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Why the Medicare Specialty Threshold Shouldn't Drive Pricing Strategy

OVERALL OBJECTIVES

- Explore the considerations that a manufacturer should evaluate when estimating the impact of the specialty threshold in determining pharmaceutical pricing strategy.
- Outline why the specialty threshold should not be a key determinant in most pricing strategies.

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INTRODUCTION

Establishing the price and subsequent market access strategy for a pharmaceutical asset is one of the most critical decisions influencing commercial success. The modern pharmaceutical executive faces many complex considerations across a diverse set of stakeholders when establishing a therapeutic's price. Some factors (e.g., payer price sensitivity, patient OOP sensitivity and the impact of payer restrictions on physician prescribing, HEOR/value calculations) unilaterally impact all therapeutics. However, there are a host of other factors that require careful consideration for their impact on pricing dynamics in certain markets.

The Medicare specialty threshold is commonly touted as an important factor that could have implications for not only the Medicare channel but also the commercial book of business. We argue that while the specialty threshold can be a key consideration for a minority of therapeutics, using the threshold as a "de facto" decision point is ill-advised for most products.

This paper will focus on how to properly evaluate the threshold's impact on pricing dynamics. Specifically, we will provide a framework to determine when the specialty threshold is applicable and highlight products where the threshold may have been appropriately (or inappropriately) considered in determining a pricing and market access strategy.

SPECIALTY THRESHOLD BACKGROUND

It is no secret that the pharmaceutical market is moving towards more targeted therapies for increasingly smaller patient populations with high unmet need. However, this added value has come at a high cost with innovative therapies carrying significantly higher price tags. This has, in turn, resulted in a deluge of spending on specialty products in recent years (Figure 1).

Figure 1: Increase in Specialty Spending

Source: *IQVIA, Medicine Use and Spending in the US, May 2019 accessed November 2020*

Government payers identified this trend over a decade ago and attempted to use a "Medicare Specialty Threshold" to passively discourage excessive pricing for products that did not add significant value for patients. As such, the Medicare specialty threshold is the definitional price point at which a product is considered "specialty" and thus will be placed on the specialty tier for Medicare beneficiaries. The specialty threshold often has cost-sharing implications for patients, requiring co-insurance ranging from 25% to 33% (until the coverage gap is met). The current monthly threshold price is $670 net; however, proposals have been made to raise this in the future.

While this policy has changed the dynamics in certain markets, executives must be cautious not to conflate pricing over the specialty threshold with lost revenue due to additional payer utilization management. Realistically, the subset of products for which the specialty threshold should be a determining factor in pricing strategy is quite limited. The hard truth is that some products will have little Medicare success despite pricing below the specialty threshold. And for these products, price concessions below the threshold could result in sacrificed revenue potential in other channels.

Specialty Threshold Pricing Considerations for Pharmaceutical Executives

- Is the specialty threshold within the optimal pricing band for my product? Or will the optimal price certainly be above or below the threshold?
- Given my patient mix, should the threshold even be a consideration?
  - If so, how will the increase in patient out-of-pocket (OOP) costs impact sales?
- Even if priced below the threshold, will my product receive Medicare coverage?
  - If my product does receive coverage, will the OOP dynamics improve? What will be the incremental impact on revenue?
- To what extent will commercial coverage mirror Medicare coverage?
  - Will changes in coverage result in lost revenue in the commercial channel?
- How will expanded Medicare coverage impact commercial uptake relative to a potential higher point?

Products Applicable for Specialty Threshold Evaluation

To evaluate the impact of the specialty threshold, it is important to distinguish product archetypes that will be relevant to the threshold (we will argue that it's a small set). This is a critical first step because many products will have an optimal price point obviously above or below the $670 per month threshold and should thus not take the specialty threshold into consideration. The only products for which the specialty threshold should be a consideration on pricing strategy are products that have a pricing band that includes price points directly above or below the threshold – and even then the impact can be highly variable, as we will discuss. The product archetypes are as follows:

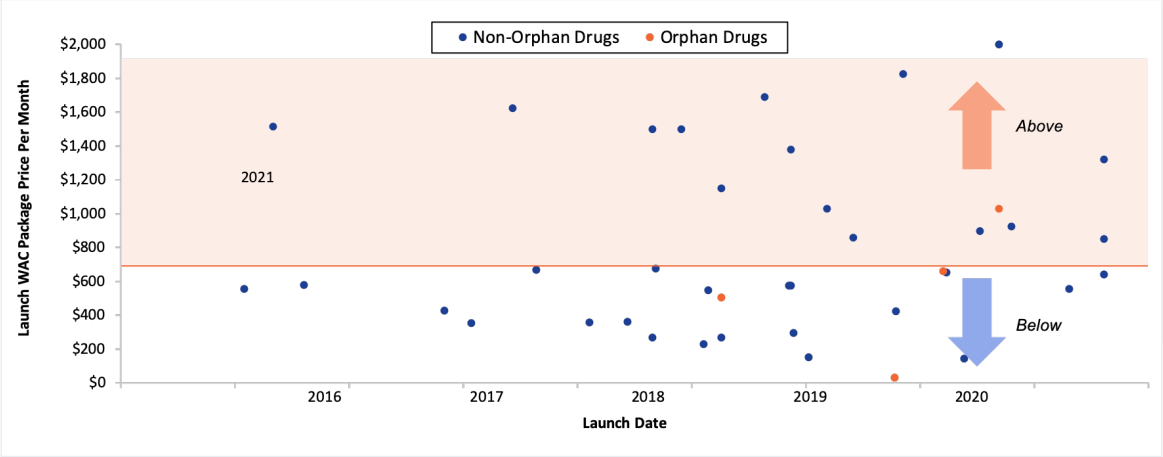
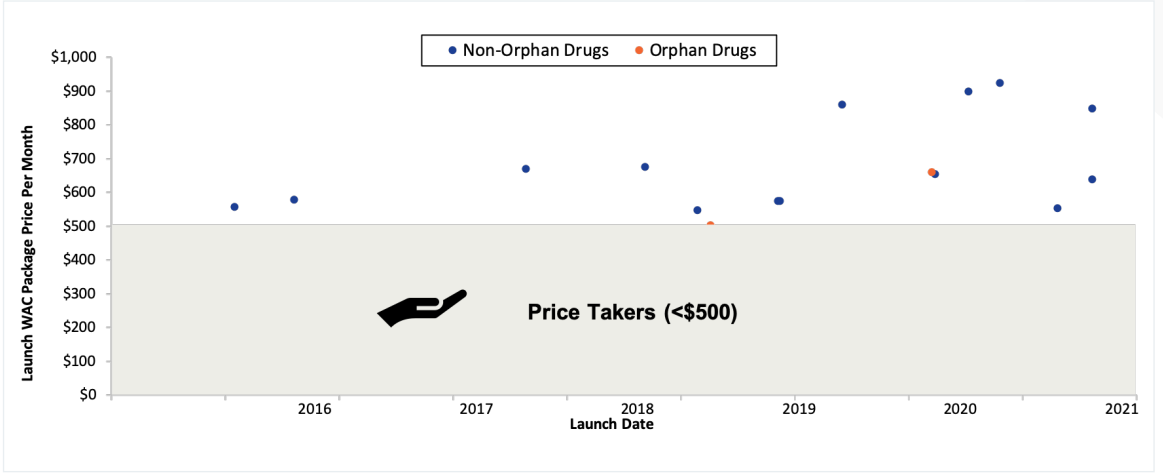


Figure 4: Launch Prices of Products from 2016 – 2020 under $2,000
Source: *Redbook*

