



Medicare Market Shares of Mail-Order Diabetes Test Strips From April Through June 2018

This Office of Inspector General (OIG) report provides the Medicare market shares for diabetes test strips (DTS) provided through the National Mail-Order Program from April through June 2018. A second report, anticipated in early 2019, will provide the market shares for the same timeframe for DTS provided via *non*-mail order (i.e., from local pharmacies or supplier storefronts). These evaluations will inform future round(s) of the Competitive Bidding Program (CBP) for DTS. All CBP contracts expired on December 31, 2018, and new contracts are not expected before the end of 2020.

RESULTS AT A GLANCE

OIG analyzed the types of strips provided through the National Mail-Order Program from April through June 2018. We found that during this timeframe:

- **Sampled suppliers provided 17 types of DTS to Medicare beneficiaries via mail order.**
- **The top two strip types accounted for 53 percent of the Medicare mail-order market.**
- **The top 10 strip types accounted for 98 percent of the Medicare mail-order market.**

Why OIG Did This Review

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the Centers for Medicare & Medicaid Services (CMS) to phase in a CBP for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). In 2008, mail-order DTS became part of the CBP in certain limited areas, and in July 2013, this was expanded nationally to include a National Mail-Order Program for diabetes testing supplies.

Legislation enacted since MMA has revised the CBP. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) prohibits CMS from awarding contracts in the National Mail-Order Program 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. (This is known as the "50-percent rule.") MIPPA requires OIG to determine the market shares of the types of DTS before each round of bidding to assist CMS in ensuring that bidding suppliers meet the 50-percent rule.

Initially, OIG based its calculations of the Medicare market shares on claims data only for DTS supplied via mail order by CBP suppliers. The Bipartisan Budget Act of 2018 amended the 50-percent rule by requiring analysis of DTS supplied via mail order as well as via non-mail order.

See Appendix A for information on diabetes; Medicare's coverage of DTS; the CBP; and the National Mail-Order Program. See Appendix B for an overview of completed OIG work on this topic. OIG will conduct future reviews of the market shares of the various types of mail-order and non-mail-order DTS, as required by MIPPA and/or as requested by CMS.

RESULTS

Sampled suppliers provided 17 types of DTS to Medicare beneficiaries via mail order; 2 types of test strips accounted for 53 percent of the mail-order market

Our sample of claims included 17 types of DTS provided to Medicare beneficiaries from April through June 2018. Two types of DTS accounted for approximately 53 percent of the Medicare mail-order market. Five types of DTS accounted for approximately 88 percent of the market, and 10 types accounted for approximately 98 percent of the market.

Exhibit 1 lists the top 10 types of mail-order DTS associated with Medicare claims for the 3-month period of April through June 2018. See Appendix C for a complete alphabetical listing of all 17 strip types. Appendix C also provides the model, manufacturer, market share, and 95-percent confidence interval for each type of DTS provided.

Exhibit 1: Top 10 Mail-Order DTS Types Associated With Medicare Claims for the 3-Month Period of April Through June 2018

Model	Manufacturer	Market Share
Prodigy	Prodigy Diabetes Care	32.98%
TRUEmetrix	Trividia Health, Inc.	19.82%
Embrace	Omnis Health	18.85%
CareSens N	i-Sens, Inc.	11.68%
Advocate Redi-Code+	BroadMaster Bio-Tech Corp.	4.64%
EASYMax	Oak Tree International Holdings, Inc.	3.52%
On Call Express	ACON Laboratories	2.69%
Unistrip1	Unistrip Technologies, LLC	1.26%
CONTOUR NEXT	PHC Holdings Corporation	1.21%
Easy Talk	Home Aide Diagnostics	1.15%
Total		97.79%*

Source: OIG analysis of supplier documentation and Medicare claims containing Healthcare Common Procedure Coding System (HCPCS) code A4253 KL for the 3-month period of April through June 2018.

* The market shares in this column do not sum to 100 percent because these strip types are only the top 10 types, not a list of all strip types provided.

CONCLUSION

This report provides CMS with information on the types of DTS provided to beneficiaries via mail order for April through June 2018. We found that during this timeframe, sampled suppliers provided 17 types of DTS to Medicare beneficiaries via mail order. The top 2 strip types accounted for just over half of the mail-order market, and the top 10 types accounted for almost all of the mail-order market.

This OIG report provides the Medicare market shares for DTS provided through the National Mail-Order Program from April through June 2018. A second report, anticipated in early 2019, will show the market shares for the same timeframe for DTS provided via *non*-mail order (i.e., from local pharmacies or supplier storefronts). These evaluations will inform future round(s) of the CBP for DTS. The CBP contracts expired on December 31, 2018, and new contracts are not expected before the end of 2020.

OIG will conduct future reviews of the market shares of the various types of mail-order and non-mail-order DTS, as required by MIPPA and/or as requested by CMS. See Appendix B for an overview of OIG's completed work on this topic.

METHODOLOGY

Data Collection

Using CMS's National Claims History file, we identified the population of Medicare Part B paid claims for DTS that were provided via mail order and had dates of service beginning between April 1, 2018, and June 30, 2018. During this period, there were nine suppliers that had CBP contracts to provide DTS. There were 313,704 claims for which Medicare was the primary payer during this period, and these claims included all 9 suppliers that had CBP contracts.¹ From this population of claims, we selected a simple random sample of 1,210 claims. This sample included all nine contract suppliers.

To identify the beneficiaries associated with the claims in our sample, we matched the beneficiary numbers from the claims with beneficiary numbers in the CMS Beneficiary Enrollment Database. We sent documentation requests to the nine suppliers associated with our sampled claims, asking that for each claim, the supplier (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 invoices) for the strips. We received responses from all 9 suppliers documenting all 1,210 claims in our sample, a 100-percent response rate.

Data Analysis

We reviewed claims data, supplier responses, and supplier documentation to determine the quantity and type of mail-order DTS associated with each claim in our sample. Each claim in our sample covered between 1 and 18 boxes, and data for the 1,210 claims provided information for a total of 5,061 boxes of strips.

We categorized the DTS types by model and manufacturer. We calculated each strip type's share of the Medicare mail-order 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 our sample. To estimate the Medicare market share of each type of DTS provided via mail order, we projected our sample data to the population of DTS provided via mail order during the timeframe we reviewed. In our results, we present the market share for the top 10 types of DTS to the second decimal place. See Appendix C for the market shares of the 17 strip types in our sample.

Limitations

Suppliers have 1 year to submit claims to CMS. Our study did not include any mail-order claims submitted after August 3, 2018, the date we collected our Medicare claims data. Therefore, our sample may not include all types of mail-order DTS reimbursed by Medicare during our timeframe.

Standards

This review was conducted in accordance with the *Quality Standards for Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

APPENDIX A

Information on Diabetes, Medicare's Coverage of DTS, Beneficiaries' Purchase of DTS, and the CBP

Diabetes and Blood Glucose Monitoring. Diabetes is a chronic disease in which a person has a high blood-sugar (glucose) level either because the body does not produce enough insulin, or because cells do not respond properly to the insulin the body does produce.² Diabetes may be managed through a variety of methods, including healthy eating, physical activity, and insulin injections to prevent medical complications (e.g., hypoglycemia or cardiovascular disease).³

A person with diabetes can use a hand-held meter to test the concentration of glucose in his or her blood. To do so, the individual pricks his or her skin with a lancet and places the resulting drop of blood on a DTS, which is a small piece of plastic meant for one-time use. The individual then inserts the strip into a meter that reads the blood sample's glucose level, providing information necessary for the individual to manage his or her diabetes. A person with diabetes may need to perform glucose tests several times a day to help maintain an appropriate glucose level.

Medicare Coverage of DTS. Medicare covers testing supplies, such as DTS, to help beneficiaries with diabetes manage their condition.⁴ To be eligible for Medicare coverage of DTS, Medicare beneficiaries with diabetes must be under the treatment of a physician for the condition. The physician's order for DTS specifies the frequency at which the beneficiary should use the strips. Each box contains 50 strips.⁵ Because some beneficiaries need to test their glucose levels more frequently than others, the number of boxes per claim varies.⁶

For each beneficiary, the supplier submits a single claim that can cover up to 3 months of DTS. The claim indicates the *number* of boxes provided to the beneficiary for the applicable time period, but it does not indicate the *type* of strips provided. The modifier KL on a claim indicates that the DTS were provided via mail order.⁷

Beneficiaries' Purchase of DTS. Medicare beneficiaries may purchase their DTS via mail order (from CBP suppliers) or via non-mail order (from local pharmacies or supplier storefronts). CMS considers all DTS that are either shipped or delivered to a beneficiary's residence to be mail order, regardless of the method of delivery.⁸ Non-mail-order DTS are those that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront. For both mail-order and non-mail-order purchases, Medicare pays 80 percent of allowed charges for DTS (less any unmet Part B deductible), and the beneficiary is responsible for the remaining 20 percent. 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.⁹

CBP. The MMA requires CMS to phase in—through several rounds of bidding—a CBP for selected DMEPOS items (including DTS).¹⁰ The CBP includes high-cost and high-volume items or those with significant savings potential. Suppliers submit bids that CMS evaluates based on the suppliers' eligibility, their financial stability, and their 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.¹¹ Generally, contract awards and payment amounts expire every 3 years, and suppliers must re compete to remain contract suppliers.¹²

MIPPA added further conditions to the competition for DTS. MIPPA required that in rounds subsequent to the first round, mail-order suppliers demonstrate in their bids that they can provide at least 50 percent, by volume, of the types of DTS provided to Medicare beneficiaries. Suppliers do this by attesting in their bids the types of DTS they intend to provide. The Bipartisan Budget Act of 2018 amended the 50-percent rule by requiring that both mail-order data and non-mail-order data be used to determine the types of DTS used to meet the 50-percent rule.¹³

Current Status of the CBP. All CBP contracts expired on December 31, 2018. In October 2018, CMS issued guidance stating that there would be a temporary gap in the CBP, starting January 1, 2019, and expected to last until December 31, 2020.¹⁴ As a result, beginning January 1, 2019, and until new contracts are awarded under the CBP, beneficiaries may receive DTS from any Medicare-enrolled DMEPOS supplier.¹⁵ According to CMS's November 2018 final rule, 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 CBP contract period (i.e., December 31, 2018), adjusted for inflation.¹⁶ For non-mail-order DTS, Medicare payment will continue to be the single payment amount for mail-order DTS that was in effect on December 31, 2018, and those amounts will not be adjusted for inflation.¹⁷

APPENDIX B

OIG's Past and Current Work on Medicare Market Shares of DTS

MIPPA section 154(d)(3)(B) requires that before each new round of bidding in the CBP, OIG must determine the market shares of DTS types provided via mail order. The Bipartisan Budget Act of 2018 amended this MIPPA section by requiring that both mail-order data and non-mail-order data be used to determine the types of DTS used to meet the 50-percent rule.

Before each prior round of the CBP, OIG reported the market shares of different types of DTS. To help CMS evaluate the CBP's effect on DTS types provided to beneficiaries, OIG also reported additional information to CMS for the 3-month periods before and after implementation of new rounds. In this January 2019 data brief, OIG is reporting the market shares for DTS provided via the National Mail-Order Program from April through June 2018. A second report, anticipated in early 2019, will determine the market shares for the same timeframe for DTS provided via non-mail order. OIG will conduct future reviews of the market shares of the various types of DTS—provided via mail order and non-mail order—as required by MIPPA and/or as requested by CMS.

See Exhibit B-1 for a timeline of OIG work on the Medicare market shares of DTS.

Exhibit B-1: OIG Work on the Medicare Market Shares of DTS

Completed Before Round 2 (Contract Period January 1, 2011, to December 31, 2013)

Release Date
December 2010

Report Title: *Medicare Market Shares of Mail Order Diabetic Testing Strips* (OEI-04-10-00130)
Time period covered: October 2009 through December 2009
Results: 75 total types—top 7 types had a 50% share of the market; top 10 types had 62%

Completed Before Round 2 Recompete (Contract Period July 1, 2016, to December 31, 2018)

Release Date
June 2014

Report Title: *Medicare Market Shares of Mail Order Diabetes Test Strips from July-September 2013* (OEI-04-13-00680)
Results: 43 total types—top 3 types had a 59% share of the market; top 10 types had 90%

Release Date
June 2014

Report Title: *Medicare Market Shares of Mail Order Diabetes Test Strips Immediately Prior to the National Mail-Order Program* (OEI-04-13-00681)
Time period covered: April 2013 through June 2013
Results: 62 total types—top 4 types had a 51% share of the market; top 10 types had 75%

Release Date
November 2014

Report Title: *Medicare Market Shares of Mail Order Diabetes Test Strips 3-6 Months After the Start of the National Mail-Order Program* (OEI-04-13-00682)
Time period covered: October 2013 through December 2013
Results: 41 total types—top 3 types had a 58% share of the market; top 10 types had 91%

Completed Before 2019 (Contracts Expired December 31, 2018)

Release Date
November 2016

Report Title: *Medicare Market Shares of Mail Order Diabetes Test Strips from April to June 2016* (OEI-04-16-00470)
Results: 30 total types—top 2 types had a 51% share of the market; top 10 types had 93%

Release Date
February 2017

Report Title: *Medicare Market Shares of Mail-Order Diabetes Test Strips from July Through September 2016* (OEI-04-16-00471)
Results: 18 total types—top 2 types had a 60% share of the market; top 10 types had 98%

Release Date
May 2017

Report Title: *Medicare Market Shares of Mail-Order Diabetes Test Strips from October Through December 2016* (OEI-04-16-00473)
Results: 19 total types—top 2 types had a 53% share of the market; top 11 types had 97%

Completed Before Next Round (No Contracts on January 1, 2019)

Release Date
January 2019

Report Title: *Medicare Market Shares of Mail-Order Diabetes Test Strips from April Through June 2018* (OEI-04-18-00440)
Results: 17 total types—top 2 types had a 53% share of the market; top 10 types had 98%

Anticipated
Release
Early 2019

Report Title: *Medicare Market Shares of Non-Mail-Order Diabetes Test Strips from April Through June 2018* (OEI-04-18-00441)
Results: to be determined

APPENDIX C

Exhibit C-1: Model, Manufacturer, and Market Share Estimates for Mail-Order DTS, April Through June 2018

Model	Manufacturer	Market Share	95-Percent Confidence Interval
Advocate Redi-Code+	BroadMaster Bio-Tech Corp.	4.64%	3.50–6.13%
CareSens N	i-Sens, Inc.	11.68%	9.71–13.99%
CONTOUR	PHC Holdings Corporation	0.12%	0.02–0.84%
CONTOUR NEXT	PHC Holdings Corporation	1.21%	0.62–2.34%
EASYMax	Oak Tree International Holdings, Inc.	3.52%	2.62–4.71%
Easy Talk	Home Aide Diagnostics	1.15%	0.64–2.03%
Embrace	Omnis Health	18.85%	16.49–21.46%
Fora G20	ForaCare, Inc.	0.12%	0.04%–0.37%
Fora V10/V12	ForaCare, Inc.	0.32%	0.11%–0.94%
GlucoCard Expression	ARKRAY	0.79%	0.40–1.57%
GlucoCard Vital	ARKRAY	0.12%	0.02–0.84%
On Call Express	ACON Laboratories	2.69%	1.82–3.96%
On Call Plus	ACON Laboratories	0.55%	0.23–1.33%
Prodigy	Prodigy Diabetes Care	32.98%	29.98–35.98%
Rightest GS 300	Bionime Corporation	0.20%	0.06–0.64%
TRUEmetrix	Trividia Health, Inc.	19.82%	17.39–22.49%
Unistrip1	Unistrip Technologies, LLC	1.26%	0.65–2.45%
Total		100.00%	

Source: OIG analysis of supplier documentation and Medicare claims containing HCPCS code A4253 KL for the 3-month period of April through June 2018.

Exhibit C-2. Medicare Market Share Estimates for Top 2, Top 5, and Top 10 Types of Mail-Order DTS, April Through June 2018

Groupings of Strip Types with Largest Market Share	Model Names	Combined Market Share	95-Percent Confidence Interval
Top 2 Strip Types	Prodigy TRUEmetrix	52.80%	49.60–55.99%
Top 5 Strip Types	Prodigy TRUEMetrix Embrace CareSens N Advocate Redi-Code+	87.97%	85.74–89.89%
Top 10 Strip Types	Prodigy TRUEMetrix Embrace CareSens N Advocate Redi-Code+ EASYMax On Call Express Unistrip1 CONTOUR NEXT Easy Talk	97.79%	96.67–98.53%

Source: OIG analysis of supplier documentation and Medicare claims containing HCPCS code A4253 KL for the 3-month period of April through June 2018.

ACKNOWLEDGMENTS

Evan Godfrey served as the team leader for this study. Other Office of Evaluation and Inspections staff from the Atlanta regional office who conducted the study include Lauren Buss and Margaret Naughton. Office of Evaluation and Inspections staff who provided support include Kevin Farber, Christine Moritz, and Michael Novello.

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

ENDNOTES

¹ There were 313,716 claims for DTS provided via mail order; however, 12 claims were submitted by suppliers that were not contracted to be in the CBP. We did not include these 12 claims in our analysis.

² National Institutes of Health (NIH), *What is Diabetes?* Accessed at <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes> on October 24, 2018.

³ NIH, *Managing Diabetes: 4 Steps to Manage Your Diabetes for Life*. Accessed at <https://www.niddk.nih.gov/health-information/diabetes/manage-monitoring-diabetes> on October 24, 2018.

⁴ Other diabetes testing supplies may include batteries, lancets, and control solution.

⁵ Generally, each box of DTS contains 50 strips. All boxes provided to beneficiaries in our sample contained 50 strips. There are some DTS available in the non-mail-order market, such as Accu-Chek Compact Plus strips, that contain 51 strips per box.

⁶ CMS, *MLN [Medicare Learning Network] Matters Number SE1008 Revised. Medicare Coverage of Blood Glucose Monitors and Testing Supplies*. Accessed at <http://www.cms.gov/MLNMattersArticles/downloads/SE1008.pdf> on October 3, 2018. Medicare covers up to 100 test strips per month (i.e., two 50-count boxes) for insulin-dependent beneficiaries with diabetes and up to 100 test strips every 3 months for non-insulin-dependent beneficiaries with diabetes. Medicare allows additional test strips if they are deemed medically necessary and documented in physician records. *Medicare LCD [Local Coverage Determination] for Glucose Monitors (L33822 for DME MAC Jurisdictions A, B, C, and D)*.

⁷ To receive Medicare reimbursement, suppliers submit claims using Healthcare Common Procedure Coding System (HCPCS) codes. Medicare claims for DTS are billed using HCPCS code A4253. For DTS provided via mail order, the HCPCS code A4253 must be followed by the KL modifier (A4253 KL). CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 36, §§ 20.5.4.1 and 50.6. A modifier is a code on Medicare claim that further describes the services performed or supplies provided to a beneficiary.

⁸ 42 CFR § 414.402 (defining “mail-order item”).

⁹ 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)). See also CMS, *MLN Matters Number MM8325 Revised. July Quarterly Update for 2013 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule*. Accessed at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8325.pdf> on December 13, 2018.

¹⁰ MMA, P.L. No. 108-173, § 302(b)(1).

¹¹ CMS recently 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 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 November 16, 2018.

¹² CMS must recompetete contracts at least once every 3 years. Social Security Act, § 1847(b)(3)(B), 42 U.S.C. § 1395w-3(b)(3)(B).

¹³ Bipartisan Budget Act of 2018, P.L. No. 115-123, § 50414(a)(1). Accessed at <https://www.congress.gov/115/bills/hr1892/BILLS-115hr1892enr.pdf> on August 17, 2018.

¹⁴ CMS, *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program: Temporary Gap Period*. Accessed at <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/DMEPOS-Temporary-Gap-Period-Fact-Sheet.pdf> on December 13, 2018.

¹⁵ Ibid.

¹⁶ 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 November 16, 2018.

¹⁷ 83 Fed. Reg. 56922, 57037 (Nov. 14, 2018). Accessed at <https://www.gpo.gov/fdsys/pkg/FR-2018-11-14/pdf/2018-24238.pdf> on November 16, 2018.