POLICY NUMBER UM ONC_1341	SUBJECT Vizimpro™ (dacomitinib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 10/10/18, 10/09/19, 12/11/19	APPROVAL DATE December 11, 2019	EFFECTIVE DATE December 11, 2019	COMMITTEE APPROVAL DATES (latest version listed last) 10/10/18, 10/09/19, 12/11/19	
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 Vizimpro (dacomitinib) usage in the treatment of cancer.

II. DEFINITIONS

Vizimpro (dacomitinib): is an irreversible inhibitor of the kinase activity of the human EGFR family (EGFR/HER1, HER2, and HER4) and certain EGFR activating mutations (exon 19 deletion or the exon 21 L858R substitution mutation). Dacomitinib also inhibited the in-vitro activity of DDR1, EPHA6, LCK, DDR2, and MNK1 at clinically relevant concentrations

Vizimpro (dacomitinib) is FDA approved for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

Vizimpro (dacomitinib) is available in 15 mg. 30 mg, and 45 mg tablets.

III. POLICY

New Century Health is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century Health may be deemed as not approvable and therefore not reimbursable. Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

Inclusion Criteria: Vizimpro (dacomitinib) may be considered medically necessary when any of the following selection criteria are met:

1. **Non-Small Cell Lung Cancer**
    a. The member has advanced NSCLC with presence of EGFR activating mutations with exon 19 deletion or the L858R mutation in exon 21 **AND**
    b. Vizimpro (dacomitinib) is being used as first line treatment or greater than 12 months from completion of last treatment **OR**
    c. As continuation therapy following disease progression on dacomitinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions.

Exclusion Criteria: Vizimpro (dacomitinib) is not considered medically necessary when any of the following selection criteria are met:

1. Concurrent use with other systemic therapy.
2. Dosing exceeds single dose limit of 45 mg.
3. Treatment exceeds the maximum limit of 90 (15 mg) or 30 (30 mg/45 mg) tablets/month.

4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

IV. PROCEDURE

Requests for Vizimpro (dacomitinib) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. **Dosage and Administration:** 45 mg orally once daily with or without food at the same time each day until disease progression or unacceptable toxicity occurs.
2. **Dosage Adjustments:**
    a. Mild to moderate impairment (CrCl 30 to 89 mL/min estimated by Cockcroft-Gault): No dose adjustment necessary
    b. Mild impairment (total bilirubin ULN or less with AST greater than ULN or total bilirubin greater than 1 to 1.5 times ULN with any AST): No dose adjustment necessary.
    c. Moderate impairment (total bilirubin greater than 1.5 to 3 times ULN with any AST): No dose adjustment necessary.
    d. Dermatologic adverse reaction (Grade 2): Withhold for persistent dermatologic adverse reaction until recovery to Grade 1 or less, then resume at the same dose level; for recurrent persistent grade 2 dermatologic adverse reaction, withhold until recovery to Grade 1 or less, then resume at a reduced dose (first dose reduction, 30 mg once daily; second dose reduction, 15 mg once daily).
    e. Dermatologic adverse reaction (Grade 3 or 4): Withhold until recovery to Grade 1 or less, then resume at a reduced dose (first dose reduction, 30 mg once daily; second dose reduction, 15 mg once daily).
    f. Diarrhea Grade 2: Hold dacomitinib therapy and promptly initiate anti-diarrheal treatment (e.g., loperamide or diphenoxylate hydrochloride with atropine sulfate). Resume treatment at the same dose level upon recovery to grade 1 or less. For recurrent grade 2 diarrhea, hold dacomitinib until recovery to grade 1 or less and then resume treatment at a reduced dose (first dose reduction, 30 mg; second dose reduction, 15 mg).
    g. Diarrhea Grade 3 or 4: Hold dacomitinib therapy and promptly initiate anti-diarrheal treatment (e.g., loperamide or diphenoxylate hydrochloride with atropine sulfate). Resume treatment at a reduced dose upon recovery to grade 1 or less (first dose reduction, 30 mg; second dose reduction, 15 mg).
    h. Interstitial Lung Disease (ILD) / Pneumonitis: Any Grade: Permanently discontinue dacomitinib therapy.
3. **Monitoring:**
    a. Evidence of disease response or stabilization is indicative of efficacy.
    b. Select patients for treatment using an FDA-approved test for the detection of EGFR mutations in non-small cell lung cancer.
    c. Verify the pregnancy status of females of reproductive potential prior to initiating therapy.
    d. Monitor patients for pulmonary symptoms indicative of interstitial lung disease or pneumonitis.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Vizimpro PI prescribing information. U.S. Pharmaceuticals, New York, NY 2010.
2. Clinical Pharmacology Elsevier Gold Standard. 2010.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2010.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2010.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2010.