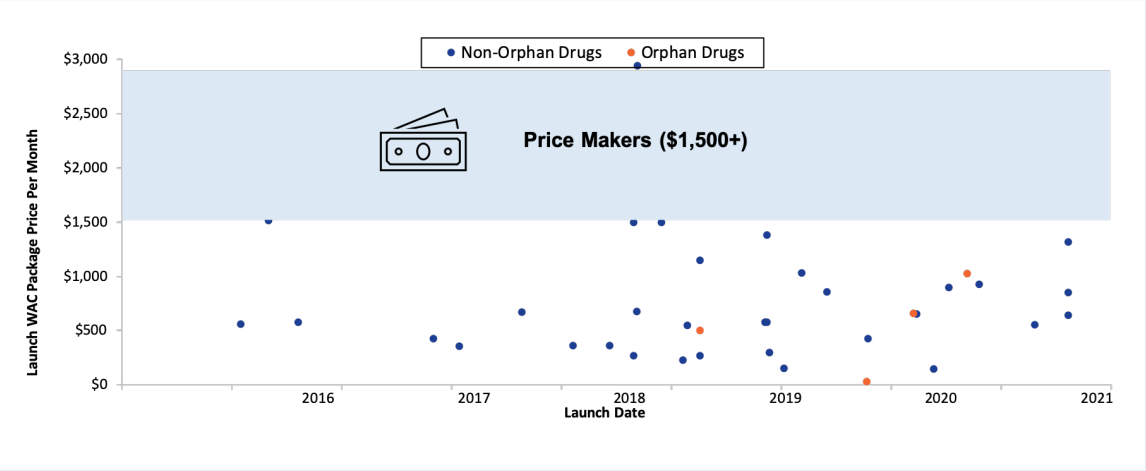
01 PRICE TAKERS

These products are typically priced below $500 net price per month, have lower differentiation in mature markets with significant competition, and often have lower patient disease burden / unmet need. While traditional considerations (e.g., payer price sensitivity, patient OOP cost) will be critical when determining price, net cost will be most impactful on the formulary placement decision. Due to the competitive net pricing pressures, **the specialty threshold will likely not be a consideration for these products due to the likelihood of non-coverage or significant management in both Medicare and commercial channels at prices approaching the specialty threshold.**



02 PRICE MAKERS

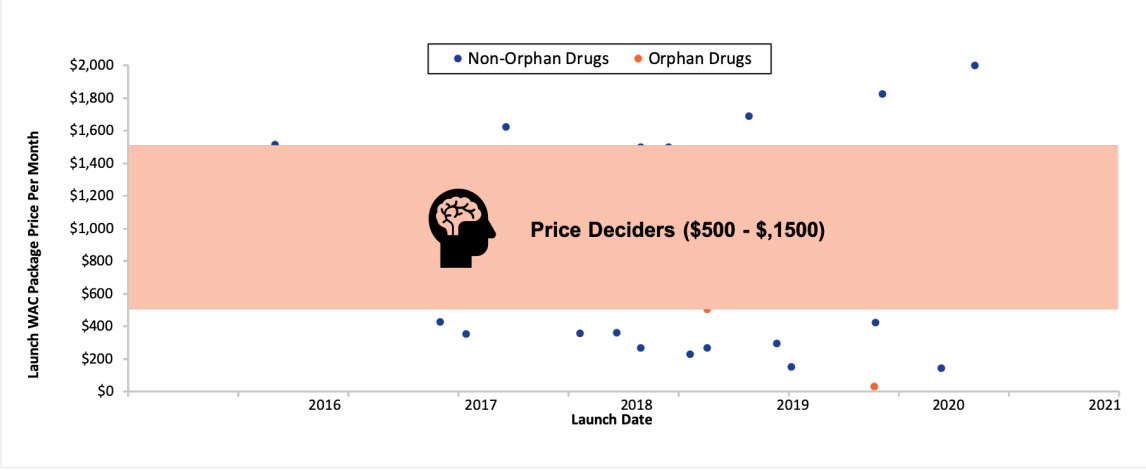
These products are often priced well above $1500 per month for indications with significant unmet need. These therapies offer clear clinical differentiation and therefore result in payers expressing higher willingness-to-pay and less OOP sensitivity from patients. Given these dynamics, pricing will be based less on traditional factors (except when pricing in reference to current competitors) and more on public perception, ICER, and the strength of the overall value proposition. This ultimately **limits the impact of the specialty threshold because products will be covered and reimbursed well above the threshold.**



NOTE: As the market has shifted towards development of highly specialized, high-priced assets, the importance of understanding the current and likely future considerations for these assets will continue to increase.

03 PRICE DECIDERS

Between these two extremes lies a smaller group of products with varying levels of clinical differentiation. These products pose a more nuanced challenge for executives when considering pricing strategy. Companies often determine that the optimal pricing band includes a number of potential price points directly above and below the $670 threshold (e.g., $400 to $1,500 per month depending on market dynamics like differentiation, disease severity, and willingness to pay). **For these products, the Medicare specialty threshold can be a real consideration. However, as we will discuss, the impact of the specialty threshold will continue to be highly variable and will require careful consideration to weigh the impact of its effect.**



