ICER SNAPSHOT

Reviewed by: COPD Foundation
The reviewing organization is not responsible for the final contents of ICER's Report or Snapshot, nor should their review be assumed to support any part of ICER's findings.
This document's language was revised with assistance from Claude (Sonnet 4.5), an AI assistant created by Anthropic.

The ICER Snapshot is a summary designed to help patients and the broader community learn about the key results and recommendations from ICER's 2026 Final Evidence Report on cytisinicline for smoking cessation.

The information included is up to date as of February 12, 2026. New information about these treatments may become available, but are not captured here.

Let's Take a Look

What are the Effects of Smoking?
Impact on Patients and Families
Treatment & Clinical Trial Results
How Did ICER Calculate a Fair Price?
Policy Recommendations & Patient Engagement



What are the Effects of Smoking?

Smoking cigarettes is the number one cause of preventable deaths in the United States (US) with about 500,000 people dying each year from smoking-related illnesses. The main smoking-related causes of death are cardiovascular (heart attacks and strokes), cancer (lung, pancreatic, esophageal, bladder, colorectal, renal, and other cancers), and pulmonary (chronic obstructive lung disease [COPD], pneumonia). **The cost of smoking in the US was estimated to be more than $600 billion in 2018.** These costs do not include the cost of tobacco products, estimated to be $75.9 billion in 2021.

There are several treatments that are shown to help people quit smoking. The **two most effective medical treatments for smoking cessation** available in the US are **varenicline** (previously Chantix®) **and combination nicotine replacement therapy** (NRT), a long-acting patch combined with short-acting nicotine (i.e., gum or lozenges). Some people also use buproprion, an antidepressant, or electronic cigarettes containing nicotine, to help quit smoking. E-cigarettes are not FDA-approved for smoking cessation and can lead to nicotine addiction.



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Impact on Patients and Families

What ICER Learned from the Community

Smoking can **difficult to quit**. It is influenced by physical dependence as well as social and psychological factors.



There is a lot of **stigma associated with smoking**. Many patients internalize this stigma and blame themselves for smoking, feeling that it's their fault if they become sick.

Patients' top reasons for wanting to quit include worries about **current and future health costs, and not liking the feeling of being addicted**. They shared how challenging it is to quit smoking.





Smoking can **contribute to or worsen several long-term health conditions**, including cardiovascular disease (CVD), reducing patient quality of life.

Treatment of Focus & Clinical Context

CYTISINICLINE

Made by Achieve Life Sciences

Cytisinicline binds to a receptor that helps to block the craving for cigarettes and stops the short-term rewards that come from smoking a cigarette. Cystisine has been used for smoking cessation, in a different form, for more than 50 years in Eastern Europe.

Cytisinicline is under FDA review as of February 2026.

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What Did Key Clinical Trials Show?

TRIAL NAMES

ORCA 2 & 3

PARTICIPANTS

1,602 adults interested in quitting smoking cigarettes

TREATMENT GROUPS

- **Group 1:** 3 mg cytisinicline 3 times a day for 6 weeks, followed by placebo for 6 weeks.
- **Group 2:** 3 mg cytisinicline 3 times a day for 12 weeks.
- **Group 3:** Placebo for 12 weeks.

All participants received behavioral support (brief counseling) as well.

RESULTS

For every 100 people attempting to quit smoking:

- 23 more people likely to quit smoking at 9-12 weeks using cytisinicline vs. placebo
- 16 more people likely to quit smoking at 9-24 weeks

SAFETY

Patients taking cytisinicline were more likely to experience **insomnia** and **abnormal dreams**.

HOW WELL DOES CYTISINICLINE COMPARE TO VARENICLINE?

In an indirect comparison between cytisinicline and varenicline, **both drugs had similar rates of success in helping people quit smoking**. Cytisinicline was less likely to cause nausea compared to varenicline.

Clinical Conclusion

Based on the reviewed evidence, cytisinicline appears safe and can help people quit smoking.

