

Louisiana Medicaid
Nitisinone (Orfadin® Nityr®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for nitisinone (Orfadin® Nityr®).

Additional Point-of-Sale edits may apply.

Approval Criteria

- The recipient has a diagnosis of hereditary tyrosinemia type 1; **AND**
- **ONE of the following is stated on the request:**
 - The recipient has had an *intolerable side effect* to generic nitisinone capsules; **OR**
 - The recipient has a *contraindication* to generic nitisinone capsules; **OR**
 - There is *clinical justification* why generic nitisinone capsules cannot be used; **AND**
- Nitisinone (Orfadin® Nityr®) is prescribed by, or the request states that it is prescribed in consultation with, a provider experienced in the treatment of hereditary tyrosinemia type 1; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

References

Nityr (nitisinone) [package insert]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; February/October 20210. [https://www.nityr.us/content/us-0389-nityr-uspi_8pp_final.pdf](https://www.nityr.us/content/nityr-uspi-us-0341-nov-2020.pdf)

Orfadin (nitisinone) [package insert]. Waltham, MA: Sobi, Inc; May 2019.

<https://www.orfadin.com/pdf/full-prescribing-information.pdf>

| Revision / Date | Implementation Date |
|-------------------------------|------------------------|
| Policy created / October 2020 | April/October 20210 |
| Added Nityr® / January 2021 | January 2021/July 2021 |