

## Access to Non-reimbursed Expensive Cancer Treatments: A Justice Perspective

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**ABSTRACT** *When the cost-effectiveness of newly approved cancer treatments is insufficient or unclear, they may not (immediately) be eligible for reimbursement through basic health insurance in publicly funded healthcare systems. Patients may seek access to non-reimbursed treatment through other channels, including individual funding requests made to hospitals, health insurers, or pharmaceutical companies. Alternatively, they may try to pay out of pocket for non-reimbursed treatments. While currently little is known of these practices, they run counter to a deeply held egalitarian ethos that is prevalent in many publicly funded healthcare systems. In this article, we investigate to what extent this ethos can be grounded in theories of justice, notably egalitarianism and prioritarianism. We argue that allowing out-of-pocket payments by patients themselves, in principle, is not unjust from the perspective of either of these theories, provided that it does not raise in-practice justice-based concerns, for instance by displacing more cost-effective care, to the detriment of other patients, or by failing to treat patients equally. In contrast, we conclude that the practice of making exceptions for individual patients by health insurers or healthcare providers does run counter to the justice-based requirements of equal treatment.*

### 1. Introduction

The costs of newly approved cancer treatments are continuously rising and constitute a growing share of healthcare budgets in publicly funded healthcare systems around the world. Sometimes a newly approved treatment is effective, yet so expensive that governments or insurers decide not to include the treatment in the basic package of healthcare offered to their citizens or clients. This has recently happened in the Netherlands, where Trodelvy, a treatment for triple-negative breast cancer that offers an estimated median survival gain of 5.4 months at a list price of 69,000 EUR per patient, was not included in the basic package.<sup>1</sup> Governments or insurers may also decide not to include a newly approved treatment temporarily, pending further price negotiations with the pharmaceutical company. When effective treatments are not reimbursed, patients may understandably seek other ways to obtain and fund them, such as out-of-pocket payment (OOP), or by making a request to their healthcare provider, their health insurer, or the pharmaceutical company. As success in finding other ways to fund the treatment may vary, it could happen that some patients receive the treatment, but others do not, possibly even within the same hospital. Can allowing alternative means of access to and funding of expensive cancer treatments be considered just? If so, under what conditions?

These questions are the topic of the current article. We will address them by applying two theories of justice: egalitarianism and prioritarianism; egalitarianism because unequal access meets with strong opposition in countries with egalitarian universal healthcare

systems, such as the UK and the Netherlands, and prioritarianism as a contrasting theory that does not focus on equality, but on how well or badly off people are in absolute terms. We will focus on healthcare systems which are collectively funded, provide a fairly comprehensive basic package of essential healthcare accessible to all citizens, and require relatively few co-payments.<sup>2</sup> Practitioners in these systems generally have a strong egalitarian ethos, which places high value on equal treatment of patients and equal access to care.<sup>3</sup> This was clearly visible when in 2008–9 the issue of allowing so-called top-up fees for expensive (cancer) treatments in the UK's National Health Service (NHS) was fiercely debated. According to many, the decision to allow OOP for treatments administered in the NHS amounted to objectionable inequalities in access to healthcare that contradict 'the founding principles of the NHS'.<sup>4</sup>

Significantly, many seem to take it at face value that permitting alternative modes of funding for non-reimbursed treatments is unfair or unjust, simply because it would lead to unequal access.<sup>5</sup> In addition, predictions are made about how these ways of funding will work out in practice and change a universal healthcare system for the worse.<sup>6</sup> Such claims, however, need empirical verification. Moreover, even if negative effects can be established, they need not be inevitable, nor constitute an overriding reason against allowing these alternatives modes of funding.

Therefore, to gain analytical clarity, in this article, we will first investigate the alternative modes of funding for non-reimbursed treatments from what we will call an *in-principle* justice perspective (Section 3). Thus, if we were to allow alternative modes of funding, including OOP for expensive treatments, would that in itself, in principle, be unjust, even if it had no negative effects on other patients, or more generally on the healthcare system? We subsequently ask: what if such negative effects *would* result as consequences of these alternative modes of funding? In doing so, we discuss potential *in-practice* justice-based objections to the various alternative modes of funding (Section 4). However, we will start by explaining why it is or can be just when some treatment is not included in the basic package of healthcare in the first place (Section 2). This is because these reasons turn out to be relevant for answering the article's main question regarding the justness of various alternative funding modes.<sup>7</sup>

## 2. Why Justice *Requires* Us Not to Cover All Expensive Cancer Treatments

There is widespread agreement that health and differences in health status between citizens are a matter of social justice.<sup>8</sup> Accordingly, societies strive to provide a decent level of healthcare that is accessible to all citizens. The various theories of health justice differ in their explanation of why just societies ought to provide adequate healthcare to their citizens. For example, Norman Daniels's influential account emphasizes the role of healthcare in supporting people to maintain normal functioning, which enables them to live what they envision as a good life.<sup>9</sup>

At the same time, there is also widespread agreement that justice does not require meeting all health needs of citizens, including, for instance, their need for very expensive cancer drugs. Because societal resources are finite, limiting the budget for healthcare in some way or another is generally seen as inevitable and just.<sup>10</sup> Health is not the only good that is necessary for living a good life. Governments also have a clear role in providing funding for education, safety, housing, the judiciary, the arts, mitigating climate change, and so on.