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What We Still Don't Know

- **Cytisinicline and varenicline** are similar drugs that appear to work the same for quitting smoking. Without directly comparing them in a study, **we cannot say for sure if one works better than the other**.
- Twelve weeks of cytisinicline works better than six weeks, but **longer treatment might be even more effective**, since it reduces cravings and blocks nicotine's rewarding effects. Varenicline, which works the same way, is often used beyond 12 weeks. Safety data shows cytisinicline appears safe for at least one year.
- **People with serious mental health conditions**—who tend to smoke more and struggle more with quitting—**were excluded from the cytisinicline trials**, making it hard to know how well it works in this population.
- **Limited research exists on cytisinicline for quitting vaping**. One small study shows promise, but more research is needed, especially since the health benefits of quitting vaping remain uncertain. A clinical trial researching cytisinicline for quitting vaping is ongoing.

Evidence Ratings

A	**Cytisinicline** provided greater benefits compared with **behavioral interventions alone** for those who want to stop smoking.
C++	**Cytisinicline** provided greater benefits compared with **behavioral interventions alone** for those who want to stop vaping.
C+	**Cytisinicline** was at least as good and possibly somewhat better when compared to **varenicline**.
I	There is not enough evidence to assess the benefits of **cytisinicline** versus **electronic cigarettes** with nicotine.
P/I	When compared to **varenicline**, **cytisinicline's** benefits were promising but inconclusive for those who want to stop vaping.

ICER's report findings are not treatment advice. Patients and families should always talk with their doctors to make shared decisions about treatment for smoking cessation.

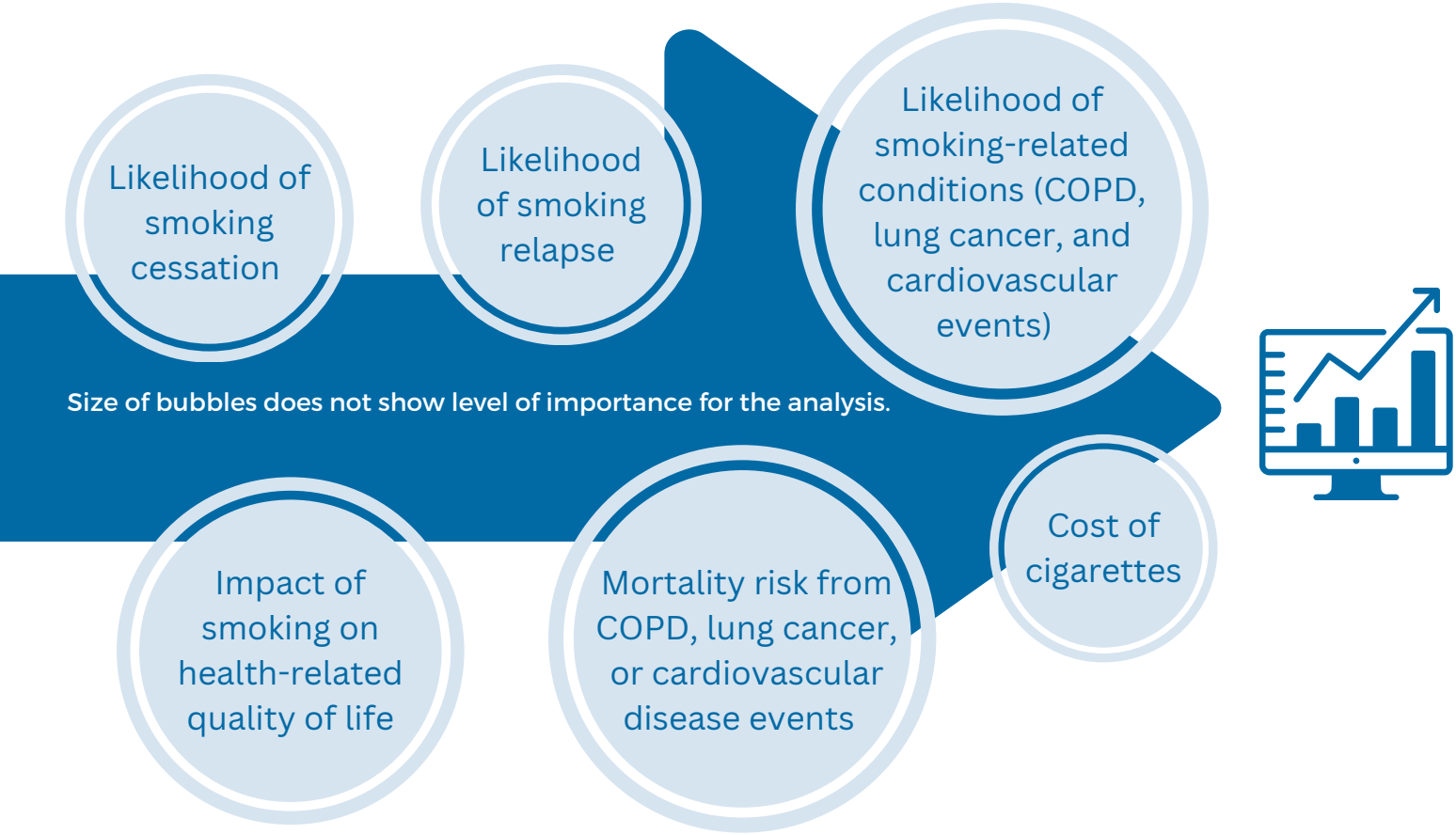
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How Did ICER Calculate Fair Prices?

