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Brief Report

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Commercial coverage of specialty drugs, 2017–2021

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Abstract

Health plans guide their enrollees' access to specialty drugs through coverage policies. We examined a set of health plan policies to determine if they have become more or less stringent over time. We did so by comparing the consistency of policies with Food and Drug Administration (FDA) label indications. We considered coverage policies for the same 187 specialty drugs issued by 17 large US commercial health plans from 2017 through 2021. Overall, the proportion of policies that were consistent with the FDA label declined from 57.1% in 2017 to 45.1% in 2021; the proportion of policies that were more restrictive than the FDA label increased from 39.5% to 51.7%. The proportion of policies excluding drug coverage remained approximately constant (3.4% in 2017; 3.2% in 2021). Trends in coverage restrictiveness varied across plans. For 13 plans, the proportion of policies with restrictions increased over time, while for 4 plans it declined.

Key words: insurance coverage; pharmaceuticals; specialty drugs.

Introduction

Health plans determine access to prescription drugs with coverage policies that aim to achieve safe, effective, and cost-effective care while also recognizing budgetary limits.[1] For specialty drugs, which are typically complex, high-cost medications, commercial health plans impose criteria that restrict coverage beyond the Food and Drug Administration's (FDA's) label indications approximately one-third of the time.[2] Plans impose different types of utilization management tools, or coverage restrictions, with different frequencies.[3–5] It is not clear, however, if plans' specialty drug coverage policies have become more or less stringent over time. We examined changes in coverage policies for the same set of specialty drugs issued by 17 large commercial health plans from 2017 through 2021.

Data and methods

Our data come from the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) database.[6] SPEC includes specialty drug coverage policies issued by 17 of the largest US commercial health plans (Appendix S1) representing approximately 188 million commercially covered lives (~70% of the total).[7] For FDA approval of a drug for multiple indications, SPEC represents each drug-indication pair separately. For example, because FDA approved bortezomib for mantle cell lymphoma and multiple myeloma, it appears twice in SPEC. This analysis included 187 drugs, corresponding to 357 drug-indication pairs (Appendix S2), for which SPEC included coverage information current in August in each year from 2017 through 2021. In other words, we examined changes in plans' coverage policies for the same set of drug-indication pairs from 2017 to 2021.

SPEC benchmarks coverage policies to each drug's corresponding FDA label indication. SPEC categorizes coverage restrictions (ie, requirements that go beyond a drug's label indication) as follows: (1) patient subgroup restrictions, or clinical criteria patients must satisfy (eg, minimum symptom severity or duration requirements); (2) step therapy protocols, or requirements that patients first experience an inadequate response to an alternative therapy before being eligible for a particular drug; (3) prescriber requirements that a particular type of physician prescribe the drug; and (4) any other type of restriction (eg, requiring a drug to be used in combination with another treatment).

We analyzed plan removal or addition of restrictions in their coverage policies for each drug-indication pair in 2 ways. The first tracks changes in the number of restrictions included in a particular drug-indication pair coverage policy. We consider a plan's coverage policy to include no restrictions if it covers the drug-indication pair for all individuals satisfying FDA's indication. Otherwise, the number of restrictions depends on how many requirements it imposes beyond criteria in FDA's indication. For example, a plan's policy for a drug-indication pair that imposes both a subgroup restriction and a step therapy protocol beyond the FDA label has 2 restrictions. We stratify findings by drug orphan designation, *International Classification of Diseases, Tenth Revision–Clinical Modification* (ICD-10-CM), diagnostic category, oncology indication, pediatric indication (eg, pediatric Crohn's disease), and FDA-expedited review program inclusion (ie, priority review, fast-track designation, accelerated approval,

