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Report to Congressional Committees

March 2021

MEDICARE PART B

Payments and Use for Selected New, High-Cost Drugs

GAO@100
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GAO-21-252

GAO@100 Highlights

Highlights of GAO-21-252, a report to congressional committees

March 2021

MEDICARE PART B

Payments and Use for Selected New, High-Cost Drugs

Why GAO Did This Study

Medicare makes "pass-through" payments under Medicare Part B when hospital outpatient departments use certain new, high-cost drugs. These temporary payments are in addition to Medicare's payments for the procedures using the drugs. They may help make the new drugs accessible for beneficiaries and also allow Medicare to collect information on the drugs' use and costs.

The Consolidated Appropriations Act, 2018 included a provision for GAO to review the effect of Medicare's policy for packaging high-cost drugs after their pass-through payments have expired. This report describes (1) the payments associated with selected high-cost drugs when eligible for pass-through payments versus when packaged, and (2) hospitals' use of those drugs when eligible for pass-through payments versus when packaged.

GAO reviewed federal regulations on pass-through payments and Medicare payment files for all seven drugs whose pass-through payments expired in 2017 or 2018 and that were subsequently packaged. All of these drugs met Medicare's definition for having a high cost relative to Medicare's payment rate for the procedure using the drug. GAO also reviewed Medicare claims data on the use of the drugs for 2017 through 2019 (the most recent available). To supplement this information, GAO also interviewed Medicare officials, as well officials from 11 organizations representing hospitals, physicians, and drug manufacturers, about payment rates, use, reporting, and clinical context for the drugs.

View GAO-21-252. For more information, contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

Hospital outpatient departments perform a wide range of procedures, including diagnostic and surgical procedures, which may use drugs that Medicare considers to function as supplies. If the drug is new, and its cost is high relative to Medicare's payment for the procedure, then hospitals can receive a separate "pass-through" payment for the drug in addition to Medicare's payment for the procedure. These pass-through payments are in effect for 2 to 3 years. When the pass-through payments expire, Medicare no longer pays separately for the drug, and payment for the drug is "packaged" with the payment for the related procedure. The payment rate for the procedure does not vary by whether or not the drug is used. Medicare intends this payment rate to be an incentive for hospitals to furnish services efficiently, such as using the most cost-efficient items that meet the patient's needs.

Examples of Types of Drugs that Medicare Considers to Function as Supplies

- **Contrast agents** are used with diagnostic imaging procedures, such as ultrasounds.
- **Diagnostic radiopharmaceuticals** are used in nuclear medicine services, a type of diagnostic imaging procedure.
- **Stress agents** are used with diagnostic tests. They are a class of drugs that are used to evaluate certain aspects of cardiac function.

Source: GAO review of federal regulations. | GAO-21-252

GAO's analysis of Medicare data showed that higher payments were associated with six of seven selected drugs when they were eligible for pass-through payments versus when their payments were packaged. For example, one drug used in cataract removal procedures was eligible for pass-through payments in 2017. That year, Medicare paid $1,824 for the procedure and $463 for the drug pass-through payment—a total payment of $2,287. If a hospital performed the same cataract removal procedure when the drug was packaged the following year, there was no longer a separate payment for the drug. Instead, Medicare paid $1,921 for the procedure whether or not the hospital used the drug.

Of the seven selected drugs, GAO also reviewed differences in use for four of them that did not have limitations on Medicare coverage during the time frame of GAO's analysis, such as coverage that was limited to certain clinical trials. GAO found that hospitals' use of three of the four drugs was lower when payments for the drugs were packaged. This was consistent with the financial incentives created by the payment system. In particular, given the lower total payment for the drug and procedure when the drug is packaged, hospitals may have a greater incentive to use a lower-cost alternative for the procedure. Hospitals' use of a fourth drug increased regardless of payment status. The financial incentives for that drug appeared minimal because the total payment for it and its related procedure was about the same when it was eligible for pass-through payments and when packaged. Other factors that can affect use of the drugs include the use of the drugs for certain populations and whether hospitals put the drugs on their formularies, which guide, in part, whether the drug is used at that hospital.

The Department of Health and Human Services reviewed a draft of this report and provided technical comments, which GAO incorporated as appropriate.

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Abbreviations

APC	ambulatory payment classification
ASC	ambulatory surgical center
CED	coverage with evidence development
CMS	Centers for Medicare & Medicaid Services
IDEAS	Imaging Dementia – Evidence for Amyloid Scanning
PET	positron emission tomography

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March 1, 2021

The Honorable Ron Wyden
Chair
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chair
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Richard Neal
Chair
The Honorable Kevin Brady
Republican Leader
Committee on Ways and Means
House of Representatives

Under Medicare Part B, Medicare pays hospitals for drugs that beneficiaries receive as part of their treatment in hospital outpatient departments.[1] A subset of these Part B drugs are those that are considered supplies for diagnostic or surgical procedures and are known as "policy-packaged drugs." Examples of policy-packaged drugs for diagnostic procedures are contrast agents, which allow providers to more clearly view soft tissue and organ function during imaging procedures, such as ultrasounds. Examples of policy-packaged drugs for surgical procedures are skin substitutes.[2] These refer to a category of products most commonly used to treat diabetic foot ulcers and venous leg ulcers,

[1]We use the term "drugs" to refer to both drugs (including radiopharmaceuticals) and biologicals. Radiopharmaceuticals are radioactive substances used for diagnostic or therapeutic purposes. Biologicals are products derived from living sources, including humans, animals, and microorganisms. In addition, this report focuses on the use of these types of drugs in hospital outpatient departments, but they can also be used for procedures in ambulatory surgical centers (ASC).

[2]Skin substitutes are also called "cellular and/or tissue-based products for wounds."

and they are applied in a surgical procedure to aid wound healing and stimulate the patient's body to regenerate lost tissue.

If a policy-packaged drug is new and high-cost, then hospitals can receive a type of Medicare payment known as a transitional "pass-through" payment for the drug.[3] Pass-through payments are separate from the payment for the related procedure and are generally in effect for 2 to 3 years. The pass-through payments may help make the new drugs accessible for beneficiaries while allowing Medicare to collect information on their use and costs.

After the pass-through payments expire, Medicare no longer pays hospitals separately for the drug. Rather, under its policy, Medicare pays hospitals for the drug as part of a single, predetermined, "packaged" payment for each primary procedure or service.[4] When paying for procedures, Medicare assigns procedures with similar costs and clinical characteristics into a payment group, called an ambulatory payment classification (APC) group, and pays the same rate for all procedures in that group. When setting the payment rate for the APC group, Medicare looks at the average cost across all the procedures in that group, inclusive of the cost of any drugs or other ancillary items used in the procedure. With this payment, Medicare intends to create an incentive for hospitals to furnish services efficiently, such as using the most cost-efficient items that meet the patient's needs. However, according to some manufacturers and providers, this creates a financial disincentive against using certain drugs that are more expensive.

