

Cost-effectiveness doubts could hit Shire's Takhzyro launch



[Madeleine Armstrong](#)



A damning report by the US pricing watchdog Icer could bode ill for the uptake of Shire's big hereditary angioedema hope.

Vertex's cystic fibrosis therapies can step aside – there are some new contenders for the dubious honour of being the least cost-effective drug. An analysis by the US Institute for Clinical and Economic Review (Icer) has concluded that Shire's hereditary angioedema drugs Cinryze and Takhzyro are among the priciest it has ever evaluated.

This could be particularly damaging for the newcomer, Takhzyro. *EvaluatePharma* sellside consensus forecasts 2024 sales of \$1.5bn, making the drug more valuable than the rest of Shire's pipeline put together – so anything that might hold back its launch would be bad news for the company.

Takhzyro got the FDA's blessing in August; in the run-up to approval Bernstein analysts noted that the Icer report and resistance from payers would probably be among the biggest hurdles standing in the way of a successful launch ([Shire dodges pricing questions as lanadelumab's big day nears](#), August 9, 2018).

Pricing backlash

It looks like the backlash has begun. The [Icer report released yesterday](#) concluded that, with a net price tag of \$16,500 per dose, prophylactic therapy with Takhzyro would cost a staggering \$1m per quality-adjusted life year (QALY) gained.

Shire's older HAE drug Cinryze outdid even this, costing \$5.9m per QALY gained, according to Icer. Although Takhzyro is more expensive than Cinryze, the former was found to lead to a greater reduction in the number of HAE attacks, in turn reducing acute treatment costs. HAE is a genetic condition characterised by episodes where various parts of the body swell.

The report also evaluated CSL's product, Haegarda, and had planned to review Pharming's Ruconest, but the latter was removed after a recent FDA rejection for prophylactic use.

Cost-effectiveness of prophylactic HAE therapies: Icer's take

Product	Company	Net price per package	Cost per QALY gained	Per-package price to achieve \$150,000 per QALY
Haegarda	CSL	\$1,393	\$243,000	\$1,376
Cinryze	Shire	\$2,725	\$5,870,000	\$1,125
Takhzyro (lanadelumab)	Shire	\$16,520	\$1,020,000	\$14,800

Source: Icer report, 11 October, 2018.

The latest analysis makes Cinryze the most expensive drug evaluated by Icer, and puts Takhzyro only slightly behind Teva's tardive dyskinesia drug Austedo at \$1.1m per QALY. Vertex's cystic fibrosis therapy Kalydeco, at \$1.03m per QALY when used in patients with a gating mutation, is also just ahead of Takhzyro ([Vertex and orphan drugs test limits of US payers](#), March 28, 2018).

Icer said that in order to meet the common cost-effectiveness limit of \$150,000 per QALY, Cinryze's price tag would need to be cut by 59% and Takhzyro's by 33%.

Whether Shire will take the watchdog's advice is another matter – the group was not available for comment at the time of publication. Icer's clout with payers and biopharma players is growing but it does not have the authority of, say, the UK's Nice.

Still, the latest analysis might help payers bargain for discounts, or it might push them towards CSL's Haegarda, which came out of the report much more favourably.

This will soon become Takeda's, rather than Shire's, problem. But Takhzyro was surely one reason behind the Japanese company's takeout – and a lacklustre launch could give Takeda shareholders, some of whom have already tried to get the merger called off, another reason to resist the deal's closure.

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