High-Priced Drugs: Estimates of Annual Per-Patient Expenditures for 150 Specialty Medications

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KEY TAKEAWAYS

$560+ billion Recent reports have projected drug spending in the United States to grow to $560 billion - $590 billion by 2020, up from $337 billion in 2015.

255 new Much of this growth will be fueled by the growing number of high-priced, specialty drugs coming to the market – an estimated 225 new specialty drugs over the next five years.

30% While specialty drugs account for less than 2 percent of all prescriptions, they make up roughly 30 percent of spending on all prescription drugs.

47.8% $100K Almost half (47.8 percent) of the specialty drugs included in this analysis cost more than $100,000 per patient per year.

150 A number of ongoing state and federal efforts are developing to address the significant challenges of high-priced drugs; and in support of these measures, this report attempts to quantify the annual per-patient expenditures for an initial sample of 150 specialty medications.

Examples of some of the most expensive medications include:

- **RAVICTI** costs **$793,632** per patient per year & **CARBAGLU** costs **$585,408** per patient per year (both prevent a build-up of nitrogen in the bloodstream that can rapidly lead to coma and death);
- **LUMIZYME** costs **$626,400** per patient per year (treats a progressive muscle weakness that can lead to heart and respiratory failure);
- **ACTIMMUNE** costs **$572,292** per patient per year (treats conditions that can disrupt normal immune system functioning and normal bone formation);
- **SOLIRIS** costs **$542,640** per patient per year (prevents the progressive destruction of red blood cells that can lead to other life-threatening conditions).

Despite the growing crisis of increasingly more expensive drugs, the manner by which these prices are established by drug companies remains a mystery. Without greater transparency into these pricing decisions, unfortunately, drug prices will only continue to climb higher.

Summary

Almost half of the 150 drugs studied cost in excess of $100,000 per year, with expenditures for 3 percent of the drugs studied exceeding half-a-million dollars per patient per year. We reviewed the FDA-approved dosing for a sample of 150 specialty medications prescribed to treat a variety of conditions and estimated the typical amount used in a year for a typical patient. We then calculated the total annual per-patient expenditure for a typical patient by multiplying the total quantity used per year by the pricing data published in the Federal Supply Schedule and the REDBOOK, as of Sept. 30, 2015. Although these medications are not the most commonly prescribed drugs, their financial impacts on the health care system continue to grow and call into question the sustainability of these extraordinary prices.

Background

Recent reports have estimated overall spending on prescription medicines in the United States to be $337 billion, in 2015.[1] Global technology company IMS Health's forecast of the world drug market, *Global Medicines Use in 2020: Outlook and Implications*, projects drug spending worldwide to reach $1.4 trillion by 2020, with U.S.-based spending totaling $560 billion - $590 billion.[2]

Although use of lower-priced generic medications is expected to exceed 90 percent of all prescriptions dispensed in the United States over the next five years, IMS anticipates 225 new medications will be introduced to the U.S. market during this same time period.[2] Many of these agents will be specialty pharmaceuticals, which are generally understood to be drugs that are structurally complex and often require special handling and delivery; are often administered in an office-setting; and can include complex molecules such as biologics.[3] Another distinguishing feature of specialty pharmaceuticals is their high prices. Previous studies have shown that specialty drugs together account for less than 2 percent of all prescriptions written; however, these drugs make up almost one-third of total spending on prescription medications.[2] It is common for these medications to cost thousands of dollars per patient per month.

Both the current state of prescription drug pricing and the projections of continued increases in drug spending in the years ahead have prompted a variety of proposals from both federal and state lawmakers. In 2016 alone, 14 state legislatures — California; Colorado; Georgia; Massachusetts; Minnesota; New Jersey; New Mexico; New York; North Carolina; Pennsylvania; Rhode Island; Tennessee; Texas; Virginia and Washington State — considered bills addressing the rising costs of prescription medications. The aim of many of these legislative efforts is to gain greater transparency into the manner by which drug companies determine these exorbitant prices. Many of these bills are focused on those medications that exceed a certain annual cost threshold, often $10,000 per patient per year.

Given the steadily increasing rate in the number of specialty pharmaceuticals coming to the market, there is, more broadly, a need to assess the prevalence of high-priced drugs and begin to quantify the magnitude of their costs to the health care system in general.

This analysis estimates the total annual drug expenditure for a typical patient, for an initial sample of 150 branded prescription medications having a total annual expenditure of at least $10,000. This list of drugs was selected from the specialty drug formularies of leading payer organizations. It is not intended to represent the entire universe of specialty medications but does provide a better understanding of what exactly is meant by the term, "*high-priced drugs.*" Unlike other studies, which tend to report aggregated drug expenditures, this analysis includes expenditures on a per-patient basis.