Therefore, they inevitably have to allocate budget to each of these, and this allocation is a matter of distributive justice, as well. Moreover, citizens value discretionary income in order to shape their own lives beyond having housing, food, education, etc., and therefore will have reason to reject too-heavy taxation. Another reason not to spend near-unlimited resources on healthcare is the fact that most of the other social goods just mentioned have a substantial impact on the health of citizens. So, even if health were believed to have priority over all other goods, it would still be prudent to invest in those other goods since they serve as social determinants of health. For these reasons, governments can necessarily spend only a limited budget on healthcare. Spending more is neither in the interest of society at large, nor just.

In the UK and the Netherlands, cost-effectiveness is one of the criteria being applied in the process of delineating the basic package of healthcare available to all citizens. That is, these healthcare systems put a maximum on the price they are willing to pay per quality-adjusted life year (QALY) gained by a given treatment. These maxima do not function as absolutes, but nevertheless they substantially guide the process of priority setting. Furthermore, in both countries, the maximum increases with the severity of the condition for which the treatment is indicated. So, for example, the UK's National Institute for Health and Care Excellence employs a regular maximum of £20,000–30,000 per QALY gained, but £50,000 for treatments for life-threatening diseases.<sup>11</sup> Through the use of a severity-depending maximum, within the confines of the budget, a balance is sought between helping as many patients who need treatment as possible, and giving priority to the worse off.

Inevitably, all this means that some treatments that have received market authorization, such as very expensive cancer treatments that yield 'merely' a few months' additional survival, such as the above-mentioned example of Trodelvy, will not be reimbursed by the state because they are insufficiently cost-effective.<sup>12</sup> Alternatively, when the cost-effectiveness of a newly approved treatment is not yet clear, reimbursement decision-making may be put 'on hold', which means that the treatment is *temporarily* not eligible for reimbursement, pending further price negotiations and/or further research into its cost-effectiveness. For treatments that are not (yet) reimbursed, patients may seek various alternative means to obtain access, by making funding requests to other parties (hospitals, health insurers, or pharmaceutical companies), or, if they are wealthy enough, by paying out of pocket.

### 3. Modes of Funding: A Justice Perspective

Below, we will assess each of these different alternative modes of funding from the perspective of egalitarianism and prioritarianism. Insofar as these modes result in unequal access to potentially life-saving treatments between patients, to what extent should this be considered unjust, and why exactly?

#### 3.1. Characterizing Egalitarianism and Prioritarianism

In the limited space of this article, it is neither possible nor necessary to employ fully worked-out theories of justice. Instead, we work with rather general characterizations of egalitarianism and prioritarianism, to see what guidance they may confer on the permissibility of each of the alternative modes of funding.

A useful but partial way to characterize theories of justice is on the basis of the distributive pattern that they recommend. At the most basic level, egalitarians favor equality, whereas prioritarians hold that those who are worse off should be given priority. Let us explain each in somewhat more detail.

Egalitarianism is best understood as a family of theories that are all committed to the fundamental notion of the equal moral worth of human beings, from which, according to egalitarians, it follows that people should have more or less equal shares of relevant goods, and should be treated equally in relevant ways.<sup>13</sup> For example, egalitarians typically favor equal distributions of income, hold that good-quality education should be available to all and not only to those who can afford private schools, and emphasize that each citizen should be treated with equal respect.

Egalitarianism is thus in essence a comparative view: the distributional pattern is evaluated in terms of how people fare relative to each other. When applied to health, some egalitarians hold that health inequalities are bad in themselves, to the extent that the unhealthy are worse off through no fault or choice of their own.<sup>14</sup> Since access to healthcare may significantly affect health (outcomes), unequal access to healthcare is, at least *prima facie*, directly in tension with the value of equality. What makes unequal access to healthcare even more problematic is the fact that it often results from differences in wealth and income, health literacy, and abilities to stand up for oneself, which may themselves have originated in ways that are unfair.

Unlike egalitarianism, prioritarianism is not concerned with how people fare relative to each other, but only with how they fare in absolute terms. Prioritarians hold that ‘benefiting people matters more the worse off these people are’.<sup>15</sup> This is the case not because they have less than those who are better off, but because of their bad position in absolute terms. Thus, when assessing the position of a severely ill person, what matters for prioritarianism is the fact that the severely ill person is in bad health compared not with other healthy individuals, but with where she would herself be if she were a healthy person. So, prioritarianism is essentially a non-comparative view and the prioritarian and egalitarian concerns are distinct concerns. Nevertheless in practice, many policies that give priority to the worse off, and help improve their lot, will at the same time help to reduce inequalities. For example, a clear prioritarian element in healthcare systems is the higher cost per QALY, referenced above, that countries are willing to pay for treatments for severe conditions. But by restoring health to those who are (severely) ill, this helps reduce inequalities in health states as well.

A few preliminary remarks are in order, before we apply the theories to alternative funding modes. First, we employ egalitarianism and prioritarianism primarily as axiological theories that order outcomes as better or worse, i.e. in terms of their moral goodness, and not as theories of right action that give definite answers as to whether allowing the various modes of funding, all things considered, is just. So, we will make claims along the lines of a theory of justice ‘providing support to’ some mode of funding, if this mode brings about a distribution of health states that is better according to that theory. This is because we conceive of the arguments we put forward in our article as considerations that should be included in deliberations by relevant institutional regulatory bodies. These bodies typically aspire to deliberate in ways so as to achieve procedural justice, and such deliberations are inevitable precisely because none of the several proposed theories of justice is universally accepted. Moreover, many adherents of theories of justice are pluralists. For example, in addition to equality, egalitarians will also value wellbeing, for otherwise

they could not prefer states of affairs in which everyone fares equally well at a high level rather than a low level of wellbeing.

