Manulife

Group Benefits
Drug Prior Authorization

Symdeko (Tezacaftor-Ivacaftor)

The purpose of this form is to obtain the medical information required to assess your request for a drug on the Prior Authorization list under your drug plan benefit coverage. To avoid delays in processing your request, please ensure that all information, including contact information is complete. Completion of this form is not a guarantee of approval. If you have already purchased the drug, please attach all original receipts along with an Extended Health Care Claim form. All costs incurred to complete this form are the plan member's responsibility. If you are registered for the Plan Member Secure Site and have provided an email address, you will receive an email notification when the prior authorization decision is available on your claims statement. If you are not registered on the Plan Member Secure Site, you will be notified of the prior authorization decision by mail.

Important: Please ensure the most current unaltered version of the form is completed and signed. To download the most recent version of the Drug Prior Authorization form go to www.manulife.ca.

1 – Plan member and patient information — To be completed by plan member

Plan contract number	Plan member certificate number	Plan sponsor

Plan member name (first)	Plan member name (middle initial)	Plan member name (last)	Plan member Date of birth (dd/mmm/yyyy)

Plan member address (number, street)	Address (suite)	City or town	Province	Postal code

Patient name (first)	Patient name (middle initial)	Patient name (last)	Patient date of birth (dd/mmm/yyyy)	Relationship to plan member

Patient's preferred daytime phone number	Patient's email address (optional)

1A – Other Group Plan

Does the patient have drug coverage under any other group plan? If Yes, please complete below: ☐ Yes ☐ No

Name of insurance company	
Plan contract number	Plan member certificate number

Is this drug covered under the other group plan? ☐ Yes ☐ No

If no, why was the drug declined by the other group plan? Please attach the other group plan decline notice (typically a letter or statement). We need this decline notice to see if this drug can be approved. If this is a renewal a current decline notice is required.

1B – Recent Coverage Change

Did your plan sponsor recently transfer your drug benefits to Manulife? ☐ Yes ☐ No

Before joining Manulife, were you receiving coverage for this drug through your previous insurance company ☐ Yes ☐ No

If Yes, attach proof of payment (a copy of a pharmacy receipt showing payment from prior insurance company or an Explanation of Benefits from the prior insurance company). Proceed to section 7.

2 – Provincial Plans — To be completed by plan member

Most provinces offer some form of drug coverage to their residents. Your Manulife drug plan supplements the coverage provided by provincial plans. It is important that you or your doctor (if required) apply to the applicable provincial program to ensure there are no delays in your drug reimbursement. Check with your doctor or login to the **Manulife Provincial Drug Plans Resource Centre** on our Plan Member Secure Site at www.manulife.ca/planmember to confirm if the drug you have been prescribed may be eligible for coverage under a provincial plan. If the drug you have been prescribed is listed under a provincial program, you will need to apply to the program before consideration can be given under your Manulife drug plan.

Has application been made to the provincial program for coverage? ☐ Yes ☐ No

If no, why?

Has the patient been approved for coverage by the provincial program for this drug? ☐ Yes ☐ No

If no, advise why the request was declined?

In Ontario, for patients that qualify for coverage under the Exceptional Access Program (EAP), if the drug is an EAP drug, a copy of the approval or denial from EAP must be submitted with this form so Manulife can complete the assessment of this request.

3 – Patient Assistance Programs — To be completed by plan member

Have you enrolled in the Patient Assistance Program for the requested drug? ☐ Yes ☐ No

If yes, please provide the details below:

Case Manager Name (first)	Case Manager name (last)	Case Manager Phone	Case Manager Email

Patient Assistance Program Name	Patient Assistance Program ID Number:

4 – Medical information — To be completed by prescribing physician

Drug strength and dosage

Where will treatment be administered?

☐ Home ☐ MD office ☐ Private Clinic ☐ Hospital/In-Patient ☐ Hospital/Out-patient

Is the MD office located in a hospital? ☐ Yes ☐ No

Will the drug be administered in the MD office or in another area of the hospital? (describe below)

If the treatment is not being administered at home, please provide:

Name of private clinic/hospital				Telephone number
Address (number, street)	Address (suite)	City or town	Province	Postal code

Please select the diagnosis for which the drug has been prescribed and respond to the corresponding questions.

