

Plain English Summary

Advanced hybrid closed loop system for people with type 1 diabetes mellitus

What does the guidance say?

Advanced hybrid closed loop (AHCL) system is not recommended for government subsidy for people with type 1 diabetes mellitus.

Why was it not recommended for subsidy?

ACE evaluates how well a medical device works in relation to how much it costs compared to the current standard of care. The AHCL system was not recommended for government subsidy because its benefits do not justify its cost. If you need an AHCL system, you can speak to a medical social worker to find out if there is other financial assistance available to help with the cost of the device.

What is type 1 diabetes mellitus?

Insulin is a hormone, made by the pancreas, that helps glucose (a type of sugar) from food enter cells in the body so it can be used as energy or stored for later use. People with type 1 diabetes mellitus have high glucose in their blood because their body does not produce enough insulin. This is usually due to the body's own immune system destroying the insulin-producing cells in the pancreas.

Over time, high blood glucose levels can cause a range of problems including vision loss, kidney disease, foot and leg problems and an increased risk of stroke and heart disease. Although type 1 diabetes mellitus is often diagnosed in childhood, it can develop at any age.

People with type 1 diabetes regularly self-monitor their blood glucose levels, usually with a finger-prick and a glucose meter or a continuous glucose monitor system. They also need to inject insulin to keep their blood glucose levels within the target range, usually with a needle and syringe, an insulin pen or an insulin pump. The timing and amount of insulin needed depends on their blood glucose reading, the amount of sugar and starch (carbohydrates or "carbs") in their food, and their current and upcoming activities.

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What is an AHCL system?

An AHCL system is a wearable device that helps people with type 1 diabetes maintain their blood glucose levels within the target range. It consists of three parts that work together:

- An insulin pump that delivers insulin into the body
- A continuous glucose monitor that checks blood glucose levels throughout the day
- A computer program (algorithm) that automatically adjusts how much insulin is needed

It is classified as a "closed-loop" system because it can automatically adjust insulin delivery according to the glucose levels detected. However, not all functions are automated, making it a "hybrid" system, which means users still need to program the device and alert the system when eating.

Insulin takes time to work and bring blood glucose levels back down. If the system is not given advance notice about a meal, it can only react after blood glucose has begun rising. This creates a significant spike in blood glucose levels while the system catches up and corrects the increase.

To prevent these spikes and reduce the risk of long-term health complications, users can input the carbohydrate content of their upcoming meal, allowing the system to administer the required amount of insulin at the right time. This keeps the blood glucose levels within the healthy range throughout the meal.

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Is this the right device for me?

There are different types of devices available for managing type 1 diabetes. Your doctor may recommend you use an AHCL system if they consider that it is the most suitable device for you. Your doctor 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 device affect my day-to-day activities?
- How well does it work compared to other devices and treatments?
- What are the side effects and risks of using the device, and how likely are they?
- How much does the device cost, and who can I approach if I want to find out whether there is financial assistance available to help with the cost of the device?
- What happens if the device stops working?
- How often will I need to replace parts of the device?
- What happens if I do not want to use the device?

Published: 7 Oct 2025

 Agency for Care Effectiveness - ACE

 Agency for Care Effectiveness (ACE)

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This summary is not, and should not be regarded as, a substitute for professional or medical advice. Please seek the advice of a qualified healthcare professional about any medical condition.

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