Drug Policy:

Tafinlar™ (dabrafenib)

POLICY NUMBER UM ONC_1250	**SUBJECT** Tafinlar™ (dabrafenib)	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
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, 05/12/21, 10/13/21, 11/15/21	**APPROVAL DATE** November 15, 2021	**EFFECTIVE DATE** November 29, 2021	**COMMITTEE APPROVAL DATES** 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, 05/12/21, 10/13/21, 11/15/21
PRIMARY BUSINESS OWNER: UM		**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** Commercial, Exchange, Medicaid	

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 Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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
2. 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

3. 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
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs.

B. BRAF V600E or V600K mutation positive Melanoma

1. NOTE: For adjuvant therapy of BRAF V600 E or V600K mutation positive, stage III melanoma, the preferred agents per NCH Policies & NCH Pathway are Opdivo (nivolumab OR Keytruda (pembrolizumab). Tafinlar (dabrafenib) + Mekinist (trametinib) is non-preferred for use in the adjuvant setting based on a lack of Level 1 evidence that nivolumab or pembrolizumab monotherapy is inferior to the above combination.
2. NOTE: For systemic therapy of metastatic BRAF V600E or V600K mutation positive melanoma the preferred oral combination, per NCH Policies and NCH Pathway, is cobimetinib + vemurafenib.
3. Tafinlar (dabrafenib) may be used as a single agent or in combination with Mekinist (trametinib) in members who have intolerance to/contraindication to the use of the preferred MEK and BRAF inhibitor combination, Cotellic (cobimetinib) + Zelboraf vemurafenib).

C. Non-Small Cell Lung Cancer (NSCLC)

1. Tafinlar (dabrafenib) may be used in combination with Mekinist (trametinib) as first line or subsequent line therapy for recurrent or metastatic BRAF V600E mutation-positive NSCLC, if anti-BRAF targeted therapy was not previously used.

D. Thyroid Cancer

1. The member has anaplastic, papillary, follicular, and Hürthle Cell thyroid carcinoma and Tafinlar (dabrafenib) may be used in combination with Mekinist (trametinib) for radioactive iodine-refractory (if radioactive iodine therapy is appropriate) BRAF V600E mutation positive unresectable/recurrent/metastatic disease.

III. EXCLUSION CRITERIA

A. The member has wild-type BRAF melanoma, NSCLC, anaplastic/non-anaplastic (all other histologies included) thyroid carcinoma.

B. Disease progression while taking Tafinlar (dabrafenib) or other BRAF inhibitor (e.g., vemurafenib or encorafenib).

C. Dosing exceeds single dose limit of Tafinlar (dabrafenib) 150 mg.

D. Treatment exceeds the maximum limit of 90 (50 mg) tablets/month or 60 (75 mg) tablets/month.

E. Treatment exceeds the maximum 12 months duration limit when used as adjuvant melanoma treatment following complete resection of the primary lesion and completion of a regional lymph node dissection.

F. Investigational use of Tafinlar (dabrafenib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.

2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Tafinlar prescribing information. Novartis Pharmaceuticals Corporation East Hanover, NJ . 2021.

B. Clinical Pharmacology Elsevier Gold Standard 2021

C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.

F. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

G. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.