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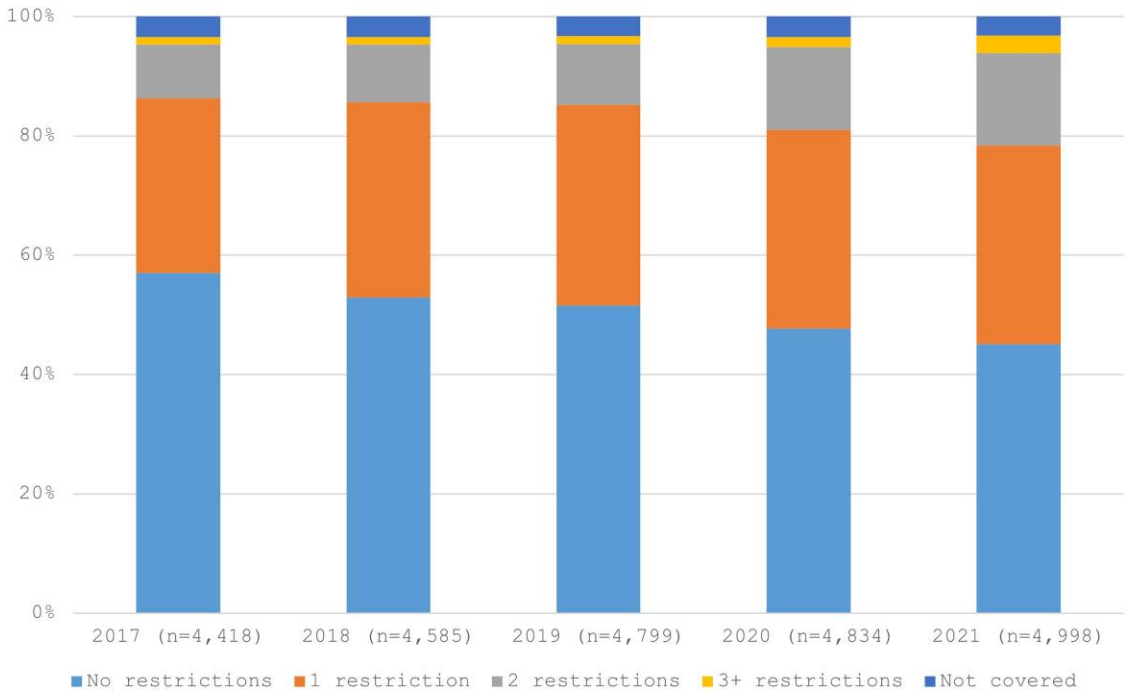

Figure 1. Health plans' use of coverage restrictions over time: Specialty Drug Evidence and Coverage (SPEC) database.[6] Inclusion criteria require US commercial payers to have a specialty drug coverage policy present at least 1 time point during the study period (2017–2021), but because coverage can change year over year, this caused the number of specialty coverage policies (the denominator) to increase over time (n = 4418 in 2017, n = 4998 in 2021).

or breakthrough therapy).[8] Appendix S3 summarizes the included drug-indication pairs. The second analysis reports changes in the proportion of drug-indication pair coverage policies in which plans include different types of restrictions.

Our study has limitations. First, our analysis does not address whether patients have appropriate access to a therapy for their condition. For instance, while a plan may have added coverage restrictions to a particular tumor necrosis factor (TNF) inhibitor, the plan may not have added the same coverage restrictions for other TNF inhibitors. Second, not all plans issued a coverage policy for each drug-indication pair in our sample at each time point. Third, it is unclear whether our findings generalize to noncommercial plans or nonspecialty drugs.

Results

The number of coverage policies for the 357 drug-indication pairs, issued by the 17 health plans, increased from 4418 in 2017 to 4998 in 2021. The proportion of policies excluding drug coverage remained approximately constant (~3%).

The proportion of plans' coverage policies with restrictions increased from 39.5% in 2017 to 51.7% in 2021. The proportion of plans' coverage policies with no restrictions decreased from 57.1% to 45.1% during this period, while the proportion of policies with multiple coverage restrictions increased from 10.2% to 18.4% (Figure 1).

Trends in coverage restrictions varied across plans. For 13 health plans, the proportion of coverage policies with at least 1 coverage restriction increased over time, while for 4 plans it declined (Table 1).