Methods

The following selection criteria were used for this initial study:

- Only patent-protected, branded prescription drugs listed on specialty pharmacy formularies were considered;
- Only those medications having Wholesale Acquisition Cost (WAC) and Average Wholesale Price (AWP) data available were included;
- Vaccines, vitamins, nutritional supplements, over-the-counter medications, and agents intended for diagnostic uses were excluded.

For each drug, estimates of the annual utilization, for a typical patient, were calculated based upon the standard dosing information found in the current FDA-approved labeling. We took the following into consideration:

- Commonly-accepted estimates of age-appropriate body weight or body surface area were used for those medications dosed by body weight or surface area. The body weights and/or surface areas used are noted in the Appendix Footnotes;
- For those medications where dosing is individualized (e.g., titrated to tolerability), the dose and schedule were derived from clinical trial data detailed in the package insert and noted in the Appendix Footnotes;
- For those medications having an indefinite duration of use (e.g., dosing until disease progression), the average duration of use was estimated from clinical trial data included in the package insert and noted in the Appendix Footnotes. Otherwise, 12 months of use was assumed;
- For those medications having use in more than one disease, calculations of the annual utilization for a typical patient were repeated for each disease because the dosing for a particular drug may be different from one condition to the next.

Next, the particular product strength and packaging configuration, or in some cases, the combination of various strengths and packaging configurations, that minimize any excess drug was identified based upon the calculated annual utilization. The corresponding National Drug Codes (NDC); as well as, the quantity of required units by packaging configuration(s) were recorded.

Drug pricing data from the September 2015 edition of The Federal Supply Schedule (FSS) were recorded for each drug by NDC.[4] Similarly, the WAC and AWP pricing data, as published in the September 2015 REDBOOK[5], were recorded. The FSS is managed by the United States Department of Veterans Affairs (VA) and supports the acquisition of over one million healthcare products and services for use by the VA as well as a number of other federal agencies. In many instances, the FSS price is the lowest, publically-available price point for a given drug. The WAC represents the prices paid by wholesalers to drug manufacturers while the AWP approximates the prices charged by wholesalers to retailers and/or large purchasing groups. Neither the WAC nor AWP reflect any discounts or rebates.

The total annual expenditure was calculated as the FSS price multiplied by the total quantity of product units to be consumed annually. The process was then repeated using the WAC and AWP pricing.

Findings

This report estimates just how high the total annual drug expenditures can be for a typical patient being prescribed one of these medications using the standard FDA-approved dosing. As summarized in Table 1, total annual drug expenditures, per patient, for many of these agents reaches six figures, and worse still, some therapies can exceed half-a-million dollars each year (*see Appendix for expenditures for each drug*).

We investigated the total treatment costs of 150 specialty drugs for each of their FDA-approved indications and found that almost half, or 97 of the 203 drugs studied (some drugs have multiple FDA-approved indications) exceeded $100,000 per year (Appendix). Of note, FOLOTYN, used to treat lymphoma, can cost $540,648 per patient per year. Patients suffering from genetic diseases are especially hard-hit as the annual expenditures for drugs like RAVICTI ($793,632), LUMIZYME ($626,400), CARBAGLU ($585,408), ACTIMMUNE ($572,292), and SOLIRIS ($542,640) place considerable strains on the budgets of private payers, public health programs (e.g., Medicaid and Medicare), and patients alike. Interestingly total annual drug expenditures based on the Federal Supply Schedule of the U.S. Department of Veterans Affairs, one of the lowest, most heavily discounted price points available, found many drugs *still* approaching half-a-million dollars per patient annually.

Table 1: Summary Of Annual Per-Patient Drug Expenditures By Indication

Condition	Range of Annual Per-Patient Expenditures*	
	Low ($)	High ($)
Hereditary Angioedema	14,292	98,040
Cancer, solid tumors	27,144	220,320
Cancer, hematological malignancies	12,897	540,648
Cancer, supportive care agents	14,183	41,576
Cystic Fibrosis	40,546	368,688
Ophthalmic Disorders	13,320	29,256
Genetic Diseases (including hereditary hypercholesteremia)	73,431	793,632
Growth Hormone Deficiency	30,064	38,944
Infectious Diseases	13,440	226,800
Immune System Disorders (including Multiple Sclerosis)	12,586	462,384
Pulmonary Arterial Hypertension	103,464	196,560
Organ Transplant	15,528	38,765
Other Miscellaneous Conditions	15,754	451,440

* Based upon Average Wholesale Prices; the "Low" entries above represent the medication with the lowest annual per-patient expenditure for the disease state while the "High" entries represent the medication with the greatest annual per-patient expenditure.

