

# Medicare Advantage Coverage Restrictions for the Costliest Physician-Administered Drugs

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Physician-administered drugs accounted for \$35 billion in Medicare Part B spending in 2018, with spending growing 9.6% annually, exceeding the overall Medicare growth rate of 4.4%.<sup>1,2</sup> Medicare Advantage (MA) insurers receive a capitated per-member per-month payment from the federal government to offer privately administered health insurance coverage to Medicare beneficiaries. The capitated payment incentivizes MA insurers to reduce spending and, combined with the growing cost pressure of physician-administered drugs, may lead MA insurers to restrict access to physician-administered drugs through utilization management tools (ie, coverage restrictions). Understanding the use of coverage restrictions to manage physician-administered drugs is important because, if used well, these tools can reduce wasteful spending but, if used inappropriately, they can harm beneficiary access. Understanding the use of these tools may also provide insights for how the Medicare program can manage very expensive drugs.

Insurers have long used coverage restrictions, such as prior authorization and step therapy, to manage high-cost drugs among non-Medicare enrollees.<sup>3</sup> Until recently, MA insurers, which insure more than 20 million older and disabled individuals, were allowed to require prior authorization for physician-administered drugs but were prohibited from using step therapy. This guidance was relaxed by CMS effective January 2019.<sup>4</sup>

Although physician-administered drugs are typically paid for through the medical (Part B) benefit, payment for physician-administered drugs can be shifted to the pharmacy (Part D) benefit when the drugs are obtained from a specialty pharmacy. Physician-administered drugs may be obtained through a specialty pharmacy and Part D benefit when a physician practice or hospital does not want to prospectively purchase a drug or when the MA insurer wants more control over the purchasing process. Thus, MA insurers may also choose to include or exclude physician-administered drugs on Part D formularies.<sup>5,6</sup> Shifting purchase of physician-administered drugs to Part D has implications for enrollee affordability because of differences in cost sharing. Enrollees are typically responsible for a 20% coinsurance payment when physician-administered

## ABSTRACT

**OBJECTIVES:** To examine the use of step therapy, prior authorization, and Part D formulary exclusion by 4 large Medicare Advantage (MA) insurers to manage 20 physician-administered drugs with the highest total Medicare expenditures (top 20 drugs).

**STUDY DESIGN:** We collected data for United Healthcare, CVS/Aetna, Humana, and Kaiser plans to create a database of 2020 Part B coverage restrictions and conducted a retrospective analysis of 2018–2020 Part D formularies.

**METHODS:** For each insurer, we calculated the number of top 20 physician-administered drugs subject to prior authorization and step therapy. For physician-administered drugs for which there were no similar or interchangeable alternatives, we examined which insurers required prior authorization or step therapy. Finally, we examined whether insurers restricted access to physician-administered drugs by reducing coverage on Part D formularies.

**RESULTS:** Of the top 20 physician-administered drugs, 17 were subject to prior authorization and 10 were subject to step therapy by at least 1 insurer. For 5 physician-administered drugs without a similar or interchangeable alternative, none were subject to step therapy and all were subject to prior authorization by at least 1 insurer. Across the 4 insurers, 16 physician-administered drugs were covered on all or some of the Part D formularies in 2018, which decreased to 6 in 2020.

**CONCLUSIONS:** Four large MA insurers managed access to expensive physician-administered drugs with a combination of prior authorization, step therapy, and Part D formulary design. When a low-cost alternative exists, these tools can help reduce wasteful spending, but the administrative barriers may also reduce access.

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## TAKEAWAY POINTS

In response to cost pressures, Medicare Advantage (MA) insurers may restrict access to physician-administered drugs through coverage restrictions and formulary design. Three of 4 large MA insurers required step therapy in 2020 for at least 1 of the top 20 drugs with the highest total expenditures (ranging from 1 to 9 drugs), a tool not allowed prior to 2019, and all 4 insurers required prior authorization for at least 1 of the top 20 drugs (ranging from 1 to 15 drugs). Additionally, all 4 insurers reduced coverage of these drugs on their Part D formularies from 2018 to 2020.

