

Patients' Access to 2018 FDA-Approved Drugs 1 Year Post Approval

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In 2018, the FDA approved 66 drugs, the most the agency has approved in any year.¹ The FDA included 65% (43/66) of these drugs in expedited review programs, which are reserved for drugs offering substantial improvements over existing therapies or addressing acute unmet clinical needs.² The large number of drug approvals was a positive development for patients. However, before a physician can prescribe a drug, a patient's health insurance plan must cover it. Novel drugs with high prices pose a challenge to health plans and their already stretched drug budgets.³⁻⁵

Plans communicate drug coverage information in 2 main ways: drug formularies and coverage policies. Plans typically communicate coverage of self-administered drugs through formularies (pharmacy benefit) and physician-administered drugs through coverage policies (medical benefit). This distinction matters because plans include different information in formularies and coverage policies. Formularies include information on plan-imposed utilization management (UM) criteria, including co-payment tier, the need for prior authorization (PA), and so on. In contrast, coverage policies describe the patient population for whom the plan considers the drug to be medically necessary, including information on required diagnostic testing, clinical criteria (eg, severity of symptoms), and step therapy protocols (ie, a requirement that patients first try and fail a prior therapy before gaining access to a particular therapy).

On occasion, plans may include the drug in both a formulary and a coverage policy. For instance, a plan may additionally include a physician-administered drug in its pharmacy benefit (and thus its formularies) to shift costs and to enable the use of formulary UM criteria. In these cases, the drug would be distributed from a pharmacy but would be administered in a physician's office.^{6,7} For self-administered drugs, plans may additionally issue coverage policies to more transparently communicate the plan's medical necessity criteria to providers and patients. This often occurs when plans include all drugs indicated for a particular indication (eg, multiple sclerosis) in a single coverage policy, irrespective of whether the indicated drugs are physician-administered or self-administered.

In this study, we examined how a set of US commercial health plans covered 2018 novel FDA-approved drugs. We reported plans'

ABSTRACT

OBJECTIVES: To examine US commercial health plans' adoption of 2018 FDA-approved drugs.

STUDY DESIGN: Database analysis.

METHODS: We identified novel drugs that the FDA approved in 2018 and categorized them as follows: cancer treatment, orphan drug, included in an expedited review program, and biosimilar. Using a data set of 17 large health plans' drug coverage policies and formularies, we examined coverage 1 year following FDA approval.

RESULTS: The FDA approved 66 drugs in 2018 (5 were not yet marketed 1 year following approval). For 60 of 61 drugs, some plans issued coverage policies whereas other plans included the drug in their formularies. Plans imposed restrictions (eg, step therapy) in 37% (275/742) of coverage policies. Plans covered biosimilars, orphan drugs, and cancer treatments more generously than drugs not in those categories ($P < .05$). Plans imposed restrictions in their policies with different frequencies (range, 7%-52%). Plans imposed utilization management (UM) in 82% (3837/4697) of formulary entries. Of those entries, plans required prior authorizations in 98%, included drugs on the highest patient co-payment tier in 70%, and imposed step therapy in 3%. Plans most often placed orphan drugs and cancer treatments on the highest cost-sharing formulary tiers (68% and 64% of the time, respectively). Plans imposed UM in their formularies with different frequencies (range, 62%-100% of entries).

CONCLUSIONS: Health plans imposed fewer coverage restrictions on cancer treatments, orphan drugs, and biosimilars than on drugs not in those categories. Some plans covered 2018 FDA-approved drugs more generously than others, which has implications for patients' access to innovative therapies.

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TAKEAWAY POINTS

- ▶ FDA approval of novel drugs in 2018 posed challenges to health plans determining coverage, with plans imposing restrictions (eg, step therapy protocols) in 37% of coverage policies and utilization management in 82% of formulary entries.
- ▶ Private US health plans provided uneven access to 2018 approved drugs with different characteristics, with plans restricting coverage more frequently for noncancer treatments than for cancer treatments (49% vs 12%), for novel therapies more frequently than for biosimilars (42% vs 18%), and for nonorphan drugs more frequently than for orphan drugs (41% vs 34%).
- ▶ Enrollee access to drugs approved in 2018 varied across plans.

mode of coverage communication (coverage policies vs formularies) and examined differences in plan coverage of drugs with different characteristics (eg, orphan vs nonorphan drugs). Understanding how US health plans adopt new technology is important given many patients' often urgent need to access these treatments.

METHODS

Data Set

We identified novel drugs that the FDA approved in 2018. When the FDA approved a drug for multiple indications, we considered each drug-indication pair separately. For example, because the FDA approved omadacycline for skin infections and for community-acquired bacterial pneumonia, we included omadacycline twice in our data set. We used information from the FDA's website to categorize each drug-indication pair as follows: included in an expedited review pathway, orphan drug status, cancer indication, and/or biosimilar ([eAppendix Table 1](#) [eAppendix available at [ajmc.com](#)]).

We explored how 17 large US commercial health plans ([eAppendix Tables 2 and 3](#)) covered each drug 1 year after approval. For example, for a drug approved on March 1, 2018, we identified and reviewed plans' publicly available coverage policies and formularies posted on their websites that were current on March 1, 2019.

We reviewed each drug coverage policy and determined whether the plan imposed restrictions beyond the drug's FDA label indication. We categorized coverage restrictions as patient subgroup restrictions (eg, a requirement that disease severity meet or exceed some level); step therapy protocols; and "other," meaning any other coverage restriction (eg, requiring the drug be used in combination with another drug). We also reported plan-imposed prescriber requirements (eg, a requirement that a neurologist prescribe the drug).

We identified the same plans' drug formularies that were in force 1 year following a drug's approval from their websites. We reviewed formulary entries for each drug and categorized UM criteria as PAs, step therapy protocols, or inclusion of a drug on the highest patient co-payment tier. We also identified quantity limits and age eligibility requirements.