The Consolidated Appropriations Act, 2018 includes a provision for us to review the effect of Medicare's policy for packaging high-cost drugs and biologicals after their pass-through payments have expired.[5] This report describes the differences in the

1. payments associated with selected high-cost drugs when eligible for pass-through payments versus when packaged, and

[3]According to 42 U.S.C. § 1395l(t)(6), the drug's cost must be high relative to Medicare's payment for the procedure using the drug.

[4]Each year from 2010 through 2019, between two and nine drugs had their pass-through payments expire and were subsequently packaged.

[5]Pub. L. 115–141, div. S, tit. XIII, § 1301(b), 132 Stat. 348, 1150.

2. use of selected high-cost drugs when eligible for pass-through payments versus when packaged.

To describe the differences in the payments associated with selected high-cost drugs, we reviewed federal regulations on pass-through payments and the payment rates for all seven drugs whose pass-through payments expired in 2017 or 2018 and that were subsequently packaged under Medicare policy.[6] See Appendix I for more information on each of the seven drugs and its related procedures. For these seven drugs, we reviewed Medicare fee-for-service payment files for calendar years 2017 through 2019 to identify the pass-through payment rates for each drug, as well as the payment rates for the APC group most commonly connected to each drug.

To describe the differences in the use of selected high-cost drugs, we analyzed Medicare fee-for-service claims data from hospital outpatient departments for calendar years 2017 through 2019 (the most recent claims data available at the time of our study) on the use of four of the seven drugs in comparison to their related procedures.[7] We focused this review of differences on these four drugs because they did not have limitations on Medicare coverage during our time frame.[8] We excluded hospitals outside of the 50 states and the District of Columbia, as well as services where Medicare was not the primary payer.

For both objectives, we assessed the reliability of Medicare payment files and claims data by reviewing related documentation, interviewing relevant officials, and comparing the information to other data sets, including to data from drug manufacturers where applicable. We found the Medicare payment files to be sufficiently reliable for the purposes of this report. In addition, we found the Medicare claims data to be sufficiently reliable for describing overall changes over time in use of the four drugs reviewed

[6]All seven drugs were eligible for pass-through payments and therefore met Medicare's definition for having an estimated cost that is high relative to Medicare's APC payment rate for the procedure using the drug.

[7]Two of the seven drugs were also used in ASCs, and we used manufacturer data to describe changes in ASCs' use of those drugs in Appendix II.

[8]Medicare's coverage of the other three drugs was limited to clinical trials in the coverage with evidence development (CED) evaluation process, and we describe the use of those three drugs in Appendix III.

and for identifying the use of the drug in comparison to its related procedures for three of the drugs.[9]

To supplement this information, we interviewed officials from the Centers for Medicare & Medicaid Services (CMS) and 11 organizations representing hospitals and ambulatory surgical centers (ASC), physicians, and drug manufacturers about payment rates, use, reporting, and clinical context for the drugs.[10] We also used the interviews to identify each drug's related procedures. We selected organizations that provided public comments or related information on the relevant federal regulations and that represented either (1) hospitals, (2) ASCs, or (3) physicians, drug manufacturers, or both for each of the types of drug in our scope, such as contrast agents and skin substitutes.

Our results for the seven drugs in our scope may not be generalizable to drugs outside of our analysis. However, these seven drugs, which have a mix of clinical indications and characteristics for diagnostic and surgical procedures, provide valuable insight on the differences that can occur in the payments associated with and use of high-cost drugs when eligible for pass-through payments versus when packaged.

We conducted this performance audit from February 2020 to March 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Medicare Payment Policy for Hospital Outpatient Services

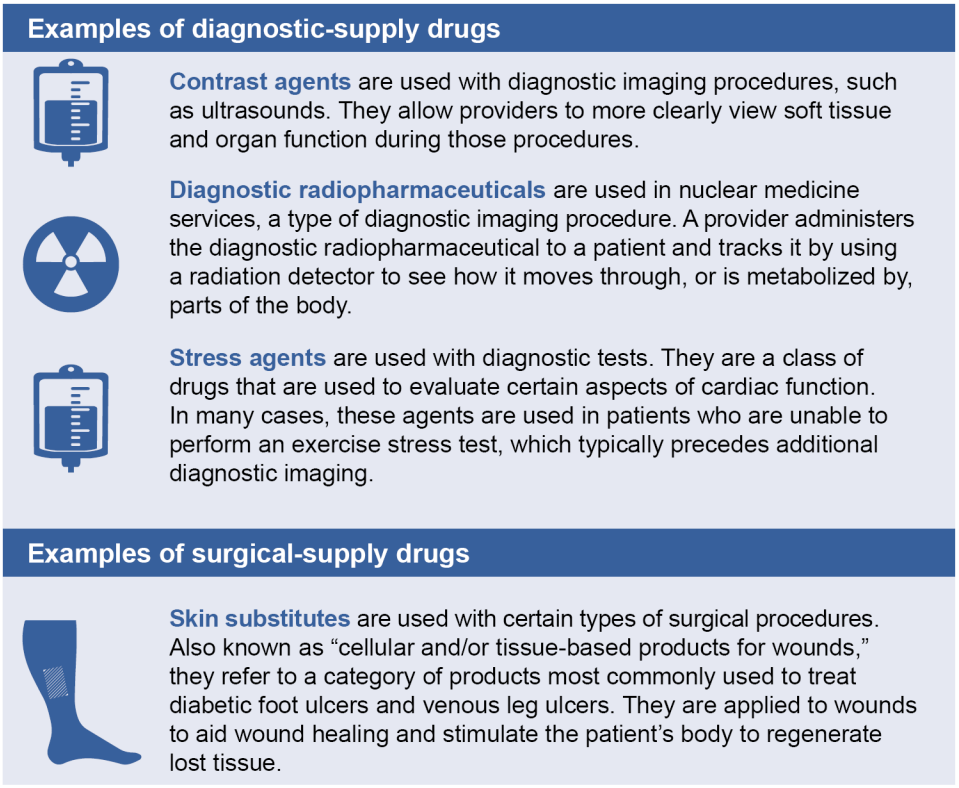
Medicare pays for a wide range of procedures, including diagnostic and surgical procedures, at hospital outpatient departments. These procedures can be performed with drugs that CMS considers to function

[9]In the case of the fourth drug, the manufacturer data and Medicare claims data showed a similar pattern for the overall change in time, but the manufacturer data differed on the number of times the drug was used each year.

[10]The clinical context of each drug does not describe health outcomes or differences in clinical benefits.

as supplies for diagnostic or surgical procedures. Figure 1 provides examples of these policy-packaged drugs.[11]

Figure 1: Types of Drugs that Medicare Considers to Function as Supplies for Diagnostic and Surgical Procedures and Are Known as Policy-Packaged Drugs



Source: GAO review of federal regulations. | GAO-21-252

Note: We use the term "drugs" to refer to both drugs (including radiopharmaceuticals) and biologicals.