- ▶ The frequency of coverage restrictions and the drugs for which each insurer applied step therapy and prior authorization requirements varied substantially.
- ▶ Step therapy and prior authorization can direct beneficiaries to lower-cost options; however, in instances where a similar lower-cost option does not exist, coverage restrictions burden clinicians and limit access to critical medications without the benefit of reduced insurer spending and beneficiary out-of-pocket costs.
- ▶ With increasing restrictions on access to physician-administered drugs, CMS should monitor the effects of coverage restrictions on beneficiary access.

drugs are purchased through the Part B benefit, but they may have a lower co-payment when drugs are purchased through the pharmacy benefit.

In this paper we sought to answer 3 key questions: (1) What is the frequency of Part B coverage restrictions (prior authorization and step therapy) for 4 large MA insurers for the 20 physician-administered drugs with the highest total expenditures?; (2) Are coverage restrictions applied to drugs for which there are not similar or interchangeable alternative drugs available?; and (3) Are MA insurers also restricting access to expensive physician-administered drugs by reducing coverage of these drugs on their Part D formularies?

## METHODS

### Data and Sample

CMS requires that MA insurers publish step therapy and prior authorization restrictions for physician-administered drugs in their annual plan-level evidence of coverage documents (EOCs). The EOCs list by drug, using brand name, generic name, or Healthcare Common Procedure Coding System (HCPCS) code, whether a drug is subject to prior authorization or step therapy. These requirements are typically provided in the EOCs at a drug class level. The primary data source for this analysis was composed of EOCs for the 1631 health maintenance organization and preferred provider organization plans offered by CVS/Aetna, Humana, Kaiser, and United Healthcare in 2020. These cover 58% of MA enrollees and are 4 of the 5 largest MA insurers in the United States.<sup>7</sup>

We used the 2018 Medicare Part B Drug Spending Dashboard to identify the 20 drugs with the highest 2018 Part B drug expenditures, excluding vaccines.<sup>8</sup> Together these drugs accounted for 59% of fee-for-service (FFS) Part B physician-administered drug spending reported in the 2018 Part B drug spending dashboard and 10% of overall FFS Part B spending.<sup>8,9</sup> Although physician-administered drug spending data are not available for MA plans, these top 20 drugs likely account for a similarly large share of MA physician-administered drug spending.

We also used data from the quarter 1 (Q1) 2018, 2019, and 2020 CMS Prescription Drug Plan Formulary Public Use Files to determine whether MA insurers included each of the top 20 drugs as part of their Part D formularies.<sup>10</sup>

Finally, we used the January 2020 Monthly Enrollment by Contract file to calculate the share of enrollees for each insurer who are in plans subject to prior authorization or step therapy.<sup>11</sup>

### Outcome Variables

To examine the use of Part B coverage restrictions, the outcome of interest was the number of the 4 large MA insurers that used prior authorization and step therapy for each of the top 20 physician-administered drugs. We

tracked coverage restrictions at the contract identifier (ID) level because MA insurers sometimes applied a coverage restriction for a physician-administered drug for only some of their MA contracts. We then aggregated the results to determine what share of an MA insurer's enrollees were subject to a coverage restriction for each drug.

Prior authorization is when a beneficiary's clinician must receive approval prior to administering a drug in order for the insurer to pay for the drug. Prior authorization is typically used to restrict access to high-cost drugs, but it can also be used to provide another level of review before a beneficiary receives a drug with safety concerns or with limited evidence to support its use. We defined a drug as being subject to prior authorization if the HCPCS code or name of the drug was included in the list of drugs subject to prior authorization in an EOC.

Step therapy is when a beneficiary must first try one drug, often a lower-cost drug, before trying another drug. We defined a drug as being subject to step therapy if the HCPCS code or name of the drug was included in the list of drugs subject to step therapy in an EOC.

