

USWM CT, LLC Expanded Access Policy

Introduction

USWM CT, LLC (an entity that is part of the US WorldMeds family of companies) is committed to supporting patients and healthcare providers by offering safe, ethical, and compliant pathways for potential access to investigational or approved cell therapy products outside of clinical trials when appropriate. This Expanded Access Policy aligns with the framework and principles reflected in the US WorldMeds corporate Expanded Access Policy available at usworldmeds.com, adapted to the specific products within the USWM CT portfolio.

USWM CT develops and commercializes autologous T-cell therapies for oncology indications. The portfolio currently includes:

- TECELRA (afamitresgene autoleucel) has accelerated approval from the FDA to treat adults with unresectable or metastatic synovial sarcoma.
- letetresgene autoleucel— investigational, clinical stage.
- Uza-cel — investigational, early-stage with no current manufacturing capability.

Expanded Access (EA) refers to the use of an investigational or approved medical product outside a clinical trial when certain criteria are met and when permitted by applicable regulations.

General Principles for Expanded Access

USWM CT evaluates Expanded Access requests according to regulatory requirements and internal policies. Consistent with regulatory frameworks (including FDA guidance), Expanded Access may be considered only when all of the following threshold criteria are met:

- The illness must be serious or life-threatening with no other satisfactory treatment options (such as approved therapies or an enrolling clinical trial).
- The patient is ineligible for, or otherwise unable to participate in, an appropriate clinical trial.
- There is sufficient evidence—based on available clinical and safety data—that the potential benefit to the patient is likely to outweigh potential risks as determined by the requesting physician, subject to review by USWM CT medical personnel.
- USWM CT has the ability to provide product in a fair and equitable manner without compromising manufacturing capacity for ongoing commercial supply or clinical development programs.
- Required starting materials and manufacturing components for the investigational cell therapy are available.
- Granting access will not compromise the integrity or scientific validity of ongoing development programs nor interfere with, delay, or divert resources from current clinical trials or regulatory filings.

All requests must be physician initiated. Regulatory requirements (e.g., FDA IND submissions, IRB approvals, informed consent) must be fulfilled before treatment can be initiated.

Product-Specific Expanded Access Policies

1. Afamitresgene autoleucel (TECELRA)

Afamitresgene autoleucel (also referred to as afami-cel) is an FDA-approved product commercially available in the United States. Expanded Access considerations arise in two categories:

Category A — Commercially Prescribed TECELRA Nonconforming Product

Patients who have been commercially prescribed TECELRA for whom manufacturing results in a product nonconforming to commercial requirements but is appropriate for clinical treatment, and when remanufacturing is not feasible due to supply chain constraints and/or patient health status, may be eligible to receive the nonconforming product through:

- Intermediate Population Expanded Access Protocol, subject to trial status and site participation: <https://clinicaltrials.gov/study/NCT06617572>

OR

- A single patient IND (spIND) or emergency IND (eIND). spIND and eINDs may be sponsored by USWM CT or by individual treating physicians. For USWM CT to serve as an eIND or spIND Sponsor, USWM CT requires patients to consent to participation in its Post Authorization Safety Study for Tecelra to support compliance with eIND/spIND follow up requirements.

This pathway is available to receive product at no charge, consistent with existing USWM CT processes for managing manufacturing non-conformances.

Category B — Patients Unable to Obtain Afami-cel Commercially

Patients who:

- Have a serious or life threatening condition appropriate for afami-cel
- Are not eligible for enrolling in afami-cel clinical trials, and
- Are unable to access TECELRA commercially (e.g., patients in countries where the product is not approved),

may be considered for Expanded Access. However, access to afami-cel for this category is only available on a *for charge* basis. Pricing reflects manufacturing and supply costs associated with individualized cellular therapy.

USWM CT's ability to support international EA/named patient pathway access to afamitresgene autoleucel is subject to country-specific requirements and request mechanisms. Additionally, in areas outside of North America, USWM CT's ability to support access may be limited due to logistics constraints; however, all requests will be assessed for feasibility on a case-by-case basis.

2. Letetresgene autoleucl (Investigational Product)

Letetresgene autoleucl (also referred to as lete-cel) is an investigational T-cell therapy under clinical development. USWM CT supports participation in clinical trials as the preferred route for access.

Where Expanded Access is requested for a patient who:

- Has a serious or life-threatening condition appropriate for lete-cel,
- Is **not eligible** for any enrolling lete-cel clinical trials, and
- Is not a candidate for commercial Tecelra treatment in accordance with its approved labeling, and
- Meets other regulatory prerequisites,

USWM CT may consider providing investigational letetresgene autoleucl through an spIND/eIND, Canadian special access or other international named patient pathway on a *for-charge* basis only, due to manufacturing costs and resource constraints.

USWM CT's ability to support international EA/named patient pathway access to letetresgene autoleucl is subject to country-specific requirements and request mechanisms. Additionally, in geographies outside of North America and Europe, USWM CT's ability to support access may be limited due to logistics constraints; however, all requests will be assessed for feasibility on a case-by-case basis.

3. Uza-cel (Investigational Product)

USWM CT is unable to offer Expanded Access to uza-cel at this time due to manufacturing feasibility.

Request Process

Requests for eIND/spIND, Canadian special access and other international named patient expanded access must be submitted by a licensed treating physician. US requests should be directed to USWM CT Regulatory Affairs at: regulatoryaffairs@usworldmeds.com. International inquiries for access are subject to applicable country-specific regulations and request mechanisms.

USWM CT reviews requests as quickly as feasible, taking into consideration:

- Clinical justification,
- Development stage of the product,
- Manufacturing and operational feasibility,
- Regulatory requirements.

USWM CT reserves the right to decline Expanded Access requests that do not meet the criteria outlined in this policy, that could compromise clinical development programs or are otherwise not feasible from a manufacturing capacity or logistics perspective.

Transparency

USWM CT complies with applicable laws requiring public posting of Expanded Access policies for investigational products.

The company remains committed to responsible, ethical, and patient-focused decision-making regarding the use of its therapies outside of clinical trials.