☐ Cystic Fibrosis with two copies of the F508 del mutation in the CFTR gene - Initial Criteria

Are you about to start a new CF treatment?

Cystic Fibrosis (CF) Canada and The Hospital for Sick Children (SickKids) have joined forces in the Program for Individualized CF Therapy (CFIT Program). The goal of the Program is to better predict who (both adults and children) will improve on new CF drugs. Manulife has agreed to let you know about this Program and that you can participate.

- No information from the study will be provided to Manulife.
- Participation is completely optional.
- Manulife won't know if you decide to participate or not.
- Your decision won't have any effect on your coverage by Manulife.

Researchers at SickKids think that if they can study the patient's genes and cells before and after starting new CF drugs, they can create more personal treatments in the future. The hope is to start effective treatments sooner and limit the effects of CF in future patients.

For more details on the **CFiT Program** please go to this website: https://lab.research.sickkids.ca/cfit/

Please contact Julie or Paul at SickKids for more information:

- Julie Avolio, Clinical Research Nurse Coordinator: 416-813 5515,julie.avolio@sickkids.ca
- Paul Eckford, CFiT Research Program Manager: 416-813-7654 ext 309467, peckford@sickkids.ca

Has the patient enrolled in the patient assistance program for Symdeko? ☐ Yes ☐ No

If no, please contact village™ Vertex Patient Support Program at 1-855-227-3571 and complete section 3. Not completing section 3 may delay the processing of your request.

Provide pretreatment percent predicted forced expiratory volume in one second (ppFEV1)	OR	Provide annual number of pulmonary exacerbations

Provide baseline levels of ALT, AST and bilirubin

ALT	AST	bilirubin

Does the prescriber agree to monitor ALT, AST and bilirubin levels every 3 months during the first year and at least yearly thereafter? ☐ Yes ☐ No

Will there be dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator? ☐ Yes ☐ No

Note: Initial and subsequent approvals are limited to 12 months. Additional information is required every 12 months, in order to assess for further coverage.

4 – Medical information (continued) **To be completed by prescribing physician**

☐ **Cystic Fibrosis with two copies of the F508 del mutation in the CFTR gene - Renewal Criteria**

Is ppFEV1 from baseline stable or there is improvement?	☐ Yes	☐ No
Is there a reduced number of pulmonary exacerbations?	☐ Yes	☐ No
Does the prescriber agree to monitor ALT, AST and bilirubin levels at least yearly?	☐ Yes	☐ No
Is there dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator?	☐ Yes	☐ No

☐ **Cystic Fibrosis with one copy of the F508del mutation and one copy of a responsive mutation (i.e. P67L, D110H, R117C, L206W, R352Q,A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, or 3849+10kbC→T) in the CFTR gene - Initial Criteria**

Are you about to start a new CF treatment?

Cystic Fibrosis (CF) Canada and The Hospital for Sick Children (SickKids) have joined forces in the Program for Individualized CF Therapy (CFIT Program). The goal of the Program is to better predict who (both adults and children) will improve on new CF drugs. Manulife has agreed to let you know about this Program and that you can participate.

- No information from the study will be provided to Manulife.
- Participation is completely optional.
- Manulife won't know if you decide to participate or not.
- Your decision won't have any effect on your coverage by Manulife.

Researchers at SickKids think that if they can study the patient's genes and cells before and after starting new CF drugs, they can create more personal treatments in the future. The hope is to start effective treatments sooner and limit the effects of CF in future patients.

For more details on the CFiT Program please go to this website: https://lab.research.sickkids.ca/cfit/

Please contact Julie or Paul at SickKids for more information:

- Julie Avolio, Clinical Research Nurse Coordinator: 416-813 5515,julie.avolio@sickkids.ca
- Paul Eckford, CFiT Research Program Manager: 416-813-7654 ext 309467, peckford@sickkids.ca

Has the patient enrolled in the patient assistance program for Symdeko? ☐ Yes ☐ No

If no, please contact village™ Vertex Patient Support Program at 1-855-227-3571 and complete section 3. Not completing section 3 may delay the processing of your request.