For the top 20 physician-administered drugs, we examined whether coverage restrictions were applied to drugs for which there are not similar or interchangeable alternatives available. We defined a drug as having an interchangeable alternative available if the FDA had approved a biosimilar prior to 2020.<sup>12</sup> We identified alternatives for drugs without biosimilars through review of the peer-reviewed literature, analysis of trends in drug utilization, and consultation with clinical experts. Drugs that we determined to have at an alternative for at least 1 indication were defined as being part of a market basket (Table 1).

Finally, to assess MA Part D formulary restrictions for the top 20 physician-administered drugs, the outcome of interest was the change from Q1 2018 to Q1 2020 in the number of top 20 drugs included on Part D formularies.

### Data Collection and Analysis

We first examined the characteristics of the top 20 physician-administered drugs, including FDA-approved indications, the number

**TABLE 1.** Characteristics of Drugs Included in Study Sample

Brand (generic) name	Similar or interchangeable drug?	HCPCS code	Total spending (2018)	Number of beneficiaries (2018)	Small molecule/biologic	FDA-approved indications	Examples
Eylea (aflibercept)	Yes—similar drug(s) available as part of market basket	J0178	\$2,573,938,387	240,910	Biologic	Neovascular (wet) age-related macular degeneration; macular edema following retinal vein occlusion; diabetic macular edema; diabetic retinopathy	Bevacizumab, ranibizumab
Keytruda (pembrolizumab)	Yes—similar drug(s) available as part of market basket	J9271	\$1,813,727,267	35,491	Biologic	Melanoma; metastatic, non-small cell lung cancer; head and neck cancer; Hodgkin lymphoma; urothelial carcinoma; gastric cancer; cervical cancer; hepatocellular carcinoma; Merkel cell carcinoma; renal cell carcinoma; small cell lung cancer; esophageal carcinoma; endometrial cancer	Other checkpoint inhibitors, including nivolumab, atezolizumab, avelumab, ipilimumab, durvalumab, dostarlimab
Opdivo (nivolumab)	Yes—similar drug(s) available as part of market basket	J9299	\$1,715,907,188	32,846	Biologic	Melanoma; metastatic non-small cell lung cancer; renal cell carcinoma; Hodgkin lymphoma; head and neck cancer; urothelial carcinoma; colorectal cancer; hepatocellular carcinoma; small cell lung cancer	Other checkpoint inhibitors, including pembrolizumab, atezolizumab, avelumab, ipilimumab, durvalumab, dostarlimab
Rituxan (rituximab)	Yes—interchangeable drug(s) available	J9310	\$1,699,302,443	70,845	Biologic	Non-Hodgkin lymphoma; chronic lymphocytic leukemia; rheumatoid arthritis; granulomatosis with polyangiitis (Wegener granulomatosis) and microscopic polyangiitis	FDA-approved biosimilars available (eg, Truxima [rituximab-abbs])
Prolia* (denosumab)	Yes—similar drug(s) available as part of market basket	J0897	\$1,416,968,973	533,286	Biologic	Osteoporosis	Zoledronic acid
Neulasta (pegfilgrastim)	Yes—interchangeable drug(s) available	J2505	\$1,370,995,237	88,742	Biologic	Febrile neutropenia for patients with cancer receiving myelosuppressive chemotherapy; hematopoietic subsyndrome of acute radiation syndrome	FDA-approved biosimilars available (eg, Fulphila [pegfilgrastim-jmdb]), Udenyca [pegfilgrastim-cbqv])
Lucentis (ranibizumab)	Yes—similar drug(s) available as part of market basket	J2778	\$1,215,701,656	123,389	Biologic	Macular degeneration; macular edema; diabetic macular edema; diabetic retinopathy; myopic choroidal neovascularization	Aflibercept, bevacizumab
Remicade (infliximab)	Yes—interchangeable drug(s) available	J1745	\$1,149,653,207	52,085	Biologic	Crohn disease; ulcerative colitis; rheumatoid arthritis; ankylosing spondylitis; psoriatic arthritis; psoriasis	FDA-approved biosimilars available (eg, Renflexis [infliximab-abda])
Avastin (bevacizumab)	Yes—interchangeable drug(s) available	J9035	\$1,011,988,293	224,023	Biologic	Colorectal cancer; non-small cell lung cancer; glioblastoma multiforme; renal cell carcinoma; cervical cancer; ovarian cancer; fallopian tube cancer; peritoneal cancer	FDA-approved biosimilars available (eg, Mvasi [bevacizumab-awwb])
Herceptin (trastuzumab)	Yes—interchangeable drug(s) available	J9355	\$821,766,302	20,586	Biologic	Adjuvant breast cancer; metastatic breast cancer; metastatic gastric cancer	FDA-approved biosimilars available (eg, Kanjinti [trastuzumab-anns])