Second, in our article, we will be using health states and health benefits as our currency. That is, we take a separate spheres approach to health, according to which healthcare policy and priority setting should be concerned only with health states and health benefits, and not with various other types of costs and benefits (e.g. economic, social) associated with decisions and policies. This approach is in line with common practice in healthcare policy and priority setting, as we will further explain below in our discussion of the prioritarian perspective on allowing OOP.

Third, and relatedly, we sidestep the difficult question whether in comparing and assessing how well off individuals are, even only with regard to their health, we should consider their overall health during their whole lifetime, including their past health, or whether we should give most importance to current and/or future health states of individuals.<sup>16</sup> This is both to keep our discussion manageable, and because in current healthcare systems, different approaches to this question are taken in different decisional contexts. For example, it is easier (and more desirable, we believe) to take a lifetime approach when choosing which diseases to prioritize for research, than when rationing scarce beds in a pandemic.

We will now employ both theories of justice to discuss the various ways patients can seek access to funding for non-reimbursed treatments, starting with payment using private funds. As explained in the introduction, for now, we bracket any further practical consequences.

### 3.2. *Out-of-Pocket Payment*

In countries with a publicly funded healthcare system, equal access to healthcare is held in high regard. Consider this statement, made in the context of the debate on top-up payments in the NHS that we referred to in the introduction:

Allowing patients to pay top-up fees vastly reduces the fairness of healthcare rationing. In practice it would mean that NHS patients with exactly the same condition could receive one treatment if they can afford to pay for it and another if they cannot. This contradicts the founding principles of the NHS, which stated that patients' access to treatments and services 'shall not depend on whether they can pay for them or on any other factor irrelevant to real need'.<sup>17</sup>

And the Dutch National Healthcare Institute, which regulates the basic package of healthcare, states: 'Our healthcare system is based on the principle of solidarity. Rich and poor, young and old, healthy and sick: everyone in the Netherlands has access to the same care'.<sup>18</sup> Finally, an interview study on OOP found that Dutch physicians are generally not in favor of allowing patients to use private funds to obtain healthcare: 'I believe that everyone should have the same opportunities, independent from how much money or connections they have'.<sup>19</sup>

Can we make sense of such views? Is it indeed a requirement of just healthcare systems that they do not allow OOP for expensive and potentially life-prolonging or life-saving cancer treatments? As noted, only egalitarianism is directly concerned with inequality. In order to better understand what exactly might be bad about unequal access, it will be helpful to introduce Parfit's distinction between teleological, or 'telic' egalitarianism

and 'deontic' egalitarianism.<sup>20</sup> According to telic egalitarianism, 'it is bad in itself if some people are worse off than others'.<sup>21</sup> Thus, equality has non-instrumental value. According to deontic egalitarianism, inequality is not bad in itself, but in cases in which inequality is problematic, it is problematic because it is unjust. Often these are cases which involve some kind of unequal treatment that violates some entitlement to equality.

We will first employ the perspective of telic egalitarianism. According to this view, if some patients get access to the treatment, but others do not, this inequality is bad in itself. Therefore, if none of the patients have access, this is better in terms of equality. Consequently, this serves as a reason not to allow OOP. To this implication, the well-known leveling down objection can be raised. The leveling down objection holds, in Parfit's terms, that if we blind all the sighted to achieve equality, and as a result, all become blind, no one is better off, and therefore we have done *nothing* good. Therefore, Parfit claims, equality has no value in itself.<sup>22</sup> Since our case concerns the question of whether or not we should allow some patients to become better off by paying for their own treatment, assuming that it is effective, here, rather, the so-called raising up objection applies.<sup>23</sup> That is, if we do not allow OOP in order to preserve equality, those who are denied OOP cannot become better off, and hence no one is better off. Here again, following Parfit, we have done nothing good. To this reasoning, proponents of telic egalitarianism will respond that in these sorts of situations, equality *does* have – impersonal, non-instrumental – value:<sup>24</sup> it is bad that some patients become better off while others do not. And therefore, there is at least *something* bad about allowing some patients to become better off while others have no opportunity to become better off. While we think the raising up objection has substantial force, for the sake of discussion, we grant telic egalitarians that equality has (some) non-instrumental value. But even on this assumption, it turns out that telic egalitarians cannot reasonably object to OOP.<sup>25</sup>

The first reason is that inequality between the patients who can afford to pay for some treatment and those who cannot is not the only normatively relevant inequality here. When making comparisons, we should also compare patients with healthy fellow citizens.<sup>26</sup> Patients are worse off than other citizens who do not suffer from some life-threatening or severely disabling disease, and this inequality is bad in itself (according to telic egalitarianism). If the treated patients were completely healed, their advantage in terms of good health over untreated patients would be of the same magnitude as the advantage that healthy fellow citizens had over them *before* they were treated. It seems, therefore, that from the perspective of telic egalitarianism, the intrinsic badness of the inequality between patients who can pay for treatment and those who cannot is on a par with the intrinsic badness of the inequality between patients and healthy people. Whether successful OOP-funded treatments cause an overall increase in inequality in health states depends on the applied measure of inequality. For example, overall inequality as measured by the Gini coefficient<sup>27</sup> would even decrease. Therefore, it is not at all evident that telic egalitarianism provides reasons against OOP on the basis of the intrinsic value of equality. On the contrary, this would require further arguments to show that OOP-funded treatments do increase inequality, which would presuppose contentious assumptions, such as the measure of equality chosen.

