

MEMO

Date: August 26, 2016
To: Lindsey Adams, PhRMA
From: Jennifer Snow, Xcenda
Re: Comparing Drug Coverage: Medicare Part D vs Veterans Affairs Program

Project Objectives

With manufacturers of branded drugs facing greater pricing scrutiny, some congressional leaders have revived proposals for the Centers for Medicare & Medicaid Services (CMS) to negotiate drug prices in Part D. In order for the proposal to be effective, a government-run plan or set formulary is likely required. By instituting one formulary for Part D, CMS would determine prices for a national formulary instead of the current policy that gives Part D plan sponsors the ability to negotiate prices directly with drug manufacturers who compete to get on plan formularies.

The Pharmaceutical Research and Manufacturers of America (PhRMA) has partnered with Xcenda to compare coverage of select drugs between the Medicare Part D marketplace and the Veterans Affairs (VA) program. To better understand how a CMS formulary would affect coverage of Part D drugs, Xcenda has compared 25 newly Federal Drug Administration (FDA)-approved, first-in-class drugs between all Part D plans and the [VA national formulary](#).

Medicare Part D and VA Program Overview

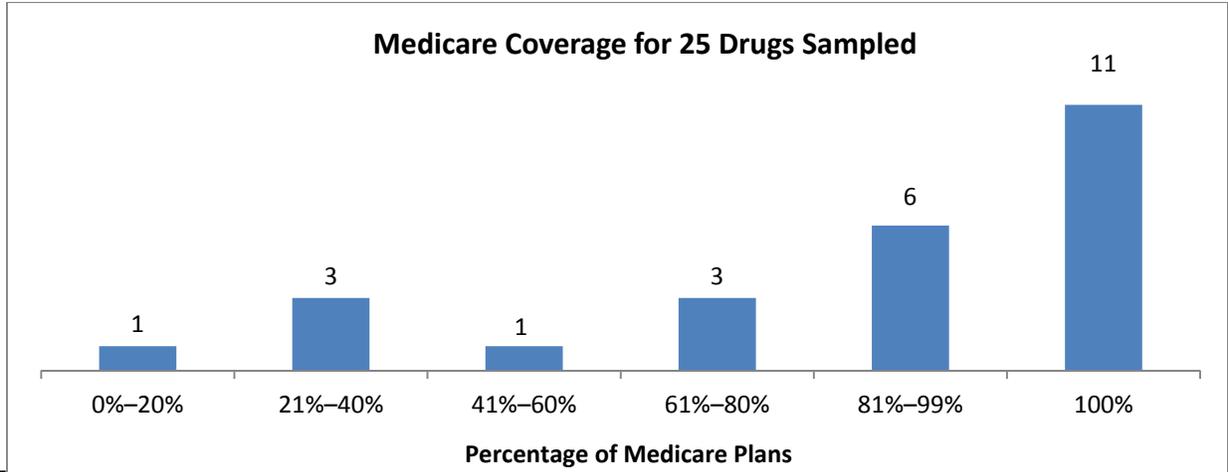
The VA manages a single national formulary to determine prescription drug coverage for its veteran enrollees; conversely, private commercial insurers administer overall Medicare Part D benefits, manage their own formularies, and establish coverage parameters specifically for their members.

Unlike the VA, Part D plans must abide by various formulary requirements such as offering broad coverage across drug categories and classes (ie, covering at least 2 drugs in each class) and covering substantially all drugs that fall in 6 protected classes.¹ On the other hand, the VA's unilateral role in setting drug prices when contracting with drug manufactures can, among other causes, restrict access and coverage for veterans.

Analysis Results^a

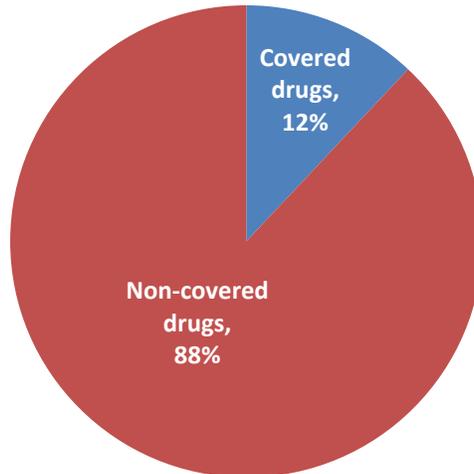
Of the 25 newly-approved drugs reviewed in this analysis, they were covered by between 5% and 100% of Medicare Part D plans. Eleven drugs were covered by 100% of the Medicare Part D plans; 9 of which fell into one of the protected class categories under Part D. Overall, coverage by all plans for all drugs averaged 81%.

^a See Appendix for drug-level Medicare and VA results.



VA coverage was considerably lower when compared to Medicare Part D. Only 12% (**3 out of 25**) of the drugs in the sample were found on the VA national formulary. These 3 drugs were also generally favorably covered among Part D plans (70%-100%). However, outside of these 3 products, the VA’s national formulary appears significantly less generous than Part D formularies as the VA formulary did not cover any of the other 22 drugs.

