SUBJECT: **Vysis ALK Break Apart FISH Test for the Selection of Xalkori**
INDEX TITLE: **Medical Management**
ORIGINAL DATE: **January 2013**

This policy applies to the following MedStar Health lines of business:
(Check those that apply.)

COMMERCIAL	[ ] HMO	[ ] PPO	[ ] Fully Insured	[ ] Individual Product	[ ] Marketplace (Exchange)	[X] All
GOVERNMENT PROGRAMS	[ ] MA HMO	[ ] MA PPO	[ ] MA C-SNP	[ ] MA D-SNP	[X] MA All	
	[ ] Medicaid					
OTHER	[X] Self-funded/ASO					

I. POLICY

It is the policy of MedStar Health, Inc. to cover the Vysis ALK Break Apart FISH Test for the Selection of Xalkori when it is medically necessary (Refer to CRM.015.MH-Medical Necessity policy) as detailed in this policy and covered under the member's specific benefit plan.

II. DEFINITIONS

Fluorescence in situ hybridization (FISH) – a cytogenetic test used to visualize and map the presence or absence of specific genes.

III. PURPOSE

The purpose of this policy is to provide the indications for coverage of the Vysis ALK Break Apart FISH Test.

IV. SCOPE

This policy applies to various MedStar Health, Inc. departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description / Background

The Vysis ALK Break Apart FISH test (commercially known as Vysis ALK test) is an FDA approved companion diagnostic test for selection of drug therapy with Xalkori® (crizotinib) for patients with non-small cell lung cancer (NSCLC). Currently the test is manufactured by Abbott Molecular, Inc. and detects whether a patient has an abnormal ALK (anaplastic lymphoma kinase) gene which can trigger cancer development and growth. This abnormality occurs in about 5% of NSCLC patients. It is thought to be a key oncogenic driver in this small subset of patients with locally advanced or metastatic NSCLC who appear to do significantly better when treated with the drug Xalkori which blocks ALK activity.

The Vysis ALK Break Apart FISH probe kit detects rearrangements involving the ALK gene via FISH tests in NSCLC tissue specimens. If the test result indicates that the patient's tumor is positive for ALK gene rearrangements, then the patient may benefit from treatment with Xalkori. The clinical interpretation of test results should be evaluated within the context of the patient's medical history and with any other diagnostic test results. Patients with these ALK gene abnormalities tend to be younger, have little or no exposure to tobacco and did not have mutations in KRAS (Kirsten Rat Sarcoma) or EGFR (epidermal growth factor receptor).

National Comprehensive Cancer Network's (NCCN) current guidelines recommend:

- ALK testing for patients with NSCLC subtypes of adenocarcinoma, large cell or NSCLC NOS (not otherwise specified).
- If ALK +, then Xalkori is the recommended treatment option.

B. Indications

Vysis ALK Break Apart FISH test is indicated only for members who meet the following criteria:

- Diagnosed advanced or metastatic NSCLC

And

- Treatment with Xalkori is being considered

C. Limitations

- For in vitro diagnostic use by prescription only
- Not generally recommended for patients with NSCLC subtype of squamous cell carcinoma
- The test must be performed by laboratories/technologists with demonstrated proficiency in this specific technology
- The assay must be performed only from 10% neutral buffered formalin-fixed, paraffin-embedded human NSCLC tissue specimens

D. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT	***Description***
88271	Molecular cytogenetics; DNA probe, each (e.g., FISH)
88274	Interphase in situ hybridization, analyze 25-99 cells
88367	Morphometric analysis; in situ hybridization (quantitative or semi-quantitative) each probe, using compute-assisted technology
88373	Each additional single probe stain procedure
88374	Each multiplex probe stain procedure
88369	Each additional single probe stain procedure
88368	Morphometric analysis; in situ hybridization (quantitative or semi-quantitative) each probe, manual

ICD-9	***Description***
162.2 -162.9	Malignant neoplasm of bronchus, lung

ICD-10	***Description***
C34.00-C34.92	Malignant neoplasm of bronchus and lung

E. Variations

N/A

F. Quality Audit

Quality Audit may monitor policy compliance or billing accuracy at the request of the MedStar Health, Inc. Assessment Committee or the Benefits Reimbursement Committee.

G. Records Retention

Records Retention for documents, regardless of medium, are provided within the MedStar Health, Inc. Policy and Procedure CORP.028.MH Records Retention.

Unless otherwise mandated by Federal or State law, or unless required to be maintained for litigation purposes, any communications recorded pursuant to this Policy are maintained for a minimum of ten (10) years from the date of recording.

H. References

Medical Literature/Clinical Information:

1. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 4.2014. Published: 06/05/2014. http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
2. ECRI Institute. Health Technology Forecast News Brief: Crizotinib shows promise in pediatric patients with ALK-driven lymphoma or neuroblastoma. Published: 06/01/2012. https://members2.ecri.org/Components/Forecast/Pages/13107.aspx?pfm=true
3. ECRI Institute. Hotline Response: Vysis ALK Break Apart FISH Test for Selection of Xalkori (Crizotinib) Treatment for Non-small Cell Lung Cancer. Published: 10/04/2011. Updated: 11/26/2011. https://members2.ecri.org/Components/Hotline/Documents/IssueFiles/12654.pdf
4. Abbott Molecular, Inc. Vysis ALK Break Apart FISH Probe Kit Brochure (AM 0513-26): Let the patient's signal guide the need for therapy. ©2013. https://www.abbottalk.com/en-us/staticAssets/IVD_ALK_Brochure_en_US.pdf

Regulatory/Government Source:

1. FDA News Release. FDA approves Xalkori with companion diagnostic for a type of late- stage lung cancer. Issued: 08/26/2011. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm269856.htm

Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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