Analyses

We categorized the mode of plans' coverage communication using the following categories: coverage policy only, drug formulary only,

both coverage policy and drug formulary, or neither. Because formularies and coverage policies include different information, we were unable to compare their contents.⁸ For example, whereas coverage policies precisely describe the criteria patients must meet before being eligible for a drug, a formulary reports only whether a PA is necessary. A PA may include similarly detailed patient eligibility requirements or may be a simple attestation that a patient has a particular diagnosis; however,

it is not possible to determine this information from a formulary. Similarly, whereas coverage policies clearly outline step therapy requirements (ie, the number of prior therapies that plans require patients to fail), formularies specify only whether a step therapy protocol is required. Further, whereas coverage policies report a plan's specific coverage criteria for each of a drug's indications, formularies do not provide indication-specific coverage information. Because of these differences, we analyzed formularies and coverage policies separately.

We explored how health plans covered drugs in 2 ways. First, we examined differences in plan coverage of drugs with different characteristics (eg, orphan drugs vs nonorphan drugs). Second, we evaluated variation in drug coverage across health plans.

RESULTS

In 2018, the FDA approved 66 novel drugs (42 new drug applications; 24 biologics license applications), corresponding to 82 drug-indication pairs ([eAppendix Table 1](#)). We excluded 5 drugs that were not yet marketed, including 3 biosimilars. The remaining 61 drugs corresponded to 70 drug-indication pairs.

Mode of Coverage Communication

On average, plans issued coverage information (coverage policies or drug formularies) for 88% (913/1037 potential instances; range, 74%-98%) of drugs ([eAppendix Figure](#)); plans issued both a coverage policy and a formulary for 35%, only a coverage policy for 27%, only a formulary for 27%, and neither for 12%. Three plans most often issued only a coverage policy, 5 plans most often issued only a formulary, and 9 plans most often issued both a coverage policy and a formulary.

For 60 of 61 drugs, some plans issued coverage policies whereas others included the drug in their formularies. All 13 plans that issued coverage information for doravirine (indicated for the treatment of HIV-1 infection) included the drug in a formulary and did not issue a separate coverage policy.

Imposed Coverage Restrictions

Coverage policies. Plan coverage was consistent with the FDA's approved indication 63% (465/742) of the time. Plans imposed coverage restrictions 37% (275/742) of the time ([Figure 1](#) and

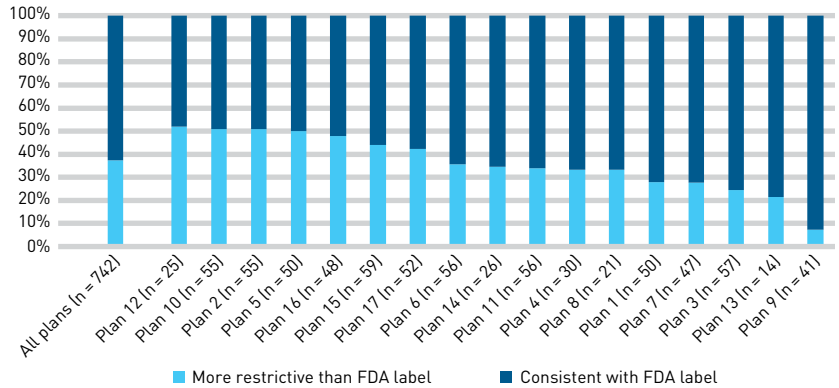
eAppendix Table 4). In 2 cases, a plan deemed a drug to be experimental/investigational and hence did not cover it. Of restricted coverage policies (n = 275), plans imposed step therapy protocols in 69% and patient subgroup restrictions in 57% (eAppendix Table 4). Plans imposed multiple restriction types in 27% of restricted coverage policies. For step therapy protocols (n = 191), plans required patients to first fail a single drug 53% of the time; 2 drugs, 34%; and 3 or more drugs, 13%.

Plans imposed coverage restrictions on noncancer treatments more often than on cancer treatments (49% vs 12%; $P < .01$), novel therapies more often than biosimilars (42% vs 18%; $P < .01$), and nonorphan drugs more often than orphan drugs (41% vs 34%; $P < .05$). Plans restricted coverage of drugs that the FDA reviewed through its standard process more often than drugs that the FDA included in an expedited review program (41% vs 35%), although this difference was not statistically significant ($P = .13$) (eAppendix Table 4). Plans tended to impose different coverage restriction types to drugs with different characteristics. For example, plans most often restricted orphan drugs (n = 137 restricted coverage policies) by applying patient subgroup restrictions (80% of the restricted policies); in contrast, plans most often restricted nonorphan drugs (n = 138 restricted coverage policies) by applying step therapy protocols (95% of restricted policies) (eAppendix Table 4).

Formularies. Health plans issued a combined total of 186 formularies (some plans issued more formularies than others) (eAppendix Table 5). Plans excluded drugs from their formularies (ie, did not cover the drug) 3% of the time (140/4697 instances) and imposed UM criteria 82% of the time (3837/4697). Of formulary entries with UM criteria (n = 3837), plans required a PA in 98%, included drugs on the highest patient co-payment tier in 70%, and imposed step therapy protocols in 3% (eAppendix Table 5). Plans imposed multiple UM tools 60% of the time (Figure 2).

Plans tended to impose different types of UM on drugs with different characteristics. For example, plans required PA more often for cancer drugs than noncancer drugs (93% vs 63%) and for orphan drugs than nonorphan drugs (86% vs 58%). Plans placed cancer drugs and orphan drugs on the highest tier of their formularies more often than noncancer drugs and nonorphan drugs (64% vs 56% and 68% vs 49%, respectively).

