2016 to 2019 Trend in Integrated Total Pharmacy Plus Medical Benefit Drug Spend — Doubling of Members with Extremely High Annual Drug Cost within a 17 Million Commercially Insured Population

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BACKGROUND

- Advances in new innovative therapies – often priced in excess of over $250,000 per year – are frequently used for rare diseases. These have become an increasingly important health care cost-driver. Of 48 new drugs approved in 2019, 21 were for rare diseases.[1] In addition, one-time (e.g., gene) therapies have entered the market at a cost of over $2.1 million.[2,3]
- Utilizers of extremely high-cost drug therapies have prompted increased use of the term "drug super spenders" to describe them.
- Total drug management requires comprehensive medical and pharmacy benefit drug claims and cost data aggregation, at the member level, with drug super spenders identified by clinical condition category.
- Health plans and pharmacy benefit managers need to understand the drug super spender growth rate and develop strategies that provide access to treatment while maintaining health insurance affordability. In addition, they need to ensure the drug therapy is priced proportionately to the value it provides, the lowest cost drug delivery channel is used, and most cost-effective drug therapy regimen is selected.

OBJECTIVE

- To categorize all members in a large commercially insured population by their total drug cost, defined as the combined cost from the pharmacy benefit and drugs covered by medical benefits, and to identify drug super spender members, defined as those with greater than $250,000 in total drug cost per year.
- To determine overall drug super spender prevalence and aggregate cost trends by clinical condition categories.

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METHODS

- We identified all members in a large, commercially insured population with any period of enrollment between January 2016 and December 2019.
- For each calendar year, for each member with any enrollment:
  - The sum of allowed cost was determined for all pharmacy claims plus all medical benefit drug claim lines with a Healthcare Common Procedural Coding System (HCPCS) code defined as a drug.
  - Medical drug claim lines with non-specific drug HCPCS codes, e.g., J3590 "Unclassified biologics," were specifically identified by National Drug Codes (NDC) codes when available on the medical claim.
  - Cost was defined as the plan plus member cost share after network discounts with no further adjustment for drug manufacturer coupons or rebates.
- For drug super spender members (i.e., members with >$250,000 in total drug cost in a calendar year):
  - Drug use for each member was further characterized by drug and drug categories using NDC codes on pharmacy claims and medical claims HCPCS codes +/- NDC codes.
  - Each drug super spender member was assigned a clinical condition category based on the drug accounting for most of their drug expenditures and the ICD-10 diagnosis codes on all medical claims for that member during the four years, 2016 to 2019.
  - For some condition categories, only a single or a few drugs accounting for nearly all drug expense were defined as the "specified" drugs. For example, the specified drugs for spinal muscular atrophy, congenital hypophosphatasia and cystinosis were, nusinersen (Spinraza®), asfotase alfa (Strensiq®), and cysteamine (Procysbi®, Cystaran®, Cystagon®), respectively.
- For other condition categories, a larger set of specified drugs was defined. For example, cancer included many different antineoplastic agents and G-CSF drugs, such as pegfilgrastim (Neulasta®); cystic fibrosis included disease-modifying agents ivacaftor (Kalydeco®), lumacaftor/ivacaftor (Orkambi®), tezacaftor/ivacaftor (Symdeco®), and elexacaftor/tezacaftor/ivacaftor (Trikafta®); and inhaled anti-bacterials (e.g., Cayston®, Tobi®, Bethkis®), dornase alfa (Pulmozyme®) and pancreatic enzymes.
- Descriptive statistics were used to describe the growth in the number of super spenders and their aggregate expense, and to subcategorize these trends by clinical condition categories.

RESULTS

- The analytic population averaged 17.9 million unique members with any eligibility in each calendar year, 2016 to 2019. The analytic population had an average of 9.7 member-months per unique member with eligibility per year.
- Tables 1 and 2 and Figures 1 and 2 show the numbers and aggregate drug cost for all members.

