

## Plain English Summary

# Burosumab for X-linked hypophosphataemia

## What does the guidance say?

Burosumab is recommended for listing on the Medication Assistance Fund (MAF) for government subsidy for patients with X-linked hypophosphataemia who meet certain clinical criteria.

## What is X-linked hypophosphataemia?

X-linked hypophosphataemia (XLH) is a rare, chronic and progressive disease characterised by low levels of phosphate and vitamin D in the blood. It is caused by a change (mutation) in the PHEX gene, which is located on the X chromosome (one of the two sex chromosomes in the body). XLH is usually inherited (passed from parents to children).

Phosphate and vitamin D are essential to build healthy bones, teeth and muscles, and maintain their strength. People with XLH have abnormally high levels of a protein called FGF23 that stops the kidneys from reabsorbing phosphate in the blood. This increases the loss of phosphate into the urine and reduces the amount of phosphate and vitamin D absorbed by the body causing the bones to develop abnormally.

Symptoms can appear at any age but often begin in early childhood. They include soft and weak bones (rickets), bowed or bent legs, below average height, bone and muscle pain, unusual walking patterns, fractures, dental problems, and hearing loss. Without treatment, these symptoms can become permanent bone abnormalities, causing lifelong disability and pain.

To determine if someone has XLH, doctors use genetic testing to identify gene mutations, blood and urine tests to measure the amount of phosphate, and X-rays to see how the bones are affected.

## What is burosumab?

Burosumab belongs to a group of medicines called recombinant monoclonal antibodies. It stops the activity of FGF23, helping the kidneys reabsorb more phosphate. This raises the phosphate levels in the blood, reducing the risk of bone abnormalities. It is given as an injection under the skin (subcutaneously).

Your doctor or your child's doctor will tell you how much to have and how long to have it for.

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## Who can have burosumab?

Adults and children 1 year of age and older can have burosumab if they have XLH confirmed with either genetic tests, or blood and urine tests along with X-rays showing signs of rickets.

Your doctor or your child's doctor can advise if burosumab is a suitable treatment.

## Why was burosumab recommended for subsidy?

ACE evaluates how well a treatment works in relation to how much it costs compared to other treatments. Burosumab was recommended for subsidy for certain patients with XLH as it was considered to be an acceptable use of healthcare resources at the price proposed by the company.

## What does listing on the MAF mean for me?

The MAF helps people pay for treatments that are clinically effective and cost effective. If your doctor or your child's doctor prescribes burosumab in line with the MAF criteria, the treatment cost will be subsidised by 40% to 75%.

**Published: 4 June 2024**

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