



Johnson&Johnson

Coverage Decisions¹

Prior Authorization (PA)

Prior authorization (also called pre-authorization or pre-auth) is a common payer-required approval process that requires providers to submit medical necessity documentation in a specific way before coverage is approved for a requested therapy or service.

PA requirements – and the list of drugs subject to PA – will vary among payers. It is not unusual for there to be different coverage rules for the same therapy among payers.

Often, a payer will provide a specific form or process for PA. Providers may want to supplement this with documentation providing enough detail to support the request, such as medical chart notes, laboratory results, and prescription records.

Coding for Diagnosis¹

ICD-10-CM Diagnosis Codes

The table below lists ICD-10 diagnosis codes that you may need for patients treated with Opsumit® or Uptravi®.

These codes are not intended to be promotional or to suggest a use that is inconsistent with international and/or local approved label use. The list is not exhaustive and additional codes may apply.

Pulmonary Arterial Hypertension

Pulmonary Arterial Hypertension	
ICD-10 Indication	ICD-10 Code
Primary pulmonary hypertension	127.0
Heritable pulmonary arterial hypertension	
Idiopathic pulmonary arterial hypertension	
Primary group 1 pulmonary hypertension	
Pulmonary hypertension, unspecified	127.20
Secondary pulmonary arterial hypertension	127.21

Checklist for Prior Authorization Submission¹ **New Patient**



Patient Authorization form (Claim Form)

- Letter of Medical Necessity (Medical Report)
 - a) Patient's medical history, comorbidities & physical findings
 - b) Date of onset or diagnosis of disease
 - c) Risk factors and family history, if any.
 - d) Description of patient's recent symptoms and condition
 - e) Diagnosis Code; Disease Scores, Results of Investigations, and date
 - f) WHO Functional Class
 - g) Risk Status
 - h) Previous therapies, hospitalizations or surgeries and response to those interventions
 - Previous pharmacological treatment (name of drugs, dose, duration, response/failure)
 - · Previous related hospitalizations or surgeries, if any.



- a) Reason for not using other lines of treatment or reason for stepping up to dual or triple therapy, if applicable.
- b) Summary of the patient's likely prognosis or disease progression without treatment by Opsumit® or Uptravi®
- c) Reference to guidelines, if needed.

Diagnosis Codes and Assessment Results

ICD Code	I27.0 Primary Pulmonary Hypertension I27.2 Other secondary pulmonary hypertension I27.21 Secondary pulmonary arterial hypertension
Investigations	Mandatory Diagnostics: 1. ECHO 2. Radiography: Chest X-ray, CT scan, cardiac MRI (gradually, as per physician's practice) 3. Right Heart Catheterization (when prescribed by physician and/or requested by insurance) 4. 6-minutes walking distance 5. NT-proBnP
	Basic Routine Tests: 1. ECG 2. Blood Tests (CBC, LFT, RFT) 3. Pregnancy test Optional Tests (used to determine PAH type) 1. Immunology 2. Ventilation Perfusion Lung Scan 3. Abdominal US 4. Pulmonary Function, Arterial Blood Gases

6MWD, 6-minute walking distance; CBC, complete blood count; CT, computed tomography; ECG, electrocardiogram; ECHO, echocardiography; LFT, liver function test; MRI, magnetic resonance imaging; NT-proBNP, N-terminal pro-brain natriuretic peptide; PAH, pulmonary arterial hypertension; RFT, renal function test; WHO, World Health Organization.

Checklist for Prior Authorization Submission¹ **Refill or Addition**



Patient Authorization form (Claim Form)



- a) Patient's medical history, comorbidities, & physical findings
- b) Date of onset or diagnosis of disease
- c) Description of patient's recent symptoms and condition
- d) WHO Functional Class
- e) Risk Status
- f) In case of a refill: Improvement, and progress if any since last prescription.
- g) In case of addition of a new PAH medication:
- i. Name of new drug, dose, duration, schedules
- ii. Reason for addition and reference to guidelines if needed.



Follow up dates since last prescription along with improvement, and progress if any:

- How have the patient's disease scores and assessments improved?
- · How has the drug improved the patient's overall quality of life?
- Why does the patient need to continue treatment on the drug?



