PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – ROS1 Inhibitor) – Ibtrozi Prior Authorization Policy
- Ibtrozi™ (taletrectinib capsules – Nuvation Bio)

REVIEW DATE: 06/18/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Ibtrozi is indicated for the treatment of locally advanced or metastatic ***ROS1*-positive** non-small cell lung cancer (**NSCLC**) in adults.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on NSCLC (version 5.2025 – June 20, 2025) recommends Ibtrozi, Augtyro™ (repotrectinib capsules), Rozlytrek® (entrectinib capsules and oral pellets), and Xalkori® (crizotinib capsules and oral pellets) as "Preferred" first-line options (all category 2A). NCCN notes that Ibtrozi, Rozlytrek, or Augtyro may be better for patients with brain metastases. For subsequent therapy, Ibtrozi (if not previously given), Augtyro (if not previously given) or Lorbrena® (lorlatinib tablets) are recommended (all category 2A). For symptomatic progression to the brain, Ibtrozi, Augtyro, or Lorbrena (all "Preferred"), or Rozlytrek (useful in certain circumstances, if previously treated with

Xalkori), or clinical trial is recommended. Augtyro or Ibtrozi is noted as an option for resistant mutations, such as *ROS1* G2032R.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ibtrozi. All approvals are provided for the duration noted below.

- **Ibtrozi™ (taletrectinib capsules – Nuvation Bio)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has locally advanced or metastatic disease; AND
   C) Patient has *ROS1*-positive non-small cell lung cancer; AND
   D) The mutation was detected by an approved test.

CONDITIONS NOT COVERED

Ibtrozi™ (taletrectinib capsules – Nuvation Bio)
is(are) considered not medically necessary for ANY other use(s). Criteria will be updated as new published data are available:

REFERENCES

1. Ibtrozi™ capsules [prescribing information]. Burlington, MA: Nuvation Bio Inc.; June 2025.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2025 – June 20, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 22, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/18/2025