

ORKAMBI (lumacaftor/ivacaftor) PRIOR AUTHORIZATION FORM

Please complete all applicable sections of this prior authorization request form and return to the fax number above. Please include all requested documentation (chart notes, laboratory data, etc.). To review the prior authorization guidelines for Orkambi, please refer to the Medical Assistance Prior Authorization of Pharmaceutical Services Handbook Chapter – Orkambi (accessible at: <http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm>).

PRIOR AUTHORIZATION REQUEST INFORMATION		PRESCRIBER INFORMATION	
<input type="checkbox"/> New request <input type="checkbox"/> Additional info (PA#: _____) <input type="checkbox"/> Renewal request # of pages in request: _____		Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		State license #:	
LTC facility contact/phone:		NPI:	MA Provider ID#:
RECIPIENT INFORMATION		Street address:	
Recipient Name:		Suite #:	City/state/zip:
Recipient ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Medication requested: <input type="checkbox"/> Orkambi	Strength:	Directions:	Qty:	Refills:
Diagnosis:			Dx code (required):	

Initial Requests

1. Is the prescriber a provider specializing in the treatment of cystic fibrosis?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Does the Recipient have results of an FDA-cleared cystic fibrosis (CF) mutation test that show the presence of the F508del mutation on both alleles of the CFTR gene?	<input type="checkbox"/> Yes – <u>submit documentation of results</u> <input type="checkbox"/> No
3. Does the Recipient have documentation of a baseline (pre-treatment) FEV ₁ ?	<input type="checkbox"/> Yes – <u>submit documentation of results</u> <input type="checkbox"/> No
4. Does the Recipient have lab results of baseline (pre-treatment) ALT and AST (liver function tests/LFTs)?	<input type="checkbox"/> Yes – <u>submit documentation of results</u> <input type="checkbox"/> No
5. Will the Recipient have repeat ALT and AST (liver function tests/LFTs) every 3 months during the first year of treatment and annually thereafter?	<input type="checkbox"/> Yes – <u>submit chart documentation</u> <input type="checkbox"/> No
6. Does the Recipient have liver disease or liver impairment?	<input type="checkbox"/> Yes – <u>submit documentation of degree of impairment</u> <input type="checkbox"/> No
7. Is the Recipient taking any of the following medications? Check all that apply. <input type="checkbox"/> Clarithromycin <input type="checkbox"/> Itraconazole <input type="checkbox"/> Nefazodone <input type="checkbox"/> Ritonavir <input type="checkbox"/> Voriconazole <input type="checkbox"/> Indinavir <input type="checkbox"/> Ketoconazole <input type="checkbox"/> Nelfinavir <input type="checkbox"/> Telithromycin	<input type="checkbox"/> Yes – <u>submit Recipient's complete current medication list</u> <input type="checkbox"/> No – <u>submit Recipient's complete current medication list</u>

Renewal Requests

1. Does the Recipient have recent lab results for ALT and AST (liver function tests/LFTs)? <i>Note: Testing should be completed every 3 months for the first year of therapy and annually thereafter.</i>	<input type="checkbox"/> Yes – <u>submit documentation of results</u> <input type="checkbox"/> No
2. Does the Recipient have liver disease or liver impairment?	<input type="checkbox"/> Yes – <u>submit documentation of degree of impairment</u> <input type="checkbox"/> No
3. Is the Recipient taking any of the following medications? Check all that apply. <input type="checkbox"/> Clarithromycin <input type="checkbox"/> Itraconazole <input type="checkbox"/> Nefazodone <input type="checkbox"/> Ritonavir <input type="checkbox"/> Voriconazole <input type="checkbox"/> Indinavir <input type="checkbox"/> Ketoconazole <input type="checkbox"/> Nelfinavir <input type="checkbox"/> Telithromycin	<input type="checkbox"/> Yes – <u>submit Recipient's complete current medication list</u> <input type="checkbox"/> No – <u>submit Recipient's complete current medication list</u>

PLEASE FAX COMPLETED FORM WITH REQUIRED CLINICAL DOCUMENTATION TO DHS – PHARMACY DIVISION

Prescriber Signature:	Date:
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