Diagnosis Codes and Assessment Results

ICD Code	I27.0 Primary Pulmonary Hypertension I27.2 Other secondary pulmonary hypertension I27.21 Secondary pulmonary arterial hypertension
Investigations	Basic Routine Tests (every 3 to 6 months) 1. ECG 2. Blood Tests (CBC, LFT, RFT) 3. Pregnancy test (as necessary) Other Diagnostics (once or twice per year, as prescribed by physician; requested by insurance and medically necessary) 1. ECHO (6 months up to 1 year) 2. Radiography: Chest X- ray, CT scan, cardiac MRI (gradually, as per physician's practice) 3. Right Heart Catheterization (when prescribed by physician and/or requested by insurance) 4. 6-minutes walking distance (165 m up to =/< 440 m; used to determine risk
	category)

CBC, complete blood count; CT, computed tomography; ECG, electrocardiogram; ECHO, echocardiography; LFT, liver function test; MRI, magnetic resonance imaging; PAH, pulmonary arterial hypertension; RFT, renal function test; WHO, World Health Organization

RESOURCES TO SUPPORT YOUR PATIENTS¹

Letter of Medical Necessity

Some payers may require that treating physicians complete a Letter of Medical Necessity before patients can receive a specific therapy.

We have provided a sample letter of Medical Necessity below.

Sample Letter of Medical Necessity

REQUEST: Authorization for treatment with Opsumit (macitentan)

DIAGNOSIS: [Insert Diagnosis] [Insert ICD]

DOSE AND FREQUENCY: [Insert Dose & Frequency]

TO WHOM IT **MAY CONCERN:**



I am writing to support my request for an authorization for the above-mentioned patient to receive treatment with Opsumit (macitentan) for the treatment of pulmonary arterial hypertension (PAH).

My request is supported by the following:

Summary of Patient's Diagnosis

[insert patient's diagnosis, date of diagnosis, lab results and date, current condition] **Summary of Patient's History**

[Insert summary of patient history per your medical judgment. You may want to include:

- Previous therapies/procedures and response to those interventions
- Previous treatment of PAH, including OPSUMIT, if applicable, and patient's response
- Brief description of the patient's recent condition and test results (e.g., right heart catheterization, acute vasoreactivity, echocardiography, functional class, oxygen use, or 6-minute walk distance)
- History of patient's routine and non-routine visits
- Summary of your professional opinion of the patient's likely prognosis without treatment with OPSUMIT

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment

[Insert summary statement for treatment rationale such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of OPSUMIT, I believe treatment with OPSUMIT at this time is medically necessary and should be a covered treatment for my patient. You may consider including documents that provide additional clinical information to support the recommendation for OPSUMIT for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization.

Enclosures: [include full Prescribing Information and the additional support noted above].

Sincerely,

[Insert Physician Name



WHY MACITENTAN?^{2,3}

2022 ESC/ERS GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF PULMONARY HYPERTENSION²

Recommendation Table 10 - Recommendations for sequential drug combination therapy for patients with idiopathic, heritable, or drug-associated pulmonary arterial hypertension

Recommendations	Class	Level
General recommendation for sequential combination therapy		
It is recommended to base treatment escalations on risk assessment and general treatment strategies	I	С
Evidence from studies with a composite morbidity/mortality endpoint as the primary outcome measure		
The addition of macitentan to PDE5is or oral/inhaled prostacyclin analogues is recommended to reduce the risk of morbidity/mortality events	I	В
The addition of selexipag to ERAsc and/or PDE5is is recommended to reduce the risk of morbidity/ mortality events	I	В
The addition of oral treprostinil to ERA or PDE5i/riociguat monotherapy is recommended to reduce the risk of morbidity/mortality events	1	В
The addition of bosentan to sildenafil is not recommended to reduce the risk of morbidity/ mortality events	Ш	В

PRESCRIBING AND DOSAGE INFORMATION

Opsumit is to be taken orally at a dose of 10 mg once daily, with or without food.³

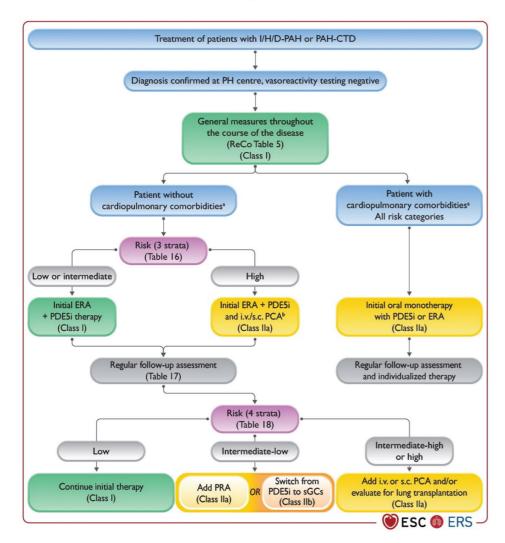
Indication Opsumit:3-6

Opsumit, as monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension PAH in adult patients of WHO Functional Class FC II to III to reduce morbidity and the risk of mortality.



ERA, endothelin receptor antagonist; ERS, European Respiratory Society; ESC, European Society of Cardiology; FC, functional class; I B, recommendation class and level (evidence grading); I c, recommendation class and level (evidence grading); PAH, pulmonary arterial hypertension; PDE5i, phosphodiesterase 5 inhibitor; WHO, World Health Organization.

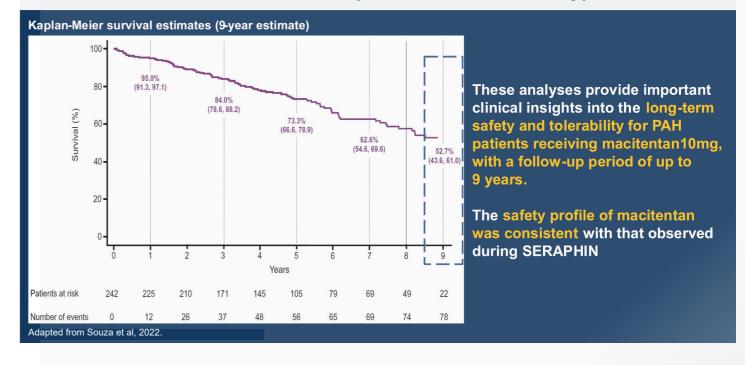
MACITENTAN IS RECOMMENDED FOR USE AS UPFRONT DUAL COMBINATION ACCORDING TO ESC/ERS GUIDELINES 2022²



- The treatment algorithm calls out patients with and without cardiopulmonary comorbidities
- In non comorbid patients
- 0 **Strong recommendation of initial dual**(ERA & PDE5i) in low & intermediate
 o Strength of recommendation from macitentan & tadalafil has been increased based on OPTIMA and TRITON.^{2,7,8}
- In comorbid patients, initial monotherapy (ERA or PDE5i) is recommended.²
- Macitentan has been evaluated as monotherapy in PAH patients with comorbidities.⁴

Recommendations	Class	Level
Initial combination therapy with ambrisentan and tadalafil is recommended.	1	В
Initial combination therapy with macitentan and tadalafil is recommended.	1	В
Initial combination therapy with other ERAs and PDE5is should be considered.	lla	В
Initial combination therapy with macitentan, tadalafil, and selexipag is not recommended.	Ш	В

Long-Term Safety, Tolerability and Survival in Patients with PAH Treated with Macitentan (SERAPHIN OLE Study)⁹



When should you be cautious when taking Opsumit?

If you have anaemia (a reduced number of red blood cells).

Before you start treatment with Opsumit and during treatment your doctor will take blood tests to control the number of blood cells and whether your liver is working properly.

Signs that your liver may not be working properly include: nausea (urge to vomit), vomiting, fever (high temperature), pain in your stomach, yellowing of your skin or the whites of your eyes (jaundice), dark-coloured urine, itching of your skin, unusual tiredness or exhaustion, flu-like syndrome (joint and muscle pain with fever). If you notice any of these signs, tell your doctor immediately.

If your disease is not due to a blocked or narrowed artery but is due to a blocked or narrowed vein of the lungs.

If you suffer from renal deficiency.

If you have an HIV infection.

Opsumit may have a negative effect on male fertility.

Opsumit should not be given to children under the age of 12 years.

Please note that, because of undesirable effects, such as headache, this medicine can adversely affect reaction speed, fitness to drive, and the ability to use machines.

Concomitant use of Opsumit and Rifampicin (Treatment of infectious disease including tuberculosis) as well as Ketoconazole and fluconazole (treatment of fungal infections) can affect each other.

Please only take Opsumit after consulting your doctor if you know that you are suffering from intolerance to some sugars such as Lactose.

Opsumit contains less than 1 mmol sodium (23 mg) per film-coated tablet, i.e. it is almost "sodium-free".

Tell your doctor or pharmacist if you

- have any other diseases,
- have any allergies, or
- are taking or applying any other medicines (including ones which you have bought yourself!).

