The Price of Cost-effectiveness Thresholds

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Abstract

Health systems around world are increasingly adopting cost-effectiveness (CE) analysis to inform decisions about access and reimbursement. We study how CE thresholds imposed by a health plan for granting reimbursement affect drug producers' pricing incentives and patients' access to new drugs. Analysing a sequential pricing game between an incumbent drug producer and a potential entrant with a new drug, we show that CE thresholds may have adverse effects for payers and patients. A stricter CE threshold may induce the incumbent to switch pricing strategy from entry accommodation to entry deterrence, limiting patients' access to the new drug. Otherwise, irrespective of whether entry is deterred or accommodated, a stricter CE threshold is never pro-competitive and may in fact facilitate a collusive outcome with higher prices of both drugs. Compared to a *laissez-faire* policy, the use of CE thresholds can only increase the surplus of a health plan if it leads to entry deterrence in which the price reduction by the incumbent necessary to deter entry outweighs the health loss to patients not getting access to the new drug.

Keywords: Pharmaceuticals; Health Plans; Cost-effectiveness analysis; ICER; Therapeutic competition

JEL Classification: I11; I18; L13; L65

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1 Introduction

Rising pharmaceutical expenditures are becoming a pressing concern in many countries as biomedicine advances new treatment opportunities for severe and rare diseases. Governments and health insurance plans are increasingly adopting health technology assessment to inform decisions about access, reimbursement, and drug prices. These assessments often include a cost-effectiveness (CE) analysis in which the incremental costs and benefits of a new treatment are measured relative to an existing baseline treatment. This incremental CE ratio (ICER) allows governments and insurers to assess the net value-added of a new treatment. If the incremental cost per unit of health gain is sufficiently small, the new treatment is more likely to be included in the health plan and granted reimbursement. In this way, the CE threshold reflects the government's willingness-to-pay for a new treatment, introducing value-based pricing in which prices of new drugs are associated with treatment effects learned from clinical trials (Lakdawalla, 2018). A key rationale for a stricter CE threshold is to reduce health care spending by exercising downward pressure on drug prices (Jena and Philipson, 2013, and Berdud et al., 2020).

An important characteristic of ICER is its anchoring to the price of the baseline (incumbent) treatment. For a given health gain of a new drug, the maximum price accepted by the health insurer (government or private plan) will be increasing in the drug price of the incumbent drug. Therefore, if the currently used treatment becomes more expensive (cheaper), the maximum price that can be charged by the producer of the new drug (entrant) automatically increases (decreases). Thus, the use of CE thresholds often works as an implicit price control on new drug treatments.[1] With the progress of advanced medicine, this role of the incumbent drug in CE analysis is important, yet overlooked, in studies of value-based pricing of new drugs.

New and improved drug treatments arrive sequentially, often allowing the latest patented drug only a few years before its incumbency position is threatened by a new entrant. Recent innovations of new Hepatitis C (HCV) drugs illustrate this pattern. Roediger et al. (2019) review three recent generations of these drugs. The first generation of HCV drugs dominated until 2010, but with the arrival of the second generation in 2011, these saw a sharp decline in market shares. The second-generation drugs had far better response rates for some types

[1] The ICER is typically used as a guide for pricing. For example, the UK's National Institute for Health and Clinical Excellence recommends that every new drug approved produces at least one additional QALY for every £30,000 that it costs.

of patients. When the third generation were launched from 2014 and onwards, the second generation had already established itself as the baseline treatment for HCV patients.

With frequent replacements of baseline treatments, drug companies need to be forward-looking in their price setting. Even if a patented drug currently enjoys a dominant incumbency position, its price does not only determine the drug producer's current profit, it may also define the unit cost of the best alternative treatment when the ICER of the next drug to enter is calculated. Often, this happens long before the incumbency is threatened by patent expiration, as illustrated by the HCV case above.

A recent example of sequential assessment is new therapies for patients with spinal muscular atrophy (SMA). Biogen's Spinraza was the first treatment of this condition to be approved, in 2016 by the US Food & Drug Administration and in 2018 by the European Medicines Agency. Due to lack of baseline treatment, the health technology assessments of Spinraza used real-world care of patients as a comparator to calculate ICER. In Norway, the regional health authorities reached an agreement with Biogen in 2018 which provided access to the drug. Three years later, Novartis entered with a competing drug Zolgensma, but in this case the health technology assessment could use Spinraza as an indirect comparator, instead of the real-world care alternative. Thus, the pricing of Spinraza had a direct impact on which price of Zolgensma that would meet the CE threshold.

In this paper we study the impact of implementing CE analysis as a means for regulating access to new drug therapies in a health plan, focusing on how this policy affects the pricing decisions by the drug producers. Since the ICER depends on the prices of the existing and new drug treatments and not the actual production costs, this means that the ICER and thus also the inclusion decision are endogenously determined by the drug producers' price setting. To capture the strategic effects of a CE policy for inclusion, we model a sequential pricing game between an incumbent offering a baseline treatment and a potential entrant offering a new and potentially better drug treatment.

Based on this set-up we derive several novel and counter-intuitive results. First, for a sufficiently strict CE threshold, the scope for entry is larger the smaller the therapeutic benefit offered by the new drug. A lower threshold reduces the incumbent's profits under entry accommodation, while it increases the incumbent's profits under entry deterrence. Thus, a sufficiently strict CE threshold might induce the incumbent to switch from an entry accommodating to an entry deterring pricing strategy. The latter option is relatively more profitable if the potential

entrant has developed a drug with a higher quality, which would make it a stronger competitor in case of entry. Second, a stricter CE threshold can lead to lower drug prices only if it switches the equilibrium outcome from entry accommodation to entry deterrence. Otherwise, whether entry is deterred or accommodated in equilibrium, a stricter CE threshold is never pro-competitive – it has either no effect on drug prices or leads to a price increase. In the latter case, CE thresholds serve as a collusion facilitating mechanism which benefits the entrant. The importance of entry decisions of already developed drugs are supported by empirical evidence. The dataset developed by Cockburn et al. (2016) shows that the mean number of countries experiencing launch of novel drugs is 22.4 out of a possible 76. Even among countries with the most developed health care systems, only about 60 percent of all drugs became available during the sample period 1983-2002.

From a policy perspective, therefore, our results do not lend strong support to the use of a CE threshold as a criterion for drug market access. Compared to a *laissez-faire* policy, where inclusion of a new drug in the health plan is granted automatically whenever it is profitable for the producer to enter the market, the use of a CE threshold as a criterion for drug inclusion might increase the health plan's surplus only if it leads to entry deterrence. The rationale behind the use of a CE threshold seems to rely on the implicit assumption that prices of the baseline treatment are exogenous and do not take into account future competition from new treatments. However, we would claim that such an assumption might be overly naïve. Potential entrants will often appear long before the incumbent's drug is off-patent and subjected to generic competition.

The rest of the paper is organised as follows. In the next section, we relate our study to the existing literature. In Section 3, we present the model. In Section 4, we characterise the subgame perfect equilibrium of the model, and in Section 5 we analyse the effect of CE-thresholds on prices and access to the new drug. In Section 6 we discuss policy implications, while in Section 7 we extend the main analysis to consider the case where the incumbent faces a price cap that binds under accommodated entry. Finally, in Section 7 we conclude and also offer an extended discussion of some of the main assumptions underlying our analysis. Proofs of the Propositions are provided in Appendix A at the end of the paper.

2 Related literature

There is a vast literature on the use of CE analysis in allocating health care resources efficiently.[2] This literature demonstrates a solid economic foundation of using such analysis to guide medical decision making after a drug therapy or medical technology is in place, which is a key reason why CE thresholds for inclusion in the health plan have become a widespread practice, especially in European countries.[3]

However, much less attention has been devoted to the incentives that CE thresholds for inclusion in the health plan impose on producers. Indeed, the approach taken by the above mentioned literature is that the health gains and costs of existing and new treatments are exogenously given. As pointed out by a few recent studies, this is a naïve and unrealistic assumption. The use of CE thresholds for inclusion in a health plan is likely to affect incentives both for innovation and pricing, and thus impacting both static and dynamic efficiency.

Jena and Philipson (2007) study the impact of CE analysis on the incentives for getting new technologies to the market, providing empirical evidence from a case study on HIV/AIDS. They argue that CE thresholds, by being implicit price controls, favour technologies from which the incremental static benefits exceed the associated costs. However, this inclusion criteria does not take into account dynamic incentives. Current CE thresholds could promote innovation when they function as price floors guaranteeing innovators the social value of their discoveries. Jena and Philipson (2008) provide a formal model of adoption of new technologies based on CE analysis and show that such a policy may have adverse effects on innovation incentives. They argue that CE analysis is closely related to the consumer surplus it generates and thus in conflict with policies that stimulates producer surplus and innovation, such as patent policy. Thus, CE analysis should be modified to account for dynamic efficiencies, implying less strict thresholds. Using an illustrative sample of technologies, they show that strict CE thresholds have adverse effects on dynamic efficiency, with the median technology having an appropriation of about 15 percent of the total surplus. Jobjörnsson et al. (2016) is also investigating how R&D incentives of pharmaceutical companies are affected by CE thresholds. In their analysis, the CE thresholds are shown to affect the design of late-stage clinical trials. The CE threshold,

[2] See, e.g., Gold et al. (1996), Garber (2000), Drummond et al. (2015).

[3] Two different approaches are used to derive optimal CE thresholds for inclusion in the health plan, see, e.g., Gold et al. (1996), Claxton et al. (2015) and Sampson et al. (forthcoming). With the 'demand-side' approach, the optimal threshold reflects the willingness-to-pay for health gains, whereas with the 'supply-side' approach, the threshold is set to reflect the opportunity cost of introducing a new treatment in the presence of a fixed health care budget.

representing the insurer's willingness to pay for improved treatment, is assumed to be uncertain. The degree of uncertainty about the threshold plays a crucial role level by having an impact on both the trials (sample size) and the drug price proposed by the company if approved.

The paper by Jena and Philipson (2013) is closer to our study as they focus on the pricing incentives that CE thresholds impose on producers. The key point is that if the CE analysis reflects prices set optimally by the producers rather than production costs, then observed CE levels will depend on how producers' pricing responds to CE policies. Similar to our study, they find that when CE is endogenously determined via producers' price setting, policy aimed at lowering spending and improving overall CE may paradoxically raise spending and lead to adoption of more resource-costly treatments. Jena and Philipson (2013) illustrate this point empirically by using data on public coverage decisions in the United Kingdom.

While the study by Jena and Philipson (2013) is close to ours at the more general level, their approach is quite different. They assume a probabilistic adoption ('listing'), allowing both the drug price and the CE threshold to affect the probability of being introduced as a treatment option in the health plan. The producer chooses a monopoly price, where the elasticity of expected demand determines the mark-up on marginal costs. Since the threshold affects the elasticity of expected demand, via the adoption probability, they are able to explore the relationship between the threshold, the drug price, and the expected drug expenditure. Thus, their study does not investigate the strategic game between an incumbent and a potential entrant, which is the key focus in our study, but considers instead a single monopoly producer.

Probabilistic adoption is also assumed by Levaggi (2014). The probability of being reimbursed depends on the price, which determines the expected cost effectiveness of the new drug. In her analysis, the threshold is exogenous, given by the new drug's expected treatment effect. The producer of the new drug sets a monopoly price, taking into account the effect of the price on the probability of being adopted ('listed'). Although this allows the benefit produced by a new drug to be equally shared with the payer, probabilistic adoption is always *ex post* inefficient since the drug might be rejected even if the ICER is below the threshold. Berdud et al. (2021) extend this line of research by analysing the impact of thresholds within a Nash-bargaining framework. The drug price is determined by Nash-bargaining between the payer and the producer. They assume that the payer can freely choose the cost-effectiveness threshold, and the buyer will do so to truncate the set of prices available to the bargainers. As in Levaggi (2014), this comes with a cost to the payer by having to turn down new drugs that are *ex post* efficient

to introduce in the health plan.

Danzon et al. (2015) are also analysing how CE thresholds affect pharmaceutical pricing, and they do so by deriving the price cap for the new drug that follows from the threshold chosen by the universal payer. A more effective drug can set a higher price and still meet the CE threshold. The payer's CE threshold acts as an indirect price control that are responsive to quality differences between the new drug and the older treatment option. This is the same price cap condition we introduce in our model of therapeutic competition.

Our paper differs substantially from these studies in that we focus on competition and the strategic interaction between an incumbent producer and a potential entrant in the presence of CE thresholds. To our knowledge, the strategic pricing game introduced by the CE analysis has not yet been studied in the existing literature. The above-mentioned studies focus exclusively on monopoly pricing. Our approach allows for several novel results on (unintended) effects of CE thresholds due to strategic pricing. This includes the entry deterring or accommodating pricing strategies by the incumbent, but also the subsequent effects on drug prices and expenditures for payers and access to new medical treatments for patients.

