

Plain English Summary

Capivasertib in combination with fulvestrant for treating HR-positive, HER2-negative locally advanced or metastatic breast cancer with *PIK3CA/AKT1/PTEN*-alteration

What does the guidance say?

Capivasertib, in combination with fulvestrant, is not recommended for government funding for patients who have had prior treatment for HR-positive, HER2-negative advanced breast cancer with one or more *PIK3CA/AKT1/PTEN*-alteration. 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 breast cancer with *PIK3CA/AKT1/PTEN*-alteration?

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 to grow. This is known as HR (hormone receptor)-positive breast cancer.

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, *AKT1* and *PTEN* are genes that help control how cells grow and divide. In some people with breast cancer, changes in these genes cause cells to multiply out of control.

What is capivasertib?

Capivasertib belongs to a group of targeted medicines called AKT inhibitors. It works by blocking AKT proteins on cancer cells, preventing cells from dividing uncontrollably and stopping the cancer from growing. It is taken orally, in combination with a hormone therapy called 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. Capivasertib, in combination with fulvestrant, was not recommended for government funding because its benefits for patients with HR-positive, HER2-negative advanced breast cancer with *PIK3CA/AKT1/PTEN*-alteration do not justify its cost. If you need capivasertib 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 HR-positive, HER2-negative locally advanced or metastatic breast cancer with *PIK3CA/AKT1/PTEN*-alteration. Your doctor may recommend capivasertib, in combination with 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?

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