patients.

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