Our framework for analysing competition in the pharmaceutical market builds on a strand of literature that uses a spatial framework in which drugs are (potentially) both horizontally and vertically differentiated.[4] Among these studies, the general set-up in our paper relates most closely to the formulation in Miraldo (2009) and Brekke et al. (2022). A key assumption in these models is that a given therapeutic class contains several drugs with different active ingredients. Although these drugs are not perfect substitutes, empirical research supports the assumption that treatment effects can be sufficiently overlapping to establish therapeutic competition.[5] While our paper builds on the modelling framework of this strand of literature, none of these studies analyse the impact of CE analysis nor consider a sequential pricing game between an incumbent and a potential entrant, which is key to our analysis.

Finally, our paper relates to the broader IO literature on entry deterrence and in particular limit pricing.[6] In a seminal paper, Bain (1949) argues that an incumbent firm can discourage

[4] See, e.g., Brekke et al. (2007), Miraldo (2009), Bardey et al. (2010), Bardey et al. (2016), Brekke et al. (2016), González et al. (2016) and Brekke et al. (2022).

[5] Kanavos et al. (2007) analysed the existence of competition between branded statins in European markets prior to patent expiry. Their results are consistent with potential price sensitivity in the branded market for statins. Danzon and Epstein (2012) found that prices of new drugs are influenced by prices of other products in the same class. Lu and Comanor (1998) analysed therapeutic competition and found that launch prices of drugs that are closer substitutes to existing brands are typically priced at comparable levels. In addition, they found that the number of branded substitutes has a substantially negative effect on launch prices.

[6] A strand of the IO literature focuses on the role of cost structure on pricing and entry by firms. For example,

entry by charging a low price. This original idea of *limit pricing* was later rejected as it did not satify the subgame perfection criterion; the incumbent has an incentive to increase its price if entry occurs, which makes a low pre-entry price not credible as in terms of entry deterrence.[7] The lack of commitment to a low (post-entry) price is the key issue. However, in our paper, regulation (i.e., the CE threshold) introduces a commitment device for the incumbent to prevent entry from newcomers. By adjusting the pre-entry price, the incumbent can manipulate the ICER and thus the inclusion criterion for a new drug producer. A related paper by Bergman and Rudholm (2003) analyse a similar regulatory mechanism for credible limit pricing, arguing that price regulation introduces a 'ratchet' effect for the incumbent producer, as prices cannot be increased after entry. Using data from the Swedish pharmaceutical market, they provide evidence of limit pricing brand-name producers prior to patent expiration to deter entry of generics in relatively smaller markets.[8]

3 Model

Consider a therapeutic market for on-patent prescription drugs where patients are uniformly distributed on a unit line with total mass equal to one. The line can be interpreted as a 'disease space' in which the distance between a drug and a patient reflects the degree of therapeutic mismatch. Each patient in the market needs one unit of drug treatment, and drug prescription choices are made by a physician who prescribes what is considered the most appropriate drug from the available choice set, which consists of the drug(s) approved by the relevant health plan. When making this decision, the prescribing physician takes into account both the patient's health benefit and the price(s) of the drug(s). Consider a drug denoted by i, which is located at z_i, has therapeutic quality v_i and costs p_i. If one unit of this drug is prescribed to a patient

Grossman (1981) considers an industry with free entry, homogeneous products, and large fixed production (non-sunk) costs. He shows that firms price more aggressively when fixed production costs are high and firms operate close to their break-even points. While this outcome has some similarities to limit pricing, as entry is negatively affected, the modelling approach is very different from ours and does not fit well with the pharmaceutical industry where entry is not free (due to patent protection), fixed costs are mostly sunk (R&D and marketing), and products are differentiated. Moreover, the entry game is also in most cases sequential with an incumbent and a potential entrant, as in our setup.

[7] Later papers, starting with Milgrom and Roberts (1982), introduced asymmetric information where the pre-entry price signals the cost type of the incumbent. While limit pricing is an equilibrium strategy in these studies, the price itself is not what deters entry but rather the underlying cost or capacity signalled by the pre-entry pricing of the incumbent.

[8] The paper is mainly empirical but contains an appendix with a short theoretical analysis of limit pricing under price regulation.

located at $x \in [0,1]$, the utility assigned to this choice by the prescribing physician is

$$u_i(x) = v_i - t|x - z_i| - \beta p_i, \tag{1}$$

where $t > 0$ measures the relative importance of therapeutic mismatch, and β measures the price sensitivity of the physician's prescription choices. We assume that $\beta \in (0,1)$, which implies that the physician gives relatively more importance to patients' health benefits than to the health plan's expenditures when making drug prescription choices.[9]

We consider a case in which there are potentially two drugs approved by the health plan and thus available in this particular therapeutic market. An incumbent producer offers a drug, denoted by I, which is located at one of the endpoints and has quality v_I. A potential entrant has developed a new drug, denoted by E. This drug has quality $v_E > v_I$ and therapeutic characteristics that correspond to a location at the other endpoint. Thus, the new drug is both horizontally and vertically differentiated from the existing one.

The potential entrant will gain access to the market only if the new drug passes a cost-effectiveness (CE) threshold. More specifically, the price of the drug must be such that the cost per additional unit of improvement in expected health benefits is below some threshold $k > 0$.[10] Since the expected (average) health benefit for drug i is given by $v_i - (t/2)$, the above described cost-effectiveness criterion translates to the condition

$$\frac{p_E - p_I}{\Delta v} \leq k, \tag{2}$$

or

$$p_E \leq p_I + k\Delta v, \tag{3}$$

where $\Delta v := v_E - v_I > 0$ measures the improvement in expected health benefits (often measured in QALYs) offered by the new drug. We will interchangeably refer to (3) as the *CE condition* or the *CE threshold*.

We assume that the costs of producer i are given by a constant marginal cost c_i and a fixed cost f_i. The marginal production costs are assumed to be equal for the two drugs and, for

[9] Notice that the interpretation of β may include patient copayments in the form of coinsurance. All else equal, a higher coinsurance rate implies a higher value of β.

[10] This is in line with current practice. For example, the UK's National Institute for Health and Clinical Excellence recommends that every new drug approved produce at least one additional QALY for every £30,000 that it costs.

simplicity, we set $c_I = c_E = 0$. On the other hand, we assume that the cost of entering the market results in higher fixed costs for the potential entrant, such that $f_E > f_I \geq 0$.[11] Thus, the profits of producer i are given by

$$\pi_i = p_i y_i - f_i, \tag{4}$$

where y_i is demand for drug $i = I, E$.[12]

Given all of the above assumptions, the entry decision results from the following three-stage game:

1. The incumbent sets a price p_I.

2. The potential entrant decides whether to enter with a price p_E, that satisfies the CE condition in (3), or not to enter the market.

3. Physicians prescribe drugs from the available choice set.

The sequential order of price setting relies on an implicit assumption that the incumbent is able to commit to a price that cannot easily be changed after the entry decision has been made at the subsequent stage of the game. Such commitment makes sense in the particular context we are studying, since price changes have to be approved by the health plan. In particular, the health plan is unlikely to sanction a price increase that cannot be justified by exogenous cost increases or other exceptional circumstances. Thus, in contrast to an ordinary market with free pricing, the particular institutional features of on-patent pharmaceutical markets are such that price reductions cannot easily be reversed. Furthermore, the application of a CE threshold for new drugs also places constraints on *ex post* price adjustments. The assumption of commitment in price setting will be more elaborately discussed in the final section of the paper.

Finally, we impose some parameter restrictions to ensure that the incumbent earns non-negative profits in all candidate equilibria. Thus, we rule out the possibility that the threat of entry can force the incumbent out of the market. This requires that both f_I and Δv are sufficiently low. More specifically, regarding the quality difference between the drugs, we assume

[11] None of our main results depend on the relative magnitude of variable versus fixed costs. Thus, setting marginal production costs equal to zero is without loss of generality.

[12] We assume that v_i is sufficiently large (for $i = I, E$) to ensure full market coverage in equilibrium.

that

$$\Delta v \leq \begin{cases} \min\left\{\frac{t}{1-\beta k}, 3t\right\} & if \quad k < \frac{1}{\beta} \\ 3t & if \quad k \geq \frac{1}{\beta} \end{cases}. \tag{5}$$

4 Analysis

In this section we solve the game by backwards induction, looking for the subgame perfect Nash equilibrium (SPNE).

4.1 Drug demand

At the last stage of the game, the prescribing physician has either one or two drugs in his prescription choice set. In the latter case, which occurs if the potential entrant decided to enter the market, drug prescription choices are made such that (1) is maximised for all patients. The patient for whom the physician is indifferent between prescribing the old or the new drug is located at $\widehat{x}$, which is implicitly given by

$$v_I - t\widehat{x} - \beta p_I = v_E - t\left(1 - \widehat{x}\right) - \beta p_E. \tag{6}$$

The demand for the incumbent drug is consequently given by

$$y_I = \frac{1}{2} + \frac{\beta\left(p_E - p_I\right) - \Delta v}{2t}, \tag{7}$$

while $y_E = 1 - y_I$ patients are prescribed the new drug. All else equal, the larger the quality improvement offered by the new drug, the lower is demand for the old drug. The latter drug's demand disadvantage can be mitigated by a lower price, but the magnitude of this mitigating effect depends on the price-responsiveness of drug prescription choices.

On the other hand, if the potential entrant decides not to enter the market, the incumbent producer remains a monopolist. In this case, the physicians' prescription choice set for this particular disease consists of only one drug, and we assume that v_I is sufficiently high such that $u_I\left(x\right) > 0$ for all $x \in [0, 1]$, implying that the drug will be prescribed to all patients. In the case of no entry, the demand for the incumbent drug is thus given by $y_I = 1$.

4.2 Entry and pricing decisions

At the second stage of the game, the potential entrant observes the price set by the incumbent producer and decides whether to stay out of the market or to enter with a price satisfying the CE condition. This decision is determined by whether the incumbent has set a price that accommodates or deters entry. We will consider each of these cases in turn.

4.2.1 Entry accommodation

In case of entry, the optimal price chosen by the potential entrant is a price that solves the following constrained maximisation problem:

$$\max_{p_E} \pi_E = p_E \left(\frac{1}{2} + \frac{\beta (p_I - p_E) + \Delta v}{2t} \right) - f_E \quad \text{such that} \quad p_E \leq p_I + k\Delta v. \tag{8}$$

The solution to this problem yields the following best-response function:

$$p_E (p_I) = \begin{cases} p_I + k\Delta v & if \quad p_I \leq \widehat{p}_I \\ \frac{p_I}{2} + \frac{t+\Delta v}{2\beta} & if \quad p_I > \widehat{p}_I \end{cases}, \tag{9}$$

where

$$\widehat{p}_I := \frac{t}{\beta} + \left(\frac{1 - 2\beta k}{\beta} \right) \Delta v. \tag{10}$$

Thus, the best-response function of the potential entrant is kinked at $\widehat{p}_I$, such that the CE condition binds for $p_I \leq \widehat{p}_I$.

At the first stage of the game, the incumbent chooses a profit-maximising price p_I, which can be either on the constrained or the unconstrained part of the entrant's best-response function. We will refer to this as, respectively, *constrained* and *unconstrained* entry accommodation. Since $\widehat{p}_I$ is monotonically decreasing in k, a lower value of k (i.e., a stricter CE threshold) will increase the scope for entry accommodation to be constrained by the CE condition. This is confirmed by deriving the equilibrium prices under accommodated entry, which are given by

$$p_I^a = \begin{cases} \widehat{p}_I & if \quad k \leq \widehat{k} \\ \frac{1}{2\beta} (3t - \Delta v) & if \quad k > \widehat{k} \end{cases} \tag{11}$$

and

$$p_E^a = \begin{cases} \widehat{p}_I + k\Delta v & if \quad k \leq \widehat{k} \\ \frac{1}{4\beta}(5t + \Delta v) & if \quad k > \widehat{k} \end{cases}, \tag{12}$$

where

$$\widehat{k} := \frac{1}{4\beta}\left(3 - \frac{t}{\Delta v}\right). \tag{13}$$

As is evident from (11)-(12), unconstrained entry accommodation requires that the CE threshold is sufficiently high, namely $k > \widehat{k}$. If instead $k < \widehat{k}$, the incumbent's profit-maximising price is on the constrained part of the entrant's best-response function.[13] Notice from (9) that $\partial p_E/\partial p_I = 1$ if $k < \widehat{k}$. Thus, as long as the CE constraint binds, a one euro increase in the incumbent's price will induce a similar price increase of the entrant's drug, which means that relative drug prices remain constant. Since total demand is fixed, a price increase that keeps relative prices constant is always profitable. Consequently, the profit-maximising price on the constrained part of the entrant's best-response function is at $p_I = \widehat{p}_I$. In other words, because of the one-to-one relationship between the two drug prices, the incumbent has an incentive to implement the highest possible price pair for which the CE condition binds. Thus, for $k < \widehat{k}$, the CE condition serves as a *collusion facilitating mechanism* under entry accommodation, where the prices of both drugs are higher than they would have been in the absence of a CE threshold.

