

<b>Clinical Policy Title:</b>	sapropterin dihydrochloride
<b>Policy Number:</b>	RxA.842
<b>Drug(s) Applied:</b>	Javygtor™
<b>Original Policy Date:</b>	10/11/2024
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Phenylketonuria (must meet all):

1. Diagnosis of Phenylketonuria;
2. Patient is actively on a phenylalanine-restricted diet.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

### II. Continued Therapy Approval

#### A. Phenylketonuria (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## References

1. Javygtor. Prescribing Information. Princeton, NJ; Dr. Reddy's Laboratories Inc.,. May 2022. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=eecdd8c7-5f8a-0af1-793a-db2e2ba0f491&type=display#section-15>. Accessed October 11, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	10/11/2024	12/05/2024
Policy reviewed.	12/11/2025	12/11/2025

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.