



# PRIOR AUTHORIZATION REQUEST

## NITISINONE

### Patient Information:

Name:	
Member ID:	
Address:	
City, State, Zip:	
Date of Birth:	

### Prescriber Information:

Name:	
NPI:	
Phone Number:	
Fax Number:	
Address:	
City, State, Zip:	

### Requested Medication

Rx Name:	
Rx Strength:	
Rx Quantity:	
Rx Frequency:	
Rx Route of Administration:	
Diagnosis and ICD Code:	

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll-free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

**SECTION A:** Please note that supporting clinical documentation is required for ALL PA requests. Pharmacy prior authorization reviews can be subject to trial with additional medications that are not listed within the criteria. The policies are subject to change based on COMAR requirements, MDH transmittals and updates to treatment guidelines.

1	Is this request for an INITIAL or a CONTINUATION of therapy?	
	<input type="checkbox"/> Initial (If checked, go to 7)	
	<input type="checkbox"/> Continuation (If checked, go to 2)	
2	Is the patient currently receiving the requested medication? [If no, skip to question 7.]	Yes      No

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3	Has the patient been receiving medication samples of the requested medication? [If yes, skip to question 7.]	Yes	No
4	Does the patient have a previously approved prior authorization (PA) on file with the current plan? [Note: If the patient does NOT have a previously approved PA on file for the requested medication with the current plan, the renewal request will be considered under initial therapy.] [If no, skip to question 7.]	Yes	No
5	Has the patient been established on therapy for AT LEAST 3 months? [If no, skip to question 7.]	Yes	No
6	Has documentation been submitted to confirm that the patient has had a significant response to therapy, as determined by the provider? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
7	What medication is being requested?  <input type="checkbox"/> Nitisinone (If checked, go to 9)  <input type="checkbox"/> Orfadin, Nityr, Harliku (If checked, go to 8)		
8	Has the patient tried treatment with generic nitisinone (for at least 3 months), which was found to be ineffective, contraindicated, or not tolerated? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
9	What is the indication or diagnosis?  <input type="checkbox"/> Hereditary tyrosinemia type 1 (If checked, go to 10)  <input type="checkbox"/> Alkaptonuria (AKU), Homogentisate 1,2-dioxygenase deficiency, Reduction of urine homogentisic acid (If checked, go to 13)  <input type="checkbox"/> Other (If checked, no further questions)		
10	According to the prescriber, has genetic testing confirmed a mutation of the <i>FAH</i> gene? [If yes, skip to question 12.]	Yes	No
11	According to the prescriber, does the patient have elevated serum levels of alpha-fetoprotein (AFP) and succinylacetone? [If no, no further questions.]	Yes	No
12	Is the requested medication prescribed in conjunction with a tyrosine- and phenylalanine-restricted diet?	Yes	No

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[No further questions.]

- |    |  |     |    |
|----|--|-----|----|
| 13 | Is the patient greater than or equal to 18 years of age?<br>[If no, no further questions.]   | Yes | No |
| 14 | Has documentation been submitted to show urinary homogentisic acid (HGA) excretion greater than 0.4 g/24 hours, consistent with alkaptonuria (AKU)?<br>ACTION REQUIRED: Submit supporting documentation.<br>[If no, no further questions.]                     | Yes | No |
| 15 | Has documentation been submitted to show genetic testing that confirms biallelic pathogenic or likely pathogenic variants in the homogentisate 1,2 dioxygenase (HGD) gene? ACTION REQUIRED: Submit supporting documentation.<br>[If no, no further questions.] | Yes | No |
| 16 | Will the patient be taking the requested medication in combination with other nitisinone products?<br>[Note: For example, concomitant use of Harliku, Orfadin, generic nitisinone capsules, and/or Nityr.]<br>[If yes, no further questions.]                  | Yes | No |
| 17 | Is the requested medication being prescribed by or in consultation with a metabolic disease specialist, hepatologist, nephrologist, rheumatologist, or another physician experienced in managing HT-1/AKU?   | Yes | No |

***Please document the diagnoses, symptoms, and/or any other information important to this review:***

### **SECTION B:** Physician Signature

PHYSICIAN SIGNATURE

DATE

**FAX COMPLETED FORM TO: 1-833-896-0656**

**Disclaimer:** An authorization is not a guarantee of payment. Member must be eligible at the time services are rendered. Services must be a covered Health Plan Benefit and medically necessary with prior authorization as per Plan policy and procedures.

**Confidentiality:** The information contained in this transmission is confidential and may be protected under the Health Insurance Portability and Accountability Act of 1996. If you are not the intended recipient any use,

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