Plans' use of coverage restrictions increased more for some indications than for other indications, increasing most for circulatory (the proportion of policies with restrictions increased from 38.1% to 61.9%) and gastroenterology (49.1% to 76.1%) conditions, and least for ICD-10-CM conditions categorized as "other" (47% to 48.7%) and nervous system conditions (53.9% to 55.2%) (Appendix S4).

Plans' use of coverage restrictions for oncology drugs, although less prevalent than for non-oncology drugs, increased more than for non-oncology drugs (the proportion of policies with restrictions increased from 17.6% to 33.5% vs 53.2% to 63.5%) (Appendix S5). Plans' use of coverage restrictions for orphan drugs, although less prevalent than for nonorphan drugs, increased more than for nonorphan drugs (from 30.9% to 47.1% vs 46.3% to 55.6%) (Appendix S6).

Plans' use of coverage restrictions for drugs approved through at least 1 FDA-expedited review program increased from 30.8% to 43.2% and for drugs that FDA reviewed through its standard processes from 46.1% to 58.3% (Appendix S7). Plans' use of coverage restrictions for nonpediatric indications increased from 38.4% to 49.8% and for pediatric indications from 45.9% to 62.6% (Appendix S8).

Health plans tended to favor certain types of restrictions. Use of prescriber requirements and step therapy protocols increased from 12% to 25% and 25.8% to 34% of policies, respectively. Use of patient subgroup and "other" restrictions remained relatively constant, increasing from 12% to 13.1% and decreasing from 1% to 0.7% of policies, respectively (Appendix S9).

Discussion

Between 2017 and 2021, for the specialty drugs in our sample, approximately 10% more coverage policies included at least 1 restriction and the number of coverage policies with multiple restrictions increased. These findings suggest that, on average, commercial coverage of these specialty drugs, particularly for oncology and orphan drugs, has become more limited. Our findings are consistent with research showing that pharmacy

Table 1. Use of coverage restrictions across health plans over time.