NO DDI between Macitentan, and PDE-5is (Sildenafil, and Tadalafil)¹⁰

Revised: March 2023

DDI, drug-drug interactions; DLCO, lung diffusion capacity for carbon monoxide; ERA, endothelin receptor antagonist; H/D-PAH, idiopathic, heritable, or drug-associated pulmonary arterial hypertension; i.v., intravenous; OLE, open label extension; PAH, pulmonary arterial hypertension; PAH-CTD, pulmonary arterial hypertension associated with connective tissue disease; PCA, prostacyclin analogue; PDE5i, phosphodiesterase 5 inhibitor; PH, pulmonary hypertension; PRA, prostacyclin receptor agonist; ReCo, recommendation; s.c., subcutaneous; sGCs, soluble guanylate cyclase stimulator.

RESOURCES TO SUPPORT YOUR PATIENTS¹¹

Letter of Medical Necessity

Some payers may require that treating physicians complete a Letter of Medical Necessity before patients can receive a specific therapy.

We have provided a sample letter of Medical Necessity below.

Sample Letter of Medical Necessity

REQUEST: Authorization for treatment with **DIAGNOSIS:** [Insert Diagnosis] [Insert ICD]

DOSE AND FREQUENCY: [Insert Dose & Frequency]

TO WHOM IT MAY CONCERN:



I am writing to support my request for an authorization for the above-mentioned patient to receive Uptravi (selexipag) for the treatment of pulmonary arterial hypertension (PAH) My request is supported by the following:

Summary of Patient's Diagnosis

[Insert patient's diagnosis, date of diagnosis, lab results and date. current condition]

Summary of Patient's History

[Insert summary of patient history per your medical judgment. You may want to include:

- Previous therapies/procedures and the patient's response to those interventions
- Previous treatment of PAH including UPTRAVI®, if applicable, and patient's response
- Brief description of the patient's recent condition and test results (e.g., right heart catheterization, acute vasoreactivity, echocardiography, functional class, oxygen use, or 6-minute walk distance)
- History of patient's routine and non-routine visits
- Summary of your professional opinion of the patient's likely prognosis without treatment with Uptravi Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.

Rationale for Treatment

[Insert summary statement for treatment rationale such as:] Considering the patient's history, condition, and the full Prescribing Information that supports uses of Uptravis, I believe treatment with Uptravis at this time is medically necessary and should be a covered therapy for my patient. You may consider including documents that provide additional clinical information ro support the recommendation for Uptravis for this patient, such as the full Prescribing information. peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization.

Enclosures: [include full Prescribing Information and the additional support noted above].

Sincerely, [Insert Physician Name]

PRESCRIBING AND DOSAGE INFORMATION¹²



- Individualized dose titration: Each patient should ne up titrated to the highest individually tolerated dose, which can range from 200 micrograms given twice daily to 1,600 micrograms given twice daily (individualized maintenance dose), usually at weekly intervals.
- Individualized maintenance dose: The highest tolerated dose reached during dose titration should be maintained.
- If the therapy over time is less tolerated at a given dose, symptomatic treatment and/ or a dose reduction to the next lower dose should be considered.
- Interruptions and discontinuations: If a dose is missed, it should be taken as soon as possible. The missed dose should not be taken if the next scheduled dose is within approximately 6 hours. If treatment is missed for 3 days or more, Uptravi should be restarted at a lower dose and then up titrated.
- If the decision to withdraw Uptravi is taken, it should be done gradually while an alternative therapy is introduced.

PAH, pulmonary arterial hypertension.

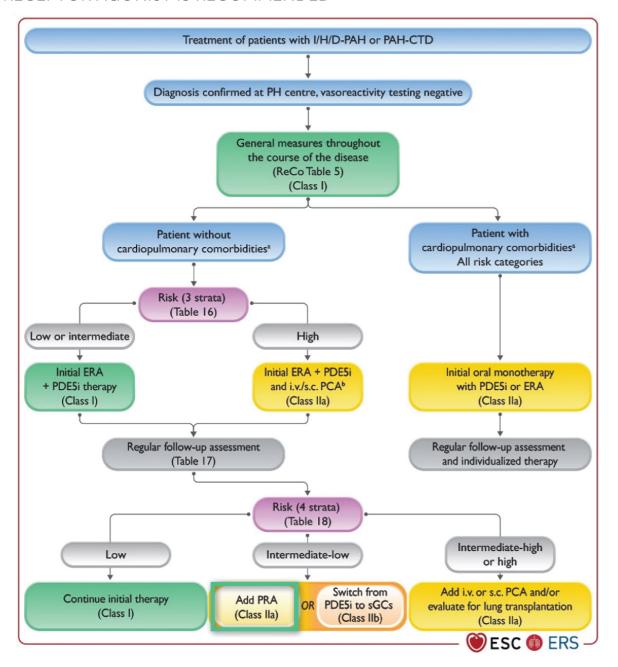


Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II—III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies.¹²



PAH TREATMENT ALGORITHM | ESC/ERS GUIDELINES²

"FOR INTERMEDIATE-LOW PAH PATIENTS ADDITION OF PROSTACYCLIN RECEPTOR AGONIST IS RECOMMENDED"



PAH TREATMENT ALGORITHM ESC/ERS 2022 GUIDELINES²

Recommendation Table 10 - Recommendations for sequential drug combination therapy for patients with idiopathic, heritable, or drug-associated pulmonary arterial hypertension

"THE **ADDITION OF UPTRAVI** TO ERA AND/OR PDE S IS **RECOMMENDED** TO REDUCE THE **RISK OF MORBID/MORTALITY EVENTS**"

Recommendations	Class	Level
General recommendation for sequential combination therapy		
It is recommended to base treatment escalations on risk assessment and general treatment strategies	1	С
Evidence from studies with a composite morbidity/mortality endpoint outcome measure	as the prii	mary
The addition of macitentan to PDE5is or oral/inhaled prostacyclin analogues is recommended to reduce the risk of morbidity/mortality events	1	В
The addition of selexipag to ERAscand/or PDE5is is recommended to reduce the risk of morbidity/ mortality events	I	В
The addition of oral treprostinil to ERA or PDE5i/riociguat monotherapy is recommended to reduce the risk of morbidity/mortality events	1	В
The addition of bosentan to sildenafil is not recommended to reduce the risk of morbidity/ mortality events	III	В

ERA, endothelin receptor antagonist; ERAsc, endothelin receptor antagonists (selexipag); ESC, European Society of Cardiology; ERS, European Respiratory Society; FC, functional class; H/D-PAH, idiopathic, heritable, or drug-associated pulmonary arterial hypertension; i.v., intravenous; I B, recommendation class and level (evidence grading); I c, recommendation class and level (evidence grading); PAH, pulmonary arterial hypertension; PAH-CTD, pulmonary arterial hypertension associated with connective tissue disease; PCA, prostacyclin analogue; PDE-5, phosphodiesterase type 5; PDE5i, phosphodiesterase 5 inhibitor; PH, pulmonary hypertension; PRA, prostacyclin receptor agonist; ReCo, recommendation; s.c., subcutaneous; sGCs, soluble guanylate cyclase stimulator; WHO, World Health Organization.

IT IS IMPORTANT TO CORRECTLY INTRODUCE Uptravi >> TO PATIENTS

Explain to each patient why UPTRAVI is being added:

Short-term benefits, like

- Improved/maintained risk status 13
- Decreased NT-proBNP 14

Long-term benefits, like

- Reduced morbidity14*
- Delayed hospitalization14
- Better long-term outcomes 14,15*
- It's important to explain that side effects are expected, and the goal is to reach the maximally tolerated dose.^{2,12}
- If side effects are not tolerable, the dose is reduced by one step. This represents the patient's personalized maintenance dose. 12

NT-proBNP, N-terminal pro-brain natriuretic peptide; PAH, pulmonary arterial hypertension.

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge.

Similarly, all codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Janssen Pharmaceuticals that these codes will be appropriate or that reimbursement will be made.

It is not intended to increase or maximize reimbursement by any payer. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it.

Please see full Prescribing Information for Opsumit® and Uptravi®.