There is a second reason. Even if we focus exclusively on patients needing treatment and grant the intrinsic value of inequality, egalitarians emphasize that all sensible versions of egalitarianism are pluralist.<sup>28</sup> So, even though equality has significant value, other values should also be considered and, if they conflict, they should be balanced with



equality. In this case, the increase in inequality between patients should be weighed against the value of the health improvements of patients paying out of pocket. Although we find it hard to decide how much weight inequality should have, it seems evident to us that the great moral good achieved by providing treatments that could improve or prolong the lives of patients outweighs the negative value of increased inequality. Each of these two reasons is sufficient to conclude that telic egalitarians cannot reasonably claim that allowing patients to pay out of pocket for non-reimbursed treatments is unjust.

We will now turn to deontic egalitarianism to see whether this theory perhaps better explains and grounds the egalitarian ethos. According to deontic egalitarianism, 'it is not in itself bad if some people are worse off than others'.<sup>29</sup> Deontic egalitarians hold that there are other reasons for which we sometimes ought to aim for equality. Such reasons often have to do with situations of differential treatment of people. In cases where people have equal claims to certain goods, but these goods are given only to some and not to others, deontic egalitarians will object. So, deontic egalitarians will typically deem situations unjust in which some entitlements or distributional norms are violated. In such situations, complaints are often made that things are 'unfair'.

Allowing OOP is at least in principle compatible with equal consideration and equal treatment of all patients. Hospitals in publicly funded healthcare systems are collectively funded through mandatory insurance and/or taxation, and as a matter of social justice, citizens have an equal entitlement to receiving adequate healthcare in those hospitals. This means that whatever care is included in the basic package of healthcare, and that citizens secure by way of coordinated action via the state, should be available to each and all, according to medical need. As long as equal consideration is guaranteed in the allocation of this basic package of adequate healthcare, it is not a problem, from a deontic egalitarian perspective, to allow some patients to use private money for additional treatments through other channels.<sup>30</sup>

We will now turn to the perspective of prioritarianism. This view holds that what matters morally is that people are in ill health. The reason that the very ill deserve priority, for example when healthcare allocation decisions are to be made, is that they are worst off and are most in need of help. This idea of 'worst off' does involve some comparison, but not to the health states of fellow citizens. Rather, it refers to some notion of 'good health', for example good enough to enable one to lead a fulfilling life, or 'within the range of normal physical and mental functioning'.<sup>31</sup>

In a first approximation, it would seem that from the perspective of prioritarianism, there is reason to allow OOP. This is because cancer patients, especially when they have a progressive cancer, are clearly among those in the worst health conditions possible. So, if some treatment they purchase indeed cures them, or significantly prolongs their lives (and the side effects are acceptable), they really benefit and their health is improved, which is good from a prioritarian point of view. And since prioritarianism is not concerned with the comparison between these patients and those who cannot afford to fund the treatment, the increased inequality within the group of patients that might all have benefitted from the treatment is no consideration against allowing OOP for that treatment.

However, it might be objected that this analysis overlooks the fact that less affluent patients are generally worse off, not in terms of health, but in terms of overall wellbeing, than more affluent patients that can afford OOP.<sup>32</sup> Therefore, prioritarianism tells us that priority should be given to those cancer patients with insufficient means.<sup>33</sup> Another way to formulate the same criticism would be to say that we treat health as a separate sphere.

That is, we are looking only at health states and not at other dimensions or constituents of wellbeing, such as income, education, etc. Were we to take into account all aspects of wellbeing, then it would be immediately clear that less affluent cancer patients are (even) worse off than rich patients. From a prioritarian perspective, should we not assist financially disadvantaged cancer patients in getting access to treatments, rather than allow more affluent patients to pay out of pocket for the same treatments?

While it is beyond doubt that, taking into account all spheres of life, the less affluent cancer patient is worse off than the more affluent cancer patient (all else being equal), there are nevertheless two reasons why we think our analysis should be limited to the sphere of health. The first reason is that it is common practice in healthcare policy making to look only at medical burdens and benefits, and abstract from patient characteristics other than those having to do with health. For example, the economic benefits that will result when ill employees recover sufficiently to take up their jobs again are not included in the cost–benefit analysis that informs the decision whether or not a treatment will be funded through the publicly funded healthcare system. And when there are waiting lists for healthcare, no priority is given to less affluent patients above more affluent patients when they are in equal need of treatment. So, the fact that when considering not only health, less affluent patients are worse off overall, is nevertheless not seen as sufficient reason to give them priority in the medical domain.

The second reason is that unlike healthcare prioritization decisions, whether or not to allow OOP for expensive treatments is not a decision concerned with distributing *collective* resources. Instead, our question concerns whether or not individual patients should be permitted to spend *private* resources to improve their health. And despite the fact that less affluent cancer patients may be in a still worse condition, affluent cancer patients are in a bad condition. Therefore, from the perspective of prioritarianism, if these patients find a way to recover or prolong their lives, this is deemed valuable. We reached this conclusion by looking only at health states, showing that it is indeed appropriate to take a separate spheres approach. In sum then, from a prioritarian perspective, it seems that no in-principle objections can be raised against OOP for expensive cancer treatments. Rather, prioritarianism gives reason, in principle, to allow OOP.

