Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Tafinlar (dabrafenib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Tafinlar (dabrafenib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Tafinlar (dabrafenib) may be approved if the following criteria are met:

Individual has a diagnosis of one of the following:

I. Unresectable or metastatic melanoma:
   A. Individual is using in combination with trametinib for disease with BRAF V600E or V600K mutation and test results confirmed; **OR**
   B. Individual is using in combination with trametinib AND has BRAF V600 activating mutation and test results confirmed; **AND**
      1. Using in subsequent therapy for disease progression (NCCN 2A); **OR**
      2. Using in re-induction therapy with disease control, but experiences disease progression/relapse > 3 months after treatment discontinuation (NCCN2A);

   OR

   C. Individual is using as monotherapy for disease with BRAF V600E mutation and test results confirmed;

OR

II. Melanoma:
   A. Individual is using as adjuvant treatment; **AND**
   B. Individual is using in combination with trametinib; **AND**
   C. Individual has BRAF V600E or V600K mutations and test results confirmed; **AND**
   D. Individual has disease involvement of lymph node(s), following complete resection;

OR

III. Locally advanced or metastatic anaplastic thyroid cancer (ATC):
   A. Individual is using in combination with trametinib; **AND**
   B. Individual has BRAF V600E mutation and test results confirmed; **AND**
   C. Individual has no satisfactory locoregional treatment options;

Market Applicability							
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Applicable	X	X	X	X	X	X	X

OR

IV. Progressive and/or symptomatic iodine-refractory BRAF-positive thyroid cancer, including papillary, follicular, and Hürthle carcinomas when clinical trials or other systemic therapies are not available (NCCN 2A);

OR

V. Metastatic Non-Small Cell Lung Cancer (NSCLC):
   A. Individual is using in combination with trametinib for disease with BRAF V600E mutation and test results confirmed; **OR**
   B. Individual is using for disease with BRAF V600E mutation, as a single agent if the combination of dabrafenib plus trametinib is not tolerated (NCCN 2A);

OR

VI. Central Nervous System (CNS) cancers (NCCN 2A):
   A. Individual has a primary diagnosis of melanoma; **AND**
   B. Disease has metastasized to the brain; **AND**
   C. Individual is using in combination with trametinib.

Tafinlar (dabrafenib) may not be approved for the following:

I. Individual with wild-type BRAF melanoma, wild-type BRAF NSCLC, or wild-type BRAF ATC.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: August 30, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on April 17, 2020.
   a. Central Nervous System Cancers. V2.2019. Revised September 16, 2019.
   b. Cutaneous Melanoma. V2.2019. Revised March 12, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

c. Non-Small Cell Lung Cancer. V7.2019. Revised August 30, 2019.
d. Thyroid Carcinoma. V2.2019. Revised September 16, 2019.