Patient portrayal.

Coverage Guide

This resource is designed to help healthcare professionals secure access to JIDEYTRO™ for prescribed patients. It includes guidance on prior authorization submissions, appeal considerations, and billing and coding information.

Guiding a Path to Treatment

Nuvalent Patient Support can help patients prescribed JIDEYTRO with treatment initiation and continued access to therapy by:

- Navigating insurance requirements
- Identifying financial assistance resources
- Providing education about therapy and medication dispensing

This guide is for informational purposes only. It is not intended to provide clinical information or to substitute the clinical decisions of a prescriber. It is the responsibility of the healthcare provider to determine the correct diagnosis, treatment, and supporting documentation included in any submissions to insurance providers. Nuvalent does not guarantee coverage or reimbursement for the product.

Please see Important Safety Information on pages 6-8 and full Prescribing Information.

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Prior Authorizations

Your patient's insurance provider may require that you submit a prior authorization (PA) request to demonstrate the patient's medical need for JIDEYTRO (zidesamtinib) to approve coverage.

Submitting a PA request

It is important to review the plan's policy for JIDEYTRO for approval criteria and required information to submit with the PA request. Nuvalent Patient Support can conduct a benefits verification to help identify required information and provide patient-specific coverage information, including whether a prior authorization may be required. Verification of benefits is not a guarantee of payment and does not take the place of written policy information. Healthcare professionals should carry out their own benefits investigation, as necessary.

To support your request for coverage, you can submit a Letter of Medical Necessity or a Letter of Medical Exception to the insurance company.

Letter of Medical Necessity (LMN)

If JIDEYTRO is not on a plan's formulary, you may choose to include an LMN to support your submission for approval of coverage. Some plans may also require the submission of an LMN according to their policy for JIDEYTRO.

To download a guide and Sample LMN template for JIDEYTRO, visit NuvalentPatientSupport.com/jideytro/hcp-resources

Letter of Medical Exception (LME)

If JIDEYTRO is on the plan's formulary, but your patient does not meet all policy requirements for JIDEYTRO (e.g., step therapy), you may choose to submit an LME to justify an exception to specific policy requirements.

To download a guide and Sample LME template for JIDEYTRO, visit NuvalentPatientSupport.com/jideytro/hcp-resources

Prior Authorizations (continued)

Tips for a PA Submission

Include detailed evidence to support your clinical judgment with your initial submission. This can help to avoid delays in your patient's treatment due to a denial citing missing information.

- **Review plan-specific requirements** so you are prepared beforehand
- **Consider including** all relevant clinical information (such as chart notes, biomarker results, and treatment history) and JIDEYTRO (zidesamtinib) clinical data, including efficacy and safety, in your submission to support medical necessity
- Ensure the prescription, diagnosis, dosing, and supporting clinical information are **current and consistent** (see page 5 for information on billing codes)
- **Complete all required fields** to prevent any delays

Post PA Submission

After the plan has reviewed your request for PA, you will receive one of the following plan decisions:

Approval

Request for additional information

Denial

The plan will provide direction for potential next steps if approval was not granted and directions on how to appeal the decision. Please see page 4 for more information on appeals.

Appeals

If your patient's insurance provider denies coverage for JIDEYTRO (zidesamtinib), you can submit an appeal of their original decision.

Reasons for Denial

Common reasons an insurance provider may deny coverage include:

The initial request for JIDEYTRO coverage did not include the required clinical documentation, such as biomarker status and laboratory results. Documentation must support that a *ROS1* fusion was detected on the biomarker panel

Note: *Include all of the information that the denial lists as missing from the original submission. If you need help identifying what information to include in the appeal, contact Nuvalent Patient Support.*

The patient does not meet the plan's criteria for approval, such as failure of other treatments required before initiation of JIDEYTRO

Note: *You may want to ensure your appeal includes your clinical rationale, including efficacy and safety, for why step therapy with other treatments is not appropriate for your patient*

JIDEYTRO is not on the plan's formulary

Note: *Consider submitting a formulary exception request (see page 2 for more information on a Letter of Medical Exception) that includes the patient's clinical history, your clinical rationale for the requested therapy, and an explanation of why formulary alternatives are not appropriate for the patient*

Appeal Considerations

When submitting an appeal, you may consider including a **Letter of Appeal (LOA)** to respond to the specific reason for denial, as well as:

- All information included in the initial submission
- Any information that may have previously been excluded
- Any new information that has emerged since your initial request (e.g., laboratory results, clinical trial data for JIDEYTRO, failure of therapy)

To download a guide and sample LOA template for JIDEYTRO, visit NuvalentPatientSupport.com/jideytro/hcp-resources

Before you file an appeal, you can request that the payer perform an **internal peer-to-peer review**. If a payer issues a final decision to deny after you appeal, you may request an **external third-party review.** We recommend that you include the most up-to-date JIDEYTRO Prescribing Information with the appeal submission.