For a hospital to receive Medicare payment for a procedure that it has performed, it submits a claim form to CMS with the procedure and its charge for that procedure. According to CMS guidelines, the hospital's claim form should also include any policy-packaged drugs that were used with the procedure and the charges for those drugs. Annually, hospitals

[11]Separate from drugs that CMS considers to function as supplies (i.e., policy-packaged drugs), there is also a different category of packaged drugs. This category includes all drugs that fall under a certain cost threshold, which generally changes each year and was $125 in calendar year 2019.

also submit cost reports to CMS that state their total charges and costs for the year and the individual hospital department charges and costs.

CMS pays hospitals for each diagnostic or surgical procedure under a prospective payment system using APC groups. CMS assigns procedures with similar costs and clinical characteristics into an APC group.[12] There can be related APC groups with different levels, and each level can vary in the number of procedures. For example, in 2019, there were four APC groups for nuclear medicine and related services with a total of 125 procedures. The level 1 group had 66 procedures, the level 2 group had 27 procedures, the level 3 group had 24 procedures, and the level 4 group had 8 procedures.[13] Procedures in level 1 are the least costly and clinically complex, and procedures in level 4 are the most costly and clinically complex. Because the procedures within a single APC group have similar costs and clinical characteristics, CMS sets a single payment rate for all procedures in that group. In other words, CMS pays hospitals the same payment rate for any procedure in a given APC group, and that payment rate also does not differ based on what policy-packaged drugs or other ancillary items are used by the hospital to perform that procedure.

When setting the payment rate for each APC group, CMS uses data from a previous year's claims and cost reports to calculate the average cost of all procedures in that group, inclusive of the cost of any policy-packaged drugs or other ancillary items.[14] As a result, the cost and relative use of those drugs affect the portion of the APC payment rate associated with policy-packaged drugs, as illustrated in figure 2 below. For example, if the relative use of a policy-packaged drug is higher, then the portion of the APC payment rate associated with that drug will reflect more of the cost of that drug. However, if the relative use of that drug is lower, then the

[12]For items and services within an APC group to be considered as having similar costs, the highest-cost item or service cannot be more than two times greater than the lowest-cost item or service. See 42 U.S.C. § 1395l(t)(2).

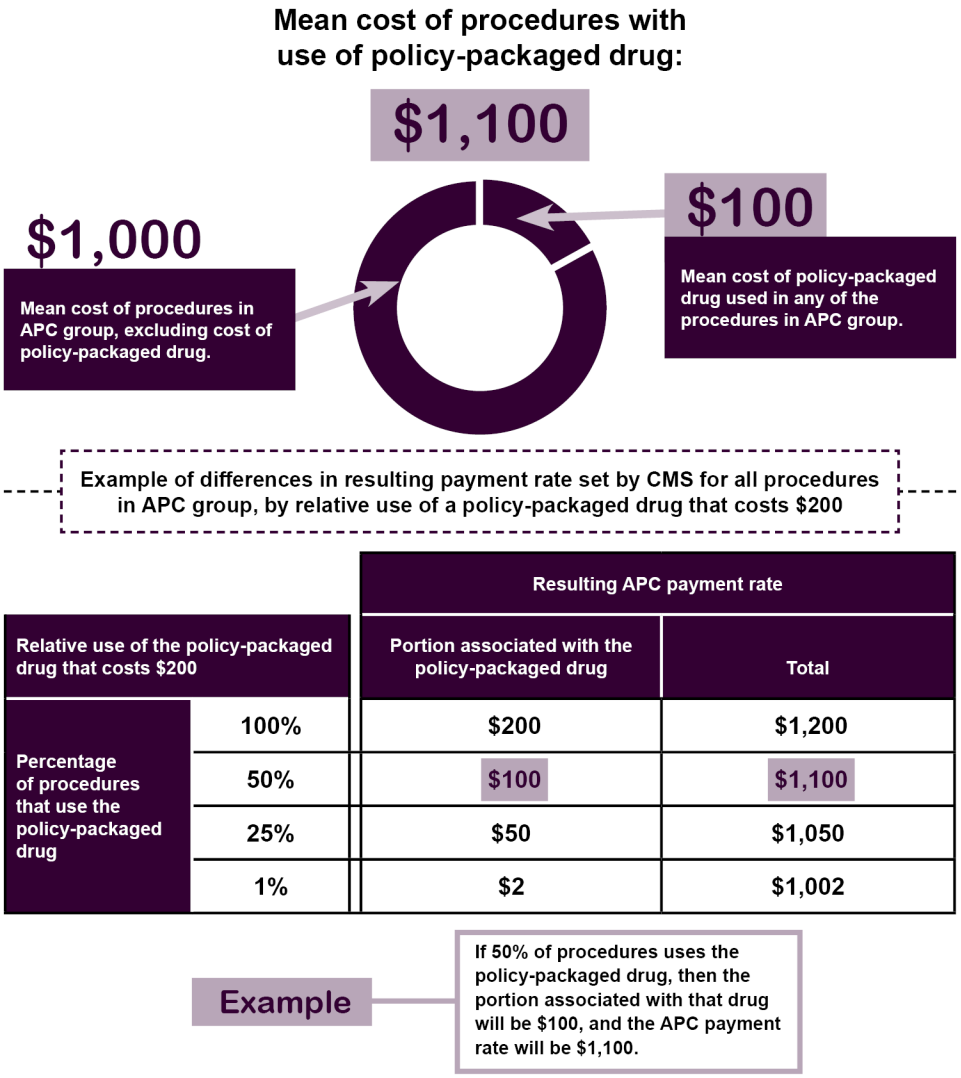
[13]CMS reviews and revises the APC assignments annually and has consolidated some APC groups in recent years. For example, in 2016, CMS consolidated 17 nuclear medicine and positron emission tomography (PET) APC groups into four APC groups for nuclear medicine and related services.

[14]Starting in 2013, CMS changed from using the median cost of all procedures in an APC group to using the geometric mean cost. According to CMS, the use of median cost was a way to minimize the effect of outliers. CMS then made the change to geometric mean cost to allow it to detect changes in the cost of services earlier, because it is more sensitive to changes in the data.

associated portion of the APC payment rate will reflect less of the cost of that drug.

Figure 2: Illustration of the Effect from a Policy-Packaged Drug on the Payment Rate for an APC Group Set by CMS

Medicare assigns similar procedures into an ambulatory payment classification (APC) group. The APC payment rate does not vary by which of those procedures are performed or which, if any, policy-packaged drugs are used.



Source: GAO. | GAO-21-252

Note: Policy-packaged drugs are those that the Centers for Medicare & Medicaid Services (CMS) considers to function as supplies for diagnostic and surgical procedures. In this illustration, there is no

variation in the amount ($1,000) for the mean cost of the procedures, excluding the cost of the policy-packaged drug.

