

UPMC Health Plan POLICY AND PROCEDURE MANUAL

POLICY NUMBER: PAY .117
REVISION DATE: N/A
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SUBJECT: BRAF V600E Mutation Test for Treatment of Melanoma
INDEX TITLE: Medical Management
ORIGINAL DATE: December 2011

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

COMMERCIAL:			
HMO ()	PPO ()		All (X)
Fully Insured ()	Self-funded/ASO ()		
Indiv Short Term ()			
CMS-MA:			
OH ()	WV ()	PA ()	All (X)
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()
DPW-MA:			
Health Choices /PH ()	Voluntary ()	Health Choices/BH ()	All ()
PID-CHIP:			
CHIP (X)			
ANCILLARY:			
UPMC Dental Advantage ()	UPMC Vision Advantage ()	COBRA ()	All ()
WORK PARTNERS:			
Commercial WC ()	Disability Services/TPA ()	Health Promotion ()	All ()

I. POLICY

It is the policy of UPMC Health Plan to cover the FDA approved BRAF V600E mutation test for melanoma when it is medically necessary as detailed in this policy and covered under the member's specific benefit plan.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the indications for BRAF V600E mutation testing.

IV. SCOPE

This policy applies to various UPMC Health Plan 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 American Cancer Society estimates that in the United States in 2011 about 70,230 new cases of melanoma will be diagnosed, and about 8,790 people will die from melanoma. Individuals diagnosed with early-stage melanoma have a 10-year survival rate of over 80%; individuals diagnosed with metastatic melanoma have a 10-year survival rate of around 12%.

The primary cause of melanoma is DNA damage from exposure to ultraviolet light (sunlight). Early-stage melanoma may be treated with simple surgical excision, while later-stage melanomas may also be treated with chemotherapy and/or immunotherapy.

In normal skin tissue, the B-raf protein transmits signals in cells to regulate cell growth and cell death. In 50%-60% of melanoma tissue, a mutation referred to as BRAF V600E, causes an altered form of the B-raf protein. This mutant form of the B-raf protein results in abnormal functioning of the protein and stimulates melanoma growth. In melanoma patients, BRAF V600E mutation may predict response to certain tyrosine kinase inhibitor medications.

BRAF-mutated metastatic melanomas treated with Zelboraf® (vemurafenib) tend to have prolonged survival compared to those treated with dacarbazine. On April 4, 2011, the FDA approved the use of Zelboraf® for the treatment of inoperable or metastatic melanoma when the patient carries a BRAF V600E mutation.

The presence of the wild-type BRAF melanoma is a contraindication for treatment with Zelboraf® because the disease is exacerbated by the drug in patients with this type of mutation. Use of Zelboraf® in patients who do not have the BRAF V600E mutation has also been demonstrated in clinical trials to result in disease exacerbation.

On August 8, 2011, the FDA approved the BRAF V600E mutation test (Roche Molecular Systems, Inc), a real-time in vitro diagnostic test intended to detect the BRAF V600E mutation in DNA extracted from human melanoma tissue as a companion test with the approval for Zelboraf®. This test is therefore used to determine a patient's eligibility for treatment with Zelboraf®. If the test result indicates that the BRAF V600E mutation is present in the melanoma cells, then the patient may receive treatment with Zelboraf®.

B. Indications

The BRAF V600E Mutation test is indicated as a companion test:

1. When the member is diagnosed with an inoperable or metastatic melanoma
AND
2. The melanoma is classified as a Stage IIIC or Stage IV melanoma
AND
3. Treatment with Zelboraf® is being considered
(Refer to pharmacy policy).

C. Limitations

BRAF V600E Mutation test is Experimental and Investigational and therefore are not a covered benefit for these diagnoses:

- Colorectal Cancer
- For the work up of Lynch Syndrome.
(There is insufficient scientific evidence to support BRAF mutation testing in treatment of these).

D. Variations

N/A

E. Quality Audit

Quality Audit may monitor policy compliance or billing accuracy at the request of the UPMC Health Plan's Technology Assessment Committee or the Benefits Reimbursement Committee.

F. Records Retention

Records Retention for documents, regardless of medium, are provided within the UPMC Health System Policy Records Retention, Management and Retirement, and as indicated in the UPMC Insurance Services Division Policy and Procedure Records Retention.

G. References

1. FDA: cobas® 4800 BRAF V600 Mutation Test - P110020 , 8/19/11
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm268836.htm>
2. FDA Letter of Approval for cobas® 4800 BRAF V600 Mutation Test, 8/17/11
http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110020a.pdf
3. FDA News Release: FDA approves Zelboraf and companion diagnostic test for late-stage skin cancer , 8/17/11
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm268241.htm>
4. FDA: Draft Guidance for Industry FDA Staff- In Vitro Companion Diagnostic Services, 7/14/11
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm262292.htm>
5. ECRI: Research and Development: Cancer (Skin), 8/7/09
<https://members2.ecri.org/Components/Forecast/Pages/5525.aspx>
6. ECRI Hotline: cobas 4800 BRAF V600 Mutation Test to Determine Eligibility for Vemurafenib (Zelboraf) Therapy for Metastatic Melanoma, 10/12/11
<https://members2.ecri.org/Components/Hotline/Pages/12655.aspx>
7. Exiqon: BRAF Mutation Analysis (Test Code 221), 10/27/11
<http://www.exiqon.com/dxps/Pages/BRAF-Mutation-Analysis.aspx>

8. Mayo clinic: BRAF Mutation Analysis (V600E), Tumor, 10/27/11
<http://www.mayomedicallaboratories.com/test-catalog/Overview/87980>

Disclaimer:

UPMC Health Plan 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 UPMC Health Plan 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.

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