Conclusion

The issue of high-priced medications has gained increasing attention in recent years from an array of public and private organizations as patients, payers, and providers increasingly struggle with steadily rising drug prices.[6-8] Although specialty drugs make up only a small fraction of all medication use, they contribute almost one-third of the total amount spent on prescriptions medications each year.[2,3] Unfortunately, their financial impact will only increase as more specialty pharmaceuticals gain FDA approval during the years ahead. Yet, despite this growing crisis, the manner by which these prices are established by drug firms remains a mystery. Without greater transparency into these pricing decisions, drug pricing will only continue to grow unchecked, leaving the rest of the health care community, save the drug companies, struggling to find ways to afford these critically important medications.

This initial report is not an exhaustive list of every drug that has an estimated annual per-patient cost of $10,000 or more. However, it is illustrative of the growing challenges faced by the health care system in making affordable medications available to all patients who need them. Going forward, this list of drugs will be updated regularly as new medications enter the market.

Appendix

Annual Per-Patient Drug Expenditure By FDA-Approved Indication *(As Of Sept. 30, 2015)*

Hereditary Angioedema					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Firazyr	Shire	Hereditary Angioedema (3 attacks/year)[1]	62,280	81,699	98,040
Firazyr	Shire	Hereditary Angioedema (3 attacks/year)[1]	41,520	54,466	65,360
Kalbitor	Dyax	Hereditary Angioedema (3 attacks/year)[1]	29,658	35,730	42,876
Firazyr	Shire	Hereditary Angioedema (1 attack/year)[1]	20,760	27,233	32,680
Kalbitor	Dyax	Hereditary Angioedema (2 attacks/year)[1]	19,772	23,820	28,584
Kalbitor	Dyax	Hereditary Angioedema (1 attack/year)[1]	9,886	11,910	14,292

Cancer, Colorectal					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Cyramza	Eli Lilly	Metastatic Colorectal Cancer[2]	183,600	183,600	220,320
Erbitux	Imclone/Eli Lilly	K-ras wild-type, EGFR+ Metastatic Colorectal Cancer[3]	135,927	138,861	166,679
Avastin	Genentech	Metastatic Colorectal Cancer (10mg/kg dosing)[2]	114,478	124,908	149,893
Zaltrap	Sanofi/ Regeneron	Metastatic Colorectal Cancer[2]	41,495	115,200	138,240
Vectibix	Amgen	K-ras wild-type, Metastatic Colorectal Cancer[2]	34,205	54,550	65,460
Stivarga	Bayer	Metastatic Colorectal Cancer	21,348	37,488	44,988

Cancer, Gastric					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Cyramza	Eli Lilly	Advanced Gastric and Gastroesophageal Junction Adenocarcinoma[2]	183,600	183,600	220,320
Gleevec	Novartis	Gastrointestinal Stromal Tumors	98,952	121,464	145,764
Sutent	Pfizer	Gastrointestinal Stromal Tumors	81,896	61,872	74,240

Cancer, Thyroid					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Lenvima	Eisai	Thyroid Cancer	125,304	167,400	200,880
Caprelsa	AstraZeneca	Thyroid Cancer	121,380	154,452	185,340
Cometriq	Exelixis	Metastatic Medullary Thyroid Cancer	21,048	38,988	46,788

High-Price Drugs Based Upon Estimated Annual Per-Patient Expenditure

Cancer, Lung					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Xalkori	Pfizer	ALK+ Non-Small Cell Lung Cancer	143,100	161,592	193,908
Zykadia	Novartis	ALK+ Non-Small Cell Lung Cancer	148,896	151,176	181,416
Cyramza	Eli Lilly	Non-Small Cell Lung Cancer[4]	122,400	122,400	146,880
Avastin	Genentech	Non-Small Cell Lung Cancer (15mg/kg dosing)[2]	83,951	91,572	109,922
Tarceva	Genentech	Advanced Non-Small Cell Lung Cancer (150mg)	65,352	80,508	96,612
Iressa	AstraZeneca	EGFR+ Metastatic Non-Small Cell Lung Cancer	77,988	80,400	96,480
Gilotrif	Boehringe-Ing	EGFR+ Non-Small Cell Lung Cancer	50,676	77,688	93,216

Cancer, Kidney					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Nexavar	Bayer/Onyx	Renal Cell Carcinoma	113,316	158,196	189,840
Inlyta	Pfizer	Advanced Renal Cell Carcinoma	121,896	136,356	163,632
Afinitor	Novartis	Renal Cell Carcinoma	113,208	126,456	151,740
Avastin	Genentech	Metastatic Renal Cell Carcinoma (10mg/kg dosing)[2]	114,478	124,908	149,893
Votrient	Novartis	Renal Cell Carcinoma	98,196	105,288	126,348
Sutent	Pfizer	Renal Cell Carcinoma	81,896	61,872	74,240

Cancer, Prostate					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Jevtana	Sanofi-Aventis	Refractory Metastatic Prostate Cancer[5]	105,312	156,024	187,236
Xtandi	Astellas	Castration-Resistant Metastatic Prostate Cancer	61,032	106,176	127,416
Zytiga	Janssen	Castration-Resistant Metastatic Prostate Cancer	64,212	95,952	115,152

