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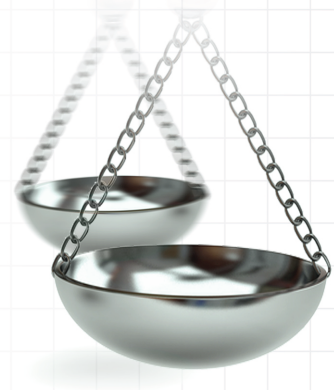

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Access in all areas? A round-up of developments in market access and health technology assessment: part 16

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> "...the binary question of whether a drug is on a plan formulary is being supplanted by a more nuanced question of how readily a patient can actually obtain a covered drug."

In this update we review new evidence on the rising prevalence of prior authorization rejections, delays and denials affecting US patients seeking access to branded prescription medications. We also examine a comparative study of cost-effectiveness thresholds cited in the USA and in countries designated as comparators under the Most-Favored-Nations Executive Order.

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Prior authorization (PA) is a mechanism used by US health insurers and the pharmacy benefit managers administering benefits on their behalf under which certain prescription medicines, even when listed on a plan's formulary, will be paid for only if the insurer has granted advance approval – typically conditional on documentation that the patient meets specified clinical or step-therapy criteria. In the retail pharmacy setting, that determination is made electronically at the point of dispensing: when the pharmacy submits the claim to the insurer's adjudication system, a response is returned in real time. If PA is required but has not been secured, the claim is rejected before the medicine can be released to the patient. Resolving the rejection generally requires the prescriber to submit clinical justification to the insurer, after which the pharmacy can resubmit the claim. This process can take days or weeks and frequently results in the patient leaving the pharmacy without their medicine. Recent evidence suggests that both the volume of PA and its stringency have been increasing. Using 2024 IQVIA pharmacy claims data, which captures the full lifecycle of pharmacy claim adjudication including rejected, reversed and paid claim lines, Wang and colleagues identified 205,896 branded medication dispensation transactions that had been initially rejected for PA reasons among 156,848 patients across all 50 US states [1]. Only about a third of these dispensations were resolved within 1 day of the initial rejection – meaning the patient either obtained the medicine that day or had the claim formally approved on the same day; the remainder took a median of 6 days, with an interquartile range of 3–12 days, before the claim was finalized. Just over half (54%) of transactions were ultimately approved, meaning that nearly half of branded prescriptions that triggered an initial PA review were never filled even after the patient had attempted to access them at the pharmacy. The US has three principal payer segments – Medicare (the federal program covering most adults aged 65 and older and certain disabled individuals), Medicaid (the federal-state program covering low-income individuals) and commercial insurance (predominantly employer-sponsored or individually purchased private cover) – and the patterns differed across them. Medicaid claims had the highest rate of same-day adjudication but the lowest approval rate (48%, compared with 60% for Medicare and 56% for commercial plans), suggesting that Medicaid PA processes resolve faster but reject more frequently. Patients with multiple disease conditions had a five-percentage point lower approval probability than those with a single condition, and prescriptions written by clinicians affiliated with corporate-owned practices had higher approval

rates than those written by independent prescribers – a pattern the authors attribute to better access to administrative support and predictive software for navigating PA requirements. Approval rates also varied substantially by molecule. Among the ten most frequently rejected branded drugs, which together accounted for nearly 70% of the analytic sample and included five glucagon-like peptide-1 (GLP-1) agonists, tirzepatide had the lowest approval rate (49%) and evolocumab, a PCSK9 monoclonal antibody, the highest (66%). The authors emphasize that their sample, although large, captures only those rejected claims that completed the entire adjudication process; the analysis cannot quantify rejected prescriptions that patients abandoned, those that prescribers declined to pursue or upstream effects on prescribing behavior driven by anticipated PA burden.

Two complementary analyses recently published by IQVIA extend this picture by examining trends over time and across the major US insurance markets [2,3]. In the commercial market, IQVIA reports that 70% of all attempts to fill a new branded medicine were initially denied coverage in 2025, up from 57% in 2021. In 2024, 24% of new-to-brand commercial claims initiated were never approved within 1 year of the first attempt, compared with 18% in 2021. Patients with more comorbidities and more prescriptions were more likely to encounter multiple rejections. Among patients who did ultimately gain approval, the average time to approval lengthened from 12 days in 2021 to 16 days in 2024, and approximately one in ten attempts faced delays exceeding 30 days [2]. The corresponding analysis of Medicare Part D – the outpatient prescription drug benefit available to Medicare beneficiaries through private plans contracted with the federal government – shows similar trends, although at lower absolute levels [3]. The share of new-to-brand Medicare attempts initially rejected rose from 37% in 2021 to 47% in 2025. In 2024, 14% of new-to-brand Medicare claims were never approved within 1 year, up only modestly from 13% in 2021 – suggesting that despite a tightening of upfront utilization management, prescribers and patients have largely been able to work through the necessary administrative requirements to gain coverage in the Medicare setting.