The outcome of the discussion so far is that in-principle justice-based objections to OOP cannot be given from the perspective of egalitarian views, while prioritarianism provides in-principle justice-based reasons in favor of allowing OOP, because some among the worst off gain an opportunity to improve their health status. However, this is only the case as long as the practice of allowing OOP has no negative impact on the comprehensiveness and quality of basic healthcare available to every citizen. As stated earlier, in Section 4, we will discuss the impact of OOP on basic healthcare. We will now turn to other modes of funding of non-reimbursed treatments.

### 3.3. *Healthcare Providers, Insurers, and Pharmaceutical Companies*

If patients lack the means to pay for treatments themselves, they can ask their physicians to request a third party to pay for the treatment, such as the hospital, the patient's health insurer, or the pharmaceutical company that manufactures the treatment. In the Dutch system, for instance, physicians can request funding from hospital budgets, which seems to happen only occasionally.<sup>34</sup> They can also ask the patient's health insurer to fund the treatment on the basis of leniency. As far as we can see, in the Netherlands, this route is



tried more frequently, although physicians report considerably varied responses from insurers to such requests.<sup>35</sup> In the UK, physicians can make so-called Individual Funding Requests (IFR) for treatments that are not available through the NHS.<sup>36</sup>

Given that these requests to third parties in the Dutch and UK healthcare systems are evaluated on an individual basis, there is a clear potential for differential treatment of patients who are similar in the relevant respects (i.e. medical need). Deontic egalitarians consider it unjust if the system fails to treat patients equally, when these patients have equal entitlements to the public good of collective healthcare that they help to uphold. They will maintain that if some hospitals or some insurers grant some requests, then all other hospitals and insurers ought to grant similar requests.<sup>37</sup> Otherwise, healthcare will become a 'postcode lottery', which refers to the phenomenon whereby the type and the quality of care one receives depend on where one lives, which is deemed problematic.

At first sight, it might seem that prioritarianism would welcome third parties granting funding requests, because the health of patients in severe medical need might be improved. However, prioritarians would also have reason to object. First of all, as pluralists, prioritarians will place at least some value, in addition to priority, on fairness and equal consideration. Second, prioritarians will have to support the rationing involved in delineating the content of the basic package of healthcare (Section 2). For even though it will favor the UK and Dutch policy of using higher maximum costs per QALY gained for treatments for more severe diseases, giving *absolute* priority to those who are worse off will give rise to the bottomless pit objection.<sup>38</sup> That is, such a policy would channel all resources to a small group of patients who are absolutely worst off, which would exhaust the finite healthcare budget, leaving many others with substantial health needs without care. Accordingly, the publicly funded healthcare system must exclude some treatments from the basic package for reasons that prioritarians subscribe to. Therefore, they cannot consistently support a practice in which the hospitals and insurers that make up that system, when granting individual requests, fund treatments that have been excluded from the basic package for good reasons. This practice not only fails to treat patients equally, but also fails to protect the healthcare budget.

The UK policy for dealing with IFRs might, however, be evaluated somewhat differently from the Dutch practice. Physicians can submit an IFR for treatments that are not available through the NHS if they believe that their patient's clinical situation justifies making an exception. These requests are evaluated by independent local panels that meet regularly and consist of, among others, a public health specialist, clinicians, a member of the public, and a pharmacist. To adhere to the founding principles of the NHS and to ensure fair and equitable decisions, only *clinical* criteria are applied. That is, the patient's physician has to establish why the patient's clinical circumstances are such that it may be expected that the patient will 'benefit more from the treatment than other patients with the same condition'.<sup>39</sup> Therefore, these guidelines may enable the NHS to treat patients with equal clinical need equally. In that way, the main objection to unequal treatment of patients with equal entitlements is avoided.

Furthermore, this policy may very well be consistent with the assumptions and methods of delineating the basic healthcare package. For *if* it is plausible that the patient on whose behalf the request is made will benefit more from a given treatment than other patients would, then this is by definition a move towards greater cost-effectiveness, which is, as already stated, a central criterion in the UK system, as in most publicly funded healthcare systems. Accordingly, the policy may be consistent with and need not undermine the

process of priority setting based on cost-effectiveness that is necessary to keep healthcare expenditures in check. According to our analysis, then, from the perspective of social justice, the UK policy of IFRs is not as clearly problematic as is the Dutch practice, in which providers and insurers, at their discretion, may fund expensive treatments for some patients but not for others with similar needs (for problematization and further discussion of this tentative conclusion, see Section 4 below).

If neither healthcare providers nor insurers are willing to fund a treatment, a final option for a treating physician is to make a request to the manufacturer. Pharmaceutical companies do not usually provide treatments for free after they have been approved for marketing. However, when companies do make exceptions, they have reason to do so fairly, and should treat similar requests in similar ways. Nevertheless, unequal treatment by pharmaceutical companies is less worrisome than unequal treatment by public institutions, since whereas patients have legitimate claims to equal treatment on public institutions, they have less of a claim on pharmaceutical companies. We might say that these companies have imperfect duties of beneficence to patients, which would allow them more leeway in implementing these imperfect duties in practice than public institutions in implementing their justice-based duties.

