

PRESCRIBER'S STATEMENT OF MEDICAL NECESSITY
Prior-Authorization for payment of Orfadin™ (nitisinone or NTBC)
Maryland Pharmacy Program

Tel#: 410-767-1455 or 1-800-492-5231 Option 3-Fax form to: 410-333-5398
(Incomplete forms will be returned)

Patient Information

Patient location: ___ home; ___ hospital ___ Clinic ___ Office DOB: _____
Patient Name: _____
MA ID#: _____ Address: _____
Tel.#:(_____) _____ - _____

Prescriber Information

Is Drug prescribed as part of a clinical study? Yes No
Specify sponsoring organization/drug manufacturer _____
List study drug: _____. Specify purpose of study: _____
Note: For the Program to approve off-label use or use of the drug at dosages other than recommended by FDA, such use must be medically necessary and be documented in one of the three official compendia (the American Hospital Formulary Service Drug Information, the Micromedex/Drugdex drug database and the U.S. Pharmacopeia.

I certify that 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) Tel# (_____) - _____ - _____ Fax# (_____) - _____ - _____
License #: _____ DEA #: _____ Specialty : _____
Consultations with: Biochemical geneticist- Hepatologist/gastroenterologist - Hematologist- Other: _____
Address: _____

Prescription/Clinical Information

Drug/strength prescribed: _____ Dosage/ dosage frequency: _____

(Adult dose: 1mg/kg/day divided bid at least 1 hr ac initially; not to exceed 2mg/kg/day;

Pediatric dose: 1mg/kg/day divided bid at least 1 hr ac initially; may increase to 1.5mg/kg/day after 1 month if biochemical parameters not normalized, not to exceed 2mg/kg/day)

List diagnosis for which the drug was prescribed:

- Transient tyrosinemia of the newborn (TTN)
- Tyrosinemia II (Richner-Hanhart syndrome)
- Tyrosinemia III
- Type I hereditary tyrosinemia (hereditary infantile tyrosinemia)- Homozygous form? Yes No
Gene mapped to band 15q23-q25? Yes No Chronic form Acute form
- Other: _____

Is patient currently placed on a liver transplantation waiting list? Yes No

Will Patient likely become a candidate for liver transplantation 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 succinylacetone at or below detectable levels? Yes No Patient's Current Weight: _____ lb or _____ kg

Urinary succinylacetone level: _____

Plasma tyrosine level: _____ umol/L Normal range: _____ Test Date: ____/____/____

Serum alpha-fetoprotein concentration: _____ Normal range: _____ Test Date: ____/____/____

Serum phosphate level: _____ Normal range: _____ Test Date: ____/____/____

Blood count, thrombocytes, leukocytes? Normal Abnormal range- Date of last blood test measurement: ____/____/____

Normal slit lamp examination prior to therapy/post-therapy? Yes No Date of last exam: ____/____/____

A copy of Patient's Medical History must accompany this request.

FOR INTERNAL USE

Approved: Denied: Date: _____ Reviewer's Initials _____
Reason for denial: _____