

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**VISIONQUEST INDUSTRIES, INC.:  
AUDIT OF MEDICARE PAYMENTS  
FOR ORTHOTIC BRACES**

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# ***Office of Inspector General***

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## Report in Brief

Date: August 2020

Report No. A-09-19-03010

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Audit

From January 1, 2016, through May 31, 2018 (audit period), Medicare paid \$1.5 billion for knee, back, and ankle-foot braces (selected orthotic braces) provided to Medicare beneficiaries. Prior OIG audits and evaluations found that some suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) billed for orthotic braces that did not comply with Medicare billing requirements. During our audit period, the Centers for Medicare & Medicaid Services found that orthotic braces were among the top 20 DMEPOS items with the highest improper payment rates. After analyzing Medicare claims data, we selected for audit Visionquest Industries, Inc. (Visionquest), an orthotic braces supplier in Irvine, California.

Our objective was to determine whether Visionquest complied with Medicare requirements when billing for selected orthotic braces.

### How OIG Did This Audit

For our audit period, Visionquest received \$4.4 million in Medicare Part B payments for selected orthotic braces provided to 3,259 Medicare beneficiaries. After excluding certain claims, we grouped the remaining claims by beneficiary and reviewed a stratified random sample of 100 beneficiaries. We provided copies of Visionquest's supporting documentation to a medical review contractor (medical reviewer) to determine whether claims for orthotic braces met Medicare requirements.

## Visionquest Industries, Inc.: Audit of Medicare Payments for Orthotic Braces

### What OIG Found

Visionquest did not fully comply with Medicare requirements when billing for selected orthotic braces. For 33 of the 100 sampled beneficiaries, Visionquest complied with the requirements. However, for the remaining 67 beneficiaries, Visionquest billed for orthotic braces that were not medically necessary. On the basis of our sample results, we estimated that Visionquest received at least \$2.5 million in unallowable Medicare payments for orthotic braces.

### What OIG Recommends and Visionquest Comments

We recommend that Visionquest: (1) refund to the durable medical equipment Medicare administrative contractors the portion of the \$2.5 million in estimated overpayments for claims that are within the 4-year reopening period, (2) exercise reasonable diligence to identify and return any additional similar overpayments, and (3) obtain as much information from beneficiary medical records as it determines necessary to assure itself that claims for orthotic braces meet Medicare requirements for medical necessity. The full text of our recommendations is shown in the report.

Visionquest stated that it did not agree with our findings and therefore did not concur with our recommendations. Visionquest stated that our medical reviewer misapplied Medicare coverage criteria and disregarded evidence in the medical records that Visionquest provided to us. Visionquest also stated that it had secured additional medical records or attestations or both from the providers for the majority of the unallowable claims. Visionquest requested that the medical reviewer re-review the sampled beneficiaries' unallowable claims in accordance with Medicare guidelines.

To address Visionquest's concerns related to the medical review decisions, we had our medical reviewer review Visionquest's written comments on our draft report as well as the additional medical records and attestations. Based on the results of this additional medical review, we revised our report to reflect that Visionquest billed for orthotic braces that were not medically necessary for 67 sampled beneficiaries instead of the 87 sampled beneficiaries identified in our draft report. With these actions taken, we revised our first recommendation to recommend that Visionquest refund \$2.5 million in estimated overpayments for orthotic braces. We maintain that our remaining findings and recommendations are valid, although we acknowledge Visionquest's rights to appeal our findings.

## TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	1
The Medicare Program.....	1
Medicare Coverage of Orthotic Braces.....	1
Medicare Requirements for Suppliers Billing for Orthotic Braces.....	2
Medicare Requirements for Suppliers To Identify and Return Overpayments.....	3
Visionquest Industries, Inc.....	3
How We Conducted This Audit.....	4
FINDINGS.....	5
Medicare Requirements.....	5
Visionquest Did Not Fully Comply With Medicare Requirements When Billing for Orthotic Braces.....	6
Visionquest Did Not Obtain Sufficient Information From Beneficiaries' Medical Records.....	7
RECOMMENDATIONS.....	8
VISIONQUEST COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	9
Contact With Visionquest.....	9
Visionquest Comments.....	9
Office of Inspector General Response.....	10
Validity of Statistical Sampling Methodology.....	10
Visionquest Comments.....	10
Office of Inspector General Response.....	11
Medical Reviewer Determinations.....	11
Visionquest Comments.....	11
Office of Inspector General Response.....	12

Deference to Treating Providers.....	12
Visionquest Comments.....	12
Office of Inspector General Response .....	13
Nonconcurrency With Recommendations .....	13
Visionquest Comments.....	13
Office of Inspector General Response .....	13
Inconsistency of Error Rate With Medicare Review Outcomes .....	14
Visionquest Comments.....	14
Office of Inspector General Response .....	14
Request for Redaction of Visionquest’s Name and Change to Title of Report .....	15
Visionquest Comments.....	15
Office of Inspector General Response .....	15

## APPENDICES

A: Audit Scope and Methodology .....	16
B: Statistical Sampling Methodology .....	18
C: Sample Results and Estimates .....	20
D: Related Office of Inspector General Reports .....	21
E: Medicare Requirements Related to Orthotic Braces.....	22
F: Visionquest Comments .....	26

## INTRODUCTION

### WHY WE DID THIS AUDIT

From January 1, 2016, through May 31, 2018 (audit period), Medicare paid approximately \$1.5 billion for knee, back, and ankle-foot braces (selected orthotic braces) provided to Medicare beneficiaries. Prior Office of Inspector General (OIG) audits and evaluations found that some suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) billed for orthotic braces that did not comply with Medicare requirements and that orthotic braces were vulnerable to fraud, waste, and abuse. (Appendix D lists related OIG reports.) During our audit period, the Centers for Medicare & Medicaid Services' (CMS's) Comprehensive Error Rate Testing program, which measures improper Medicare fee-for-service payments, found that orthotic braces were among the top 20 DMEPOS items with the highest improper payment rates.

After analyzing Medicare claims data for our audit period, we selected several DMEPOS suppliers (suppliers) for audit based on: (1) Medicare Part B payments to the suppliers and (2) other risk factors, including the percentage of Medicare payments for selected orthotic braces. This report covers one of those suppliers, Visionquest Industries, Inc. (Visionquest), an orthotic braces supplier in Irvine, California.

### OBJECTIVE

Our objective was to determine whether Visionquest complied with Medicare requirements when billing for selected orthotic braces.

### BACKGROUND

#### The Medicare Program

The Medicare program provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. CMS administers the program. Medicare Part B provides supplementary medical insurance for medical and other health services.

#### Medicare Coverage of Orthotic Braces

Medicare Part B covers DMEPOS, including orthotic braces.<sup>1</sup> To be paid by Medicare, a service or an item must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.<sup>2</sup> Orthotic braces are defined as

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<sup>1</sup> The Social Security Act (the Act) § 1832(a)(1) and §§ 1861(s)(5), (s)(6), (s)(8), and (s)(9).

<sup>2</sup> The Act § 1862(a)(1)(A).

“rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.”<sup>3</sup>

The figure shows examples of knee, back, and ankle-foot braces.

**Figure: Knee, Back, and Ankle-Foot Braces**



CMS contracts with two durable medical equipment Medicare administrative contractors (DME MACs) to process and pay Medicare Part B claims for DMEPOS, including orthotic braces. Each DME MAC processes claims for two of four jurisdictions (A, B, C, and D), which include specific States and territories.<sup>4</sup> Suppliers must submit claims to the DME MAC that serves the State or territory in which a Medicare beneficiary permanently resides.

When submitting claims to DME MACs for orthotic braces, suppliers use Healthcare Common Procedure Coding System (HCPCS) codes.<sup>5</sup> Under Medicare Part B, the DME MACs reimburse suppliers for orthotic braces based on a fee schedule.

### **Medicare Requirements for Suppliers Billing for Orthotic Braces**

The DME MACs develop local coverage determinations (LCDs)<sup>6</sup> for some covered orthotic braces. The LCDs outline the conditions under which DME MACs will pay suppliers for those braces.

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<sup>3</sup> CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 15, § 130.

<sup>4</sup> Before July 1, 2016, there were four DME MACs, each covering one jurisdiction.

<sup>5</sup> HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

<sup>6</sup> An LCD is a decision by a Medicare contractor, such as a DME MAC, whether to cover a particular item or service on a contractor-wide basis in accordance with section 1862(a)(1)(A) of the Act (the Act § 1869(f)(2)(B)).

DME MACs list certain documentation that they expect a supplier to have on file before the supplier submits a claim for an orthotic brace, including:<sup>7</sup>

- written documentation of a verbal order or a preliminary written order from the treating physician (if applicable),
- a detailed written order from the treating physician,
- information from the treating physician concerning the beneficiary's diagnosis,
- any information required for the use of specific modifiers,<sup>8</sup> and
- proof of delivery of the orthotic brace to the beneficiary.

The supplier should also obtain as much documentation from the beneficiary's medical record as it determines necessary to assure itself that the orthotic brace meets Medicare requirements.

### **Medicare Requirements for Suppliers To Identify and Return Overpayments**

OIG believes that this audit report constitutes credible information of potential overpayments. Suppliers that receive notification of these potential overpayments must: (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (60-day rule).<sup>9</sup>

### **Visionquest Industries, Inc.**

Visionquest is a provider of noninvasive medical solutions focused on bone, joint, and soft-tissue conditions. Visionquest is located in Irvine, California. For our audit period, Visionquest received \$5,345,427 in Medicare Part B payments. Approximately 82 percent of these payments were for the selected orthotic braces and the related DMEPOS accessories (e.g., various add-on components) provided to 3,259 Medicare beneficiaries in 44 States. (The remaining 18 percent of payments were for other DMEPOS items.) Table 1 on the following page shows a breakdown of the payments.

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<sup>7</sup> CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08 (the Manual), chapter 5, §§ 5.2.2; Local Coverage Article (LCA): Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426). The documentation standards contained within LCA A55426 were originally found within each individual DME MAC LCD as they applied to that particular LCD. However, such information was removed from all DME MAC LCDs and moved to the LCA effective January 1, 2017. Although these standards are not a basis for a denial of payment, we looked at whether the supplier complied with these standards; however, we did not have any findings based on these standards.

<sup>8</sup> A modifier is a two-digit code that further describes the service performed, such as indicating the limb affected.

<sup>9</sup> The Act § 1128J(d); 42 CFR §§ 401.301-401.305; and 81 Fed. Reg. 7654 (Feb. 12, 2016).

**Table 1: Medicare Part B Payments to Visionquest  
for Knee, Back, and Ankle-Foot Braces<sup>10</sup> and Other DMEPOS**

Year	Payment for Knee Braces	Payment for Back Braces	Payment for Ankle-Foot Braces	Payment for Other DMEPOS	Total Payments by Year
2016	\$1,384,074	\$473,450	\$8,597	\$98,028	\$1,964,149
2017	1,194,317	589,450	15,631	587,042	2,386,440
2018 (Jan.–May)	456,958	251,173	4,656	282,051	994,838
<b>Total</b>	<b>\$3,035,349</b>	<b>\$1,314,073</b>	<b>\$28,884</b>	<b>\$967,121</b>	<b>\$5,345,427</b>
Percentage of Total Payment	56.8%	24.6%	0.5%	18.1%	100%

**HOW WE CONDUCTED THIS AUDIT**

Visionquest received Medicare Part B payments of \$4,378,306 for selected orthotic braces<sup>11</sup> provided to 3,259 Medicare beneficiaries, representing 4,260 paid claims with dates of service during our audit period. We excluded from our audit certain claims that had been reviewed by the recovery audit contractors (RACs)<sup>12</sup> and other review entities (such as the DME MACs). We then grouped the claims by beneficiary. As a result, our audit covered 3,205 beneficiaries, representing 4,194 paid claims totaling \$4,320,337. We selected a stratified random sample of 100 beneficiaries<sup>13</sup> and reviewed 163 claims, totaling \$178,360, that were associated with the sampled beneficiaries.<sup>14</sup>

Visionquest provided us with supporting documentation for the sampled beneficiaries. The documentation included physician orders, proof of delivery, and medical records that Visionquest obtained from the treating physicians. We provided copies of the documentation to an

<sup>10</sup> The payment amounts represent the total paid amounts for the claims, which included the selected orthotic braces and the related DMEPOS accessories (e.g., various add-on components).

<sup>11</sup> We limited our audit to claims that included at least 1 of the 126 HCPCS codes that suppliers used to bill for knee, back, and ankle-foot braces during our audit period.

<sup>12</sup> CMS contracts with RACs to identify improper payments of Medicare claims. RACs conduct postpayment reviews to identify improper payments and recoup any overpayments identified.

<sup>13</sup> The sample unit was a beneficiary, not a claim, because some beneficiaries in the sampling frame had more than one claim for orthotic braces.

<sup>14</sup> For two sampled beneficiaries, two claims were canceled before the start of our audit. We treated these two claims and the related payments as allowable.

independent medical review contractor (medical reviewer) to determine whether the claims for orthotic braces met Medicare requirements.<sup>15</sup>

We conducted this performance audit 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.

Appendix A describes our audit scope and methodology, Appendix B describes our statistical sampling methodology, and Appendix C contains our sample results and estimates.

## FINDINGS

Visionquest did not fully comply with Medicare requirements when billing for selected orthotic braces. For 33 of the 100 sampled beneficiaries, Visionquest complied with the requirements. However, for the remaining 67 beneficiaries, with payments totaling \$137,318, Visionquest billed for orthotic braces that were not medically necessary.

These deficiencies occurred because Visionquest did not obtain sufficient information from the beneficiaries' medical records to assure itself that all the claims submitted to the DME MAC for orthotic braces met Medicare requirements for medical necessity. On the basis of our sample results, we estimated that Visionquest received at least \$2.5 million<sup>16</sup> in unallowable Medicare payments for orthotic braces. As of the publication of this report, these overpayments include claims outside of the 4-year reopening period.<sup>17, 18</sup>

## MEDICARE REQUIREMENTS

To be paid by Medicare, an item or a service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body

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<sup>15</sup> The medical reviewer's staff included, but was not limited to, physicians and certified medical professionals. In addition, the medical reviewer had quality assurance procedures to ensure that all medical review determinations made by its staff were factually accurate, complete, and concise.

<sup>16</sup> Without rounding, the amount is \$2,504,829.

<sup>17</sup> 42 CFR § 405.980(b)(2) (permitting a contractor to reopen an initial determination within 4 years for good cause) and 42 CFR § 405.980(c)(2) (permitting a supplier to request that a contractor reopen within 4 years for good cause).

<sup>18</sup> Notwithstanding, a supplier can request that a contractor reopen an initial determination for the purpose of reporting and returning overpayments under the 60-day rule without being limited by the 4-year reopening period. 42 CFR § 405.980(c)(4).

member (Social Security Act (the Act) § 1862(a)(1)(A)). Medicare pays for an orthotic brace if it is medically necessary and supported by the beneficiary's medical record.

Payment must not be made to a supplier for an item or a service unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (the Act § 1833(e)).

Appendix E contains details on the Medicare requirements related to orthotic braces.

### **VISIONQUEST DID NOT FULLY COMPLY WITH MEDICARE REQUIREMENTS WHEN BILLING FOR ORTHOTIC BRACES**

For 67 sampled beneficiaries, Visionquest billed for orthotic braces that were not medically necessary. Specifically, the medical reviewer found that the information in the beneficiaries' medical records did not support the medical necessity of the orthotic braces.

The following are examples of medically unnecessary back and knee braces provided to beneficiaries.

#### **Example of Medically Unnecessary Back and Knee Braces for the Same Beneficiary**

Medicare paid Visionquest \$3,498 for providing a back brace on July 12, 2016, and custom left and right knee braces on July 22, 2016, to a 48-year-old beneficiary. According to the physician order, a back brace (HCPCS code L0650), a left knee brace (HCPCS code L1844), and a right knee brace (HCPCS L1846) were prescribed. The beneficiary was seen on February 19, 2016, for complaints of pain in the left groin area. The medical records did not indicate that the beneficiary had a back injury, spinal deformity or weak muscles, or any back pain, nor did they indicate that the beneficiary had had a surgical procedure performed. The medical records also did not indicate that the beneficiary had had a recent knee injury or a recent surgical procedure, nor did they indicate the ambulatory status of the beneficiary. The physical exam did not indicate that the beneficiary had knee instability documented by examination of the beneficiary with an "objective description of joint laxity." Custom knee braces are covered when there is a documented physical characteristic that requires the use of custom knee braces instead of prefabricated knee braces. There was no documentation to support that the beneficiary had the physical characteristics, such as disproportionate thigh and calf sizes, that require the use of custom knee braces, nor was there documentation as to why the custom knee braces were medically necessary instead of the prefabricated knee braces. As a result, the medical reviewer found that the back and knee braces were not medically necessary.

### Example of a Medically Unnecessary Knee Brace

Medicare paid Visionquest \$1,585 for providing a custom knee brace to a 67-year-old beneficiary on November 29, 2017. According to the physician order, a knee brace (HCPCS code L1844) was prescribed on November 14, 2017. The beneficiary had been seen on November 7, 2017, for a second knee injection. (The first knee injection was performed a week earlier.) The medical records included a handwritten addendum 1 week after the office visit that stated the provider was referring the beneficiary for a custom knee brace for instability and muscle mass issues. The medical records did not indicate that the beneficiary had had a recent knee injury or a recent surgical procedure. The physical exam did not indicate that the beneficiary had knee instability documented by examination of the beneficiary with an “objective description of joint laxity.” A custom knee brace is covered when there is a documented physical characteristic that requires the use of a custom knee brace instead of a prefabricated knee brace. There was no documentation to support that the beneficiary had the physical characteristics, such as minimal muscle mass, that require the use of a custom knee brace, nor was there documentation as to why the custom knee brace was medically necessary instead of a prefabricated knee brace. As a result, the medical reviewer found that the knee brace was not medically necessary.

### **VISIONQUEST DID NOT OBTAIN SUFFICIENT INFORMATION FROM BENEFICIARIES’ MEDICAL RECORDS**

Although Visionquest had adequate documentation related to the physician orders and proof of delivery for the orthotic braces, it did not obtain sufficient information from the beneficiaries’ medical records to assure itself that all the claims for orthotic braces met Medicare requirements for medical necessity. The medical reviewer’s evaluation of 67 of the 100 sampled beneficiaries’ medical records found that the medical records did not contain sufficient information related to the medical necessity of each of the items ordered.

On the basis of our sample results, we estimated that Visionquest received at least \$2.5 million in unallowable Medicare payments for orthotic braces.

## RECOMMENDATIONS

We recommend that Visionquest Industries, Inc.:

- refund to the DME MACs the portion of the \$2,504,829 in estimated overpayments for claims that are within the 4-year reopening period;<sup>19</sup>
- exercise reasonable diligence to identify and return any additional similar overpayments in accordance with the 60-day rule,<sup>20</sup> and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- obtain as much information from beneficiary medical records as it determines necessary to assure itself that claims for orthotic braces meet Medicare requirements for medical necessity.

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<sup>19</sup> OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to Department of Health and Human Services action officials. CMS, acting through a MAC or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with CMS's policies and procedures. If a disallowance is taken, a supplier has the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a decision by the Office of Medicare Hearings and Appeals. If a supplier exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

<sup>20</sup> This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based upon the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

## **VISIONQUEST COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, Visionquest stated that it did not agree with our findings and therefore did not concur with our recommendations. Visionquest prepared a claim response summary for each unallowable sampled beneficiary, which addressed each of our medical reviewer's reasons for finding the claims associated with the sampled beneficiary to be unallowable. Visionquest stated that our medical reviewer misapplied Medicare coverage criteria and disregarded evidence in the medical records that Visionquest provided to us. Visionquest also stated that it had secured additional medical records or attestations or both from the providers for the majority of the unallowable claims and included the additional medical records and attestations in its response to our draft report. Visionquest requested that the medical reviewer re-review the sampled beneficiaries' unallowable claims in accordance with Medicare guidelines. Visionquest's comments are included as Appendix F.<sup>21</sup>

To address Visionquest's concerns related to the medical review decisions, we had our medical reviewer review Visionquest's written comments on our draft report as well as the additional medical records and attestations.

Based on the results of this additional medical review, we revised our report to reflect that Visionquest billed for orthotic braces that were not medically necessary for 67 sampled beneficiaries instead of the 87 sampled beneficiaries identified in our draft report. With these actions taken, we revised our first recommendation to recommend that Visionquest refund to the DME MACs \$2,504,829 in estimated overpayments for orthotic braces. We maintain that our remaining findings and recommendations are valid, although we acknowledge Visionquest's rights to appeal our findings. Below is a summary of Visionquest's comments and our responses.

### **CONTACT WITH VISIONQUEST**

#### **Visionquest Comments**

Visionquest stated that it produced documentation for the 100 sampled beneficiaries (such as proof of delivery, detailed written orders, and medical records) within 5 days as we had

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<sup>21</sup> Visionquest also attached two appendices to its comments on our draft report. One appendix contained a claim-by-claim rebuttal of the findings in our draft report and included the original medical records and the additional medical records and attestations. We provided this appendix to our medical reviewer as part of our request for an additional review of claims identified as having errors. However, because this appendix contained a considerable amount of personally identifiable information, we excluded it from our report. The other appendix contained the Visionquest statistician's review of our statistical sampling methodology and additional sampling materials we provided to Visionquest. Because Visionquest included its concerns regarding our sampling methodology in its main comments, we excluded this appendix from our report. In addition, Visionquest provided two supplemental letters dated November 18, 2019, for six sampled beneficiaries and dated December 23, 2019, for four sampled beneficiaries. Because these letters contained a considerable amount of personally identifiable information, we excluded them from our report. We are providing Visionquest's comments and two supplemental letters in their entirety to CMS.

requested. Visionquest stated that we held an entrance conference on August 28, 2018, and that approximately 1 year later, on August 7, 2019, OIG provided the results of the audit determination for each sampled beneficiary.

### **Office of Inspector General Response**

Between August 28, 2018, and August 8, 2019, we requested additional documentation from Visionquest, which it provided on several occasions. We made a final request for documentation on February 22, 2019. However, Visionquest continued to provide additional documentation (i.e., medical records and attestations): more than 1,800 pages of documentation for 87 sampled beneficiaries after our draft report was issued; a supplemental letter dated November 18, 2019, for 6 sampled beneficiaries; and a supplemental letter dated December 23, 2019, for 4 sampled beneficiaries. We submitted these documents to our medical reviewer to address Visionquest's concerns related to the medical review decisions.

### **VALIDITY OF STATISTICAL SAMPLING METHODOLOGY**

#### **Visionquest Comments**

Visionquest stated that Visionquest's statistician reviewed "all the materials released by OIG to date" and concluded that our statistical sampling methodology was not statistically valid. Visionquest summarized the statistician's findings as follows:

- Visionquest stated that we biased our overpayment estimate upward by removing zero-paid claims from the sampling frame and by not calculating an estimate to all of the claims within the audit period (referred to by Visionquest as "the universe"). Visionquest stated that the only way to estimate the net overpayments is to include all the zero-paid claims in the sampling frame.
- Visionquest stated that we did not provide information sufficient to re-create the sampling frame or the sample, including the universe and a statement of the sort order of the sampling frame. Visionquest stated that because of our failure to specify the sort order, our sample "cannot be verified to be statistically valid or to have been generated by a random process free from human interference."
- Visionquest stated that our sample failed *samptest*, a computer simulation used to evaluate sampling plans. Visionquest stated that *samptest* shows that the two-sided confidence level of our overpayment estimate "falls as low as 83 percent and never reaches 90 percent."

Visionquest stated that its statistician concluded that any one of the above conclusions stands either on its own or in combination with the other conclusions to invalidate our estimate. Visionquest requested that the overpayment projection be removed and that the "alleged overpayment be reduced to the actual payment amounts for the denied claims."

## Office of Inspector General Response

We carefully reviewed the documentation that Visionquest provided regarding our sampling and estimation methods, and we maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare to Visionquest.

The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology. *See John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at \*12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012). We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. The “universe” of claims for our estimate does not go beyond our sampling frame. Contrary to Visionquest’s assertion, a valid sampling frame does not need to cover all zero-paid claims within the audit period.

We provided Visionquest with all the information necessary to replicate the sample from the sampling frame, including the ordering of the sampling frame, and to recalculate the estimated overpayment amount. In addition, Visionquest has direct access to its own claim information, which it can use to validate the sampling frame.

Visionquest’s statistician stated that our sample failed *samptest*, a computer simulation test. We do not believe that such testing is required; however, even if it were required, the statistician performed the test incorrectly by including both the upper and lower limits in the analysis. The lower limit is the relevant quantity, because it is the number used to identify the recommended recovery amount. When the test is performed on the lower limit, it affirms the validity of our estimate.

## MEDICAL REVIEWER DETERMINATIONS

### Visionquest Comments

Visionquest stated that it did not agree with our medical review determinations. Visionquest also stated that our medical reviewer misapplied Medicare coverage criteria and disregarded evidence in the beneficiary medical records that Visionquest provided to us. Further, Visionquest prepared a claim response summary for each unallowable sampled beneficiary, which addressed each of our medical reviewer’s reasons for finding the claims associated with the sampled beneficiary to be unallowable. Visionquest provided 3 examples of claims for back braces and 3 examples of claims for knee braces from the 87 sampled beneficiaries identified in our draft report; it stated that these examples established the misapplication of Medicare coverage criteria and the disregarding of evidence from the medical records.

Visionquest stated that it had secured additional medical records or attestations or both from the providers for the majority of the unallowable claims and included the additional medical records and attestations in its response to our draft report. Visionquest requested that our medical reviewer re-review the sampled beneficiaries' unallowable claims in accordance with the correct Medicare coverage criteria and in consideration of all evidence in the beneficiaries' medical records.

### **Office of Inspector General Response**

To address Visionquest's concerns related to the medical review decisions, we had our medical reviewer review Visionquest's written comments on our draft report as well as the additional medical records and attestations. Based on the results of this additional review, we revised our report to reflect that Visionquest billed for orthotic braces that were not medically necessary for 67 sampled beneficiaries instead of 87 sampled beneficiaries.

According to sections 1862(a)(1)(A) and 1833(e) of the Act, no payment may be made for an item or service that is not medically necessary, nor may payment be made unless there has been furnished such information as may be necessary to determine the amounts due such provider. Each of the relevant LCDs states that the beneficiary's medical records should reflect the need for the care provided: "The beneficiary's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request." An attestation, on its own, is not enough to support medical necessity. There must be enough documentation within the medical records to support the medical necessity of each item.

Our medical reviewer examined all the documentation that Visionquest submitted and evaluated this information to determine whether the orthotic braces met Medicare requirements. The medical reviewer reached carefully considered conclusions as to whether the orthotic braces were medically necessary. As part of its reviews, our medical reviewer employs a quality assurance process that is designed to ensure that each review is factually accurate and complete, with conclusions based on applicable criteria.

Accordingly, having revised our findings and the associated recommendation with respect to 20 sampled beneficiaries that we questioned in our draft report, we maintain that our findings for the remaining 67 sampled beneficiaries and the amount in our revised recommendation are valid.

### **DEFERENCE TO TREATING PROVIDERS**

#### **Visionquest Comments**

Visionquest stated that our medical reviewer failed to grant any deference to the treating providers who actually treated the beneficiaries and ordered the orthotics for them.

Visionquest also stated that the courts have long acknowledged that the treating physician should be granted additional weight and deference in any dispute over medical necessity.

### **Office of Inspector General Response**

According to section 1862(a)(1)(A) of the Act, no payment may be made under Medicare Part A or Part B for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. If the information in the medical record does not adequately support the medical necessity of the orthotic brace, the supplier is responsible for the payment of the orthotic brace. According to the relevant LCDs, “[t]he beneficiary’s medical records include the physician’s office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.” If those records do not support medical necessity, the claim will be denied as not medically necessary.

### **NONCONCURRENCE WITH RECOMMENDATIONS**

#### **Visionquest Comments**

Visionquest stated that it did not agree with our recommendations as follows:

- Regarding our first recommendation, Visionquest stated that it did not concur because the beneficiary claims selected for review were not billed incorrectly. Specifically, Visionquest stated that the medical reviewer misapplied the Medicare coverage criteria and disregarded information in the medical records. Visionquest also stated that our sampling methodology was statistically invalid.
- Regarding our second recommendation, Visionquest stated that it did not concur because the overpayments we identified were in error and, therefore, there are no additional similar overpayments outside of the audit period. Visionquest stated that it believes it is premature to initiate a review of similar claims because it intends to vigorously contest the claim determinations and the validity of our sampling methodology through the Medicare administrative appeals process.
- Regarding our third recommendation, Visionquest stated that it did not concur because Visionquest already obtains as much information from the beneficiary medical records as necessary to assure itself that claims for orthotic braces meet Medicare requirements for medical necessity.

### **Office of Inspector General Response**

Regarding our first recommendation, based on the results of the medical reviewer’s re-review of the claims associated with the sampled beneficiaries and the additional documentation that

Visionquest provided, we revised our report to reflect that Visionquest billed for orthotic braces that were not medically necessary for 67 sampled beneficiaries instead of 87 sampled beneficiaries. (Our responses to Visionquest’s comments on the validity of our sampling methodology are included above.) With these actions taken, we revised our first recommendation to recommend that Visionquest refund to the DME MACs \$2,504,829 in estimated overpayments for orthotic braces.

Regarding our second and third recommendations, although we revised our determinations for some of the sampled beneficiaries, we still determined that 67 sampled beneficiaries’ claims were unallowable. Therefore, Visionquest should identify and return any additional similar overpayments in accordance with the 60-day rule and obtain as much information from the beneficiary medical records as necessary to assure itself that claims for orthotic braces meet Medicare requirements for medical necessity.

We clarified in the footnote to our first recommendation that OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to Department of Health and Human Services action officials. Action officials at CMS, acting through a MAC or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with CMS’s policies and procedures. If a disallowance is taken, a supplier has the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

## **INCONSISTENCY OF ERROR RATE WITH MEDICARE REVIEW OUTCOMES**

### **Visionquest Comments**

Visionquest stated that the findings in our draft report are “wholly inconsistent” with the audit findings from multiple CMS contractors for the same period. Visionquest also stated that it had reviewed 65 of the 66 claims that we excluded from our audit (which had been reviewed by other review entities). Visionquest provided a table showing that the percentage of claims denied by these contractors ranged from 0 to 50 percent (with an average of 9 percent), which it stated was “nowhere near OIG’s purported beneficiary claim denial rate of 87%.” Visionquest stated that the “alleged medical necessity failure rate of 87%” in our audit versus the 9-percent error rate from the same period and same patient population identified by CMS contractors indicated that the medical reviewer applied a significantly different standard than numerous other CMS contractors.

### **Office of Inspector General Response**

The results of our audits are usually similar to the results identified by CMS and its Medicare contractors. However, at times the results of our audits may not be directly comparable because of significant differences in audit scope and methodology. The claims that Visionquest identified were not part of our sampling frame and were not covered by our estimate. As

already discussed, we believe the results of our audit are valid and well supported. We decline to speculate about whether we would have reached the same conclusions as the CMS contractors if we had reviewed the excluded claims.

## **REQUEST FOR REDACTION OF VISIONQUEST’S NAME AND CHANGE TO TITLE OF REPORT**

### **Visionquest Comments**

Visionquest requested that its name be redacted in our final report because it “will cause serious harm to the company’s reputation and serious financial loss.” Furthermore, Visionquest stated that the title of our report was “grossly misleading to the public and one-sided in favor of OIG’s opinion.” Visionquest also stated that if we disregarded its request to redact its name, the title must be renamed to reflect the position of both parties.

### **Office of Inspector General Response**

It is not OIG’s practice to redact the auditee’s name from our reports. However, we revised the title of the final report to remove the reference to our findings: *Visionquest Industries, Inc.: Audit of Medicare Payments for Orthotic Braces*.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Visionquest received Medicare Part B payments of \$4,378,306 for selected orthotic braces provided to 3,259 Medicare beneficiaries, representing 4,260 paid claims with dates of service from January 1, 2016, through May 31, 2018. We excluded from our audit 1 claim, totaling \$762, that had been reviewed by the RACs and 65 claims, totaling \$57,207, that had been reviewed by other review entities.<sup>22</sup> We then grouped the claims by beneficiary and created a sampling frame of 3,205 beneficiaries, representing 4,194 claims totaling \$4,320,337. We selected a stratified random sample of 100 beneficiaries and reviewed 163 claims, totaling \$178,360, that were associated with the sampled beneficiaries. For two sampled beneficiaries, two claims were canceled before the start of our audit. We treated these two claims and the related payments as allowable.

Visionquest provided us with supporting documentation for the sampled beneficiaries. The documentation included physician orders, proof of delivery, and medical records that Visionquest obtained from the treating physicians. We provided copies of the documentation to a medical reviewer to determine whether the claims for orthotic braces met Medicare requirements.

We did not review Visionquest's overall internal control structure. Rather, we limited our review of internal controls to those that were significant to our objective.

We conducted our fieldwork at Visionquest's offices in Irvine, California.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed Visionquest's policies and procedures for billing claims for orthotic braces;
- interviewed Visionquest officials to obtain an understanding of Visionquest's procedures for: (1) providing orthotic braces to beneficiaries, (2) maintaining documentation for billed orthotic braces, and (3) billing Medicare for orthotic braces;

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<sup>22</sup> CMS created a RAC data warehouse to track information about claims reviewed by the RACs. Other review entities used this data warehouse to identify claims they had previously reviewed so that the claims could be excluded from RAC reviews. DMEPOS review entities include DME MACs, OIG, and law enforcement entities.

- obtained from CMS’s National Claims History (NCH) file the paid Medicare Part B claims for selected orthotic braces that Visionquest billed to Medicare for our audit period;<sup>23</sup>
- created a sampling frame of 3,205 beneficiaries and reviewed a stratified random sample of 100 beneficiaries (Appendix B);
- reviewed data from CMS’s Common Working File for the sampled beneficiaries’ claims to determine whether claims had been canceled or adjusted;
- obtained documentation from Visionquest for the orthotic braces for the sampled beneficiaries and provided the documentation to a medical reviewer, which determined whether the claims met Medicare requirements;
- reviewed and summarized the medical reviewer’s results;
- estimated the amount of the unallowable payments for selected orthotic braces billed by Visionquest (Appendix C); and
- discussed the results of our audit with Visionquest officials.

After receiving Visionquest’s written comments on our draft report, we asked the medical reviewer to perform an additional medical review of all the claims questioned in the draft, and we incorporated into our final report any determinations of allowability of the claims.

We conducted this performance audit 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.

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<sup>23</sup> Our audit allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS’s NCH file, but we did not assess the completeness of the file.

## APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

### TARGET POPULATION

The target population consisted of Visionquest’s paid Medicare Part B claims that: (1) included at least one of the selected HCPCS codes for orthotic braces and (2) had service dates during our audit period.<sup>24</sup>

### SAMPLING FRAME

We obtained claims data from CMS’s NCH file, representing 4,260 paid claims totaling \$4,378,306. We removed 1 claim, totaling \$762, that had been reviewed by the RACs and removed 65 claims, totaling \$57,207, that had been reviewed by other review entities. We then grouped the claims by beneficiary. As a result, the sampling frame consisted of 3,205 beneficiaries, representing 4,194 paid claims totaling \$4,320,337.

### SAMPLE UNIT

The sample unit was a beneficiary.<sup>25</sup> We reviewed the claims associated with each beneficiary.

### SAMPLE DESIGN

We used a stratified random sample, consisting of two strata (Table 2).

**Table 2: Strata**

<b>Stratum</b>	<b>Description</b>	<b>No. of Beneficiaries</b>	<b>Payment</b>
1	Beneficiaries with one Medicare claim	2,408	\$2,131,932
2	Beneficiaries with more than one Medicare claim	797	2,188,405
<b>Total</b>		<b>3,205</b>	<b>\$4,320,337</b>

### SAMPLE SIZE

We selected a total of 100 beneficiaries. We selected 50 beneficiaries from each stratum.

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<sup>24</sup> We limited our audit to claims that included at least 1 of the 126 HCPCS codes that suppliers used to bill for knee, back, and ankle-foot braces during our audit period.

<sup>25</sup> The sample unit was a beneficiary, not a claim, because some beneficiaries in the sampling frame had more than one claim for orthotic braces.

## **SOURCE OF RANDOM NUMBERS**

We generated the random numbers with the OIG, Office of Audit Services (OAS), statistical software.

## **METHOD OF SELECTING SAMPLE ITEMS**

We consecutively numbered the sample units in each stratum. After generating random numbers for each stratum, we selected the corresponding frame items.

## **ESTIMATION METHODOLOGY**

We used the OIG/OAS statistical software to estimate the amount of unallowable payments. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

**APPENDIX C: SAMPLE RESULTS AND ESTIMATES**

**Table 3: Sample Results**

<b>Stratum</b>	<b>No. of Items in Sampling Frame</b>	<b>Value of Frame</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>No. of Unallowable Sample Items</b>	<b>Value of Unallowable Sample Items</b>
1	2,408	\$2,131,932	50	\$44,643	19	\$22,370
2	797	2,188,405	50	133,717	48	114,948
<b>Total</b>	<b>3,205</b>	<b>\$4,320,337</b>	<b>100</b>	<b>\$178,360</b>	<b>67</b>	<b>\$137,318</b>

**Table 4: Estimated Value of Unallowable Payments  
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$2,909,606
Lower limit	2,504,829
Upper limit	3,314,382

**APPENDIX D: RELATED OFFICE OF INSPECTOR GENERAL REPORTS**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Desoto Home Health Care, Inc.: Audit of Medicare Payments for Orthotic Braces</i>	<a href="#"><u>A-09-19-03021</u></a>	8/6/2020
<i>Freedom Orthotics, Inc.: Audit of Medicare Payments for Orthotic Braces</i>	<a href="#"><u>A-09-19-03012</u></a>	7/6/2020
<i>Kelley Medical Equipment and Supply, LLC, Received Unallowable Medicare Payments for Orthotic Braces</i>	<a href="#"><u>A-09-17-03030</u></a>	1/17/2019
<i>Pacific Medical, Inc., Received Some Unallowable Medicare Payments for Orthotic Braces</i>	<a href="#"><u>A-09-17-03027</u></a>	12/31/2018
<i>Medicare Payments for Orthotics: Inappropriate Payments</i>	<a href="#"><u>OEI-02-99-00120</u></a>	March 2000
<i>Medicare Allowed Charges for Orthotic Body Jackets</i>	<a href="#"><u>OEI-04-97-00391</u></a>	March 2000
<i>Orthotic Procedure Code Claims Paid to Medassist-OP, Inc. by Medicare During the Period January 1, 1994 to December 31, 1996</i>	<a href="#"><u>A-02-97-01039</u></a>	11/2/1999
<i>Medicare Payments for Orthotic Body Jackets</i>	<a href="#"><u>OEI-04-97-00390</u></a>	September 1999
<i>Medicare Orthotics</i>	<a href="#"><u>OEI-02-95-00380</u></a>	October 1997
<i>Medicare Payments for Orthotic Body Jackets</i>	<a href="#"><u>OEI-04-92-01080</u></a>	June 1994

## APPENDIX E: MEDICARE REQUIREMENTS RELATED TO ORTHOTIC BRACES

### MEDICAL NECESSITY REQUIREMENTS

#### Social Security Act

The Act, section 1862(a)(1)(A), states: “. . . no payment may be made under part A or part B for any expenses incurred for items or services—(1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

#### Local Coverage Determinations

The LCDs outline the conditions under which the DME MACs will cover knee, back, and ankle-foot braces. (These braces are referred to in the LCDs as “orthoses.”)