A final concern applies to funding by healthcare providers, insurers, and pharmaceutical companies alike: patient access to non-standard treatment options will depend in part on the experience and efforts of their doctors.<sup>40</sup> Patients who are cared for by doctors who are familiar with asking third parties for funding of non-reimbursed medicines will likely have better chances to obtain treatment. In addition, more assertive or better-educated patients may have better chances of persuading their physicians to request third parties to pay for treatments or provide them free of charge. This is another way in which inequalities in access between patients may arise, which would be in direct conflict with physicians' commitment to justice as a medical-ethical principle, independent from any further impact on the healthcare system.

#### 4. In-Practice Justice-Based Objections

Informed by our discussion of when and why unequal access to treatment through alternative modes of funding is unjust, we will now consider, for each of these funding modes, under what circumstances they would lead to in-practice justice-based objections. To start with funding by third parties, when done on an individual basis, this can negatively impact the quality of the healthcare system. Generally, treatments are not reimbursed for reasons of insufficient or unclear cost-effectiveness. Therefore, if insurers or providers regularly fund treatments that are not included in the basic package, this means that a non-negligible share of the healthcare budget will be spent on moderate- or low-value care. After all, many newly approved anti-cancer treatments only lead to marginal improvements of clinical outcomes.<sup>41</sup> Accordingly, several commentators argue that the current practice in high-income countries of spending considerable resources on end-of-life cancer care is indefensible from a justice perspective and may be regarded as unfounded prioritization of cancer care.<sup>42</sup> This is because the provision of low-value care has a clear opportunity cost, namely: the displacement of higher-value care for other patients. Displacement of higher-value care is unjust, may be harmful to other patients, and, as stated, is not consistent with the need to limit public spending on healthcare. In sum, any negative impact on the quality of the healthcare system would be a major

objection to a practice in which insurers or care providers regularly fund insufficiently cost-effective treatments.

This charge does not apply to the UK's policy of IFRs *insofar* as the treatments granted indeed provide more benefit to the individual patient to such an extent that they reach accepted cost-effectiveness thresholds. However, in practice, there seems to be considerable variety between geographical regions within the UK with respect to the share and type of IFRs being granted.<sup>43</sup> Such variability most likely means that sometimes, treatments that *do not* meet the threshold of cost-effectiveness *are* granted to some individual patients, and treatments that *do* meet these thresholds *are not* granted to other patients. Moreover, this variability is also directly unfair, since like cases are not being treated alike. To sum up, funding by providers or insurers for non-reimbursed treatments raises both in-principle and in-practice objections. This may be reason to disincentivize these practices.

Turning to OOP for expensive non-reimbursed treatments, allowing this would in fact lead to the introduction or extension of a two-tiered healthcare system. Both critics and defenders of two-tiered healthcare systems seem to agree that the most important ethical question is whether the second tier inevitably undermines the first tier, or whether this can be prevented with sound policy.<sup>44</sup> Now, there are at least the following two ways in which OOP can undermine the first, basic, tier.<sup>45</sup> In the Netherlands, there are no private hospitals with the capacity to deliver complex cancer care, so the self-funded treatments must be administered in public hospitals. Therefore, first, there are clear risks that these treatments draw from financial and personnel resources that are earmarked for public healthcare. And even if the treatments could be administered privately, complications would likely need to be treated in public hospitals, which, again, would displace other, more cost-effective, care provision. To avoid drawing from financial resources, it is proposed that individual patients who pay out of pocket for non-reimbursed treatments should also pay for any ancillary costs associated with self-funded treatment and its follow-up. However, these costs are often hard to assess accurately, and, furthermore, assessing and billing for them involves an additional administrative burden.<sup>46</sup> Thus, the concern that at least some additional costs will fall on the publicly funded healthcare system cannot be fully dispelled.

Moreover, in case there is *absolute scarcity* of beds and personnel, policies of charging patients for ancillary costs can partly solve the problem, but leave the problem of drawing from personnel unaddressed. In the current context of increasing scarcity of healthcare personnel, which is evident internationally, allowing OOP for non-reimbursed treatments would only put additional strain on publicly funded healthcare systems, to the detriment of the patient population. This problem cannot be solved by charging OOP patients for any additional use of health services.

However, it is, perhaps surprisingly, not evident that this would be problematic from the perspective of egalitarianism and prioritarianism. Consider again the case of Trodelvy, a treatment for triple-negative breast cancer that, as stated, provides a median 5.4-month overall survival gain at a list price of 69,000 EUR per patient. From the perspective of telic egalitarianism, women with triple-negative breast cancer are worse off compared to healthy persons and also compared to persons with less severe or minor health problems. Therefore, when a woman purchases a Trodelvy treatment which is administered in a public hospital, arguably, the resulting prolongation of her life renders her more equal to other persons, including those with minor health problems. Accordingly, telic egalitarians would evaluate a state in which these women can be treated with Trodelvy as

favorable, even if it may come at the expense of some other citizens, whose treatment for minor problems is delayed or canceled because of shortages in personnel. Similarly, for prioritarians, this state of health outcomes is favorable compared to the state in which these women cannot be treated with Trodelvy on an OOP basis, as these women are (much) worse off compared to other citizens with minor health problems and should thus be prioritized for treatment.