According to CMS, the use of larger payment bundles—which involves packaging and also payments by APC groups—provides hospitals with greater predictability and accuracy of payment for services over time, as well as incentives to furnish services efficiently. This includes the incentive for hospitals to use the most cost-efficient item that meets the patient's needs, as previously mentioned. In addition, according to CMS, packaging can encourage hospitals to negotiate with manufacturers regarding the purchase price of items and services. It can also encourage hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources.

Pass-Through Payments

When a drug is eligible for pass-through payments, CMS pays hospitals for the drug based on its sales price; the agency sets the payment at 106 percent of the drug's average sales price, which is commonly referred to as average sales price plus 6 percent. This pass-through payment is separate from the APC payment rate for the procedure using the drug. However, CMS reduces the amount of the pass-through payments by the portion of that APC payment rate that is associated with policy-packaged drugs.[15] For example, if the amount of the pass-through payment based on sales price is $250 and the portion of the APC payment rate associated with policy-packaged drugs is $100, CMS would subtract $100 from $250—resulting in a final pass-through payment of $150. According to CMS, this ensures that no duplicate payments are made.

In order to be eligible for pass-through payments, drugs, by law, must have a "not insignificant" cost compared to the APC payment rate for the procedure using the drug.[16] CMS has three criteria to make this determination, and drugs must meet all three criteria. First, the estimated cost of the drug must exceed 10 percent of the APC payment rate. Second, the estimated cost of the drug must exceed the portion of the APC payment rate associated with policy-packaged drugs by at least 25 percent. Third, the difference between the estimated cost of the drug and the portion of the APC payment rate associated with policy-packaged

[15]Pass-through drugs administered in a hospital outpatient setting are not subject to beneficiary copayments if they would otherwise be policy-packaged. See 42 U.S.C. § 1395l(t)(8)(E).

[16]See 42 U.S.C. § 1395l(t)(6).

drugs must exceed 10 percent of the APC payment rate. For example, if the APC payment rate is $1,100 and the policy-packaged portion of the APC payment rate is $100, the estimated of cost of the drug would have to be greater than $210 to meet these three criteria and be eligible for pass-through payments.

Drug manufacturers submit applications to CMS for pass-through payments—which, by law, are in effect for at least 2 years but not more than 3 years.[17] CMS starts pass-through payments on a quarterly basis in either January, April, July, or October, though CMS has changed how it determines the end date. For drugs that have been approved for pass-through payments since 2017, their payments have expired on a quarterly basis, which allows drugs to have pass-through payments for as close to the full 3 years as possible. For drugs that were approved for pass-through payments in 2016 or earlier, their payments expired on an annual basis at the end of December. This meant that the duration of pass-through payments for a particular drug varied. For example, if a drug's pass-through payments started in January, they were in effect for 3 years. However, if a drug's pass-through payments started in October, they were in effect for 2 years and 3 months.

Congress took action for certain drugs that were packaged after their pass-through payments expired in December 2017 or December 2018.[18] Congress reinstated their pass-through payments from October 2018 through September 2020 and from January 2020 through September 2020, respectively.

[17]See 42 U.S.C. § 1395l(t)(6)(C).

[18]See Consolidated Appropriations Act, 2018, Pub. L. 115–141, div. S, tit. XII, § 1301(a)(1)(C), 132 Stat. 348, 1149; and Further Consolidated Appropriations Act, 2020, Pub. L. 116-94, div. N, tit. I, § 107(a), 133 Stat. 2534, 3102 (2019). The Further Consolidated Appropriations Act, 2020 also specified that it applied only to drugs furnished in a clinical trial under the CED evaluation process.

Payments Associated with Selected High-Cost Drugs Generally Decreased After Pass-Through Payments Expired and They Were Packaged

High-cost drugs that were packaged after expiration of pass-through payments

Pass-through payments expired in 2017:

- Amyvid:
Diagnostic radiopharmaceutical
- Lumason:
Contrast agent
- Omidria:
Surgical-supply drug
- PuraPly:
Skin substitute

Pass-through payments expired in 2018:

- Choline C11:
Diagnostic radiopharmaceutical
- Neuraceq:
Diagnostic radiopharmaceutical
- Vizamyl:
Diagnostic radiopharmaceutical

See Appendix I for more information on each drug.

Source: GAO. | GAO-21-252

Our analysis of Medicare payment data showed that, for six of the seven selected drugs, the total payment associated with the drug and procedure decreased when the drug's pass-through payments expired and it was packaged; see table 1. CMS considers these seven drugs to function as supplies, so the packaged payment is intended to create a financial incentive for hospitals to use the most cost-efficient item that meets patients' needs. For example, Omidria was eligible for pass-through payments in 2017. During that time, if a hospital performed a cataract removal procedure and used Omidria for that procedure, CMS paid $1,824 for the APC payment rate and also $463 for the drug pass-through payment rate—a total of $2,287 for the procedure and drug combined. After Omidria's pass-through payments expired in December 2017, it was packaged from January to September 2018. During those 9 months, if a hospital performed that same cataract removal procedure and used Omidria, CMS paid $1,921 for APC payment rate—which was the total for the procedure and drug combined because of packaging. CMS also paid $1,921 if the hospital performed the procedure and did not use Omidria. Congress also reinstated separate pass-through payments for various time frames for six of the drugs in our analysis, including Omidria from October 2018 to September 2020 (see table 1).

Table 1: Differences in Total Payments Associated with Selected High-Cost Drugs and Related Procedures, 2017 — 2019

Medicare assigns similar procedures into an ambulatory payment classification (APC) group. The APC payment rate does not vary by which of those procedures are performed or which, if any, policy-packaged drugs are used.

		Payment amount in dollars, by time period[b]		
Drug	**Type of payment[a]**	**With initial pass-through payments**	**When packaged**	**With reinstated pass-through payments**
Amyvid	**Total for procedure and drug**	**3,841**	**1,377**	**4,152**
	Nuclear medicine and related services APC	1,321	1,377	1,377
	Drug pass-through	2,520	0	2,775
Choline C11	**Total for procedure and drug**	**6,829**	**1,376**	**Not applicable**
	Nuclear medicine and related services APC	1,377	1,376	
	Drug pass-through	5,452	0	
Lumason	**Total for procedure and drug**	**681**	**682**	**695**
	Imaging with contrast APC	657	682	682
	Drug pass-through[c]	24	0	14
Neuraceq	**Total for procedure and drug**	**4,097**	**1,376**	**Not applicable**
	Nuclear medicine and related services APC	1,377	1,376	
	Drug pass-through	2,720	0	
Omidria	**Total for procedure and drug**	**2,287**	**1,921**	**2,380**
	Intraocular procedures APC	1,824	1,921	1,921
	Drug pass-through	463	0	459
PuraPly	**Total for procedure and drug**	**3,719**	**1,568**	**3,801**
	Skin procedures APC	1,427	1,568	1,568
	Drug pass-through[d]	2,292	0	2,233
Vizamyl	**Total for procedure and drug**	**4,627**	**1,376**	**Not applicable**
	Nuclear medicine and related services APC	1,377	1,376	
	Drug pass-through	3,250	0	

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) payment files. | GAO-21-252

Note: These are all seven drugs whose pass-through payments expired in 2017 or 2018 and that were subsequently packaged. We use the term “drugs” to refer to both drugs (including radiopharmaceuticals) and biologicals. Policy-packaged drugs are those that CMS considers to function as supplies for diagnostic and surgical procedures.

[a]There are related APC groups with different levels, and the amount shown for each drug is for the APC group most commonly connected to that drug. The pass-through payment shown is the calculated amount based on sales price minus the portion of the APC payment rate associated with policy-packaged drugs. Numbers may not sum to totals due to rounding.

[b]The dates of the amounts for Amyvid, Lumason, Omidria, and PuraPly are (1) October through December 2017, which is the last quarter before expiration of their initial pass-through payments; (2) January through September 2018, when they were packaged; and (3) October through December 2018, which is the first quarter after their pass-through payments were effectively reinstated by the Consolidated Appropriations Act, 2018. The reinstated pass-through payments subsequently expired in September 2020. The dates of the amounts for Choline C11, Neuraceq, and Vizamyl are (1) October through December 2018, which is the last quarter before expiration of their initial pass-

through payments; and (2) January through December 2019, when they were packaged. Although the Further Consolidated Appropriations Act, 2020 effectively reinstated pass-through payments for Neuraceq and Vizamyl from January through September 2020, payment rates for 2020 are outside of our scope.

[c]Pass-through payments for Lumason depend on the number of milliliters used, and the amount shown is for five milliliters. This is based on the size of the single-patient vial and CMS payment policies for such vials.

[d]Pass-through payments for PuraPly depend on the number of square centimeters used, and the amount shown is for 25 square centimeters. This is based on the average number of units in CMS data on Part B drug utilization.

Although there were decreases in the total payment associated with six of the seven selected drugs in our review and their related procedures, there were generally increases in the payment rates for the APC groups most commonly connected to the seven drugs. For example, the payment rate for the APC group most commonly connected to Omidria increased from $1,824 to $1,921. Part of this increase was due to an increase in the portion of the APC payment associated with policy-packaged drugs, which includes Omidria. As shown in table 2, this portion increased by $4 (from $10 to $14) from 2017 to 2018, which may be related, in part, to the expiration of Omidria's pass-through payments in December 2017. A hospital receives the full APC payment rate regardless of which, if any, policy-packaged drugs it uses for that procedure. As another example, this portion increased by $78 (from $248 to $326) for the APC group most commonly connected to Choline C11, Neuraceq, and Vizamyl from 2018 to 2019. This increase may be related, in part, to the expiration of those drugs' pass-through payments in December 2018.

Table 2: Portion of APC Payment Rate Associated with Policy-Packaged Drugs, 2017 — 2019

Medicare assigns similar procedures into an ambulatory payment classification (APC) group. The APC payment rate does not vary by which of those procedures are performed or which, if any, policy-packaged drugs are used.

	Payment amount associated with policy-packaged drugs in dollars, by year		
APC group	**2017**	**2018**	**2019**
Nuclear medicine and related services APC group using Amyvid, Choline C11, Neuraceq, and Vizamyl	236	248	326
Imaging with contrast APC group using Lumason	82	93	96
Intraocular procedures APC group using Omidria	10	14	34
Skin procedures APC group using PuraPly	727	787	731

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) payment files. | GAO-21-252

Note: These are all seven drugs whose pass-through payments expired in 2017 or 2018 and that were subsequently packaged. We use the term "drugs" to refer to both drugs (including radiopharmaceuticals) and biologicals. Policy-packaged drugs are those that CMS considers to function as supplies for diagnostic and surgical procedures. There are related APC groups with

different levels, and the amounts shown are for the APC group most commonly connected to each drug.

Use of Selected High-Cost Drugs Differed When Eligible for Pass-Through Payments Versus When Packaged

Our analysis of Medicare claims data for four of the drugs in our scope—Choline C11, Lumason, Omidria, and PuraPly—showed differences in hospitals' use of those drugs when they were eligible for pass-through payments versus when packaged, which may relate to the financial incentives created under the payment system.[19] In particular, hospitals' use of Choline C11, Omidria, and PuraPly in comparison to their related procedures was higher when the drugs were eligible for pass-through payments and lower when their payments were packaged. For example, as shown in table 3, hospitals used Omidria for 4 percent of the related procedures when it was eligible for pass-through payments in 2017 and for 5 percent when it was eligible for reinstated pass-through payments from October 2018 through December 2019. However, when Omidria was packaged, which was from January through September 2018, hospitals used it less frequently—1 percent of the related procedures.

Table 3: Use of Selected High-Cost Drugs Compared to Use of Their Related Procedures, by Hospital Outpatient Departments, 2017 — 2019

Drug and related procedures	Change in use from when drug was eligible for pass-through payments to when it was packaged[a]	Change in use from when drug was packaged to when pass-through payments were reinstated[b]
Choline C11 with positron emission tomography scans for identifying potential sites of prostate cancer recurrence	Decrease: 13 to 11 percent	Not applicable[b]
Omidria with cataract removal and removal of lens material	Decrease: 4 to 1 percent	Increase: 1 to 5 percent
PuraPly with application of skin substitute graft	Decrease: 24 to 20 percent	Increase: 20 to 28 percent

Source: GAO analysis of Medicare claims data. | GAO-21-252

Notes: Our overall scope included all seven drugs whose pass-through payments expired in 2017 or 2018 and that were subsequently packaged, but we focused this table on the drugs that did not have limitations on Medicare coverage during our time frame, such as coverage that was limited to certain clinical trials. We also did not include data on one drug because of some inconsistencies between the claims and manufacturer data.

We use the term "drugs" to refer to both drugs (including radiopharmaceuticals) and biologicals. Use reflects the number of times a drug was reported in the claims and not total dosage units.

[a]The change shown for Choline C11 is from January through December 2018 (when it was eligible for pass-through payments) to January through December 2019 (when it was packaged). The change shown for Omidria and PuraPly is from January through December 2017 (when they was eligible for pass-through payments) to January through September 2018 (when they were packaged).

[19]Medicare's coverage of three drugs in our scope—Amyvid, Neuraceq, and Vizamyl—was limited to clinical trials in the CED evaluation process. See appendix III.

[b]There is no change shown for Choline C11 because its pass-through payments were not reinstated. The change shown for Omidria and PuraPly is from January through September 2018 (when they were packaged) to October 2018 through December 2019 (when their pass-through payments were effectively reinstated by the Consolidated Appropriations Act, 2018). The reinstated pass-through payments subsequently expired in September 2020.