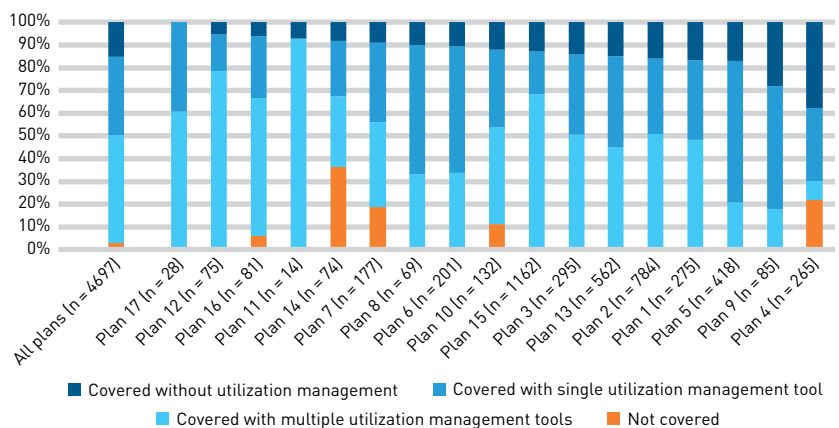
FIGURE 1. Coverage Policy Restrictiveness of Drugs Approved by the FDA in 2018, by Health Plan^a



^aNumber of coverage policies issued by health plans in parentheses. In 2 instances, health plan 4 did not provide coverage (revelfenacin for maintenance treatment of patients with chronic obstructive pulmonary disease and rifamycin for travelers' diarrhea).

Source: Authors' analysis of data examining how 17 large commercial health plans covered 2018 FDA-approved drugs for their enrollees at 1 year after a drug's approval date.

FIGURE 2. Formulary Utilization Management of Drugs Approved by the FDA in 2018, by Health Plan^a



^aNumber of formulary decisions issued by health plans in parentheses. We considered each instance a plan included a drug in their formulary separately (ie, if a plan included erenumab in 5 formularies, each of the 5 instances are treated as separate observations). We considered 3 types of utilization management tools: prior authorizations, step therapy protocols, and placement on the highest tier.

Source: Authors' analysis of data examining how 17 large commercial health plans covered 2018 FDA-approved drugs for their enrollees at 1 year after a drug's approval date.

Variation in Drug Coverage Across Health Plans

Coverage policies. Health plans imposed coverage restrictions with different frequencies (range, 7%-52% of coverage policies) (Figure 1). Four plans imposed coverage restrictions in a majority of their policies; 7 plans did so in fewer than one-third of their policies.

Drug formularies. All plans imposed UM criteria with different frequencies (range, 62%-100% of formulary entries) (Figure 2). Eight plans imposed UM in more than 90% of formulary entries; 2 plans did so in fewer than 75% of entries.

DISCUSSION

Health plan adoption of novel technology is critical to patients' access to innovative therapies, but plans must balance drug costs with providing their enrollees access to innovative treatments. Our study provides a snapshot of patients' access to 2018 FDA-approved drugs and important lessons for how plans adopt novel therapies in general.

We found that plans inconsistently issued coverage information (some issued coverage policies whereas others issued formularies) for all but 1 drug in our sample. This inconsistency is notable as it suggests that enrollees in different plans have access to different levels of drug coverage information.⁹

Our findings suggest that plans grappled with drugs approved in 2018; overall, health plans imposed coverage restrictions in more than one-third of their coverage policies and UM criteria in more than 80% of formulary entries. Plans tended to offer more generous access to some categories of drugs than others. For instance, plans less often imposed coverage restrictions on biosimilars, orphan drugs, and cancer treatments compared with drugs not in those categories. Our findings highlight often complex, and sometimes conflicting, patient access criteria. For example, whereas plans less often imposed coverage restrictions on cancer and orphan treatments, plans most often placed these drugs on the highest cost-sharing formulary tiers.¹⁰

Some plans more often restricted their enrollees' access to drugs than other plans. This variation can have important implications, as it means patients' access to novel therapies may depend on the plan in which they are enrolled. Future studies should examine the plan characteristics associated with drug coverage generosity. For example, research that examines whether plans with higher premiums provide more generous access to innovative therapies, or whether plans in more competitive markets are more likely to adopt novel drugs, would be valuable.

For novel drug approvals, health plans must typically rely only on a product's registration study, which may be placebo controlled, when adjudicating drug coverage. A lack of information on how a novel drug performs in a real-world setting relative to existing treatments complicates decision-making. Future research should examine how plans adjust drug coverage as a drug's evidence base matures. This research would improve decision-making transparency and provide valuable information on how plans use different types of evidence when formulating drug coverage policies. Early engagement between drug manufacturers and health plans would also be beneficial, as it may help ensure that plans have faster access to the evidence they need, thus speeding patients' access to care. Expanded use of "core outcomes sets," which are standardized outcomes agreed upon by experts and stakeholders to include in clinical studies, may also speed patients' access to care.¹¹

Limitations

Our study has a number of limitations. First, our findings may not generalize to other commercial plans, to public payers (eg, Medicaid), or to other drug approval years. Second, we do not account for

when plans provide access to drugs in the absence of promulgated coverage policies or for enrollee power to appeal coverage denials. Third, we did not account for differences in the health status of each health plan's enrollee population, which may affect how a plan prioritizes coverage of different drugs. Finally, although we analyzed health plan assignment of drugs to their most expensive patient co-payment tiers, we did not have information to compare the magnitude of required co-payments.

CONCLUSIONS

We examined US health plan adoption of 2018 FDA-approved drugs and found important differences in how plans communicated their drug coverage decisions to their enrollees. Plans tended to cover to particular categories of drugs (eg, biosimilars, orphan drugs, and cancer treatments) more generously than drugs not in those categories. Some health plans covered 2018 FDA-approved drugs more generously than others, suggesting that a patient's plan may have affected their access to innovative therapies. ■

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2018 Approvals Manuscript Supplementary File

Supplementary Tables

eAppendix Table 1: Characteristics of drugs FDA approved in 2018

See accompanying Excel file.

SOURCE: Authors' analysis of FDA's documentation for drugs approved in 2018.