Drug Super Spenders (members with >$250,000 total pharmacy and medical benefit drug cost in a calendar year)

- In 2016, there were 2,994 members (0.017% of all members) accounting for $1,325 million (M) drug spend, which was 6.3% of all drug spend.
- In 2019, there were 5,894 members (0.032% of all members) accounting for $2,579M drug spend, which was 9.7% of all drug spend.

2016 to 2019 Drug Super Spender Trends

- 97% increase in drug super spenders or 2,900 additional drug super spenders in 2019
- 95% increase in drug super spenders costs or additional $1,254M cost for drug super spenders
- Of the $1,254M increase from 2016 to 2019 in drug super spenders total drug expense:
  - Cancer condition categories accounted for $662M (53%) of the total increase, with the largest increases for specified drugs to treat breast, multiple myeloma, lung, kidney and non-Hodgkin's lymphoma cancers.
  - Inherited single gene disorders accounted for $377M (30%) of the total increase with the largest increases seen for hemophilia A and B, cystic fibrosis, spinal muscular atrophy, congenital hypophosphatasia, hereditary angioedema, cystinosis and Duchenne muscular dystrophy drug therapies.
  - The other categories accounting for nearly all the remaining increase in super spender expense from 2016 to 2019 were: the treatment conditions for eculizumab (Soliris®) including hemolytic-uremic syndrome, paroxysmal nocturnal hemoglobinuria, and myasthenia gravis; pulmonary hypertension; multiple sclerosis; and anti-inflammatory biologics.
- The number of unique members in the highest cost band, ≥$750,000 per year, was 256 in 2016 and 464 in 2019 (81% increase), with their total drug cost increasing from $297M in 2016 to $517M in 2019 (74% increase).

TABLE 1

Members by Drug Super Spender Cost Bands

	Members (% of Members)			
Member annual drug spend cost band	2016	2017	2018	2019
≥ $750K	256 (0.001%)	314 (0.002%)	354 (0.002%)	464 (0.003%)
$500K–<$750K	421 (0.002%)	489 (0.003%)	701 (0.004%)	858 (0.005%)
>$250K–<$500K	2,317 (0.013%)	2,838 (0.016%)	3,814 (0.021%)	4,572 (0.025%)
>$250K	**2,994 (0.017%)**	**3,641 (0.021%)**	**4,869 (0.027%)**	**5,894 (0.032%)**
Total membership	17,625,170	17,394,515	18,221,200	18,236,336

Cost Band = sum of total pharmacy claims plus total medical benefit drug claim lines expense for individual member; K = thousands of dollars; Member = distinct member with any pharmacy plus medical benefit eligibility during calendar year; Cost = plan plus member cost share after network discounts with no further adjustment for drug manufacturer coupons or rebates.

TABLE 2

Annual Drug Cost by Member Super Spender Drug Cost Bands

	Cost in $ Millions (% of Cost)			
Member annual drug spend cost band	2016	2017	2018	2019
≥ $750K	$297 (1.4%)	$384 (1.7%)	$417 (1.7%)	$517 (1.9%)
$500K–<$750K	$254 (1.2%)	$290 (1.3%)	$422 (1.7%)	$519 (2.0%)
>$250K–<$500K	$773 (3.7%)	$943 (4.3%)	$1,280 (5.2%)	$1,542 (5.8%)
>$250K	**$1,325 (6.3%)**	**$1,617 (7.4%)**	**$2,119 (8.6%)**	**$2,579 (9.7%)**
Total drug cost	$20,885	$21,972	$24,555	$26,618

Cost Band = sum of total pharmacy claims plus total medical benefit drug claim lines expense for individual member; K = thousands of dollars; Member = distinct member with any pharmacy plus medical benefit eligibility during calendar year; Cost = plan plus member cost share after network discounts with no further adjustment for drug manufacturer coupons or rebates.