Visit **JIDEYTROhcp.com** for more information about JIDEYTRO.

Billing and Coding Overview

When preparing a claim for JIDEYTRO (zidesamtinib), it is important to ensure that the appropriate product and diagnosis codes are included in your submission.

Product Codes

PRODUCT	NDC	PACKAGING
	The NDCs for JIDEYTRO are listed below	
JIDEYTRO 25 mg	11-digit: 85001-0101-01	1 bottle (30 tablets)
JIDEYTRO 100 mg	11-digit: 85001-0102-01	1 bottle (30 tablets)

Potential Diagnosis Codes

ICD-10-CM CODES	DESCRIPTION
C34.00-C34.02	Malignant neoplasm of main bronchus
C34.10-C34.12	Malignant neoplasm of upper lobe, bronchus, or lung
C34.2	Malignant neoplasm of middle lobe, bronchus, or lung
C34.30-C34.32	Malignant neoplasm of lower lobe, bronchus, or lung
C34.80-C34.82	Malignant neoplasm of overlapping sites of bronchus and lung
C34.90-C34.92	Malignant neoplasm of unspecified part of bronchus or lung

Please note: Appropriate codes may differ for each patient and payer. The list of codes presented above is not comprehensive. Selection of the appropriate diagnosis and product codes is the responsibility of the prescriber.

Nuvalent Patient Support is available to provide access support for you and your patients. To enroll your patients, please call **(844) 688-5333**, Monday through Friday, 8 AM to 8 PM ET or visit **NuvalentPatientSupport.com**.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

Please see Important Safety Information on pages 6-8 and full Prescribing Information.

Nuvalent PATIENT SUPPORT

Jideytro™ (zidesamtinib) | 25 mg 100 mg tablets

INDICATION and IMPORTANT SAFETY INFORMATION

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS:

Warnings and Precautions reflect the pooled safety population (N=446) who received JIDEYTRO at a dose of 100 mg orally once daily until disease progression or unacceptable toxicity in ARROS-1.

Central Nervous System (CNS) Adverse Reactions (AR):

- Dizziness, ataxia, cognitive and psychiatric disorders occurred in 25% of patients; of these, 2.5% were Grade 3 or 4. One patient (0.2%) with brain metastases experienced a Grade 3 seizure.
- Dizziness, including vertigo, presyncope, and positional dizziness, occurred in 12% of patients; of these, 0.2% were Grade 3. Dosage interruption for dizziness was required in 0.4% and dose reduction in 0.7% of patients.
- Ataxia, including gait disturbance and balance disorder, occurred in 2% of patients; all were Grade 1 or 2.
- Cognitive impairment occurred in 9% of patients; of these, 1.6% were Grade 3 or 4. Cognitive impairment included memory impairment (3.1%), cognitive disorder (1.6%), hallucination (1.1%), delirium (1.1%), aphasia (0.9%), amnesia (0.7%), confusional state (0.7%), anterograde amnesia (0.2%), disturbance in attention (0.4%), and slow speech (0.2%). Dose interruption for cognitive impairment was required in 1.3% of patients.
- Psychiatric disorders occurred in 6% of patients; of these, 0.7% were Grade 3 or 4. Psychiatric disorders included anxiety (3.1%), depression (1.3%), agitation (0.7%), affect lability (0.4%), irritability (0.4%), abnormal behavior (0.2%), depressed mood (0.2%), personality change (0.2%), psychotic disorder (0.2%), and suicidal ideation (0.2%). Dosage interruption for psychiatric disorders was required in 0.9% of patients.
- Advise patients to avoid engaging in hazardous tasks requiring mental alertness and motor coordination, such as operating machinery or driving a motor vehicle if they are experiencing CNS reactions.
- Monitor patients for CNS adverse reactions and suicidal thoughts and behaviors during treatment with JIDEYTRO. Withhold and then resume at the same or reduced dose upon improvement or permanently discontinue JIDEYTRO based on severity.

QTc Interval Prolongation:

- JIDEYTRO can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (e.g., torsades de pointes) or sudden death. JIDEYTRO has not been studied in patients with a history of QTcF >450 msec on more than one assessment prior to initiation.
- Of the 435 patients who underwent at least one post-baseline electrocardiogram (ECG) assessment, 2% experienced an increase in QTcF of >60 msec compared to baseline after receiving JIDEYTRO and 0.2% increase in QTcF to >500 msec. QTc prolongation led to dose interruption in 0.4% of patients.