Impact of the Specialty Threshold

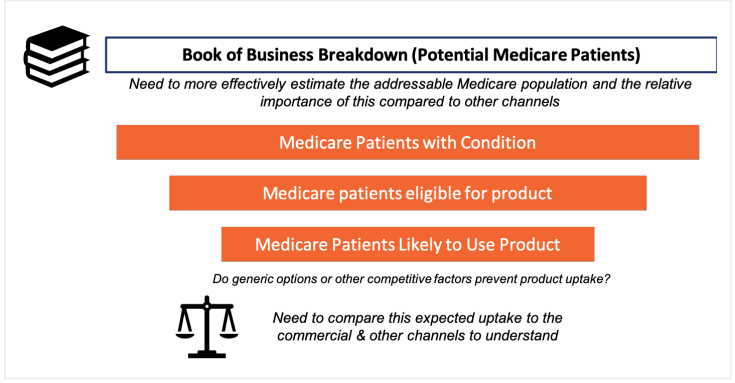
As a pricing decision maker, you find yourself with a product which is a "price decider." So, let's consider a framework to evaluate the impact of the Specialty Threshold on your product. To start, it is important to reject the initial instinct to view the specialty threshold as a proxy for access in the Medicare channel. This instinct assumes that when priced below the threshold, an innovative product can expect favorable formulary placement (e.g., Tier 2), while if priced above the threshold, the same product may have significant utilization management and be associated with a correspondingly higher co-insurance burden that will limit patient fulfillment. However, in practice, access in Medicare cannot be so easily distilled, and depends significantly on the underlying value proposition and market landscape for the asset under consideration. With these complexities in mind, we propose five factors (Box 1) that will serve as a more reliable proxy for access in Medicare.

BOX 1

CONSIDERATIONS FOR MEDICARE ACCESS

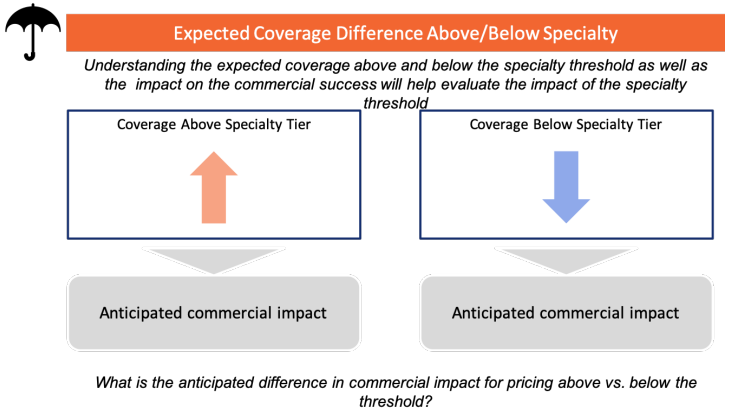
01 BOOK OF BUSINESS BREAKDOWN: what share of treated patients are likely to be covered by Medicare?

- What share of current patients would likely switch to the product from existing options?
- How, if at all, will Medicare decision-making influence coverage in the commercial channel?



02 SEVERITY OF MANAGEMENT: given the market dynamics and pricing strategy, is there an opportunity for access in Medicare?

- What access is feasible if priced above or below the threshold? Will the product receive the same coverage in Medicare regardless?
- What will be the anticipated differences in coverage above versus below the threshold? What will be the commercial impact of these differences?



03 OOP SENSITIVITY: how sensitive is the patient population to out-of-pocket (OOP) costs?

- To what extent will the expected OOP cost change by pricing above or below the threshold?
  - What will be the impact of this difference on fulfillment?
- Given other therapeutics required to treat the condition or common comorbidities, will an average patient reach the coverage gap or catastrophic coverage? catastrophic coverage?

04 COMPETITIVE INTENSITY: what value is offered by the novel therapy relative to competing brands and generics?

- How will competition influence access?
- How will the OOP differential impact competitive dynamics?

