

## Ziihera

Thailand · access guide

# Ziihera access in Thailand: the Thai FDA named-patient pathway

Last reviewed 2026-05-18 by Reserve Meds clinical and regulatory team.

## Quick orientation

Patients in Thailand access Ziihera (zanidatamab-hrii) for previously treated unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC) through the Thai FDA named-patient pathway, a the Thai Food and Drug Administration of the Ministry of Public Health-administered mechanism that allows a Thai-licensed physician at a registered facility to import the FDA-labelled product for a specific named patient. This page details the documentation, approval timeline, and real cost in THB.

## Why Thai patients need Ziihera through the named-patient pathway

The Kingdom of Thailand operates a structured pharmaceutical regulatory environment. Ziihera (zanidatamab-hrii) is regulated through Thai FDA (the Thai Food and Drug Administration of the Ministry of Public Health) channels, and a Thai family asking for Ziihera is rarely asking for a medicine that does not exist locally. They are usually asking for a precise version of it that the local market has not caught up to.

Four converging patterns drive these cases. First, indication lag. Ziihera's newer FDA-approved indications and dosing expansions often reach local registration 12 to 36 months after the US label. A family whose treating physician has documented a clear FDA-label fit may still find that the local label has not caught up. Second, presentation gaps. The exact strength, weight-banded dose, or pen format the prescriber needs may not be stocked at the local agent even when the medicine is registered. Third, payer denial. The Universal Coverage Scheme (UCS) administered by the National Health Security Office, the Civil Servant Medical Benefit Scheme (CSMBS), the Social Security Scheme (SSS), and the major private insurers including Bupa Thailand, AXA Insurance Thailand, Allianz Ayudhya, and AIA Thailand each assess specialty therapies case by case, and step-therapy or formulary rules often produce denials even when the drug is on the local register. Cash-pay families pursue cross-border supply rather than wait through appeals. Fourth, continuity of supply. When a US-stable patient relocates to Thailand or visits family for an extended period, maintaining the original FDA-sourced regimen matters more than switching to a different local presentation.

In each pattern, the Thai FDA named-patient pathway is the mechanism that connects a Thai-licensed physician's clinical decision with US-sourced, FDA-labeled product for a specific patient. Clinically, Ziihera is a humanized HER2-targeted bispecific antibody that binds two non-overlapping epitopes (ECD2 and ECD4) of HER2, administered by IV infusion every two or three weeks, and the named-patient route preserves that mechanism rather than substituting a non-equivalent local option.

## **The Thai FDA named-patient pathway for Ziihera**

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The pathway for a Thai-licensed physician to obtain a medicine that is not registered or not stocked locally is the Special Access Scheme (SAS) named-patient import authorisation administered by the Thai Food and Drug Administration (Thai FDA) of the Ministry of Public Health under the Drug Act B.E. 2510 (1967) and subsequent amendments, which allows a treating physician at a registered tertiary facility to apply for the import of an unregistered medicine for a specific named patient where the medicine is approved by a recognised reference authority and no clinically equivalent locally registered alternative is suitable; in practice the import is routed through a Thai-licensed importer-pharmacist with the Thai FDA issuing the per-patient import permit. The framework allows registered healthcare facilities to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. For Ziihera specifically, the clinical justification typically frames the case around the precise FDA-approved indication and the documented gap in the local route.

A complete application includes a clinical justification letter from the treating physician (diagnosis, severity, prior therapies, why this specific drug, why the locally stocked option is not suitable for this case), the treating physician's Thai medical license verification through the Medical Council of Thailand and the Thai FDA, an anonymised patient identifier where the Thai FDA submission allows, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity requested, intended treatment duration), the destination dispensing facility name, license number, and pharmacy in charge, and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy.

For Ziihera, the clinical justification angle typically rests on one or more of three documented elements: a pediatric or weight-banded request that fits the FDA label but not the local label, a denied biologic or specialty claim where prior step-therapy has been documented, or a continuity-of-supply request for a patient previously stabilised on the US-sourced presentation. The treating physician documents the relevant clinical criteria for the prescribed indication: severity scores, biomarker levels, prior therapy failures, and the rationale for Ziihera versus the next-in-line local alternative.