VA Coverage for 25 Drugs Sampled



Policy Implications

The analysis paints a stark contrast in coverage of newly approved drugs between the 2 programs, suggesting that a national formulary could restrict access options for beneficiaries and limit the availability of the latest and most advanced treatments.

As noted above, drugs covered under the Part D protected class provision—but not covered by the VA—account for 9 of the 25 products examined.^b While critics may point to mandated Part D coverage requirements such as this, the findings of this analysis of select drugs reveal that overall Part D coverage **still outpaced** that of the VA. Even excluding the products in this overall list with protected class status, Part D plan coverage for the remaining 16 drugs averaged 45% while the VA covered 3 of the 16 drugs

^b See Appendix for a list of the 9 protected class drugs.

(19% of the adjusted sample). Therefore, comparing the formularies, the VA still would not cover a majority of the drugs analyzed if coverage was required as under Part D. In an effort to maintain program costs, instituting a single CMS formulary could potentially result in more restrictive access to Part D therapies.

Methodology

Sample Selection^c

Xcenda began selection for a sample of 25 drugs by using annual FDA Center for Drug Evaluation and Research (CDER) novel drug reports² to compile a list of all newly approved drugs from 2011 to 2015. This list was then filtered for drugs that met following criteria:

1. First-in-class status
2. Oral formulations only (eg, tablets, capsules; no injectables)
3. No pediatric-only indications
4. Covered Part D drug status

There were a total of 42 drugs that met the selection criteria. For each drug, the total number of Medicare scripts to date³ was calculated starting when each one was launched on the market. Then, with the drugs grouped and separated by approval year, the top 5 most utilized medications were determined within each year and consolidated afterward to arrive at the sample of 25 drugs.^d

Analysis

Xcenda utilized the Medi-Span⁴ drug compendium to obtain all National Drugs Codes (NDCs) associated with the sample of 25 drugs. Using the NDCs, Xcenda then analyzed all Part D plan formularies⁵ to assess coverage for each drug of interest. Once coverage was determined, Xcenda calculated the percentage of plans^e covering each drug.

To evaluate VA coverage, Xcenda analyzed the VA formulary⁶ using the generic name of each drug (since the VA formulary does not list brand names). Xcenda categorized drugs found on the formulary as covered medications.

Summary of Data Sources

Data Source	Data Point	Date
FDA CDER Novel Drug Summary Reports ²	Drug sample	2011–2015
Prescription drug data and distribution information available through AmerisourceBergen ³	Prescription count	January 2011–June 2016
Medi-Span drug information ⁴	NDC	May 2015
Part D Public Use Formulary ⁵	Drug coverage	July 2016
VA National Formulary ⁶	Drug coverage	July 2016

References

^c See Appendix for summary of the 25 drugs used in this analysis.

^d Only 4 drugs approved in 2015 met the selection criteria; in the complete the sample of 25 drugs, the drug that (i) had the highest overall utilization in the 2011 to 2015 review timeframe and (ii) was outside of the top 5 in each year was selected for the sample; Erivedge, approved in 2012, was added, which brought the number of drugs in 2012 from 5 to 6.

^e Includes all Medicare plans that offer Part D coverage such as Medicare Advantage Prescription Drug plans, standalone Medicare Prescription Drug Plans, Medicare Advantage Special Needs Plans, and Medicare-Medicaid Plans.

1. CMS. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D drugs and formulary requirements. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.
2. FDA. New drugs at FDA: CDER's new molecular entities and new therapeutic biological products. <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm20025676.htm>.
3. Prescription drug data and distribution information available through AmerisourceBergen, 1/1/2011 to 6/30/2016.
4. Medi-Span. Drug information from May 2016.
5. CMS. Prescription drug plan formulary, pharmacy network, and pricing information files. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PrescriptionDrugPlanFormularyPharmacyNetworkandPricingInformationFiles.html>.
6. US Department of Veterans Affairs. Pharmacy benefits management services. <http://www.pbm.va.gov/NationalFormulary.asp>.