Health plan	2017			2018			2019			2020			2021		
	≥1 Restriction	No restrictions	Not covered	≥1 Restriction	No restrictions	Not covered	≥1 Restriction	No restrictions	Not covered	≥1 Restriction	No restrictions	Not covered	≥1 Restriction	No restrictions	Not covered
Plan 1	148 (44.0%)	176 (52.4%)	12 (3.6%)	151 (43.5%)	185 (53.3%)	11 (3.2%)	151 (43.5%)	185 (53.3%)	11 (3.2%)	112 (31.9%)	229 (65.2%)	10 (2.8%)	102 (29.1%)	238 (67.8%)	11 (3.1%)
Plan 2	119 (47.8%)	127 (51.0%)	3 (1.2%)	145 (48.3%)	153 (51.0%)	2 (0.7%)	141 (42.7%)	187 (56.7%)	2 (0.6%)	146 (44.2%)	181 (54.8%)	3 (0.9%)	146 (44.4%)	180 (54.7%)	3 (0.9%)
Plan 3	170 (52%)	145 (44.3%)	12 (3.7%)	163 (49.7%)	153 (46.6%)	12 (3.7%)	170 (51.7%)	147 (44.7%)	12 (3.6%)	179 (55.1%)	135 (41.5%)	11 (3.4%)	181 (56.9%)	126 (39.6%)	11 (3.5%)
Plan 4	104 (60.5%)	65 (37.8%)	3 (1.7%)	113 (63.5%)	62 (34.8%)	3 (1.7%)	121 (64.0%)	65 (34.4%)	3 (1.6%)	115 (59.3%)	68 (35.1%)	11 (5.7%)	126 (52.5%)	103 (42.9%)	11 (4.6%)
Plan 5	185 (74.6%)	51 (20.6%)	12 (4.8%)	202 (73.7%)	61 (22.3%)	11 (4.0%)	215 (70.7%)	78 (25.7%)	11 (3.6%)	216 (70.8%)	78 (25.6%)	11 (3.6%)	194 (68.1%)	80 (28.1%)	11 (3.9%)
Plan 6	78 (27.5%)	197 (69.4%)	9 (3.2%)	123 (42.1%)	159 (54.5%)	10 (3.4%)	150 (52.6%)	125 (43.9%)	10 (3.5%)	154 (53.3%)	125 (43.3%)	10 (3.5%)	203 (67.7%)	87 (29.0%)	10 (3.3%)
Plan 7	90 (38.5%)	133 (56.8%)	11 (4.7%)	100 (42.2%)	126 (53.2%)	11 (4.6%)	100 (42.0%)	127 (53.4%)	11 (4.6%)	177 (75.0%)	48 (20.3%)	11 (4.7%)	192 (80.0%)	37 (15.4%)	11 (4.6%)
Plan 8	72 (33.6%)	134 (62.6%)	8 (3.7%)	76 (36.2%)	125 (59.5%)	9 (4.3%)	72 (33.5%)	135 (62.8%)	8 (3.7%)	84 (39.4%)	121 (56.8%)	8 (3.8%)	93 (43.5%)	113 (52.8%)	8 (3.7%)
Plan 9	63 (22.7%)	206 (74.1%)	9 (3.2%)	74 (22.9%)	240 (74.3%)	9 (2.8%)	81 (24.4%)	242 (72.9%)	9 (2.7%)	85 (24.9%)	247 (72.4%)	9 (2.6%)	101 (29.7%)	230 (67.6%)	9 (2.6%)
Plan 10	161 (51.8%)	147 (47.3%)	3 (1.0%)	202 (79.5%)	41 (16.1%)	11 (4.3%)	246 (84.8%)	32 (11%)	12 (4.1%)	290 (91.5%)	16 (5.0%)	11 (3.5%)	305 (92.4%)	14 (4.2%)	11 (3.3%)
Plan 11	113 (36.2%)	189 (60.6%)	10 (3.2%)	120 (37.7%)	190 (59.7%)	8 (2.5%)	128 (38.1%)	198 (58.9%)	10 (3.0%)	144 (43.2%)	179 (53.8%)	10 (3.0%)	187 (53.3%)	154 (43.9%)	10 (2.8%)
Plan 12	61 (37.4%)	92 (56.4%)	10 (6.1%)	76 (42.9%)	92 (52.0%)	9 (5.1%)	96 (44.7%)	110 (51.2%)	9 (4.2%)	111 (51.6%)	95 (44.2%)	9 (4.2%)	119 (55.3%)	87 (40.5%)	9 (4.2%)
Plan 13	14 (8.2%)	142 (83.5%)	14 (8.2%)	18 (10.3%)	144 (82.8%)	12 (6.9%)	21 (11.9%)	144 (81.4%)	12 (6.8%)	27 (15.5%)	135 (77.6%)	12 (6.9%)	101 (37.1%)	167 (61.4%)	4 (1.5%)
Plan 14	85 (38.6%)	125 (56.8%)	10 (4.5%)	87 (36.9%)	138 (58.5%)	11 (4.7%)	89 (36.2%)	146 (59.3%)	11 (4.5%)	95 (38.5%)	141 (57.1%)	11 (4.5%)	109 (43.4%)	131 (52.2%)	11 (4.4%)
Plan 15	129 (37.9%)	209 (61.5%)	2 (0.6%)	142 (42.1%)	193 (57.3%)	2 (0.6%)	156 (44.7%)	191 (54.7%)	2 (0.6%)	146 (42.7%)	194 (56.7%)	2 (0.6%)	140 (41.4%)	196 (58.0%)	2 (0.6%)
Plan 16	105 (38.6%)	157 (57.7%)	10 (3.7%)	106 (39.0%)	156 (57.4%)	10 (3.7%)	119 (41.8%)	156 (54.7%)	10 (3.5%)	138 (48.1%)	139 (48.4%)	10 (3.5%)	134 (46.7%)	142 (49.5%)	11 (3.8%)
Plan 17	49 (17.0%)	226 (78.5%)	13 (4.5%)	106 (32.3%)	208 (63.4%)	14 (4.3%)	109 (32.8%)	209 (63.0%)	14 (4.2%)	146 (43.6%)	174 (51.9%)	15 (4.5%)	152 (45.1%)	169 (50.1%)	16 (4.7%)
All plans	1746 (39.5%)	2521 (57.1%)	151 (3.4%)	2004 (43.7%)	2426 (52.9%)	155 (3.4%)	2165 (45.1%)	2477 (51.6%)	157 (3.3%)	2365 (48.9%)	2305 (47.7%)	164 (3.4%)	2585 (51.7%)	2254 (45.1%)	159 (3.2%)