(continued)

**TABLE 1.** (Continued) Characteristics of Drugs Included in Study Sample

Brand (generic) name	Similar or interchangeable drug?	HCPCS code	Total spending (2018)	Number of beneficiaries (2018)	Small molecule/biologic	FDA-approved indications	Examples
Orencia* (abatacept)	Yes—similar drug(s) available as part of market basket	J0129	\$799,286,087	26,726	Biologic	Rheumatoid arthritis; juvenile idiopathic arthritis; psoriatic arthritis	Other immunologic drugs exist, including alemtuzumab, anakinra
Darzalex (daratumumab)	No	J9145	\$645,375,454	9309	Biologic	Multiple myeloma	N/A
Ocrevus (ocrelizumab)	No	J2350	\$488,832,130	9704	Biologic	Multiple sclerosis	N/A
Alimta (pemetrexed disodium)	No	J9305	\$471,369,648	19,306	Small molecule	Malignant pleural mesothelioma; non-small cell lung cancer	N/A
Velcade (bortezomib)	No	J9041	\$443,373,929	20,262	Small molecule	Multiple myeloma	N/A
Sandostatin LAR Depot (octreotide acetate mi-spheres)	Yes—similar drug(s) available as part of market basket	J2353	\$414,142,370	9949	Small molecule	Acromegaly; carcinoid tumors; vasoactive intestinal peptide tumors	Lanreotide
Soliris (eculizumab)	Yes—similar drug(s) available as part of market basket	J1300	\$395,796,137	1161	Biologic	Paroxysmal nocturnal hemoglobinuria; hemolytic uremic syndrome; myasthenia gravis	Ravulizumab
Xolair (omalizumab)	No	J2357	\$395,083,351	17,070	Biologic	Asthma; chronic idiopathic urticaria	N/A
Gammagard Liquid (immunoglobulin G)	Yes—interchangeable drug(s) available	J1569	\$378,891,063	17,633	Biologic	Primary humoral immunodeficiency; multifocal motor neuropathy	Numerous other immunoglobulin products exist (eg, Gamunex-C)
Gammaked* (immunoglobulin A)	Yes—interchangeable drug(s) available	J1561	\$370,456,943	15,991	Biologic	Chronic inflammatory demyelinating polyneuropathy; primary humoral immunodeficiency; idiopathic thrombocytopenic purpura	Numerous other immunoglobulin products exist (eg, Gamunex-C)

HCPCS, Healthcare Common Procedure Coding System; LAR, long-acting release; N/A, not applicable.

\*Indicates a drug with multiple brand or generic names for the given HCPCS code.

Information on total spending and the number of beneficiaries is from the Medicare Part B Drug Spending Dashboard.

of FFS beneficiaries receiving each drug, total FFS spending, and whether each drug was a biologic or small-molecule product.

We hand-collected EOCs for 1631 plans to create a database of coverage restrictions at the contract ID level for the top 20 physician-administered drugs across the 4 MA insurers. For each insurer, we calculated the percentage of their enrollees who were subject to prior authorization and step therapy for each of those 20 drugs.

For drugs without a similar or interchangeable alternative, we used the database of EOCs to determine whether each drug was subject to prior authorization or step therapy, and, if so, for how many of the 4 insurers.

