HPR84

Commercial Coverage of Accelerated Approval Drugs

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BACKGROUND & OBJECTIVE

- The Food and Drug Administration's (FDA) Accelerated Approval (AA) program has come under increased scrutiny and calls for reform.
- The program was developed to expedite the approval of drugs using a surrogate endpoint for serious conditions that provide a meaningful advantage over available therapies..
- AA drugs often pose a challenge for payers due to the limited evidence and high costs.
- This study explores variation in how AA drugs are covered by commercial payers by examining:
  - Restrictions beyond the FDA label
  - Oncology vs non-oncology drugs
  - Orphan vs. non-orphan drugs

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 large US commercial payers, representing roughly 170 million lives, or 70% of the market.
- Coverage policies were current as of April 2023.

Analysis

- We identified 1,239 coverage policies for 60 AA drugs approved between 2016 and 2021 that met a coverage threshold of at least 10 policies.
- Included drugs were stratified by oncology/non-oncology and orphan/non-orphan. 89% (n=1,079) of active coverage decisions were for oncology indications and 70% (n=841) for orphan indications.
- We examined payer coverage restrictiveness, including step therapy protocols and subgroup restrictions.

RESULTS

Figure 1: US Commercial payer coverage restrictiveness for Accelerated Approval drugs, April 2023 (n=1,206 coverage policies)

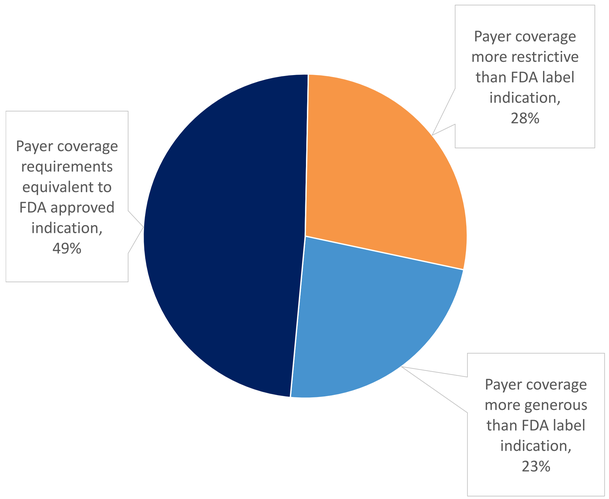


Figure 3: US Commercial payer coverage restrictiveness for Accelerated Approval drugs (Orphan vs. Non-Orphan), April 2023

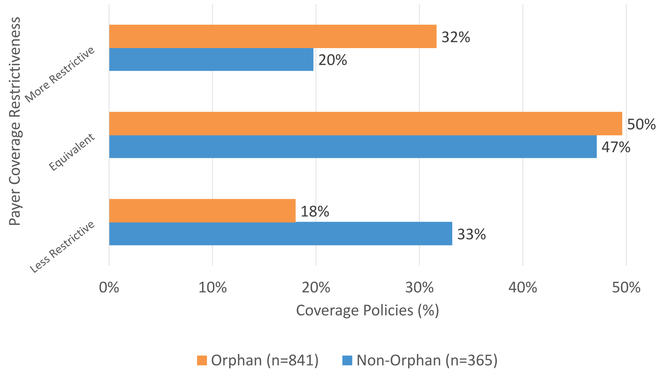
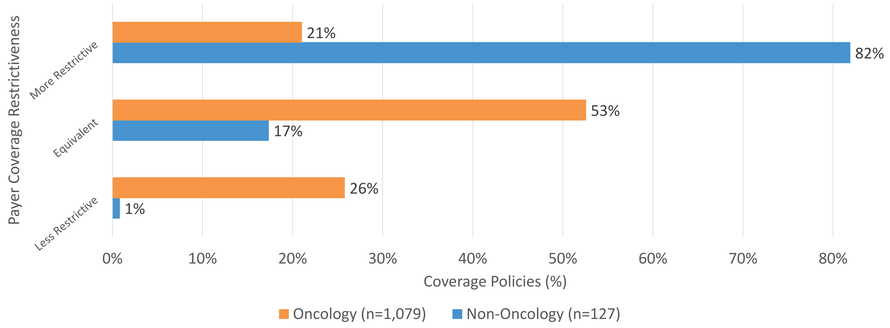


Figure 2: US Commercial payer coverage restrictiveness for Accelerated Approval drugs (Oncology vs. Non-Oncology), April 2023



Key Points

- 1,206 (97%) policies provided some degree of coverage for AA drugs and 33 (3%) did not.
- 589 (49%) were equivalent to the drug's FDA label indications, i.e., the plan covered the drugs for the same patient population as the FDA, and 279 (23%) more generously than the drugs' FDA label indications
- 338 (28%) of AA drug coverage policies included restrictions beyond the FDA label (subgroup restrictions were the most common restriction type).
- 83 (7%) included step therapy protocols. Step therapy requirements were most often consistent with the FDA label (92%).
- Oncology drugs were covered with restrictions beyond the drugs' FDA labels less often than non-oncology drugs, 21% vs. 82%.
- Overall, orphan drugs were more often covered with restrictions (32%) than non-orphan drugs (20%).

CONCLUSION

- Despite criticisms of the AA program, payers frequently permit their enrollees' access to AA drugs through coverage policies.
- When payers do impose coverage limits on AA drugs it is typically for non-oncology and/or orphan drugs.
- This study provides new insight into how commercial payers facilitate enrollee access to AA drugs given FDA guidance.

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