NOTES: We excluded five non-marketed drugs from all further analysis.

eAppendix Table 1. Characteristics of drugs FDA approved in 2018

Active ingredient	Brand	Indication	FDA approval date	Marketed 1-year post-approval?	Cancer treatment	Biosimilar	Orphan drug	Any expedited approval	Priority review	Fast track	Accelerated approval	Breakthrough therapy
lutetium dotatate lu-177	Lutathera	Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	1/26/18	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No
bictegravir, embitcitabine, tenofovir alafenamide	Biktarvy	Human immunodeficiency virus type 1	2/7/18	Yes	No	No	No	Yes	Yes	No	No	No
ivacaftor; ivacaftor, tezacaftor	Symdeko	Cystic fibrosis (CF)	2/12/18	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes
apalutamide	Erleada	Non-metastatic, castration-resistant prostate cancer	2/14/18	Yes	Yes	No	No	Yes	Yes	Yes	No	No
ibalizumab-uiyk	Trogarzo	Multidrug resistant HIV	3/6/18	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes
tildrakizumab-asmn	Ilumya	Plaque Psoriasis	3/20/18	Yes	No	No	No	No	No	No	No	No
burosumab-twza	Crysvita	X-linked hypophosphatemia (XLH)	4/17/18	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes
fostamatinib	Tavalisse	Thrombocytopenia in adult patients with chronic immune thrombocytopenia	4/17/18	Yes	No	No	Yes	No	No	No	No	No

avatrombopag	Doptelet	Thrombocytopenia in adult patients with chronic liver disease	5/21/18	Yes	No	No	No	Yes	Yes	No	No	No
pegvaliase-pqpz	Palynziq	Reduce blood phenylalanine concentrations in adult patients with phenylketonuria	5/24/18	Yes	No	No	Yes	Yes	Yes	Yes	No	No
baricitinib	Olumiant	Rheumatoid Arthritis	5/31/18	Yes	No	No	No	No	No	No	No	No
pegfilgrastim-jmdb	Fulphila	Patients with Cancer Receiving Myelosuppressive Chemotherapy	6/4/18	Yes	No	Yes	No	No	No	No	No	No
moxidectin	Moxidectin	Onchocerciasis	6/13/18	No	No	No	Yes	Yes	Yes	No	No	No
cannabidiol	Epidiolex	Seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS)	6/25/18	Yes	No	No	Yes	Yes	Yes	Yes	No	No
plazomicin	Zemdri	Complicated Urinary Tract Infections (cUTI), including Pyelonephritis	6/25/18	Yes	No	No	No	Yes	Yes	No	No	No
encorafenib	Braftovi	Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation	6/27/18	Yes	Yes	No	Yes	No	No	No	No	No

binimetinib	Mektovi	Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation	6/27/18	Yes	Yes	No	Yes	No	No	No	No	No
tecovirimat	Tpoxx	Treatment of Human Smallpox Disease	7/13/18	No	No	No	Yes	Yes	Yes	Yes	No	No
tafenoquine	Krintafel	Radical cure (prevention of relapse) of Plasmodium vivax malaria	7/20/18	Yes	No	No	Yes	Yes	Yes	No	No	Yes
filgrastim-aafi	Nivestym	Patients Undergoing Autologous Peripheral Blood Progenitor Cell Collection and Therapy	7/20/18	Yes	No	Yes	No	No	No	No	No	No
filgrastim-aafi	Nivestym	Patients with Acute Myeloid Leukemia Receiving Induction or Consolidation Chemotherapy	7/20/18	Yes	No	Yes	No	No	No	No	No	No
filgrastim-aafi	Nivestym	Patients with Cancer Receiving Myelosuppressive Chemotherapy	7/20/18	Yes	No	Yes	No	No	No	No	No	No

filgrastim-aafi	Nivestym	Patients with Cancer Undergoing Bone Marrow Transplantation	7/20/18	Yes	No	Yes	No	No	No	No	No	No
filgrastim-aafi	Nivestym	Patients with Severe Chronic Neutropenia	7/20/18	Yes	No	Yes	No	No	No	No	No	No
ivosidenib	Tibsovo	Acute Myeloid Leukemia	7/20/18	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No
elagolix	Orilissa	Endometriosis	7/23/18	Yes	No	No	No	Yes	Yes	No	No	No
fish oil triglycerides	Omegaven	Parenteral nutrition-associated cholestasis (PNAC)	7/27/18	Yes	No	No	Yes	Yes	Yes	Yes	No	No
lusutrombopag	Mulpleta	Thrombocytopenia in adult patients with chronic liver disease	7/31/18	Yes	No	No	No	Yes	Yes	Yes	No	No
mogamulizumab-kpkc	Poteligeo	Relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS)	8/8/18	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes
segesterone acetate and ethinyl estradiol vaginal system	Annovera	Pregnancy prevention	8/10/18	Yes	No	No	No	No	No	No	No	No
migalastat	Galafold	Fabry Disease	8/10/18	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No
patisiran	Onpatro	Hereditary transthyretin-mediated amyloidosis	8/10/18	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes

stiripentol	Diacomit	Seizures associated with Dravet syndrome	8/20/18	Yes	No	No	Yes	Yes	Yes	No	No	No
cenegermin-bkbj	Oxervate	Neurotrophic keratitis	8/22/18	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes
lanadelumab	Takhzyro	Hereditary angioedema	8/23/18	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes
eravacycline	Xerava	Complicated Intra-abdominal Infections	8/27/18	Yes	No	No	No	Yes	Yes	Yes	No	No
doravirine	Pifeltro	Human immunodeficiency virus type 1	8/30/18	Yes	No	No	No	No	No	No	No	No
moxetumomab pasudotox-tdfk	Lumoxiti	Relapsed or refractory hairy cell leukemia	9/13/18	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No
fremanezumab-vfrm	Ajovy	Migraine	9/14/18	Yes	No	No	No	Yes	Yes	No	No	No
duvelisib	Copiktra	Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)	9/24/18	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No
duvelisib	Copiktra	Follicular Lymphoma (FL)	9/24/18	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No
galcanezumab-gnlm	Emgality	Migraine	9/27/18	Yes	No	No	No	No	No	No	No	No
dacomitinib	Vizimpro	Metastatic non-small cell lung cancer (NSCLC)	9/27/18	Yes	Yes	No	Yes	Yes	Yes	No	No	No
cemiplimab-rwlc	Libtayo	Cutaneous squamous cell carcinoma	9/28/18	Yes	Yes	No	No	Yes	Yes	No	No	Yes