From the perspective of deontic egalitarianism, however, OOP for Trodelvy should be prohibited whenever this results in denying treatment to said citizens with minor health problems. This is because these citizens, like all citizens, are entitled to the basic package of healthcare, and if the treatment they require is part of that basic package, any delay or cancellation of their treatment – as a result of OOP-based treatment of fellow citizens with triple-negative breast cancer – is unacceptable. As already noted, most telic egalitarians and prioritarians are pluralists, and will be susceptible to the consideration of equal entitlement to care included in the basic package.

In addition, and related to the deontic egalitarian concerns, undermining the priority setting system and procedures by way of allowing or tolerating OOP in a context of increasing absolute scarcity of personnel compromises procedural justice within the system, and will undermine solidarity and citizens' trust, which are needed to uphold publicly funded healthcare systems. For, out-of-pocket paid-for treatments might, then, lead to longer waiting lists for other care. Thus, there is a real danger that OOP will undermine the quality of the basic healthcare available to all citizens, which would be unjust and would constitute an in-practice justice-based reason not to allow OOP.

Second, allowing OOP may undermine the comprehensiveness of the basic healthcare package.<sup>47</sup> The existence of alternative modes of funding may make it easier (or less unattractive) in the future for healthcare authorities not to include expensive treatments in the basic package.<sup>48</sup> For when patients in need manage to access these treatments using alternative routes, they are not as likely to put pressure on authorities to arrange reimbursement through the public healthcare system. As a result, the quality of the first tier might deteriorate, which could undermine social support for it, and disadvantage the less well off. However, even if OOP might serve as a perverse incentive to exclude expensive new treatments from the basic package, it is by no means inevitable that the basic package would disintegrate, and it is in the hands of governments to prevent this from happening. As long as the basic tier remains acceptable to all citizens because it provides comprehensive and good-quality cost-effective healthcare, there will be no demand for a (full-blown) second, private, tier.<sup>49</sup> Further empirical research would be required to see if there is ground for these concerns. It would be worthwhile to know whether and to what extent these concerns have materialized in the UK after OOP was allowed in the NHS in 2009. Also, further empirical research might elucidate whether the introduction of this policy has affected citizens' and patients' experiences of (equal) moral worth as expressed by the healthcare system.<sup>50</sup>

Finally, it should be noted that the above in-practice objections increase in force when the distributions of income and wealth in societies are unjustifiably unequal. In such societies, there might be in-principle justice-based objections to allowing alternative funding routes, because structural inequalities will have led to low incomes in certain groups, which then lack the means for OOP through no fault of their own. These thoughts merit further analysis elsewhere. If in such societies, allowing OOP by more affluent patients causes a decrease in the quality of basic healthcare for low-income citizens, the

disadvantage within this group will double. In this case, unjust income and wealth distributions are replicated in the form of an unjust distribution of good-quality healthcare. This seems good reason to disallow alternative funding routes in societies with unfairly unequal distributions of income and wealth.

## 5. Concluding Remarks

We have evaluated various modes of funding of non-reimbursed cancer treatments from the perspective of egalitarianism and prioritarianism. Payment by third parties, including healthcare providers, health insurers, and pharmaceutical companies, faces both in-principle and in-practice objections. It involves unequal treatment of equally entitled patients who are equally in need. Moreover, when third-party payments occur on a substantial scale, they may lead to the displacement of more cost-effective care. This is in tension with cost-effectiveness as an important guiding principle for delineating the basic healthcare package in publicly funded healthcare systems in order to keep these systems sustainable, and may be harmful to other patients. Together, these considerations give reason to be very hesitant with third-party funding, at least by insurers and providers.

With regard to OOP made by individual patients for treatments that are not (yet) reimbursed, our evaluation is different. The strong egalitarian *ethos* in universal healthcare systems that speaks principally against OOP seems unsupported by both telic and deontic egalitarianism. Moreover, prioritarianism is clearly in favor of allowing OOP for non-reimbursed cancer treatments, as patients who need recourse to OOP are generally among the worst off, and, as the scope of our article is limited to *approved* treatments, these patients are likely to derive (some) health benefit from having the treatment. Therefore, in principle, OOP should not be considered as unjust.

At this point, we wish to highlight the tension between the broadly supported egalitarian ethos and sentiment in (at least some) publicly funded healthcare systems on the one hand, and our analysis from the perspective of justice on the other. Many healthcare workers have great difficulty with OOP, but seem far less disturbed when health insurers or healthcare providers treat similar patients differently when granting, rejecting, or pursuing funding requests for individual patients. Our argument is for the reverse: OOP can be allowed on the basis of justice, but unequal treatment by insurers and providers is in tension with the justice-based requirements of equal treatment.

A possible explanation of this tension is the difference in visibility. Perhaps it is less painful to let an unjust but implicit practice exist of differential treatment by providers and insurers that remains largely out of sight, than an (in-principle) just but explicit policy of allowing OOP that, however, leads to very salient differences in access to cancer treatments on the basis of ability to pay. Allowing OOP might lead to experiences that are painful: doctors and patients would know and see that ability to pay makes a difference between receiving treatment and giving up hope for a possible therapy. While it is understandable that one would wish to avoid these experiences, ultimately, healthcare systems should work to align practice with policies that, on reflection, are more just.