The profits of the two producers under accommodated entry are given by

$$\pi_I^a = \begin{cases} \frac{(t+(1-2\beta k)\Delta v)(t-(1-\beta k)\Delta v)}{2\beta t} - f_I & if \quad k \leq \widehat{k} \\ \frac{(3t-\Delta v)^2}{16\beta t} - f_I & if \quad k > \widehat{k} \end{cases} \tag{14}$$

and

$$\pi_E^a = \begin{cases} \frac{(t+(1-\beta k)\Delta v)^2}{2\beta t} - f_E & if \quad k \leq \widehat{k} \\ \frac{(5t+\Delta v)^2}{32\beta t} - f_E & if \quad k > \widehat{k} \end{cases}. \tag{15}$$

Entry accommodation (constrained or unconstrained) is a feasible candidate equilibrium for any value of k if

$$f_E < \overline{f} := \frac{(5t + \Delta v)^2}{32\beta t}. \tag{16}$$

If $f_E > \overline{f}$, entry is blockaded for all $k \geq \widehat{k}$, which we rule out by assumption. Thus, we assume that $f_E < \overline{f}$ throughout the analysis.

[13] Notice that constrained entry accommodation is a feasible candidate equilibrium only if the quality difference between the drugs is sufficiently high. It follows from (13) that the parameter set $k \in \left[0, \widehat{k}\right]$ is non-empty if $\Delta v > t/3$.

How does the level of the CE threshold (k) affect equilibrium prices and profits under entry accommodation? The answer is given by the following Lemma:

Lemma 1 *Under accommodated entry, (i) if $k > \widehat{k}$, a stricter CE threshold has no impact on prices and profits, while (ii) if $k < \widehat{k}$, a stricter CE threshold leads to higher prices for both drugs, and higher (lower) profits for the entrant (incumbent).*

These are discouraging results for proponents of a CE-based policy to contain drug prices. Under entry accommodation, to the extent that the implementation of a (stricter) CE threshold affects drug prices, it leads to higher instead of lower prices.

[Figure 1 and 2 here]

The results in Lemma 1 are illustrated in Figure 1 and 2, where we draw the unrestricted best-response curve of the potential entrant along with the CE condition. The actual best-response curve, when taking the CE condition into account, is therefore given by the thick part of the curves. Figure 1 illustrates the case of *unconstrained entry accommodation*, where there incumbent's profits along the entrant's best-response curve are maximised on the unconstrained part of the curve (at point A), where $p_I^a > \widehat{p}_I$. In this case, a stricter CE threshold ($k_1 < k_0$) will shift down the constrained part of the best-response curve, thus making the CE condition bind for a larger segment of the entrant's best response curve. However, this will not affect the equilibrium prices as long as $\widehat{p}_I(k_1) < p_1^a$.

Figure 2, on the other hand, illustrates the case of *constrained entry accommodation*, where the incumbent's profits are maximised on the constrained part of the entrant's best-response curve. Because of the collusion facilitating mechanism described above, the equilibrium is at the kink point of the best-response curve, where $p_1^a = \widehat{p}_I$. A reduction in k from k_0 to k_1 will now shift the equilibrium point from A_0 to A_1, leading to higher prices for both drugs. Notice, however, that such a reduction in k is not in the interest of the incumbent firm, despite the price increase, because it brings the equilibrium further away from the unconstrained optimum (which in Figure 2 is a point on the unconstrained best-response curve somewhere to the left of A_0). Instead, it is the entrant that benefits from a stricter CE threshold, because, paradoxically, it allows the firm to enter the market with a higher price.

4.2.2 Entry deterrence

As long as $f_E > f_I$, the incumbent can in principle deter entry by setting a lower price; a price that is just low enough for entry to be unprofitable. Formally, the optimal entry-deterring price, p_I^d, is implicitly given by

$$\pi_E\left(p_I^d, p_E\left(p_I^d\right)\right) = 0. \tag{17}$$

As for the case of accommodated entry, the optimal entry-deterring price can be either on the constrained or the unconstrained part of the potential entrant's best-response function, depending on whether the price that solves (17) is lower or higher than $\widehat{p}_I$. In line with our previously adopted terminology, we will refer to these two cases as, respectively, *constrained* and *unconstrained* entry deterrence.

Using (9), the potential entrant's maximum profit, as a function of p_I, is given by

$$\pi_E\left(p_I\right) = \begin{cases} \frac{(t+(1-\beta k)\Delta v)(p_I+k\Delta v)}{2t} - f_E & if \quad p_I \leq \widehat{p}_I \\ \frac{\left(t+\Delta v+\beta p_I\right)^2}{8\beta t} - f_E & if \quad p_I > \widehat{p}_I \end{cases}. \tag{18}$$

The resulting optimal entry-deterring price is then given by

$$p_I^d = \begin{cases} \frac{2tf_E}{t+(1-\beta k)\Delta v} - k\Delta v & if \quad f_E \leq f_1 \\ \frac{1}{\beta}\left(2\sqrt{2\beta t f_E} - t - \Delta v\right) & if \quad f_E > f_1 \end{cases}, \tag{19}$$

where

$$f_1 := \frac{\left(t + (1-k\beta)\Delta v\right)^2}{2\beta t}. \tag{20}$$

Under deterred entry, the incumbent's equilibrium profits are therefore given by

$$\pi_I^d = \begin{cases} \frac{2tf_E}{t+(1-\beta k)\Delta v} - k\Delta v - f_I & if \quad f_E \leq f_1 \\ \frac{1}{\beta}\left(2\sqrt{2\beta t f_E} - t - \Delta v\right) - f_I & if \quad f_E > f_1 \end{cases}. \tag{21}$$

Whether entry deterrence is constrained or unconstrained depends on the magnitude of the entry costs. If these costs are sufficiently high, such that $f_E > f_1$, the maximum price that deters entry is higher than $\widehat{p}_I$ and thus on the unconstrained part of the potential entrant's best response function. However, if $f_E < f_1$, it is only possible to deter entry by setting a price that is lower than $\widehat{p}_I$, implying that the optimal entry-deterring price is constrained by (3) and thus depends on the CE threshold k. The next Lemma summarises how a (stricter) CE threshold

affects prices and profits under deterred entry.

Lemma 2 *Under entry deterrence, (i) if $f_E > f_1$, a stricter CE threshold has no effect on prices and profits, while (ii) if $f_E \leq f_1$, a stricter CE threshold leads to higher price and profits for the incumbent drug producer.*

Also in case of entry deterrence, a CE-based policy has a potentially counterproductive effect on drug prices. If f_E is sufficiently low, such that the CE condition binds, a stricter threshold leads to higher instead of lower drug prices. In this case, the reason is simply that a reduction in k makes it easier for the incumbent to deter entry; i.e., entry can be deterred at a higher price, which obviously benefits the incumbent producer, all else being equal.

[Figure 3 and 4 here]

The results in Lemma 2 are illustrated in Figure 3 and 4. The case of *unconstrained entry deterrence* is illustrated in Figure 3, where the entry costs are so high ($f_E > f_1$) that the incumbent can deter entry by setting a price that is higher than $\widehat{p}_I$. In this case, a stricter CE condition has no price effects as long as $p_I^d > \widehat{p}_I$. The case of $f_E < f_1$ is illustrated in Figure 4, where entry can only be deterred by setting a price below $\widehat{p}_I$, which implies *constrained entry deterrence*. In this case, a reduction in k from k_0 to k_1 shifts the equilibrium point from D_0 to D_1. As explained above, such a tightening of the CE condition reduces the price at which the new drug can enter the market, all else equal, thus allowing the incumbent to deter entry at a higher price (i.e., $p_I^d(k_1) > p_I^d(k_0)$).

4.3 The subgame-perfect Nash equilibrium

The previous analysis defines four candidate SPNE outcomes: constrained or unconstrained entry accommodation, and constrained or unconstrained entry deterrence. At the first stage of the game, the incumbent effectively selects the most profitable among these outcomes. In order to characterise this selection, we make the following parameter definitions:

$$f_2 := \frac{1}{2t}\left(k\Delta v + \frac{(3t-\Delta v)^2}{16\beta t}\right)(t + (1-\beta k)\Delta v), \tag{22}$$

$$f_3 := \frac{(t+(1-\beta k)\Delta v)^2 (t-(1-2\beta k)\Delta v)}{4\beta t^2}, \tag{23}$$

$$f_4 := \frac{(5t + \Delta v)^4}{2048\beta t^3}. \tag{24}$$

It is also useful to note that $f_1 = f_2 = f_4$ if $k = \widetilde{k}$, where

$$\widetilde{k} := \frac{22t\Delta v + 7t^2 - (\Delta v)^2}{32\beta t \Delta v} > \widehat{k}. \tag{25}$$

With these parameter definitions, we can fully characterise the SPNE outcome as follows:[14]

Proposition 1 *(i) If $k \leq \widehat{k}$, the SPNE outcome is constrained entry accommodation for $f_E \leq f_3$ and constrained entry deterrence for $f_E > f_3$.*

(ii) If $k \in \left(\widehat{k}, \widetilde{k}\right]$, the SPNE outcome is unconstrained entry accommodation for $f_E \leq f_2$, constrained entry deterrence for $f_E \in (f_2, f_1]$, and unconstrained entry deterrence for $f_E > f_1$.

(iii) If $k > \widetilde{k}$, the SPNE outcome is unconstrained entry accommodation for $f_E \leq f_4$ and unconstrained entry deterrence for $f_E > f_4$.

Two basic observations can immediately be made. The first observation is that each of the four possible outcomes can appear as an equilibrium outcome, depending on parameter values. The second observation is that the equilibrium configuration is characterised by a clear and intuitive pattern. All else equal, a higher entry cost (which implies a higher f_E) increases the scope for entry deterrence instead of entry accommodation, whereas a stricter CE threshold (lower k) increases the scope for the CE condition to bind in equilibrium. The results in Proposition 1 are illustrated in Figure 5 for a particular numerical example, where $t = 2$, $\beta = 0.6$ and $\Delta v = 2$. Different parameter values yield a qualitatively similar picture.

[Figure 5 here]

5 Effects of CE thresholds on entry and drug prices

The application of a cost-effectiveness threshold for market access can in principle have two different effects in the context of our analysis. First, it can affect the likelihood that a new drug enters the market. Second, regardless of whether a new drug enters or not, it can affect the drug price(s) in the market. In this section we will consider each of these effects in turn.

[14] Proofs of all Propositions are given in Appendix A.

5.1 CE thresholds and entry of new drugs

Regarding the likelihood of entry, Figure 5 illustrates that the application of a CE threshold can facilitate the adoption of an entry deterring pricing strategy by the incumbent producer. If $f_E \leq f_4$, the equilibrium outcome is entry accommodation in the absence of a CE threshold (which can formally be thought of as $k \to \infty$). However, a sufficiently strict CE condition might incentivise the incumbent to switch from an entry accommodating to an entry deterring pricing strategy. In Figure 5, the SPNE outcome is actually always entry deterrence if k is sufficiently low, as long as $f_E > 0$. And notice that entry is deterred not because of the CE threshold itself, but because the existence of a CE threshold facilitates an entry deterring pricing strategy by the incumbent.

Perhaps the most interesting aspect of the entry deterring effect of a CE threshold is how this effect depends on the drug quality improvement offered by the potential entrant. Our next Proposition highlights this aspect.

Proposition 2 *For a sufficiently strict CE threshold, and given that $\Delta v > t/3$, the scope for entry is larger the smaller the therapeutic benefit offered by the new drug.*

The intuition for this result follows from the analysis in Section 4. Suppose that $\Delta v > t/3$, such that constrained entry accommodation is a feasible candidate equilibrium. In this case, a lower value of k reduces the incumbent's profits under constrained entry accommodation (Lemma 1) while it increases the incumbent's profits under constrained entry deterrence (Lemma 2). Thus, a sufficiently strict CE threshold might induce the incumbent to switch from an entry accommodating to an entry deterring pricing strategy. The latter option is relatively more profitable if the potential entrant produces a drug with a higher quality, which would make it a stronger competitor in case of entry. Thus, the lower (higher) the quality of the new drug, the less (more) likely it is that it will be deterred from entering the market when k is sufficiently low.

Once more, the use of cost-effectiveness thresholds is shown to have potentially counter-productive effects when we take into account the incentives for strategic behaviour by the incumbent. If the cost-effectiveness threshold is sufficiently strict, then the use of such thresholds reduces the probability of entry for drugs that offer a larger increase in therapeutic benefit, compared to drugs with a smaller therapeutic value added, all else equal. Paradoxically, this is the opposite of what is normally considered to be the intended effects of using a market access

policy based on CE thresholds.