Cancer, Melanoma					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Zelboraf	Genentech	BRAF V600E+ Melanoma	129,552	130,200	156,240
Mekinist	Novartis	BRAF V600E+ or V600K+ Melanoma	118,908	120,852	145,032
Yervoy	BMS	Metastatic Melanoma[6]	114,692	119,862	143,838
Erivedge	Genentech	Metastatic Basal Cell Carcinoma	94,728	112,692	135,228
Keytruda	Merck	Metastatic Melanoma[7]	110,616	110,064	132,072
Tafinlar	Novartis	BRAF V600E+ Melanoma	103,872	105,564	126,696

High-Price Drugs Based Upon Estimated Annual Per-Patient Expenditure

Cancer, Brain					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Afinitor	Novartis	Subependymal Giant Cell Astrocytoma	113,208	126,456	151,740
Avastin	Genentech	Glioblastoma Multiforme (10mg/kg dosing)[2]	114,478	124,908	149,893
Temodar	Merck	Glioblastoma Multiforme[3]	37,872	51,000	61,212
Temodar	Merck	Refractory Anaplastic Astrocytoma[3]	32,388	43,620	52,344
Wafers	Eisai/Arbor	Malignant Glioma and Glioblastoma Multiforme	25,971	29,035	34,841

Cancer, Breast					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Kadcyla	Genentech	HER2+ Metastatic Breast Cancer[8]	148,548	150,888	181,056
Ibrance	Pfizer	ER+ HER2+ Breast Cancer	116,424	117,660	141,840
Tykerb	Novartis	Advanced Breast Cancer (1500mg dosing)	62,268	66,768	80,124
Tykerb	Novartis	Advanced Breast Cancer (1250mg dosing)	41,512	44,512	53,416

Cancer, Other Tumor Types					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Nexavar	Bayer/Onyx	Hepatocellular Carcinoma	113,316	158,196	189,840
Sutent	Pfizer	Pancreatic Neuroendrocine Tumor	126,576	139,200	167,052
Erbitux	Imclone/Eli Lilly	Head-and-Neck Cancer	135,927	138,861	166,679
Lynparza	AstraZeneca	BRCA+ Ovarian Cancer	131,023	134,400	161,280
Avastin	Genentech	Advanced Ovarian Cancer (10mg/kg dosing)[2]	114,478	124,908	149,893
Votrient	Novartis	Soft-Tissue Sarcoma	98,196	105,288	126,348
Avastin	Genentech	Cervical Cancer (15mg/kg dosing)[2]	83,951	91,572	109,922
Tarceva	Genentech	Advanced Pancreatic Cancer	57,780	71,184	85,416
Xgeva	Amgen	Bone Metastases/Giant Cell Tumor of Bone	20,658	22,620	27,144

High-Price Drugs Based Upon Estimated Annual Per-Patient Expenditure

Cancer, Lymphomas					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Folotyn	Allos	Peripheral T-Cell Lymphoma[9]	344,664	450,540	540,648
Adcetris	Seattle Genetics	Hodgkin's Lymphoma and Large Cell Lymphoma[10]	232,608	281,376	337,632
Imbruvica	Abbvie/ Janssen	Mantel Cell Lymphoma	98,988	146,700	176,040
Zolinza	Merck	Cutaneous T-Cell Lymphoma	102,192	140,676	168,804
Revlimid	Celgene	Mantel Cell Lymphoma	99,036	121,800	146,172
Zydelig	Gilead	Chronic Lymphocytic Leukemia; Non-Hodgkin's & Small Cell Lymphoma	65,136	94,956	113,940
ARRANON, Adult	Novartis	T-Cell Acute Lymphoblastic Leukemia & T-Cell Lymphoblastic Lymphoma	75,870	77,112	92,520
Treanda	Cephalon	Non-Hodgkin's Lymphoma	74,208	75,341	90,416
Rituxan	Genentech	Non-Hodgkin's Lymphoma	33,425	38,142	45,771
Velcade	Millenium	Mantel Cell Lymphoma	31,471	33,810	40,572
ARRANON, Child	Novartis	T-Cell Acute Lymphoblastic Leukemia & T-Cell Lymphoblastic Lymphoma	31,614	32,130	38,550