The important empirical question remains, however, whether, in practice, allowing OOP may lead to problems of justice. Some seem inevitable, especially the worry that self-funded treatments draw resources from already understaffed publicly funded healthcare systems and may negatively affect the basic package of healthcare, to the detriment of the wider

patient population and possibly exacerbating existing health inequalities. Therefore, despite considerations in favor of OOP, these practical problems may very well turn out to be substantial, leading to injustices that may carry more weight. In that case, in-practice considerations might justify hospitals or healthcare systems in deciding against the allowing of OOP for expensive non-reimbursed treatments.

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## NOTES

- 1 Ministry of Health, Welfare and Sport, “Geneesmiddel Trodelvy.”
- 2 In the UK, public healthcare is provided by the NHS, funded by taxes, and free for all citizens. UK citizens can take out private health insurance to have access to private healthcare, mainly to avoid waiting times and for (what they perceive as) higher-quality care. In the Netherlands, the healthcare system is funded by a mix of mandatory private health insurance with community-rated premiums, and taxes. Even though insurers are private organizations, as Maarse and Bartholomée (“Public–Private Analysis”) convincingly argue, they fulfil a distinctly public role in a mandatory and collectively funded universal healthcare system. By virtue of this role as public actors, the requirement of social justice of equal treatment of patients applies to them as well.
- 3 Bomhof *et al.*, “Physicians’ Perspectives.”
- 4 Bloor, “Patients.”
- 5 E.g. *ibid.*; Bomhof *et al.*, “Physicians’ Perspectives.”
- 6 Desai *et al.*, “Top-up Payments.”
- 7 In another article, we ask similar questions regarding yet another mode of funding, namely voluntary health insurance for expensive non-reimbursed treatments. The other article and the current article are clearly distinct: the other article on voluntary health insurance contains an extensive discussion of relational egalitarianism, which is not covered in the current article. The current article on OOP and third-party payment employs the priority view, which is absent from the other article, and provides a much more in-depth discussion of the relevance of the increasing absolute scarcity of beds and personnel. See Smids and Bunnik, “Voluntary Health Insurance.”
- 8 Schramme, *Theories*.
- 9 Daniels, *Just Health*.
- 10 *Ibid.*; Ehni, “Expensive Cancer Drugs”; Schramme, *Theories*.
- 11 Dillon and Landells, “NICE.”
- 12 This ‘merely’ is speaking from the perspective of cost-effectiveness, because for patients, these months are often highly valuable.
- 13 Cf. Arneson, “Egalitarianism”
- 14 Eyal, “Leveling Down Health.”
- 15 Parfit, “Equality and Priority,” 213.
- 16 Cf. Hausman, “Significance”; Herlitz, “Health.”
- 17 Bloor, “Patients.”
- 18 Ministry of Health, Welfare and Sport, “Home.”



- 19 Bomhof *et al.*, “Physicians’ Perspectives.” 281
- 20 Parfit, “Equality.”
- 21 *Ibid.*, 204.
- 22 *Ibid.*, 210–11.
- 23 Cf. Eyal, “Leveling Down Health,” 198.
- 24 *Ibid.*
- 25 Cf. Smids and Bunnik, “Voluntary Health Insurance.”
- 26 For this insight, see also Färdow *et al.*, “Co-Payment,” 7, who, however, do not discuss it in connection to the raising-up objection.
- 27 Regidor, “Measures.”
- 28 Eyal, “Leveling Down Health”; Temkin, “Inequality and Health.”
- 29 Parfit, “Equality,” 207.
- 30 It might very well be the case that the egalitarian ethos underlying opposition to OOP for non-reimbursed treatment can be better expressed and supported in terms of relational egalitarianism. However, discussing this complex theory of justice is beyond the scope of the present article. But see our Smids and Bunnik, “Voluntary Health Insurance.”
- 31 Cf. Daniels, *Just Health*.
- 32 Cf. Hausman, “Significance.”
- 33 We thank two anonymous reviewers for raising this point.
- 34 Bomhof *et al.*, “Physicians’ Perspectives.”
- 35 *Ibid.*
- 36 NHS England. “Individual funding requests for specialised services a guide for patients,” <https://www.england.nhs.uk/publication/individual-funding-requests-for-specialised-services-a-guide-for-patients/>.
- 37 It might be objected that insurers in the Dutch system are private parties (though almost all are non-profit), and (should) have some leeway to decide whether or not to grant individual requests. But see endnote 2.
- 38 Cf. Fourie, “Sufficiency View.”
- 39 NHS England. “Individual funding requests for specialised services a guide for patients,” p. 5. <https://www.england.nhs.uk/publication/individual-funding-requests-for-specialised-services-a-guide-for-patients/>.
- 40 Bunnik *et al.*, “Little to Lose.”
- 41 Davis *et al.*, “Availability.”
- 42 Tännsjö, *Setting Health-Care Priorities*; Brock, “Ethical and Value Issues”; Culyer, “Ethics.”
- 43 Coombes, “Rules”; Iacobucci, “Pressure.”
- 44 Brett, “Two-Tiered Health Care”; Krohmal and Emanuel, “Access.”
- 45 Fenton, “Mind the Gap”; Jackson, “Top-up Payments.”
- 46 Jackson, “Top-up Payments,” 411–12.
- 47 *Ibid.*, 419–20.
- 48 Fenton, “Mind the Gap,” 4.
- 49 Cf. Krohmal and Emanuel, “Access.”
- 50 We could not find literature discussing these issues in follow-up to the 2009 debate. This blog post suggests that OOP may be fully integrated in NHS care: Urch, “Beyond NHS Treatment.”

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