Provide pretreatment percent predicted forced expiratory volume in one second (ppFEV1)	OR	Provide annual number of pulmonary exacerbations

Provide baseline levels of ALT, AST and bilirubin

ALT	AST	bilirubin

Does the prescriber agree to monitor ALT, AST and bilirubin levels every 3 months during the first year and at least yearly thereafter?	☐ Yes	☐ No
Will there be dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator?	☐ Yes	☐ No

Note: Initial and subsequent approvals are limited to 12 months. Additional information is required every 12 months, in order to assess for further coverage.

☐ **Cystic Fibrosis with one copy of the F508del mutation and one copy of a responsive mutation (i.e. P67L, D110H, R117C, L206W, R352Q,A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, or 3849+10kbC→T) in the CFTR gene - Renewal Criteria**

Is ppFEV1 from baseline stable or there is improvement?	☐ Yes	☐ No
Is there a reduced number of pulmonary exacerbations?	☐ Yes	☐ No
Does the prescriber agree to monitor ALT, AST and bilirubin levels at least yearly?	☐ Yes	☐ No
Is there dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator?	☐ Yes	☐ No

☐ **Any Other Diagnosis**

Please provide the specific diagnosis and any Canadian clinical research that supports the use of this drug in your patient's context.

5 – Drug history — To be completed by prescribing physician

If no previous therapies have been tried for the selected diagnosis, please specify the rationale:

☐ Risk of drug interaction ☐ Patient has contraindication

☐ Other

Please provide medical rationale

For the selected diagnosis, please provide all previous and current drug therapies in the area below:

Drug name	Start date (yyyy/mmm)	End date (yyyy/mmm)	Specify Outcome:
			☐ Intolerance (Allergy/Adverse Event) ☐ Inadequate/Suboptimal Response
Will the patient be continuing this medication in addition to new therapy?			☐ Yes ☐ No
Drug name	**Start date (yyyy/mmm)**	**End date (yyyy/mmm)**	**Specify Outcome:** ☐ Intolerance (Allergy/Adverse Event) ☐ Inadequate/Suboptimal Response
Will the patient be continuing this medication in addition to new therapy?			☐ Yes ☐ No
Drug name	**Start date (yyyy/mmm)**	**End date (yyyy/mmm)**	**Specify Outcome:** ☐ Intolerance (Allergy/Adverse Event) ☐ Inadequate/Suboptimal Response
Will the patient be continuing this medication in addition to new therapy?			☐ Yes ☐ No
Drug name	**Start date (yyyy/mmm)**	**End date (yyyy/mmm)**	**Specify Outcome:** ☐ Intolerance (Allergy/Adverse Event) ☐ Inadequate/Suboptimal Response
Will the patient be continuing this medication in addition to new therapy?			☐ Yes ☐ No
Drug name	**Start date (yyyy/mmm)**	**End date (yyyy/mmm)**	**Specify Outcome:** ☐ Intolerance (Allergy/Adverse Event) ☐ Inadequate/Suboptimal Response
Will the patient be continuing this medication in addition to new therapy?			☐ Yes ☐ No

6 – Physician information — To be completed by prescribing physician

Prescribing physician’s name (first)	Prescribing physician’s name (last)	College/License Number	Specialty

Address (number, street)	Address (suite)

City or town	Province	Postal code

Telephone number	Extension	Fax number

Physician authorization

I certify that the information in this form is true and complete to the best of my knowledge. The information in this statement will be kept in a Group Benefits health file with Manulife and might be accessible by the patient or third parties to whom access has been granted or those authorized by law. By providing the information, I consent to such unedited release of any information contained herein.

Physician Signature	Date (dd/mmm/yyyy)

7 – Authorization and Plan member signature — To be signed by plan member

I certify that I, my spouse and/or my dependents of minor or major age ("Dependents") require the drug named on this form (or an equivalent drug that Manulife proposes).

