

## Plain English Summary

# Inavolisib in combination with palbociclib and fulvestrant for treating *PIK3CA*-mutated, HR-positive, HER2-negative locally advanced or metastatic breast cancer

## What does the guidance say?

Inavolisib, in combination with palbociclib and fulvestrant, is not recommended for government funding for patients with *PIK3CA*-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer who have had adjuvant endocrine therapy. It is not subsidised and cannot be claimed under MediShield Life.

## What is locally advanced or metastatic breast cancer?

Breast cancer occurs when abnormal cells grow uncontrollably in the ducts or lobules of the breast and spread into the surrounding breast tissue. When the cancer spreads close to where it first started, this is known as locally advanced disease. When it spreads to other parts of the body, this is known as advanced or metastatic disease.

## What is HR-positive, HER2-negative, *PIK3CA*-mutated breast cancer?

Doctors test cancer cells for certain proteins (receptors) and mutations to determine the most appropriate type of treatment. Estrogen and progesterone are hormones that play an important role in the female reproductive system. Sometimes breast cancer cells contain proteins (receptors) that bind to these hormones and help the cancer grow. This is known as HR (hormone receptor)-positive breast cancer. Following initial treatment, patients with HR-positive cancer can be prescribed adjuvant endocrine therapy to prevent the cancer from coming back by blocking hormone receptors or lowering hormone levels.

Some breast cancer cells have too much of a protein (receptor) called HER2 (human epidermal growth factor receptor 2) on the surface of their cells which encourages cancer cells to divide and grow. This is known as HER2-positive breast cancer. Conversely, breast cancers with HER2 levels below a certain threshold are known as HER2-negative.

*PIK3CA* is a gene that helps control how cells grow and divide. Some people with breast cancer have an altered or faulty *PIK3CA* gene, causing cells to multiply out of control. This is known as *PIK3CA*-mutated breast cancer.

## What is inavolisib?

Inavolisib belongs to a group of targeted medicines called PI3K inhibitors. It specifically blocks and breaks down the mutated PI3K protein in cancer cells, helping to stop cancer growth. It is taken orally, in combination with other breast cancer drugs called palbociclib and fulvestrant.

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## Why was it not recommended for funding?

ACE evaluates how well a treatment works in relation to how much it costs compared to other treatments. Inavolisib, in combination with palbociclib and fulvestrant, was not recommended for government funding because its benefits for patients with *PIK3CA*-mutated, HR-positive, HER2-negative locally advanced or metastatic breast cancer do not justify its cost. If you need inavolisib, you can speak to a medical social worker to find out if there is other financial assistance available to help with the cost of treatment.

## Is this the right treatment for me?

There are different types of treatments available for *PIK3CA*-mutated, HR-positive, HER2-negative locally advanced or metastatic breast cancer. Your doctor may recommend inavolisib, in combination with palbociclib and fulvestrant, if they consider it is the most suitable treatment for you. They should give you clear information, listen to your views and concerns, and talk to you about your treatment options.

Some of the questions you may want to ask your doctor when making decisions about your care are:

- How will the treatment affect my day-to-day activities?
- How well does it work compared to other treatments?
- What are the side effects and risks of treatment, and how likely are they?
- How much does the treatment cost, and who can I approach if I want to find out whether there is financial assistance available to help with the cost of treatment?
- How long will I need to be on the treatment for?
- What happens if the treatment stops working?
- What happens if I do not want to have treatment?

**Published: 6 February 2026**

 Agency for Care Effectiveness - ACE

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