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MEDICARE FORMULARY COVERAGE FOR TOP-SELLING BIOLOGICS

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"Biologics" are therapeutics produced through recombinant deoxyribonucleic acid (DNA) technology or other biological processes. The number of available biologics and expenditures for them have increased dramatically in recent years. While insurance coverage policies must balance patient and societal needs of access and affordability, insurers may also adopt strategies to manage the use of these expensive drugs. Such strategies include a more complex tiered formulary (e.g., adding a specialty tier that requires higher patient cost-sharing), prior authorization (e.g., requiring physicians to obtain approval from the health plan prior to prescription for coverage), and the use of specialty pharmacy vendors[1-3]. Despite the growing importance of biologics, little is known about their coverage, cost-sharing, and management tools, or how they vary across drug characteristics. Current evidence is limited to studies of selected health plans[2, 3], geographical areas[4], or diseases[5].

We examined coverage, cost-sharing, and utilization management for the top-selling biologics in 2006 and 2009 using nationally representative data from the Medicare prescription drug plan formulary files (n=3,075 stand-alone and Medicare Advantage prescription drug plans in 2006; n=4,207 stand-alone and Medicare Advantage prescription drug plans in 2009). The unit of analysis is each Part D product (i.e., at the organization/plan level). Our research goal was to understand how common biologics were covered. We examined the top 20 biologics (per global sales in 2006) with three specific aims: (1) baseline patterns in 2006, (2) whether coverage varied by drug characteristics (presence of a black box warning and monthly costs), and (3) trends between 2006 and 2009. Medicare Part D drug coverage was examined for several reasons. First, this program expanded coverage for patients, and thus had a strong impact on drug demand. Second, Medicare coverage policies often drive coverage decisions for private payers. Finally, Medicare formulary data are nationally representative. Analysis of the 2006 Medicare formularies provides a baseline understanding of coverage patterns found immediately after the implementation of this prescription drug benefit. The drugs examined represented approximately 75% of the global biotech drug market in 2006[6]. To investigate the trend over time, we compared the coverage patterns between 2006 and 2009. These findings are important to patients, insurers, and policy makers, but also to manufacturers and developers of biologics, given a lack of consensus about how expensive biologics should be covered and managed.

Patterns of formulary coverage, cost-sharing, and utilization management for top-selling biologics among the Medicare prescription drug plans are summarized in Table 1. The baseline findings for 2006 demonstrate that the top-selling biologics were covered by the majority of

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Medicare prescription drug plans, but were placed in a tier with high patient cost-sharing and were subject to prior authorization. The percentage of Medicare prescription drug plans including these drugs in their formularies ranged from ~99% for etanercept (Enbrel), interferon beta-1b (Betaseron), and infliximab (Remicade), to 42% for trastuzumab (Herceptin) and 12% for insulin detemir (Levemir), the most recently approved drug in the sample (2005). It is important to note that some biologics may only be covered under Part B: when administered in a physician's office or infusion center (e.g., bevacizumab, trastuzumab, rituximab, infliximab)[7] or other certain circumstances8. This may result in a lower coverage rate under Part D.

We found that patient cost-sharing was commonly used by these plans to manage the utilization of these biologics. Tiered formularies, where drugs are divided into “tiers” with different levels of patient cost-sharing, are used by health plans to encourage the use of lower cost drugs. Most of these biologics were categorized in tier 4, which requires the highest level of cost-sharing, except for diabetes drugs (tiers 2 or 3), and trastuzumab, a cancer drug (tier 2). The out-of-pocket cost to patients was as high as $60 for a 30-day supply purchased at preferred pharmacies with a co-payment. We also found that the most common cost-sharing method for these drugs was co-insurance (with a mostly commonly rate of 25%). Co-insurance requires Medicare beneficiaries to pay a percentage of the drug cost which creates a greater financial burden than does a flat fee co-payment. For example, patients on Aranesp ($1,098 per month) would face a monthly out-of-pocket cost of $275.

Excepting diabetes drugs, the reviewed biologics required prior authorization. Drugs with greater coverage and within a higher cost-sharing tier (e.g., rheumatoid arthritis and anemia drugs) were more likely to be associated with prior authorization requirements than those within a lower cost-sharing tier (e.g., diabetes and cancer drugs). Other utilization management strategies were used less often. Less than one-third of drug plans imposed quantity limits for these biologics, and less than 10% of these plans used step therapy, which would require patients to try a first-line medication (e.g., the most cost-effective and safest drugs) before receiving coverage for a second-line medication (e.g., more costly or risky drugs). One interesting comparison of utilization management between biologics and small molecule drugs is that studies on small molecule drugs such as psychotropic drugs found only a minority of Part D plans imposed prior authorization for these drugs[9].