FIGURE 1

Drug Super Spenders Trend, 2016 to 2019

Members by Super Spender Cost Band

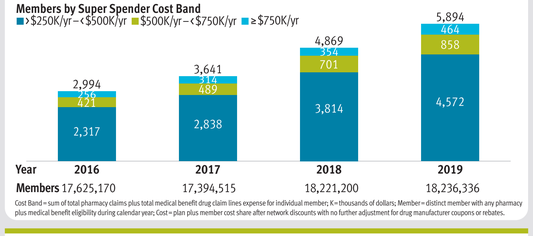

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FIGURE 2

Drug Super Spenders Cost Trend, 2016 to 2019

Drug Cost in Millions by Super Spender Cost Band

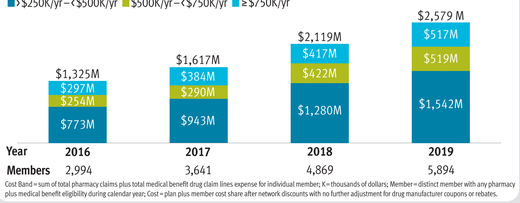

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TABLE 3

Drug Super Spenders and Cost from 2016 to 2019 by Drug Condition Categories

	Super spender members		Medical plus pharmacy claims cost for specified drugs (in millions)		
Clinical condition category	Year 2016	Year 2019	Year 2016	Year 2019	Change '16 to '19
Cancer, total	**1,141**	**2,776**	**$431.6**	**$1,094.0**	**$662.4**
Breast	259	575	$96.8	$231.9	$135.1
Lung	117	378	$43.2	$168.3	$125.2
Multiple myeloma	112	456	$37.2	$163.4	$126.2
Melanoma	134	198	$60.9	$84.7	$23.7
Non-Hodgkin's lymphoma	76	159	$27.4	$62.0	$34.5
Colorectal	104	156	$41.1	$61.3	$20.2
Kidney	28	161	$9.2	$60.5	$51.4
Malignant neuroendocrine	30	102	$9.8	$43.0	$33.2
Acute lymphoblastic leukemia	51	62	$26.9	$29.8	$2.8
Ovary	27	65	$10.3	$24.7	$14.4
Hodgkin's disease	27	58	$10.0	$24.7	$14.7
Prostate	35	44	$9.5	$16.8	$7.4
Other cancer	141	362	$49.3	$132.8	$83.5
Inherited single gene disorders, total	**878**	**1,770**	**$435.3**	**$812.4**	**$377.1**
Hemophilia A	229	347	$128.8	$202.6	$73.8
Cystic fibrosis	205	550	$64.6	$193.3	$128.7
Hereditary angioedema	97	127	$63.8	$77.6	$13.8
Spinal muscular atrophy	-	115	$0.0	$65.2	$65.2
Hemophilia B	52	68	$27.7	$45.4	$17.7
Fabry's disease	52	67	$20.8	$26.8	$6.0
Congenital hypophosphatasia	13	20	$10.1	$24.7	$14.6
Pompe disease	22	30	$18.4	$24.5	$6.1
Gaucher's disease	50	54	$20.8	$24.5	$3.7
Mucopolysaccharidoses	31	29	$20.6	$18.9	($1.6)
Urea cycle disorders	9	21	$5.6	$13.6	$7.9
Cystinosis	15	19	$7.1	$11.8	$4.7
Chronic granulomatous disease	21	16	$9.3	$9.8	$0.6
Gout	4	22	$1.7	$9.2	$7.6
Duchenne muscular dystrophy	-	8	$0.0	$7.5	$7.5
Other single gene disorders	78	133	$36.1	$56.9	$20.8
End-stage renal disease	**370**	**453**	**$143.0**	**$184.6**	**$41.6**
Autoimmune disorders	**195**	**467**	**$73.1**	**$163.8**	**$90.7**
Inflammatory bowel disease	43	166	$15.6	$50.5	$34.9
Multiple sclerosis	47	103	$16.7	$38.5	$21.7
Chronic inflammatory demyelinating polyneuritis	34	59	$13.6	$22.7	$9.1
Other	71	139	$27.2	$52.1	$25.0
Disorders treated w/ complement inhibitors	**104**	**190**	**$75.2**	**$139.9**	**$64.7**
Hemolytic-uremic syndrome	55	80	$44.4	$68.4	$24.1
Paroxysmal nocturnal hemoglobinuria	49	64	$30.8	$39.9	$9.1
Myasthenia gravis	-	46	$0.0	$31.5	$31.5
Pulmonary hypertension	**88**	**189**	**$26.9**	**$67.6**	**$40.8**
Cushing's syndrome	**7**	**32**	**$2.3**	**$12.9**	**$10.6**
Immunoglobulins	**13**	**23**	**$13.7**	**$9.8**	**($3.9)**
Hepatitis C	**76**	**-**	**$22.5**	**$0.0**	**($22.5)**
All others	**122**	**138**	**$38.6**	**$41.6**	**$3.0**
Total specified specialty drugs	**2,994**	**5,894**	**$1,262.1**	**$2,526.7**	**$1,264.5**
Total all medical plus pharmacy drugs	**2,994**	**5,894**	**$1,324.5**	**$2,578.7**	**$1,254.2**

