

## DRUG POLICY

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# Ibuprofen™ (taletrectinib)

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-Approved Indications

Treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)

### Compendial Uses

NSCLC, recurrent, advanced or metastatic ROS1 rearrangement-positive tumors

## POLICY

### Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. ROS1 status (where applicable)

### Criteria for Initial Approval

#### **Non-Small Cell Lung Cancer (NSCLC)**

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic ROS1-positive non-small cell lung cancer as a single agent.

### Continuation of Therapy

#### **Non-Small Cell Lung Cancer (NSCLC)**

Authorization of 12 months may be granted for continued treatment of ROS1-positive non-small cell lung cancer (NSCLC) in members requesting reauthorization when there is no evidence of unacceptable toxicity while on the current regimen.

Ibuprofen (taletrectinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

#### Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

#### Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Ibuprofen (taletrectinib) 200 mg capsules	90 capsules per 30 days	600 mg orally once daily  <b>Dose adjustments due to adverse reactions:</b> <ul style="list-style-type: none"><li>• First dose reduction: 400 mg once daily</li><li>• Second dose reduction: 200 mg once daily</li></ul> <i>Permanently discontinue in patients unable to tolerate 200 mg once daily.</i>

## PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

## REFERENCES

Ibuprofen [package insert]. Burlington, MA: Nuvation Bio Inc.; June 2025.

The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed June 23, 2025.

## POLICY HISTORY

**Policy #:** 05.05.98

**Original Effective Date:** September 25, 2025

**Reviewed:**

**Revised:**

**Current Effective Date:** September 25, 2025