Finally, to examine whether access was also restricted on Part D formularies, we analyzed whether the top 20 physician-administered drugs were included on each insurer's Part D formularies for their integrated MA plus Part D products. Using the Q1 2020 formulary public use files, we calculated for each of the top 20 drugs the

share of Part D formularies for CVS/Aetna, Humana, Kaiser, and United that included the drug. We also tracked the change over time using the equivalent files for Q1 2018 and Q1 2019 to examine whether coverage of these drugs on Part D formularies had become more stringent.

## RESULTS

Table 1 depicts the characteristics of each of the drugs included in the analysis. Among the top 20 drugs, 17 are biologics. The number of FFS beneficiaries treated by these drugs in 2018 ranged from 1161 (eculizumab) to 533,286 (denosumab) and total FFS spending ranged from \$370 million for the 20th-ranked drug (immunoglobulin A) to \$2.6 billion for the 1st-ranked drug (afibercept). The drugs are FDA approved to treat a wide range of conditions, such as cancers (10 drugs), macular degeneration (2 drugs), and osteoporosis (2 drugs).

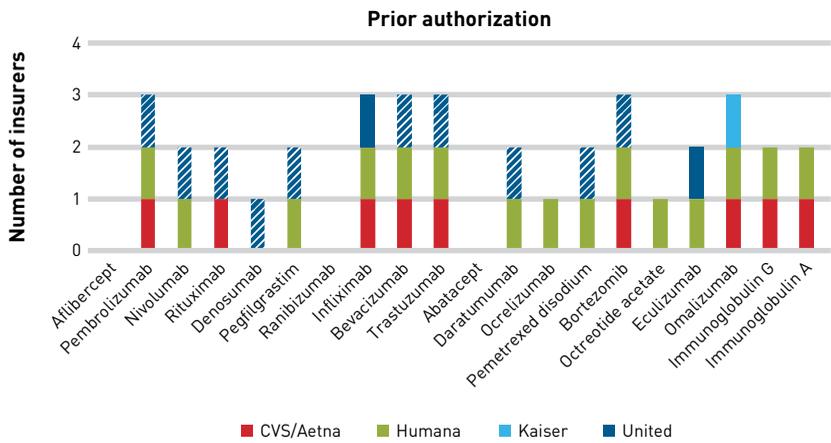
**Figure 1** depicts MA insurers' use of prior authorization for the top 20 physician-administered drugs during 2020. For 17 of these 20, at least 1 of the MA insurers required prior authorization. For the top 20 drugs, all Humana enrollees needed prior authorization for 15 drugs, all CVS/Aetna enrollees needed prior authorization for 9 drugs, and all Kaiser enrollees needed prior authorization for 1 drug. United required enrollees to obtain prior authorization for 12 of the top 20 drugs, but approximately 1% of United enrollees were in plans exempt from this restriction and needed prior authorization for only 2 of the top 20 drugs.

**Figure 2** depicts MA insurers' use of step therapy for top 20 physician-administered drugs during 2020. For 10 of the top 20 drugs, at least 1 MA insurer applied a step therapy restriction. For the top 20 drugs, all of CVS/Aetna's enrollees were subject to step therapy for 9 drugs, all of Humana's enrollees were subject to step therapy for 5 drugs, and Kaiser did not require step therapy. United enrollees were subject to step therapy for 1 drug, but approximately 20% of United's enrollees were in plans exempt from this restriction. No insurer used step therapy more often than prior authorization for the top 20 drugs.

Of the top 20 physician-administered drugs, 7 drugs have an interchangeable alternative and 8 other drugs have a similar drug available as part of the market basket (Table 1). Humana required prior authorization for all 5 drugs without a similar or interchangeable alternative (Table 2). United required prior authorization for 80% of its enrollees for 3 of the drugs, CVS/Aetna required prior authorization for 2 of the drugs, and Kaiser required prior authorization for 1 of the drugs without a similar or interchangeable alternative. None of the 4 insurers applied step therapy to a top-20 drug without a similar or interchangeable alternative.

