Alignment of Commercial Health Plan Specialty Drug Utilization Management Criteria with Clinical Treatment Guidelines

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Health plans applied additional utilization management criteria in most coverage decisions for drugs with favorable and unfavorable guidelines

BACKGROUND & OBJECTIVE

- Utilization management (UM) criteria are pivotal in regulating patient access to specialty drugs.
- There is a significant gap in understanding the consistency of UM criteria and relevant clinical treatment guidelines.
- We investigated the alignment between commercial health plans' UM criteria and clinical treatment guideline recommendations.

METHODS

Health plan coverage policies

- The Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database includes specialty drug coverage decisions issued by 18 of the largest US commercial health plans.

Clinical Guidelines

- We searched Guideline Central, UpToDate, PubMed and Embase for relevant clinical treatment guidelines.
- We searched for relevant US-based clinical treatment guidelines for 389 drug-indication pairs in SPEC.
- We classified each guideline's recommendation for each drug-indication pair into three mutually exclusive categories, benchmarked against the FDA label indication:

1. Favorable recommendation (i.e., in alignment with FDA label); or
2. Unfavorable recommendation (i.e., narrower recommendation than FDA label indication).

RESULTS

Analyses

We combined guideline favorability and coverage information and categorized coverage decisions into four groups

1. 'Consistent – Guideline Favorable' – the guideline is favorable, and the coverage decision aligns with the FDA label without imposing UM;

2. 'Consistent – Guideline Unfavorable' – the guideline is unfavorable, and the coverage decision imposes UM beyond the FDA label;

3. 'Inconsistent – Guideline Favorable', the guideline is favorable, but the coverage decision imposes UM beyond the FDA label;

4. 'Inconsistent – Guideline Unfavorable' - the guideline is unfavorable, but the coverage decision does not impose additional UM beyond the FDA label.

- Drug characteristics with the most guidelines available: Orphan (36%), pediatric (19%), expedited approval (35%), and Rheumatology (23%).
- We identified at least one guideline for 195 drug-indication pairs and categorized 132 (68%) as 'favorable' and 63 (32%) as 'unfavorable'.

Table 1: Health Plan Coverage Restrictions by Guideline Favorability (n= 2,899 coverage decisions)

	Coverage decisions with additional UM beyond FDA (n, %)	
Guideline Favorability	Yes	No
Favorable	Inconsistent: 1,262 63.2%	Consistent: 734 36.8%*
Unfavorable	Consistent: 605 67%	Inconsistent: 298 33%*
Total	1,867 64.4%	1,032 35.6%

*Chi-square results show a significant association between favorable guidelines and the absence of coverage restrictions (37% vs. 33%, OR 1.18, p=0.0495)

- Of the 2,899 decisions with available guidelines, 1,996 (69%) were associated with a favorable recommendation and 903 (31%) were not; however, health plans included restrictions beyond the FDA label in 1,262 (63%) coverage decisions associated with a favorable guideline and 605 (67%) of coverage decisions associated with an unfavorable guideline (Table 1).

Table 2: Alignment of Health Plan Coverage with Guidelines (n= 2,899 coverage decisions)

Decisions consistent with guidelines (i.e., no additional UM beyond label) n= 1,339 (46.2%)		Decisions inconsistent with guidelines (i.e., additional UM beyond label) n= 1,560 (53.8%)	
Favorable guideline n=734 (54.8%)	Unfavorable guideline n=605 (45.2%)	Favorable guideline n=1262 (80.9%)	Unfavorable guideline n=298 (19.1%)

- Of the 2,899 decisions linked to a clinical guideline, 1,339 (46.2%) were consistent (no UM beyond the label) and 1,560 (53.8%) were inconsistent (UM beyond the label) (Table 2).
- Of the 1,339 consistent decisions, 734 (54.8%) were linked to favorable guidelines, and 605 (45.2%) to unfavorable guidelines. Of the 1,560 inconsistent decisions, 1,262 (80.9%) were linked to favorable guidelines, and 298 (19.1%) to unfavorable guidelines (Table 2).

CONCLUSION

- Health plans applied additional UM criteria in most coverage decisions for drugs with favorable and unfavorable clinical guidelines.
  - 4% less often for drugs with favorable guidelines than for unfavorable guidelines
- We found a misalignment between clinical guidelines and health plan UM in specialty drug coverage policies.
- Our findings suggest that plans often cover drugs more narrowly than the FDA's approved indication.
- Although some restrictions may be justified and backed by evidence, this research raises questions about potentially overly restrictive UM.

REFERENCES

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