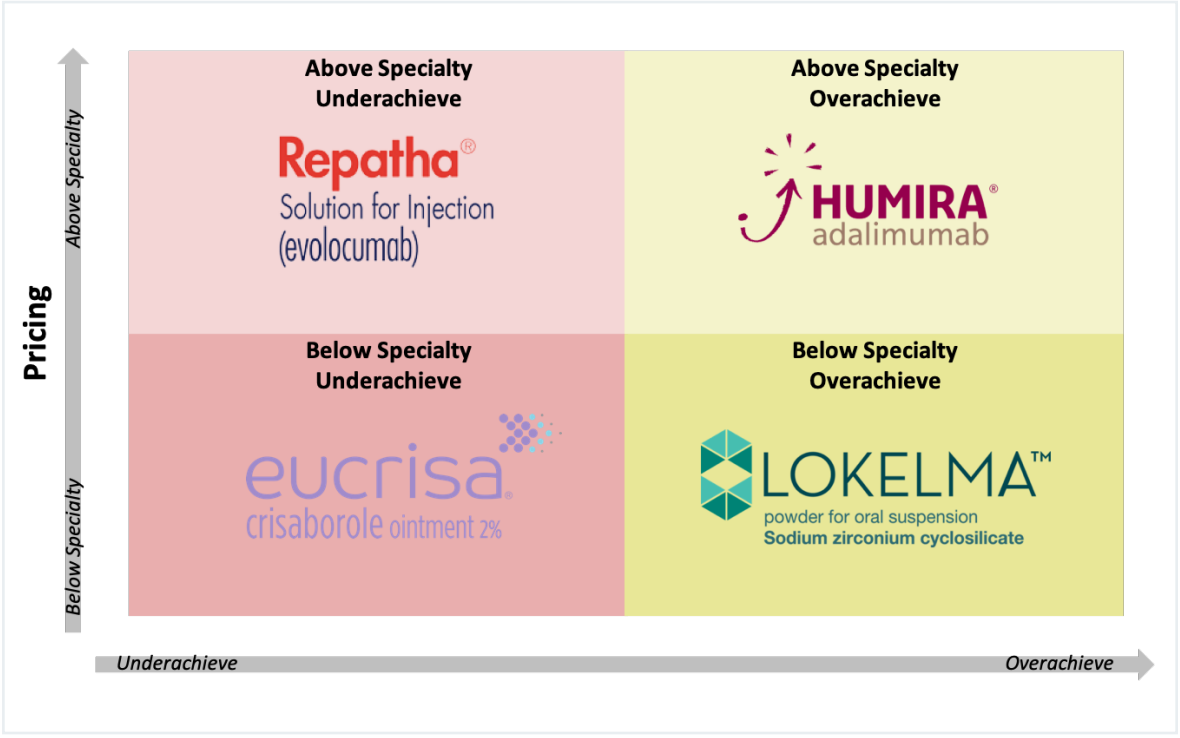
05 SATISFYING UNMET NEED: objectively, what clinical value does the therapy provide?

- How will pricing differentials between current and future treatments be viewed given unmet needs?
- How will the therapy be reviewed by external parties such as ICER in terms of cost effectiveness relative to unmet need?

Strategic Considerations for the Medicare Specialty Threshold: Selected Case Studies

To illustrate our strategic pricing approach, we have summarized two case studies (Boxes 2-3), including successes and pitfalls to avoid.

We begin by outlining Amgen's efforts to reset the list price for Repatha (evolocumab), and the long-term impact of rebuilding relationships with payers once a poor pricing precedent has been set. However, we contrast this outcome with that of Eucrisa (crisaborole) to highlight the importance of proper evaluation of an asset in determining pricing strategy, rather than arbitrary use of the specialty threshold as a proxy for access in Medicare. Together, these two case studies underscore the importance of a strategic approach to pricing and the need for a multifaceted understanding of the dynamics surrounding an asset launch.



01. Repatha (evolocumab) Case Study: Underperformance Above the Specialty Threshold

Situation: Despite establishing a new therapeutic class, Repatha has underperformed consensus to date, declining from $2.3B in 2022 US sales forecast at/around launch to just $780M in the most recent forecast.

Key Considerations: At the time of approval in mid-2015, trials evaluating cardiovascular outcomes for the class were ongoing, resulting in an uncertain value proposition at launch. While Amgen-sponsored studies suggested a net price of just under ~$10K to achieve cost-effectiveness, value-based pricing suggested by ICER ranged from $5,300 - $7,600 on an annual basis. Subsequent outcomes data did not show a mortality benefit. At that time, ICER released an updated analysis, suggesting a ~$2K value-based price, while Amgen held firm with their pricing strategy.

Framework Analysis (Should Repatha be Priced BELOW the Specialty Threshold?):

Book of Business	OOP Sensitivity	Competitive Intesity	Satisfying Unmet Need	Severity of Management
Y	Y	Y	Y	-
Patients with significant cardiovascular risk factors are more often Medicare than Commercial	Hypertension and heart disease patients typically have higher OOP spend overall and for Rx drugs	Although only two competitors, dynamics were such that a potential 1:1 was feasible	Lack of cardiovascular outcomes data at launch (and mixed outcomes to follow) limits value prop	While coverage was likely, even above the threshold, utilization management was expected to be severe
Recommendation: Launch **BELOW** the threshold (new MoA does not address unmet need and Medicare beneficiaries are the key patient population)				

OUTCOMES

Amgen relented in 2018 by lowering its list price for Repatha by ~60% (followed by Praluent in 2019). While this brought Repatha below the specialty threshold, Amgen continued to suffer from a high share of patients covered under the non-preferred tier (~2:1 ratio vs preferred tier), which has a higher median co-insurance rate than the specialty tier (38% vs 25%). Within 1-2 years, Amgen's efforts had finally translated into favorable access for Repatha (~1:4 ratio of non-preferred vs preferred).