5.2 CE thresholds and drug prices

The effects of CE thresholds on equilibrium drug prices within each type of equilibrium were described in Lemmas 1 and 2. When we also consider the possibility that a change in the threshold might change the type of equilibrium, the overall relationship between the CE threshold and equilibrium drug prices are given as follows:

Proposition 3 *A stricter CE threshold can lead to lower drug prices only if it switches the equilibrium outcome from entry accommodation to entry deterrence. Otherwise, whether entry is deterred or accommodated in equilibrium, a stricter CE threshold is never pro-competitive; it has either no effect on drug prices or leads to a price increase.*

The explanation for this result follows from the previously explained intuition for Lemmas 1 and 2. When seen in conjunction with Proposition 1, it appears that the application of a CE threshold for drug approvals can induce lower drug prices only if the entry cost is sufficiently low ($f_E \leq f_4$), and only if it deters entry of new drugs. Thus, any potentially price-reducing effect of CE thresholds comes at the cost of lower therapeutic benefits.

6 Policy implications

From a policy perspective, the results derived in the previous sections do not seem to lend strong support to the use of a cost-effectiveness threshold as a criterion for drug market access. In fact, a natural question to ask is whether the use of CE thresholds is ever preferable to a *laissez-faire* policy, where inclusion of a new drug in the health plan is automatically granted whenever it is profitable for the producer to enter the market. When answering this question, we will assume that the policy objective is to maximise the surplus of the health plan, given by total health benefits to patients net of drug purchasing costs. If both drugs are included in the health plan, this surplus is given by

$$S(I,E) = \int_0^{y_I} (v_I - p_I - tx)\, dx + \int_{y_I}^1 (v_E - p_E - t(1-x))\, dx. \tag{26}$$

On the other hand, if the incumbent remains a monopolist in the market, the health plan's surplus is given by

$$S(I) = v_I - p_I - \frac{t}{2}. \tag{27}$$

Under a *laissez-faire* policy, the SPNE outcome is unconstrained entry deterrence for $f_E > f_4$. In this case, the use of a CE threshold can only switch the outcome to constrained entry deterrence, if k is set sufficiently low (cf. Figure 5). However, this would only lead to an increase in the price of the incumbent drug (Lemma 2), which obviously reduces the health plan's surplus.

On the other hand, if $f_E \leq f_4$, implying that the SPNE outcome is unconstrained entry accommodation under a *laissez-faire* policy, the use of a CE threshold can switch the outcome either to constrained entry accommodation or to constrained entry deterrence, depending on the chosen value of k. In former case, the health plan's surplus would decrease for two different reasons. First, we know from Lemma 1 that this would lead to higher prices for both drugs, thus increasing the costs of the health plan. Second, a comparison of (11) and (12) reveals that the price difference between the drugs $(p_E - p_I)$ would also increase, which implies that demand would shift in the direction of the lower-quality drug, thus increasing the treatment distortion caused by the higher price for the higher-quality drug, leading to higher mismatch costs and therefore lower overall health benefits.

Thus, the only possibility for the use of a CE threshold to increase the health plan's surplus is if such a policy switches the SPNE outcome from unconstrained entry accommodation to constrained entry deterrence. The benefit of such a policy would be that it induces the incumbent to switch from a high-price (accommodation) to a low-price (deterrence) strategy, thus reducing the costs of the health plan. On the other hand, such a policy would exclude the higher-quality drug from the market, thus reducing the total health benefits. Using the previously derived equilibrium expressions, the change in the health plan's surplus resulting from a switch from unconstrained entry accommodation to constrained entry deterrence is given by

$$S(I) - S(I, E) = \frac{(t + (1 - \beta k)\Delta v)\,\Phi - 128\beta t^2 f_E}{64\,(t + (1 - \beta k)\Delta v)\,\beta t}, \tag{28}$$

where

$$\Phi := (86 - 15\beta)\,t^2 + ((6 - 7\beta)\Delta v - 4t - 38\beta t + 64\beta k t)\,\Delta v. \tag{29}$$

It is easily confirmed that (28) is positive, implying that the effect of lower prices dominates, for a subset of the relevant parameter space. Overall, this leads us to the following answer to our original question:

Proposition 4 *Compared to a laissez-faire policy, the use of a CE threshold as a criterion for drug inclusion might increase the health plan's surplus only if it leads to entry deterrence.*

In other words, basing drug inclusion decisions on a CE threshold is potentially beneficial only if inclusion is never granted. This is arguably a rather paradoxical result and might serve as an illustration of the potential problems with such a policy. The root of the problem is that the inclusion criterion depends directly on the prices of existing drugs in the market. The rationale behind the use of CE thresholds therefore relies on the implicit assumption that existing drug prices are exogenous. However, such an assumption might be overly naïve, since the presence of a (sufficiently strict) CE threshold gives incumbent drug producers an incentive to strategically adjust their prices *ex ante* in the face of potential entry from new drugs which represent a therapeutic alternative to existing ones.[15]

There are several alternative inclusion criteria that would generally outperform a criterion based on CE thresholds. To give one example, suppose that the incumbent producer and the potential new entrant were invited to compete for an exclusive contract by submitting price bids, with the contract being awarded to the drug that yields the higher surplus for the health plan. If $f_E - f_I < \Delta v$, such a contest would be won by the new entrant with an equilibrium bid of $p_E = f_I + \Delta v$, which would yield a health plan surplus of

$$S(E) = v_I - f_I - \frac{t}{2}, \tag{30}$$

which is the value of the health plan's outside option (awarding the exclusive contract to the incumbent instead of the new potential entrant). In contrast, if the health plan uses an inclusion criterion based on a CE threshold, it follows from Proposition 4 that the maximum surplus that can be achieved is found by inserting the equilibrium price under constrained entry deterrence, given by (19) for $f_E \leq f_1$, into (27), yielding

$$S(I) = v_I - \frac{t}{2} + k\Delta v - \frac{2tf_E}{(t + (1 - \beta k)\Delta v)}. \tag{31}$$

[15] Keep in mind that the strategic adjustment by the incumbent implies a price reduction compared to the monopoly price under no threat of entry. Thus, it is likely that a health plan is willing to accept such a price adjustment for the baseline treatment by the incumbent.

Comparing (30) and (31), it is relatively straightforward to confirm that $S(E) > S(I)$ for the entire set of relevant parameter values (i.e., $f_E > f_3$, which is required for constrained entry deterrence to be an SPNE outcome, and f_I low enough to ensure positive profits and thus equilibrium existence). Thus, for $f_E - f_I < \Delta v$, competition for an exclusive contract would always yield a higher health plan surplus than using an inclusion criterion based on an optimally chosen CE threshold.

Competition for an exclusive contract is of course only one of several different options available to the health plan. Using a similar theoretical framework, Brekke et al. (2022) analyse the relative merits of both exclusive and non-exclusive contracts, where the drug producers are allowed to compete for these contracts using either uniform pricing or two-part tariffs, and we refer the interested reader to that paper for an in-depth analysis of these different options. Although the optimal choice is likely to depend on the specific characteristics of drug demand and therapeutic benefits, our main claim is that, instead of basing inclusion decisions on a criterion that depends on existing prices in the market, a health plan would generally be better off letting incumbent drug producers compete with potential new entrants for (continued) inclusion in the plan.

Exclusivity contracts are indeed also observed in practice. Health plans and providers are often using competitive tenders offering exclusivity (or preferred provider status) when procuring drugs; see e.g., Dalen et al. (2021) on procurement of biosimilars to hospitals in Norway. However, exclusivity contracts may raise ethical concerns if the winning drug is less effective than other available drugs. This can explain why health plans in some cases offer the winning drug producer a preferred provider status rather than 100 percent exclusivity.[16] Preferred provider contracts ensure a given market share to the winner and also access to alternative therapies to patients that are likely to benefit more from these drugs than the preferred drug. Our analysis of exclusivity contracts should also apply to preferred provider contracts as the winner is ensured a given market share.

7 Extension: binding price cap for the incumbent

Our main analysis is conducted under the assumption that the incumbent monopolist is not constrained by price cap regulation when choosing its price. Since therapeutic competition

[16] Pure exclusivity contracts are mostly observed for generics or biosimilars, whereas for competitive tender among alternative drug therapies the procurer often offer preferred provider status.

imposes a downward pressure on prices, the equilibrium prices under both accommodated and deterred entry are typically lower than the optimal monopoly price under no threat of entry. As previously emphasised, an anti-competitive effect of a (stricter) CE threshold, as described by Proposition 3, means that *drug prices decrease less than they would have done in the absence of such a threshold.* Thus, our previous analysis is fully compatible with an assumption of a price cap for the incumbent producer that binds if there is no threat of entry, but does not bind in the equilibria characterised by Proposition 1.

An alternative possibility, which we will briefly explore in this section, is that the incumbent producer is constrained by a price cap that also binds under accommodated entry, but not under deterred entry, which implies a lower price for the incumbent drug.[17] In this case, the equilibrium prices in case of entry are given by

$$p_I^a = \overline{p}_I \tag{32}$$

and

$$p_E^a = \begin{cases} \overline{p}_I + k\Delta v & if \quad \overline{p}_I \leq \frac{t+\Delta v}{\beta} - 2k\Delta v \\ \frac{\overline{p}_I}{2} + \frac{t+\Delta v}{2\beta} & if \quad \overline{p}_I > \frac{t+\Delta v}{\beta} - 2k\Delta v \end{cases}, \tag{33}$$

where $\overline{p}_I$ is the incumbent's price cap and p_E^a is found by inserting this price cap into the best-response function of the potential entrant, given by (9). The corresponding profits are given by

$$\pi_I^a = \begin{cases} \frac{\overline{p}_I(t-(1-\beta k)\Delta v)}{2t} - f_I & if \quad \overline{p}_I \leq \frac{t+\Delta v}{\beta} - 2k\Delta v \\ \frac{\overline{p}_I(3t-\Delta v-\beta\overline{p}_I)}{4t} - f_I & if \quad \overline{p}_I > \frac{t+\Delta v}{\beta} - 2k\Delta v \end{cases} \tag{34}$$

and

$$\pi_E^a = \begin{cases} \frac{(\overline{p}_I+k\Delta v)(t+(1-\beta k)\Delta v)}{2t} - f_E & if \quad \overline{p}_I \leq \frac{t+\Delta v}{\beta} - 2k\Delta v \\ \frac{(t+\Delta v+\beta\overline{p}_I)^2}{8t\beta} - f_E & if \quad \overline{p}_I > \frac{t+\Delta v}{\beta} - 2k\Delta v \end{cases}. \tag{35}$$

The price effects of a stricter CE threshold are now potentially different from the effects reported in Lemma 1. If the price cap is sufficiently low, such that the entrant's optimal price is constrained by the CE condition, a reduction in k will now lead to a price reduction instead of a price increase. This is quite intuitive, since the binding price cap prevents the incumbent from increasing its price. In this case, a stricter CE threshold just means that the entrant has to set a lower price in order to enter the market.

[17] A price cap that also binds under deterred entry would of course make entry infeasible and therefore make the entire analysis uninteresting.

As we know from our previous analysis, the alternative to this candidate equilibrium is that the incumbent deters entry by setting a sufficiently low price. Given that the optimal entry deterring price is lower than $\overline{p}_I$, the incumbent's profits in the candidate equilibrium with entry deterrence is still given by (21). A comparison of (34) and (21) reveals that a reduction in k makes entry deterrence relatively more profitable for the incumbent. This is fairly intuitive, since a lower k forces the potential entrant to lower its price, thus capturing a larger market share in case of entry. Thus, even if a stricter CE threshold might lead to lower drug prices, it also increases the scope for entry deterrence. These insights are summarised in our final proposition:

Proposition 5 *Suppose that the incumbent faces a price cap that is binding under accommodated entry but not under deterred entry. In this case, a stricter CE threshold will lead to a lower drug price for the new drug under constrained entry accommodation, but it will also increase the incumbent's incentives to deter entry.*

8 Discussion and concluding remarks

Cost-effectiveness (CE) analysis has become widely popular among health insurers to assess whether a new technology or medical treatment should be included in the plan and thus granted reimbursement. By using an existing baseline treatment as a benchmark for computing the incremental health gains and costs of a new treatment, the use of CE thresholds implies an implicit price control on new treatments.

The novelty of our study is the analysis of the pricing game between an incumbent and a potential entrant when CE thresholds are used for inclusion of new treatments in the health plan. A key insight is that CE thresholds may be counterproductive in providing access to new and better treatments to patients and for inducing lower prices and cost savings for the insurer. The main reason for this somewhat counterintuitive result is that the incumbent has an incentive to manipulate the maximum price compatible with the CE threshold by strategically adjusting the price of the existing baseline treatment in presence of a potential entrant.

