BACKGROUND AND OBJECTIVE

Because health plans formulate their own coverage decisions, how they cover specialty products can vary. This variation can have important implications for patients’ access to care.

Hemophilia A, a genetic disorder caused by missing or defective factor VIII (FVIII), which is an essential blood-clotting protein.

Hemophilia A is a rare disease that is associated with high treatment costs. Research has shown that on-demand (to stop bleeding) and prophylactic (to prevent bleeding) treatment may exceed $200,000 and $300,000 annually, respectively.

In this study, we examine how large US commercial health plans cover hemophilia A treatments.

METHODS

The starting point for this research was the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database, which contains publicly available specialty product coverage policies issued by 17 of the largest US commercial health plans.

We identified coverage decisions for hemophilia A treatments in the SPEC Database. When a hemophilia A treatment was not included in SPEC, we searched for and obtained the coverage policies from the health plans’ websites.

Our sample included 26 hemophilia A treatments: one biologic, three bypassing agents, two desmopressin products, five plasma-derived FVIII products, and fifteen recombinant FVIII products.

Coverage decisions were current as of August 2019.

Coverage Restrictiveness

We compared each coverage decision with the treatment’s FDA labeled indication. We categorized decisions as:

- Less restrictive than the FDA labeled indication: the plan covers a broader population than the FDA labeled indication;
- Equivalent to the FDA labeled indication;
- More restrictive than the FDA labeled indication: the plan placed conditions on coverage beyond those in the FDA indication;
- Mixed coverage restrictiveness: the plan covers more restrictively than the FDA labeled indication in one way, but less restrictively in another;
- Not covered: the plan does not cover the treatment.

Restriction Types

We considered a coverage decision to be more restrictive than the drug’s FDA label if a health plan applied one or more of the following restriction types:

- Step therapy protocol: plan requires the patient to first fail an alternative treatment before gaining access to the drug;
- Patient subgroup restriction: plan requires patients to meet particular clinical criteria (e.g., the patient is suffering from symptoms of a particular severity or duration);
- Prescriber requirement: plan requires a certain type of physician (e.g., a hematologist) to prescribe the drug;
- Other restrictions: plan applies any other types of coverage restrictions.

We examined variation in treatment coverage across the included plans.

RESULTS

Sixteen of the seventeen health plans issued publicly available coverage policies for hemophilia A treatments (n=297 coverage decisions).

We classified 51% of coverage decisions as ‘more restrictive’, 7% as ‘less restrictive’, 35% as ‘equivalent’, and 7% as ‘mixed’, and <1% as ‘not covered’.

In restricted decisions, plans most frequently applied patient subgroup restrictions (82% of decisions), followed by step therapy protocols (29%).

Variation Across Health Plans

Plans varied in the frequency that they applied coverage restrictions, ranging from 5% to 100% of their decisions (Figure 1).

Four plans applied coverage restrictions in 100% of their decisions; eleven plans applied restrictions in at least half of their decisions.

Variation Across Hemophilia A Treatments

Health plans covered some hemophilia A treatment classes more restrictively than other classes (Figure 2).

No treatment was covered consistently across all 16 plans, i.e., some plans applied coverage restrictions, while other plans did not.

For 19 of the 26 treatments, at least half of health plans applied restrictions in their coverage decisions.

Plans most often applied restrictions in their coverage decisions for the only available biologic, emicizumab (12/15 decisions); plans least often applied restrictions in their decisions for a bypassing agent (NovoSeven, 1/13 decisions).

CONCLUSION

Overall, US commercial health plans applied restrictions in more than half of their coverage decisions for hemophilia A treatments. Health plans tended to cover some treatments more restrictively than others.

Variation across health plan coverage decisions suggest that a patient’s plan may influence their access to hemophilia A treatments.

REFERENCES


FUNDING

Genentech, Inc. funded this research.