ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Tafinlar® (dabrafenib)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Tafinlar® (dabrafenib)

Diagnosis (documentation supportive of diagnosis and mutation status is required)

☐ Unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test (e.g. THxID™-BRAF), as monotherapy

☐ Unresectable or metastatic melanoma with BRAF V600E or V600K mutation, in combination with Mekinist™ (trametinib)

☐ Other (please state): _____

Clinical Consideration (please acknowledge the following):

☐ Tafinlar is NOT indicated and will NOT be covered for the treatment of patients with wild-type BRAF melanoma

☐ FDA **approval was based on Progression Free Survival (PFS)**. The median PFS for Tafinlar was 2.4 months longer compared with dacarbazine (5.1 vs. 2.7 months) in previously untreated adults (n=250).

☐ FDA **approval was based on Progression Free Survival (PFS)**. The median PFS for Mekinist + Tafinlar was 3.6 months longer (9.4 vs 5.8 months) than the median PFS for patients who received Tafinlar monotherapy (n=162). **Improvement in disease-related symptoms or overall survival has not been demonstrated.**

☐ Tafinlar 75mg capsule (120): $9,576/month + Mekinist 2mg oral tablet (30): $10,962/month = **$20,538/month**

Physician Specialty

☐ Oncologist
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to: ☐ Patient's Home ☐ Physician Office		Other:
Prescriber or Authorized Signature:		Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Tafinlar® (dabrafenib)

CLASSIFICATION

- Antineoplastic Agent
- Kinase inhibitor

DESCRIPTION

- Dabrafenib inhibits BRAF V600E kinases and other kinases, including BRAF V600K, BRAF V600D, and wild-type BRAF and CRAF kinases. Some mutations in the BRAF gene, including those that result in BRAF V600E, can result in activated BRAF kinases that may stimulate tumor cell growth; therefore, dabrafenib is not indicated to treat wild-type BRAF melanoma.

Tafinlar Monotherapy:

- Dabrafenib is a kinase inhibitor indicated as monotherapy for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutations as detected by an FDA-approved test. It is NOT indicated to treat BRAF wild-type melanoma.
- In the pivotal phase III randomized, open-label study (n=250), BRAF V600E-mutated metastatic melanoma patients with histologically confirmed unresectable stage III or measurable stage IV melanoma who had received no previous antitumor therapy (other than interleukin-2) were randomized to receive either dabrafenib 150 mg orally twice daily (n=187) or dacarbazine 1000 mg/m(2) IV every 3 weeks (n=63). If disease progression was confirmed, patients in the dacarbazine group were allowed to crossover to receive dabrafenib. For the primary endpoint, investigator assessed median PFS, dabrafenib treatment significantly improved progression-free survival compared with dacarbazine (5.1 vs 2.7 months) (HR, 0.3; 95% CI, 0.18 to 0.51; $p < 0.0001$). Objective response rate (ORR), as assessed by the IRC, occurred in 50% (95% CI, 42.4% to 57.1%) in the dabrafenib group (3% achieving a complete response [CR], 47% a partial response [PR]), with a median duration of 5.5 months. In the dacarbazine group, an IRC-confirmed ORR occurred in 6% (95% CI, 1.8% to 15.5%); 2% and 5% of patients achieved a CR and PR, respectively. At the time of cut-off, 46% (13 of 28) of patients in the dacarbazine arm who had crossed over to receive dabrafenib treatment had a PR.
- In an open-label, noncomparative, phase II study of adults with BRAF-mutant melanoma with brain metastases (n=172), an overall intracranial response was achieved in 39.2% of patients with Val600Glu BRAF-mutant melanoma who had not received previous treatment for brain metastases (n=74) and 30.8% of patients with Val600Glu BRAF-mutant melanoma and progressive brain metastases after previous local treatments (n=65).
- Most common adverse reactions (≥20%) for Tafinlar as a single agent are hyperkeratosis, headache, pyrexia, arthralgia, papilloma, alopecia, and palmar-plantar erythrodysesthesia syndrome.

Tafinlar in combination with Mekinist:

- Tafinlar in combination with Mekinist is indicated for the treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by a **FDA** approved test; **improvement in disease-related symptoms or overall survival has not been demonstrated for trametinib in combination with dabrafenib. FDA approval was based on Progression Free Survival (PFS). The median PFS for Mekinist + Tafinlar was 3.6 months longer (9.4 vs 5.8 months) than the median PFS for patients who received Tafinlar monotherapy (n=162).**
- Most common adverse reactions (≥20%) for Tafinlar in combination with trametinib are pyrexia, chills, fatigue, rash, nausea, vomiting, diarrhea, abdominal pain, peripheral edema, cough, headache, arthralgia, night sweats, decreased appetite, constipation, and myalgia
- Tafinlar (dabrafenib) is a specialty drug. Rocky Mountain Health Plans preferred Specialty Pharmacy Network is Modern Health®.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 3
Commercial Formulary: Tier 3
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Tafinlar® (dabrafenib) meets the definition of **medical necessity** for the following:

- Unresectable or metastatic melanoma with BRAF V600E mutations as detected by an FDA-approved test (e.g. THxID™-BRAF, cobas® 4800 BRAF V600 Mutation Test), as monotherapy.
  - Documentation supporting diagnosis of unresectable or metastatic melanoma AND documentation of BRAF V600E mutations as detected by an FDA-approved test is required.
- Unresectable or Metastatic Melanoma with BRAF V600E or V600K mutation, in combination with Mekinist™ (trametinib).
  - Documentation supporting diagnosis of unresectable or metastatic melanoma AND documentation of BRAF V600E or V600K mutations as detected by an FDA-approved test is required.