Approval timelines for routine cases are typically 10 to 25 business days. Complex cases (rare indication, larger quantities, first import of a given pediatric or weight-banded format) can extend to 6 to 10 weeks. Thai FDA retains discretion on timing, and we do not promise specific durations.

## **Where Ziihera gets dispensed in Thailand**

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A small group of Thai institutions handle named-patient imports as established workflow, with in-house import pharmacy infrastructure and physicians experienced with the application set. Tertiary and major private hospitals that meet this profile include Bumrungrad International Hospital in Bangkok, Bangkok Hospital (the Bangkok Dusit Medical Services flagship), and Samitivej Sukhumvit Hospital in Bangkok. Each maintains pharmacy infrastructure appropriate to the storage requirements of the imported medicine (2 to 8 degrees Celsius cold-chain for biologics, ambient storage for oral therapies, ultra-cold or specialised handling where the FDA label requires it).

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a specialty importer that holds a pharmaceutical establishment license and files the Thai FDA application on the prescribing physician's behalf. The medicine then moves into the prescribing hospital's outpatient or specialty pharmacy under chain-of-custody documentation.

## **Real cost picture for Ziihera in Thailand**

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US WAC for Ziihera runs in the range of USD 276,000 to USD 324,000 per year at the standard FDA-labelled regimen for previously treated unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC). THB is trading at approximately 35.5 THB to 1 USD, so the annual reference range converts to roughly THB 9,798,000 to THB 11,502,000 for the drug itself at US WAC equivalents.

International logistics for shipment to Thailand typically runs USD 350 to USD 1300 depending on destination city, urgency, and presentation (cold-chain biologics carry the higher end of the range; ambient oral solids the lower). The Kingdom of Thailand customs and Thai FDA permit fees are nominal relative to drug cost. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, the Universal Coverage Scheme (UCS) administered by the National Health Security Office, the Civil Servant Medical Benefit Scheme (CSMBS), the Social Security Scheme (SSS), and the major private insurers including Bupa Thailand, AXA Insurance Thailand, Allianz Ayudhya, and AIA Thailand each assess named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and many require pre-authorisation. We do not promise coverage from any insurer. US manufacturer copay cards and patient assistance programs do not extend internationally; cross-border patients pay cash or rely on local payer coverage.

## **Typical timeline for Ziihera in Thailand**

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Thai FDA routine processing is typically 10 to 25 business days from a complete filing. International logistics adds 2 to 5 additional days depending on whether the presentation is ambient or cold-chain, the dispensing city, and customs clearance. End-to-end, most routine adult cases complete within 3 to 6 weeks from first complete documentation. Pediatric, weight-banded, or first-import cases can run slightly longer because presentation selection and first-import scrutiny can extend Thai FDA review.

For temperature-sensitive products, the dispensing facility must maintain validated storage with continuous monitoring; the manufacturer's room-temperature excursion runway on the FDA label informs how we plan the shipping lane, and the cold chain is broken only at the dispensing pharmacy under documented control.

When a case is on a clinical clock (a flare, a new diagnosis with an active disease, or a treatment cycle scheduled at the dispensing centre), the practical question is which step controls the timeline. In our experience the binding step is rarely the Thai FDA review itself when the application is filed clean; it is usually documentation completeness on the prescriber's side or, for cold-chain biologics, the dispensing facility's storage and monitoring confirmation. The intake is where we lock the case-team contact, gather the documents in parallel, and start the US sourcing clock so that approval and product land in the same week rather than serially.

## What your physician needs to provide

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For a Thai-licensed specialist prescribing Ziihera through the Thai FDA pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's confirmed diagnosis for previously treated unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC), severity assessment (scoring instrument, biomarker, imaging, or biopsy as appropriate for the indication), prior therapy history including first-line options tried, and a clinical rationale for why Ziihera is the appropriate next step given a humanized HER2-targeted bispecific antibody that binds two non-overlapping epitopes (ECD2 and ECD4) of HER2, administered by IV infusion every two or three weeks.