Using economic modeling, we calculated the cost-effectiveness of how the medications help with smoking cessation and prevent serious smoking-related health problems like CVD, COPD, and lung cancer. See below for what types of information ICER considered to calculate a fair price range for this treatment.

Population:
Adult smokers (20 cigarettes/day) who are interested in quitting

Factors Included in ICER's Economic Analysis



Fair Price Range for Cytisinicline

$1,900-$2,700
for a 12-week course of cytisinicline

A fair price is how much a treatment should cost based on how well it works for patients. Our economic analysis concluded that **a 12-week course of cytisinicline would be cost-effective if priced between $1,900 and $2,700.**

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Key Policy Recommendations

The Policy Roundtable at the ICER public meeting included 2 patient experts, 2 clinical experts, and 3 health care company representatives. Their contributions informed several policy recommendations for pricing, access, guidelines, and future research in smoking cessation. A few key recommendations are summarized below.

1. Patient advocacy organizations should **promote peer support**. Peer support can play a significant role in smoking cessation by **providing encouragement, shared experiences, practical advice, and accountability**, which can improve the likelihood of quitting successfully.

2. All stakeholders have a responsibility and an important role to play in ensuring that an effective new treatment for people who smoke is introduced in a way that will **help reduce health inequities and stigma**.

3. Payers should ensure that patients have access to smoking cessation counseling and medications **through telehealth, which reduces barriers** and could help more people get the support they need to quit, especially younger patients.

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Patient populations including those with **psychiatric and cardiovascular conditions were not included in the cytisinicline trials**. Cytisinicline should be studied in these populations, as there are additional opportunities to advance smoking cessation efforts.

Impact of Patient Engagement

Patient input helped us understand how **difficult it is for people who smoke to quit smoking, and how** shaped by a combination of many factors including **physical, psychological and environmental factors**.

There is a lot of **stigma associated with smoking**. We heard from the patient community that this stigma could **cause anxiety and isolation** for people who smoke, further discouraging quit attempts.

We learned that **smoking is usually depicted as a moral failure** for patients and **more clinical experts need to be educated and sensitized** on encouraging patients to quit with compassion.

The Institute for Clinical and Economic Review (ICER) is an independent nonprofit organization that does research on how well new treatments work and what a fair price should be. Patients and families should always talk with their doctor to make shared decisions about the best treatment option for them.

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