Pharmacy Drug Policy & Procedure

Policy Name:	Orfadin, Nityr, and nitisinone	Policy #:	2450P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Orfadin, Nityr, and nitisinone.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Orfadin or Nityr under the Specialty Pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Hereditary Tyrosinemia type 1

1.1 Diagnosis of hereditary tyrosinemia type 1 confirmed by diagnostic/DNA testing

1.2 Orfadin or Nityr will be used in addition to dietary restriction of tyrosine and phenylalanine

1.3 Coverage of Orfadin capsules requires previous trial with equivalent generic nitisinone capsules

2. Approval Time

2.1 Initial: 12 months

2.2 Reapproval: 12 months if

- Dietary restrictions of tyrosine and phenylalanine are continued
- Member is compliant with Orfadin or Nityr regimen

CPT Codes

HCPCS Codes

References

1. Nityr (nitisinone) [prescribing information]. Cambridge, UK: Cycle Pharmaceuticals; January 2024.
2. Orfadin (nitisinone) [prescribing information]. Waltham, MA: Sobi Inc; November 2021.
3. Bartlett DC, Lloyd C, McKiernan PJ, Newsome PN. Early nitisinone treatment reduces the need for liver transplantation in children with tyrosinaemia type 1 and improves post-transplant renal function. J Inherit Metab Dis 2014; 37:745.
4. Larochelle J, Alvarez F, Bussières JF, et al. Effect of nitisinone (NTBC) treatment on the clinical course of hepatorenal tyrosinemia in Québec. Mol Genet Metab 2012; 107:49.
5. Chinsky JM, Singh R, Ficicioglu C, et al. Diagnosis and treatment of tyrosinemia type I: a US and Canadian consensus group review and recommendations. Genet Med 2017; 19

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.