The letter also specifies the exact dosing plan per the FDA-approved label: starting dose, maintenance dose, route of administration, schedule, and intended duration of therapy. Monitoring plan should reference any baseline laboratory or imaging requirements specific to Ziihera (full blood count, liver function, infection screen, ophthalmology assessment, or pregnancy testing where the FDA label requires it), planned follow-up intervals, and dose-modification criteria for the most common adverse events.

The treating physician's Thai license number, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. For cold-chain or specialty-handling products, the dispensing pharmacy's documented storage protocol and continuous-temperature-monitoring log are part of the chain-of-custody record we share with the importer.

## Common questions about Ziihera in Thailand

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**Will the Universal Coverage Scheme (UCS) administered by the National Health Security Office, the Civil Servant Medical Benefit Scheme (CSMBS), the Social Security Scheme (SSS), and the major private insurers including Bupa Thailand, AXA Insurance Thailand, Allianz Ayudhya, and AIA Thailand cover this?** Each insurer assesses named-patient imports case by case. Some reimburse fully when Ziihera is on their formulary even if not currently stocked, some reimburse a percentage subject to copay, and many require pre-authorization. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

**Is the FDA-approved indication recognised by Thai FDA?** The Thai FDA named-patient pathway exists precisely to permit access when the local registration or stocking lags the FDA label. The application documents the FDA indication, the reference-authority approval, and the local gap; Thai FDA review focuses on the clinical justification rather than re-litigating the FDA decision.

**My physician is licensed in one region and the hospital is in another. Is that fine?** Any Thai-licensed physician practicing in good standing in the jurisdiction of the dispensing facility has signing authority on the clinical justification letter. The Medical Council of Thailand and the Thai FDA verifies the active license; the Thai FDA application records both the prescribing physician and the dispensing facility.

**Can I receive Ziihera at home?** The dispensing facility must be Thai-licensed. The hospital outpatient or specialty pharmacy releases the medicine to you after final verification, and you then administer or self-administer at home where the FDA label permits, after the dispensing pharmacy's training. The cold-chain or controlled-storage handoff ends at the dispensing pharmacy; home storage and any handling protocol are part of your patient onboarding kit.

**What about competitors or alternative therapies in the same class?** Choice of therapy depends on the patient's full phenotype, prior therapy, and the prescriber's judgment. Reserve Meds coordinates whichever medicine the physician has prescribed; we do not substitute, advise on substitution, or promote one brand over another.

## Where Reserve Meds fits in Ziihera cases

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Reserve Meds is a US-based concierge coordinator. We do not replace your treating physician, we do not replace Thai FDA, and we do not replace your dispensing pharmacy. For Ziihera specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated logistics (cold-chain with continuous temperature logging where the FDA label requires it) into Thailand, and assign a single named coordinator through the case. Standard named-patient coordination under our specialty playbook applies. Presentation selection, dose-band confirmation, and patient onboarding for self-administration where applicable are the recurring operational fundamentals we expect for this drug.

Operationally, a typical Ziihera case runs across four parallel tracks. The clinical track is the physician's: justification letter, dosing plan, monitoring schedule, and the next patient-facing follow-up. The regulatory track is the Thai FDA application packaged by the importer; we provide the documentation template, the dispensing facility license check, and the chain-of-custody attestation. The logistics track is the US-side sourcing and the validated international shipment with continuous temperature logging and customs broker coordination. The patient-experience track is the named coordinator who keeps everyone aligned on dates, addresses dispensing-pharmacy questions, and confirms the medicine has been received and stored correctly. The four tracks are run in parallel rather than in series; that is the operational difference between a 3-week and a 9-week case.

### *Reserve Meds's role*

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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### **Reserve Meds**

*reserved for you.*

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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