SPECIALTY GUIDELINE MANAGEMENT

ORFADIN (nitisinone)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Orfadin is indicated as an adjunct to dietary restriction of tyrosine and phenylalanine in the treatment of patients with hereditary tyrosinemia type 1 (HT-1).

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of indefinite approval may be granted for treatment of hereditary tyrosinemia type 1 (HT-1) when the diagnosis is confirmed by biochemical testing (e.g., detection of succinylacetone in urine) or DNA testing.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCE

1. Orfadin [package insert]. Ardmore, PA: Sobi, Inc; June 2016.