More precisely, we show that a (stricter) CE threshold may induce the incumbent to switch pricing strategy from entry accommodation to entry deterrence, resulting in the new treatment being foreclosed from the market. Otherwise, if the pricing strategy is either deterrence or accommodation, a (stricter) CE threshold is never pro-competitive. It has either no effect on

drug prices or may in fact facilitate a collusive outcome with higher prices of both drugs in the case of entry accommodation. Compared to a *laissez-faire* policy, the use of CE thresholds can only increase the surplus of a health plan if it leads to entry deterrence in which the price reduction by the incumbent necessary to deter entry outweighs the health loss to patients who do not get access to the new drug. Thus, there are likely other mechanisms than CE thresholds that ensure lower prices and better access to new treatments, as illustrated by our analysis of exclusive contracts.

Our analysis is cast in a particular setting, and based on a set of assumptions, that deserve further discussion. Importantly, our results are derived from a sequential pricing game, which implicitly relies on the assumption that the incumbent producer cannot easily make *ex post* price adjustments. This assumption is justified by the particular institutional context of our analysis, where price adjustments have to be approved by the regulator (health plan). In three out of the four possible equilibria, the incumbent's *ex post* incentives for price adjustments would imply either price increases or a violation of the CE condition for entry. The only exception is the case of unconstrained accommodated entry, in which the CE condition does not bind and the incumbent would have an incentive to reduce the price *ex post*. However, if we allow for *ex post* price adjustments in this case, implying that the simultaneous-move price equilibrium would be played under unconstrained entry accommodation, this would not qualitatively affect the equilibrium configuration given by Proposition 1 and illustrated in Figure 5. Thus, our analysis essentially relies on the assumption that the regulator would not sanction *ex post* price adjustments that either lead to higher prices or that violate the restriction on relative prices given by the CE condition.

It is also worth mentioning that we conduct our analysis in a single-market setting, which implies that we rule out potential spillover effects to other markets where one or both of the producers might be active. Due to the widespread use of international reference pricing, this is not necessarily an innocuous assumption.[18] However, in Appendix B we extend the analysis to allow for a potential cross-market price contagion effect, in the sense that a higher (lower) price in the market in question will increase (reduce) the profits earned from sales of the same drug in other markets, and we show that all our main results are qualitatively robust to such a price contagion effect.

[18] International (or external) reference pricing is a price regulation scheme where the price cap imposed on a particular drug is based on the prices of the same drug in other (usually similar) countries.

Our analysis is also cast in a setting where the incumbent is a monopolist and, as already discussed in Section 7, is not restricted by price cap regulation in its pricing choices when selecting among the different candidate equilibria derived in Section 4. How should we interpret this assumption in the context of a more dynamic setting where new and better drugs are continuously developed and introduced over time, and where new drugs have to meet a CE threshold when entering the market? A key factor here is the magnitude of the quality improvement offered by the potential entrant. In the context of our model, there are potentially two different cases: (i) if $\Delta v < 3t$, the incumbent can profitably remain in the market after entry, and entry therefore implies (stronger) therapeutic competition, or (ii) if $\Delta v > 3t$, the incumbent drug will be replaced by the new drug, creating a monopoly status for the new entrant. Our analysis considers a situation where an incumbent monopolist faces potential entry of type (i), whereas the incumbent's ex ante monopoly status can be interpreted as resulting from previous entry of type (ii). Our analysis is therefore consistent with the presence of a CE condition for the previous entry of the current incumbent. If this firm previously entered the market with a drug of sufficiently higher quality than the then incumbent firm(s), the CE condition applying for the current incumbent would be sufficiently high not to bind in any of our candidate equilibria.

In our model, the entrant enters or not, and this decision is shown to depend on the fixed cost of entry, quality differences and the strictness of the regulatory policy (CE thresholds). In practice, a pharmaceutical company with a novel drug does not make a single one-shot decision to enter or not. Instead, the company will often repeatedly evaluate when to enter the new market (see Cockburn et al., 2016, and Kyle, 2007). Although our model cannot explain the timing of a possible entry as such, our results are expected translate into decisions to delay entry. Following Cockburn et al. (2016), the decision to launch a drug in any given country is sensitive to the company's assessment of anticipated profits relative to specific costs of entry. Entry costs are, among other things, related to establishing distribution capacity, educating prescribers, and obtaining reimbursement from private or public insurers. In our model, these costs are assumed to be common knowledge. In practice, though, the entry costs will be both uncertain and country-specific. Assuming a stochastic process that allows the expected entry costs to evolve over time, entry will be delayed until a sufficiently low expected cost is realised. In such a stochastic environment, the incumbent no longer chooses between entry deterrence or accommodation, but will instead influence the probability of entry. Developing insight about the relationship between CE thresholds and entry under uncertainty is left for future research.

Our study does not address how the use of CE thresholds affects the innovation incentives of the drug producers. This is an important topic of pharmaceutical policy design in general (see, e.g., Lakdawalla and Sood, 2009, Levaggi et al., 2017, and Agha et al., 2022), but beyond the scope of this paper and left for future research. The fact that CE thresholds work as an implicit price control on new treatments might suggest that the patent rent for an average innovation is lower than under a *laissez-faire* policy (i.e., inclusion in plan as long as entry is profitable). However, our analysis has shown that the opposite might be the case if the use of CE thresholds gives the incumbent an incentive for constrained entry accommodation, in which case the price reduction of the incumbent is smaller than in the absence of a CE threshold, leaving higher profits for the entrant. The use of such thresholds might also affect producers' incentives to spend resources on drastic versus minor ('me-too') innovations, since the probability of successful entry depends on the therapeutic benefit offered by the new drug. Once more, our analysis has shown that the effect of CE thresholds is far from obvious and often counterintuitive, with the probability of entry being higher for innovations with smaller therapeutic benefit under sufficiently strict CE thresholds (cf. Proposition 2). Thus, the net effects on innovation incentives of the widespread use of CE analysis by health plans are far from straightforward and would need a careful analysis that explicitly takes into account the innovation stage.

Finally, we have not derived the socially optimal policy for assessing new treatments or technologies for inclusion in a health plan. Instead, we have focused on possible adverse and unintentional effects of the current schemes relying heavily on CE analysis. Our policy analysis is only partial in the sense that we show under which circumstances CE thresholds may improve the surplus compared to the case of no regulatory restrictions. We have also pointed at competition for exclusive contracts as one example of a mechanism that is likely to improve the surplus of a health plan maximising the health gains to patients net of the drug expenditures. There may be other mechanisms that improve the social surplus, including different payment schemes like two-part tariffs. However, a full welfare analysis that ends with an optimal policy is beyond the scope of this paper and thus left for future research.

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Appendix A: Proofs

Proof of Proposition 1

(i) If $k \leq \widehat{k}$, it follows from (11)-(12) that entry acommodation is constrained by the CE condition. Furthermore, a comparison of (16) and (20) shows that

$$f_1 - \overline{f} = \frac{(9t + (5 - 4\beta k)\,\Delta v)\,((3 - 4\beta k)\,\Delta v - t)}{32t\beta} \geq 0 \text{ if } k \leq \widehat{k}, \tag{A1}$$

which, from (19), implies that entry deterrence is also constrained by the CE condition. Thus, if $k \leq \widehat{k}$, the incumbent chooses between constrained entry accommodation and constrained entry deterrence. A comparison of (14) and (21) shows that

$$\pi_I^a|_{k\leq\widehat{k}} - \pi_I^d\Big|_{f_E\leq f_1} = \frac{(t - (1 - 2\beta k)\,\Delta v)\,(t + (1 - \beta k)\,\Delta v)^2 - 4\beta t^2 f_E}{2\,(t + (1 - \beta k)\,\Delta v)\,\beta t} \geq (<)\,0 \text{ if } f_E \leq (>)\,f_3. \tag{A2}$$

Thus, if $k \leq \widehat{k}$, the SPNE outcome is constrained entry accommodation for $f \leq f_3$ and constrained entry deterrence for $f > f_3$.

(ii) Suppose that $k \in \left(\widehat{k}, \widetilde{k}\right]$. In this case, entry accommodation is unconstrained. If, in addition, $f_E \leq f_1$, the incumbent chooses between unconstrained entry accommodation and constrained entry deterrence. A comparison of (14) and (21) shows that

$$\pi_I^a|_{k>\widehat{k}} - \pi_I^d\Big|_{f_E\leq f_1} = \frac{\left((3t - \Delta v)^2 + 16\beta k t \Delta v\right)(t + (1 - \beta k)\,\Delta v) - 32\beta t^2 f_E}{16\,(t + (1 - \beta k)\,\Delta v)\,\beta t} \geq (<)\,0 \text{ if } f_E \leq (>)\,f_2. \tag{A3}$$

Furthermore, we have that

$$f_1 - f_2 = \frac{(t + (1 - \beta k)\,\Delta v)\left(22t\Delta v + 7t^2 - (\Delta v)^2 - 32\beta k t \Delta v\right)}{32\beta t^2} \geq (<)\,0 \text{ for } k \leq (>)\,\widetilde{k}, \tag{A4}$$

implying that the parameter set given by $f_E \in (f_2, f_1]$ is non-empty for all $k \in \left(\widehat{k}, \widetilde{k}\right]$. Thus, if $k \in \left(\widehat{k}, \widetilde{k}\right]$, the SPNE outcome is unconstrained entry accommodation for $f_E \leq f_2$ and constrained entry deterrence for $f_E \in (f_2, f_1]$.

Suppose instead that $f_E > f_1$. In this case, entry deterrence is unconstrained, implying that the incumbent now chooses between unconstrained entry accommodation and unconstrained

entry deterrence. A comparison of (14) and (21) shows that

$$\pi_I^d\Big|_{f_E>f_1} > \pi_I^a|_{k>\widehat{k}} \quad if \quad \frac{2\sqrt{2\beta t f_E} - t - \Delta v}{\beta} > \frac{(3t-\Delta v)^2}{16t\beta}, \tag{A5}$$

or

$$8\beta t f_E > \left(\frac{(3t-\Delta v)^2}{16t} + t + \Delta v\right)^2, \tag{A6}$$

or

$$f_E > \frac{(5t+\Delta v)^4}{2048\beta t^3} = f_4. \tag{A7}$$

Furthermore, we have that

$$\begin{aligned} f_1 - f_4 &= \frac{\left((22-32\beta k)\,t\Delta v + 7t^2 - (\Delta v)^2\right)\left((42-32\beta k)\,t\Delta v + 57t^2 + (\Delta v)^2\right)}{2048\beta t^3} \\ &\geq (<)\,0 \text{ if } k \leq (>)\,\widetilde{k}. \end{aligned} \tag{A8}$$

Thus, $\pi_I^d\big|_{f_E>f_1} > \pi_I^a|_{k>\widehat{k}}$, implying that the SPNE outcome if unconstrained entry deterrence, for all $k \in \left(\widehat{k}, \widetilde{k}\right]$ and $f_E > f_1$.

(iii) Suppose that $k > \widetilde{k}$, which, since $\widetilde{k} > \widehat{k}$, means that the entry accommodation is unconstrained. Furthermore, entry deterrence is unconstrained if $f_E > f_1$. We have already shown that unconstrained entry deterrence is more profitable than unconstrained entry accommodation if $f_E > f_4$, and from (A8) we know that $\max\{f_1, f_4\} = f_4$ for $k > \widetilde{k}$. Thus, the SPNE is unconstrained entry deterrence if $k > \widetilde{k}$ and $f_E > f_4$. If instead $f_E \leq f_1$, the incumbent chooses between unconstrained entry accommodation and constrained entry deterrence. But from (A3) we know that $\pi_I^a|_{k>\widehat{k}} > \pi_I^d\big|_{f_E\leq f_1}$ if $f_E < f_2$, and from (A4) we know that $f_2 > f_1$ if $k > \widetilde{k}$. Thus, $\pi_I^a|_{k>\widehat{k}} > \pi_I^d\big|_{f_E\leq f_1}$ if $f_E \leq f_1$ and $k > \widetilde{k}$, and we already know that $\pi_I^a|_{k>\widehat{k}} > \pi_I^d\big|_{f_E>f_1}$ if $f_E \in (f_1, f_4)$. Thus, the SPNE is unconstrained entry accommodation if $k > \widetilde{k}$ and $f_E \leq f_4$.

Proof of Proposition 2

From part (i) of Proposition 1, the incumbent chooses an entry deterring strategy that is constrained by the CE condition if $k \leq \widehat{k}$ and $f_E > f_3$. From (23) we derive

$$\frac{\partial f_3}{\partial(\Delta v)} = -\frac{(t + (1-\beta k)\,\Delta v)\,(3\,(1-\beta k)\,(1-2\beta k)\,\Delta v - t)}{4\beta t^2}. \tag{A9}$$

Under the condition that $\Delta v > t/3$, it is straightforward to verify that $\partial f_3/\partial(\Delta v) < 0$ if k is sufficiently small. In this case, an increase in Δv implies that the condition $f_E > f_3$ holds for a larger set of parameter values, thus increasing the scope for constrained entry deterrence.