Appendix – Summary of 25 Drugs Sampled

Brand Name	Generic Name	Drug Group	Drug Class	Used for	Approval Date	Part D Coverage by Plan	VA Coverage
Aubagio	teriflunomide	Psychotherapeutic and neurological agents – misc.	Multiple sclerosis agents	For the treatment of adults with relapsing forms of multiple sclerosis	9/12/2012	54%	No
Belsomra	suvorexant	Hypnotics/sedatives/sleep disorder agents	Orexin receptor antagonists	To treat difficulty in falling and staying asleep (insomnia)	8/13/2014	24%	No
Corlanor	ivabradine	Cardiovascular agents – misc.	Sinus node inhibitors	To reduce hospitalization from worsening heart failure	4/15/2015	37%	No
Daliresp	roflumilast	Antiasthmatic and bronchodilator agents	Selective phosphodiesterase 4 (PDE4) inhibitors	To decrease the frequency of flare-ups (exacerbations) or worsening of symptoms from severe chronic obstructive pulmonary disease (COPD)	2/28/2011	100%	No
Entresto	sacubitril/valsartan	Cardiovascular agents – misc.	Cardiovascular agents misc. – combinations	To treat heart failure	7/7/2015	79%	No
Erivedge	vismodegib	Antineoplastics and adjunctive therapies	Antineoplastic – hedgehog pathway inhibitors ^a	To treat adult patients with basal cell carcinoma	1/30/2012	100%	No
Fycompa	perampanel	Anticonvulsants	AMPA glutamate receptor antagonists ^a	To treat partial onset seizures in patients with epilepsy ages 12 years and older	10/22/2012	100%	No
Harvoni	ledipasvir/sofosbuvir	Antivirals	Hepatitis agents	To treat chronic hepatitis C virus (HCV) genotype 1 infection	10/10/2014	98%	Yes
Ibrance	palbociclib	Antineoplastics and adjunctive therapies	Antineoplastic enzyme inhibitors ^a	To treat advanced (metastatic) breast cancer	2/3/2015	100%	No

Brand Name	Generic Name	Drug Group	Drug Class	Used for	Approval Date	Part D Coverage by Plan	VA Coverage
Imbruvica	ibrutinib	Antineoplastics and adjunctive therapies	Antineoplastic enzyme inhibitors ^a	To treat patients with mantle cell lymphoma (MCL)	11/13/2013	100%	No
Invokana	canagliflozin	Antidiabetics	Sodium-glucose cotransporter 2 (SGLT2) inhibitors	Used with diet and exercise to improve glycemic control in adults with type 2 diabetes	3/29/2013	89%	No
Jakafi	ruxolitinib	Antineoplastics and adjunctive therapies	Antineoplastic enzyme inhibitors ^a	To treat patients with myelofibrosis	11/16/2011	100%	No
Kerydin	tavaborole	Dermatologicals	Antifungals – topical	For the topical treatment of onychomycosis of the toenails	7/7/2014	5%	No
Linzess	linaclotide	Gastrointestinal agents – misc.	Irritable bowel syndrome (IBS) agents	To treat chronic idiopathic constipation and to treat irritable bowel syndrome with constipation (IBS-C) in adults	8/30/2012	94%	No
Mekinist	trametinib	Antineoplastics and adjunctive therapies	Antineoplastic enzyme inhibitors ^a	To treat patients whose tumors express the BRAF V600E or V600K gene mutations	5/29/2013	100%	No
Myrbetriq	mirabegron	Urinary antispasmodics	Urinary antispasmodics – beta-3 adrenergic agonists	To treat adults with overactive bladder	6/28/2012	90%	No
Ofev	nintedanib	Respiratory agents – misc.	Pulmonary fibrosis agents	For the treatment of idiopathic pulmonary fibrosis (IPF)	10/15/2014	93%	No
Orkambi	lumacaftor 200 mg/ ivacaftor 125 mg	Respiratory agents – misc.	Cystic fibrosis agents	To treat cystic fibrosis	7/2/2015	85%	No

Brand Name	Generic Name	Drug Group	Drug Class	Used for	Approval Date	Part D Coverage by Plan	VA Coverage
Otezla	apremilast	Analgesics – anti-inflammatory	Phosphodiesterase 4 (PDE4) inhibitors	To treat adults with active psoriatic arthritis (PsA)	3/21/2014	40%	No
Picato	ingenol mebutate	Dermatologicals	Antineoplastic or premalignant lesion agents – topical	For the topical treatment of actinic keratosis	1/23/2012	68%	No
Potiga	ezogabine	Anticonvulsants	Anticonvulsants – misc. ^a	An add-on medication to treat seizures associated with epilepsy in adults	6/10/2011	100%	No
Sovaldi	sofosbuvir	Antivirals	Hepatitis agents	To treat chronic hepatitis C virus (HCV) infection	12/6/2013	100%	Yes
Tecfidera	dimethyl fumarate	Psychotherapeutic and neurological agents – misc.	Multiple sclerosis agents	To treat adults with relapsing forms of multiple sclerosis (MS)	3/27/2013	70%	Yes
Xalkori	crizotinib	Antineoplastics and adjunctive therapies	Antineoplastic enzyme inhibitors ^a	Certain patients with late-stage (locally advanced or metastatic), non-small cell lung cancers who express the abnormal anaplastic lymphoma kinase gene	8/26/2011	100%	No
Zytiga	abiraterone acetate	Antineoplastics and adjunctive therapies	Antineoplastic – hormonal and related agents ^a	In combination with prednisone to treat patients with late-stage (metastatic) castration resistant prostate cancer who have received docetaxel (chemotherapy)	4/28/2011	100%	No

^a Part D protected class drug.