sarecycline	Seysara	Inflammatory lesions of non-nodular moderate to severe acne vulgaris	10/1/18	Yes	No	No	No	No	No	No	No	No
omadacycline	Nuzyra	Acute Bacterial Skin and Skin Structure Infections	10/3/18	Yes	No	No	No	Yes	Yes	Yes	No	No
omadacycline	Nuzyra	Community-Acquired Bacterial Pneumonia (CABP)	10/3/18	Yes	No	No	No	Yes	Yes	Yes	No	No
elapegamase-ivlr	Revcovi	Adenosine deaminase severe combined immune deficiency (ADA-SCID)	10/5/18	Yes	No	No	Yes	Yes	Yes	Yes	No	No
inotersen	Tegsedi	Hereditary transthyretin-mediated amyloidosis	10/5/18	Yes	No	No	Yes	Yes	Yes	Yes	No	No
talazoparib	Talzenna	Germline BRCA-mutated HER2-negative Metastatic Breast Cancer	10/16/18	Yes	Yes	No	No	Yes	Yes	No	No	No
baloxavir marboxil	Xofluza	Acute uncomplicated influenza	10/24/18	Yes	No	No	No	Yes	Yes	No	No	No
adalimumab-adaz	Hyrimoz	Ankylosing Spondylitis	10/31/18	No	No	Yes	No	No	No	No	No	No
adalimumab-adaz	Hyrimoz	Crohn's Disease	10/31/18	No	No	Yes	No	No	No	No	No	No
adalimumab-adaz	Hyrimoz	Plaque Psoriasis	10/31/18	No	No	Yes	No	No	No	No	No	No

adalimumab-adaz	Hyrimoz	Polyarticular Juvenile Idiopathic Arthritis	10/31/18	No	No	Yes	No	No	No	No	No	No
adalimumab-adaz	Hyrimoz	Psoriatic Arthritis	10/31/18	No	No	Yes	No	No	No	No	No	No
adalimumab-adaz	Hyrimoz	Rheumatoid Arthritis	10/31/18	No	No	Yes	No	No	No	No	No	No
adalimumab-adaz	Hyrimoz	Ulcerative Colitis	10/31/18	No	No	Yes	No	No	No	No	No	No
lorlatinib	Lorbrena	Anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer	11/2/18	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes
pegfilgrastim-cbqv	Udenyca	Patients with Cancer Receiving Myelosuppressive Chemotherapy	11/2/18	Yes	No	Yes	No	No	No	No	No	No
revefenacin	Yupelri	Maintenance treatment of patients with chronic obstructive pulmonary disease	11/8/18	Yes	No	No	No	No	No	No	No	No
rifamycin sodium	Aemcolo	Travelers' Diarrhea	11/16/18	Yes	No	No	No	Yes	Yes	Yes	No	No
emapalumab-lzsg	Gamifant	Primary hemophagocytic lymphohistiocytosis	11/20/18	Yes	No	No	Yes	Yes	Yes	No	No	Yes

glasdegib	Daurismo	Newly-diagnosed acute myeloid leukemia (AML)	11/21/18	Yes	Yes	No	Yes	Yes	Yes	No	No	No
larotrectinib	Vitrakvi	Solid tumors	11/26/18	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes
rituximab-abbs	Truxima	Non-Hodgkin Lymphoma (NHL)	11/28/18	No	Yes	No	No	No	No	No	No	No
amifampridine	Firdapse	Lambert-Eaton myasthenic syndrome	11/28/18	Yes	No	No	Yes	Yes	Yes	No	No	Yes
gilteritinib	Xospata	Acute Myeloid Leukemia	11/28/18	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No
trastuzumab-pkrb	Herzuma	Adjuvant Breast Cancer	12/14/18	No	Yes	Yes	No	No	No	No	No	No
trastuzumab-pkrb	Herzuma	Metastatic Breast Cancer	12/14/18	No	Yes	Yes	No	No	No	No	No	No
prucalopride	Motegrity	Chronic idiopathic constipation	12/14/18	Yes	No	No	No	No	No	No	No	No
calaspargase pegol-mknl	Asparlas	Acute Lymphoblastic Leukemia	12/20/18	Yes	Yes	No	No	No	No	No	No	No
tagraxofusp-erzs	Elzonris	Blastic plasmacytoid dendritic cell neoplasm	12/21/18	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes
ravulizumab-cwvz	Ultomiris	Paroxysmal Nocturnal Hemoglobinuria (PNH)	12/21/18	Yes	No	No	Yes	Yes	Yes	No	No	No

eAppendix Table 2. Health plans included in the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database

- Aetna Inc.
- Anthem Inc.
- Blue Cross Blue Shield Massachusetts
- Blue Cross Blue Shield Michigan
- Blue Cross Blue Shield New Jersey
- Blue Cross Blue Shield North Carolina
- Blue Cross Blue Shield Tennessee
- Carefirst Inc.
- Centene Corporation
- Cigna
- EmblemHealth
- Guidewell (Florida's Blue Cross and Blue Shield)
- Health Care Service Corporation (HCSC)
- Highmark Inc.
- Humana Inc.
- Independence Health Group
- UnitedHealth Group

SOURCE: 2019 Accident and Health Policy Experience Report. Market Share Reports For the Top 125 Accident and Health Insurance Groups and Companies by State and Countrywide. Page 283. Available here: <https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf>

NOTES: Health plans are listed in alphabetical order. Five of the largest 22 plans were excluded because they only offer Medicare and/or Medicaid products (n=3) or did not make a sufficient number of policies publicly available (n=2). HCSC is comprised of BCBS Plans in Illinois, Montana, New Mexico, Oklahoma, and Texas.

eAppendix Table 3: SPEC Database health plan inclusion criteria

Attribute	Criteria
Plan size	SPEC includes 17 of the largest US commercial health plans (in terms of premiums earned)—information that represents the majority of the country’s largest health plans in terms of covered lives. We identified these plans from the 2015 NAIC Accident and Health Policy Experience Report.
Lines of business	SPEC includes coverage policies pertaining to the included plans’ commercial lines of business (not their Medicaid or Medicare offerings).
Publicly available information	SPEC includes only health plans that make their coverage policies publicly available (Kaiser Permanente and UPMC Health Plan) do not issue a sufficient number of publicly available policies and thus are not included in SPEC).