Nuvalent PATIENT SUPPORT

Jideytro™ (zidesamtinib) | 25 mg 100 mg tablets

IMPORTANT SAFETY INFORMATION (CONT'D)

QTc Interval Prolongation (cont'd):

- Evaluate ECGs and electrolytes prior to administration of JIDEYTRO and monitor periodically during treatment. Adjust the frequency of monitoring based on risk factors such as known long QT syndromes, clinically significant bradyarrhythmias, severe or uncontrolled heart failure, and concomitant medications associated with QTc interval prolongation.
- Withhold, then resume at the same or reduced dose, or permanently discontinue JIDEYTRO based on severity

Interstitial Lung Disease (ILD)/Pneumonitis:

- JIDEYTRO can cause severe or life-threatening ILD or pneumonitis.
- ILD/pneumonitis occurred in 1.8% of patients, including Grade 3 or 4 in 0.4%.
- ILD/pneumonitis led to dose interruption in 0.7%, dose reduction in 0.2%, and permanent discontinuation in 0.4% of patients.
- Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold JIDEYTRO in patients with suspected ILD/pneumonitis, then upon recovery resume at the same or reduced dose or permanently discontinue based on severity.

Skeletal Fractures:

- JIDEYTRO can increase the risk of skeletal fractures.
- Five patients (1.1%) experienced skeletal fractures. Grade 3 ankle fractures occurred in two patients (0.4%). Dose interruptions for fractures occurred in 0.4% of patients.
- Promptly evaluate patients with signs or symptoms of fractures.

Myalgia with Creatine Phosphokinase (CPK) Elevation:

- JIDEYTRO can cause myalgia with creatine phosphokinase (CPK) elevation.
- Myalgia occurred in 13% of patients. Based on laboratory values, concurrent myalgia with increased CPK occurred in 2.1% of patients.
- Advise patients to report unexplained muscle pain or tenderness. Monitor serum CPK levels prior to administration of JIDEYTRO and every 2 weeks during the first month of treatment and then every 1 to 2 months and as clinically indicated in patients reporting unexplained muscle pain or tenderness. Withhold, then resume JIDEYTRO at the same or reduced dose, or permanently discontinue JIDEYTRO based on severity.

Pancreatic Toxicity:

- JIDEYTRO can cause pancreatic toxicity. In the pooled safety population, among the subgroup of patients who underwent pancreatic lab testing, increased amylase and lipase levels occurred in 22%, and 25% respectively, with Grade 3 increased lipase in 8% of patients. Grade 3 lipase elevation resulted in JIDEYTRO dose reduction in one patient. In the pooled safety population, Grade 3 pancreatitis occurred in one patient (0.2%).
- Evaluate amylase and lipase prior to administration of JIDEYTRO and monitor periodically during treatment. Based on the severity of the adverse reaction, temporarily withhold, reduce the dose, or permanently discontinue JIDEYTRO.

Please see Full Prescribing Information.

Nuvalent PATIENT SUPPORT

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IMPORTANT SAFETY INFORMATION (CONT'D)

Embryo-Fetal Toxicity:

- Based on literature reports in humans with congenital mutations leading to changes in tropomyosin receptor kinase (TRK) signaling, findings from animal studies and its mechanism of action, JIDEYTRO can cause fetal harm when administered to a pregnant woman.
- Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 6 months after the last dose.
- Advise male patients with female partners of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 3 months after the last dose.

ADVERSE REACTIONS:

- The most common adverse reactions (≥15%) were edema, peripheral neuropathy, constipation, fatigue, and dyspnea.
- The most common Grade 3 or 4 laboratory abnormalities (≥2%) were increased lipase, increased CPK, increased triglycerides, decreased lymphocytes, and decreased hemoglobin.
- Clinically relevant adverse reactions in <10% of patients receiving JIDEYTRO were cognitive disorders, psychiatric disorders, stomatitis, ataxia, ILD/pneumonitis, QTc prolongation, pancreatitis, and ankle fracture.

DRUG INTERACTIONS:

Strong and Moderate CYP3A Inhibitors:

- Avoid concomitant use of JIDEYTRO with a strong or moderate CYP3A inhibitor as this could increase JIDEYTRO exposure, which may increase the risk of JIDEYTRO adverse reactions.

Strong and Moderate CYP3A Inducers:

- Avoid concomitant use of JIDEYTRO with strong or moderate CYP3A inducers as this could decrease JIDEYTRO exposure, which may decrease the effectiveness of JIDEYTRO.

INDICATION

JIDEYTRO™ (zidesamtinib) is indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who received a prior ROS1 kinase inhibitor.

Please see Full Prescribing Information.

To learn more about Nuvalent Patient Support and its offerings, please visit **NuvalentPatientSupport.com**.

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