



Orladeyo (Berotralstat), Takhzyro (Lanadelumab) for Hereditary Angioedema (HAE)

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	
Medication Requested: Orladeyo (berotralstat)		Takhzyro (lanadelumab)	
Strength and Dosage Form:	Regimen and 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:		
For routine prevention of attacks of Hereditary Angioedema (HAE) type I or II		
Other:		
For patients currently receiving the requested drug (or other long-term prophylactic treatment and intending to switch to the requested drug), please provide:		
Current treatment: _____ Treatment initiation date: _____		
Please provide the baseline number of HAE attacks, within any 4-week period BEFORE initiating treatment with the requested drug (or other long-term prophylactic treatment), that required the use of an acute injectable treatment.		
Number of HAE attacks: _____ /4 weeks	Start date: _____	End date: _____
Please select YES or NO to the following:		
Diagnosis of HAE type I or II is made by a specialist physician who has experience in the diagnosis of HAE.	☐ YES	☐ NO
Patient is under the care of a specialist experienced in the diagnosis and management of patients with angioedema.	☐ YES	☐ NO
Patient is at least 12 years of age.	☐ YES	☐ NO
Will the requested medication be used in combination with other medications used for long-term prophylactic treatment of angioedema (e.g., C1-INH, plasma kallikrein inhibitors, etc.)?	☐ YES	☐ NO

Will the dose of berotralstat exceed 150mg once daily OR the dose of lanadelumab exceed 300 mg every two weeks?	☐ YES	☐ NO
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Additional Relevant Clinical Information:

For INITIAL RENEWAL:		
Please provide the number of HAE attacks, within any four-week period within the last 3 months of treatment with the requested drug, for which acute injectable treatment was received.		
Number of HAE attacks: _____ /4 weeks	Start Date: _____ End Date: _____	
Current dose/regimen of requested medication:		
Please select YES or NO to the following:		
Patient continues to be under the care of a specialist experienced in the diagnosis and management of patients with angioedema.	☐ YES	☐ NO
Berotralstat or lanadelumab is NOT being used in combination with other medications used for long-term prophylactic treatment of angioedema (e.g., C1-INH, plasma kallikrein inhibitors, etc.).	☐ YES	☐ NO

For ONGOING RENEWALS:		
Please provide the number of HAE attacks, within any four-week period within the last 6 months of treatment with the requested drug, for which acute injectable treatment was received.		
Number of HAE attacks: _____ /4 weeks	Start Date: _____ End Date: _____	
Current dose/regimen of requested medication:		
Please select YES or NO to the following:		
Patient continues to be under the care of a specialist experienced in the diagnosis and management of patients with angioedema.	☐ YES	☐ NO
Berotralstat or lanadelumab is NOT being used in combination with other medications used for long-term prophylactic treatment of angioedema (e.g., C1-INH, plasma kallikrein inhibitors, etc.).	☐ YES	☐ NO

☐ 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.

Prescriber Signature and Date:	
Date:	Prescriber Signature: