Letters

RESEARCH LETTER

Utilization Management Trends in Medicare Part D Oncology Drugs, 2010-2020

Utilization management—such as prior authorization—is prevalent, and evidence from medical services indicates it disproportionately affects oncology treatments.[1] Orally administered cancer drugs are increasing in number and cost.[2] These products have mandatory coverage in Medicare Part D as a protected class; less is known about utilization management. Utilization management introduces administrative burdens on clinicians and patients to monitor or modify utilization, which can lead to delayed or forgone care.[3] We quantified Medicare Part D beneficiaries' exposure to utilization management for oral oncology drugs.

Supplemental content

Methods | We used 2010-2020 Medicare Part D formulary files to identify plans' use of prior authorization, quantity limits, and step therapy for each unique drug-dose-formulary combination of orally administered oncology drugs, the level at which a prescription would be written. We used the Master Beneficiary Summary Files to calculate midyear enrollment for each formulary and year. We identified oncology drugs using the 2021 Oncology Care Model drug list.[4] The Harvard Medical School Institutional Review Board waived review of this study.

We categorized drugs designated by Medicare as specialty (monthly cost above $600 in 2010-2016 and $670 in 2017-2020[5]) or nonspecialty and brand or generic. For each year, we estimated the enrollment-weighted proportion of drug-dose-formulary combinations subject to utilization management using Stata version 16 (StataCorp). Medicare beneficiaries' total potential exposure to utilization management includes the coverage policy for every drug-dose-formulary combination, weighted by number of enrollees in each plan.

Because noncoverage is a form of utilization management, we also examined coverage of brand specialty drugs when generic substitutes became available.

Results | In 2010, 28 030 290 beneficiaries were enrolled in 333 formularies covering 62 oral oncology drugs (26 specialty brand, 0 specialty generic, 28 nonspecialty brand, and 8 nonspecialty generic) (**Table**). In 2020, 47 337 020 beneficiaries were enrolled in 548 formularies covering 249 oral oncology drugs (139 specialty brand, 9 specialty generic, 86 nonspecialty brand, and 15 nonspecialty generic). Unique drug-dose-formulary prescribing combinations increased from 19 004 to 122 173 between 2010 and 2020.

The proportion of drug-dose-formulary combinations requiring prior authorization increased over time (**Figure**, A). For specialty brand drugs, the proportion increased from 72.8% to 95.4% between 2010 and 2020. Specialty generic drugs entered the market in 2016; prior authorization use increased from 91.1% in 2016 to 95.0% in 2020. For nonspecialty brand drugs, the proportion of drug-dose-formulary combinations requiring prior authorization increased from 15.9% to 78.2% and for nonspecialty generic drugs from 1.0% to 8.0% between 2010 and 2020.

The proportion of drug-dose-formulary combinations for oral oncology drugs requiring quantity limits for specialty brand drugs increased from 31.4% to 62.5% between 2010 and 2020 (Figure, B). For specialty generic drugs, the proportion increased from 32.7% to 77.8% between 2016 and 2020. For nonspecialty brand drugs, the proportion with quantity limits increased from 11.8% to 47.3% and for nonspecialty generic drugs from 9.7% to 18.8% between 2010 and 2020.

Step therapy was rare in all oral oncology drug categories, and less than 1% of drug-dose-formulary combinations required step therapy for any of these drugs from 2013 onward (Figure, C). Coverage of specialty brand drugs declined once generic alternatives were available (Table).

Discussion | Utilization management for Medicare Part D oral oncology drugs increased between 2010 and 2020. Prior authorization was the most prevalent strategy for specialty brand and generic drugs, as well as nonspecialty brand drugs. Quantity limit use increased and was the most common strategy for nonspecialty generic drugs. Step therapy use was rare, perhaps because oral oncology drugs have few substitutes. Study limitations included a focus on Medicare and oral oncology drugs; future work could expand this scope.

Utilization management is entwined with spending[2]: it was most prevalent among specialty drugs—the most costly and least affordable to patients.[6] Utilization management may be appropriate for some oncology drugs, such as those approved with provisional evidence of efficacy. It is less clear why prior authorization is required for highly effective, first-line drugs such as generic imatinib. Policies aimed at reforming utilization management should prioritize reducing barriers to high-value treatment.