We found that coverage varied both across and within drug classes (defined as therapeutic class or indication). Most plans covered at least one biologic in each drug class, ranging from 100% for diabetes drugs to 55.6% for cancer drugs. Within the same drug class, coverage varied: although consistent within rheumatoid arthritis (91.9%-99.6%) and cancer drugs (42.1%-45.9%), anemia (65.8%-95.4%) and diabetes drugs (11%-97.8%) showed greater variation.

We also examined whether coverage varied by drug characteristics (data not shown but are available upon request). Two drug characteristics were examined: presence of a black box warning and monthly costs. In general, drugs with a black box warning and higher monthly costs were associated with reduced coverage, a higher cost sharing tier, and prior authorization requirements by the majority of Medicare prescription drug plans.

We examined the trend over time by comparing coverage patterns of 2006 and 2009. In general, we found that an increasing number of plans included these biologics in their formularies in 2009, especially for cancer drugs and Levemir (which was a new drug in 2006). However, by 2009 significantly more plans adopted co-insurance as the cost-sharing method of choice for these biologics (except diabetes drugs), increased the co-insurance rate (with a most commonly used rate of 33% vs. 25% in 2006), and increased the co-payment amount. Use of prior

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authorization and quantity limits requirements also increased significantly for most of these biologics.

In sum, top-selling biologics were covered by the majority of Medicare prescription drug plans in 2006, but access to these biologics was limited by high patient cost-sharing and prior authorization requirements. By 2009, patient cost-sharing and utilization management requirements increased even further. In addition, we found significant variations by drug, drug class, and drug characteristics.

Our findings serve as a first step toward understanding and addressing the coverage issues for these expensive biologics, with important implications for drug access, formulary decisions, and strategic planning for drug development. Our findings about the coverage, cost-sharing, and prior authorization for biologics are in general consistent with other studies examining the specialty tiers broadly[10-12], and we additionally examined variations in drug characteristics, other utilization management tools, and trends over time. Further research is needed to understand the impact of policies that relate formulary placement, such as codifying protected drug classes, to model patient out-of-pocket expenditures under different cost-sharing scenarios.

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Table 1

Formulary coverage, cost sharing, and utilization management for top-selling biologies in 2006, 2006 vs. 2009

Drug Class / Indication	Generic name	Brand name	Year of FDA approval[a]	Black Box Warning in 2006[b]	Average Monthly Cost[c]	Formulary coverage[d] (%)		Tier (modal value)[e] 2006/ 2009	Type of cost-sharing as co-insurance[f] (%)		Co-pay amount[g] (modal value)		Prior authorization[h] (%)		Quantity limit[i] (%)	
						2006	2009		2006	2009	2006	2009	2006	2009	2006	2009
Anemia						99.9[k]										
	darbepoetin alfa	ARANESP	2001	No	$1,098	92.9	91.7*	4/4	65.0	89.0*	$20	$35	90.8	97.4*	13.3	41.3*
	epoetin alfa	EPOGEN	1989	No	$576	65.8	74.9*	4/4	72.4	86.9*	$40	$59	89.1	96.7*	12.8	69.0*
	epoetin alfa	PROCRIT	1990	No	$901	95.4	98.7*	4/4	65.3	72.5*	$20	$35	77.1	97.6*	9.9	66.4*
Cancer						55.6*										
	Bevacizumab	AVASTIN	2004	Yes	$2,750	45.9	74.1*	4/4	57.4	89.0*	$30	$80	47.6	69.9*	3.5	14.9*
	Trastuzumab	HERCEPTIN	1998	Yes	$3,047	42.1	76.6*	2/4	53.6	87.2*	$30	$59	42.1	40.8	4.3	1.0*
	Rituximab	RITUXAN	1997	Yes	$2,969	43.7	100*	4/4	57.4	87.2*	$20	$35	57.1	81.3*	4.0	11.0*
Diabetes						100%										
	insulin lispro	HUMALOG	1996	No	$170	86.3	90.1*	2/2	14.8	11.2*	$30	$35	5.0	10.6*	7.4	8.3
	insulin glargine	LANTUS	2000	No	$165	97.8	99.9*	2/2	16.4	14.3*	$30	$35	5.0	6.4*	6.7	8.1*
	insulin detemir	LEVEMIR	2005	No	$167	11.5	99.1*	3/2	24.6	14.6*	$60	$35	0.9	6.5*	11.3	13.3
	insulin human regular	NOVOLIN	1982	No	$53	95.1	93.6*	2/2	17.4	15.2*	$30	$35	3.1	8.9*	6.4	7.6
Hepatitis B&C	peginterferon alfa-2a	PEGASYS	2002	Yes	$1,908	78.8	100*	4/4	62.2	92.3*	$20	$35	77.4	91.2*	27.9	38.7*
Multiple sclerosis						99.9										
	interferon beta-1a	AVONEX	1996	No	$1,672	96.3	93.8*	4/4	66.8	95.9*	$20	$59	61.6	71.1*	15.4	40.6*
	interferon beta-1b	BETASERON	1993	No	$1,898	99.5	100*	4/4	72.3	96.1*	$20	$29	64.7	71.8*	17.8	38.4*
	interferon beta-1a	REBIF	2002	No	$1,926	76.8	91.2*	4/4	63.0	97.9*	$50	$40	64.1	74.5*	15.9	42.0*
Neutropenia						99.3										
	Pegfilgrastim	NEULASTA	2002	No	$3,348	70.6	90.1*	4/4	63.5	92.9*	$25	$59	40.2	80.8*	10.2	33.8*
	Filgrastim	NEUPOGEN	1991	No	$261	90.3	100*	4/4	67.5	95.1*	$20	$59	58.5	79.9*	7.4	29.4*

