Clinical Policy Title:	nitisinone
Policy Number:	RxA.238
Drug(s) Applied:	Nityr®, Orfadin® nitisinone
Original Policy Date:	02/07/2020
Last Review Date:	12/05/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Hereditary Tyrosinemia Type 1 (must meet all):

1. Diagnosis of hereditary tyrosinemia type 1;
2. Diagnosis confirmed by one of the following (a or b):
   a. Biochemical testing confirms elevated levels of succinylacetone in the urine or blood;
   b. Genetic testing confirms a mutation of the FAH gene;
3. Medication prescribed as an adjunct to dietary restriction of tyrosine and phenylalanine.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Hereditary Tyrosinemia Type 1 (must meet all):

1. Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
2. Medication prescribed as an adjunct to dietary restriction of tyrosine and phenylalanine.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Chinsky JM, Singh R, Ficicioglu C, et al. Diagnosis and treatment of tyrosinemia type I: a US and Canadian consensus group review and recommendations. Genetics in Medicine. 2017. Dec; 19(12). Available at: https://pubmed.ncbi.nlm.nih.gov/28771246/. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving	07/30/2020	09/14/2020

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.

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medication that has been authorized by RxAdvance..." 5. References were updated.		
Policy was reviewed: 1. Updated initial criteria for approval and duration of approval. 2. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 3. References were reviewed and updated.	02/24/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria I.A.3 and Continued Approval Criteria II.A.3 were updated to add, Request is for use as an adjunct to dietary restriction of tyrosine and phenylalanine. 2. References were reviewed and updated.	01/07/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Member has a clinical diagnosis of HT-1 confirmed by biochemical testing (e.g., detection of succinylacetone in the urine or blood), enzyme assay, or genetic testing to Diagnosis of HT-1 confirmed by one of the following (a or b): a. Biochemical testing confirms elevated levels of succinylacetone in the urine or blood; b. Genetic testing confirms a mutation of the FAH gene; 2. References were reviewed and updated.	12/28/2022	04/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed prescriber restrictions. 2. Removed dose restrictions. 3. Updated Continued therapy approval with the new verbiage containing 120 days lookback period. 4. Removed reauthorization requirement for positive response to therapy. 5. Updated approval duration verbiage. 6. Reference was reviewed and updated.	08/28/2024	9/13/2024
Policy was reviewed.	12/05/2024	N/A

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