Proof of Proposition 3

Lemmas 1 and 2 establish the non-positive relationship between k and equilibrium drug prices within each candidate SPNE outcome. It follows from Proposition 1 that, for a given value of f_E, a reduction in k can lead to a switch (i) from unconstrained to constrained entry accommodation, (ii) from unconstrained to constrained entry deterrence, (iii) from unconstrained entry accommodation to constrained entry deterrence, and (iv) from constrained entry accommodation to constrained entry deterrence. For case (i) we know that the unconstrained equilibrium prices are independent of k, while the constrained equilibrium prices are monotonically decreasing in k. From Lemma 2 we know that the same is true for case (ii). Thus, a switch from unconstrained to constrained entry accommodation or entry deterrence always leads to higher drug prices. On the other hand, a switch from (unconstrained or constrained) entry accommodation to constrained entry deterrence, i.e., cases (iii) or (iv), must necessarily imply a reduction in the price of the incumbent drug.

Proof of Proposition 4

Consider constrained entry accommodation as a candidate equilibrium. From (9) and (10), this requires

$$\overline{p}_I \leq \frac{t + \Delta v}{\beta} - 2k\Delta v, \tag{A10}$$

or, equivalently,

$$k < \frac{1}{2\Delta v}\left(\frac{t + \Delta v}{\beta} - \overline{p}_I\right). \tag{A11}$$

The alternative candidate equilibrium is (constrained or unconstrained) entry deterrence. The SPNE outcome is determined by a comparison of (14) and (21). Suppose first that $f_E \leq f_1$, which implies that the feasible alternative to constrained entry accommodation is constrained entry deterrence. In this case, a comparison of (14) and (21) shows that the incumbent prefers to deter entry if

$$f_E > \widetilde{f} := \frac{\left(k\Delta v + \frac{\overline{p}_I}{2t}\left(t - (1 - \beta k)\Delta v\right)\right)\left(t + (1 - \beta k)\Delta v\right)}{2t}. \tag{A12}$$

From (A12) we derive

$$\frac{\partial \widetilde{f}}{\partial k} = \frac{t\left(t + (1 - 2\beta k)\,\Delta v\right) + \beta\,(1 - \beta k)\,\overline{p}_I \Delta v}{2t^2}\Delta v > 0 \text{ if } k < \frac{1}{2\Delta v}\left(\frac{t + \Delta v}{\beta} - \overline{p}_I\right). \qquad \text{(A13)}$$

Thus, within the relevant parameter set, a lower value of k enlarges the subset of parameters for which the incumbent prefers entry deterrence over constrained entry accommodation. Suppose next that $f_E > f_1$, which implies that the feasible alternative to constrained entry accommodation is unconstrained entry deterrence. In this case, the incumbent's profits in case of deterred entry do not depend on k, while corresponding profits under constrained entry accommodation are monotonically increasing in k, as can be readily verified from (14). Thus, within the relevant parameter set, a lower value of k makes constrained entry accommodation relatively less profitable for the incumbent, which once more enlarges the subset of parameters for which entry deterrence is the SPNE outcome.

Appendix B: Cross-market price contagion

The main analysis is made under the assumption that the prices charged in the market in question have no profit effects in other markets in which the firms operate. However, due to the widespread use of international reference pricing, there might be cross-market price contagion effects in the sense that a higher (lower) price in a given market might lead to a similar price increase (reduction) in other markets where the same drug is sold. A simple way to incorporate this possibility is to reformulate the profit function of producer i as

$$\pi_i' = \pi_i + \theta p_i, \qquad \text{(B1)}$$

where π_i is given by (4) and $\theta > 0$ measures the strength of the price contagion effect to other markets. The remaining modelling assumptions are unchanged.

Using the reformulated profit function given by (B1), the best-response function of the potential entrant in case of accommodated entry is now given by

$$p_E = \begin{cases} p_I + k\Delta v & if \quad p_I \leq \widehat{p}_I' \\ \frac{p_I}{2} + \frac{(1+2\theta)t + \Delta v}{2\beta} & if \quad p_I > \widehat{p}_I' \end{cases}, \qquad \text{(B2)}$$

where

$$\widehat{p}'_I := \frac{(1+2\theta)\,t + \Delta v}{\beta} - 2k\Delta v. \tag{B3}$$

The resulting Nash equilibrium prices under entry accommodation are

$$p_I^{a\prime} = \begin{cases} \widehat{p}'_I & if \quad k < \widehat{k}' \\ \frac{1}{2\beta}\left(3t\left(1+2\theta\right) - \Delta v\right) & if \quad k \geq \widehat{k}' \end{cases} \tag{B4}$$

and

$$p_E^{a\prime} = \begin{cases} \widehat{p}'_I + k\Delta v & if \quad k < \widehat{k}' \\ \frac{1}{4\beta}\left(5t\left(1+2\theta\right) + \Delta v\right) & if \quad k \geq \widehat{k}' \end{cases} \tag{B5}$$

where

$$\widehat{k}' := \frac{1}{4\beta}\left(3 - \frac{t\left(1+2\theta\right)}{\Delta v}\right), \tag{B6}$$

and the resulting profits are

$$\pi_I^{a\prime} = \begin{cases} \frac{(1+2\theta)^2t^2 - ((1-\beta k)(1-2\beta k)\Delta v + (1+2\theta)t\beta k)\Delta v}{2\beta t} - f_I & if \quad k < \widehat{k}' \\ \frac{9(1+2\theta)^2t^2 - (6(1+2\theta)t - \Delta v)\Delta v}{16\beta t} - f_I & if \quad k \geq \widehat{k}' \end{cases} \tag{B7}$$

and

$$\pi_E^{a\prime} = \begin{cases} \frac{(1+2\theta)^2t^2 + (1-\beta k)((1-\beta k)\Delta v + 2(1+2\theta)t)\Delta v}{2\beta t} - f_E & if \quad k < \widehat{k}' \\ \frac{25t^2(1+2\theta)^2 + (10(1+2\theta)t + \Delta v)\Delta v}{32\beta t} - f_E & if \quad k \geq \widehat{k}' \end{cases} \tag{B8}$$

Entry is not blockaded if

$$f_E < \overline{f}' := \frac{25t^2\left(1+2\theta\right)^2 + \left(10\left(1+2\theta\right)t + \Delta v\right)\Delta v}{32\beta t}. \tag{B9}$$

In case of deterred entry, the optimal entry-deterring price is given by

$$p_I^{d\prime} = \begin{cases} \frac{2tf_E - ((1+2\theta)t + (1-\beta k)\Delta v)k\Delta v}{(1+2\theta)t + (1-\beta k)\Delta v} & if \quad f_E \leq f_1 \\ \frac{1}{\beta}\left(2\sqrt{2\beta t f_E} - \left(1+2\theta\right)t - \Delta v\right) & if \quad f_E > f_1 \end{cases}, \tag{B10}$$

where

$$f_1' := \frac{\left(1+2\theta\right)^2t^2 + \Delta v\left(1-\beta k\right)\left(2\left(1+2\theta\right)t + \Delta v\left(1-\beta k\right)\right)}{2\beta t}. \tag{B11}$$

This yields the following incumbent profits:

$$\pi_I^{d\prime} = \begin{cases} (1+\theta)\left(\frac{2tf_E-((1+2\theta)t+(1-\beta k)\Delta v)k\Delta v}{(1+2\theta)t+(1-\beta k)\Delta v}\right) - f_I & if \quad f_E \leq f_1 \\ \frac{(1+\theta)}{\beta}\left(2\sqrt{2\beta t f_E} - (1+2\theta)\,t - \Delta v\right) - f_I & if \quad f_E > f_1 \end{cases} \tag{B12}$$

Based on the above stated price and profit expressions in each of the candidate equilibria, it is straightforward to verify that all the results in Lemma 1 and 2 hold also in the case of cross-market price contagion.

We proceed by characterising the SPNE under this alternative model formulation, starting by defining the three different threshold values of f_E that are equivalent to (22)-(24) in the main analysis. These are given by

$$f_2' := \frac{9\,(1+2\theta)^3\,t^3 + \left(\begin{array}{c}((1-\beta k)\,\Delta v - (5\,(1+2\theta) + (8\,(1+\theta)\,\beta k - 11 - 14\theta)\,2\beta k)\,t)\,\Delta v \\ +\,(1+2\theta)\,(3\,(1+2\theta) + (7-2\theta)\,\beta k)\,t^2\end{array}\right)\Delta v}{32\,(1+\theta)\,\beta t^2}, \tag{B13}$$

$$f_3' := \frac{(1+2\theta)^3\,t^3 + \left(\begin{array}{c}(1+2\theta)\,(1+2\theta\,(1-\beta k))\,t^2 \\ -\,(1-k\beta)\,((1-\beta k)\,(1-2\beta k)\,\Delta v + ((1+2\theta) - (3+4\theta)\,\beta k)\,t)\,\Delta v\end{array}\right)\Delta v}{4\,(1+\theta)\,\beta t^2}, \tag{B14}$$

$$f_4' := \frac{1}{2\beta t}\left(\frac{(25+34\theta)\,(1+2\theta)\,t^2 + (2t\,(5+2\theta) + \Delta v)\,\Delta v}{32\,(1+\theta)\,t}\right)^2. \tag{B15}$$

Notice that $f_2' = f_3' = f_4'$ if

$$k = \widetilde{k}' := \frac{(1+2\theta)\,(7-2\theta)\,t^2 + (2\,(11+14\theta)\,t - \Delta v)\,\Delta v}{32\,(1+\theta)\,\beta t \Delta v} > \widehat{k}'. \tag{B16}$$

Based on these parameter definitions, we replicate the various steps in the proof of Proposition 1 for the reformulated model:

(i) If $k \leq \widehat{k}'$, it follows from (B4)-(B5) that entry accommodation is constrained by the CE condition. Furthermore, a comparison of (B9) and (B11) shows that

$$f_1' - \overline{f}' = \frac{((3-4\beta k)\,\Delta v - (1+2\theta)\,t)\,((5-4k\beta)\,\Delta v + 9\,(1+2\theta)\,t)}{32\beta t} \geq 0 \text{ if } k \leq \widehat{k}', \tag{B17}$$

which, from (B10), implies that entry deterrence is also constrained by the CE condition. Thus, if $k \leq \widehat{k}'$, the incumbent chooses between constrained entry accommodation and constrained

entry deterrence. A comparison of (B7) and (B12) shows that

$$\pi_I^{a\prime}\big|_{k\leq\widehat{k}'} - \pi_I^{d\prime}\Big|_{f_E\leq f_1'} = \frac{(1+2\theta)^3 t^3 - 4(1+\theta)\beta t^2 f_E + \Theta\Delta v}{2\left((1+2\theta)t + (1-\beta k)\Delta v\right)\beta t} \geq (<)\, 0 \text{ if } f_E \leq (>)\, f_3', \quad \text{(B18)}$$

where

$$\Theta := (1+2\theta)\left(1+(1-\beta k)2\theta\right)t^2 + (1-\beta k)\left(\left((3+4\theta)\beta k - (1+2\theta)\right)t - (1-\beta k)(1-2\beta k)\Delta v\right)\Delta v. \quad \text{(B19)}$$

Thus, if $k \leq \widehat{k}'$, the SPNE outcome is constrained entry accommodation for $f \leq f_3'$ and constrained entry deterrence for $f > f_3'$.

(ii) Suppose that $k \in \left(\widehat{k}, \widetilde{k}\right]$. In this case, entry accommodation is unconstrained. If, in addition, $f_E \leq f_1'$, the incumbent chooses between unconstrained entry accommodation and constrained entry deterrence. A comparison of (B7) and (B12) shows that

$$\pi_I^{a\prime}\big|_{k>\widehat{k}'} - \pi_I^{d\prime}\Big|_{f_E\leq f_1'} = \frac{9(1+2\theta)^3 t^3 - 32(1+\theta)\beta t^2 f_E + \Psi\Delta v}{16\left((1+2\theta)t + (1-\beta k)\Delta v\right)\beta t} \geq (<)\, 0 \text{ if } f_E \leq (>)\, f_2'. \quad \text{(B20)}$$

where

$$\begin{aligned}\Psi \;:\; &= \left((1-\beta k)\Delta v - \left(5(1+2\theta) - 2\left(11+14\theta-8(1+\theta)\beta k\right)\beta k\right)t\right)\Delta v \\ &\quad + (1+2\theta)\left(3(1+2\theta) + (7-2\theta)\beta k\right)t^2. \end{aligned} \quad \text{(B21)}$$

Furthermore, we have that

$$f_1' - f_2' = \frac{\varpi\left((1+2\theta)t + (1-\beta k)\Delta v\right)}{32(1+\theta)\beta t^2} \geq (<)\, 0 \text{ for } k \leq (>)\, \widetilde{k}', \quad \text{(B22)}$$

where

$$\varpi := \left((1+2\theta)(7-2\theta)t^2 + \left(2\left(11+14\theta-16(1+\theta)\beta k\right)t - \Delta v\right)\right)\Delta v, \quad \text{(B23)}$$

implying that the parameter set given by $f_E \in (f_2', f_1']$ is non-empty for all $k \in \left(\widehat{k}', \widetilde{k}'\right]$. Thus, if $k \in \left(\widehat{k}', \widetilde{k}'\right]$, the SPNE outcome is unconstrained entry accommodation for $f_E \leq f_2'$ and constrained entry deterrence for $f_E \in (f_2', f_1']$.