I authorize:

Manulife and/or its service providers, its reinsurers, and their service providers to collect, use, maintain and disclose my personal information related to this application ("Personal Information") for the purposes of:

- The assessment of the drug authorization request
- Managing my Group Benefits plan
- Assessing and processing claims
- Auditing and investigation of claims
- Patient assistance programs, if applicable
- And/or other purposes identified in the Personal Information Statement for Employers' Group Benefits plans (collectively, the "Purposes").

Any person or organization who has Personal Information about me that is required for Manulife to assess this drug authorization request, including any medical and health care professionals, institution, pharmacy or any other medical or health care related facility, professional regulatory bodies, any employer, group plan administrator, insurer, investigative agency, and any other administrators of other benefits programs to collect, use, maintain, disclose and exchange this information with each other and with Manulife, its reinsurers and/or its service providers, for the Purposes.

I understand:

- A Manulife approved pharmacy vendor may engage me in the capacity of case management to provide support as part of this program. I acknowledge that participation in this program is entirely voluntary. My decision to participate will not have any impact on the assessment of my claim.
- If my Manulife plan recommends purchasing a drug that requires prior authorization from a preferred pharmacy or provider, a case manager may contact me, my doctor and/or patient assistance program to arrange to have my prescription(s) transferred to the preferred pharmacy or provider.
- That except where there are contractual restrictions, Manulife employees, authorized organizations, service providers and reinsurers are located both within Canada and outside of Canada. Therefore, my Personal Information may be subject to interprovincial or cross-border transfers for the Purposes and may be subject to the laws of those jurisdictions.
- I may withdraw my consent for certain uses of my Personal Information, subject to legal and contractual restrictions. If I do so, Manulife may treat my withdrawal of consent as a request to dismiss, rescind or terminate my claim.

I agree:

- A photocopy or electronic version of this consent is valid.
- I have the right to access and verify my Personal Information maintained in Manulife's files and to request any factually inaccurate Personal Information be corrected, if appropriate.
- Requests can be sent to: Privacy Officer Manulife, P.O. Box 1602, Del Stn 500-4-A, Waterloo, Ontario N2J 4C6 or Canada_Privacy@manulife.ca
- For more information, I can review the Personal Information Statement for Employers' Group Benefits Plans and the Canadian Privacy Policy.

I confirm that:

- The information I have given in this request is true and accurate.
- By signing, I give permission to and/or confirm that I have obtained the individual's consent for the collection, use, disclosure or otherwise processing of the individual's Personal Information for the Purposes (as these terms are defined above).

Plan member's signature	Date signed (dd/mmm/yyyy)

Protecting your personal information is important to us. People who can see your personal information are:

- Manulife employees who need to see your information to do their jobs.
- People you've given permission to.

To find out more about Manulife's privacy policy please see manulife.ca

8 – Submission instructions

Plan Member Secure Site

1. Log in to the **Plan Member Secure Site**.
2. Choose **"Claims"**
3. Go to **"Submit a Claim."**
4. Under **Service Provider**, select **"Other."**
5. Choose **"Estimate"** as the **Claim Type**.

Mobile App Site

1. Open the **Mobile Site** on your device.
2. Select **"Submit a Claim."**
3. Choose **"Estimate"** as the **Claim Type**.

Mail or fax

If you live in Quebec:
Manulife Group Benefits Health Claims
Attention Prior Authorization Team
PO BOX 2580, STATION B
MONTREAL QC H3B 5C6

Fax: 1-855-752-0404

If you live outside Quebec:
Manulife Group Benefits Health Claims
Attention Prior Authorization Team
PO BOX 1653
WATERLOO ON N2J 4W1

Fax: 1-855-752-0404

Please retain a photocopy for your files.

Manulife, Manulife & Stylized M Design, and Stylized M Design are trademarks of The Manufacturers Life Insurance Company and are used by it, and by its affiliates under license. © 2021 The Manufacturers Life Insurance Company. All rights reserved. Manulife, PO Box 670, Stn Waterloo, Waterloo, ON N2J 4B8. manulife.ca 1-800-268-3763