Cancer, Leukemias					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Oncaspar	Baxalta	Acute Lymphoblastic Leukemia[11]	103,836	323,208	387,864
Revlimid	Celgene	Myelodysplastic Syndrome	116,556	162,408	194,892
Iclusig	Ariad	Chronic Myelogenous Leukemia & Ph-Chromosome+ Acute Myelogenous Leukemia	136,044	143,400	172,080
Bosulif	Pfizer	Ph-Chromosome+ Chronic Myelogenous Leukemia	112,212	130,776	156,939
Sprycel	BMS/Otsuka	Ph-Chromosome+ Chronic Myelogenous Leukemia & Acute Lymphocytic Leukemia	106,812	124,284	149,136
Gleevec	Novartis	Chronic Myelogenous Leukemia	98,952	121,464	145,764
Tasigna	Novartis	Ph-Chromosome+ Chronic Myelogenous Leukemia	102,684	116,040	139,248
Arzerra	Novartis	Chronic Lymphocytic Leukemia	107,316	112,344	134,808
Erwinaze	Jazz Pharm.	Acute Lymphoblastic Leukemia[12]	71,412	110,664	132,798
Imbruvica	Abbvie/ Janssen	Chronic Lymphocytic Leukemia	74,424	110,028	132,036
Treanada	Cephalon	Chronic Lymphocytic Leukemia (6 treatment cycles)	43,131	52,322	62,787
Trisenox	Teva/ Cephalon	Acute Promyelocytic Leukemia[2]	42,384	50,760	60,912
Gazyva	Genentech	Chronic Lymphocytic Leukemia	40,656	42,416	76,344
Rituxan	Genentech	Chronic Lymphocytic Leukemia (6 treatment cycles)	32,113	36,647	43,976
Oforta	Sanofi	Chronic Lymphocytic Leukemia (6 treatment cycles)	-----	16,971	18,885

High-Price Drugs Based Upon Estimated Annual Per-Patient Expenditure

Cancer, Myelomas					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Pomalyst	Celgene	Multiple Myeloma[13]	119,736	141,072	169,296
Revlimid	Celgene	Multiple Myeloma	99,036	121,800	146,172
Farydak	Novartis	Multiple Myeloma[14]	54,000	54,880	65,856
Velcade	Millenium	Multiple Myeloma	49,455	53,130	63,756
Thalomid	Celgene	Multiple Myeloma	41,362	53,061	63,673
Zometa	Novartis	Multiple Myeloma	10,575	10,747	12,897

Cancer, Supportive Care Agents					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Elitek, Adults	Sanofi	Hyperuricemia Associated with Tumor Lysis Syndrome	22,500	34,647	41,576
Mozobil	Genzyme	Hematopoietic Stem Cell Mobilizer for Autologous Transplant	20,220	28,628	34,352
Xgeva	Amgen	Hypercalcemia of Malignancy	20,658	22,620	27,144
Neulasta	Amgen	Prevention of Febrile Neutropenia in Cancer	13,720	19,659	23,591
Ethyol	MedImmune	Reduction of Chemotherapy-Associated Renal Toxicity	-----	15,146	18,176
Elitek, Child	Sanofi	Hyperuricemia Associated with Tumor Lysis Syndrome	9,000	13,859	16,631
Kepivance	Sobi	Severe Oral Mucositis	10,626	11,819	14,183

Cystic Fibrosis					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Kalydeco	Vertex	Cystic Fibrosis	302,004	307,236	368,688
Tobi Podhaler	Novartis	Cystic Fibrosis[15]	43,320	48,384	58,062
Pulmozyme	Genentech	Cystic Fibrosis	24,681	33,789	40,546

High Cholesterol, Hereditary					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Juxtapid	Aegerion	Homozygous Familial Hypercholesteremia[16]	220,788	346,620	415,944
Kynamro	Genzyme	Homozygous Familial Hypercholesteremia	159,996	253,188	303,828

High-Price Drugs Based Upon Estimated Annual Per-Patient Expenditure

Ophthalmic Disorders					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Lucentis	Genentech	Neovascular Macular Degeneration/ Macular Edema	23,004	23,400	29,256
Eylea	Regeneron	Diabetic Macular Edema/Retinopathy	14,726	14,800	17,760
Lucentis	Genentech	Diabetic Macular Edema/Retinopathy	13,800	14,040	16,848
Eylea	Regeneron	Neovascular, Age-Related Macular Degeneration	12,885	12,950	15,540
Eylea	Regeneron	Macular Edema/Retinal Vein Occlusion	11,044	11,100	13,320