#### *Knee Braces*

A knee orthosis with joints (L1810, L1812) or knee orthosis with condylar pads and joints with or without patellar control (L1820) are covered for ambulatory beneficiaries who have weakness or deformity of the knee and require stabilization. If [the knee orthosis] is provided but the criteria above are not met, the orthosis will be denied as not reasonable and necessary [*LCD: Knee Orthoses (L33318)*].

A knee immobilizer without joints (L1830), or a knee orthosis with adjustable knee joints (L1832, L1833), or a knee orthosis, with an adjustable flexion and extension joint that provides both medial-lateral and rotation control (L1843, L1845, L1851, L1852), are covered if the beneficiary has had recent injury to or a surgical procedure on the knee(s). . . . Knee orthoses L1832, L1833, L1843, L1845, L1851 and L1852 are also covered for a beneficiary who is ambulatory and has knee instability due to a condition specified in the [diagnosis] codes that Support Medical Necessity . . . . knee instability must be documented by examination of the beneficiary and objective description of joint laxity (e.g., varus/valgus instability, anterior/posterior Drawer test). Claims for [these knee orthoses] will be denied as not reasonable and necessary when the beneficiary does not meet the above criteria for coverage. For example, they will be denied if only pain or a subjective description of joint instability is documented [*LCD: Knee Orthoses (L33318)*].

A custom fabricated orthosis is covered when there is a documented physical characteristic which requires the use of a custom fabricated orthosis instead of a prefabricated orthosis. Examples of situations which meet the criterion for a

custom fabricated orthosis include, but are not limited to: (1) Deformity of the leg or knee; (2) Size of thigh and calf; (3) Minimal muscle mass upon which to suspend an orthosis. . . . If a custom fabricated orthosis is provided but the medical record does not document why that item is medically necessary instead of a prefabricated orthosis, the custom fabricated orthosis will be denied as not reasonable and necessary. . . . A custom fabricated knee orthosis with an adjustable flexion and extension joint (L1844, L1846) is covered if criteria 1 and 2 are met: (1) The coverage criteria for the prefabricated orthosis codes L1843, L1845, L1851, and L1852 are met; and (2) The general criterion defined above for a custom fabricated orthosis is met. If an L1844 or L1846 orthosis is provided and both criteria 1 and 2 are not met the orthosis will be denied as not reasonable and necessary [*LCD: Knee Orthoses (L33318)*].

### *Back Braces*

A [back] orthosis ([HCPCS codes] L0450 - L0651) is covered when it is ordered for one of the following indications: (1) to reduce pain by restricting mobility of the trunk; or (2) to facilitate healing following an injury to the [back] or related soft tissue; or (3) to facilitate healing following a surgical procedure on the [back] or related soft tissue; or (4) to otherwise support weak [back] muscles and/or a deformed [back]. If a [back] orthosis is provided and the coverage criteria are not met, the item will be denied as not medically necessary [*LCD: Spinal Orthoses: TLSO and LSO (L33790)*].

### *Ankle-Foot Braces*

Ankle-foot orthoses [L1900, L1902-L1990, L2106-L2116, L4350, L4360, L4361, L4386, L4387, L4631] . . . are covered for ambulatory beneficiaries with weakness or deformity of the foot and ankle, who: (1) require stabilization for medical reasons, and, (2) have the potential to benefit functionally. . . . If the basic coverage criteria for [ankle-foot orthoses] are not met, the orthosis will be denied as not reasonable and necessary [*LCD: Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686)*].

## **DOCUMENTATION REQUIREMENTS**

### **Social Security Act**

The Act, section 1833(e), states: “No payment shall be made to any [supplier] of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such [supplier] or other person under this part for the period with respect to which the amounts are being paid or for any prior period.”

## CMS GUIDANCE<sup>26</sup>

### Medicare Program Integrity Manual

The *Medicare Program Integrity Manual* (the Manual), chapter 5, section 5.7, outlines guidance for documenting medical necessity:

For any DMEPOS item to be covered by Medicare, the [beneficiary's] medical record must contain sufficient documentation of the [beneficiary's] medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the [beneficiary's] diagnosis and other pertinent information including, but not limited to, duration of the [beneficiary's] condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. . . .

Neither a physician's order nor a CMN [Certificate of Medical Necessity] nor a DIF [DME Information Form] nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. . . .

The documentation in the [beneficiary's] medical record does not have to be routinely sent to the supplier or to the DME MACs, DME PSCs [program safeguard contractors], or ZPICs [zone program integrity contractors]. However, the DME MACs, DME PSCs, or ZPICs may request this information in selected cases. If [they] do not receive the information when requested or if the information in the [beneficiary's] medical record does not adequately support the medical necessity for the item, then on assigned claims the supplier is liable for the dollar amount involved . . . .

The Manual, chapter 5, section 5.8.A, provides additional guidance for documenting medical necessity:

The supplier should also obtain as much documentation from the [beneficiary's] medical record as they determine they need to assure themselves that coverage criteria for an item have been met. If the information in the [beneficiary's] medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed [Advance Beneficiary Notice] of possible denial has been obtained.

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<sup>26</sup> All Manual provisions were used strictly as guidance. We did not have any findings based on the guidance found within the Manual.

Documentation must be maintained in the supplier's files for seven (7) years from date of service.

The Manual (chapter 5, §§ 5.2.2 and 5.8(A), (B), and (D))<sup>27</sup> details the documentation guidance for orthotic braces:

Suppliers may dispense most items of DMEPOS based on a verbal order or preliminary written order from the treating physician. This order must include: a description of the item, the beneficiary's name, the physician's name and the start date of the order. Suppliers must maintain the preliminary written order or written documentation of the verbal order and this documentation must be available to the DME MACs, Zone Program Integrity Contractors (ZPICs) or other CMS review contractor upon request. If the supplier does not have an order from the treating physician before dispensing an item, the contractor shall consider the item as noncovered.

Before submitting a claim to the DME MAC the supplier must have on file a dispensing order, the detailed written order, the CMN (if applicable), the DIF (if applicable), information from the treating physician concerning the [beneficiary's] diagnosis, and any information required for the use of specific modifiers or attestation statements as defined in certain DME MAC policies. Documentation must be maintained in the supplier's files for seven (7) years from date of service. . . .

Proof of delivery documentation must be available to the DME MAC, Recovery Auditor, CERT and ZPIC on request. All items that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested.

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<sup>27</sup> The Manual, chapter 5, section 5.8, was updated during our audit period under Rev. 750, effective November 20, 2017. Subsection 5.8(D) was removed, but similar language is included in 5.8(B): "In certain instances, compliance with proof of delivery may be required as a condition of payment, and must be available to the DME MAC, RAC, SMRC [supplemental medical review contractor], CERT, and ZPIC/UPIC [unified program integrity contractor] on request. For such items, if the supplier does not have appropriate proof of delivery documentation within the prescribed timeframes, associated claims will be denied and overpayments recouped."

APPENDIX F: VISIONQUEST COMMENTS<sup>28</sup>



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RE: Response to Draft Report  
Report Number: A-09-19-03010

Liles Parker PLLC represents Visionquest Industries, Inc. ("Visionquest"). This letter constitutes Visionquest's response to the Department of Health and Human Services, Office of Inspector General's (OIG) draft report entitled *Visionquest Industries, Inc., Received Medicare Payments for Orthotic Braces That Were Not Medically Necessary*. As set out herein, Visionquest does not agree with OIG's findings and therefore does not concur with OIG's associated recommendations.

I. Background on Visionquest

Founded in 1989, Visionquest is a leading provider of noninvasive medical solutions focused on bone, joint, and soft-tissue conditions. Services include in-home patient fitting of braces and medical devices, technology-enabled compliance monitoring, and around-the-clock patient care. Visionquest is based in Irvine, California with field locations nationwide. Visionquest's manufacturing facilities, located in Vista, California, produce many of their proprietary products. Visionquest is licensed by the California Department of Health Services as a medical device retailer and manufacturer. Visionquest is also registered with the U.S. Food and Drug Administration as a medical device manufacturer and specification developer. Visionquest follows stringent federal guidelines for manufacturing, inspection, handling, storage, distribution, and delivery of controlled medical devices to patients. These federal regulations help ensure safety and efficacy for patients and the community.

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<sup>28</sup> **OIG Note:** We redacted text in several places in this appendix because it is personally identifiable information.

Visionquest was founded on a patient-centered business model. This means Visionquest advocates for the best products, services, and care for the patients they serve.

Visionquest maintains the highest ethical and legal standards. Its corporate governance program is overseen by a corporate compliance officer and includes strictly-enforced employee compliance guidelines, a Code of Ethics, and a comprehensive employee training program. Visionquest considers its independent corporate governance program among the most comprehensive in the industry.

## II. Overview of OIG's Audit

OIG Senior Auditor [REDACTED] first called Visionquest on August 13, 2018 regarding this audit. By letter dated August 14, 2018, OIG formally notified Visionquest of its intention to audit Medicare payments made to Visionquest for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). OIG indicated that its audit would cover payments made for claims from January 1, 2016 through May 31, 2018. OIG stated that its objective was to determine whether Visionquest complied with Medicare requirements when billing for selected orthotic braces. On August 22, 2018, OIG electronically transmitted an excel titled A-09-18-03002 Visionquest List of Claims.xlsx to Visionquest. This document requested the following materials for 100 beneficiary claims, 50 of which were identified in an excel sheet called Stratum 1 and 50 of which were identified in an excel sheet called Stratum 2:

- 1) CMS 1500 Health Insurance Claim Form
- 2) Remittance Advice
- 3) Proof of Delivery
- 4) Dispensing Order, if applicable
- 5) Detailed Written Order
- 6) Medical Records

Visionquest produced the requested documentation within five days as requested by OIG. An Entrance Conference was held by OIG on August 28, 2018. Approximately one year later, on August 7, 2019, OIG electronically transmitted an excel titled A-09-10-03010 Results to Visionquest.xlsx to Visionquest. This excel included a listing of all 100 beneficiary claims with an audit determination for each beneficiary claim in Column M – 13 claims were marked “Allowable” and 87 claims were marked “Not Medically Necessary”. This was the extent of the denial detail provided by OIG to Visionquest. An Exit Conference was held by OIG on August 8, 2019. OIG went over one custom fabricated knee orthosis beneficiary claim denial example during the Exit Conference, and otherwise told Visionquest that OIG would not provide denial details for all 87 denied claims, that all 87 denied claims were denied due to insufficient medical records, and that OIG would be issuing a draft report in a few weeks.

On September 6, 2019, the draft report was electronically transmitted to us (A091903010\_Draft.pdf). OIG requested that Visionquest provide its written comments within 15 days from the date of the letter. We immediately requested an extension for Visionquest's response to November 6, 2019. OIG initially granted an extension to Monday, October 7, 2019 but

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ultimately granted an extension to Friday, October 18, 2019. The draft report did not include, and we thus requested, the following materials: the universe file; the sampling frame; information needed to recreate the sampling frame from the universe, including the sort order and strata definitions; identification of the random number generator used; the random number seeds, one for each stratum; the medical review results; the steps taken in calculating the overpayment; a sampling plan that pre-dates the selection of the sample and the medical review; and OIG's independent medical review contractor's claim review determination reports. On September 18, 2019, OIG transmitted the following files to us electronically:

- 1) A-09-18-03002 (Stratum 1).pdf
- 2) A-09-18-03002 (Stratum 2).pdf
- 3) A-09-18-03002 File for Projection.xlsx
- 4) A-09-18-03002 Projection FINAL.pdf
- 5) A-09-18-03002 Sampling Plan - Stratified - Final01.pdf
- 6) A-09-19-03010 Visionquest Determinations for Unallowable Sample Items.pdf
- 7) A-09-19-03010 Visionquest Sampling Frame by Claim.xlsx
- 8) A-09-19-03010 Visionquest Unallowable.xlsx
- 9) CompManual 2010.pdf

OIG did not produce the universe,<sup>1</sup> a statement of the sort order for the sampling frame, or a sampling plan which pre-dates the selection of the sample and the medical review. We sent a Freedom of Information Act (FOIA) request to OIG on September 19, 2019 for the universe file and all information needed to recreate the sampling frame from the universe, including the sort order and strata definitions, but have not received the requested materials to date.

### III. Statement of Nonconurrence

Visionquest does not agree with OIG's recommendations as follows:

- 1) OIG recommends that Visionquest "*refund to the DME MACs \$3,397,767 in estimated overpayments for orthotic braces*".

Visionquest does not concur with this recommendation because the beneficiary claims selected for review were not billed incorrectly. As established *infra*, OIG's medical review determinations are fundamentally flawed. OIG's reviewer engaged in misapplication of Medicare coverage criteria and disregarded information expressly detailed in the medical records provided by Visionquest. Furthermore, OIG's sampling methodology is

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<sup>1</sup> We initially requested the universe file from OIG on September 9, 2019. On September 10, 2019, [REDACTED] responded that "the sampling frame" was sent to our client. By e-mail dated September 15, 2019, we explained that the sampling frame is not the same thing as the universe file and renewed our request for the universe file. On September 18, 2019, [REDACTED] wrote in regard to the universe file, "*We do not provide any claims outside of the sampling frame without a formal FOIA request. Our estimate applies only to the sampling frame. If there are claims outside of the sampling frame that are in error, they are not covered by our audit and are not included in our overpayment estimate. Moreover, the provider can verify the validity of the claims within the sampling frame with its own claims data. To submit a formal FOIA request, go to <https://oig.hhs.gov/foia/>.*"

statistically invalid as established in greater detail below. Visionquest thus does not owe \$3,397,767 to the Medicare program.

- 2) OIG recommends that Visionquest “*exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation*”.

Visionquest does not concur with this recommendation because the alleged overpayments identified by OIG are in error and there are thus no “additional similar overpayments” outside of OIG’s audit period. Visionquest is fully aware of and committed to its legal obligation to report any overpayments within 60 days pursuant to 42 C.F.R. § 401.305. The Centers for Medicare and Medicaid Services (CMS) has expressly stated that a provider may reasonably assess that it is premature to initiate an investigation into similar claims based on receipt of notice of an overpayment until it has worked the overpayment through the administrative appeals process.<sup>2</sup> Visionquest reasonably believes that it is premature to initiate a review of similar claims based on OIG’s draft report as it intends to vigorously contest the adverse claim determinations and the validity of OIG’s sampling methodology in the Medicare administrative appeals process and anticipates that OIG’s claim determinations will be reversed on appeal.

- 3) OIG recommends that Visionquest “*obtain as much information from beneficiary medical records as it determines necessary to assure itself that claims for orthotic braces meet Medicare requirements for medical necessity*”.

Visionquest does not concur with this recommendation because it already obtains as much information from beneficiary medical records as necessary to assure itself that claims for orthotic braces meet Medicare requirements for medical necessity. As established herein, OIG’s reviewer misapplied Medicare coverage criteria and disregarded evidence documented in the beneficiaries’ medical records.

#### IV. OIG’s Sampling Methodology is Not Statistically Valid

In its draft report, OIG states that it selected a stratified random sample of 100 beneficiaries. OIG refers to several appendices enclosed with its draft report as follows: “*Appendix A describes our audit scope and methodology, Appendix B describes our statistical sampling methodology, and Appendix C contains our sample results and estimates.*” As noted above, we had to follow-up with OIG for many documents relating to its sampling methodology that were not provided with the draft report, and OIG released most of the requested materials to us on September 18, 2019, though not the universe, a statement of the sort order for the sampling frame, or a sampling plan which pre-dates the selection of the sample and the medical review. Visionquest’s statistician, Ross Mitchell Cox, Ph.D., reviewed all materials released by OIG to date and concluded that OIG’s

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<sup>2</sup> See Medicare Program; Reporting and Returning Overpayments, 81 Fed. Reg. 7,654, 7,667 (Feb. 12, 2016).

sampling methodology is not statistically valid. Dr. Cox's report is enclosed as **Appendix A**. His findings are briefly summarized as follows:

- 1) OIG's sample fails *samptest*, a computer simulation used to evaluate sampling plans. *samptest* shows that the two-sided confidence level of OIG's overpayment estimate falls as low as 83.9% and never reaches 90%. OIG therefore has not satisfied its own requirement, as stated in paragraph 14 of its sampling plan, that its reimbursement demand be the lower bound of a two-sided 90% confidence interval. OIG's failure to satisfy these requirements is a direct result of its failure to follow its own sampling guidelines as published by OIG with respect to Corporate Integrity Agreements ("CIA"). Specifically, OIG's CIA guidelines provide that a sample size estimator should be used to estimate the size of the Full Sample when using RAT-STATs. However, OIG simply chose a size of 50 for both of its stratum samples with the result that it failed to achieve its nominal confidence level.
- 2) OIG does not provide information sufficient to re-create the sampling frame or the sample, including the universe and a statement of the sort order of the sampling frame. Because of its failure to specify the sort order of its sampling frame, OIG's sample cannot be verified to be statistically valid or to have been generated by a random process free from human interference. Additionally, unless the universe is provided along with the sampling frame, Visionquest cannot be sure that vital information about the universe was not left out of the sampling frame and hence the sample. The whole purpose of statistical extrapolation is to say something useful about the universe, not the sampling frame. The sampling frame is merely an intermediate construct needed to form the sample. This is particularly important in the current case because OIG states in paragraph 3 of its sampling plan that it took the illegitimate step of removing all the zero paid claims from its sampling frame. Every zero paid claim is a potential underpayment and removing the zero paid claims prevents the auditor from estimating the total net overpayment in the universe which must be the goal of the extrapolation. By failing to provide the universe, OIG has prevented Visionquest from assessing the impact on the estimated overpayment of removing the zero paid claims because it has prevented Visionquest from knowing the number and value of these removed claims.
- 3) OIG has biased its overpayment estimate upwards by removing potential underpayments from its sampling frame. The goal of the extrapolation must be to estimate the total net overpayment and not the total gross overpayment or some quantity between the two. The only way to estimate the net overpayment is to include all the overpayments and all the underpayments in the sampling frame. The fact that OIG removed these unpaid claims from its sampling frame is, by itself, fatal to its extrapolation. There is no way to repair this defect by adding additional claims to the existing sample or by drawing an altogether new sample because the unpaid claims have been removed from the sampling frame from which the sampling units are drawn. There is also no way to estimate the harm inflicted on Visionquest by the removal of the unpaid claims because neither the number of these claims nor the underpayment

they represent are known since OIG also removed these claims from all the other audit materials it has provided.

Dr. Cox has concluded that any one of the above conclusions stands either on its own or in combination with the other conclusions to invalidate OIG's estimate. Therefore, we request that the overpayment projection be removed and that the alleged overpayment be reduced to the actual payment amounts for the denied claims, which total \$123,854.43.

#### V. OIG's Medical Review Determinations are Incorrect

In its draft report, OIG states that it found that Visionquest billed for orthotic braces that were not medically necessary for 87 of the 100 sampled beneficiaries. OIG contends that these deficiencies occurred because Visionquest did not obtain sufficient information from the beneficiaries' medical records to assure itself that all the claims submitted to the DME MAC for orthotic braces met Medicare requirements for medical necessity. OIG's independent medical review contractor reviewed the following clinical factors for each claim:

- Medical necessity
- Prescription order requirements
- Dispensing order requirements
- Proof of delivery
- Coding

OIG concedes that Visionquest had adequate documentation related to all of these clinical factors except medical necessity. The sole issue in this audit is thus whether the beneficiaries' medical records established that the Medicare coverage criteria for medical necessity of the orthotics were met. We will establish herein that the beneficiaries' medical records did establish that the Medicare coverage criteria for medical necessity of the orthotic were met, and that OIG's reviewer misapplied Medicare coverage criteria and disregarded evidence in the medical records that Visionquest provided to OIG. It is important to note that OIG has refused to identify its independent medical review contractor or the reviewer(s) who assessed the records for these claims.

#### 1) Back Braces

Under Medicare guidelines applicable nationwide, back braces (HCPCS codes L0450 through L0651) are covered for any one of the following indications:

1. To reduce pain by restricting mobility of the trunk; or
2. To facilitate healing following an injury to the spine or related soft tissues; or
3. To facilitate healing following a surgical procedure on the spine or related soft tissue; or
4. To otherwise support weak spinal muscles and/or a deformed spine.

See Local Coverage Determination L33790 and Policy Article A52500. In terms of documentation requirements, the LCD provides,

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*“It is expected that the beneficiary’s medical records will reflect the need for the care provided. The beneficiary’s medical records include the physician’s office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports.”*

There are no additional documentation requirements with respect to the covered indications as relate to beneficiary medical records. There are no specific physical exam findings or objective descriptions that must be documented.<sup>3</sup> So long as the beneficiary’s medical record indicates a covered indication, the Medicare coverage criteria for a back brace have been met with respect to medical necessity.

A careful review of the OIG’s reviewer’s claim review determination reports with respect to the denied back brace claims establishes that OIG’s reviewer misapplied Medicare coverage criteria and disregarded evidence from the beneficiary medical records. The following examples highlight these issues:

Example 1: S1-12  
DOS 11/14/2017  
HCPCS code L0642

By way of background, on November 6, 2017, S1-12, a 79-year-old Medicare beneficiary, visited her medical doctor due to low back pain. She had sustained a fall and had been experiencing low back pain for three-to-four weeks. On exam, she had tenderness over the L4-L5 and L5-S1 facet joints. There was also mild tenderness over the right and left greater trochanteric area. The physician summarized the radiograph findings as follows: *“Radiologic evaluation of lumbar spine indicated 15-20% compression fracture of T11-T12 and also 30% compression of L3 and 20% compression of the L4.”*<sup>4</sup> The physician diagnosed S1-12 with osteoporosis and multiple compression fracture of the spine. S1-12 was prescribed a back brace to reduce her low back pain by restricting mobility of her trunk and referred S1-12 to physical therapy for core abdominal exercises. (S1-12, pp. 6-7).

OIG’s reviewer made the following materially inaccurate or misleading assertions with respect to this claim:

**OIG Claim:** The reviewer asserted, *“Theoretically for osteoporotic fractures, the use of a spinal orthosis maintains neutral spinal alignment and limits flexion, thus reducing axial*

<sup>3</sup> In contrast, for example, the LCD for knee orthoses (L33318) requires examination of the beneficiary and objective description of joint laxity to document knee instability. The LCDs detail specific documentation and examination requirements where they are required.

<sup>4</sup> Visionquest obtained copies of the referenced radiographs and the radiograph reports have been enclosed. (S1-12, pp. 8-10). She had undergone radiographs of the sacrum and coccyx and lumbar spine, and an ultrasound of the pelvis, on October 18, 2017. The sacrum and coccyx radiograph report revealed advanced facet arthropathy of the lower lumbar spine, as well as right sacroiliitis. The lumbar spine radiograph report revealed a mild compression fracture along the superior endplate of the L4 vertebrae and multi-level facet arthropathy.

*loading on the fractured vertebra. Additionally, the brace allows for less fatigue of the paraspinal musculature and muscle spasm relief. A review of the literature reveals that this finding has not consistently held up to electromyography with some studies showing increased activity in the spinal muscles with bracing. The literature reveals that lumbosacral orthoses are also available for lumbar fractures but are only effective in restricting sagittal plane motion in the upper lumbar spine (L1-L3). Intervertebral motion has been shown to actually increase from L4-S1 with a lumbosacral orthoses brace. Finally, with prolonged periods of bracing, there is potential for deconditioning and atrophy of the trunk and paraspinal muscles. As such, there is a movement away from recommending rigid braces and towards light-weight, soft braces, except in cases of severe deformity. Physical therapy should assist with early mobilization in the acute phase and prevent further injuries in the long term.”* The reviewer also asserted, *“For this patient, a lumbosacral orthosis would not be effective for the thoracic compression fractures. The orthosis may assist in restricting sagittal plan motion at L1-L3, but per the literature will not help the L4-S1 area. Furthermore, the documentation did not reveal findings of physical exam pain at the L3 level.”* See A-09-18-03002A, S1-12, p. 3.

**Response:** Not only does OIG’s reviewer fail to provide citations for the referenced literature, but Medicare suppliers are only bound by Medicare coverage criteria. The referenced literature is not included in the LCD. As shown above, LCD L33790 provides for four different indications for which a spinal orthosis (L0450 - L0651) is covered, including to reduce pain by restricting mobility of the trunk and to facilitate healing following an injury to the spine or related soft tissues. These are the reasons this beneficiary received a back brace. While only one indication is necessary to warrant a back brace, two indications are satisfied in this case. There are no additional documentation requirements in the LCD or associated Policy Article A52500. The LCD does not state that back braces are only medically necessary for lumbar fractures at L1-L3 necessitating restriction of sagittal plane motion in the upper lumbar spine. In fact, the LCD and Policy Article do not identify any covered or non-covered diagnoses. This beneficiary presented with low back pain and was diagnosed with osteoporosis and multiple compression fractures of the spine on November 6, 2017. (S1-12, pp. 6-7). The fractures were specifically diagnosed as initial encounter for closed fracture unspecified fracture of unspecified lumbar vertebra (ICD-10 S32.009A) and initial encounter for closed fracture of unspecified fracture of sacrum (ICD-10 S32.10XA). (S1-12, pp. 5, 11). Additionally, the ordering provider attested on 10/08/19, *“I ordered the back brace to reduce [S1-12’s] pain by restricting mobility of her trunk and to facilitate healing following these injuries to her spine.”* (S1-12, p. 11). These statements made by OIG’s reviewer are not founded in Medicare coverage criteria.

**OIG Claim:** The reviewer asserted that were no tests of range of motion of the lumbar spine or provocative testing that revealed that the patient required trunk immobility to reduce her pain. See A-09-18-03002A, S1-12, p. 3.

