The list of shame no biopharma wants to join

An upcoming Icer report will put the spotlight on unjustified price increases even as signs of moderation emerge.

It is not just high drug prices that have payers and policymakers worried. They are also concerned about big and unpredictable increases that defy explanation. Now the US pricing watchdog Icer is taking a close look at large rises to develop a list of the biggest culprits on which no biopharma executive will want its products to appear.

Icer’s analysis will examine whether external factors like new clinical data or a rise in manufacturing costs could explain the increases. The report could spur lawmakers to summon executives to Capitol Hill if companies cannot provide any evidence that price hikes are justified. This might be a deterrent to those still hoping to make large annual price increases, as few executives want to become the next Heather Bresch or Martin Shkreli.

The list could be a test of Icer’s growing influence: the organisation has until now mostly busied itself with cost-effectiveness analyses of new drugs, much as Nice in the UK and IQwig in Germany have done for years.

“The Icer report continues the path that they’ve been on, which is really about transparency,” says Chronis Manolis, chief pharmacy officer at the UPMC Health Plan, an insurer in Pennsylvania.

Do old drugs get better with age?

Analysing cost increases with older agents is a bigger step into the politics of drug prices for Icer, especially as the biggest public outrage about drug prices so far has been triggered by big hikes for products like Mylan’s EpiPen and Turing’s daraprim. Notably, these cases led to Ms Bresch and Mr Shkreli respectively having to explain themselves before Congress.

And the new Congress is showing no dropoff in interest in drug prices, with two hearings having already taken place in January alone – and members of Congress have developed their own lists of big increases.

Icer’s report, the first in what is planned as a series of annual assessments, is due in October. It will first examine which of the 100 biggest-selling drugs had the greatest hikes in their list prices, and from there attempt to determine which had the greatest impact on healthcare spending based on their net price rises.

Icer will then review the top 10 drugs to determine whether their price increases can be justified based on benefit. Three additional special-interest products may also face analysis because the increases make them
unaffordable for patients or because they have had a big impact on a small number of patients with rare diseases.

In most cases, justifying a price increase would require clinical data showing additional benefit not seen in approval trials, or a new indication, and could even include off-label use if supported by investigator-led studies, says Dr Mark Fendrick, director of the University of Michigan Center for Value-Based Insurance Design. “From a purely conceptual or theoretical standpoint, it absolutely is value creation,” Dr Fendrick says.

The Icer research protocol suggests other reasons that might justify a big price increase, including raised production cost, evidence of how use of the drug can yield savings elsewhere in the healthcare system, or evidence from competitor products that demonstrate the relative advantages of the drug being examined.

**Ten for that, you must be mad**

What will probably not fly is a massive increase in the price of an old drug. Companies have sometimes made these rises when there was a lack of competition, then excused them by saying they would plough the money back into R&D, as was the case with Mr Shkreli’s company Turing Pharmaceuticals, now named Vyera Pharmaceuticals.

Meanwhile, standard above-inflation increases, such as those routinely made by companies like Allergan, which has a penchant for raising prices at just below 10% a year, should also be in the spotlight.

UPMC’s Mr Manolis says the act of measuring these kinds of increases could help keep pharma companies in check, and points to the effect Icer has had on some new drug prices. “The [CGRP] migraine drugs, I think they’re coming in at prices that are less than people expected,” he says.

However, what payers can do with the information from Icer’s new list might be limited. “If Icer comes out with its top 13 drugs, and seven are for drugs that have lots of product competition, most plans have done something about it. If the other six have no competition or they are for unmet medical needs, there’s not a whole lot we can do.”

For his part, Dr Fendrick challenges the validity of the Icer analysis because it relies first on list price, the “wholesale acquisition cost”, to identify drugs to be potentially included in the report. He questions whether a real net price can be found since every payer has a different cost based on their negotiations with pharma companies.

“The price the purchaser pays is never included in these discussions,” he says. “Until we know the difference between list and net price it’s a little difficult to say what is justified.”

Nevertheless, the potential for negative publicity from being included on this list should have biopharma commercial teams thinking hard about their pricing strategies. Without good data to back up any rises, the risk is that they will have to explain themselves publicly.