Suppose instead that $f_E > f_1'$. In this case, entry deterrence is unconstrained, implying that the incumbent now chooses between unconstrained entry accommodation and unconstrained

entry deterrence. A comparison of (B7) and (B12) shows that $\pi_I^{d\prime}\big|_{f_E>f_1'} > \pi_I^{a\prime}|_{k>\widehat{k}'}$ if

$$(1+\theta)\left(\frac{2\sqrt{2\beta t f_E}-(1+2\theta)\,t-\Delta v}{\beta}\right) > \frac{9\,(1+2\theta)^2\,t^2-(6\,(1+2\theta)\,t-\Delta v)\,\Delta v}{16t\beta}, \tag{B24}$$

or

$$f_E > \frac{1}{2\beta t}\left(\frac{(25+34\theta)\,(1+2\theta)\,t^2+(2\,(5+2\theta)\,t+\Delta v)\,\Delta v}{32\,(1+\theta)\,t}\right)^2 = f_4'. \tag{B25}$$

Furthermore, we have that

$$f_1'-f_4' = \frac{\rho\sigma}{2048\,(1+\theta)^2\,\beta t^3} \geq (<)\,0 \text{ if } k \leq (>)\,\widetilde{k}', \tag{B26}$$

where

$$\rho := (2\,(11+14\theta-16\,(1+\theta)\,\beta k)\,t-\Delta v)\,\Delta v+(1+2\theta)\,(7-2\theta)\,t^2 \tag{B27}$$

and

$$\sigma := ((6\,(7+6\theta)-32\,(1+\theta)\,\beta k)\,t+\Delta v)\,\Delta v+3\,(19+22\theta)\,(1+2\theta)\,t^2. \tag{B28}$$

Thus, $\pi_I^{d\prime}\big|_{f_E>f_1'} > \pi_I^{a\prime}|_{k>\widehat{k}'}$, implying that the SPNE outcome if unconstrained entry deterrence, for all $k \in \left(\widehat{k}', \widetilde{k}'\right]$ and $f_E > f_1'$.

(iii) Suppose that $k > \widetilde{k}'$, which, since $\widetilde{k}' > \widehat{k}'$, means that the entry accommodation is unconstrained. Furthermore, entry deterrence is unconstrained if $f_E > f_1'$. We have already shown that unconstrained entry deterrence is more profitable than unconstrained entry accommodation if $f_E > f_4'$, and from (B26) we know that $\max\{f_1', f_4'\} = f_4'$ for $k > \widetilde{k}'$. Thus, the SPNE is unconstrained entry deterrence if $k > \widetilde{k}'$ and $f_E > f_4'$. If instead $f_E \leq f_1'$, the incumbent chooses between unconstrained entry accommodation and constrained entry deterrence. But from (B20) we know that $\pi_I^{a\prime}|_{k>\widehat{k}'} > \pi_I^{d\prime}\big|_{f_E\leq f_1'}$ if $f_E < f_2'$, and from (B22) we know that $f_2' > f_1'$ if $k > \widetilde{k}'$. Thus, $\pi_I^{a\prime}|_{k>\widehat{k}'} > \pi_I^{d\prime}\big|_{f_E\leq f_1'}$ if $f_E \leq f_1'$ and $k > \widetilde{k}'$, and we already know that $\pi_I^{a\prime}|_{k>\widehat{k}'} > \pi_I^{d\prime}\big|_{f_E>f_1'}$ if $f_E \in (f_1', f_4')$. Thus, the SPNE is unconstrained entry accommodation if $k > \widetilde{k}'$ and $f_E \leq f_4'$.

Based on (i)-(iii), we conclude that Proposition 1 holds for the reformulated model after replacing f_1, f_2, f_3, f_4, $\widehat{k}$ and $\widetilde{k}$ by, respectively, f_1', f_2', f_3', f_4', $\widehat{k}'$ and $\widetilde{k}'$.

Furthermore, from (B14) we derive

$$\frac{\partial f_3'}{\partial\,(\Delta v)} = -\frac{(1-\beta k)\,\Omega-(1+2\theta)\,t^2}{4\,(1+\theta)\,\beta t^2}, \tag{B29}$$

where

$$\Omega := \left(2\left(1+2\theta-\left(4\theta+3\right)\beta k\right)t+3\left(1-\beta k\right)\left(1-2\beta k\right)\Delta v\right)\Delta v-2\theta\left(1+2\theta\right)t^{2}. \tag{B30}$$

The sign of (B29) is negative if the numerator is positive, which is true if k is sufficiently low and $\Delta v > \left(1+2\theta\right)t/3$. To see this, we evaluate (B29) at the limit $k \to 0$, which yields

$$\left.\frac{\partial f_3'}{\partial\left(\Delta v\right)}\right|_{k\to 0} = -\frac{\left(3\Delta v-\left(1+2\theta\right)t\right)\left(\left(1+2\theta\right)t+\Delta v\right)}{4\left(1+\theta\right)\beta t^{2}} < 0 \text{ if } \Delta v > \frac{\left(1+2\theta\right)t}{3}. \tag{B31}$$

By continuity, the sign of $\partial f_3'/\partial\left(\Delta v\right)$ must be negative also for sufficiently small values of k. Since $\Delta v > \left(1+2\theta\right)t/3$ is the condition for $\widehat{k}' > 0$, and thus the condition for constrained entry accommodation to be a feasible candidate equilibrium, Proposition 2 qualitatively holds also in this reformulated version of the model. The same must necessarily be true for Proposition 3, since this proposition follows from Lemma 1 and 2 and Proposition 1.

Figure 1. Stricter CE threshold under unconstrained entry accommodation

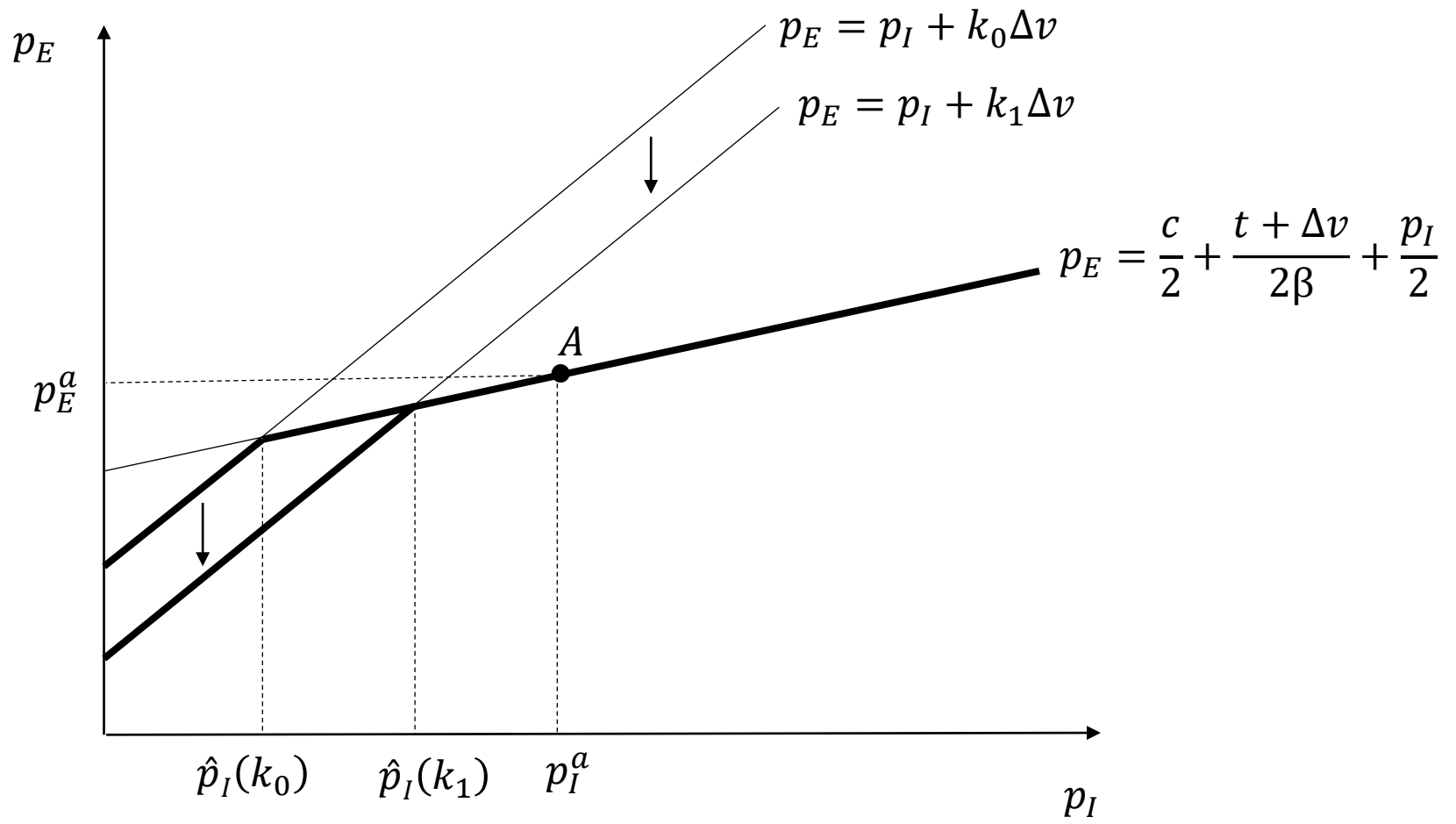


Figure 2: Stricter CE threshold under constrained entry accommodation

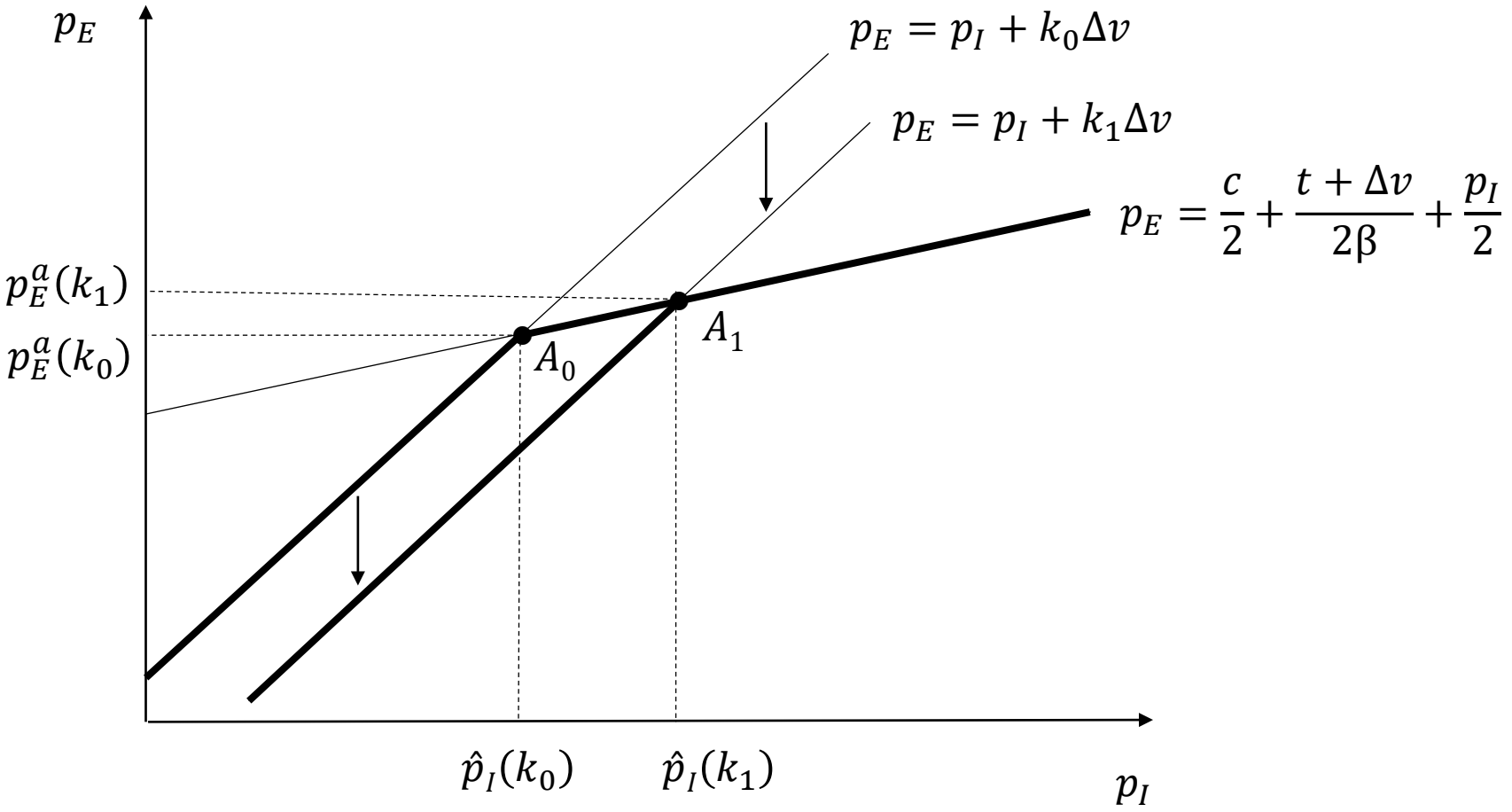


Figure 3. Stricter CE threshold under unconstrained entry deterrence ($f_E > f_1$)

