Drug Prior Authorization Form
Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor), Symdeko (ivacaftor/tezacaftor and ivacaftor)

The purpose of this form is to obtain information required to assess your drug claim.

IMPORTANT: Please answer all questions. Your claim assessment will be delayed if this form is incomplete or contains errors.

Any costs incurred for the completion of this form are the responsibility of the plan member/patient.

Canada Life recognizes and respects the importance of privacy. Personal information collected is used for the purposes of assessing eligibility for this drug and for administering the group benefits plan. For a copy of our Privacy Guidelines, or if you have questions about Canada Life's personal information policies and practices (including with respect to service providers), refer to www.canadalife.com or write to Canada Life's Chief Compliance Officer.

I authorize Canada Life, any healthcare provider, my plan administrator, any insurance or reinsurance company, administrators of government benefits or patient assistance programs or other benefits programs, other organizations, or service providers working with Canada Life or any of the above, located inside or outside Canada, to exchange personal information when relevant and necessary for these purposes. I understand that personal information may be subject to disclosure to those authorized under applicable law within or outside Canada.

I acknowledge that the personal information is needed to assess eligibility for this drug and to administer the group benefits plan. I acknowledge that providing consent will help Canada Life to assess my claim and that refusing to consent may result in delay or denial of my claim. Canada Life reserves the right to audit the information provided on this form at any time and this consent extends to any audit of my claim. This consent may be revoked by me at any time by sending written instruction to that effect.

I also consent to the use of my personal information for Canada Life and its affiliates' internal data management and analytics purposes.

If the patient is a person other than myself, I confirm that the patient has given their consent to provide their personal information and for Canada Life to use and disclose it as set out above.

I certify that the information given below is true, correct, and complete to the best of my knowledge. Failure to provide true, correct and complete information on this form could result in revocation of any approval decision, a requirement to repay paid claims or other appropriate action.

Plan Member's signature: _____ Date: _____

Form Completion Instructions:

1. **Complete "Patient Information" sections.**
2. **Have the prescribing physician complete the "Physician Information" sections.**
3. **Send all pages of the completed form to us by mail, fax or email as noted below.**

Note: As email is not a secure medium, any person with concerns about their prior authorization form/medical information being intercepted by an unauthorized party is encouraged to submit their form by other means.

Mail to: **The Canada Life Assurance Company**
Drug Claims Management
PO Box 6000
Winnipeg MB R3C 3A5

Fax to: **The Canada Life Assurance Company**
Fax 1-204-946-7664
Attention: Drug Claims Management

Email to: **cldrug.services@canadalife.com**
Attention: Drug Claims Management

For additional information regarding Prior Authorization and Health Case Management, please visit our Canada Life website at www.canadalife.com or contact Group Customer Contact Services at 1-800-957-9777. Deaf or hard of hearing and require access to a telecommunications relay service? Please contact us at 711 for TTY to Voice or 1-800-855-0511 for Voice to TTY.

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Patient Information
Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor), Symdeko (ivacaftor/tezacaftor and ivacaftor)

Plan Member Information – Complete all sections of this page (please print)

Plan Member:	Patient Name:	
Plan Name:	Plan Number:	Plan Member ID Number:
Patient Date of Birth (DD/MM/YYYY):	Address (number, street, city, province, postal code):	

Please indicate preferred contact number and if there are any times when telephone contact with you about your claim would be most convenient.

May we contact you by email? (Note that some correspondence may still need to be sent by regular mail).

☐ Yes ☐ No If yes, please provide email address: _____

Tell us if you have been on this drug before

Is the patient currently on, or previously been on this drug? ☐ Yes ☐ No

If Yes, a) indicate start date (DD/MM/YYYY): _____

b) coverage provided by: _____

(if coverage is not provided by Canada Life please provide pharmacy print-out showing purchase of this drug)

Tell us if you have coverage with any other benefits plan

Does the patient have drug coverage under any other group benefits plan? ☐ Yes ☐ No

If Yes, name of other Insurance Company: _____

If other plan is with Canada Life, tell us the plan and ID number: _____

Name of plan member: _____

Relationship to patient: _____

Provide details and attach documentation of acceptance or decline:

_____

_____

Tell us about any Provincial or other coverage you may have

Does the patient have coverage under a provincial program or from any other source? ☐ Yes ☐ No

If Yes, name of program or other source: _____

Provide details and attach documentation of acceptance or decline: _____

Is the patient currently receiving disability benefits for the condition for which this drug has been prescribed? ☐ Yes ☐ No

Tell us about any Patient Assistance Program you might be enrolled in

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

If Yes, please provide the following information:

1. Patient assistance program patient ID Number: _____
2. Patient assistance program contact person name and phone number:

   Contact Name: _____ Phone Number: _____

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Physician Information
Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor), Symdeko (ivacaftor/tezacaftor and ivacaftor)

Note to Physician: **In order to assess a patient's claim for this drug, we require detailed information on the patient's prescription drug history as requested below.**

Attach extra information if necessary. ***GENETIC TEST RESULTS ARE NOT REQUIRED***

Physician's Information (please print)

Name of prescribing physician:

Specialty:

Address (number, street, city, province, postal code):

Telephone Number (including area code):	Fax Number (including area code):

1. Prescribed Medication:
   - ☐ Kalydeco (ivacaftor)
   - ☐ Orkambi (ivacaftor/lumacaftor)
   - ☐ Symdeko (tezacaftor/ivacaftor and ivacaftor)

2. Health Canada indication (include date of initial diagnosis) (MM/YYYY): _____

[1]Approved Health Canada Indications and Clinical Use for Kalydeco:

☐ KALYDECO (ivacaftor) tablets (150 mg) are indicated for the treatment of patients with cystic fibrosis (CF) aged 6 years and older and weighing 25 kg or more who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

☐ KALYDECO tablets (150 mg) are also indicated for the treatment of cystic fibrosis (CF) in patients age 18 years and older with an R117H mutation in the CFTR gene.

