Variation in Coverage of Specialty Therapies and Barriers to Fair Access

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BACKGROUND & OBJECTIVE

➢ What constitutes "fair" or "appropriate" access criteria for specialty therapies is a matter of debate. In an attempt to do so, the Institute for Clinical and Economic Review (ICER) established an ethical framework to assess appropriateness of prior authorization criteria.

➢ In its recent *Assessment of Barriers to Fair Access*, ICER found a high degree of alignment between plans' coverage requirements for 18 drugs and ICER's fairness criteria.

➢ Despite these findings, patients with different plans may have inconsistent access to the same drug.

➢ In this study, we examined how access to these drugs varied across 18 large commercial plans.

METHODS

Data Source

➢ We analyzed data from the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database, which includes specialty drug coverage decisions issued by 18 of the largest US commercial health plans.

➢ SPEC contains coverage criteria including:
1. *Patient subgroup restrictions* (patients must meet particular clinical criteria, e.g., symptoms of particular severity or duration);
2. *Step therapy protocols* (patients must first try and fail an alternative drug or treatment);
3. *Prescriber requirements* (a certain type of physician must prescribe a drug);
4. *Any other type of restriction* (e.g., a drug must be used in combination with another treatment)

Analyses

➢ For the 18 health plans included in SPEC we analyzed 213 coverage policies for 14 of the 18 ICER-assessed drugs; four drugs (Haegarda, Cinryze, Nexleto, and Nexlizet) that are not included in SPEC.

➢ For each coverage policy, we assessed whether plan-imposed coverage restrictions relative to the drugs' FDA approval and examined the specifics of these restrictions.

➢ We quantified the frequency of step therapy protocols and subgroup restrictions.

➢ Coverage policies were current as of April 2023.

RESULTS

➢ We found significant coverage variation among plans for 14 specialty drugs (Figure 1) and by drug across plans (Figure 2).

➢ As an example, Rinvoq is approved as second-line therapy for atopic dermatitis, however only 4/18 plans covered it that way. The remaining plans covered it as 3rd-6th line of therapy (Table 1).

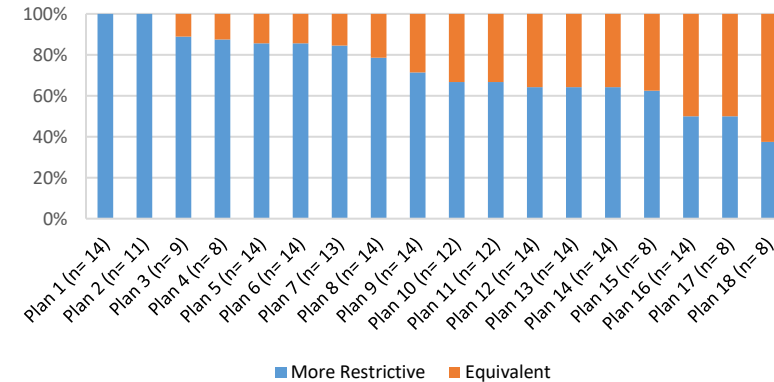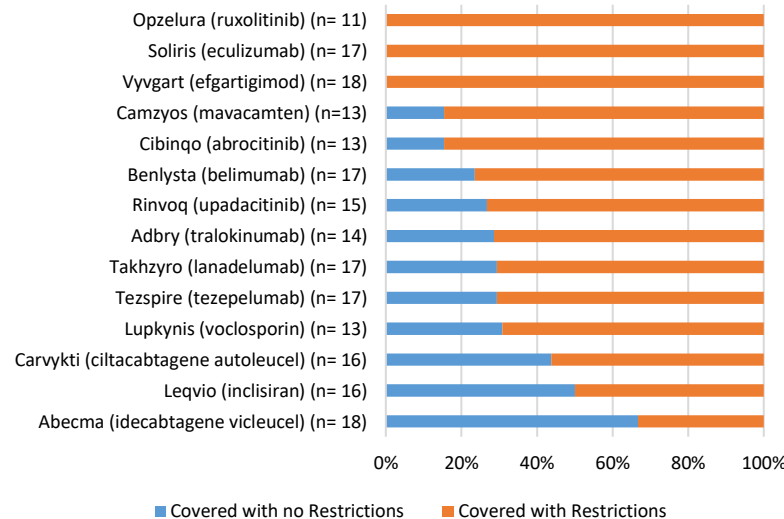Figure 1. Variation in US commercial plan restrictiveness for 14 specialty drugs, by plan, April 2023

Figure 2. Variation in US commercial plan coverage restrictions for 14 specialty drugs, by drug, April 2023

Table 1. Variation in US commercial plan step therapy protocols for Rinvoq for atopic dermatitis, April 2023

Required step through therapies before patients can access Rinvoq for atopic dermatitis	Consistent with FDA approved indication (Yes/No)	Plan covered line of therapy	Number of plans requiring this step
Systemic drugs, including biologics	Yes	2nd	4
Topical corticosteroid or calcineurin inhibitor AND systemic drugs, including biologics	No	3rd	5
Topical corticosteroid AND calcineurin inhibitor	No	3rd	2
Topical corticosteroid, calcineurin inhibitor, AND systemic drugs, including biologics	No	4th	2
2 Topical corticosteroids, calcineurin inhibitor, 1 systemic agent (azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine)	No	5th	1
Topical corticosteroid, calcineurin inhibitor, narrow-band ultraviolet B (NB-UVB) phototherapy, one systemic agent (azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine), and dupilumab	No	6th	1

CONCLUSION

➢ We identified substantial variation in coverage criteria among the largest health plans for drugs included in ICER's recent Fair Access report.

➢ Plan criteria differed even for drugs that ICER deemed 'fair', regardless of ICER's pricing judgement.

➢ This variability in coverage criteria has significant implications for patient access to healthcare.

For more information on the SPEC database, contact James Chambers at james.chambers@tuftsmedicine.org.