

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Sapropterin dihydrochloride (Zelvysia)

Notes:

- Zelvysia is a branded generic medication.
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Initiation (new start) criteria: Non-formulary **sapropterin dihydrochloride (Zelvysia)** will be covered on the prescription drug benefit when the following criteria are met:

- The prescriber is a metabolic disease specialist or geneticist
- Patient has a diagnosis of phenylketonuria (PKU)
- Patient has documented contraindication, intolerance*, or treatment failure to trial of the preferred generic formulation of sapropterin dihydrochloride.

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary **sapropterin dihydrochloride (Zelvysia)** will be covered on the prescription drug benefit when the following criteria are met:

- The prescriber is a metabolic disease specialist or geneticist
- Patient has a diagnosis of phenylketonuria (PKU)
- Patient has documented contraindication, intolerance*, or treatment failure to trial of the preferred generic formulation of sapropterin dihydrochloride.

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **sapropterin dihydrochloride (Zelvysia)** will be covered on the prescription drug benefit when the following criteria are met:

- The prescriber is a metabolic disease specialist or geneticist
- Patient has a diagnosis of phenylketonuria (PKU)
- Patient has documented contraindication, intolerance*, or treatment failure to trial of the preferred generic formulation of sapropterin dihydrochloride.