Sotatercept approved for use in England and Wales

A significant step forward, and the start of the work ahead

A statement for people living with PH, and their loved ones

14th May 2026

On 14th May 2026, the National Institute for Health and Care Excellence (NICE) announced that **sotatercept (Winrevair®)** has been recommended for use in eligible patients with pulmonary arterial hypertension (PAH) in England and Wales. The drug was approved in Scotland by the Scottish Medicines Consortium (SMC) in April 2026. Northern Ireland will make its own separate decision in due course, taking the NICE recommendation into account.

This is a significant moment, and one that PHA UK has worked hard to help bring about. This document contains important information to provide the full context of the decision, and what it means for you.

> **We know this news will feel different depending on where you are in your journey.**
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> For some, it will bring real hope and the possibility of a new treatment option in the months ahead. For others those at a different stage of their disease, or who don't yet meet the criteria for this treatment it may feel more complicated, or even painful. We want you to know that you have not been forgotten. PHA UK's commitment is to every person living with pulmonary hypertension, at every stage. The work to secure access for a wider group of patients continues, and we are leading it on your behalf.

Who is eligible for sotatercept?

NICE has approved sotatercept for adults with PAH whose condition has not improved enough with combination therapy, and who were assessed as 'intermediate-low risk' at their last specialist check-up. In plain terms, this is likely to mean it will be available to patients who remain significantly limited by their symptoms despite existing treatment, but who are not yet at the highest risk level.

If you are unsure whether this applies to you, your specialist team will be best placed to advise — and they will be in touch when the time is right.

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When will sotatercept be available?

Sotatercept will not be available for prescription immediately. Following a NICE recommendation, NHS commissioning must be put in place , a process that can take up to 90 days in England and 60 days in Wales. PHA UK is actively working to ensure this happens as quickly as possible.

It is also important to understand that starting sotatercept is not a straightforward process. It requires several clinic appointments in a relatively short period of time while the dosage is carefully established and your response is monitored. Specialist centres across the country are currently working through how to manage this safely and equitably for all eligible patients and that takes time to get right.

For this reason, we ask that you allow your specialist team to contact you when sotatercept is available and the right pathway is in place for you.

Please do not reach out to them in the meantime and when the time comes, they will be ready for you.

PHA UK's role in this decision

PHA UK played a direct and active role in this outcome. As a formal stakeholder in the NICE appraisal process, we attended review meetings, submitted evidence of the unmet needs faced by people living with PAH, and in March 2026 made a formal representation to NICE to challenge the process and push for a faster decision.

But our ability to influence this decision was grounded in something deeper than attendance at meetings. Over recent years, PHA UK has conducted several significant research studies drawing directly on the lived experience of our membership what it feels like to live with PH day to day, what the system gets right and gets wrong, and what patients need that they are not currently getting.

That evidence, built by our community and presented in our own voice, formed a substantial and compelling part of our formal submission to NICE. Two PHA UK members also gave direct testimony at the first review meeting and their courage in doing so was made more powerful by the research that stood behind them.

This is why your involvement in our work matters. It is not background noise; it is the evidence base. And it is why we believe, fundamentally, that the patient must be central to every decision made about their care. That principle did not stop with this approval. It drives everything we do, and the research continues.

Statement from Dr Iain Armstrong, Chair, PHA UK

> "This is a significant moment for the PAH community. More patients will now have access to an important new therapy, and the approval matters because it was earned. Our members shared their experiences, their evidence, and their determination and that found its way into the formal process when it was needed most.
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> "But I want to be clear: a positive NICE recommendation is not the end of the road. It is the beginning of the next stage. Access on paper must become access in practice and that requires sustained, active work. PHA UK will continue to work alongside the clinical community, NHS England, and MSD to make sure the pathway from recommendation to prescription is clear, fast, and equitable for every eligible patient. And we will not stop advocating for the patients who fall outside the initial criteria, and who deserve a pathway too.
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> "The work is not done. It has entered a new phase and PHA UK is leading it."

About sotatercept

Sotatercept represents a completely new approach to treating PAH. Most existing treatments are known as vasodilators, which work by relaxing and widening narrowed blood vessels. These help manage symptoms but do not address the underlying cause of the disease.

Sotatercept works differently. It targets the signalling pathways involved in the disease process itself, helping to rebalance the proteins that drive PAH. This makes it the first treatment of its kind to act more directly on the root cause of the condition.

It is important to note that sotatercept is not a cure. It is also not suitable for everyone. There are, for same, significant side effects. Those who are eligible, it is used alongside existing treatments and is given as an injection under the skin every three weeks.

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