☐ KALYDECO granules (50 mg and 75 mg) are indicated for the treatment of children with cystic fibrosis (CF) aged 12 months and older and weighing 7 kg to less than 25 kg who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

[1]Approved Health Canada Indications and Clinical Use for Orkambi:

☐ ORKAMBI (lumacaftor/ivacaftor) is indicated for the treatment of cystic fibrosis (CF) in patients 2 years of age and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

[1]Approved Health Canada Indications and Clinical Use for Symdeko:

☐ SYMDEKO (tezacaftor/ivacaftor and ivacaftor) is indicated for the treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who are heterozygous for the F508del mutation and have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: P67L, D110H, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, and 3849+10kbC→T.

☐ Other (approved by Health Canada): _____

Complete questions 1 - 7 and Other condition (Health Canada approved)

Is this drug being prescribed in accordance with approved Health Canada indications[1]?

☐ Yes, complete questions 1 - 7 and Physician's Information

☐ No, prescribed use is not approved by Health Canada: _____

Complete questions 1 –7 and Off-label use

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Physician Information
Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor), Symdeko (ivacaftor/tezacaftor and ivacaftor)

Physician's Information *(continued)* (please print)

3. Prescribed dosage and regimen: _____

Provide rationale: _____

4. What is the anticipated duration of treatment with this drug? _____

5. Where will treatment be administered? ☐ Home ☐ Physician's Office ☐ Private clinic ☐ Hospital in-patient ☐ Hospital out-patient

6. Please provide medical rationale why this drug has been prescribed instead of an alternate drug in the same therapeutic class:

_____

_____

7. Drug and Treatment History – **must be completed for every request.**

Drug(s) and Treatment(s) past and present	Dosing Regimen	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Clinical Results/Outcome
				☐ Failure ☐ Intolerance ☐ Other Clinical details:
				☐ Failure ☐ Intolerance ☐ Other Clinical details:
				☐ Failure ☐ Intolerance ☐ Other Clinical details:

Cystic Fibrosis – Genetic test results are not required

Required Documentation: Please ensure the following test results are included in the application.

☐ Baseline Sweat Chloride Test Result

☐ Pulmonary function tests (current within 6 months of this application)

Other Supporting Information:

Body Mass Index (indicate date measured): _____

Baseline CFQ-R score: _____

Number of exacerbations and hospitalizations in the past year: _____

Provide dates of exacerbation/hospitalizations:

_____

_____

Other condition (Health Canada approved) – Genetic test results are not required

Please provide any relevant information related to the disease and attach supporting documentation.

_____

_____

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Renewal Request – Genetic test results are not required

Initial Renewal Only

Required Documentation: Please ensure the following test results are included in the application.

☐ Pulmonary function tests (current within 6 months of this application)

Other supporting information:

Body Mass Index (indicate date measured): _____

Current CFQ-R score: _____

Number of exacerbations and hospitalizations in the past year: _____

Provide dates of exacerbation/hospitalizations:

_____

_____

For All Renewals

Is the patient still receiving a clinical benefit from their cystic fibrosis drug therapy? ☐ Yes ☐ No

Describe the patient's response to treatment, particularly in relation to the signs and symptoms of their disease at initial presentation. Please provide objective evidence of effectiveness. Attach copies of relevant test results, specialist consultations or clinical notes.

_____

_____

_____

_____

Off-label use – Genetic test results are not required

Questions 1 - 7 must be completed.

Date of initial diagnosis (DD/MM/YYYY): _____

Is there clinical evidence supporting the off-label use of this drug? ☐ Yes ☐ No

Provide clinical literature/studies to support the request for off-label use, such as:

- At least two Phase II or two Phase III clinical trials showing consistent results of efficacy; and
- Published recommendations in evidence-based guidelines supporting its use.

Provide medical rationale why this drug has been prescribed off-label instead of an alternate drug with an approved indication for this condition.

_____

_____

Provide any pertinent medical history or information to support this off-label request.

_____

_____

If this is a renewal request, provide documentation showing treatment efficacy since previous request.

_____

Physician Information
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Note for Physician: To be eligible for reimbursement, Canada Life may require your patient to purchase a drug requiring prior authorization from a pharmacy designated by Canada Life. If applicable, a health case manager will contact you with further information.

I certify that the information provided is true, correct, and complete.

Physician's Signature: _____ Date: _____

License Number: _____

It is important to provide the requested information in detail to help avoid delay in assessing claims for the above drug. This form may be subject to audit. The completed form can be returned to Canada Life by mail, fax, or email.

Note: As email is not a secure medium, any person with concerns about their prior authorization form/medical information being intercepted by an unauthorized party is encouraged to submit their form by other means.

Mail to: **The Canada Life Assurance Company**
Drug Claims Management
PO Box 6000
Winnipeg MB R3C 3A5

Email to: **cldrug.services@canadalife.com**
Attention: Drug Claims Management

Fax to: **The Canada Life Assurance Company**
Fax 1-204-946-7664
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