

Examining US Commercial Health Plans' Use of Step Therapy Protocols for Specialty Drugs: An Empirical Analysis

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BACKGROUND AND OBJECTIVE

- Step therapy protocols require patients to first fail an alternative cheaper treatment before gaining access to a more expensive drug.
- Health plans use step therapy protocols to optimize prescribing, but there is a risk that their inappropriate application can impede patients’ access to much needed treatments.
- We determined (i) the proportion of coverage policies that included a step therapy protocol, (ii) the average number of steps each health plan incorporated in their step therapy protocols, and (iii) the top indications requiring a step edit.

METHODS

- The starting point for this work 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 (representing >130 million lives).
- SPEC includes 282 drugs, corresponding to 575 drug-indication pairs and 7,571 coverage policies as of December 2019. For example, because vedolizumab is indicated for Crohn’s disease and ulcerative colitis it is featured twice in SPEC.
- We considered a plan to have applied a step therapy protocol if it required patients to first fail at least one prior alternative treatment before accessing a particular drug.
- We examined the frequency plans applied step edits by health plan and by indication.
- We identified the diseases for which plans most often applied step therapy protocols. We report findings for diseases for which SPEC includes at least 4 indicated drugs,

RESULTS

- Overall, health plans applied step therapy protocols in 38.9% (2,872/7,380) of their coverage policies (range 20.6 to 57.5%) (Figure 1).
- On average, health plans included 1.5 steps in their step therapy protocols (standard deviation 0.8).
- Plans included a single step in their protocols 66.6% (1,912/2,872) of the time, two steps 22.7% (652/2,872), three steps 7.6% (218/2,872), and four or more steps 3.1% (90/2,872).
- The five indications for which plans most often applied step therapy protocols include: chronic migraine (100% of decisions, mean number of steps 2.2), plaque psoriasis (92%, 2.0 steps), ankylosing spondylitis (82%, 2.0 steps), rheumatoid arthritis (78%, 2.0 steps), and psoriatic arthritis (74%, 1.9 steps) (Table 1).

RESULTS (CONTINUED)

Figure 1. Percentage of health plan coverage decisions with step therapy protocols

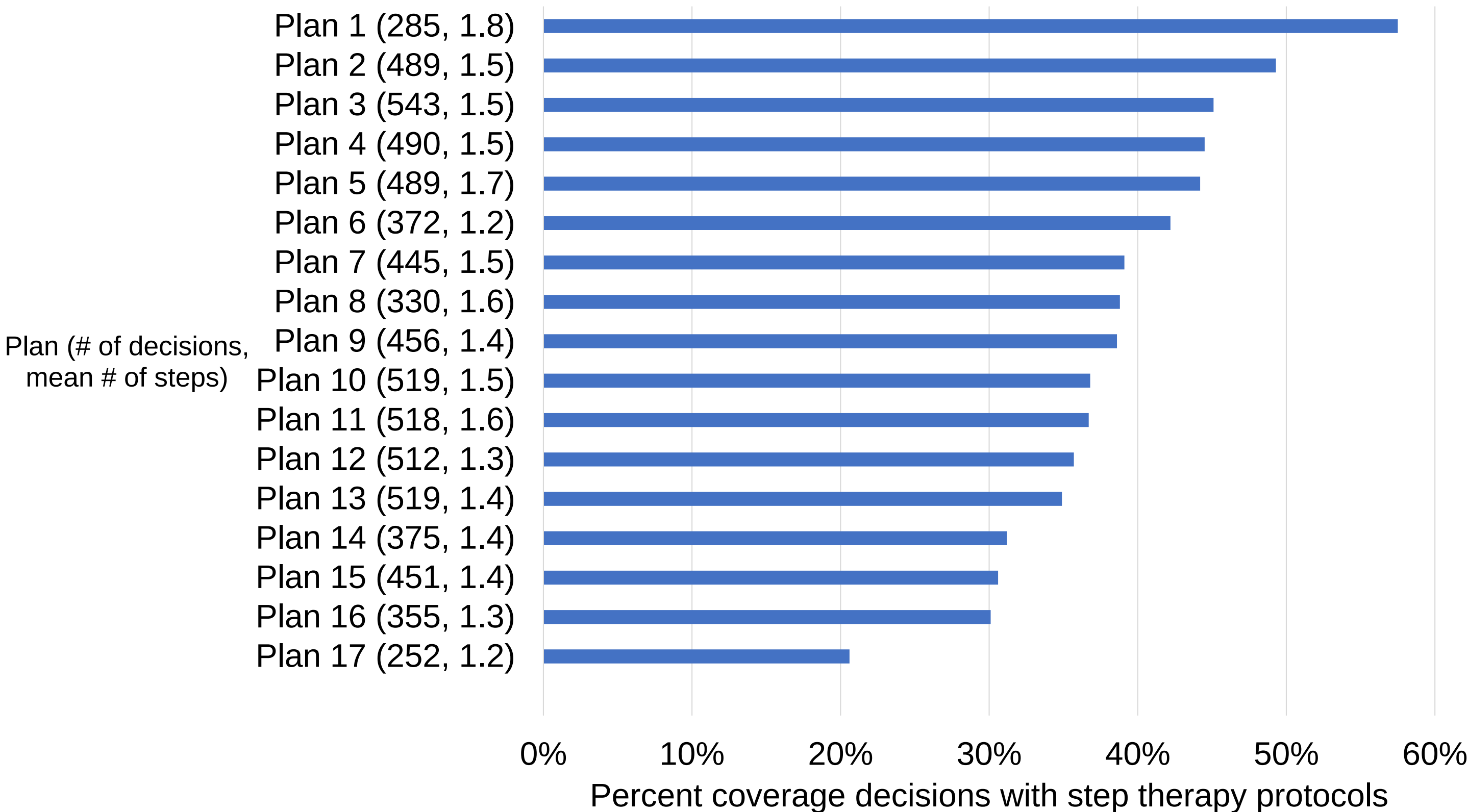


Table 1. Diseases for which health plans most often applied step therapy protocols

Indication	Mean number of steps	# of drugs	# of decisions	# of decisions with a step edit	% of decisions with a step edit
Chronic Migraine	2.2	4	46	46	100%
Plaque Psoriasis	2.0	14	194	178	92%
Ankylosing Spondylitis	2.0	9	134	110	82%
Rheumatoid Arthritis	2.0	15	222	174	78%
Adult Psoriatic Arthritis (PsA)	1.9	14	202	150	74%
Polyarticular Juvenile Idiopathic Arthritis	1.5	4	58	42	72%
Ulcerative Colitis	1.7	8	113	61	54%
Hepatitis C	1.5	12	117	55	47%
Crohn's Disease	1.5	8	130	60	46%
Pediatric Crohn's Disease	1.1	4	63	27	43%
Patients with Acute Myeloid Leukemia Receiving Induction or Consolidation Chemotherapy	1.2	4	51	21	41%
Patients with Cancer Receiving Myelosuppressive Chemotherapy	1.3	6	83	30	36%
Pulmonary arterial hypertension (PAH)	1.2	13	161	56	35%
Multiple Sclerosis	1.8	18	181	46	25%
Anemia Due to Chemotherapy in Patients With Cancer	1.1	4	67	16	24%
Anemia Due to Chronic Kidney Disease	1.1	5	82	19	23%
Type 1 Gaucher disease	1.3	5	74	12	16%
Prostate cancer	1.0	5	45	3	7%
Metastatic Breast Cancer	1.1	6	84	5	6%
Cervical dystonia	1.3	4	68	4	6%

DISCLOSURE

This study was funded by Genentech.