KEY TAKEAWAYS

An uncertain and evolving value proposition at and following product launch did not justify pricing above the specialty threshold. Significant rebates prior to "relaunch" did not improve the situation. Manufacturers can eventually recover from initial pricing strategy faux paus, but the long-term impact on revenue potential can be substantial. In this instance, a clear value proposition supported by meaningful trials allowed Amgen to eventually improve the situation.

02. Eucrisa (crisaborole) Case Study: Underperformance Below the Specialty Threshold

Situation: Despite establishing a new therapeutic class, projections for Eucrisa have tapered dramatically over time, with the most recent consensus at just $180M in 2022 (down from $500M-$1B at launch).

Key Considerations: Atopic dermatitis prevalence is considered "U-shaped" (high in children, somewhat elevated in the elderly). However, undifferentiated efficacy and undefined safety benefits (e.g., "steroid-free" positioning) for the elderly (compared to children) limit its value in a largely genericized competitive landscape (e.g., Protopic lost exclusivity in 2014). Despite these factors, Pfizer launched Eucrisa below the specialty threshold, potentially due, in part, to an interest in gaining favorable access in Medicare.

Framework Analysis (Should Repatha be Priced BELOW the Specialty Threshold?):

Book of Business	OOP Sensitivity	Competitive Intesity	Satisfying Unmet Need	Severity of Management
-	N	N	N	N
While disease prevalence is highest among children, a somewhat elevated rate is observed in the elderly / Medicare beneficiares	Mild/Moderate severity patients are not in critical condition and have a low-cost burden at baseline leading to high OOP sensitivity	Generic TCS/TCI are inexpensive and highly effective with limited side effects and long-term risk	Lack of improved efficacy and issues of tolerability limit the value proposition for elderly patients	Due to the competitive intensity from generics and low unmet need coverage is unlikely even below specialty threshold

Recommendation: Launch **ABOVE** the threshold (new MoA does not address unmet need; Medicare is not a **key** patient population)

OUTCOMES

Eucrisa has been broadly inaccessible in Medicare to date, lacking coverage for over ~85% of lives and remaining unrestricted for only ~5%, despite pricing below the specialty threshold throughout the product's life cycle.

KEY TAKEAWAYS

An unclear value proposition at and following launch did not justify pricing below the specialty threshold. Deprioritizing Medicare access may maximize value in the commercial channel for products that do not offer a real value proposition to Medicare beneficiaries.

As our case studies illustrated, pricing based on the specialty threshold is too simplistic and can result in significant underperformance relative to market expectations.

Conclusion

In conclusion, establishing the optimal price for a pharmaceutical asset is a complex process that should not overly rely on the Specialty Threshold as a determinant. A traditional pricing analysis which estimates payers' willingness-to-pay, physicians' willingness-to-prescribe, and patients' willingness-to-purchase combined with a nuanced approach to specifically evaluate the specialty threshold will lead to a more informed pricing strategy.

1. Impact of the specialty threshold should always be viewed in the context of broader pricing analyses across channels
2. The specialty threshold is only a consideration for a small number of products that have an optimal pricing band that extends directly above and below $670 (net, monthly)
3. Rather than a rudimentary assessment that assumes significant Medicare access below $670 and poor access above, a more nuanced framework can help to define product pricing around the threshold
4. Case studies illustrate that over-reliance on the threshold as a pricing proxy can result in underperformance relative to company and analyst expectations

Realistically, the specialty threshold is a particularly important consideration for a very small segment of therapies. For many products, price concessions below the threshold could result in underwhelming commercial performance.

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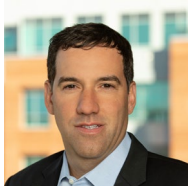

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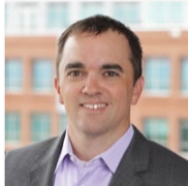

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