**Response:** The LCD and associated Policy Article do not require range of motion or provocative testing for spinal orthoses.

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**OIG Claim:** The reviewer asserted that the documentation did not reveal pain at the L3 level on exam that would require restricted mobility to reduce pain through a brace. *See* A-09-18-03002A, S1-12, p. 3.

**Response:** The LCD and associated Policy Article do not require pain at the L3 level specifically. In fact, the HCPCS code descriptor for L0642 in the LCD provides that “posterior extends from L-1 to below L-5 vertebra”. As stated *supra*, the coverage indication per the LCD relating to pain is “to reduce pain by restricting mobility of the trunk.” This is all that is required under the LCD. The LCD does not confine this coverage indication to specific lumbar vertebrae as OIG’s reviewer suggests. In fact, neither the LCD or Policy Article even provide for a list of covered diagnosis codes.

S1-12 presented with back pain status post fall. She was diagnosed with osteoporosis and multiple compression fracture of the spine, including lumbar vertebrae and sacrum fractures. Her physician ordered a back brace to reduce S1-12’s pain by restricting mobility of her trunk and to facilitate healing following these injuries to her spine. Additionally, this physician attested in part on 10/08/19 that “I ordered the back brace to reduce [S1-12]’s pain by restricting mobility of her trunk and to facilitate healing following these injuries to her spine” and “[a]s the ordering provider, it is my determination that the back brace satisfied the Medicare coverage criteria as set forth Local Coverage Determination L33790 and Policy Article A52500.” (S1-12, p. 11). The Medicare coverage criteria for back brace L0642 was thus properly met. OIG’s reviewer denied this claim in error.

Example 2: S1-17  
DOS 07/26/2017  
HCPCS code L0650

By way of background, Medicare beneficiary S1-17 was a 73-year-old male when he received the back brace on July 26, 2017. S1-17 was seen by a nurse practitioner on July 7, 2017. S1-17 visited the nurse practitioner because he was experiencing constant lower back pain. He informed the nurse practitioner that the pain started about three weeks before this visit; he was moving, so he had been spending an increased amount of time driving. S1-17 then stated that since the initial flare-up, he had been in constant pain, with pain radiating into his left glutes and left lower extremity. S1-17 reported that he had to “resort back to using Norco for pain management,” and that, at the time of the visit, he was taking Norco every four hours and Naproxen every six hours. He then stated that the Norco was helping but he was discouraged as he had previously made very good progress with his lower back pain, but now it was not responding as quickly. (S1-17, pp. 7-11).

During her examination of S1-17, the nurse practitioner noted that S1-17 had kyphosis and paravertebral spasm, and that he suffered from moderate pain and hypertonicity and spasm with palpation of “B/L L/s erectors and QL B/L.” She also noted the following regarding elements of his spine, ribs, and pelvis range of motion: flexion and extension restricted, lateral bending and rotation range of motion restricted. S1-17 also had limited spinal, rib, and pelvis stability, and the strength and tone of his spine, ribs, and pelvis were diminished due to his pain. The nurse

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practitioner then performed an extensive examination of S1-17's lumbar region, finding the following: (1) moderate loss of lumbar range of motion and flexibility with respect to his lumbar flexion; (2) severe loss of lumbar range of motion and flexibility with respect to his lumbar extension; (3) moderate loss of lumbar range of motion and flexibility with respect to his lumbar left lateral flexion; (4) moderate loss of lumbar range of motion and flexibility with respect to his lumbar right lateral flexion; and (5) orthopedic testing findings indicating radiating pain and spasm in his left side. (S1-17, pp. 7-11).

After her examination, the nurse practitioner determined that S1-17's lower back pain was being caused by hypolordosis and a severe amount of degenerative disc disease in his lower back. The nurse practitioner also determined that the flare-up was due to S1-17's poor core strength and decreased lower back strength. She diagnosed S1-17 with other spondylosis with radiculopathy, lumbar region; other intervertebral disc degeneration, lumbar region; radiculopathy, lumbar region; sciatica, left side; sacroiliitis, not elsewhere classified; and muscle spasm of back. The nurse practitioner explained to S1-17 that he needed to complete his at-home physical therapy exercises three times a week to help maintain the progress he made prior to the flare-up; he had previously admitted to only performing them once a week. The nurse practitioner then ordered a low back brace for S1-17, stating, "*Due to patient pain, hypertonicity, spasm causing instabilities, it is medically indicated for patient to receive low back brace. The back brace L0650 is medically necessary to reduce pain by restricting mobility of the trunk and to support weak spinal muscles.*" (S1-17, pp. 7-11).

OIG's reviewer made the following materially inaccurate or misleading assertions with respect to this claim:

**OIG Claim:** The reviewer asserted, "*Theoretical mechanisms for the prevention of low back pain include providing trunk support and prevention of pain-producing events, reminders of "proper lifting technique," and an increase in intra-abdominal pressure and a decrease in intradiscal pressure. The evidence that these braces reduce intradiscal pressure is limited. The quality of available evidence is limited and there is no clear evidence of efficacy for the use of lumbar supports for short- or long-term treatment or prevention of low back pain. Lumbar braces may be useful for specific treatment of specific conditions such as spondylolisthesis, documented instability, or post-operative treatment. Lumbar supports also attempt to enforce reduced mobility which is in contrast to evidence that increasing activity levels actually reduces low back pain.*" See A-09-18-03002A, S1-17, p. 3.

**Response:** Not only does OIG's reviewer fail to provide citations for the referenced "evidence", but Medicare suppliers are only bound by Medicare coverage criteria. In fact, the LCD indicates "N/A" (or not applicable) under the "Summary of Evidence" and "Analysis of Evidence" sections of the LCD. As shown above, LCD L33790 provides for four different indications for which a spinal orthosis (L0450 - L0651) is covered. There are no additional documentation requirements in the LCD or associated Policy Article A52500. These statements made by OIG's reviewer are not founded in Medicare coverage criteria.

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**OIG Claim:** The reviewer asserted that the patient had a normal gait and was in no acute distress on exam. *See* A-09-18-03002A, S1-17, p. 3.

**Response:** This statement is materially inaccurate. S1-17 was in acute distress as he rated his pain a 9 out of 10 in severity during the July 7, 2017 office visit. (S1-17, p. 7). Furthermore, there is no requirement that the patient needs to have an abnormal gait to qualify for coverage for a back brace. Medicare suppliers are only bound by Medicare coverage criteria. As shown above, LCD L33790 provides for four different indications for which a spinal orthosis (L0450 - L0651) is covered. There are no additional documentation requirements in the LCD or associated Policy Article A52500. This statement made by OIG's reviewer is materially inaccurate and not founded in Medicare coverage criteria.

**OIG Claim:** The reviewer asserted, "*The brace prescription form was conflicting with the provider's documentation. The brace prescription noted that indications relating to medical necessity were to reduce pain, instability and increase/maintain ROM, and improve ADLs/functioning. There was no evidence of lumbar instability. The documentation did not reveal evidence of pain on examination of lumbar range of motion testing. There was no indication that the patient was unable to perform ADLs.*" *See* A-09-18-03002A, S1-17, p. 3.

**Response:** These statements are materially false. The July 7, 2017 progress note demonstrates that the patient experienced spasms in his lumbar spine, and that he experienced pain in his lumbar spine. The progress note also identified that the patient experienced pain when walking, with exertion, during prolonged sitting, and during prolonged standing, all of which relate to and/or constitute activities of daily living (ADLs). The provider diagnosed the beneficiary with spondylosis and intervertebral disc degeneration, among other diagnoses. In regard to OIG's reviewer's assertion that there was no evidence of lumbar instability, spondylosis by definition is a crack in the pars interarticularis of a vertebrae which can create instability. Additionally, degenerative disc disease also suggests instability of the spine. This beneficiary's lack of normal separation of the vertebrae combined with lack of muscle tone can cause instability and, as such, it was not conflicting for the ordering provider to select "reduce instability" on the prescription as one of the indications relating to medical necessity for the back brace. It should also be noted that there are no standard instability tests of the back like there are for the knee. The prescription does not conflict with the provider's documentation, and these statements made by OIG's reviewer are materially false. (S1-17, pp. 6-11).

**OIG Claim:** The reviewer asserted that the provider noted that the patient required a brace to restrict mobility and support weak spine muscles and the provider's documentation noted that the patient had diminished strength on exam due to pain which is not indicative of true muscle weakness. *See* A-09-18-03002A, S1-17, p. 3.

**Response:** These statements are materially inaccurate. Medicare suppliers are only bound by Medicare coverage criteria. As shown above, LCD L33790 provides for four different indications for which a spinal orthosis (L0450 - L0651) is covered. A back brace is covered

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to support weak spinal muscles. There are no additional documentation requirements in the LCD or associated Policy Article A52500. The nurse practitioner expressly documented “*Diminished strength and tone due to pain*” in regard to strength and tone of spine, ribs, and pelvis areas, and “*Patient flare up of LBP is also being caused by poor core strength and decreased LB strengthening, patient states he only completes his at home physical therapy exercises 1x week*”. (S1-17, pp. 9, 11). Therefore, the documentation does support weak spinal muscles in accordance with the LCD and Policy Article. Furthermore, the documentation actually supports that two coverage criteria are met: to reduce pain by restricting mobility of the trunk and to support weak spinal muscles. These statements made by OIG’s reviewer do not accurately reflect what is expressly documented in the beneficiary’s medical record and are not founded in Medicare coverage criteria.

**OIG Claim:** The reviewer asserted: “*It is unclear why the provider’s prescription form and the progress notes reveal a brace is needed to restrict trunk mobility and the prescription noted that the brace was to increase mobility. Furthermore, the physical exam revealed evidence of reduced trunk mobility on exam. The documentation does not support that immobility of the trunk would reduce this patient’s pain.*” See A-09-18-03002A, S1-17, p. 3.

**Response:** These statements are materially false. The prescription form does not state that the brace was to “increase mobility”; instead, the prescription provides that indications relating to medical necessity included to manage pain, reduce instability, increase / maintain range of motion, and improve ADLs / functioning. (S1-17, p. 6). These indications also neither state nor imply that the benefits would occur immediately or while the patient is actually wearing the back brace. Rather, they may be long-term benefits of having used the back brace in accordance with the provider’s orders (i.e., the provider’s intent is for the patient to be able to increase / maintain their range of motion by their having worn the back brace in accordance with the provider’s orders). Also, the patient having reduced trunk mobility upon exam did not mean that medically restricted mobility of the trunk via a prescribed back brace would not reduce this patient’s pain. There is an obvious difference clinically between pain and spasm causing loss of range of motion and flexibility versus specifically restricted mobility of the trunk via a back brace intended to reduce pain and support weak spinal muscles. Furthermore, OIG’s reviewer references “immobility” which is not a term used in the LCD; the LCD provides that a covered indication for a back brace is to reduce pain by restricting mobility of the trunk, not by immobilizing the trunk. These statements made by OIG’s reviewer are not founded in Medicare coverage criteria or medical science.

S1-17 was diagnosed with, among other conditions, other spondylosis with radiculopathy, lumbar region (ICD-10 M47.26) and radiculopathy, lumbar region (ICD-10 M54.16), which caused him constant pain that was not relieved with pain medication. The nurse practitioner ordered a back brace to reduce S1-17’s pain by restricting mobility of his trunk, as well as to support his documented weak spinal muscles. The Medicare coverage criteria for the back brace (HCPCS code L0650) was thus met. The nurse practitioner also attested on September 27, 2019 that, as the

ordering provider, she continues to believe the Medicare coverage criteria were met for the back brace at issue. (S1-17, p. 12).

Example 3: S2-12  
DOS 12/10/2016  
HCPCS code L0650

By way of background, S2-12 was a 66-year-old male when he received the back brace on December 10, 2016. He presented to his physician's office on November 30, 2016 with complaints of low back pain which had started three years prior. S2-12 reported that he experienced pain every day and that it came and went at no particular time. He described the pain as alternating between sharp and dull, and he reported that sometimes it radiated down his left leg. He reported that he had had magnetic resonance imaging (MRI) three years prior and was told he had L5 degenerative joint disease. He reported using Nonsteroidal Anti-inflammatory Drugs (NSAIDs) periodically but that they were not effective. The physician examined his spine, including lumbar and sacral areas. In terms of his lumbar spine, S2-12 was unable to touch his toes due to pain and tenderness and had limb length disparity related to scoliosis. In terms of his sacral spine, the physician noted tenderness and decreased range of motion in all planes. Overall, the physician observed diffuse paravertebral tenderness. S2-12 was assessed with back pain (ICD-10 M54.9). The physician documented:

*"Patient requires semi-rigid back brace LSO to support weak spinal muscles and restrict mobility of tenderness spine to reduce pain as a result of degenerative disc disease M19.90, M54.9. Patient has had chronic back pain for 12+ months using pain medication, topicals, [injections, heat and cold with minimal relief. Treatment goal is to reduce pain and increase activities of daily living".*

(S2-12, pp. 7-10).

OIG's reviewer made the following materially inaccurate or misleading assertions with respect to this claim:

**OIG Claim:** The reviewer asserted that there was no documentation of clear association of pain with motion of the spine. *See* A-09-18-03002B, S2-12, p. 3.

