POLICY NUMBER UM ONC_1249	**SUBJECT** Mekinist™ (trametinib)		**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, 02/14/18, 02/13/19, 12/11/19, 02/12/20	**APPROVAL DATE** February 12, 2020	**EFFECTIVE DATE** March 01, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 09/18/13, 10/06/14, 11/12/14, 04/07/16, 02/06/17, 02/14/18, 02/13/19, 12/11/19. 02/12/20	
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 Mekinist (trametinib) 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: http://pathways.newcenturyhealth.com **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. **Melanoma**
    a. The member has BRAF V600E mutation positive melanoma and Mekinist (trametinib) is being used in combination with Tafinlar (dabrafenib) as any of the following:
        i. As adjuvant treatment after complete resection of the primary lesion andcompletion of a regional lymphode dissection **OR**

ii. As initial treatment for recurrent/metastatic disease, including satellite/in-transit recurrence or metastases **OR**

iii. As first line, second-line, or subsequent treatment for metastatic or unresectable disease, if targeted therapy not previously used.

3. **Non-Small Cell Lung Cancer (NSCLC)**

   a. The member has recurrent, advanced, or metastatic BRAF V600E mutation-positive NSCLC and Mekinist (trametinib) is being used in combination with Tafinlar (dabrafenib) as any of the following:

      i. First line therapy **OR**

      ii. Subsequent therapy if targeted therapy not previously used.

4. **Thyroid Carcinoma**

   a. The member has locally advanced or metastatic BRAF V600E mutation-positive anaplastic thyroid cancer and Mekinist (trametinib) is being used in combination with Tafinlar (dabrafenib) as first or second-line therapy for metastatic disease.

5. **Colorectal Cancer**

   a. The member has unresectable, advanced, or metastatic BRAF V600E mutation positive colorectal cancer and Mekinist (trametinib) is being used in combination with dabrafenib and cetuximab/panitumumab as any of the following:

      i. Primary treatment **OR**

      ii. Subsequent therapy if targeted therapy not previously used.

6. **Ovarian Cancer**

   a. Mekinist (trametinib) is being used as recurrent therapy for low grade serous carcinoma.

III. EXCLUSION CRITERIA

1. The member has BRAF wild-type melanoma, NSCLC, anaplastic thyroid cancer, or colorectal cancer.
2. Disease progression while taking Mekinist (trametinib) or other MEK inhibitors.
3. Previous treatment with BRAF or MEK inhibitor (i.e. vemurafenib, dabrafenib, cobimetinib, binimetinib, or trametinib).
4. Dosing exceeds single dose limit of Mekinist (trametinib) 2mg.
5. Treatment exceeds the maximum limit of (30) 2 mg tablets/month or (120) 0.5 mg tablets/month.
6. 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 – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Mekinist prescribing information. GlaxoSmithKline Research Triangle Park, NC. 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.