POLICY NUMBER UM ONC_1250	SUBJECT Tafinlar™ (dabrafenib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 09/18/13, 10/06/14, 11/12/14, 04/07/16, 02/06/17, 08/08/18, 07/10/19, 12/11/19, 04/08/20, 06/10/20	APPROVAL DATE June 10, 2020	EFFECTIVE DATE June 26, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 09/18/13, 10/06/14, 11/12/14, 04/07/16, 02/06/17, 08/08/18, 07/10/19, 12/11/19, 04/08/20, 06/10/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

To define and describe the accepted indications for Tafinlar (dabrafenib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**

b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**

c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**

d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**

e. When available, generic alternatives are preferred over brand-name drugs.

2. BRAF V600E positive Melanoma

a. **NOTE: For stage III melanoma, the preferred agents per NCH Policies & NCH Pathway, for adjuvant therapy are Nivolumab OR Pembrolizumab.**

b. **NOTE: For systemic therapy of metastatic BRAF V600E melanoma the preferred combination, per NCH Policies and NCH Pathway, is cobimetinib + vemurafenib.**

c. Tafinlar (dabrafenib) may be used in combination with Mekinist (trametinib) in members who have intolerance to/contraindication to the use of [Cobimetinib + Vemurafenib].

3. **Non-Small Cell Lung Cancer (NSCLC)**
    a. Tafinlar (dabrafenib) may be used as a single agent or in combination with Mekinist (trametinib) as first line or subsequent line therapy for recurrent or metastatic BRAF V600E mutation-positive NSCLC.
4. **Thyroid Cancer**
    a. The member has papillary, follicular, and Hürthle Cell carcinoma and Tafinlar (dabrafenib) may be used as a single agent/in combination with Mekinist (trametinib) for radioactive iodine-refractory (if radioactive iodine therapy is appropriate) BRAF V600E-positive unresectable/recurrent/metastatic disease.

III. EXCLUSION CRITERIA

1. The member has wild-type BRAF melanoma, NSCLC, anaplastic/non-anaplastic (all other histologies included) thyroid carcinoma.
2. Disease progression while taking Tafinlar (dabrafenib) or other BRAF inhibitor (i.e. vemurafenib or encorafenib).
3. Dosing exceeds single dose limit of Tafinlar (dabrafenib) 150 mg.
4. Treatment exceeds the maximum limit of 90 (50 mg) tablets/month or 60 (75 mg) tablets/month.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Tafinlar prescribing information. Novartis Pharmaceuticals Corporation East Hanover, NJ . 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.