

Sohonos (Palovarotene)

EXCEPTION DRUG STATUS (EDS) REQUEST FORM

Fax: (204) 942-2030 or 1-877-208-3588

Prescriber Name:		Fax Number:	
Prescriber Address:		Phone Number:	
		Prescriber License Number (NOT Billing Number):	
Patient First Name:	PHIN:	MHSC:	
Patient Last Name:	Patient's Date of Birth:		
New Request		Renewal Request	
Dose and Regimen:	Expected Duration:		

Exception Drug Status (EDS) approval is only granted upon demonstration that the patient meets the coverage criteria of the EDS listing. Please provide the following details about how this patient meets the specific criteria for coverage. Manitoba Health may request additional documentation to support this EDS request.

For INITIAL Requests:				
Diagnosis				
Indication:	To reduce the formation of heterotopic ossification (HO) in patients with fibrodysplasia (myositis) ossificans progressiva (FOP).			
	Other: _____			
The patient is female and ≥8 years of age OR male and ≥10 years of age.			YES	NO
The patient has a clinical diagnosis of fibrodysplasia (myositis) ossificans progressiva (FOP).			YES	NO
The patient has a R206H ACVR1 mutation as confirmed by genetic testing (provide a copy of the genetic test report).			YES	NO
Does the patient have complete ankylosis of the whole body?			YES	NO
The patient is under the care of a specialist with experience in the diagnosis and management of FOP.			YES	NO
Symptoms and Treatment Goals				
Provide a description for each of the following:				
	Patient's <u>Baseline</u> Assessment	Individualized Treatment Goal		
Ability to eat and feed				
Ability to perform other activities of daily living				
Pain				
Mobility				

Joint range of motion		
Pulmonary function		
Extent of ankylosis		
Other (optional)		
Additional Relevant Information (optional):		

For RENEWAL Requests:

The patient has demonstrated continued benefit with palovarotene treatment.	YES	NO
The patient continues to be under the care of a specialist with experience in the diagnosis and management of FOP.	YES	NO
Has the patient's disease progressed such that they have complete ankylosis of the whole body?	YES	NO

Symptoms and Treatment Goals

Provide a description for each of the following:

	Patient's <u>Current</u> Assessment	Treatment Goals Established at Initiation Met?
Ability to eat and feed		
Ability to perform other activities of daily living		
Pain		
Mobility		
Joint range of motion		
Pulmonary function		
Extent of ankylosis		
Other (optional)		

Provide a summary of the individual benefit/risk assessment for the patient and rationale for continuing treatment with palovarotene.

Prescriber Signature and Date:

Please check the following:

I have discussed with the patient that the purpose of releasing their information to Manitoba Health, Seniors and Long-Term Care is to obtain Exception Drug Status for prescription coverage.

Date:

Prescriber Signature: