

Janssen PAH Link for OPSUMIT[®]

Janssen PAH Link Program enables eligible patients to receive OPSUMIT[®] (macitentan) at no cost until you receive coverage or through the rest of the calendar year if an approval decision has not been made in 90 days.

Janssen PAH Link Program Requirements



- You have been prescribed OPSUMIT[®] for an on-label, FDA-approved indication
- You have commercial insurance that has delayed (>5 business days) or denied your treatment
- You do not use any state or federal government-funded healthcare program to cover a portion of medication costs, such as Medicare, Medicaid, TRICARE, Department of Defense, or Veterans Administration
- You cannot submit the value of the free product as a claim for payment to any third-party payer
- You are not eligible if the prior authorization is denied due to missing information on coverage determination form, use for a non-FDA approved indication, or invalid clinical rationale
- You must contact Janssen CarePath if you switch from commercial health insurance coverage to a government-funded healthcare program at any point during the program year



- Your prescriber must complete and submit a Prescription and Statement of Medical Necessity form to Janssen CarePath to enroll you in Janssen PAH Link
 - Janssen CarePath cannot accept any information without a Patient Authorization on file. The patient authorization can be found on the Prescription and Statement of Medical Necessity form.
- Your prescriber completes and submits a form of coverage determination (ie, prior authorization or prior authorization with exception) to the commercial insurance
- If coverage is denied, your prescriber challenges the coverage denial with an exception, Letter of Medical Necessity, or appeal

How the Janssen PAH Link Program works

- Program covers the cost of therapy only
- No portion of the value of the free product will count towards the patient's applicable out-of-pocket cost-sharing obligations
- Program year runs January 1 – December 31
- Janssen CarePath reserves the right to cancel or modify Janssen PAH Link at any time

Please read the full [Prescribing Information](#) and [Medication Guide](#) for OPSUMIT[®], including an Important Warning about Serious Birth Defects.

What is OPSUMIT® (macitentan)?

OPSUMIT® is a prescription medicine used to treat pulmonary arterial hypertension (PAH, WHO Group 1). PAH is high blood pressure in the arteries of your lungs. OPSUMIT® can:

- Improve your ability to exercise as measured by the 6-minute walk distance (6MWD). In a clinical study of mainly WHO FC II-III patients, those taking OPSUMIT® walked, on average, 22 meters farther at Month 6 than patients not taking it
- Improve some of your symptoms
- Help slow down the progression of your disease
- Lower your chance of being hospitalized for PAH

It is not known if OPSUMIT® is safe and effective in children.

The most important information about OPSUMIT® (macitentan)

Do not take OPSUMIT® if you are pregnant or trying to get pregnant. OPSUMIT® can cause serious birth defects if taken while pregnant.

Women who are able to get pregnant must have negative pregnancy tests:

- Before starting OPSUMIT®
- Each month while taking OPSUMIT®
- For 1 month after stopping OPSUMIT®

Your doctor will decide when you should take pregnancy tests.

You are medically able to get pregnant if you are a woman who fits all of the following guidelines:

- has started puberty, even if you have not had a menstrual period yet
- has a uterus
- has not gone through menopause (menopause means you have not had a menstrual period for at least 12 months for natural reasons, or have had your ovaries removed)

You are not medically able to get pregnant if you are a woman who fits at least 1 of the following guidelines:

- has not started puberty
- does not have a uterus
- has gone through menopause (you have not had a menstrual period for at least 12 months for natural reasons, or have had your ovaries removed)
- is infertile for other medical reasons and this infertility is permanent and cannot be reversed

While taking OPSUMIT®, and for 1 month after stopping OPSUMIT®, women who are able to get pregnant must use 2 acceptable forms of birth control. Women who have had a tubal sterilization, a progesterone implant, or have an IUD (intrauterine device) do not need a second form of birth control. Talk to your doctor or gynecologist about which birth control to use while on OPSUMIT®. If you decide to change your form of birth control, talk with your doctor or gynecologist. This way you can be sure to choose another acceptable form of birth control. **Also review the Medication Guide for acceptable birth control options.**

It's important not to have unprotected sex while taking OPSUMIT®. Tell your doctor right away if you have unprotected sex, think your birth control has failed, miss a menstrual period, or think you may be pregnant. He or she may recommend using a form of emergency birth control.

If you are the parent or caregiver of a female child who started taking OPSUMIT® before reaching puberty, check with your child regularly for any signs of puberty. **Your child may reach puberty before having her first menstrual period.** Talk to your doctor if you think your child is showing signs of puberty or if you have any questions about the signs of puberty.

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The most important information about OPSUMIT® (continued)

Before starting OPSUMIT®, women must enroll in a program called the OPSUMIT® Risk Evaluation and Mitigation Strategy (REMS). If you are a woman who is able to get pregnant, you must talk to your doctor to learn the benefits and risks of OPSUMIT®. You must also agree to all of the instructions in the program. Men who are prescribed OPSUMIT® do not need to enroll in this program.

Who should not take OPSUMIT®?

Do not take OPSUMIT® if you are pregnant, plan to become pregnant, or become pregnant during treatment with OPSUMIT®. OPSUMIT® can cause serious birth defects. See “The most important information about OPSUMIT®.”

Do not take OPSUMIT® if you are allergic to macitentan or any of the ingredients in OPSUMIT®. See the Medication Guide for a complete list of ingredients in OPSUMIT®.

Talk to your doctor about all your medical conditions, as well as all the medicines, vitamins, and supplements you take. OPSUMIT® and other medicines may affect each other causing side effects. Tell your doctor right away if you take an HIV medicine. Do not start any new medicine until you check with your doctor.

What should I avoid while taking OPSUMIT®?

- **Do not get pregnant.** OPSUMIT® can cause serious birth defects. See “The most important information about OPSUMIT®.” If you miss a menstrual period or think you may be pregnant, call your doctor right away
- **You should not breastfeed if you take OPSUMIT®.** It is not known if OPSUMIT® passes into your breast milk. Talk to your doctor about the best way to feed your baby

What are the possible side effects of OPSUMIT®?

OPSUMIT® can cause serious side effects, including:

- **Serious birth defects.** See “The most important information about OPSUMIT®”
- **Some medicines that are like OPSUMIT® can cause liver problems.** Your doctor should do blood tests to check your liver before you start OPSUMIT®. Tell your doctor if you have any of these symptoms, which could be a sign of liver problems while on OPSUMIT®:
 - Nausea or vomiting
 - Pain in the upper right stomach
 - Feeling tired
 - Loss of appetite
 - Your skin or the whites of your eyes turn yellow
 - Dark urine
 - Fever
 - Itching
- **Fluid retention** could happen during the first weeks after starting OPSUMIT®. Tell your doctor right away if you notice unusual weight gain or swelling in your ankles or legs. Your doctor will look for the cause
- **Low red blood cell levels (anemia) can happen while taking OPSUMIT®, usually during the first weeks after starting OPSUMIT®. In some cases a blood transfusion may be needed, but this is not common.** Your doctor will do blood tests to check for anemia before you start OPSUMIT®. You may also need to do these blood tests while taking OPSUMIT®
- **Decreased sperm counts.** OPSUMIT®, and other medicines like OPSUMIT®, may cause decreased sperm counts in men who take these medicines. If fathering a child is important to you, tell your doctor

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What are the possible side effects of OPSUMIT[®]? (continued)

The most common side effects are:

- Stuffy nose or sore throat
- Irritation of the airways (bronchitis)
- Headache
- Flu
- Urinary tract infection

Talk to your doctor if you have a side effect that bothers you or does not go away. These are not all the possible side effects of OPSUMIT[®]. For more information, ask your doctor or pharmacist.

You may report side effects to FDA at **1-800-FDA-1088** or www.fda.gov/medwatch.

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