Genetic Diseases					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Ravicti	Horizon	Urea Cycle Disorders[17]	339,384	661,344	793,632
Lumizyme	Genzyme	Pompe's Disease[18]	524,088	522,000	626,400
Carbaglu	Recordati	Acute and Chronic Hyperammonemia[19]	418,524	487,824	585,408
Actimmune	Horizon	Severe, Malignant Osteopetrosis and Chronic Granulomatous Disease	244,104	476,916	572,292
Soliris	Alexion	Paroxysmal Nocturnal Hemoglobinuria	432,240	452,220	542,640
Demser	Valeant	Pheochromocytoma Induced Hypertension	96,804	393,528	472,236
Cholbam	Asklepion	Bile Acid Synth & Peroxisomal Disorders[20]	227,544	297,900	357,480
Zavesca	Actellion	Type 1 Gaucher Disease	142,188	294,840	353,808
Aldurazyme	Genzyme	Mucopolysaccharidosis I	279,268	293,384	352,061
Fabrazyme	Genzyme	Fabry's Disease[21]	229,488	251,328	301,584
Arcalyst	Regeneron	Cryopyrin-Associated Periodic Syndrome	236,376	240,000	288,000
Xenazine	Prestwick	Huntington's Chorea[22]	66,282	111,810	134,172
Ilaris	Novartis	Cyropyrin-Associated Periodic Syndrome[23]	94,674	96,330	115,596
Kuvan	BioMarin	Treatment of Hyperphenylalaninemia	91,574	94,368	113,232
Exjade	Novartis	Non-Transfusion Dependent Thalassemia	54,785	61,193	73,431

Growth Hormone Deficiency					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Norditropin	Novo Nordisk	Growth Hormone Deficiency	-----	32,453	38,944
Humatrope	Eli Lilly	Growth Hormone Deficiency	17,874	29,974	35,968
Genotropin	Pfizer	Growth Hormone Deficiency	22,547	25,053	30,064

High-Price Drugs Based Upon Estimated Annual Per-Patient Expenditure

Infectious Diseases, Hepatitis C					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Harvoni	Gilead	Hepatitis C Infection (24-week course)	170,952	189,000	226,800
Sovaldi	Gilead	Hepatitis C Infection (24-week course)	99,720	168,000	201,600
Viekira Pak	Abbvie	Hepatitis C Infection (24-week course)	123,816	166,638	199,968
Olysio	Janssen	Hepatitis C Infection (24-week course)	130,722	132,720	159,264
Harvoni	Gilead	Hepatitis C Infection (24-week course)	85,476	94,500	113,400
Sovaldi	Gilead	Hepatitis C Infection (24-week course)	49,860	84,000	100,800
Viekira Pak	Abbvie	Hepatitis C Infection (24-week course)	61,908	83,319	99,984
Technivie	Abbvie	Hepatitis C Infection (24-week course)	56,589	76,653	91,983
Olysio	Janssen	Hepatitis C Infection (24-week course)	65,361	66,360	79,632
Daklinza	BMS	Hepatitis C Infection (24-week course)	47,157	63,000	75,600
Pegintron	Schering/ Merck	Hepatitis C	19,744	39,804	47,765
Pegasys	Roche	Hepatitis C	27,864	39,612	47,535
Copegus	Roche	Hepatitis C	-----	39,271	47,125
Rebetol	Schering/ Merck	Hepatitis C	17,512	17,802	21,362

Infectious Diseases, HIV/AIDS					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Fuzeon	Roche	Anti-Retroviral Treatment of HIV-1 Infection	27,085	37,596	45,108
Viracept	GSK/ViiV	Treatment of HIV-1 Infection	10,150	11,692	14,031
Viread	Gilead	Treatment of HIV-1 Infection	6,807	11,200	13,440

Infectious Diseases, Other Infections					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Valcyte	Genentech	Treatment of Cytomegalovirus Retinitis	37,417	54,752	65,702
Synagis	MedImmune	Prevention of Respiratory Syncytial Virus Disease	31,554	35,571	42,685

High-Price Drugs Based Upon Estimated Annual Per-Patient Expenditure

Immune System Disorders					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Ilaris	Novartis	Systemic Juvenile Idiopathic Arthritis[23]	378,696	385,320	462,384
Promacta	Novartis	Idiopathic Thrombocytopenia Purpura	100,404	107,664	129,192
Esbriet	Intermune	Idiopathic Thrombocytopenia Purpura	92,184	93,600	112,320
Stelara	Janssen	Psoriasis (90mg dosing)[24]	47,770	81,900	98,275
Nplate	Amgen	Chronic Immune Thrombocytopenia	68,189	75,733	90,879
Tysabri	BiogenIdec	Crohn's Disease	37,574	63,096	75,715
Simponi	Janssen	Ulcerative Colitis	38,372	56,345	67,614
Cosentyx	Novartis	Plaque Psoriasis	53,840	54,840	70,195
Enbrel	Amgen	Plaque Psoriasis	30,879	51,835	62,202
Humira	AbbVie	Crohn's Disease/Ulcerative Colitis, adults	19,260	48,372	58,044
Humira	AbbVie	Plaque Psoriasis, adults	17,892	44,916	53,904
Simponi	Janssen	Rheumatoid Arthritis/Psoriatic Arthritis/Ankylosing Spondylitis	20,837	41,997	50,396
Enbrel	Amgen	Rheumatoid Arthritis/Psoriatic Arthritis/Ankylosing Spondylitis	24,703	41,468	49,762
Humira	AbbVie	Rheumatoid Arthritis/Psoriatic Arthritis/Ankylosing Spondylitis	16,500	41,460	49,752
Cimzia	UCB Pharma	Rheumatoid Arthritis/Psoriatic Arthritis/Ankylosing Spondylitis/Crohn's Disease	13,616	39,563	47,475
Entyvio	Takeda	Ulcerative Colitis/Crohn's Disease (8 doses/year)	38,556	38,556	46,260
Orencia	BMS	Adult Rheumatoid Arthritis (SC dosing)	18,175	38,436	46,128
Benlysta	GSK	Systemic Lupus Erythematosus	34,230	36,285	43,542
Orencia	BMS	Adult Rheumatoid Arthritis (IV dosing)	23,105	33,054	39,662
Remicade	Janssen	Crohn's Disease/Ulcerative Colitis/Psoriasis/Psoriatic Arthritis	20,705	32,686	39,223
Xeljanz	Pfizer	Rheumatoid Arthritis	26,826	32,206	38,647
Rituxan	Genentech	Rheumatoid Arthritis	26,216	29,916	35,898
Stelara	Janssen	Psoriasis (45mg dosing)[24]	27,190	25,655	30,785
Xolair	Genentech	Chronic Idiopathic Urticaria	8,818	10,488	12,586

High-Price Drugs Based Upon Estimated Annual Per-Patient Expenditure

Multiple Sclerosis					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
H.P. Acthar Gel	Mallinckrodt	Exacerbations of Multiple Sclerosis[25]	151,035	170,170	204,205
Lemtrada	Genzyme	Multiple Sclerosis (5 day course/year)[26]	98,980	98,750	118,500
Gilenya	Novartis	Relapsing Multiple Sclerosis	64,644	69,972	83,964
Tecfidera	BiogenIdec	Relapsing Multiple Sclerosis	54,012	69,456	83,352
Rebif	EMD Serono	Relapsing Multiple Sclerosis (22 or 44ug dosing)	28,575	69,117	82,940
Betaseron	Bayer	Relapsing Multiple Sclerosis	34,809	67,775	81,330
Aubagio	Sanofi-Aventis	Relapsing Multiple Sclerosis	50,232	64,596	77,520
Avonex	BiogenIdec	Relapsing Multiple Sclerosis	49,948	64,032	76,836
Plegridy	BiogenIdec	Relapsing Multiple Sclerosis	59,496	64,032	76,836
Tysabri	BiogenIdec	Relapsing Multiple Sclerosis	37,574	63,096	75,715
Extavia	Novartis	Relapsing Multiple Sclerosis	51,516	60,576	72,696
Lemtrada	Genzyme	Multiple Sclerosis (3 day course/year)[26]	59,388	59,250	71,100

Pulmonary Arterial Hypertension					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Tyvaso	United	Pulmonary Arterial Hypertension	106,872	163,800	196,560
Tracleer	Acetilion	Pulmonary Arterial Hypertension	58,488	98,640	118,368
Adempas	Bayer	Pulmonary Arterial Hypertension	83,328	98,268	117,912
Orenitram	United	Pulmonary Arterial Hypertension[27]	71,526	95,550	114,660
Letairis	Gilead	Pulmonary Arterial Hypertension	35,700	88,368	106,116
Opsumit	Acetilion	Pulmonary Arterial Hypertension	35,578	86,220	103,464

Organ Transplant Related					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Nulojix	BMS	Prophylaxis of Organ Rejection/ Kidney Transplant	4,952	32,305	38,765
Cellcept	Genentech	Cardiac or Hepatic Transplant (3g/day dosing)	15,558	30,858	37,029
Cellcept	Genentech	Renal Transplant (2g/day dosing)	10,372	20,572	24,686
Myfortic	Novartis	Organ Rejection/Kidney Transplant, adults	10,113	12,940	15,528

Other Miscellaneous Conditions					
Drug	Mfr	Indication	Annual Per-Patient Expenditure ($)		
			FSS	WAC	AWP
Gattex	NPS Pharma	Short Bowel Syndrome[2]	378,084	376,200	451,440
Krystexxa	Savient	Chronic Gout	113,160	336,000	403,200
Sabril	Lundbeck	Refractory Complex Partial Seizures[28]	101,580	158,508	190,224
Signifor	Novartis	Cushing's Syndrome[29]	135,864	138,084	165,696
Exjade	Novartis	Transfusional Iron Overload	109,568	122,383	146,860
Jakafi	Incyte	Myelofibrosis	91,621	119,844	143,808
H.P. Acthar Gel	Mallinckrodt	Infantile Spasms[30]	90,621	102,102	122,523
Ofev	Boehringer-Ing	Idiopathic Pulmonary Fibrosis	71,664	96,000	115,200
Hetlioz	Vanda	Sleep Disorder	31,452	67,362	80,838
Xolair	Genentech	Asthma	52,908	62,930	75,516
Zorbtive	EMD Serono	Short Bowel Syndrome[31]	17,384	29,068	34,880
Epogen	Amgen	Anemia due to Zidovudine Treatment of HIV	-----	17,505	21,006
Epogen	Amgen	Anemia due to Chronic Kidney Disease	-----	13,128	15,754