Taken together, the Wang study and the two IQVIA analyses paint a consistent picture of an access environment in which the binary question of whether a drug is on a plan formulary is being supplanted by a more nuanced question of how readily a patient can actually obtain a covered drug. For manufacturers, several implications follow. First, list-price negotiations and rebate strategies that secure formulary placement may deliver less commercial value than expected if a substantial proportion of intended utilization is being lost to PA-related abandonment. The Wang finding that approval rates differ markedly between molecules within the same therapeutic class – for example across GLP-1 agonists – suggests that PA processes themselves may be shaping market share independently of clinical positioning. Second, the demonstration that prescriptions written by clinicians embedded in corporately affiliated practices fare better at PA than those from independent prescribers points to the importance of investing in provider-facing tools such as electronic PA platforms and benefits-investigation services, particularly for products marketed in fragmented community settings. Third, the disproportionate burden borne by Medicaid enrollees and patients with multiple chronic conditions is consistent with broader concerns about equity in access and may inform the design of patient support programs; although manufacturer-funded support is itself the subject of evolving regulatory scrutiny. Fourth, the IQVIA observation that the proportion of attempts ultimately denied within a year has risen meaningfully in commercial markets while remaining roughly stable in Medicare highlights that strategies must be tailored to the institutional dynamics of each market segment.

The methodological foundations underpinning value assessment in the USA and in countries identified as Most-Favored-Nation (MFN) comparators are themselves coming under scrutiny as noted in previous parts of this series [4]. A study by Yu and colleagues provides the first systematic comparison of cost-effectiveness thresholds cited in the academic cost-effectiveness analysis (CEA) literature in the USA and in the eight nations referenced by the GENEROUS Model – the UK, France, Germany, Italy, Canada, Japan, Denmark and Switzerland [5,6]. Drawing on 6876 cost-per-quality-adjusted life year studies indexed in the Tufts CEA Registry between 1979 and 2023, the authors standardized reported thresholds as multiples of each country's GDP per capita and used logistic regression to assess the probability that a study cited a threshold above one-times GDP per capita, adjusting for region, intervention type, disease area and study period. Two findings stand out. First, US studies consistently referenced thresholds above the one-times-GDP-per-capita benchmark across all time periods examined, with an estimated 88% of US CEAs predicted to cite thresholds above this level after adjustment. By contrast, MFN comparator country studies have shifted progressively toward lower thresholds; in the post-2020 period, fewer than half of MFN comparator studies cited thresholds above one-times GDP per capita. The Yu analysis makes explicit what was previously only inferred: the implicit willingness-to-pay benchmarks reflected in published economic evaluations from MFN countries are systematically lower than those reflected in the US literature, and the gap has been widening rather than narrowing. To the extent that MFN policies tether US prices to those obtained

in jurisdictions where reimbursement decisions are anchored to materially lower thresholds, manufacturers face the prospect of having their US revenues benchmarked against valuations that reflect the budget constraints, opportunity costs and institutional priorities of national health systems quite different from the US. The authors caution policymakers against importing pricing benchmarks developed in distinct fiscal and institutional contexts without consideration of how those contexts shape the underlying value judgments. For manufacturers, this work reinforces the strategic importance of engaging with the methodology of value assessment – not only the price negotiations that follow it – and of building evidence packages that can speak credibly to the heterogeneous valuation conventions encountered across MFN jurisdictions.

The two strands of evidence reviewed in this update describe complementary dimensions of the same underlying phenomenon: payers are exercising increasingly tight control over the conditions under which branded prescription medicines are made available to patients. In the US, that control manifests operationally – through rising rates of initial PA rejection, longer adjudication times and a growing share of prescriptions never approved within a year. The MFN policy framework now being operationalized proposes to align US prices with those obtained in jurisdictions where tight methodological constraints are in place to lower drug prices. Manufacturers should therefore anticipate that future commercial success will depend not only on pricing decisions and formulary placement, but on the practical mechanics of getting medicines into patients' hands and on engagement with the underlying methodological standards that increasingly shape what constitutes acceptable value across markets.

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