Concurrent with some insurers restricting access to the top 20 physician-administered drugs through coverage restrictions, coverage through Part D declined (Figure 3). For CVS/Aetna, 12 drugs were covered for all Part D formularies and 3 additional drugs were included on some Part D formularies in 2018, but by 2020, only 4 drugs were included on all CVS/Aetna Part D formularies. Similarly, 14 of the top 20 drugs were included on all Humana Part D formularies in 2019, but only 4 drugs were included in 2020. The pattern was consistent for Kaiser,

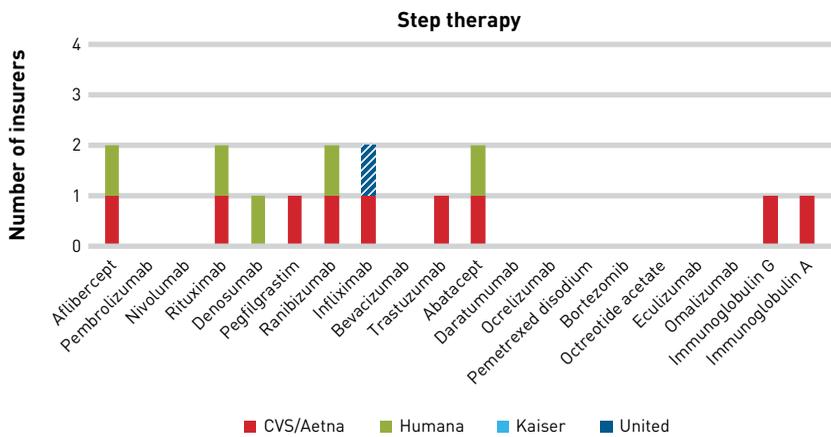
**FIGURE 1. MA Insurers' Use of Prior Authorization for Top 20 Physician-Administered Drugs, 2020\***



MA, Medicare Advantage.

\*Drugs are sorted based on total Medicare spending in 2018 based on the Part B Drug Spending Dashboard, highest to lowest from left to right. Gradient shading indicates instances in which some, but not all, enrollees are subject to prior authorization. Drugs that do not have any bars are not subject to prior authorization for CVS/Aetna, Humana, Kaiser, or United health maintenance organization or preferred provider organization plans. Prior authorization is when an enrollee's clinician must receive advance approval prior to administering a drug in order for the health plan to pay for the drug.

**FIGURE 2. MA Insurers' Use of Step Therapy for Top 20 Physician-Administered Drugs, 2020\***



MA, Medicare Advantage.

\*Drugs are sorted based on total Medicare spending in 2018 based on the Part B Drug Spending Dashboard, highest to lowest from left to right. Gradient shading indicates instances in which some, but not all, enrollees are subject to step therapy. Drugs that do not have any bars are not subject to step therapy for CVS/Aetna, Humana, Kaiser, or United health maintenance organization or preferred provider organization plans. Step therapy is when an enrollee must first try one drug, often a lower-cost drug, before trying another drug.

for which 16 drugs were covered on all Part D formularies in 2018, but only 6 drugs were included on the Part D formularies in 2020. Finally, for United, 11 drugs were included in 2018 on all Part D formularies and an additional 5 drugs were included on some Part D formularies. In 2020, only 2 drugs were included on all United Part

