

SENTARA COMMUNITY PLAN (MEDICAID)

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; fax to 1-800-750-9692. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If the information provided is not complete, correct, or legible, the authorization process can be delayed.

Nitisinone Products

Drug Requested: select ONE drug below

☐ Harliku (nitisinone)	☐ nitisinone capsules (generic Orfadin [®])
☐ Nityr[™] (nitisinone)	☐ Orfadin[®] (nitisinone) capsules/suspension

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

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☐ **DIAGNOSIS: Hereditary Tyrosinemia Type 1 (HT-1)**

☐ **For generic nitisinone, Nityr & Brand Orfadin requests only**

Initial Authorization: 6 months

- ☐ Member must have a diagnosis of hereditary tyrosinemia type 1 (HT-1)
- ☐ Member must be using the prescribed medication as an adjunct to dietary restriction of tyrosine and phenylalanine
- ☐ Member's current patient's plasma tyrosine level is maintained at <500 mcmmol/L (**submit documentation**)
- ☐ A laboratory test documenting baseline urinary or plasma succinylacetone level must have been completed within the last 30 days
- ☐ Member had had a baseline ophthalmologic examination with a normal slit lamp examination
- ☐ A complete blood count was completed within the last 30 days and has been submitted with request
- ☐ **For Nityr and Brand Orfadin capsule requests:** Member must have trial and failure of generic nitisinone capsules (**chart notes documenting clinically significant adverse effects and submission of completed MedWatch form are required for documentation**)
- ☐ **For Orfadin suspension requests:** Provider must submit documentation to confirm the member is unable to swallow nitisinone capsules (**submit documentation of intolerance to capsules**)
- ☐ Member's current weight must be noted in submitted chart notes; Maximum approved dosage will be 2 mg/kg/day

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ☐ All initial authorization criteria continues to be met
- ☐ Member must meet **ONE** of the following (**submit documentation**):
 - ☐ Member's urinary succinylacetone concentration has decreased to less than 1 mmol/mol creatinine from baseline level
 - ☐ Member's plasma succinylacetone concentration has decreased to less than 0.1 micromol/L from baseline level
- ☐ A complete blood count was completed within the last 30 days and has been submitted with request
- ☐ Member's current weight must be noted in submitted chart notes; Maximum approved dosage will be 2 mg/kg/day

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☐ **DIAGNOSIS: Alkaptonuria (AKU)**

☐ **For Harliku, generic nitisinone, Nityr or Orfadin requests**

Initial Authorization: 6 months

- ☐ Member is 18 years of age or older
- ☐ Prescribed by or in consultation with an endocrinologist or a metabolic or genetic disease specialist
- ☐ Member has a diagnosis of alkaptonuria as confirmed by **ONE** of the following (**submit documentation**):
 - ☐ Baseline urinary HGA excretion greater than 0.4 g/24 hours
 - ☐ HGD (homogentisate 1,2-dioxygenase) biallelic gene mutation (mutations in both copies of the HGD gene) as evidenced by genetic testing
- ☐ **For Nityr and Brand Orfadin capsule requests:** Member must have trial and failure of generic nitisinone capsules (**chart notes documenting clinically significant adverse effects and submission of completed MedWatch form are required for documentation**)
- ☐ **For Orfadin suspension requests:** Provider must submit documentation to confirm the member is unable to swallow nitisinone capsules (**submit documentation of intolerance to capsules**)
- ☐ **For Harliku requests:** Member must have trial and failure of **BOTH** of the following unless contraindicated or clinically significant adverse effects are experienced [**verified by chart notes and/or pharmacy paid claims. Provider must submit documentation as to why the member cannot be prescribed a preferred agent. Include details and a completed FDA MedWatch Form (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>) is required to be attached for adverse reactions to prerequisite therapies.**]
 - ☐ Generic nitisinone capsules or Brand Orfadin capsules/suspension ***requires prior authorization***
 - ☐ Nityr ***requires prior authorization***
- ☐ Member is **NOT** using two different nitisinone products concurrently
- ☐ Prescribed dose does not exceed 2 mg per day

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ☐ Member continues to meet all initial authorization criteria
- ☐ Member is responding positively to therapy as evidenced by at least **ONE** of the following (**check all that apply, submit documentation**):
 - ☐ Reduced levels of urinary HGA
 - ☐ Improved joint (e.g., hip, spine, knee, shoulder) symptoms (e.g., range of motion, pain, stiffness)

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Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.