



# Vyndaqel/Vyndamax (Tafamidis meglumine/Tafamidis)

## 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:	

Initial Request	Renewal Request
Medication, Strength, and Regimen Requested: Tafamidis (Vyndamax) 61 mg PO daily Tafamidis meglumine (Vyndaqel) 80 mg PO daily	

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.

<b>For INITIAL Requests:</b>		
Diagnosis/Indication:	Cardiomyopathy due to TTR-mediated amyloidosis (ATTR-CM)	
	Other: _____	
Type:	Wild-type	Hereditary
Variant TTR genotype:	Absent	Present. Associated with cardiomyopathy and presenting with a cardiomyopathy phenotype
<b>Please select YES or NO to the following statements.</b>		
A copy of the genotype report is attached. (required)	YES	NO
The patient is 18 years of age or older.	YES	NO
The patient is under the care of a specialist with experience in the diagnosis and management of ATTR-CM.	YES	NO
The patient has the following characteristics:		
Evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness > 12 mm.	YES	NO
Positive findings on technetium-99m pyrophosphate (Tc-99m-PYP) scintigraphy with single-photon emission computed tomography (SPECT) scanning.	YES	NO
OR Presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac).	YES	NO
<b>For wild-type only:</b> TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry.	YES	NO
New York Heart Association (NYHA) class I to III.	YES	NO
History of heart failure, defined as at least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic.	YES	NO
Has NOT received a heart or liver transplant.	YES	NO
Does NOT have an implanted cardiac mechanical assist device (CMAD).	YES	NO
Is NOT receiving other disease-modifying treatments for ATTR.	YES	NO

**Additional Relevant Clinical Information:****For RENEWAL Requests:****Please select YES or NO to the following statements.**

The patient has the following characteristics:

New York Heart Association (NYHA) class I to III.	YES	NO
Has NOT received a heart or liver transplant.	YES	NO
Does NOT have an implanted cardiac mechanical assist device (CMAD).	YES	NO
Is NOT receiving other disease-modifying treatments for ATTR.	YES	NO

**Prescriber Signature and Date:****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: