AvMed

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 1-305-671-0200**. 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.**

Drug Requested: (select drug below)

❑ **Orfadin®** (nitisinone) **capsules or suspension**	❑ **Nityr™** (nitisinone) **tablets**	❑ **nitisinone capsules**

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

Member Name: _____

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

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

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

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight: _____ **Date:** _____

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.

Initial Authorization Approval: 6 months

- ❑ Member must have a diagnosis of hereditary tyrosinemia type 1 (HT-1)

AND

- ❑ Member must be using the prescribed medication as an adjunct to dietary restriction of tyrosine and phenylalanine

AND

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- ❑ Member's current patient's plasma tyrosine level is maintained at <500 mcmol/L

AND

- ❑ A laboratory test documenting baseline urinary or plasma succinylacetone level must have been completed within the last 30 days

AND

- ❑ Member had had a baseline ophthalmologic examination with a normal slit lamp examination

AND

- ❑ A complete blood count was completed within the last 30 days

AND

- ❑ Member must have trial and failure of nitisinone for approval of brand name Orfadin or Nityr. Chart notes documenting clinically significant adverse effects and submission of completed MedWatch form are required for documentation

AND

- ❑ Maximum approved dosage will be 2mg/kg/day; member's current weight must be noted in submitted chart notes

Reauthorization Approval: 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 of the criteria for initial approval continues to be met

AND

- ❑ One of the following has been met:
  - ❑ Member's urinary succinylacetone concentration has decreased to less than 1 mmol/mol creatinine from baseline level; **OR**
  - ❑ Member's plasma succinylacetone concentration has decreased to less than 0.1 micromol/L from baseline level

AND

- ❑ A complete blood count was completed within the last 30 days

AND

- ❑ Member's current patient's plasma tyrosine level is maintained at <500 mcmol/L

AND

- ❑ Member must have trial and failure of nitisinone for approval of brand name Orfadin or Nityr. Chart notes documenting clinically significant adverse effects and submission of completed MedWatch form are required

AND

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- ❑ Maximum approved dosage will be 2mg/kg/day; member's current weight must be noted in submitted chart notes

Medication being provided by Specialty Pharmacy - PropriumRx

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.__

***Approved by Pharmacy and Therapeutics Committee**: 11/21/2019
REVISED/UPDATED: ~~2/25/2020;10/11/2021;~~ **10/27/2023**