Data from the SPEC database.[6] Measured use of UM by breaking down analysis by payer (anonymized plans). "No restrictions" indicates coverage decisions that were identified as equivalent to or less restrictive than the FDA label; "≥1 Restrictions" indicates coverage decisions with restrictions beyond the FDA label, mixed and/or more restrictive than the label; "Not covered" indicates no coverage.
Abbreviations: FDA, Food and Drug Administration; SPEC, Specialty Drug Evidence and Coverage; UM, Utilization Management.

benefit managers have increasingly excluded drugs from their formularies.[9]

While most plans increased restrictions between 2017 and 2021, 4 did not. Reasons for the differences in plan behavior may include individual plans' fiscal circumstances and their need to tailor coverage to their populations. Of note, CVS Caremark acquired Aetna in 2018, and Aetna was 1 of the 4 payers with fewer coverage restrictions in 2021 than in 2017.[10] This finding suggests that plan mergers may impact plan enrollees' access to specialty drugs.

Plans increased their use of prescriber requirements and step therapy protocols more than they increased use of other restrictions. A prescriber requirement stipulating that a physician with sufficient expertise prescribes a particular drug can promote appropriate use of a therapy, but it could also delay or impede access to care.[5]

The use of step therapy protocols, which can encourage use of effective treatment that is less expensive, has increased over time. The introduction of more novel therapies over the study period may have encouraged this trend by providing additional treatment options. For example, FDA's 2019 approval of risankizumab-rzaa increased competition among therapies to treat plaque psoriasis. The FDA also approved several biosimilar drugs during the study period, including epoetin alfa-epbx in 2018 and infliximab-axxq in 2019. These introductions provided health plans with additional step therapy protocol options.

Rising drug and other health costs may be driving more frequent imposition of utilization management measures. With respect to drugs, prices have increased,[11] although overall cost increases appear more modest after accounting for manufacturer rebates.[12] The introduction of costly innovative technologies, such as gene therapies (FDA-approved onasemnogene abeparvovec-xioi for spinal muscular atrophy in 2019), has increased pressure on plan drug budgets.

Health plan coverage policies are powerful tools to curb inappropriate drug use and to contain costs. Coverage policies also serve to aid negotiations, allowing plans to propose favorable coverage in return for larger rebates from product manufacturers. However, the American Medical Association and others have raised concerns about the burden of overly restrictive policies on patients, physicians, and on associated health care system costs.[13,14]

It is important to monitor how specialty drug coverage policies evolve. Future research should consider changes in patient cost-sharing and the extent to which other health plan programs, such as copay accumulators, has affected access to care. Research to assess whether recent legislative efforts to protect patients from the potential negative impacts of step therapy has affected how plans use this tool would also be valuable.[15,16]

Conclusion

For a set of 187 specialty drugs, US commercial health plans increased their restrictions between 2017 through 2021, with prescriber requirements and step protocols becoming increasingly common, although restrictions varied across health plans and drug attributes.

Supplementary material

Supplementary material is available at *Health Affairs Scholar* online.

Conflicts of interest

This study was funded by the National Pharmaceutical Council. The Center for the Evaluation of Value and Risk in Health at Tufts Medical Center is supported by multiple grants from federal, foundation, and industry research sponsors. More information is available upon request.

Notes

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