References

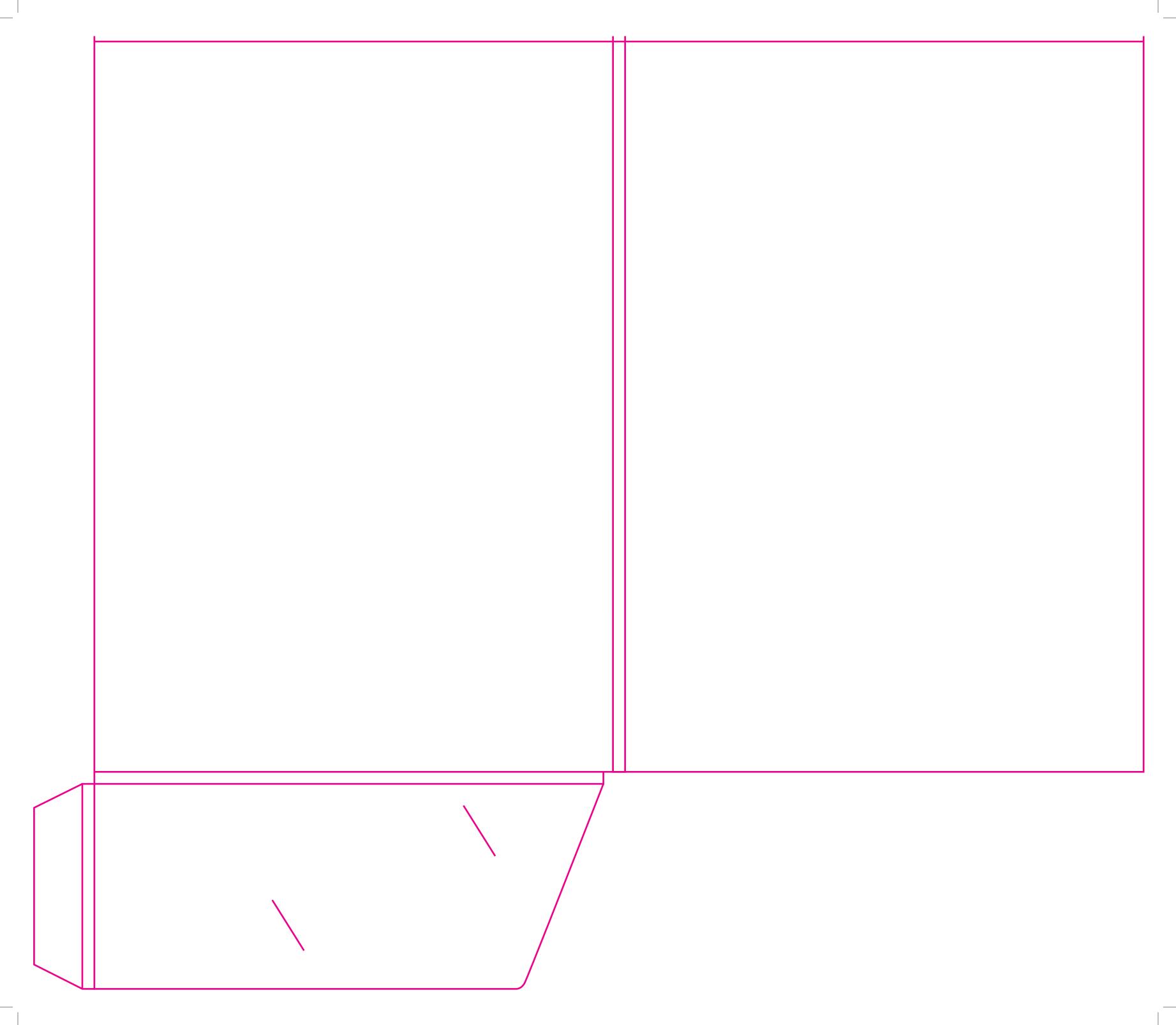
- 1. Janssen CarePath for patients and Caregivers. Available at: https://www.janssencarepath.com/hcp/opsumit/ (Accessed: 09 October 2024).
- 2. Humbert M, et al. Eur Heart J 2022;43:3618-3731.
- 3. OPSUMIT Summary of Product Characteristics, June 2022.
- 4. Pulido T, et al. N Engl J Med 2013;369:809-18.
- 5. Sitbon O, et al. Lancet Respir Med 2019;7:594-604.
- 6. Jansa P, Pulido T. Am J Cardiovasc Drugs 2018;18:1-11.
- 7. Sitbon O, et al. Eur Respir J 2020;56:2000673.
- 8. Chin KM, et al. J Am Coll Cardiol 2021;78:1393-1403.
- 9. Souza R, et al. Adv Ther 2022;39:4374-4390.
- 10. Opsumit Prescribing Information, March 2023.
- 11. Janssen CarePath for patients and Caregivers. Available at: https://www.janssencarepath.com/hcp/uptravi/ (Accessed: 09 October 2024).
- 12. UPTRAVI Summary of Product Characteristics, May 2022.
- 13. Farber HW, et al. Am J Respir Crit Care Med 2019;199.
- 14. Sitbon O, et al. N Engl J Med 2015;373:2522-33.
- Galie N, et al. Presented at ESC 2018.

^{*}As measured by a composite primary morbidity-mortality endpoint, results were driven by a decrease in PAH worsening and do not apply to mortality on its own. This was measured by death due to PAH or hospitalization for worsening of PAH. 14.15





Johnson&Johnson



Hand in Hand Program

EXTRA SERVICES



The program will support patients who hold a valid prescription of Janssen products, whom may experience insurance approval challenges.

HOW does insurance navigation service work

- Patient is diagnosed and prescribed Product
- Patient is insured and may experience insurance approval challenges.
- 3 Complete Statement of Medication Necessity Application and select the insurance coordination service.
- 4 Axios insurance coordinator will contact the patient.
- 5 Axios Shall communicate with the insurance on behalf of the patient and inform him with the update



On-Time Access is an innovative solution to overcome the delay in patient's treatment initiation on the medication. The On-Time Access will be available for those patients facing delays in starting the treatment on a medication due to approval delays from insurance providers or charities. A patient will be eligible to participate in the On-Time Access only if the following cumulative eligibility criteria.



Hand in Hand

How we help your patients

Patient Assistance Program

Email: HandInHand@axiosint.com Landline: +971 4 770 8146

Fax: +971 4 360 7655

Mob: +971 56 339 8186 | +971 52 205 8900

We understand the difficulties patients face in paying for their medication and the impact this has on their disease outcomes.

Therefore **JANSSEN**, **Axios & their strategic partners** have joined forces to design the **HAND IN HAND PAP** Patient Assistance Program, to help your patients cover the cost of their supported treatment through the program.



WHO are eligible to the program

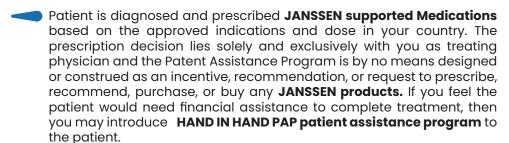
All patients who are prescribed JANSSEN Medications, with no or limited insurance coverage and do not have full course of treatment plan coverage.

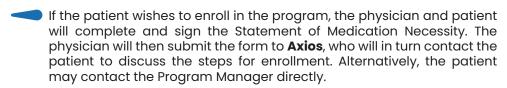


HOW does the program work



DURING the Medical Appointment







The patient can learn more about the program in two ways:

- The patient calls **Axios** to speak to a representative about the program
- 2 The patient will be contacted directly via phone within 24 working hours based on the information from the **Statement of Medical Necessity Application**



Patient Means-Based **ASSESSMENT**

Patients will undergo a confidential means-based assessment using **Axios'** validated tool to determine their ability to pay. Once the assessment results are completed, it will be communicated to you and the patient. The results will be accompanied by a treatment plan that indicates how many boxes the patient will be asked to pay and how many boxes will be covered by the program to complete a one-year treatment plan. **After the first year of treatment**, if the treating physician wishes to continue the same treatment, the patient must undergo a means-based assessment annually to determine if their financial situation has changed. Upon request, the physician or the nurse may also receive this information.

Axios may refer patients who cannot afford paying the minimum quantities of medicines in their charge to a charity partner (if available in the implemented)

Once patient deemed eligible and document completed, Axios will then provide the patient with a Copayment voucher to be used for collection of the medication in the designated pharmacy and upon purchasing what the patient can afford, the patient will need to send the receipt of purchase, copy of new prescription to **Axios** for verification. **Axios** will then provide the patient with a Medication Release Letter to be used for collection of the supported medication (boxes) from designated pharmacy that are in charge of dispensing the supported medication in the program.



The patient will continue to return to their physician for follow-up as needed. After one year, if treatment is still necessary as per your independent medical judgement.

Statement of Medication Necessity Application



Once completed, please submit this form by: e-mail handinhand@axiosint.com or fax 043607655

PHYSICIAN NAME	Hospital / Clinic name
PHYSICIAN/CLINIC Contact details	Email Address
PATIENT INFORMATION	
Name Date of Birth Day Month Year / /	Telephone Mobile Alternative number E-mail
DIAGNOSIS	
Medication Opsumit	Uptravi Selexipag Dose:
Indication Pulmonary Arterial Hypertensia	on (PAH)
Services Patient needs to consent on terms and conditio	Insurance Co-ordination Solution Affordability Solutions [Co-Payment or Sefl Pay]

By signing below, I certify that:

Physician signature and stamp:

a) The above therapy is medically necessary as per my independent medical judgement and I do understand that I will report patient medical status over the program time. b) I am authorized to release the above-referenced information like diagnostic tests, patient medical status and other protected health information for the purpose of seeking the evaluation of the patients eligibility to the Program and or to facilitate his enrolment to any of the needed solution and I do understand that only medically and financially eligible patients will be supported in the program. c) I understand that Axios might contact me to confirm the data validity or to acquire further information related to the patient enrolment in this program. d) I will not sell or bill for any free product if received on behalf of the patient from the Program e) I agree to report any Adverse Event that may occur to any patients enrolled in the Program and, if requested, to provide related clinical patients' data f) I agree to comply with the Program guidelines and understand that Johnson & Johnson

I, hereby, acknowledge by signing this form that I adhere to the Insurance Co-ordination and Affordability solutions

a) To let my doctors, release my personal and health information including, but not limited to, info about all my health records related to my treatment, information about my health insurance plan and my personal contact details as indicated below b) My personal health information will be used to help apply and qualify for HAND IN HAND Program, Insurance Co-ordination or affordability service and for tracking supported medications c) I will use the received supported medication from the Program as prescribed by my treating physician and will not sell or distribute any supported medications also I understand that the program does not have any relation with my medical management or any impact on my medical situation because of the medication supported by the program. I understand that violation of this will result in losing access to the Program d) I agree that I will collect the supported medications from Program's designated pharmacies for the duration of my treatment e) This application and consent does not guarantee that I will be eligible for the Hand in Hand Program nor does it guarantee that the treatment will be reimbursed/approved by the insurance company f) All information I have given, and will give in the future, is complete, true and accurate to the best of my knowledge and I agree to inform my doctors and Axios of any future changes to my insurance status or any future changes in my financial or social status during the supported treatment plan g) All information may need to be verified through the request of documentation h) I am aware that if it becomes evident that I have provided false information, I may be excluded from the Program i) I understand and agree that failure to provide to Axios International mandatory information and/or documentation needed for my financial assessment or, if applicable, re-assessment, may automatically trigger the ineligibility status of my application for the Program i) I agree that, if I will be eligible for the Program, I will promptly inform Axios throughout my course of treatment about any changes regarding the information initially disclosed for my financial assessment, treatment coverage or, if applicable, re-assessment and failure to do so may result in my exclusion from the Program k) I understand and agree that Axios may need to visit me at my home address, as voluntarily disclosed by me in this form, in order to check the information provided for my financial assessment I) I understand and agree that any communication about the Program can only be addressed to Axios or their strategic partners and/or to my treating physician and I should not contact Johnson & Johnson at any point in time m) I understand and agree that any medical related questions that I may have must be addressed only to my treating physician and Axios will always refer me to my treating physician n) I understand and agree that Johnson & Johnson has the right to cancel or suspend the program anytime at its sole discretion and I will be informed of such decision by Axios. I also understand and agree that I will not be entitled to any compensation or remedy as a result of Program's cancellation or suspension. •) This consent is in effect for a duration of Full treatment plan if I have been enrolled in the program or 2 year upon date of signature p) understand that my participation is voluntary, and I may withdraw it in verbally or in writing at any time. I understand that all my information will be handled as strictly confidential and will not be shared or disclosed to any other party or stakeholder other than Axios partners and for the purpose of this program (Insurance, Charities, Distributors or pharmacies) q) I allow Axios to report any adverse event, that may be identified during our interactions, to Johnson & Johnson and also agree that Johnson & Johnson may contact my treating physician to get more details if needed (excluding my personal information) r) I confirm having received, read and understood the patient information pack describing HAND IN HAND Patient Support Program and I agree with all the terms and conditions of the Program mentioned in the patient information pack. s) If I undergo any adverse event, I am committed to report it to the HAND IN HAND program team. t) I also expressly authorize Axios to collect, process, and use my personal data - namely my name, home address, telephone number(s) and email address, as these are disclosed voluntarily above and my sensitive personal data namely financial information regarding my employment, salary or other income sources, savings, assets, bank accounts, investments or any other personal information provided during and for my financial assessment, along with information about my health including medical diagnosis, medical tests, medication and treatment, medical appointments as such may be disclosed by me in this form and/or at a later stage or by my physician throughout the course of the Program, for purposes of proper assessment of my application, potential enrollment in Hand In Hand Patient Support Program and management of the Hand In Hand Patient Support Program, where my personal data disclosed above will be electronically stored, processed and used for further interactions conducted within Hand In Hand Patient Support Program. u) I furthermore agree that Axios may transfer my above-referenced personal data for the same purposes to the charity partners, health authorities, program partner excluding Johnson & Johnson and the pharmacies in the Patient Support Program and external service providers which may be contracted by Axios for maintaining the data base, for review and processing purposes, within and outside the Middle East. Axios will perform itself or have the service provider perform such data processing and use in accordance with the applicable data protection laws. v) I understand that I am free to withdraw my consent at any time with future effect by sending a written or verbal message to Axios program manager at the address below: I understand that signing this consent is voluntary and I confirm having read this consent in full before signing below

Patient signature:	Date:
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