**Response:** As stated *supra*, the coverage indication per the LCD relating to pain is "to reduce pain by restricting mobility of the trunk." This is all that is required under the LCD. The LCD does not require "documentation of clear association of pain with motion of the spine". In fact, neither the LCD or Policy Article even provide for a list of covered diagnosis codes. Furthermore, on exam, the physician clearly documented that S2-12 was unable to touch his toes due to pain and tenderness (which is a motion associated with pain / tenderness). (S2-12, p. 8). This is the equivalent of forward flexion. The reviewer's assertions have no merit.

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**OIG Claim:** The reviewer asserted that the patient had normal muscle strength and tone and normal station. *See* A-09-18-03002B, S2-12, p. 3.

**Response:** This is a materially misleading assertion. The physician's November 30, 2016 encounter note does provide under the neurological system on physical exam that S2-12 demonstrated "normal station" with respect to gait and station and normal muscle strength and tone with respect to muscles. However, under the musculoskeletal system portion of the physical exam, and specifically in regard to the spine exam, the physician documented that S2-12 was unable to touch his toes due to pain and tenderness, had limb length disparity related to scoliosis, exhibited tenderness and decreased range of motion in all sacral planes, and had diffuse paravertebral tenderness. (S2-12, p. 8). Later in the encounter note, the physician noted that she had determined that S2-12 required a back brace to support weak spinal muscles and restrict mobility of the spine to reduce pain as a result of degenerative disc disease. (S2-12, p. 9).

**OIG Claim:** The reviewer asserted that there was no evidence of spinal deformity. *See* A-09-18-03002B, S2-12, p. 3.

**Response:** This statement is materially inaccurate and contradicts the reviewer's admission that the patient was documented to have had "*limb length disparity related to scoliosis*". *See* A-09-18-03002B, S2-12, p. 1. Scoliosis is clinically a coronal plane (i.e. side to side) spinal deformity. Furthermore, a spinal deformity is not required in order for a beneficiary to be eligible for a back brace. One covered indication for a back brace is to reduce pain by restricting mobility of the trunk, which is why this beneficiary was prescribed the back brace at issue.

S2-12 presented with complaints of low back pain and exhibited pain and tenderness, decreased range of motion, and limb length disparity on exam of his spine. A back brace was ordered to reduce his pain by restricting mobility of his trunk, which is a covered indication for a back brace pursuant to Medicare coverage criteria. The physician also attested on October 1, 2019 that the back brace satisfied Medicare coverage criteria. (S2-12, pp. 21-22).

As these three examples establish, OIG's reviewer misapplied Medicare coverage criteria with respect to back braces and disregarded information expressly contained in the beneficiaries' medical records. We therefore respectfully request that the back brace claims be re-reviewed in accordance with the correct Medicare coverage criteria and in consideration of all evidence in the beneficiaries' medical records.

It should also be noted that OIG's reviewer repeatedly mispresents HCPCS code L0637 as a "custom fit" (as expressly opposed to a prefabricated back brace) or "custom fabricated" back brace. *See, e.g.,* A-09-18-03002A, S1-14 and S1-49, p. 3. L0637 is not and has never been a custom fabricated back brace; it is a prefabricated item that has been customized to fit a specific patient.

## 2) Knee Braces

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Under Medicare guidelines applicable nationwide, knee orthoses represented by HCPCS codes L1832, L1833, L1843, L1845, L1851<sup>5</sup> and L1852<sup>6</sup> are covered for a beneficiary who is ambulatory and has knee instability due to a condition specified in the Group 4 Codes in the "ICD-10 Codes that are Covered" section of the LCD-related Policy Article. Knee instability must be documented by examination of the beneficiary and objective description of joint laxity (e.g., varus/valgus instability, anterior/posterior Drawer test). Custom fabricated knee orthoses represented by HCPCS codes L1834, L1840, L1844, L1846, and L1860 are covered for an ambulatory beneficiary who has a documented physical characteristic that requires the use of a custom fabricated orthosis instead of a prefabricated orthosis. Examples of situations that meet the criteria for a custom fabricated orthosis include but are not limited to: (1) deformity of the leg or knee; (2) size of thigh and calf; and (3) minimal muscle mass upon which to suspend an orthosis. If a custom fabricated orthosis is provided, but the medical record does not document why it is medically necessary instead of a prefabricated orthosis, then the custom fabricated orthosis will be denied as not reasonable and necessary. Knee orthoses represented by HCPCS codes L1832, L1833, L1843, L1845, L1851, and L1852 may also be covered for a beneficiary who has had a recent injury to or a surgical procedure on the knee(s). See LCD L33318 and Policy Article A52465.

A careful review of the OIG's reviewer's claim review determination reports with respect to the denied knee brace claims establishes that OIG's reviewer misapplied Medicare coverage criteria and disregarded evidence from the beneficiary medical records, and also made other mistakes. The following examples highlight these issues:

Example 1: S2-5

DOS: 03/01/2017

HCPCS codes L1844, L2397

By way of background, Medicare beneficiary S2-5 was an 80-year-old ambulatory female when she received a custom knee orthosis for her left knee on March 1, 2017. S2-5 was seen by a physician assistant on February 23, 2017. She presented with continued complaints of low back and left knee pain. She indicated the pain was frequent with standing and walking. S2-5 reported that her ADLs had decreased as a result of the pain. She relayed that while her medications reduced pain, they also caused drowsiness. On exam, S2-5 was ambulatory with antalgic gait. Varus/valgus stress test was positive to left knee. The physician assistant also observed slight crepitus, slight effusion, and medial joint line tenderness. He assessed S2-5 with left knee unilateral primary osteoarthritis (ICD-10 M17.12), as well as medial and lateral collateral ligament sprain of the knee. He ordered a "[l]eft knee unloading orthosis, medial, custom molded due to minimal muscle mass". (S2-5, pp. 4-6).

OIG's reviewer made the following materially inaccurate or misleading assertions with respect to this claim:

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<sup>5</sup> Formerly HCPCS code K0901.

<sup>6</sup> Formerly HCPCS code K0902.

**OIG Claim:** The reviewer asserted that while the patient's left knee was reported to have minimal muscle mass, no measurements were documented. *See A-09-18-03002B, S2-5, p. 1.*

**Response:** LCD L33318 does not require measurements. The LCD simply states that an example of a situation which meets the criterion for a custom fabricated orthosis include minimal muscle mass upon which to suspend an orthosis. OIG's reviewer acknowledges that the documentation indicates that the patient had minimal muscle mass to her left knee. The physician assistant further attested on October 1, 2019 that, "*I ordered a "[l]eft knee unloading orthosis, medial, custom molded due to minimal muscle mass". I signed the prescription for the left custom knee brace on February 23, 2017. On the prescription, the box for "Minimal muscle mass" was checked under the custom brace criteria.*" (S2-5, p. 7). The LCD requirements have thus been met.

**OIG Claim:** The reviewer asserted the documentation did not reveal a deformity, atrophy, or other extenuating factor on physical exam that would require a custom fabricated knee orthosis for the knee. *See A-09-18-03002B, S2-5, p. 4.*

**Response:** LCD L33318 expressly discusses the Medicare coverage criteria for custom knee orthoses, which are detailed above. The LCD provides that a situation where the criterion for a custom knee orthosis is met is "*minimal muscle mass upon which to suspend an orthosis*". The LCD does not require that the criterion for a custom fabricated orthosis be specifically discussed in the physical exam section of an encounter note. The beneficiary's medical record need only document the physical characteristic which requires the use of a custom fabricated orthosis (e.g., minimal muscle mass). OIG's reviewer already conceded "*that the patient's left knee was reported to have minimal muscle mass*". *See A-09-18-03002B, S2-5, p. 1.* The Medicare coverage criteria for a custom fabricated knee orthosis has thus been satisfied.

S2-5 was ambulatory and had left knee instability due to a qualifying condition in the Policy Article, namely left knee osteoarthritis. S2-5 presented due to complaints of pain and required a left knee custom orthosis due to minimal muscle mass. The Medicare coverage criteria for the knee orthosis represented by HCPCS code L1844 was met for S2-5's left knee and the accompanying suspension wrap L2397 is thus also medically necessary. Additionally, the physician assistant has attested that she continues to believe that the Medicare coverage criteria have been met.

Example 2: S2-12  
DOS: 12/10/2016  
HCPCS code K0901

By way of background, S2-12 presented to his doctor on November 30, 2016 with chief complaints of "*knee instability, buckling, quad weakness*". He reported joint pain to his knees, as well as to other joints. He reported that he had had gout for about three years and that sometimes he felt "*minor flares*" in his knees. S2-12 relayed that he had difficulty walking and climbing stairs. S2-12 reported that pain medication, topicals, injections, and application of hot / cold provided only

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minimal relief. He was noted to have crepitus and decreased range of motion on exam. The encounter note provides that S2-12 had significant disuse atrophy to his right quadricep muscle and varus instability of the right knee secondary to osteoarthritis of the right knee. (S2-12, pp. 17-20).

OIG's reviewer made the following materially inaccurate assertion with respect to this claim:

**OIG Claim:** The reviewer asserted that there was no documentation by physical examination of right knee joint laxity such as by valgus stress testing. *See* A -09-18-03002B, S2-12, p. 5.

**Response:** This statement is materially inaccurate. LCD L33318 provides varus/valgus instability as an example of objective description of joint laxity. The November 30, 2016 encounter note specifically documents right knee "varus+ instability". (S2-12, p. 19). The plus (+) sign following a test is a common documentation method for identifying a positive stress test. Additionally, the physician attested on October 1, 2019 that "I assessed varus/valgus instability" and "I ordered the right knee brace for [S2-12]'s right knee instability secondary to right knee osteoarthritis based on beneficiary exam and objective description of joint laxity (i.e., positive varus instability to right knee)." (S2-12, p. 21). The LCD requirement for objective description of joint laxity has been met.

S2-12 was ambulatory and had right knee instability due to a qualifying condition in the Policy Article, namely primary unilateral right knee osteoarthritis (ICD-10 M17.11). Knee instability was documented by examination of the beneficiary and objective description of joint laxity. The Medicare coverage criteria for knee orthosis K0901 was thus met. The physician also attested on October 1, 2019 that the right knee orthosis satisfied Medicare coverage criteria.

Example 3: S2-13  
DOS 06/02/2017  
HCPCS codes L1846 (2)

By way of background, Medicare beneficiary S2-13 was an ambulatory 70-year-old male when he received the custom fabricated bilateral knee orthoses on June 2, 2017. S2-13 had an office visit with a nurse practitioner on May 4, 2017, at which time he reported that he sustained a fall because his bilateral knees gave out. On exam on May 4, 2017, the nurse practitioner noted positive varus/valgus as well as instability of knees, left greater than right. The encounter note indicates that the nurse practitioner ordered custom fabricated knee orthoses on account of minimal muscle mass. Prior to this office visit, S2-13 had had bilateral x-rays of his knees with oblique views on February 9, 2017 and was found to have mild medial compartment narrowing to both knees, as well as mild degenerative changes to the right knee.<sup>7</sup> (S2-13, pp. 8, 16-18).

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<sup>7</sup> Visionquest did not originally provide these x-ray reports but is including them with this response to the draft report. (S2-13, pp. 17-18).

OIG's reviewer made the following materially inaccurate or misleading assertions with respect to this claim:

**OIG Claim:** The reviewer asserts the instability of the knees were greater on the right than left. See A- 09-18-03002B, S2-13, pp. 1, 4.

**Response:** This is materially inaccurate. The May 4, 2017 encounter note provides that knee instability was greater on the left than right. (S2-13, pp. 8, 16). OIG's reviewer misread the medical record and stated the opposite of what the medical record provides.

**OIG Claim:** The reviewer asserted that the documentation did not indicate objective evidence to support minimal muscle mass (and points out that the patient had a greater than normal body mass index) and there was otherwise no documentation of a deformity, atrophy, or other extenuating factor that would require custom fabricated knee orthoses. See A- 09-18-03002B, S2-13, pp. 4, 7.

**Response:** LCD L33318 expressly provides that "*minimal muscle mass upon which to suspend an orthosis*" is an example of a potential situation where a custom fabricated orthosis may be appropriate. The nurse practitioner documented in her May 4, 2017 encounter note that custom braces were indicated due to minimal muscle mass. (S2-13, pp. 8, 16). This is sufficient for purposes of the LCD. The LCD requirements have been met. The LCD does not mandate 'objective evidence' to support minimal muscle mass beyond documentation of minimal muscle mass.<sup>8</sup> Additionally, the encounter note is consistent with the prescription, which includes a checked box for minimal muscle mass under the custom brace criteria. (S2-13, pp. 6, 14). Furthermore, it is completely misleading for the OIG reviewer to suggest that a greater than normal body mass index is mutually exclusive with minimal muscle mass. For example, a thigh with excessive adipose tissue, especially those with sagging medial folds, may be considered to have minimal muscle mass upon which to suspend and orthosis. Minimal muscle mass can refer to the quality of the tissue (adipose versus muscle) and not just the quantity. It is entirely possible for someone to be overweight and have minimal muscle mass to their bilateral lower extremities, as here.

S2-13 was ambulatory and had bilateral knee instability due to a qualifying condition in the Policy Article, namely bilateral primary osteoarthritis of the knees. S2-13 presented due to complaints of fall secondary to knees buckling and required custom orthoses due to documented minimal muscle mass. The Medicare coverage criteria for the bilateral custom fabricated knee orthoses (HCPCS code L1846) was met.

As these three examples establish, OIG's reviewer misapplied Medicare coverage criteria with respect to knee braces and disregarded information expressly contained in the beneficiaries' medical records. We therefore respectfully request that the knee brace claims be re-reviewed in

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<sup>8</sup> In contrast, for example, the LCD for knee orthoses (LCD L33318) specifically requires a beneficiary exam and objective description of joint laxity if the patient is receiving a knee orthosis on account of knee instability. Where the LCDs require an exam and / or an objective description, they specify accordingly.

accordance with the correct Medicare coverage criteria and in consideration of all evidence in the beneficiaries' medical records.

### 3) All Denials

In regard to all of the denied claims at issue in the draft report, Visionquest does not agree with OIG's medical review determinations. Visionquest has prepared a claim response summary for each denied beneficiary claim which addresses each of OIG's reviewer's denial reasons. While it is Visionquest's position that they obtained (and provided) as much information from beneficiary medical records as necessary to assure itself that these claims for orthotic braces met Medicare requirements for medical necessity, Visionquest has secured additional medical records and / or attestations from the providers for the majority of the denied claims. These materials are enclosed with Visionquest's claim response summaries in **Appendix B**.

In footnote 16 of its draft report, OIG states the independent medical review contractor "*had quality assurance procedures to ensure all medical review determinations made by its staff were factually accurate, complete, and concise*". Unfortunately, it is evident that these procedures failed. In addition to the misapplication of Medicare coverage criteria and disregard for evidence in the beneficiaries' medical records exemplified repeatedly above, the reviewer's claim review reports are replete with errors highlighting the carelessness and neglect with which the claim reviews were handled, and the claim review reports were prepared. We identified incorrect date of service references (*see, e.g.,* A-09-18-03002A, S1-11, p. 1 and A-09-18-03002B, S2-31, pp. 1, 4); references to the wrong joint or extremity (*see, e.g.,* A-09-18-03002B, S2-48, p. 7)<sup>9</sup>; and unfounded statements that directly conflicted with evidence in the medical records (*see, e.g.,* A-09-18-03002A, S1-11, p. 1).<sup>10</sup>

Relative to the issue of medical necessity, it appears that OIG's reviewer failed to grant any deference to the treating providers who actually treated the patients and ordered the orthotics for the patients. Medicare program regulations provide that a "*physician has a major role in determining utilization of health services furnished by providers*".<sup>11</sup> Additionally, courts have long acknowledged that the treating physician should be granted additional weight and deference in any dispute over medical necessity.<sup>12</sup> The reasoning underpinning these holdings is abundantly clear:

<sup>9</sup> In regard to the denial rationale for the left knee orthosis, OIG's reviewer writes, "*The documentation did not include recent injury or surgical procedure to the right knee; there was no date documented related to the meniscus tear*" (emphasis added). These errors appear to be a result of OIG's reviewer copying and pasting denial language.

<sup>10</sup> OIG's reviewer asserted the patient's medication regimen was not specified when the current medications and dosages are detailed in an expansive table within the August 30, 2016 encounter note. (S1-11, pp. 6-7). The plan section of the note also provides that several of S1-11's medications were refilled at the time of the August 30, 2016 visit, including Percocet, Zanaflex, and Tramadol. (S1-11, p. 8).

<sup>11</sup> *See* 42 C.F.R. § 424.10(a).

<sup>12</sup> In *State of New York o/b/o Holland v. Sullivan*, the United States Court of Appeals for the Second Circuit concluded that,

*"Though the considerations bearing on the weight to be accorded a treating physician's opinion are not necessarily identical in the [Social Security disability] and Medicare context, we would expect the Secretary to place significant reliance on the informed opinion of a treating physician and either to apply the treating*

a treating and ordering physician has a unique opportunity to personally examine and assess the clinical condition of a patient and subsequently prescribe a course of treatment. A third-party reviewer (such as OIG's independent medical review contractor), by contrast, must base its opinion on a cold record, often years after the treating physician evaluated the patient.

Not only does OIG's reviewer fail to give the treating providers any deference, but they actually do the opposite and consistently try and construe the beneficiaries' medical records against the providers in an effort to deny the claims. For example, in regard to S1-1, OIG's reviewer argues that the documented objective evidence (positive varus/valgus stress test, positive Apley's & McMurray's test, Kemp's and Yeoman's test) in the beneficiary's medical record did not specify laterality of instability on the lower extremity physical exam and did not specify side. *See* A-09-18-03002A, S1-1, p. 3. However, the medical record expressly provides that the patient presented with complaints of bilateral knee pain, the provider diagnosed the patient with bilateral knee osteoarthritis, and the provider recommended bilateral "knee braces to aid stability to lower limb joints" in the September 7, 2016 encounter note. (S1-1, pp. 7-8). Rather than deferring to the treating provider that the knee examination findings applied to both knees based on her references to the patient's bilateral knee complaints, bilateral knee diagnoses, and bilateral brace recommendation,<sup>13</sup> OIG's reviewer does the opposite and concludes that the documented objective evidence did not specify laterality of instability on the lower extremity physical exam and did not specify side such that it opted to deny the knee brace at issue.

Enclosed in **Appendix B** to this response are additional signed attestations by the treating providers reiterating their findings and the medical necessity for the orthotics at issue in accordance with Medicare coverage criteria. It is troubling that a nameless reviewer, from an anonymous contractor, is allowed to perform a retrospective review of medical necessity without any deference to the treating providers and with far reaching implications. Given the punitive nature of the findings, and the severe financial penalties involved, a contractor reviewer should be held to the highest standard and not be allowed to exist behind a shield of anonymity while making retrospective and erroneous clinical judgments.

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*physician rule, with its component of 'some extra weight' to be accorded that opinion, or to supply a reasoned basis, in conformity with statutory purposes, for declining to do so."*

927 F.2d 57, 60 (2d Cir. 1991); *see also* *Schiller v. Bowen*, 851 F.2d 43, 47 (2d Cir. 1988). Similarly, in *Marsh v. Bowen*, the United States District Court for the District of Connecticut observed that there is a "well-settled principle that the opinion of the treating [physician] is entitled to special deference unless it is contradicted by substantial evidence." 1985 WL 69272 (D. Conn. 1985) (emphasis added). The Court ultimately held that the opinion of a medical advisor representing the government was *not* sufficient to equal the substantial evidence necessary to overcome the opinion of treating physicians. *Id.* This principle, known as the "Treating Physician Rule", has been applied in a number of cases where courts have held that a treating physician's determination regarding the care of his or her patient is of paramount importance. *See Keefe v. Shalala*, 71 F.3d 1060, 1064 (2d Cir. 1995) (suggesting that the treating physician rule applies to Medicare cases); *Klementowski v. Sec'y of HHS*, 801 F. Supp. 1022 (W.D.N.Y. 1992) (holding that the treating physician rule applies in a case where a plaintiff sought reimbursement for air ambulance services under Medicare Part B); *Hirsh v. Bowen*, 655 F. Supp. 342 (S.D.N.Y. 1987); *Gartmann v. Sec'y of HHS*, 633 F. Supp. 671 (E.D.N.Y. 1986).

<sup>13</sup> The provider also specifically labeled the positive Apley's & McMurray's test and Kemp's and Yeoman's tests as "ICD-10 Assessments" which correlated to "ICD-10 [Diagnosis] Codes" which included both bilateral left and right knee osteoarthritis. S1-1, p. 8.

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VI. OIG's Error Rate is Inconsistent with Medicare Review Outcomes for the Same Period

OIG noted in its draft report that it excluded 66 claims from its review that had been reviewed by other review entities. Visionquest was able to track down 65 of these claim reviews. OIG's findings as set out in its draft report are wholly inconsistent with audit findings by multiple CMS contractors for the same time period, including Health Integrity, LLC (now Qlarant Integrity Solutions, LLC); National Government Services, Inc.; Noridian Healthcare Solutions, LLC; and Performant Recovery, Inc. The following numbers take into consideration the contractors' original review determinations and any favorable outcomes in the Medicare administrative appeals process:

- Twenty (20) 2016 back brace claims were reviewed and none were denied for lack of medical necessity (0%).
- Thirty-three (33) 2017 back brace back brace claims were reviewed and three (3) were denied for lack of medical necessity, or nine (9) percent.
- One (1) 2018 back brace claim was reviewed, and it was not denied for lack of medical necessity (0%).
- Six (6) 2016 knee brace claims were reviewed and one (1) was denied for lack of medical necessity, or 17%.
- And four (4) 2017 knee brace claims were reviewed and two (2) were denied for lack of medical necessity, or 50%.
- No ankle foot orthoses from 2016 through 2018 were reviewed by other review entities.

These numbers are nowhere near OIG's purported beneficiary claim denial rate of 87% (*see* Table 1).

Year	Orthoses Type	Total Claims	Denied for Medical Necessity	Percent
2016	Knee brace	6	1	17%
2017	Knee brace	4	2	50%
2016	Back brace	20	0	0%
2017	Back brace	33	3	9%
2018	Back brace	1	0	0%
	Totals	64	6	9%

Table 1

As stated previously, Visionquest is fully licensed, certified, and in good standing with all relevant state and federal government regulatory agencies and insurance providers (including Medicare, Medicaid, and commercial insurers). Visionquest has never been suspended or terminated by CMS, or any commercial insurer, nor has it ever been subjected to fines or licensure revocations or restrictions of any kind. Seven years prior to the Medicare Improvement for Patients and Providers Act of 2008 which included mandated DMEPOS accreditation, Visionquest became fully accredited by the Community Health Accreditation Program (CHAP), a CMS approved, non-profit organization with a long record of conducting high quality accreditation and inspection services. During the same 2001 timeframe, Visionquest established a Compliance Committee, to oversee all routine internal audit functions, review external audits and assess any areas of non-compliance, including claims transmitted to CMS for payment.

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Visionquest facilities and processes are routinely subject to unannounced visits and detailed inspections by federal and state regulators, CMS contractors, and numerous independent accreditation organizations. All of the survey inspections conducted at Visionquest over the past 30 years have resulted in determinations that Visionquest was in substantial compliance with all federal, state, CMS, and accreditation and license requirements.

The certification and audit processes (both internal and CMS-directed) are critical opportunities for Visionquest to receive feedback that can be used to improve upon the already high level of quality care and products provided. The alleged medical necessity failure rate of 87% indicated in this audit versus the 9% error rate from the same time period and same patient population identified by CMS contractors, including Medicare Administrative Contractors (MACs), Recovery Audit Contractors (RACs), Supplemental Medical Review Contractors (SMRCs), and Zone Program Integrity Contractors (ZPICs)<sup>14</sup>, clearly indicates OIG's independent medical review contractor in this OIG audit was applying a significantly different standard than numerous other CMS contractors.

The flagrant disregard for applying the appropriate standards detailed previously, as well as the vast difference between the results of this OIG audit and audits by other CMS contractors, raise a serious concern regarding the validity of OIG's review process and the conclusions reached.

#### VII. Request for Redaction of Visionquest's name in the Final Report

We hereby request that Visionquest's name be redacted in the Final Report published by OIG. The publication of the Final Report with Visionquest's name will cause serious harm to the company's reputation and serious financial loss. There is no purpose for publishing the company's name and Visionquest does not consent to OIG doing so.

Furthermore, the proposed title *Visionquest Industries, Inc., Received Medicare Payments for Orthotic Braces That Were Not Medically Necessary* is grossly misleading to the public and one-sided in favor of OIG's opinion, and Section 8M of the Inspector General Act, 5 U.S.C. App. does not require that the report be titled in this misleading and one-sided manner. An accurate title, which should be used instead, would read: *OIG Believes Visionquest Industries, Inc. Received Medicare Payments for Orthotic Braces That Were Not Medically Necessary and Visionquest Industries, Inc. Disagrees*. Again, Visionquest does not consent to its name being published in OIG's Final Report and insists its name must be redacted; however, if OIG is going to disregard Visionquest's request, then the title must be renamed to reflect the position of both parties, and not just OIG.

#### VIII. Conclusion

As established herein, the beneficiary claims selected for review were not billed incorrectly as OIG asserts. Additionally, OIG's sampling methodology is statistically invalid. We respectfully request that OIG direct its independent medical review contractor to re-review the denied claims in

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<sup>14</sup> Now Unified Program Integrity Contractors (UPICs).

Response to Draft Report - Report Number: A-09-19-03010  
October 16, 2019  
Page 23 of 23

accordance with published Medicare guidelines in advance of finalizing its report and that any refund recommendation be based on the actual payment amounts. While Visionquest adamantly disagrees with OIG's findings as summarized in its draft report and intends to vigorously contest OIG's adverse determinations through the Medicare administrative appeals process, Visionquest does appreciate the opportunity to respond to the draft report.

Sincerely,  
/s/ Lorraine A. Rosado  
Liles Parker PLLC

Encl.  
Appendix A (Ross Mitchell Cox, Ph.D.'s Expert Report)  
Appendix B (87 Claim Response Summaries and Medical Records)

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