Maryland Medicaid
Pharmacy Program
Fax: (866) 440-9345
Phone: (800) 932-3918

Orfadin and Nityr
Prior Authorization Form

Incomplete forms will not be reviewed.

MARYLAND Department of Health

Participant (Patient's) Information: Date: _____

Name: DOB:

Maryland Medicaid Number: Sex: ☐ M ☐ F

Contact Person for this Request:

Name: Phone # Fax #

Prescriber's Information:

Is the Drug prescribed part of a clinical study? ☐ Yes ☐ No

I certify that this Patient is **not** enrolled in any study involving the requested drug. I will be supervising the patient's treatment accordingly. Supporting medical documentation is kept on file in the patient's medical record.

_____, M.D. Prescriber's Name_____ Date_____
(Prescriber's signature)

License (NPI) # _____ DEA # _____ Specialty_____

Address _____ City _____ State _____ Zip _____

Consultation(s) with: ☐ Biochemical geneticist ☐ Hepatologist/Gastroenterologist ☐ Hematologist

☐ Other(s) _____

Clinical Criteria:

☐ Diagnosis: Hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine

☐ Yes ☐ No Homozygous form?

☐ Yes ☐ No Gene mapped to band 15q23-q25?

☐ Yes - Chronic Form? ☐ Yes - Acute Form?

Other: _____

AND

☐ Diagnosis confirmed by biochemical or DNA testing;

AND

☐ Attestation of nutritionist and metabolic specialist as part of the care team to create dietary restrictions of tyrosine and phenylalanine;

AND

☐ Provider must provide clinical justification for use of Nityr over Orfadin;

AND

Quantity Limits (QL): Maximum dosage is 1 mg/kg orally twice daily (2mg/kg/day. Titrate dose based on the evaluation of all biochemical parameters and/or clinical response, as described in the full prescribing information.

PA approval: 12 months

Patient's History:

☐ Yes ☐ No Is the patient currently on a liver transplant waiting list?

☐ Yes ☐ No Will Patient likely become a candidate for a liver transplant within the next year?

☐ Yes ☐ No Is patient under a care of a skilled nutritionist and on diet restricted in tyrosine and phenylalanine?

☐ Yes ☐ No Are the dietary restrictions of tyrosine and phenylalanine alone sufficient to maintain the urinary succinyl acetone at or below detectable levels?

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I certify that the patient is being monitored, as needed, for the following:

Patient's Weight
Patient's Height
Urinary succinyl acetone level
Plasma tyrosine level
Serum alpha-fetoprotein concentration
Serum phosphate level
Blood count, thrombocytes, leukocytes
Normal slit lamp examination prior to therapy/post-therapy?

_____, M.D. Prescriber's Name_____ Date_____
(Prescriber's signature)

FOR INTERNAL USE Date: _____ ☐ Approved ☐ Denied Reviewer's Initials: _____

Reason for denial:_____

_____