Duration of coverage is given in 6 month increments. Documentation of no disease progression is required for coverage renewal.

Tafinlar® (dabrafenib) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported.
- Tafinlar is NOT covered in patients with BRAF V600K mutation metastatic melanoma when used as monotherapy.
- Tafinlar is NOT covered in patients with prior BRAF inhibitor therapy (e.g. Zelboraf).
- Tafinlar is NOT covered when used in combination with Zelboraf.
- Tafinlar is NOT covered in patients with wild-type BRAF melanoma.
- Tafinlar is NOT covered in patients with other solid tumors or other BRAF mutation-positive cancers.

Required Provider Specialty:

- Approval is limited to Oncology

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients less):

- Malignant melanoma, Unresectable or metastatic, with BRAF V600E mutation, monotherapy: the recommended dose is 150 mg orally twice daily, approximately 12 hours apart. Take at least 1 hour before or at least 2 hours after a meal. Continue therapy until disease progression or unacceptable toxicity occurs.
- Malignant melanoma, Unresectable or metastatic with BRAF V600E or V600K mutation, in combination with trametinib: 150 mg ORALLY every 12 hours with trametinib 2 mg ORALLY once daily; take doses at least 1 hour before or at least 2 hours after a meal; continue treatment until disease progression or unacceptable toxicity occurs
- See product labeling for recommended dose modifications.

PRECAUTIONS

- Tumor promotion in BRAF wild-type melanoma: confirm BRAF V600E mutation status prior to starting treatment.
- Avoid concomitant use of strong inhibitors or strong inducers of CYP3A4 or CYP2C8, or CYP3A4 or CYP2C9 substrates.
- Glucose-6-phosphate dehydrogenase deficiency: monitor closely for hemolytic anemia.
- Serious febrile drug reactions, (serious fever or fever of any severity accompanied by hypotension, rigors or chills, dehydration, or renal failure without another identifiable cause) have been reported. Monitoring is recommended; therapy interruption or discontinuation may be required.
- Hyperglycemia that required initiation of or increase in insulin or oral hypoglycemic agents has been reported. Monitor serum glucose levels in patients with preexisting diabetes or hyperglycemia.
- Embryofetal toxicity: Tafinlar can cause fetal harm. Nonhormonal contraception during and for at least 2 weeks after treatment recommended for women with reproductive potential; when combined with trametinib, continue nonhormonal contraception for 4 months after treatment. Tafinlar may render hormonal contraceptives less effective.
- Uveitis and iritis have been reported. Monitor patients routinely for visual symptoms. Therapy interruption or discontinuation may be necessary.
- Basal cell carcinoma has been reported when used in combination with trametinib. Monitoring is recommended.
- New primary cutaneous malignancies, including cutaneous squamous cell carcinoma, keratoacanthoma, and melanoma, have been reported; Monitoring is recommended.
- New primary noncutaneous malignancies, including pancreatic adenocarcinoma, colorectal carcinoma, head and neck carcinoma, and glioblastoma, have been reported when used in combination with trametinib. Monitoring is recommended. Permanently discontinue for RAS mutation-positive noncutaneous malignancies.
- BRAF wild-type melanoma; increased cell proliferation with exposure to BRAF inhibitors in vitro; confirm BRAF V600E or V600K mutation status prior to initiation of treatment.
- Symptomatic and asymptomatic cardiomyopathy (i.e., decreased left ventricular ejection fraction) has been reported when used in combination with trametinib. Monitoring is recommended. Therapy interruption may be required.
- Febrile reactions, serious, and fever of any severity accompanied by hypotension, rigors or chills, dehydration, or renal failure, have been reported. Incidence and severity increase when used in combination with trametinib. Monitoring is recommended. May require dosage reduction, or interruption or discontinuation of therapy.
- Intracranial or gastric hemorrhages, including fatalities, have been reported when used in combination with trametinib. Therapy interruption or discontinuation may be necessary.
- Interstitial lung disease may occur when used in combination with trametinib.
- Retinal pigment epithelial detachments, typically bilateral and multifocal, have been reported when used in combination with trametinib.
- Retinal vein occlusion may occur when used in combination with trametinib.
- Skin toxicity, grade 3/4 and some requiring hospitalization, has been reported when used in combination with trametinib. May require dosage reduction, or interruption or discontinuation of therapy.
- Venous thromboembolism (e.g., DVT and pulmonary embolism), including fatalities, has been reported when used in combination with trametinib. Therapy interruption or discontinuation of therapy may be necessary.

Billing/Coding information

HCPCS Coding:

C9399	Unclassified drugs or biologicals (This code should only be used for drugs and biologicals that are approved by the FDA on or after January 1, 2004) (Hospital Outpatient Use ONLY)
J8999	Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

COST

- AWP (May 2013): Tafinlar 75mg oral capsule (120): $9,120
- AWP (January 2014): Tafinlar 75mg oral capsule (120): $9,576
- AWP (January 2014): Tafinlar 75mg oral capsule (120): $9,576 + Mekinist 2mg oral tablet (30): $10,962 = $20,538/month

COMMITTEE APPROVAL

- September 2013

GUIDELINE UPDATE INFORMATION

August 2013	Prior authorization and coverage policy created
May 2014	Coverage policy updated

REFERENCES

- DRUGDEX®, accessed 08/01/2013, 09/07/20135/11/2014.
- Product Information: Tafinlar® (dabrafenib), capsules for oral use. GlaxoSmithKline, Research Triangle Park, NC, 5/2013, 1/2014.