Changes in the use of Omidria, PuraPly, and Choline C11 by hospital outpatient departments generally mirrored the overall lower use of those drugs when their payments were packaged. However, there was variation among hospitals, and some hospitals had a greater decrease in use. For example, 38 hospitals used Omidria at least 50 times per quarter when the drug had pass-through status in 2017.[20] Out of those 38 hospitals, 35 decreased their use of Omidria, including 10 that stopped using it altogether, when the drug was packaged in the first three quarters of 2018. The collective use of Omidria by those 38 hospitals dropped by 89 percent. The other three hospitals increased their use but to a much lesser degree—a collective increase of 10 percent. As another example, 17 hospitals used PuraPly at least 50 times per quarter when it had pass-through status.[21] Out of those 17 hospitals, 12 decreased their use of PuraPly when it was packaged with a collective decrease of 40 percent. The other five hospitals increased their use collectively by 12 percent.

Selected new, high-cost drugs may have alternative options

- Choline C11:
  One possible alternative for positron emission tomography (PET) scans for identifying potential sites of prostate cancer recurrence.
- Lumason:
  Two possible alternatives for echocardiogram procedures.
- Omidria and PuraPly:
  Several possible alternatives with similar clinical purposes.

Source: GAO. | GAO-21-252

The financial incentives created by the payment system may relate to the changes in the use of Omidria, PuraPly, and Choline C11. In particular, the decrease in the use of these three drugs when they were no longer eligible-for pass-through payments was consistent with the financial incentives created under the payment system. For example, officials representing ophthalmological providers said that there are possible alternatives with similar clinical purposes and that Omidria has a higher cost than its alternatives. If hospitals used Omidria when it was eligible for pass-through payments, they received the separate pass-through payment, which reflected the cost of the drug and was added to the APC payment rate for the related procedure. Subsequently, if hospitals used Omidria when its payment was packaged, hospitals received only the APC payment rate, which does not vary by which policy-packaged drugs (such as Omidria) are used. As a result, hospitals may have an incentive to use a lower-cost alternative for the related procedure.

[20]The 38 hospitals provided over two-thirds of the total use of Omidria in 2017.

[21]The 17 hospitals provided just under one-fifth of the total use of PuraPly in 2017.

For the fourth drug, Lumason, Medicare claims data showed that hospitals used it for an increasing proportion of its related procedures from 2017 to 2019 regardless of its payment status, which may relate to the minimal financial incentives created by the payment system.[22] The financial incentives appeared to be minimal because the total Medicare payment amount that hospitals received when using the drug and performing its related procedure was about the same when it was eligible for pass-through payments and when it was packaged. According to officials representing echocardiography providers, another factor for the increased use was that Lumason was easier for some providers to use than its two possible alternatives. They also said that Lumason was a new option for patients with allergies to those alternatives.

Although the financial incentives created by the payment system may relate to changes in the use of some drugs, other factors may have also affected the use of the four drugs regardless of their payment status.

- **Hospitals' formulary processes can affect the use of drugs, particularly new drugs.** A hospital's formulary lists the drugs and therapies that it identified as most medically appropriate and cost-effective for treating its patient population—meaning a hospital's formulary may affect the use of a drug at that particular hospital.[23] According to officials for groups representing hospitals and health care finance professionals, as part of a hospital's process for determining which drugs are on that hospital's formulary, doctors and other hospital officials assess a drug's quality outcomes versus its cost and alternative drugs, if applicable. In particular, for drugs that are newer, there may be limited information in published literature, and the hospital may want to learn more about patients' experiences with that drug before making a decision. This can include not just clinical outcomes but also aspects such as side effects or patients' recovery time.

[22]The manufacturer data we reviewed also showed an increased use of Lumason in hospital outpatient departments, but the manufacturer data differed from the Medicare claims data on the number of times Lumason was used each year. As a result, we only report the direction of change over time. We examined the use of Lumason in comparison to the use of echocardiograms and certain other types of ultrasound with contrast; see appendix I.

[23]Officials for a group representing pharmacists said that, if a hospital has narrower formularies with fewer drugs, it will generally have a process in which doctors can request an exemption to use a drug not on the formulary.

- **A drug may have specific benefits for certain populations for whom use remains higher.** One of our selected drugs, Omidria, is used to maintain pupil size during cataract removal and related procedures, and our claims analysis shows that hospitals continued to use it at a slightly higher rate for the subset of patients with a diagnosis of floppy iris syndrome, though use decreased for those patients too when it was packaged.[24] When Omidria was eligible for pass-through payments in 2017 and from October 2018 through December 2019, hospitals used it for 7 to 8 percent of related procedures where patients had a diagnosis of floppy iris syndrome versus 5 percent of procedures for all patients. Similarly, when it was packaged, hospitals used it for 3 percent of procedures for such patients versus 1 percent of procedures for all patients. According to officials representing ophthalmological providers, Omidria is particularly useful for preventing excessive constriction of the pupil in these patients.
- **A drug may have specific challenges that limit its overall use.** According to groups representing radiology providers and diagnostic radiopharmaceutical manufacturers, another of our drugs, Choline C11, had overall low usage regardless of payment status. They said this was due to the limited number of sites that produced it and its short half-life. More specifically, our review of manufacturer data showed that fewer than five hospitals produced Choline C11, and it must be administered to the patient within an hour of when it was produced because of that short half-life. As a result, only those hospitals or hospitals located close to the manufacturing sites could use it.
- **Payment factors outside of pass-through payments may also affect use.** For example, there is a Medicare program that rewards physicians with additional payments for reporting quality measures and providing high-quality, efficient care, including on procedures such as cataract removal.[25] These cost metrics include Part B drugs, including, for example, Omidria. According to officials representing ophthalmological providers, some of their members thought that costs

[24]Patients who have a diagnosis of floppy iris syndrome tend to have pupils that dilate poorly, which makes cataract removal more difficult.

[25]This is part of the Merit-based Incentive Payment System, which started assessing the total cost of care for procedures and services, in 2018. Physicians who participate in it are assessed based on their performance in four categories: quality, cost, improvement activities, and advancing care information. Depending on their performance, physicians may be subject to a payment adjustment. This payment system was intended to improve quality of care and health outcomes, and reduce the cost of care.

related to Omidria should be excluded from the calculations and that not doing so would negatively affect the use of Omidria. However, those same officials also said that the calculation of costs excluded complex cataract procedures, which are the ones most likely to benefit from the use of Omidria.