Appendix Footnotes

1 Drugs used to treat Hereditary Angioedema (FIRAZYR and KALBITOR) are administered only at the time of an attack. The number of attacks any patient can experience over the course of a year can vary widely. Here, we assumed 1-3 attacks per year based upon counts of attacks reported in the clinical trials section of the package insert.
2 Assumed a 75kg patient.
3 Assumed a body surface area of 1.7m2.
4 Dosing is 10mg/kg on day 1 of a 21-day cycle; assuming a 75kg patient and 17 doses administered per year.
5 Dosing is 25mg/m2 every three weeks; assuming a body surface area of 1.7m2 and 17 doses administered per year.
6 YERVOY dosing is 3mg/kg every three weeks for a total of four doses. Assuming a 75kg patient, then one dose would be 225mg or 900mg for all four doses.
7 Dosing is 2mg/kg every three weeks; assumed a 75kg patient and 17 doses administered per year.
8 Dosing is up to 3.6mg/kg every three weeks; assuming a 75kg patient and 17 doses administered per year.
9 Each dose is 30mg/m2, and assuming an average body surface area of 1.7m2 and 36 doses per year.
10 Dosing is 1.8 mg/kg and assuming a 75kg patient and up to a maximum of 16 doses per year.
11 Dosing is 2500 IU/m2 twice per month; assuming a 12 year-old patient with a body surface area of 1.33m2.
12 Dosing is 25,000 IU/m2 for six doses administered over a two week period. Based upon clinical data reported in the package insert, an average ALL patient is about 10 years-old with a body surface area of 1.14m2; therefore, assumed each dose to be 28,500 IU's. ERWINAZE is packaged in a carton of 3 vials X 10,000 IU/vial; thus, one carton is needed per dose. Assumed only one, six-dose course of therapy per year.
13 Assumes the 4mg/day dose for days 1-21 or a 28-day cycle.
14 Assumed eight cycles of treatment per year.
15 Patients being treated with TOBI PODHALER are treated on alternating months.
16 Assumes a 20mg/day dose.
17 Assuming the daily maximum dose of 17.5mL X 1.1g/mL solution (19g/day), then each package of four, 25mL vials is about a one week supply.
18 Using the example in the package insert, assuming a 68kg patient and a dose of 20mg/kg would consume 28 of the 50mg vials per dose. Therefore, each infusion would require three of the ten-vial packages (50mg/vial X 10 vials/package). Assumed two infusions per month.
19 Assuming an 8kg infant and a dose of 200mg/kg/day would require a dose of 1600mg/day (8 X 200mg tablets per day). Therefore, a one month supply would require four bottles of the 60 X 200mg capsules.
20 For pediatric patients, assuming a body weight of 15kg and a dose of 10mg/kg/day, will require 3 X 50 mg capsules per day.
21 Assuming a 75kg patient and 26 doses per year.
22 Assumed a dose of 50mg per day administered as one 25mg capsule twice per day.
23 ILARIS dosing in Juvenile Arthritis patients is 300mg every four weeks or two 180mg vials per month. Dosing in Periodic Syndrome patients is 150mg every eight weeks or six of the 180mg vials per year.
24 A total of five doses of STELARA, either 90mg or 45mg depending on the patient's body weight, are administered over one year.
25 Assumes a middle-dose of 100 USP Units/day for 20 days; or one vial every four days. Assumes one course of treatment per year.
26 LEMTRADA is administered as one 12mg vial per day for five days; followed one year later, by one 12 mg vial per day for three days. Thus in any given year, some patients will be taking their first, 5-day course; while other patients will be taking their second course of 3-days.
27 Dosing of ORENITRAM is titrated to tolerability and therefore individualized. However, as reported in the FDA-approved package insert, the average dosing of patients participating in clinical trials was 3.4mg twice per day. Thus, an average patient will take on 2.5mg

tablet and one 1.0mg tablet per day. The average patient will need seven prescriptions of the 2.5mg and 1.0mg tablets per year.

28 Dosing is 2000-3000mg/day, assuming a middle-dose of 2500mg/day then requires five of the 500mg tablets per day. Over the course of one year, a typical patient would require 18 bottles of the 100 X 500mg tablets per bottle.

29 Assumes the 0.9mg/mL dose twice daily.

30 Dosing in infantile spasms is 75 USP Units/m2 twice daily. Assumed a body surface area of 0.30m2 yielding a dose of 45 USP Units per day.

31 Assumed an 8mg per day maximum dose administered daily for four weeks.

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