SOURCE: Inclusion criteria for health plans indexed the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database.

eAppendix Table 4: Coverage policy details for drugs FDA approved in 2018

Characteristic (number of decisions)	Frequency by restrictiveness category*		Frequency plans applied different restriction types					
	Consistent with FDA label (% of all decisions)	More restrictive than FDA label (% of all decisions)	Prescriber requirement (% of all decisions)	Step therapy protocol (% of restricted decisions)	Patient subgroup restriction (% of restricted decisions)	Other restriction (% of restricted decisions)	Single restriction type (% of restricted decisions)	Multiple restriction types (% of restricted decisions)
Overall (n= 742)	465 (63%)	275 (37%)	133 (18%)	191 (69%)	157 (57%)	2 (1%)	201 (73%)	74 (27%)
Approval characteristic								
Non-orphan disease (n= 337)	197 (58%)	138 (41%)	39 (12%)	131 (95%)	48 (35%)	0 (0%)	97 (70%)	41 (30%)
Orphan disease (n= 405)	268 (66%)	137 (34%)	94 (23%)	60 (44%)	109 (80%)	2 (1%)	104 (76%)	33 (24%)
Non-cancer treatment (n= 508)	260 (51%)	248 (49%)	96 (19%)	180 (73%)	134 (54%)	1 (0%)	177 (71%)	69 (28%)
Cancer treatment (n= 234)	205 (88%)	29 (12%)	37 (16%)	11 (38%)	23 (79%)	1 (3%)	24 (83%)	5 (17%)
Novel molecules (n= 599)	348 (58%)	249 (42%)	122 (20%)	166 (67%)	156 (63%)	2 (1%)	175 (70%)	74 (30%)
Biosimilar (n= 143)	117 (82%)	26 (18%)	11 (8%)	25 (96%)	1 (4%)	0 (0%)	26 (100%)	0 (0%)
Standard approval (n= 274)	162 (59%)	111 (41%)	30 (11%)	104 (94%)	43 (39%)	0 (0%)	75 (68%)	36 (32%)
Any expedited program (n= 468)	303 (65%)	164 (35%)	103 (22%)	87 (53%)	114 (70%)	2 (1%)	126 (77%)	38 (23%)
Accelerated approval (n= 52)	49 (94%)	3 (6%)	11 (21%)	1 (33%)	2 (67%)	0 (0%)	3 (100%)	0 (0%)
Breakthrough therapy (n= 186)	115 (62%)	71 (38%)	47 (25%)	28 (39%)	61 (86%)	0 (0%)	53 (75%)	18 (25%)
Fast-track (n= 272)	163 (60%)	109 (40%)	68 (25%)	59 (54%)	76 (70%)	1 (1%)	83 (76%)	26 (24%)

Priority review (n=445)	303 (65%)	164 (35%)	103 (22%)	87 (53%)	114 (70%)	2 (1%)	126 (77%)	38 (23%)
Health plan								
Plan 1 (n= 50)	36 (72%)	14 (28%)	0 (0%)	8 (57%)	10 (71%)	0 (0%)	10 (71%)	4 (29%)
Plan 2 (n= 55)	27 (49%)	28 (51%)	0 (0%)	21 (75%)	13 (46%)	0 (0%)	22 (79%)	6 (21%)
Plan 3 (n= 57)	43 (75%)	14 (25%)	8 (14%)	9 (64%)	11 (79%)	0 (0%)	8 (57%)	6 (43%)
Plan 4 (n= 30)	20 (67%)	8 (27%)	6 (20%)	6 (75%)	8 (100%)	0 (0%)	2 (25%)	6 (75%)
Plan 5 (n= 50)	25 (50%)	25 (50%)	15 (30%)	17 (68%)	14 (56%)	1 (4%)	19 (76%)	6 (24%)
Plan 6 (n= 56)	36 (64%)	20 (36%)	18 (32%)	17 (85%)	11 (55%)	0 (0%)	12 (60%)	8 (40%)
Plan 7 (n= 47)	34 (72%)	13 (28%)	0 (0%)	5 (38%)	11 (85%)	0 (0%)	10 (77%)	3 (23%)
Plan 8 (n= 21)	14 (67%)	7 (33%)	0 (0%)	4 (57%)	7 (100%)	0 (0%)	3 (43%)	4 (57%)
Plan 9 (n= 41)	38 (93%)	3 (7%)	0 (0%)	1 (33%)	2 (67%)	0 (0%)	3 (100%)	0 (0%)
Plan 10 (n= 55)	27 (47%)	28 (51%)	41 (75%)	25 (89%)	9 (32%)	0 (0%)	22 (79%)	6 (21%)
Plan 11 (n= 56)	37 (66%)	19 (34%)	5 (9%)	14 (74%)	8 (42%)	0 (0%)	16 (84%)	3 (16%)
Plan 12 (n= 25)	12 (48%)	13 (52%)	5 (20%)	9 (69%)	8 (62%)	0 (0%)	9 (69%)	4 (31%)
Plan 13 (n= 14)	11 (79%)	3 (21%)	0 (0%)	1 (33%)	3 (100%)	0 (0%)	2 (67%)	1 (33%)
Plan 14 (n= 26)	17 (65%)	9 (35%)	4 (15%)	3 (33%)	8 (89%)	0 (0%)	7 (78%)	2 (22%)
Plan 15 (n= 59)	33 (56%)	26 (44%)	3 (5%)	21 (81%)	10 (38%)	1 (4%)	20 (77%)	6 (23%)
Plan 16 (n= 48)	25 (52%)	23 (48%)	14 (29%)	14 (61%)	14 (61%)	0 (0%)	18 (78%)	5 (22%)
Plan 17 (n= 52)	30 (58%)	22 (42%)	14 (27%)	16 (73%)	10 (45%)	0 (0%)	18 (82%)	4 (18%)

SOURCE: Authors' analysis of data examining how 17 large commercial health plans covered 2018 FDA approved drugs for their enrollees one year post a drug's approval date.

NOTES: Number of coverage policies issued by health plans in parentheses. *In two instances, health plan 4 did not provide coverage (revefenacin for maintenance treatment of patients with chronic obstructive pulmonary disease & rifamycin for travelers' diarrhea).

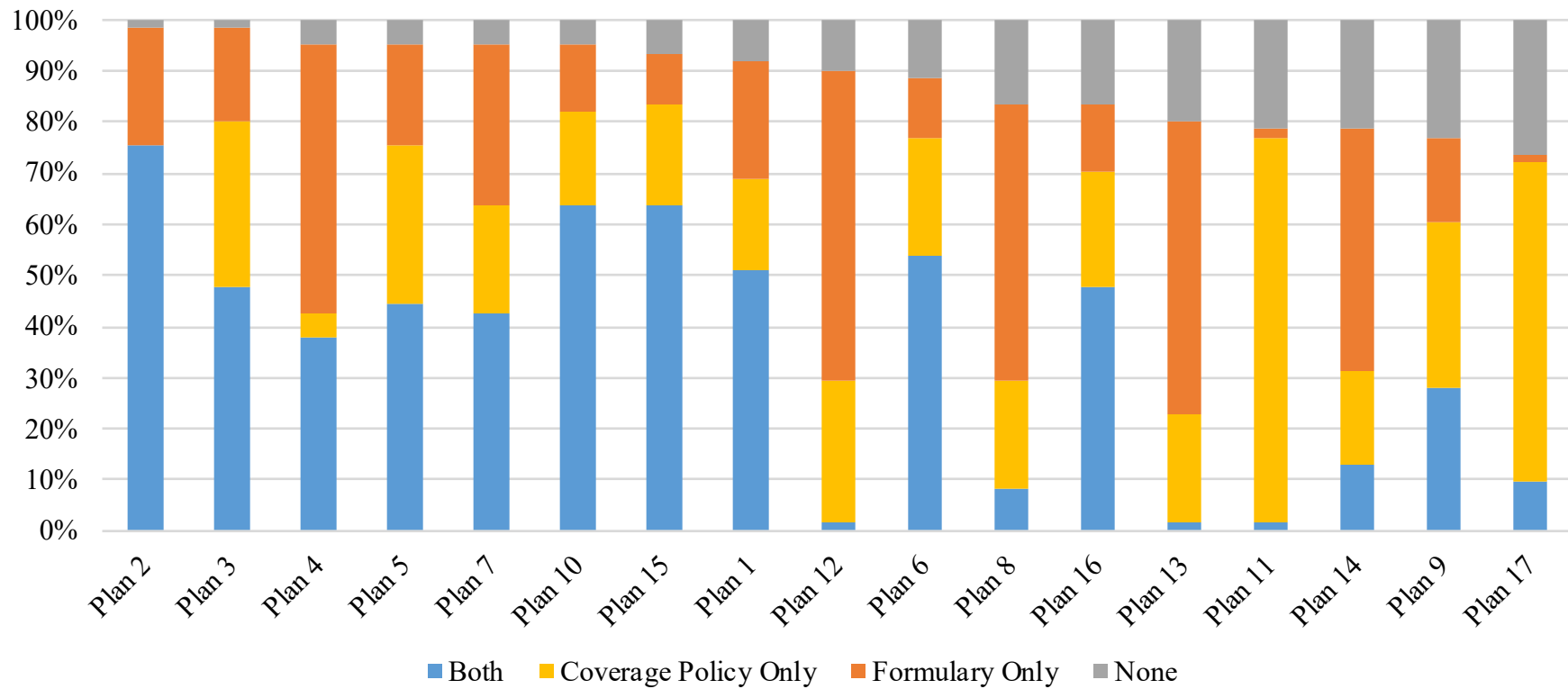
eAppendix Table 5: Formulary details for drugs FDA approved in 2018

Drugs approved in 2018	Formulary coverage summary			Formulary restriction details (when featured & covered)					
Active ingredient	Featured	Covered	% Covered	Quantity limit	Age limit	Any restriction	Prior authorization	Step therapy	Highest tier
All drugs	4697	4557	97%	73%	0%	84%	73%	2%	59%
Approval characteristic									
Non-orphan disease	2336	2238	96%	1597	0	1728	1307	94	1093
Orphan disease	2361	2319	98%	1812	4	2109	2005	13	1576
Non-cancer treatment	3216	3097	96%	2127	0	2441	1949	106	1729
Cancer treatment	1481	1460	99%	1282	4	1396	1363	1	940
Novel molecules	4306	4174	97%	3237	4	3545	3044	107	2456
Biosimilar	391	383	98%	172	0	292	268	0	213
Standard review	1531	1462	95%	1036	0	1230	1026	85	796
Any expedited program	3166	3095	98%	2373	4	2607	2286	22	1873
Accelerated approval	467	464	99%	419	2	454	442	1	322
Breakthrough therapy	820	797	97%	613	2	686	622	3	527
Fast-track	1623	1597	98%	1201	1	1426	1293	11	1013
Priority review	3166	3095	98%	2373	4	2607	2286	22	1873
Drugs									
amifampridine	94	89	95%	75	0	83	83	0	72
apalutamide	131	131	100%	124	0	129	129	0	73
avatrombopag	58	54	93%	50	0	48	48	0	47
baloxavir marboxil	154	153	99%	104	0	55	1	0	54
baricitinib	64	59	92%	50	0	55	52	8	52
bictegravir, embitcitabine, tenofovir alafenamide	156	156	100%	90	0	74	5	0	69
binimetinib	131	131	100%	108	0	121	118	0	85
burosumab-twza	17	17	100%	12	0	13	13	0	13