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Drug Class / Indication	Generic name	Brand name	Year of FDA approval[a]	Black Box Warning in 2006[b]	Average Monthly Cost[c]	Formulary coverage[d] (%)		Tier (modal value)[e] 2006/ 2009	Type of cost-sharing as co-insurance[f] (%)		Co-pay amount[g] (modal value)		Prior authorization[h] (%)		Quantity limit[i] (%)	
						2006	2009		2006	2009	2006	2009	2006	2009	2006	2009
Rheumatoid arthritis						98.8										
	Etanercept	ENBREL	1998	No	$755	99.6	99.6	4/4	67.5	96.0*	$20	$59	86.1	86.1	22.3	39.4*
	Adalimumab	HUMIRA	2002	Yes	$1,510	91.9	99.6*	4/4	69.0	96.3*	$20	$59	79.8	86.0*	23.5	38.2*
	Infliximab	REMICADE	1998	Yes	$671	98.5	99.4*	4/4	71.8	97.4*	$40	$40	80.7	87.9*	2.0	0.8*

Data sources:

Authors' analysis of the Medicare Prescription Drug Plan Formulary Files, March 2006 and July 2009. N=3,075 prescription drug plans in 2006 (1,446 stand-alone prescription drug plans (PDP) and 1,629 Medicare Advantage prescription drug plans (MAPD)); N=4,207 prescription drug plans in 2009 (1,611 PDPs, and 2,596 MAPDs).

Notes:

j: Reports the percentage of the Medicare prescription drug plans that required step therapy for the drug

*P<0.05, chi-square test (null hypothesis: the rate in 2006 equals to the rate in 2009). Four sets of tests were conducted: (1) the percentage of plans covering the drug in their formulary in 2006 vs. in 2009; (2) the percentage of plans requiring co-insurance for the drug in 2006 vs. in 2009; (3) the percentage of plans requiring prior authorization for the drug in 2006 vs. in 2009; (4) the percentage of plans requiring quantity limit for the drug in 2006 vs. in 2009.

[a]Data on the year of approval are from the FDA.

[b]A black box warning is a labeling requirement imposed by the U.S. Food and Drug Administration (FDA) indicating that a drug may cause serious adverse effects. Data on the black box warning are from the FDA.

[c]The monthly cost is based on the average wholesale price of commonly prescribed doses. Data on the average wholesale price are from the 2007 Redbook and data on the commonly prescribed doses are from the MICROMEDEX database. Average wholesale price is used to serve as benchmark pricing. The monthly costs based on average wholesale price presented here are likely to be overestimated.

[d]Reports the percentage of the Medicare prescription drug plans that included the drug in their formulary coverage.

[e]Reports the tier in which the drug was most frequently placed (the modal value) among the Medicare prescription drug plans. In tiered formularies, drugs are divided into "tiers," with the first tier typically representing generics at the lowest level of patient cost sharing, and a higher tier requiring higher patient cost sharing.

[f]Reports the percentage of the Medicare prescription drug plans that used co-insurance (vs. co-payment) as the type of cost-sharing for the drug.

[g]Among plans that use co-payments, reports the co-payment amount that was most frequently used (the modal value) among the Medicare prescription drug plans.

[h]Reports the percentage of the Medicare prescription drug plans that required prior authorization for the drug.

[i]Reports the percentage of the Medicare prescription drug plans that required quantity limit for the drug.

[k]Coverage for drug class is defined as the coverage of at least one of these drugs within the class.