HHS-OIG Data Snapshot

Medicare Market Shares of Diabetes Test Strips From April Through June 2019

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Why OIG Did This Review

In 2011, the Centers for Medicare & Medicaid Services (CMS) implemented a Competitive Bidding Program (CBP) for mail-order diabetes test strips (DTS) in limited areas, and in July 2013, CMS expanded the program nationally to include a national mail-order program (the National Mail-Order Program).[1,2] The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) currently prohibits CMS from awarding a CBP contract to a DTS supplier if the supplier's bid does not cover at least 50 percent, by volume, of the DTS types provided to Medicare beneficiaries.[3] (This is known as the 50-percent rule.) This rule is intended to ensure that Medicare beneficiaries have access to top-selling DTS via the National Mail-Order Program. MIPPA requires the Office of Inspector General (OIG) to determine the Medicare market shares for DTS before each round of bidding. The Bipartisan Budget Act of 2018 amended the 50-percent rule by requiring that, for bids to furnish DTS on or after January 1, 2019, CMS must use multiple sources of data (from the mail-order and non-mail-order Medicare markets).[4] OIG's analysis assists CMS in determining whether bidding suppliers meet this 50-percent rule. Since 2010, OIG has released nine reports evaluating the Medicare market shares for mail-order and non-mail-order DTS.[5]

Results

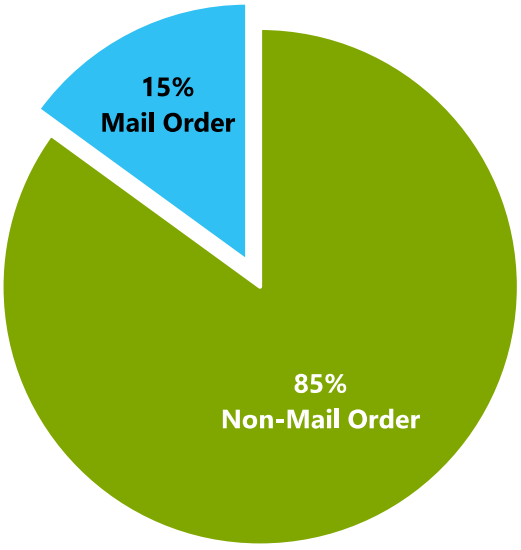
DTS was more commonly provided via non-mail order than mail order to Medicare beneficiaries for the 3-month period of April through June 2019.

Medicare was the primary payer for 1,402,636 claims for DTS provided via non-mail order and 256,373 claims for DTS provided via mail order during the time period we reviewed.

CMS will determine how to combine OIG's data from the separate Medicare markets for mail-order DTS and non-mail-order DTS, in addition to other market-based data sources that may be used, when assessing if suppliers' bids to participate in the National Mail-Order Program meet the 50-percent rule. Therefore, we present our data as separate markets in this report.

Exhibit 1 shows the percentages of total Medicare claims for DTS provided via mail order and non-mail order.

Exhibit 1: Non-mail-order claims composed 85 percent of the total Medicare market for DTS during the time period we reviewed.



Source: OIG analysis of Medicare claims containing Healthcare Common Procedure Coding System (HCPCS) code A4253. Mail-order claims contain the KL modifier, while non-mail-order claims do not contain the KL modifier.

Results

The suppliers in our sample provided 25 types of DTS to Medicare beneficiaries via non-mail order.

Our sample of claims includes 25 types of DTS provided to Medicare beneficiaries via non-mail order from April through June 2019. The top 10 types of strips accounted for 93 percent of the market.

Table 1 lists the top 10 types of non-mail-order DTS associated with Medicare claims for the time period we reviewed. See Appendix A for the full listing of market shares for DTS in the non-mail-order market.

Table 1: The top 10 non-mail-order strip types

Model	Market Share
OneTouch Ultra	26.33%
CONTOUR NEXT	13.14%
FreeStyle Lite	10.90%
TRUEmetrix	10.84%
OneTouch Verio	9.82%
ACCU-CHEK Aviva Plus	9.37%
CONTOUR	6.57%
ACCU-CHEK Smartview	2.23%
TRUEtrack	1.91%
Prodigy	1.79%
Total	92.90%

Source: OIG analysis of Medicare claims containing HCPCS code A4253, but without the KL modifier.

The suppliers in our sample provided 21 types of DTS to Medicare beneficiaries via mail order.

Our sample of claims includes 21 types of DTS provided to Medicare beneficiaries via mail order from April through June 2019. The top 10 types of strips accounted for 99 percent of the market.

Table 2 lists the top 10 types of mail-order DTS associated with Medicare claims for the time period we reviewed. See Appendix B for the full listing of market shares for DTS in the mail-order market.

Table 2: The top 10* mail-order strip types

Model	Market Share**
Prodigy	38.04%
TRUEmetrix	17.31%
Embrace	15.87%
CareSens N	9.35%
Advocate Redi-Code+	6.09%
On Call Express	4.23%
EASYMax	3.64%
Fora V10/V12	1.44%
Unistrip1	1.18%
Embrace Talk*	0.68%
GlucoCard Expression*	0.68%
Total	98.48%

Source: OIG analysis of Medicare claims containing HCPCS code A4253 and the KL modifier.

* This list contains 11 types, because the last 2 strip types—Embrace Talk and GlucoCard Expression—tied for the 10th highest market share.

** The market shares in this column do not sum to the total because of rounding.

The suppliers in our samples provided eight types of DTS to Medicare beneficiaries both via non-mail order and mail order.

Of the 38 unique types of DTS across our samples, 8 types of DTS were provided in both samples. Two of these 8 strip types—Prodigy and TRUEmetrix—are included in the top 10 for both markets.

Table 3 lists these eight strip types and their respective market shares.

Table 3: The eight strip types in both markets

Model	Non-Mail Order	Mail Order
CONTOUR NEXT	13.14%	0.34%
FreeStyle Lite	10.90%	0.08%
TRUEmetrix	10.84%	17.31%
CONTOUR	6.57%	0.08%
Prodigy	1.79%	38.04%
EASYMax	0.89%	3.64%
Embrace	0.38%	15.87%
GlucoCard Expression	0.32%	0.68%

Source: OIG analysis of Medicare claims containing HCPCS code A4253.

Additional Context

DMEPOS Competitive Bidding Program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires CMS to phase in—through several rounds of bidding—a CBP for selected durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items.[6] The statute allows for the phase-in of items and services under the program, beginning with the highest-cost and highest-volume items and services or those with the largest savings potential.[7,8] CMS evaluates suppliers' bids based on the suppliers' eligibility, financial stability, and bid prices. Generally, CMS awards contracts to the suppliers that offer lower bid prices and meet applicable quality and financial standards. The payment amounts resulting from winning bids replace the Medicare fee-schedule amounts for the selected items.[9] Generally, contract awards and payment amounts expire every 3 years, and suppliers must recompete to remain contract suppliers.

MIPPA added further conditions to the competition for DTS. MIPPA required that in rounds subsequent to the first round, a supplier must demonstrate that its bid covers at least 50 percent, by volume, of the DTS types provided to Medicare beneficiaries. (This is known as the 50-percent rule.) The Bipartisan Budget Act of 2018 amended the 50-percent rule by requiring that, for bids to furnish DTS on or after January 1, 2019, CMS must use multiple sources of data (from the mail-order and non-mail-order Medicare markets) to determine the volume for such types of products.[10] Therefore, in future rounds of competitive bidding, CMS will use these multiple sources of data to determine if suppliers' bids for the National Mail-Order Program meet the 50-percent rule.

DTS provided via non-mail order are not included in the CBP. However, effective for dates of service on or after July 1, 2013, Medicare adjusts the fee-schedule amounts for non-mail-order DTS so that they are equal to the single payment amounts that the National Mail-Order Program establishes for mail-order DTS.[11] During the last round of competitive bidding, this rate was $8.32 per 50-count box.[12]

Current Status of the DMEPOS Competitive Bidding Program. All CBP contracts expired on December 31, 2018. In October 2018, CMS issued guidance stating there would be a temporary gap in the CBP beginning January 1, 2019.[13] As a result, beginning January 1, 2019, and until new CBP contracts are awarded, beneficiaries may receive DTS from any Medicare-enrolled DMEPOS supplier.[14] During the temporary gap in the CBP, Medicare will pay for mail-order DTS at the single payment amount that was in effect for the last day of the National Mail-Order Program contract period (i.e., December 31, 2018), adjusted for inflation.[15]

On March 7, 2019, CMS announced plans to initiate a new round of competitive bidding that will take effect on January 1, 2021; however, the National Mail-Order Program for DTS will not be included in this round.[16] CMS has not yet announced when the National Mail-Order Program for DTS will resume being included in the CBP.

Appendix A: Model, Manufacturer, and Market Share Estimates for Non-Mail-Order DTS for April Through June 2019

Model	Manufacturer	Market Share*	95-Percent Confidence Interval
OneTouch Ultra	LifeScan, Inc.	26.33%	21.91%–30.76%
CONTOUR NEXT	PHC Holdings Corporation	13.14%	10.04%–17.01%
FreeStyle Lite	Abbott Diabetes Care, Inc.	10.90%	8.28%–14.23%
TRUEmetrix	Trividia Health, Inc.	10.84%	8.42%–13.85%
OneTouch Verio	LifeScan, Inc.	9.82%	7.27%–13.14%
ACCU-CHEK Aviva Plus	Roche	9.37%	6.77%–12.84%
CONTOUR	PHC Holdings Corporation	6.57%	4.19%–10.15%
ACCU-CHEK Smartview	Roche	2.23%	1.04%–4.74%
TRUEtrack	Trividia Health, Inc.	1.91%	1.00%–3.62%
Prodigy	Prodigy Diabetes Care	1.79%	0.99%–3.19%
ACCU-CHEK Guide	Roche	1.28%	0.48%–3.32%
ACCU-CHEK Compact Plus	Roche	1.04%	0.38%–2.79%
WaveSense Presto	AgaMatrix	1.02%	0.38%–2.69%
EASYMax	Oak Tree International Holdings, Inc.	0.89%	0.26%–2.98%
EasyTouch	MHC Medical Products	0.64%	0.26%–1.53%
Embrace	Omnis Health	0.38%	0.14%–1.08%
FreeStyle	Abbott Diabetes Care, Inc.	0.38%	0.14%–1.08%
FreeStyle InsuLinx	Abbott Diabetes Care, Inc.	0.38%	0.09%–1.64%
GlucoCard Expression	ARKRAY	0.32%	0.10%–1.03%
FreeStyle Precision NEO	Abbott Diabetes Care, Inc.	0.19%	0.04%–0.83%
Fora V30 G30 Premium V10	ForaCare, Inc.	0.13%	0.02%–0.91%
GlucoCard Vital	ARKRAY	0.13%	0.02%–0.91%
EvenCare G2	Medline	0.13%	0.02%–0.91%
GlucoCard Shine	ARKRAY	0.13%	0.02%–0.91%
Precision Xtra	Abbott Diabetes Care, Inc.	0.06%	0.01%–0.45%

Source: OIG analysis of supplier documentation and Medicare claims containing HCPCS code A4253, but without the KL modifier, for the 3-month period of April through June 2019.

* The market shares in this column do not sum to 100 percent because of rounding.

Appendix B: Model, Manufacturer, and Market Share Estimates for Mail-Order DTS for April Through June 2019

Model	Manufacturer	Market Share*	95-Percent Confidence Interval
Prodigy	Prodigy Diabetes Care	38.04%	33.58%–42.51%
TRUEmetrix	Trividia Health, Inc.	17.31%	14.09%–21.08%
Embrace	Omnis Health	15.87%	12.63%–19.76%
CareSens N	i-Sens, Inc.	9.35%	6.98%–12.42%
Advocate Redi-Code+	BroadMaster Bio-Tech Corp.	6.09%	4.28%–8.61%
On Call Express	ACON Laboratories	4.23%	2.69%–6.61%
EASYMax	Oak Tree International Holdings, Inc.	3.64%	2.36%–5.57%
Fora V10/V12	ForaCare, Inc.	1.44%	0.66%–3.09%
Unistrip1	Unistrip Technologies, LLC	1.18%	0.49%–2.84%
Embrace Talk	Omnis Health	0.68%	0.27%–1.69%
GlucoCard Expression	ARKRAY	0.68%	0.25%–1.79%
Easy Talk	Home Aide Diagnostics	0.42%	0.12%–1.54%
CONTOUR NEXT	PHC Holdings Corporation	0.34%	0.13%–0.90%
Fora G20	ForaCare, Inc.	0.17%	0.02%–1.20%
OneTouch Verio	LifeScan, Inc.	0.08%	0.01%–0.60%
NovaMax	Nova Biomedical	0.08%	0.01%–0.60%
CONTOUR	PHC Holdings Corporation	0.08%	0.01%–0.60%
Rightest GS 300	Bionime Corporation	0.08%	0.01%–0.60%
Embrace Evo	Omnis Health	0.08%	0.01%–0.60%
FreeStyle Lite	Abbott Diabetes Care, Inc.	0.08%	0.01%–0.60%
OneTouch Ultra	LifeScan, Inc.	0.04%	0.01%–0.30%

Source: OIG analysis of supplier documentation and Medicare claims containing HCPCS code A4253 and the KL modifier for the 3-month period of April through June 2019.

* The market shares in this column do not sum to 100 percent because of rounding.

Methodology

Data Collection

Using CMS's National Claims History file, we identified the population of Medicare Part B paid claims for DTS that had dates of service beginning between April 1, 2019, and June 30, 2019. There were 1,402,636 non-mail-order claims and 256,373 mail-order claims for which Medicare was the primary payer during this period. From these populations, we selected a simple random sample of 600 non-mail-order claims and 600 mail-order claims.

To identify the beneficiaries associated with the claims in our samples, we matched the beneficiary numbers from the claims with beneficiary numbers in the CMS Beneficiary Enrollment Database. We sent documentation requests to the 594 non-mail-order suppliers and the 18 mail-order suppliers associated with the claims in our samples. In some cases, we were able to aggregate individual non-mail-order suppliers under a large retailer chain (e.g., CVS Health). In these cases, we sent documentation requests to the large retailer for a response on behalf of all suppliers that had been aggregated under it. For each claim, we asked the large retailer or individual supplier to (1) indicate the type (model and manufacturer) of DTS that it provided to the Medicare beneficiary we identified and (2) submit relevant documentation (such as packing slips or box labels) for the strips. We received responses from all 594 non-mail-order suppliers documenting 600 claims in our sample, a 100-percent response rate. We received responses from 17 mail-order suppliers documenting 599 claims in our sample, a 99-percent response rate.

Data Analysis

We reviewed claims data, supplier responses, and supplier documentation to determine the quantity and type of mail-order or non-mail-order DTS associated with each claim in our sample. Each claim in our non-mail-order sample covered between 1 and 15 boxes. Data for the 600 non-mail-order claims provided information for a total of 1,578 boxes of strips. Each claim in our mail-order sample covered between 1 and 18 boxes. Data for the 599 mail-order claims provided information for a total of 2,364 boxes of strips.

We categorized the DTS types by model and manufacturer in both our non-mail-order and mail-order samples. We determined the market share estimates for each DTS model type (strip type) that each of our samples captured. We calculated each strip type's share of its respective Medicare market by determining the total number of 50-count boxes of each strip type provided to beneficiaries in our sample and dividing that number by the total number of boxes across all strip types in each sample.[17] To estimate the Medicare market share of each type of DTS provided via non-mail order and mail order, we projected our sample data to each of the populations of DTS during the timeframe we reviewed.

For the non-mail-order claims in our sample, we identified 1 type of DTS that was sold exclusively by a single retailer. This 1 type of DTS accounted for 5 claims and 10 boxes in our non-mail-order sample. We removed these claims from our sample to assist CMS in meeting the Bipartisan Budget Act of 2018's requirement for CMS to use multiple sources of data, including market-based data measuring sales of DTS products that are not sold exclusively by a single retailer.[18] This reduced our non-mail-order sample of claims from 600 to 595, with a corresponding total of 1,568 boxes.

Lastly, we reviewed the market share lists for both the non-mail-order market and the mail-order market to determine which strip types were provided via both methods.

Limitations

Suppliers have 1 year to submit claims to CMS. Our study did not include any Medicare claims submitted after August 1, 2019, the date we collected our claims data for non-mail-order DTS and mail-order DTS. Therefore, our sample may not include all types of non-mail-order and mail-order DTS reimbursed by Medicare during our timeframe. Additionally, the market share analysis reflects only the suppliers that responded to our documentation request.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

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This report was prepared under the direction of Dwayne Grant, Regional Inspector General for Evaluation and Inspections in the Atlanta regional office; Evan Godfrey, Deputy Regional Inspector General; and Jaime Stewart, Assistant Regional Inspector General.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Sources

[1] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), P.L. No. 108-173, § 302(b)(1). CMS implemented Round 1 of the CBP in 2008 for 2 weeks until the contacts were terminated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), P.L. No. 110-275, § 154(a)(1). As required by MIPPA, CMS conducted the supplier competition again in 2009, referring to it as the Round 1 Rebid, which began on January 1, 2011.

[2] MIPPA authorized CMS to phase in a national mail-order program after 2010. MIPPA, P.L. No. 110-275 § 154(a)(1)(A)(iii) (amending Social Security Act, § 1847(a)(1)(B)(i)(III), and 42 U.S.C. § 1395w-3(a)(1)(B)(i)(III)).

[3] MIPPA, P. L. No. 110-275 § 154(d)(3)(B) (adding new paragraph Social Security Act, § 1847(b)(10)(A), 42 U.S.C. § 1395w-3(b)(10)(A)).

[4] Bipartisan Budget Act of 2018, P.L. No. 115-123, § 50414(a)(1)(amending Social Security Act, § 1847(b)(10)(A), 42 U.S.C. § 1395w-3(b)(10)(A)).

[5] These nine reports include OEI-04-10-00130, OEI-04-13-00680, OEI-04-13-00681, OEI-04-13-000682, OEI-04-16-00470, OEI-04-16-00471, OEI-04-16-00473, OEI-04-18-00440, and OEI-04-18-00441.

[6] MMA, P.L. No. 108-173, § 302(b)(1).

[7] Social Security Act, § 1847(a)(1)(B)(ii), 42 U.S.C. § 1395w-3(a)(1)(B)(ii).

[8] The statute also allows CMS to exempt items and services from the CBP if the application of competitive bidding for these items and services is not likely to result in significant savings. Social Security Act, § 1847(a)(3)(B), 42 U.S.C. § 1395w-3(a)(3)(B).

[9] In November 2018, CMS revised its CBP rules to change the processes for submitting bids, evaluating bids, and calculating single payment amounts. Specifically, CMS will replace the bidding method that was in effect through 2018—in which a supplier submits a bid for each item in the product category—with what is known as lead item pricing. Under lead item pricing, a bidding supplier would submit a bid for one item—known as the lead item—in the product category. The maximum winning bid for the lead item would be used to establish single payment amounts for both the lead item and all other items in the product category. 83 Fed. Reg. 56922 (Nov. 14, 2018). Accessed at https://www.gpo.gov/fdsys/pkg/FR-2018-11-14/pdf/2018-24238.pdf on September 19, 2019.

[10] Bipartisan Budget Act of 2018, P.L. No. 115-123, § 50414(a)(1)(amending Social Security Act, § 1847(b)(10)(A), 42 U.S.C. § 1395w-3(b)(10)(A)).

[11] American Taxpayer Relief Act of 2012, P.L. No.112-240 § 636 (added new paragraph to Social Security Act, § 1834(a)(1)(H), 42 U.S.C. § 1395m(a)(1)(H)).

[12] CMS, *Public Use File V0817*. Accessed at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule-Items/DME16-C.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending on November 7, 2019.

[13] CMS, *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program: Temporary Gap Period*, October 2018. Accessed at https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/DMEPOS-Temporary-Gap-Period-Fact-Sheet.pdf on October 1, 2019.

[14] Ibid.

[15] The single payment amount for mail-order DTS that was in effect on December 31, 2018, will be increased by the projected percentage change in the Consumer Price Index For All Urban Consumers for the 12-month period on the date after the contract period ended. 42 CFR § 414.210(g)(10) (as added by 83 Fed. Reg. 56922, 57071 (Nov. 14, 2018)). Accessed at https://www.gpo.gov/fdsys/pkg/FR-2018-11-14/pdf/2018-24238.pdf on September 19, 2019.

[16] CMS, *DMEPOS Competitive Bidding Round 2021*, March 8, 2019. Accessed at https://www.cms.gov/newsroom/fact-sheets/dmepos-competitive-bidding-round-2021 on November 4, 2019.

[17] Generally, each box of DTS contains 50 strips. Some types of DTS are packaged as 51-count boxes instead of 50-count boxes, but Medicare pays for these boxes as though they were 50-count boxes. In our analysis, we counted these boxes of DTS as containing 51 strips.

[18] Bipartisan Budget Act of 2018, P.L. No. 115-123, § 50414(a)(1) (amending Social Security Act, § 1847(b)(10)(A), 42 U.S.C. § 1395w-3(b)(10)(A)).