Cystic Fibrosis Research News

Title:
Current Prices versus Minimum Costs of Production for CFTR Modulators

Lay Title:
Current Prices versus Minimum Costs of Production for CFTR Modulators

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What was your research question?
What are the lowest possible costs of producing CFTR modulators, and are they a lot lower than current prices?

Why is this important?
The development of CFTR modulators has vastly improved the lives of people with CF. However, their high prices mean the drugs are only available to people in the richest countries around the world, creating a two-tiered standard of care. In the past, prices for other types of medications have fallen by over 90% when they can be produced generically without the brand name, allowing millions access to lifesaving drugs. Therefore, we wanted to estimate the minimum costs of producing CFTR modulators, and compare those costs with current prices around the world to see if similar strategies would be possible to improve access.

What did you do?
We used a tried and tested method of calculating production costs based upon prices of active pharmaceutical ingredients. We obtained the costs for a kilogram of each active ingredient from shipments from international import/export databases over the past 5 years. Following this we calculated the costs of purchasing enough active ingredients for a one-year course of each combination CFTR modulator and the costs to convert the active ingredient into a tablet, also taking into account taxes and profit. We also searched a variety of national drug pricing
databases to work out the costs of one year of treatment with each combination CFTR modulator for comparison.

**What did you find?**

Our analysis estimated that it would cost $9659 to produce a one-year course of Orkambi, $3943 for Symkevi and $5676 for Trikafta. In comparison, the commercial US list price for a one-year course was $284,800 for Orkambi (29 times higher than our estimated production costs), $305,000 for Symkevi (78 times higher) and $325,300 for Trikafta (57 times higher). For each combination treatment the highest international price found was from commercial US pharmacies, and the lowest in Argentina. This is likely because in Argentina CFTR modulators are currently not under patent protection, and as such generic versions are available. In all cases commercial prices around the world were many times higher than the costs estimated by our model.

**What does this mean and reasons for caution?**

Our results show that the cost of producing CFTR modulators could be much lower than current prices. While costs of research and development for these drugs are quite high, the profits made by selling at such high prices seem excessive. Modulator therapies are not available to everyone with CF across the world by a large margin, therefore unless steps are taken urgently to address their prohibitively high prices, tens of thousands of people with CF who do not have access to them may be left behind.

Our estimates represent the lowest feasible estimates of production costs for this class of drugs. Whilst the calculations have been tested against many other types of medication, they are an indication of possible prices rather than definite predictions. Additionally, as these drugs are new, we had limited information available regarding shipments of active ingredient which limits the accuracy of our results.

**What’s next?**

In the past access for other medications has successfully been improved through using originator-issued voluntary licenses. These allow specific companies in specific countries to produce a medication if the company holding the patent chooses not to produce it themselves. We think that this would be a practical and achievable way to improve access to these transformative therapies around the world.

**Original manuscript citation in PubMed**

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Annual Cost of Elexacaftor/Tezacaftor/Ivacaftor Treatment

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<thead>
<tr>
<th>Country</th>
<th>Price (USD)</th>
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<tbody>
<tr>
<td>US (Commercial)</td>
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<tr>
<td>Denmark</td>
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<td>Estimated Cost</td>
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