Palovarotene

Goal(s):

- Promote safe & cost-effective therapy for fibrodysplasia ossificans progressiva (FOP).
- Incorporate 2-step review process for drugs on the high-cost drug carve-out list.

Length of Authorization:

- Up to 12 months

Requires PA:

- Palovarotene

Covered Populations: FFS and CCO patients beginning 1/1/26

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. FDA-Approved Minimum Age

Sex	Age
Female	8 years or older
Male	10 years or older

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for continuation of therapy previously approved by FFS system?	**Yes**: Go to **Renewal Criteria**	**No:** Go to #3
3. Is the diagnosis heterotopic ossification (HO) due to fibrodysplasia ossificans progressiva (FOP)?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is the diagnosis confirmed by molecular genetic testing indicating the presence of a mutation in the activin receptor IA (ACVR1) gene?	**Yes**: Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the request for an FDA-approved age in Table 1?	**Yes**: Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the drug prescribed by or in consultation with a specialist in FOP? (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist)	**Yes**: Go to #7	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
7. Is there a baseline assessment of skeletal maturity including • hand/wrist and knee x-rays • standard growth curves • pubertal staging -AND- Is there documentation that indicates plans to continue monitoring these factors for the duration of therapy until skeletal maturity or adult final height is reached?	**Yes**: Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Has the provider documented goals of therapy with objective baseline assessment(s) for one or more of the following: • Cumulative analog joint involvement scale (CAJIS) score? • Reduction or improvement in HO symptoms? • Reduction of HO flare-ups from baseline? • Reduction, stabilization, or slowing of the rate of annualized volume of new heterotopic ossification (HO)? Note: these same assessments should be evaluated for continuation of treatment	**Yes**: Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Has the prescriber performed a recent review of the patient's current medication regimen and attests that there is no concomitant use of strong/moderate 3A4 inducers (e.g., carbamazepine, phenytoin, rifampin, etc.), Vitamin A, and tetracyclines per the FDA label?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness
10. Is the patient female and of reproductive age?	**Yes:** Go to #11	**No:** Pass to RPh. Pend; Refer to DMAP for secondary review. Duration: Approvals cover 12 months
11. Is there documentation that prescriber has plans to give pregnancy test within 1 week prior to treatment and monitor periodically during therapy?	**Yes**: Pass to RPh. Pend; Refer to DMAP for secondary review. Duration: Approvals cover 12 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is there documentation that skeletal maturity or adult final height has been reached?	**Yes**: Go to #3	**No:** Go to #2
2. Is there documentation that the patient has been assessed in the last year for skeletal maturity including • hand/wrist and knee x-rays • standard growth curves • pubertal staging?	**Yes**: Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. If the patient is female and of reproductive age?	**Yes**: Go to #4	**No:** Go to #5
4. Is there documentation that the prescriber has plans to monitor pregnancy status periodically during therapy?	**Yes**: Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Has the patient been adherent to therapy as verified by claims history or prescriber attestation?	**Yes:** Go to #6 Note: pharmacy profile may be reviewed to verify >80% adherence	**No:** Pass to RPh. Deny; medical appropriateness
6. Has the prescriber performed a recent review of the patient's current medication regimen and attests that the patient is avoiding concomitant use of strong/moderate 3A4 inducers (e.g., carbamazepine, phenytoin, rifampin, etc.), Vitamin A, and tetracyclines per the FDA label?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. Has there been a documented positive response to treatment compared to baseline as evidenced by one or more of the following: • Decreased or stabilized cumulative analog joint involvement scale (CAJIS) score? • Reduction or improvement in HO symptoms? • Reduction of HO flare-ups from baseline? • Reduction, stabilization, or slowing of the rate of annualized volume of new heterotopic ossification (HO)?	**Yes:** Pass to RPh. Pend; Refer to DMAP for secondary review. Duration: Approvals cover 12 months	**No:** Pass to RPh. Deny; medical appropriateness