Drug Super Spenders = individual members with > $250,000 in pharmacy plus medical drug cost per year; Cost = plan plus member cost share after network discounts with no further adjustment for drug manufacturer coupons or rebates; Drug Indication Category = clinical condition for high drug cost deduced from a combination of information from the specific drugs accounting for most of the member's drug expense and ICD-10 diagnosis codes on all medical claims; Specified Drugs = set of specific specialty drugs for each condition category derived from preliminary exploratory analysis: Mucopolysaccharidoses = Mucopolysaccharidosis I, II, IVa, VI, and VII combined; complement inhibitors = eculizumab (Soliris®) and ravulizumab (Ultomiris®); Total all medical plus pharmacy drugs = sum of expense for specified specialty drugs (see METHODS section) and all other drugs for super spenders.

LIMITATIONS

- Although this study was conducted using a large population, many of the individual conditions described are too rare to accurately estimate prevalence.
- These results represent commercially insured lives from many different clients of a national pharmacy benefit manager. The findings cannot be extrapolated to populations such as Medicare/Medicaid and may differ from other commercially insured populations with different attributes.
- Extraordinarily high drug expense, i.e., drug super spenders, for an individual member can result from a variety of different factors acting alone or in combination. Use of drugs for which manufacturers have set very high prices is a common factor. In some cases, contractual agreements play a very important role, such as agreement by a health plan to pay a percentage of charges for medical claims by a facility combined with the facility's decisions about what to charge.

CONCLUSIONS

- Pharmaceutical innovation is bringing needed therapies to market but driving more drug super spenders, members with over $250,000 a year in total drug costs. This small, 32 per 100,000, but fast-growing segment of insured members currently accounts for 9.7% of total drug cost through the medical and pharmacy benefit. Continuing the past four year trend out the next five years, we forecast drug super spenders will account for over 15% of all combined drug spend through the medical and pharmacy benefits.
- In 2019, the 5,894 drug super spenders out of 18.2 million commercially insured members had over $2.6 billion in total drug cost with drug super spend cost accounting for $1 of every $10 in total drug cost.
- Drug super spenders are expected to rapidly grow, and it takes only one or two approved therapies to have a cost impact. Drug costs for one condition category, cystic fibrosis, increased 199% over the four-year period as a result of two new drugs. Cystic fibrosis disease-modifying therapies have an annual price tag around $300,000, and experts believe they are well overpriced for the value. Health plans need total drug cost management strategies for anticipating and tracking specialty drugs and one-time (e.g., gene) therapies.
- Management strategies require integrated medical and pharmacy benefit data, predictive modeling and a dedicated team to optimize drug therapy combined with robust case management, innovative manufacturer contracting, e.g., value-based contracting, and fraud, waste and abuse capabilities.

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