

NITISINONE (Orfadin[®], Nityr[®])

(Maximum Length of Therapy is 12 Months)

Note: Form must be completed in full. An incomplete form may be returned.

Review Criteria

1. If the patient can be maintained on dietary restrictions alone, Orfadin[®] or Nityr[®] is not approved. (If the answer to question two is **YES**, do not approve.)
2. If the patient is on a liver transplantation list, approval period is only for six months.
3. If in the physician's opinion, the patient will become a liver transplant candidate within the next year, the approval period is only six months.
4. All other approvals are for a one-year period.
5. Limit the dose to 2 mg/kg for Orfadin[®] and Nityr[®].
6. Orfadin[®] is packaged in a high density (HD) polyethylene container of **60 capsules and cannot be repackaged and dispensed in a different container** or a 90 mL suspension is available of 4 mg/mL.
7. Nityr[®] is available in tablet formulation.