PICKING UP PIK3CA

For eligible patients,

FREE PLASMA AND/OR TUMOR TISSUE ANALYSIS WITH THE PIK3CA MUTATION TESTING PROGRAM

NeoGenomics Laboratories will conduct plasma and tissue testing using the QIAGEN *therascreen*® PIK3CA RGQ PCR test.[1]

Accessing the program

Appropriate patients may receive one free plasma or tumor tissue test using the QIAGEN *therascreen*® PIK3CA RGQ PCR test for the purpose of determining whether or not the patient has a PIK3CA mutation and is eligible for alpelisib for an FDA-approved indication, without regard to purchase of any prescribed drug or any other product.

If the patient tests negative for PIK3CA mutation using plasma, eligible patients may also receive one free PIK3CA reflex tissue test. No patient, health care program, or beneficiary shall be billed for these mutation tests.

If no mutation is detected in a plasma specimen, test tumor tissue.[2]

PLASMA SPECIMEN

PIK3CA mutations can be detected in circulating tumor DNA. If no mutation is found in a plasma specimen, test tumor tissue.[2]

TUMOR TISSUE

PIK3CA mutations can be detected in primary or metastatic breast cancer tumor tissue.[3]

ORDER A PIK3CA MUTATION PLASMA TEST

CONTACT
NeoGenomics Client Services at 1-866-776-5907 to start your order

If the patient tests negative for PIK3CA mutation using plasma, **eligible patients may also receive one free PIK3CA reflex tissue test.**

ORDER A PIK3CA MUTATION TUMOR TISSUE TEST DOWNLOAD

Visit PIK3CA-CDx-order.com to download the PIK3CA Mutation CDx Test Request Form

RETURN
the completed PIK3CA Mutation CDx Test Request Form to NeoGenomics Laboratories

Existing NeoGenomics Laboratories Customers

Please include the pathology report and submit by fax to 1-239-690-4237, or include with patient's specimen in the provided shipper.

First-time NeoGenomics Laboratories Customers

Please contact NeoGenomics Laboratories Client Services at 1-866-776-5907 to set up your new customer account before sending in your Request Form.

Get status updates when you order the PIK3CA mutation test from NEOLINK at lis.neogenomics.com*

*This is an external website independently operated and not managed by Novartis Pharmaceuticals Corporation. Novartis assumes no responsibility for the site.

Health care providers who participate in the program are prohibited from seeking reimbursement of any kind from any patient, insurer, prescriber, or government program.

Indication
PIQRAY® (alpelisib) 50 mg, 150 mg, 200 mg tablets is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

Important Safety Information
PIQRAY is contraindicated in patients with severe hypersensitivity to it or any of its components.

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Please see Indication and full Important Safety Information for alpelisib on the reverse side and click here for full Prescribing Information.

NEO GENOMICS

Important Safety Information (cont)

Severe Hypersensitivity: Severe hypersensitivity reactions, including anaphylaxis and anaphylactic shock, can occur in patients treated with PIQRAY. Severe hypersensitivity reactions were manifested by symptoms including, but not limited to, dyspnea, flushing, rash, fever, or tachycardia. Advise patients of the signs and symptoms of severe hypersensitivity reactions. Permanently discontinue PIQRAY in the event of severe hypersensitivity.

Severe Cutaneous Adverse Reactions (SCARs): PIQRAY can cause SCARs, including Stevens-Johnson syndrome (SJS), erythema multiforme (EM), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS). Interrupt PIQRAY if signs or symptoms of SCARs occur (eg, a prodrome of fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy), until etiology of the reaction has been determined. Advise patients of the signs and symptoms of SCARs. Consider consultation with a dermatologist. Permanently discontinue PIQRAY if a SCAR is confirmed.

Hyperglycemia: PIQRAY can cause severe hyperglycemia, including ketoacidosis. Before initiating treatment with PIQRAY, test fasting plasma glucose (FPG), HbA1c, and optimize blood glucose. After initiating treatment, monitor fasting glucose (FPG or fasting blood glucose) at least once every week for the first 2 weeks, then at least once every 4 weeks, and as clinically indicated. Monitor HbA1c every 3 months and as clinically indicated. Initiate or optimize antihyperglycemic medications as clinically indicated. Interrupt, reduce dose, or discontinue PIQRAY if severe hyperglycemia occurs. The safety of PIQRAY in patients with type 1 and uncontrolled type 2 diabetes has not been established. Patients with a history of diabetes mellitus may require intensified diabetic treatment. Closely monitor patients with diabetes.

Advise patients of the signs and symptoms of hyperglycemia (eg, excessive thirst, urinating more often than usual or higher amount of urine than usual, or increased appetite with weight loss).

Pneumonitis: PIQRAY can cause severe pneumonitis, including acute interstitial pneumonitis and interstitial lung disease. Monitor for clinical symptoms or radiological changes. Consider a diagnosis of noninfectious pneumonitis in patients presenting with nonspecific respiratory signs and symptoms such as hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams and in whom infectious, neoplastic, and other causes have been excluded by means of appropriate investigations. Interrupt or discontinue PIQRAY if severe pneumonitis occurs. Advise patients to immediately report new or worsening respiratory symptoms.

Diarrhea: PIQRAY can cause severe cases of diarrhea, including dehydration and acute kidney injury. Based on the severity of the diarrhea, PIQRAY may require dose interruption, reduction, or discontinuation. Advise patients to start antidiarrheal treatment, increase oral fluids, and notify their health care provider if diarrhea occurs while taking PIQRAY.

Embryo-Fetal Toxicity: PIQRAY can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception. Refer to full Prescribing Information of fulvestrant for pregnancy and contraception information.

Most common adverse reactions, including laboratory abnormalities (all grades, incidence ≥20%) were glucose increased (79%), creatinine increased (67%), diarrhea (58%), rash (52%), lymphocyte count decreased (52%), gamma-glutamyl transferase increased (52%), nausea (45%), alanine aminotransferase increased (44%), fatigue (42%), hemoglobin decreased (42%), lipase increased (42%), decreased appetite (36%), stomatitis (30%), vomiting (27%), weight decreased (27%), calcium decreased (27%), glucose decreased (26%), activated partial thromboplastin time prolonged (21%), and alopecia (20%).

Please click here for full Prescribing Information.

References: 1. *therascreen*® PIK3CA RGQ PCR Kit Instructions for Use. Germantown, MD: QIAGEN; May 2019. **2.** Piqray [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2020. **3.** Data on file. Novartis Pharmaceuticals Corp; 2018.

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