Michael Anne Kyle, PhD, RN
Stacie B. Dusetzina, PhD
Nancy L. Keating, MD, MPH

Author Affiliations: Department of Health Care Policy, Harvard Medical School, Boston, Massachusetts (Kyle, Keating); Department of Health Policy, Vanderbilt University Medical Center, Nashville, Tennessee (Dusetzina).

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Corresponding Author: Michael Anne Kyle, PhD, RN, Department of Health Care Policy, Harvard Medical School, 180A Longwood Ave, Boston, MA 02115 (kyle@hcp.med.harvard.edu).

Table. Medicare Part D Beneficiaries, Formularies, and Oncology Drugs, 2010-2020

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Unweighted sample, No.											
Part D beneficiaries[a]	28 030 290	29 566 659	31 876 809	35 739 990	37 765 387	39 535 253	41 252 891	42 793 998	44 256 719	45 827 260	47 337 020
Part D formularies[b]	333	305	337	481	511	482	461	460	474	498	548
Oral oncology drugs[c]	62	74	88	110	123	137	159	173	191	232	249
Specialty brand[d]	26	35	49	70	75	86	103	117	134	137	139
Specialty generic[e]	NA	NA	NA	NA	NA	NA	2	2	2	6	9
Nonspecialty brand	28	29	29	30	34	36	38	41	42	74	86
Nonspecialty generic	8	10	10	10	14	15	16	13	13	15	15
Drug-dose-formulary combinations[f]	19 004	20 871	27 581	46 781	56 726	60 426	67 507	72 984	82 702	105 605	122 173
Formularies covering specialty brand vs generic substitute, %[g]											
Brand imatinib	100	100	100	100	100	100	70.7	33.4	12.9	8.0	7.7
Generic imatinib	NA	NA	NA	NA	NA	NA	88.7	91.8	100	100	100
Brand erlotinib	100	100	100	100	100	100	100	100	100	75.7	14.8
Generic erlotinib	NA	NA	NA	NA	NA	NA	NA	NA	NA	97.8	99.8
Brand abiraterone	NA	98.0[h]	100	100	100	100	100	100	100	52.7	34.1
Generic abiraterone	NA	NA	NA	NA	NA	NA	NA	NA	NA	90.4	93.6
Brand everolimus[i,j]	100	100	100	100	100	100	100	100	100	100	73.5
Generic everolimus[i,j]	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	89.6

Abbreviation: NA, not applicable.

[a] Unique Part D beneficiaries derived from Medicare Master Beneficiary Summary Files annual midyear enrollment.

[b] Unique formularies derived from Medicare Part D Formulary Files (Research Identifiable Files).

[c] Oral oncology drugs identified using the Oncology Care Model drug list.

[d] Describes brand-name oncology drugs meeting the Medicare definition of specialty drug (cost >$600 per month in 2010-2016 or >$670 per month in 2017-2020).

[e] Describes generic oncology drugs meeting the Medicare definition of specialty drug (cost >$600 per month in 2010-2016 or >$670 per month in 2017-2020).

[f] Describes unique drug-dose-formulary combinations of oncology drugs, which accounts for every potential permutation a prescriber can consider based on the drug, the dose, and the patient's insurance.

