

ORKAMBI (lumacaftor/ivacaftor) PRIOR AUTHORIZATION FORM

Orkambi and Quantity Limits/Daily Dose Limits prior authorization guidelines are accessible on the DHS Pharmacy Services website at <http://www.dhs.pa.gov/provider/pharmacyservices/index.htm>.

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

CLINICAL INFORMATION

Medication requested: Orkambi	Dosage form: <input type="checkbox"/> tablet <input type="checkbox"/> granule packet <input type="checkbox"/> _____	Strength:
Directions:		Qty: Refills:
Diagnosis:		Dx code (required):
Specialty Pharmacy Drug Program: Orkambi is part of the DHS Specialty Pharmacy Drug Program and is only available from one of the two DHS specialty pharmacies – Walgreen's Specialty Pharmacy .		
Is the medication being prescribed by, or in consultation with, a pulmonologist or cystic fibrosis specialist?		<input type="checkbox"/> Yes <input type="checkbox"/> No

Initial requests

1. Does the beneficiary have results of an FDA-cleared cystic fibrosis (CF) mutation test that shows the presence of a mutation(s) in the CFTR gene as noted in the package labeling?	<input type="checkbox"/> Yes – <i>Submit documentation of results.</i> <input type="checkbox"/> No
2. Does the beneficiary have documentation of a baseline (pre-treatment) FEV ₁ ?	<input type="checkbox"/> Yes – <i>Submit documentation of results.</i> <input type="checkbox"/> No
3. Does the beneficiary have lab results of baseline (pre-treatment) ALT and AST (liver function tests/LFTs)?	<input type="checkbox"/> Yes – <i>Submit documentation of results.</i> <input type="checkbox"/> No
4. Will the beneficiary have repeat liver function tests (ALT, AST, bilirubin) every 3 months during the first year of treatment and annually thereafter?	<input type="checkbox"/> Yes – <i>Submit chart documentation.</i> <input type="checkbox"/> No
5. Does the beneficiary have liver disease or liver impairment?	<input type="checkbox"/> Yes <i>Submit documentation of degree of impairment.</i> <input type="checkbox"/> No
6. Is the beneficiary taking any of the following medications? <u>Check all that apply.</u> <input type="checkbox"/> strong P450 3A inducer (e.g., carbamazepine, phenobarbital, phenytoin, rifampin, etc.) <input type="checkbox"/> strong P450 3A inhibitor (e.g., ketoconazole, itraconazole, clarithromycin, ritonavir, etc.)	<input type="checkbox"/> Yes <i>Submit beneficiary's complete current medication list.</i> <input type="checkbox"/> No

Renewal requests

1. Does the beneficiary have recent lab results of liver function tests (ALT, AST, bilirubin)? <i>Note: Testing should be completed every 3 months for the first year of therapy and annually thereafter.</i>	<input type="checkbox"/> Yes – <i>Submit documentation of results.</i> <input type="checkbox"/> No
2. Does the beneficiary have liver disease or liver impairment?	<input type="checkbox"/> Yes <i>Submit documentation of degree of impairment.</i> <input type="checkbox"/> No
3. Is the beneficiary receiving clinical benefit from Orkambi?	<input type="checkbox"/> Yes <i>Submit documentation of beneficiary's clinical response.</i> <input type="checkbox"/> No
4. Is the beneficiary taking any of the following medications? <u>Check all that apply.</u> <input type="checkbox"/> strong P450 3A inducer (e.g., carbamazepine, phenobarbital, phenytoin, rifampin, etc.) <input type="checkbox"/> strong P450 3A inhibitor (e.g., ketoconazole, itraconazole, clarithromycin, ritonavir, etc.)	<input type="checkbox"/> Yes <i>Submit beneficiary's complete current medication list.</i> <input type="checkbox"/> No

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

Prescriber Signature:	Date:
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