Agency Comments

We provided a draft of this product to the Department of Health and Human Services for review and comment. The Department of Health and Human Services provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or CosgroveJ@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs can be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

James Cosgrove
Director, Health Care

Appendix I: Characteristics of Selected High-Cost Drugs

Table 4: Characteristics of High-Cost Drugs Whose Pass-Through Payments Expired in 2017 or 2018 and That Were Subsequently Packaged, 2017 — 2019

Drug commercial name (Healthcare Common Procedure Coding System and description)	Initial expiration date of pass-through payments	Clinical purpose	Related procedures	Ambulatory Payment Classification group for related procedures
Contrast agents				
Lumason (Q9950, sulfur hexafluoride lipid microsphere)	December 2017[a]	Characterize certain types of liver lesions in adult and pediatric patients Evaluate certain aspects of the urinary tract in pediatric patients	Ultrasound of abdomen with contrast/ Ultrasound with contrast using targeted microbubbles (1 procedure code)	Level 1 imaging with contrast
		More clearly view certain parts of the heart in adult and pediatric patients with suboptimal echocardiograms	Echocardiogram with contrast (10 procedure codes)[b]	Level 2 imaging with contrast Level 3 imaging with contrast
Diagnostic radiopharmaceuticals				
Amyvid (A9586, Florbetapir F18)	December 2017[a]	Evaluate certain adult patients for Alzheimer's Disease and other causes of cognitive decline by estimating the density of beta amyloid, a type of protein, in the patient's brain[d]	Positron emission tomography (PET) scan of a limited body area (2 procedure codes)	Level 3 nuclear medicine and related services Level 4 nuclear medicine and related services
Neuraceq (Q9983, Florbetaben F18)	December 2018[c]			
Vizamyl (Q9982, Flutemetamol F18)	December 2018[c]			
Choline C11 (A9515, Choline C11)	December 2018	Identify potential sites of prostate cancer recurrence	PET scan of skull base to mid-thigh (2 procedure codes)[e]	Level 4 nuclear medicine and related services
Skin substitutes (also called "cellular and/or tissue-based products for wounds")				
PuraPly (Q4172, PuraPly, any type; Q4195, PuraPly; and Q4196, PuraPly AM[f])	December 2017[a]	Manage wounds	Application of skin substitute graft (4 procedure codes)	Level 4 skin procedures Level 5 skin procedures
Surgical-supply drugs				
Omidria (C9447 and J1097, Phenylephrine and ketorolac[g])	December 2017[a]	Maintain pupil size during the procedure and reduce ocular pain after the procedure	Cataract removal (2 procedure codes) Removal of lens material (3 procedure codes)	Level 1 intraocular procedures Level 2 intraocular procedures

Source: GAO analysis of Centers for Medicare & Medicaid Services and Food and Drug Administration data. | GAO-21-252

Note: These are all seven drugs whose pass-through payments expired in 2017 or 2018 and that were subsequently packaged. We use the term "drugs" to refer to both drugs (including radiopharmaceuticals) and biologicals.

[a]The Consolidated Appropriations Act, 2018 effectively reinstated pass-through payments for Lumason, Amyvid, PuraPly, and Omidria from October 2018 through September 2020.

[b]The Medicare claims data also showed the use of Lumason with echocardiograms and certain other types of ultrasound that do not specify the use of a contrast agent. We did not list those procedures because they are assigned to ambulatory payment classification groups for imaging without contrast.

[c]The Further Consolidated Appropriations Act, 2020 effectively reinstated pass-through payments for Neuraceq and Vizamyl from January 2020 through September 2020.

[d]Medicare's coverage of these drugs is limited to clinical trials in the coverage with evidence development (CED) evaluation process described in Appendix III.

[e]We further narrowed this to PET scans for identifying potential sites of prostate cancer recurrence.

[f]For PuraPly, Q4172 was effective through December 2018 and was for PuraPly, any type. It was replaced by three separate codes in January 2019: Q4195 for PuraPly, Q4196 for PuraPly AM, and Q4197 for PuraPly XT. Our scope included two of those codes (Q4195 and Q4196)—the ones whose pass-through payments were reinstated from October 2018 through September 2020.

[g]For Omidria, C9447 was effective through September 2019, and it was replaced by J1097 in October 2019.

Appendix II: Ambulatory Surgical Centers

Ambulatory surgical centers (ASC) provide same-day outpatient surgical services and can stand alone or be owned by a hospital. These services can be performed with drugs that Medicare considers supplies for surgical procedures, such as skin substitutes, which are known as "policy-packaged drugs."[1]

The Centers for Medicare & Medicaid Services (CMS) pays ASCs under a prospective payment system that is linked to the prospective payment system for hospital outpatient departments.[2] Like the hospital outpatient payment system, the ASC payment system uses ambulatory payment classification (APC) groups that contain procedures with similar costs and clinical characteristics. Also, the relative value of the different APCs are generally the same in ASCs and hospital outpatient departments. However, the Medicare payment to an ASC is less than the payment to a hospital outpatient department for the same APC. According to CMS, in 2018, ASCs were paid, in aggregate, approximately 55 percent of the rate paid to hospital outpatient departments. This is not the case when ASCs are receiving pass-through payments for drugs. Specifically, when an ASC receives pass-through payments for a drug, CMS pays the ASC for the drug based on sales price—average sales price plus 6 percent—which is the same rate that CMS pays hospital outpatient departments.[3]

Out of the seven drugs in our scope, only Omidria and PuraPly were used in ASCs, and their use increased when providers received pass-through payments versus when the payments were packaged. According to data from their manufacturers, both drugs had higher use in ASCs when they were eligible for pass-through payments and lower use when packaged. In addition, the manufacturers' data shows that, the difference in use of the drugs when eligible for pass-through payments versus when packaged was greater in ASCs than in hospitals. According to officials

[1]We use the term "drugs" to refer to both drugs (including radiopharmaceuticals) and biologicals. Skin substitutes are also called "cellular and/or tissue-based products for wounds."

[2]In 2008, CMS revised the ASC payment system to be based on the hospital outpatient prospective payment system based, in part, on our findings that the ambulatory payment classification (APC) groups used in hospital outpatient departments accurately reflect the relative costs of procedures performed in ASCs. See *Medicare: Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System,* GAO-07-86 (Washington, D.C.: Nov. 30, 2006).

[3]Medicare beneficiaries are generally responsible for copayments for procedures performed in an ASC setting, and they are subject to additional copayments for pass-through drugs, including those that would otherwise be policy-packaged in the hospital outpatient prospective payment system.

representing ASCs, the financial incentives created by the payment system are more acute for ASCs than for hospitals. This is because, given that the APC payment rates are smaller as a whole, the dollar amount of the portion of the APC payment rate associated with policy-packaged drugs is smaller for ASCs versus hospitals. This may give ASCs a greater incentive to use a lower-cost alternative for the related procedure. CMS has made a similar point when it was responding to public comments on the effect of packaging on non-opioid pain management treatments. In particular, CMS said that fluctuations in payment rates for specific services may impact ASCs more acutely than hospital outpatient departments. CMS said that this was because, in comparison to hospital outpatient departments, ASCs tend to provide specialized care and a more limited range of services and receive a lower aggregate payment rate than hospitals.[4]

[4]See Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58818, 58854, 58856 (Nov. 21, 2018) (preamble, II.A.3.b.). Since October 2020, CMS has excluded Omidria from packaging under the ASC payment system as a non-opioid pain management drug. See Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 85 Fed. Reg. 85866, 85898 (Dec. 29, 2020) (preamble, II.A.3.b.).