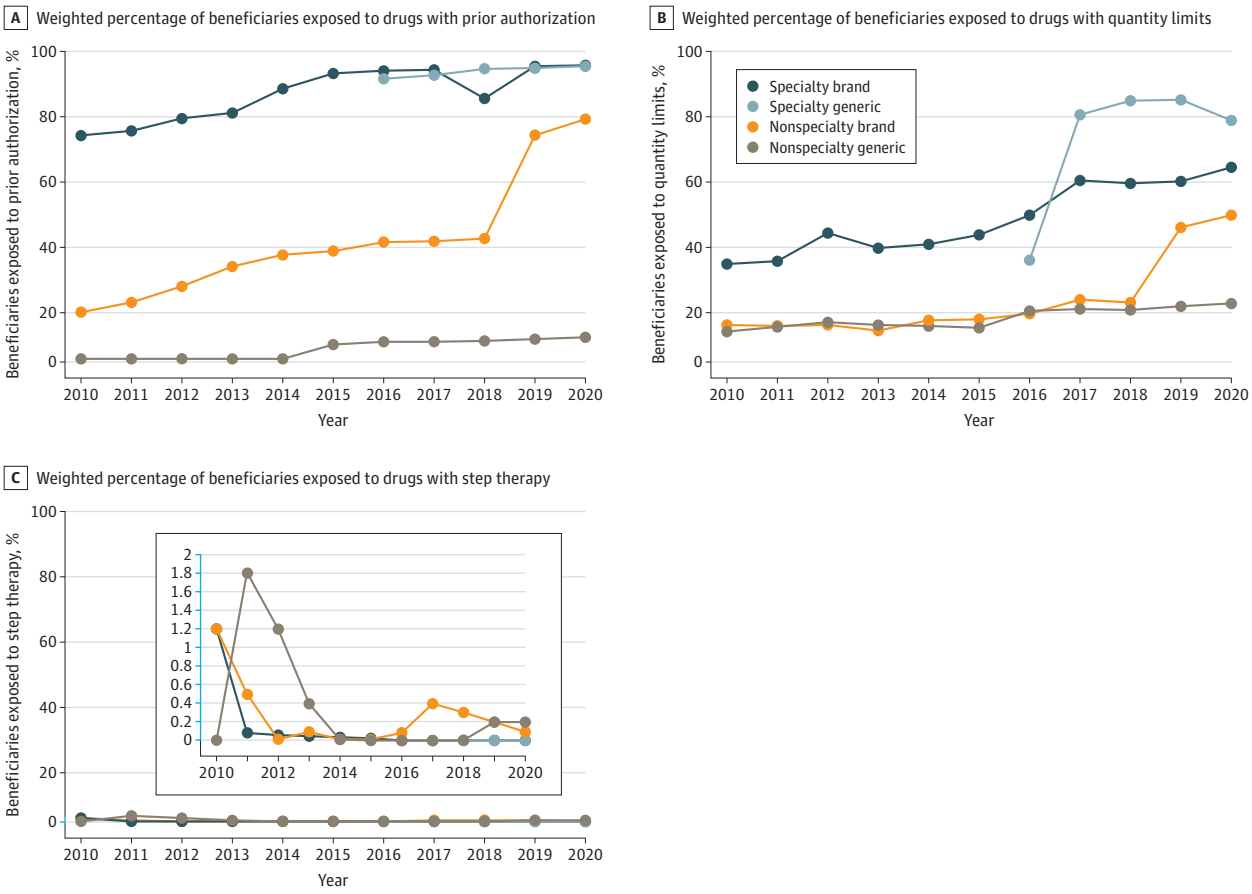
[g] Describes changing formulary coverage for specialty brand drugs when generic substitutes become available.

[h] Approval of brand abiraterone in April 2011 may explain why it was not documented in 6 formularies.

[i] Both brand and generic everolimus include only those formulations approved for oncology indications.

[j] Brand everolimus includes only Afinitor and not Afinitor Disperz because the latter did not have a generic substitute at the time of this analysis.

Figure. Trends in Utilization Management Strategies for Medicare Part D Oncology Drugs, 2010-2020



A, Unique drug-dose-formulary combinations requiring prior authorization weighted by formulary enrollment are shown. The drug-dose-formulary unit of analysis is the level at which a prescription is written, which considers the drug, the dose, and the patient's insurance. Weighting each possible prescribing combination by formulary enrollment captures how frequently beneficiaries may be exposed to prior authorization (eg, one formulary requires prior authorization for a given drug-dose combination and another does not, but 90% of patients are covered by the first formulary). B, The same analysis described in panel A but for quantity limits is shown. C, The same analysis described in panel A but for step therapy is shown.

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Concept and design: All authors.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Kyle.
Critical revision of the manuscript for important intellectual content: Dusetzina, Keating.
Statistical analysis: Kyle.
Supervision: Keating.

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Data Sharing Statement: See the Supplement.

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Data Sharing Statement

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Data
Data available: No

Additional Information
Explanation for why data not available: This analysis uses Medicare Part D Research Identified Files under a data use agreement that precludes data sharing; interested researchers can acquire this data directly from CMS.