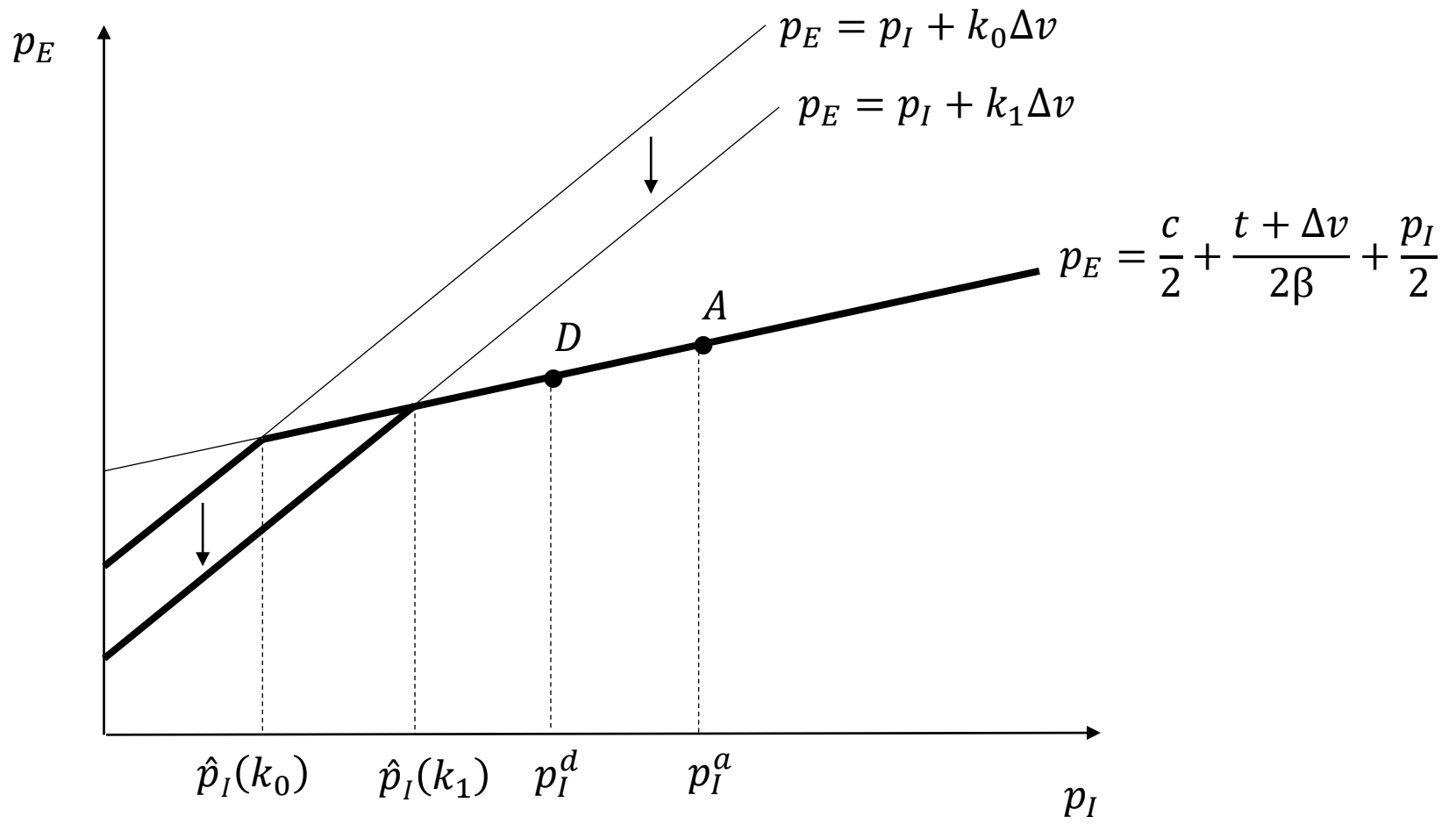


Figure 4. Stricter CE threshold under constrained entry deterrence ($f_E < f_1$)

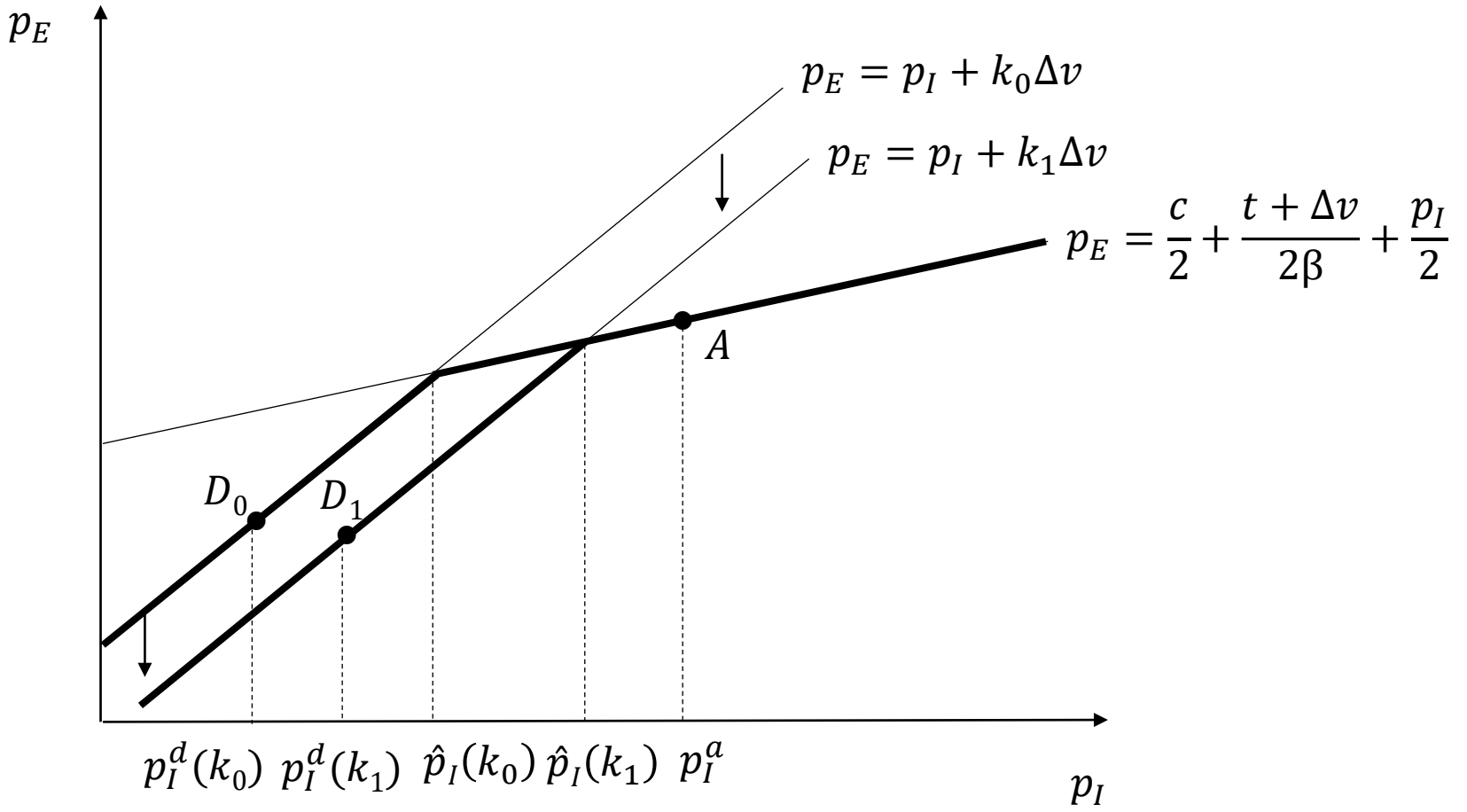
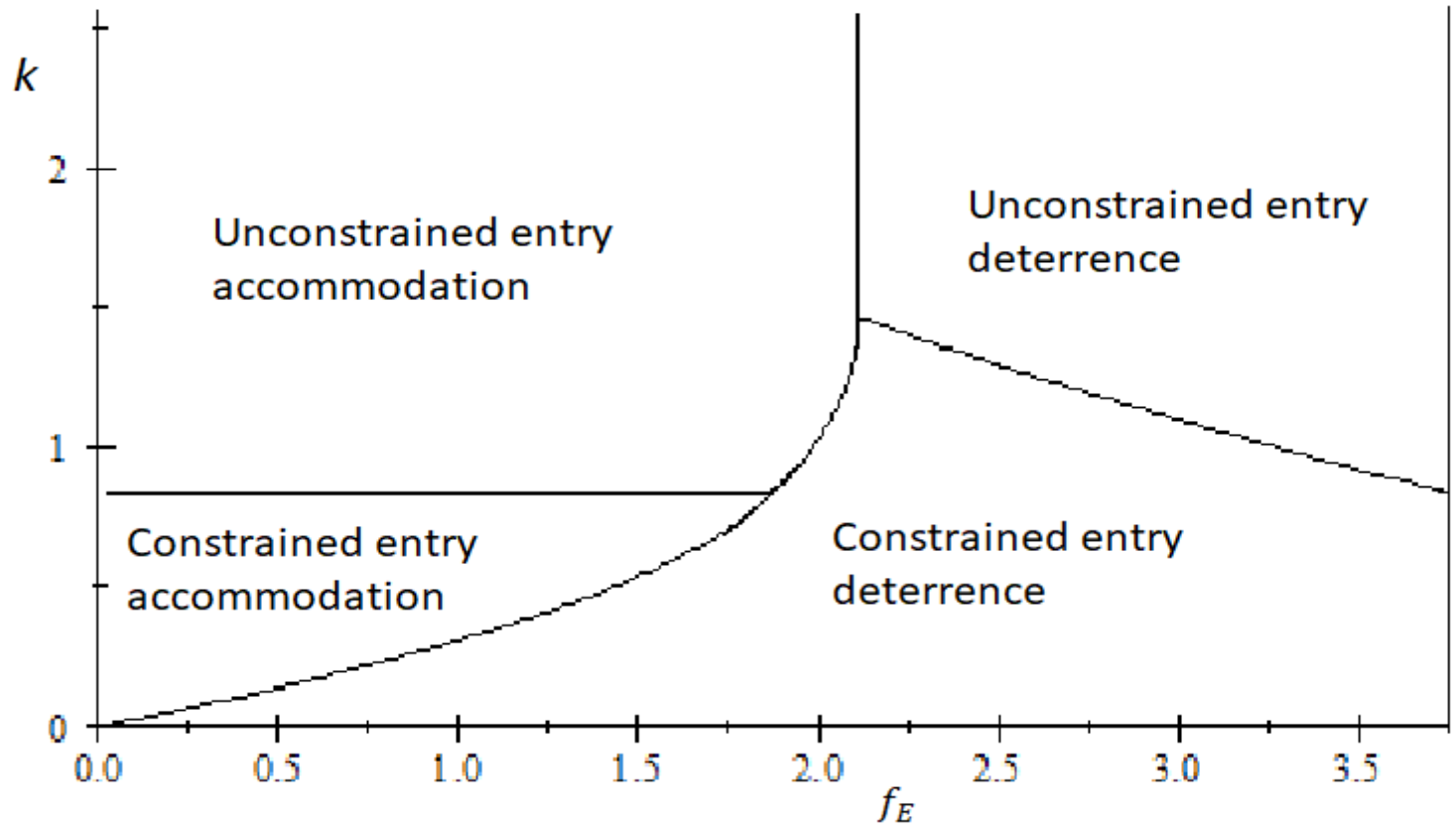


Figure 5: SPNE outcomes



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