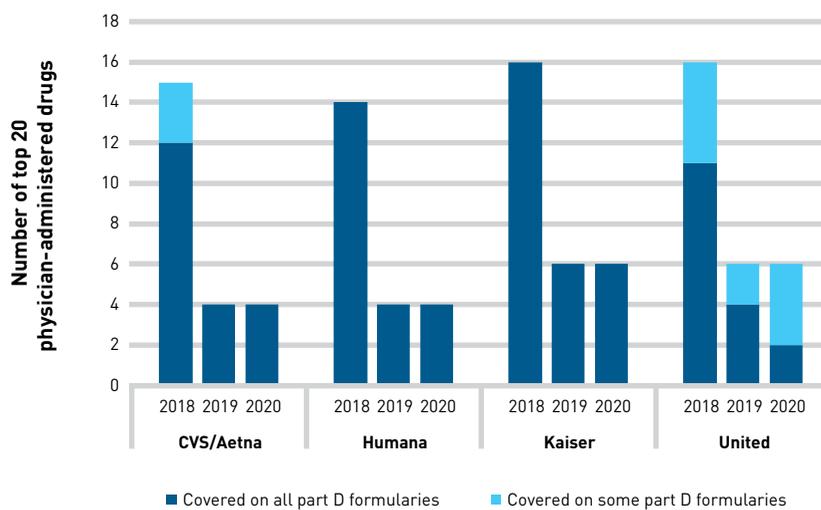
## POLICY

**TABLE 2.** Use of Prior Authorization for Top 20 Drugs Without a Similar or Interchangeable Alternative<sup>a</sup>

Brand name	Generic name	CVS/Aetna	Humana	Kaiser	United
Darzalex	Daratumumab		✓		✓*
Ocrevus	Ocrelizumab		✓		
Alimta	Pemetrexed disodium		✓		✓*
Velcade	Bortezomib	✓	✓		✓*
Xolair	Omalizumab	✓	✓	✓	

<sup>a</sup>A check mark indicates that the Medicare Advantage insurer requires prior authorization for the drug for 1 or more of the insurer's contract identifiers. An asterisk indicates instances in which some, but not all, enrollees are subject to prior authorization.

**FIGURE 3.** Coverage of the Top 20 Physician-Administered Drugs on Part D Formularies, Q1 2018, Q1 2019, and Q1 2020<sup>a</sup>



HCPICS, Healthcare Common Procedure Coding System; NDC, National Drug Code; Q, quarter.

<sup>a</sup>We used the quarterly Average Sales Price HCPICS-NDC Crosswalks published by CMS to identify the NDCs for the top 20 physician-administered drugs.

D formularies and an additional 4 drugs were included on some United Part D formularies. Collectively, in Q1 2018, 10 of the top 20 drugs were covered on all Part D formularies for Kaiser, CVS/Aetna, Humana, and United, and another 6 drugs were covered on some formularies. By Q1 2020, only 2 of the top 20 drugs were covered on all Part D formularies for Kaiser, CVS/Aetna, Humana, and United, and only 4 were covered on some Part D formularies.

## DISCUSSION

These findings suggest that MA insurers responded to the updated CMS guidance by imposing greater restrictions on access to physician-administered drugs. Three of 4 insurers required step therapy for a subset of the top 20 physician-administered drugs (ranging from 1 to 9 drugs), a tool not allowed prior to 2019, and all 4 insurers required prior authorization for at least 1 (and up to 15) of the top 20 drugs.

Additionally, all 4 insurers reduced coverage of these drugs on their Part D formularies from 2018 to 2020. Although these results are limited to select insurers and products, they underscore one way that insurers are responding to cost pressures related to prescription drugs.

Although there has been substantial research on coverage restrictions for retail pharmacy drugs,<sup>13-15</sup> our findings provide some of the first evidence on coverage restrictions to manage physician-administered drugs in Medicare. To our knowledge, only 1 paper explores the use of coverage determinations for physician-administered drugs in Medicare. Schwartz et al found that Aetna's prior authorization policies would apply to drugs that account for 58% of Medicare FFS spending on physician-administered drugs.<sup>16</sup> This highlights the potential effects of prior authorization policies on MA spending on physician-administered drugs, particularly as other insurers may more extensively use prior authorization policies (such as we see with Humana) and employ other tools including step therapy. More broadly, Chambers and colleagues analyzed the use of coverage determinations for commercial insurance plans.<sup>3,17,18</sup> The authors found that commercial plans varied in their use of coverage determinations (similar to our finding regarding variation among MA insurers). Future research should examine whether insurers apply the same coverage determinations across their commercial and MA products.