calaspargase pegol-mknl	13	8	62%	8	0	8	8	0	3
cannabidiol	128	128	100%	31	0	122	117	4	84
cemiplimab-rwlc	18	18	100%	10	0	14	10	0	7
cenegermin-bkbj	88	87	99%	67	0	81	75	3	66
dacomitinib	124	122	98%	110	0	118	119	0	84
doravirine	107	101	94%	0	0	57	0	0	57
duvelisib	123	121	98%	115	0	118	113	0	83
elagolix	101	96	95%	86	0	90	90	2	24
elapegademase-ivlr	56	56	100%	23	0	28	24	0	17
emapalumab-lzsg	17	17	100%	12	0	17	17	0	8
encorafenib	133	132	99%	110	0	123	119	0	87
epoetin alfa-epbx	123	122	99%	67	0	118	117	0	77
eravacycline	18	18	100%	0	0	7	0	0	7
erenumab-aooe	90	89	99%	82	0	88	88	5	19
filgrastim-aafi	83	81	98%	29	0	55	46	0	44
fish oil triglycerides	13	12	92%	0	0	3	0	0	6
fosnetupitant chloride hydrochloride; palonosetron hydrochloride	138	133	96%	123	0	114	87	11	66
fostamatinib	84	83	99%	71	0	81	81	0	75
fremanezumab-vfrm	54	45	83%	40	0	43	45	7	25
galcanezumab-gnlm	130	130	100%	116	0	128	124	11	23
gilteritinib	124	123	99%	115	1	121	122	0	86
glasdegib	124	123	99%	115	1	117	117	0	86
ibalizumab-uiyk	17	17	100%	12	0	13	12	0	11
inotersen	89	87	98%	78	0	84	80	0	65
ivacaftor; ivacaftor, tezacaftor	81	81	100%	67	0	79	78	0	67
ivosidenib	127	126	99%	110	0	124	123	0	81
lanadelumab	69	64	93%	54	0	62	59	0	53

larotrectinib	128	128	100%	116	0	126	125	0	84
lofexidine hydrochloride	78	77	99%	63	0	56	30	0	38
lorlatinib	122	121	99%	110	2	119	120	2	87
lusutrombopag	93	93	100%	80	0	83	82	0	45
lutetium dotatate lu-177	6	6	100%	6	0	6	6	0	2
migalastat	94	94	100%	80	0	91	86	0	70
mogamulizumab-kpkc	18	18	100%	0	0	7	0	0	7
moxetumomab pasudotox-tdfk	18	18	100%	12	0	14	12	0	7
omadacycline	86	85	99%	54	0	61	22	0	48
patisiran	18	18	100%	12	0	18	17	0	14
pegfilgrastim-cbqv	96	94	98%	37	0	59	52	0	49
pegfilgrastim-jmdb	89	86	97%	39	0	60	53	0	47
pegvaliase-pqpz	86	84	98%	49	0	78	78	5	63
plazomicin	19	19	100%	0	0	8	0	0	8
prucalopride	42	32	76%	31	0	30	21	14	16
ravulizumab-cwvz	16	11	69%	11	0	11	11	0	11
revefenacin	55	45	82%	0	0	34	25	5	29
rifamycin sodium	62	54	87%	48	0	35	22	0	32
sarecycline	35	24	69%	18	0	23	4	17	17
segesterone acetate and ethinyl estradiol vaginal system	16	16	100%	11	0	5	0	0	9
sodium zirconium cyclosilicate	78	73	94%	25	0	48	22	8	42
stiripentol	84	83	99%	74	0	77	77	2	77
tafenoquine	116	111	96%	59	0	43	7	0	40
tagraxofusp-erzs	16	11	69%	11	0	11	11	0	5
talazoparib	125	123	98%	110	0	120	119	0	81
tildrakizumab-asmn	24	23	96%	19	0	23	22	7	23

SOURCE: Authors' analysis of data examining how 17 large commercial health plans covered 2018 FDA approved drugs for their enrollees one year post a drug's approval date.



eAppendix Figure. Availability of coverage information for the 61 marketed drugs approved by FDA in 2018

SOURCE: Authors' analysis of data examining how 17 large commercial health plans covered 2018 FDA approved drugs for their enrollees one year post a drug's approval date.

NOTES: In some cases, plans included a drug in some of their formularies but not others. We considered information to be available when a plan included a drug in at least one formulary.

eAppendix Figure . Availability of coverage information for the 61 marketed drugs approved by FDA in 2018

Health plan	None		Coverage Policy Only		Formulary Only		Both		Number of decisions (at drug level)	Any Coverage (%)
	# of decisions	%	# of decisions	%	# of decisions	%	# of decisions	%		
Plan 2	1	2%	0	0%	14	23%	46	75%	61	98%
Plan 3	1	2%	20	33%	11	18%	29	48%	61	98%
Plan 4	3	5%	3	5%	32	52%	23	38%	61	95%
Plan 5	3	5%	19	31%	12	20%	27	44%	61	95%
Plan 7	3	5%	13	21%	19	31%	26	43%	61	95%
Plan 10	3	5%	11	18%	8	13%	39	64%	61	95%
Plan 15	4	7%	12	20%	6	10%	39	64%	61	93%
Plan 1	5	8%	11	18%	14	23%	31	51%	61	92%
Plan 12	6	10%	17	28%	37	61%	1	2%	61	90%
Plan 6	7	11%	14	23%	7	11%	33	54%	61	89%
Plan 8	10	16%	13	21%	33	54%	5	8%	61	84%
Plan 16	10	16%	14	23%	8	13%	29	48%	61	84%
Plan 13	12	20%	13	21%	35	57%	1	2%	61	80%
Plan 11	13	21%	46	75%	1	2%	1	2%	61	79%
Plan 14	13	21%	11	18%	29	48%	8	13%	61	79%
Plan 9	14	23%	20	33%	10	16%	17	28%	61	77%
Plan 17	16	26%	38	62%	1	2%	6	10%	61	74%
All plans	124	12%	275	27%	277	27%	361	35%	1037	88%