ALBERTA BLUE CROSS®

TAFAMIDIS FOR ATTR-CM
SPECIAL AUTHORIZATION REQUEST FORM

Patients may or may not meet eligibility requirements as established by Alberta government sponsored drug programs.

Please complete all required sections to allow your request to be processed.

PATIENT INFORMATION				**COVERAGE TYPE**
LAST NAME	FIRST NAME		INITIAL	☐ Alberta Blue Cross
BIRTH DATE (YYYY-MM-DD)	ALBERTA PERSONAL HEALTH NUMBER			☐ Alberta Human Services ☐ Other _____
ADDRESS	CITY	PROV	POSTAL CODE	ID/CLIENT/COVERAGE NUMBER

PRESCRIBER INFORMATION		
PRESCRIBER LAST NAME FIRST NAME INITIAL	PRESCRIBER PROFESSIONAL ASSOCIATION REGISTRATION	
ADDRESS	☐ CPSA ☐ ACO ☐ CARNA ☐ ADA+C ☐ ACP ☐ Other	REGISTRATION NUMBER
CITY, PROVINCE	PHONE	FAX
POSTAL CODE	FAX NUMBER MUST BE PROVIDED WITH EACH REQUEST SUBMITTED	

Please provide the following information for ALL requests

Requested Drug ☐ Tafamidis (e.g. Vyndamax) ☐ Tafamidis meglumine (e.g. Vyndaqel)

Dosage and frequency requested

Diagnosis

☐ cardiomyopathy due to transthyretin-mediated amyloidosis (ATTR-CM)

☐ Other (specify)_____

Please indicate if this patient is

☐ starting drug upon approval ……....complete section I

☐ new to coverage but currently maintained on drug …..complete section I & II

☐ submitting renewal request …… complete section II

Combination use

Please indicate if the patient will be using the requested drug in combination with other disease modifying treatments for ATTR including interfering ribonucleic acid drugs or transthyretin stabilizers ☐ Yes ☐ No

Section I: INITIAL requests for treatment naïve and treatment experienced patients

Please indicate which of the following apply to this patient at treatment initiation (check all that apply)

☐ for wild-type ATTR-CM: absence of a variant TTR genotype

☐ evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm

☐ presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac) OR Tc-99m-pyrophosphate nuclear scintigraphy (PYP scan) indicating TTR-related cardiac amyloidosis

☐ for wild-type ATTR-CM: TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry

☐ for hereditary ATTR-CM: presence of a variant TTR genotype associated with cardiomyopathy and presenting with a cardiomyopathy phenotype

☐ New York Heart Association (NYHA) class I to III

☐ a history of heart failure (HF), defined as at least one prior hospitalization for HF or clinical evidence of HF that required treatment with a diuretic

☐ has NOT received a heart or liver transplant

☐ does NOT have an implanted cardiac mechanical assist device (CMAD)

Section II: RENEWAL requests and INITIAL requests for treatment experienced patients

Please indicate if the following currently apply to this patient (check Yes or No for a-c below)	**Yes**	**No**
a) progressed to NYHA class IV	☐	☐
b) received a heart or liver transplant	☐	☐
c) received an implanted CMAD	☐	☐

Additional information relating to request

PRESCRIBER'S SIGNATURE	DATE (YYYY-MM-DD)	Please forward this request to **Alberta Blue Cross, Clinical Drug Services** **10009 108 Street NW, Edmonton, Alberta T5J 3C5** FAX **780-498-8384** in Edmonton • **1-877-828-4106** toll free all other areas

ONCE YOUR REQUEST HAS SUCCESSFULLY TRANSMITTED, PLEASE DO NOT MAIL OR RE-FAX YOUR REQUEST.

TAFAMIDIS FOR ATTR-CM
SPECIAL AUTHORIZATION CRITERIA

Patients may or may not meet eligibility requirements as established by Alberta government sponsored drug programs.

Criteria for coverage

TAFAMIDIS MEGLUMINE (e.g. Vyndaqel) and TAFAMIDIS (e.g. Vyndamax) special authorization criteria

"For the treatment of cardiomyopathy due to transthyretin-mediated amyloidosis (ATTR-CM), wild-type or hereditary, to reduce cardiovascular mortality and cardiovascular-related hospitalization in adult patients who meet the following criteria:

- Documented wild-type ATTR-CM* OR documented hereditary ATTR-CM**

AND

- New York Heart Association (NYHA) class I to III

AND

- a 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

AND

- have not received a heart or liver transplant

AND

- do not have an implanted cardiac mechanical assist device (CMAD)

* Documented wild-type ATTR-CM consists of all of the following: absence of a variant TTR genotype; and evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; and presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac) OR Tc-99m-pyrophosphate nuclear scintigraphy (PYP scan) indicating TTR-related cardiac amyloidosis; and TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry.
** Documented hereditary ATTR-CM consists of all of the following: presence of a variant TTR genotype associated with cardiomyopathy and presenting with a cardiomyopathy phenotype; and evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; and presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac) OR PYP scan indicating TTR-related cardiac amyloidosis.

For coverage, this drug must be prescribed by a Specialist in Cardiology, Internal Medicine or Oncology.

Initial coverage may be approved up to 80 mg of tafamidis meglumine or 61 mg of tafamidis once daily for 6 months. Patients will be limited to receiving a one-month supply of tafamidis meglumine or tafamidis per prescription at their pharmacy.

For renewal of coverage, patients must NOT have:
- progressed to NYHA class IV, NOR
- received a heart or liver transplant, NOR
- received an implanted CMAD

Continued coverage may be approved for up to 80 mg of tafamidis meglumine or 61 mg of tafamidis once daily for a period of 6 months.

Coverage cannot be provided for use in combination with other disease modifying treatments for ATTR including interfering ribonucleic acid drugs or transthyretin stabilizers."

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