For drugs such as biologics for which there are biosimilar alternatives, step therapy and prior authorization can direct beneficiaries

to lower-cost options. However, in instances where a similar lower-cost option does not exist, coverage restrictions burden clinicians and limit access to critical medications without the potential benefit of reduced wasteful spending. For the top 20 physician-administered drugs, step therapy was not applied to any drugs without a similar or interchangeable alternative; however, prior authorization was required by at least 1 insurer for all 5 drugs lacking a similar or interchangeable alternative. Prior authorization can be a particularly useful tool to manage use of high-cost drugs, but cost savings associated with this tool, particularly in instances where an alternative drug does not exist, must be weighed against administrative burden for clinicians<sup>19</sup> and potential harms stemming from delayed beneficiary access.<sup>20-22</sup> Additionally, by placing barriers to accessing expensive physician-administered drugs, MA insurers may discourage individuals who need these drugs from enrolling, thus cherry-picking healthier, less expensive enrollees.

Kaiser required step therapy and prior authorization less frequently than other insurers, which may reflect Kaiser's ability, as an integrated care organization, to internally manage drug purchasing and administration without formal step therapy or prior authorization policies. When comparing CVS/Aetna, Humana, and United, we found substantial variation in the frequency of coverage restrictions and the drugs for which each insurer chose to apply coverage restrictions. Thus, MA enrollees could theoretically select a plan without coverage restrictions for their physician-administered drug regimen; however, doing so requires careful research and understanding of formulary design and coverage restrictions. Minimizing coverage restrictions for their physician-administered drugs may also be a lower priority than other dimensions of coverage, such as provider networks and coverage of other drugs. Beneficiaries may struggle to select the best MA plan for their physician-administered drug needs even if, and in some instances because, there is a wide range of benefit designs available.<sup>23,24</sup> Additionally, beneficiaries who have not historically received a physician-administered drug may not consider this dimension of benefit design. As a result, it is important for CMS to monitor the use of coverage restrictions and beneficiary access.

In instances in which a physician-administered drug is subject to a Part B coverage restriction, a clinician may—if the drug is covered on the Part D formulary without a coverage restriction—be able to avoid the prior authorization or step therapy requirement by obtaining the drug through a specialty pharmacy. Reductions in the number of top 20 physician-administered drugs that are covered on Part D formularies is further evidence of MA insurers managing access to these medications. Although physician-administered drugs that are typically paid for under the medical benefit are eligible to be covered through the Part D pharmacy benefit, differences in handling and storage requirements for the drugs make them more or less suitable to be obtained through a specialty pharmacy and paid for through the Part D pharmacy benefit. However, given that 16 of the top 20 drugs were covered by some or all of the Part D formularies for CVS/Aetna, Humana, Kaiser, and United in 2018, and that only a few of these drugs were covered on the formularies in 2020, it appears that the changes reflect tightening access to the drugs, as opposed to poor suitability.

## Limitations

This study has several limitations. First, we focused on large MA insurers and the top 20 physician-administered drugs. As a result, we cannot generalize the findings of this research to smaller insurers and to less expensive physician-administered drugs. Second, we collected data on the use of coverage restrictions in early 2020, approximately 1 year after the CMS policy change for step therapy. Use of step therapy may increase over time as insurers become more accustomed to using this tool to manage physician-administered drug spending for their Medicare enrollees. Third, the EOCs often provided prior authorization and step therapy requirements at the drug class level (eg, immunologics) rather than the drug indication

level, although the appropriateness and effects of such tools may vary by indication. Fourth, this analysis focused on the use of these tools but did not measure the effects of these tools (eg, on patient adherence). Future research should monitor the effects of more stringent coverage restrictions and formulary design on utilization of physician-administered drugs and on patient outcomes.

## CONCLUSIONS

We found that 4 large MA insurers managed access to expensive physician-administered drugs with a combination of prior authorization, step therapy, and Part D formulary design. In instances where a low-cost alternative exists, these tools can help reduce wasteful spending, but in instances where a beneficiary's preferred drug is not covered or is subject to administrative barriers, these tools may reduce access. ■

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**Authorship Information:** Concept and design (KEA); acquisition of data (KEA, CM); analysis and interpretation of data (KEA, GCA, SMD, APS); drafting of the manuscript (KEA); critical revision of the manuscript for important intellectual content (KEA, GCA, CM, SMD, APS); statistical analysis (KEA); administrative, technical, or logistic support (CM); and supervision (GCA, SMD, APS).

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