

kygevvi™

[doxecitine and doxribtimine]

Powder for Oral Solution

2 g/2 g per packet

Getting Patients Started With KYGEVVI

This resource includes an overview of KYGEVVI acquisition and information that may be required for a prior authorization.

The information provided in this guide is of a general nature and for information purposes only. The responsibility to determine coverage and appropriate coding for a particular patient and/or procedure is always that of the provider or physician.

INDICATION

KYGEVVI is indicated for the treatment of thymidine kinase 2 deficiency (TK2d) in adult and pediatric patients with an age of symptom onset on or before 12 years.

IMPORTANT SAFETY INFORMATION

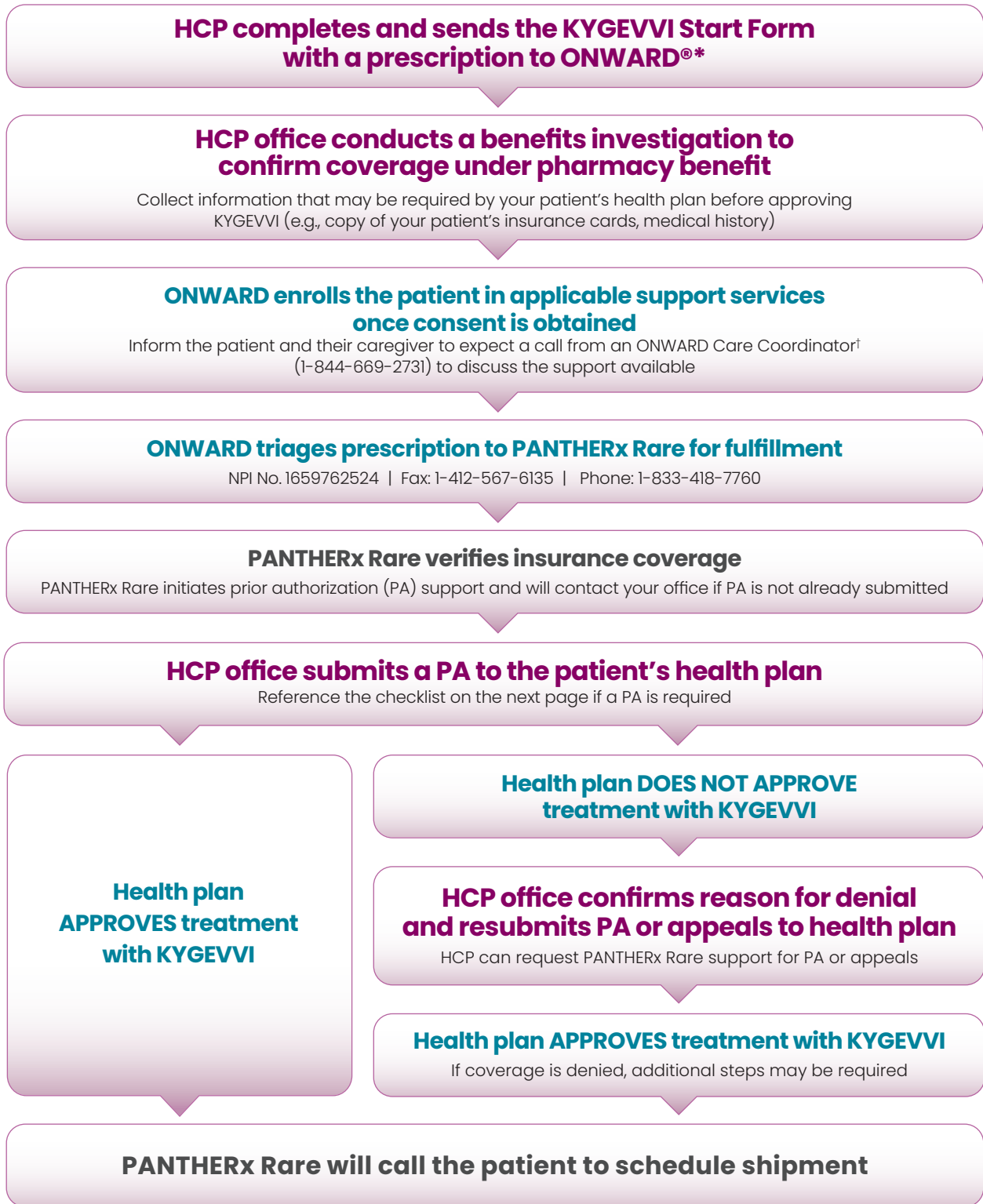
Increase in Liver Transaminases

Elevated liver transaminase [alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST)] levels were reported in patients treated with KYGEVVI. Obtain baseline liver transaminase (ALT, AST) and total bilirubin levels in patients prior to treatment initiation with KYGEVVI. If signs or symptoms consistent with liver injury are observed, interrupt treatment with KYGEVVI until liver transaminase (ALT, AST) and total bilirubin levels have either returned to baseline or stabilized at a new baseline value. Consider permanently discontinuing KYGEVVI if signs or symptoms consistent with liver injury persist or worsen. Monitor liver transaminases and total bilirubin levels yearly and as clinically indicated.

Please see additional Important Safety Information throughout and the full [Prescribing Information](#).

Acquisition Process Overview

KYGEVVI must be obtained through PANTHERx Rare, the exclusive, authorized specialty pharmacy. If applicable, communicate to your patient and their caregiver that KYGEVVI must be obtained from PANTHERx Rare even if their health insurance has a preferred specialty pharmacy. See the flow chart below for a general overview of the process for getting patients started on KYGEVVI.



*The Start Form is used to enroll patients in the ONWARD Patient Support Program for access to important resources and support.

†Please note that when patients receive this call, they may see "ONWARD" on their caller ID.

HCP=healthcare professional; NPI=National Provider Identifier.

Please see Important Safety Information throughout and the full Prescribing Information.

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Prior Authorization Checklist

Your patient's health plan may require a PA before KYGEVVI coverage can be approved. A common reason for coverage denial is incomplete or missing information (see 1-5 below) as indicated on the request form. Contact the patient's payer for requirements and clinical coverage guidelines for KYGEVVI, if available. This checklist is provided as an educational resource regarding potential PA requirements for KYGEVVI.

1 Diagnosis Code^{1,*}

- | | |
|--|---|
| <input type="checkbox"/> E88.40 Mitochondrial metabolism disorder, unspecified | <input type="checkbox"/> E88.49 Other mitochondrial metabolism disorders |
| <input type="checkbox"/> E88.8 Other specified metabolic disorders | <input type="checkbox"/> G71.3 Mitochondrial myopathy, not elsewhere classified |
| <input type="checkbox"/> Z15.89 Genetic susceptibility to other disease | <input type="checkbox"/> Other: _____ |

*An ICD-10-CM code specific to thymidine kinase 2 deficiency (TK2d) is not available. The diagnosis codes provided are informational and are not intended to be directive or a guarantee of reimbursement. Please consult the most recent version of the ICD-10-CM for a full list of codes that may be applicable.

2 Clinical Information

Provide relevant information and supporting documentation regarding age of symptom onset, including chart notes and lab tests.

Patient's age: _____ Age at symptom onset: _____

Baseline functional status: _____

Comorbidities (if any): _____

Confirmed genetic variant(s) in *TK2* gene: Yes No Not known Date of assessment: _____

Include results of additional tests that may have been conducted to confirm TK2d diagnosis. These tests may not be required and can include blood tests, muscle biopsy, brain or skeletal muscle MRI, and electromyography tests.

3 Disease Management History

Include information on medical equipment or devices (e.g., adaptive eating utensils, back braces, breathing support devices, wheelchair/walker) and medications the patient uses to manage symptoms and address muscle weakness.

4 Prescribed Dose²

Initiate with starting dose and titrate up to maintenance dose: 260 mg/kg/day divided equally TID approximately 6 hours apart (plus or minus 2 hours) with food for a minimum of 2 weeks, then increase to 520 mg/kg/day divided equally TID for a minimum of 2 weeks, then increase to 800 mg/kg/day divided equally TID thereafter

Maintenance dose only: 800 mg/kg/day divided equally TID approximately 6 hours apart (plus or minus 2 hours) with food

Other: _____

Route of administration: Oral Feeding tube

Dispense days supply: _____ days Refills: Refill for 1 year Other: _____

5 Reauthorization

If the patient has already been approved for KYGEVVI under this plan, provide documentation demonstrating continued clinical benefit for the patient.

FDA=US Food and Drug Administration; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; MRI=magnetic resonance imaging; PA=prior authorization; TID=three times a day; TK2=thymidine kinase 2 gene.

IMPORTANT SAFETY INFORMATION (cont'd)

Gastrointestinal Adverse Reactions

Diarrhea and vomiting leading to hospitalization, dose reduction, and permanent discontinuation were reported in patients treated with KYGEVVI. Based on the severity of the diarrhea and/or vomiting, reduce the dosage of KYGEVVI or interrupt treatment until diarrhea and/or vomiting improves or returns to baseline. Consider restarting KYGEVVI at the last tolerated dose, and increase the dose as tolerated. For persistent or recurring diarrhea and/or vomiting, consider discontinuing KYGEVVI permanently and provide supportive care with electrolyte repletion as clinically indicated.

Please see additional Important Safety Information throughout and the full Prescribing Information.

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Patient Support for KYGEVVI



Patient Support

If you have questions about enrolling your patients who are receiving KYGEVVI in the ONWARD® Patient Support Program, please visit ucbONWARD.com to access resources for healthcare professionals.

ONWARD is provided as a service of UCB and is intended to support the appropriate use of UCB medicines. ONWARD may be amended or canceled at any time without notice. Some program and eligibility restrictions may apply.

If you have questions or for more information, please contact your Mito Case Manager

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

The most common adverse reactions (incidence $\geq 5\%$) are diarrhea, abdominal pain (including abdominal pain upper), vomiting, alanine aminotransferase increased (ALT), and aspartate aminotransferase increased (AST).

Please see the full [Prescribing Information](#).

For more information about KYGEVVI, visit KYGEVVIhcp.com.

For additional information, contact UCBCares® at 1-844-599-CARE (2273).

References: 1. Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Available at: <https://www.cms.gov/medicare/coding-billing/icd-10-codes>. Accessed November 19, 2025. 2. KYGEVVI [prescribing information]. Smyrna, GA: UCB, Inc.



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