Appendix III: Coverage with Evidence Development

Medicare's coverage of three drugs in our scope—Amyvid, Neuraceq, and Vizamyl—was limited to clinical trials in the coverage with evidence development (CED) evaluation process. The Centers for Medicare & Medicaid Services (CMS) introduced the CED evaluation process in 2005 to determine whether an item or service is reasonable and necessary and should receive Medicare payment coverage. Individuals or entities, such as manufacturers and providers, submit requests for a CED evaluation that identifies an item or service as a potential benefit or to prevent potential harm to Medicare beneficiaries.[1] In September 2013, CMS approved coverage of amyloid positron emission tomography (PET) imaging under the CED evaluation process to determine if these PET scans are valuable for beneficiaries who are being evaluated for Alzheimer's disease or other causes of cognitive decline.[2] This type of imaging requires the use of diagnostic radiopharmaceuticals, and Amyvid, Neuraceq, and Vizamyl are currently the only such diagnostic radiopharmaceuticals that can be used for this type of imaging.

If CMS approves the item or service for a CED evaluation, CMS covers it only for beneficiaries who are diagnosed with specific clinical indications and who are enrolled in a CMS-approved clinical trial that meets federal guidelines. CMS uses the results of the trial to document the appropriateness of the use of the item or service under current coverage, consider changes in coverage, and generate clinical evidence. According to officials from a group representing radiology providers and manufacturers, the primary CED clinical trial for amyloid PET imaging was the "Imaging Dementia – Evidence for Amyloid Scanning" (IDEAS) Study, which was designed to learn if amyloid PET images of the brain can guide providers in patient management and improve long-term outcomes.

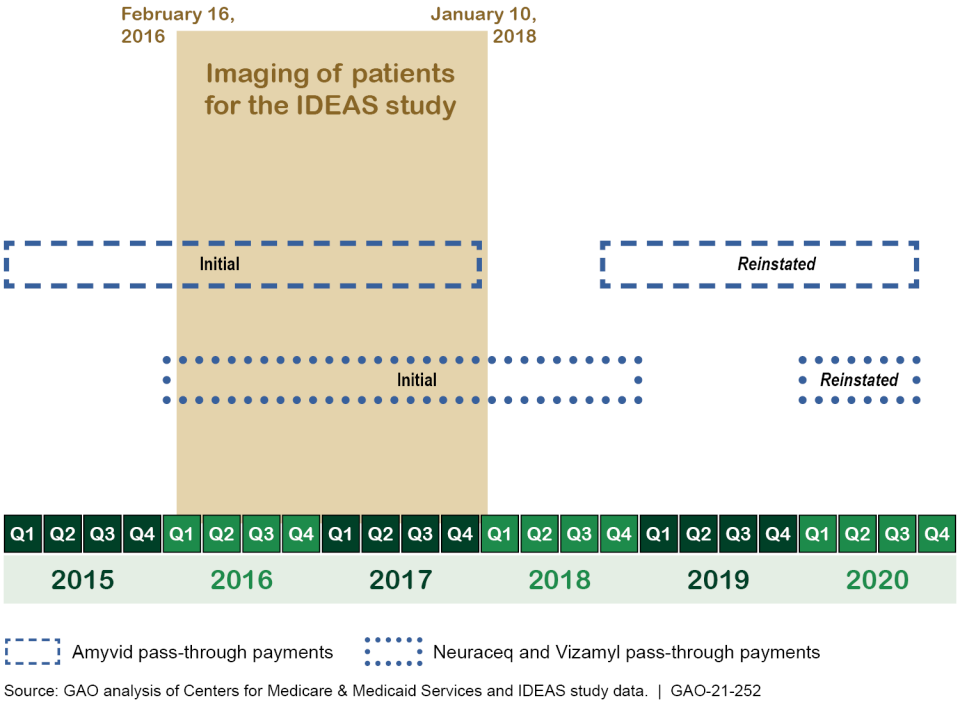
PET imaging of patients occurred for the IDEAS Study from February 2016 to January 2018, and hospital outpatient departments received pass-through payments for Amyvid, Neuraceq, and Vizamyl for most or all

[1]According to the CED guidelines, the CED evaluation does not replace the Food and Drug Administration's authority in assuring the safety, efficacy, and security of drugs.

[2]See Centers for Medicare & Medicaid Services, "Final Decision Memorandum for: CAG-00431N: Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease," Sep. 27, 2013. Amyloid, also known as beta amyloid, is a type of protein that can build up between neurons in the brain and that occurs in patients with Alzheimer's disease and other causes of cognitive decline.

of that time.[3] (See fig. 3.) Amyvid, Neuraceq, and Vizamyl were also eligible for pass-through payments at various points after the study concluded in January 2018.

Figure 3: Timing of Amyvid, Neuraceq, and Vizamyl Pass-Through Payments and of the "Imaging Dementia – Evidence for Amyloid Scanning" (IDEAS) Study



Source: GAO analysis of Centers for Medicare & Medicaid Services and IDEAS study data. | GAO-21-252

A new CED clinical trial on amyloid PET imaging started enrolling patients in December 2020. Known as the "New IDEAS" Study, it is designed to assess the relationship between amyloid PET imaging and patient-centered outcomes in an expanded manner focusing on ethnically and clinically diverse groups of Medicare beneficiaries. When the New IDEAS Study started, the pass-through payments for Amyvid, Neuraceq, and Vizamyl had expired, and payment for the drugs was packaged with the

[3]PET imaging of patients (and therefore use of the diagnostic radiopharmaceuticals) occurred in independent diagnostic testing facilities, in addition to hospital outpatient departments, according to the drug manufacturers and the organizers of the IDEAS Study. Independent diagnostic testing facilities are a type of Medicare provider that offers diagnostic procedures, but are independent both of a physician's office and of a hospital. See 42 C.F.R. § 410.33(a)(1) (2019). They are paid under the Medicare Physician Fee Schedule.

payment for the ambulatory payment classification group for nuclear medicine and related services. According to the organizers of the IDEAS Study, as of November 2020, four of the six hospitals initially invited to participate in the study have declined to do so. The study organizers said that those hospitals, which had all participated in the original IDEAS Study, declined to participate because the packaged payment would cause them to incur a financial loss for each procedure performed. This may pose a challenge because, according to the study organizers, hospitals associated with academic institutions have much of the expertise in recruiting ethnically and clinically diverse groups into such trials.

Appendix IV: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

In addition to the individual named above, Gregory Giusto (Assistant Director), Corissa Kiyan-Fukumoto (Analyst-in-Charge), Sam Amrhein, George Bogart, Bianca Eugene, Cynthia Khan, Vikki Porter, and Caylin Rathburn-Smith made key contributions to this report.