



Utilization and Cost of Surgery for Lumbar Spinal Stenosis in a Commercially Insured Population

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EXECUTIVE SUMMARY

Symptomatic lumbar spinal stenosis (LSS) is one of the most frequent indications for spinal surgery. Current evidence suggests that surgery for symptomatic LSS is more effective than nonoperative medical treatment when nonoperative treatment has failed to relieve symptoms after 6 months.^{1 2 3} Surgical treatment of LSS typically includes decompression alone (laminectomy) or decompression with lumbar fusion. Similar clinical benefits with respect to pain, disability or walking ability have been reported in studies comparing decompression with lumbar fusion to decompression alone in the treatment of symptomatic LSS.⁴ Decompression with lumbar fusion versus decompression alone for LSS results in similar reoperation/revision rates at 2 and 5 years post-surgery (for commercially insured members) and at 2 years post-surgery (for Medicare FFS beneficiaries).^{5 6 7} Higher rates of major complications, 30 day mortality and resource use have been reported following decompression with lumbar fusion compared to decompression alone.^{7 8 9}

This analysis was intended to quantify the frequency and cost of LSS related decompression and lumbar fusion surgeries in a commercially insured population as well as the portion of cases that had a decompression or lumbar fusion in the preceding 4 years. In addition, we modeled the cost impact of replacing a portion of lumbar fusion cases with decompression and use of an intralaminar lumbar stabilization (ILS) device. An ILS is a motion-preserving stabilization device for the lumbar spine, inserted during decompression surgery as an alternative to spinal fusion.

Table 1 provides the number of all decompressions and lumbar fusions (LSS- and non LS- related) and the allowed cost per member per month (\$PMPM) associated with these procedures. LSS-related decompressions cost \$0.54 PMPM and account for 37% of lumbar decompressions while LSS-related lumbar fusions cost \$2.13 PMPM and account for 50% of total lumbar fusions. The total \$PMPM in 2013 for our denominator population was \$403.07.

Table 1: 2013 Count and Cost of Lumbar Fusions and Decompressions

	All Procedures (LSS- and non LSS-Related)	LSS-related Procedures Only	% Total Procedures that are LSS-Related	Allowed \$PMPM for All Procedures	Allowed \$PMPM for LSS-Related Procedures	% Total Procedure \$PMPM Contributed by LSS-Related Procedures
Surgical Decompressions	28,009	12,752	46%	\$1.45	\$0.54	37%
Lumbar Fusions	20,987	9,764	47%	\$4.25	\$2.13	50%
Total	48,996	22,516	46%	\$5.70	\$2.67	47%

Source: Milliman analysis of 2013 MarketScan commercial data. See methodology section of this report.

Allowed cost includes the amount contracted by the payer with the provider, including the member's cost sharing payment. Cost of decompressions and fusions for inpatient procedures includes all allowed cost (facility and professional) from admission through discharge date and for outpatient procedures, all allowed costs on the day of the outpatient procedure.

Based on a 4 year longitudinal look back analysis, we identified 83% of the 2013 LSS related lumbar fusions and 90% of the LSS related decompressions as "primary" surgeries – those having no claims for a decompression or lumbar fusion in the preceding 4 years. Table 2 shows the number, frequency, and cost of 2013 LSS related surgeries, split by whether the surgeries are primary or secondary.

Table 2: Primary and Secondary Surgeries for Lumbar Spinal Stenosis

LSS-related Spinal Procedure Type	2013 Procedure Count	Frequency of Decompressions and Fusions in Preceding 4 years	Count of 2013 Procedures by Number of Preceding Decompressions/ Fusions	% of 2013 Procedures by Number of Preceding Decompressions/ Fusions	Allowed \$PMPM for Procedures
Surgical Decompressions	12,752	0 (primary)	11,463	90%	\$0.48
		1+ (secondary)	1,289	10%	\$0.06
Lumbar Fusions	9,764	0 (primary)	8,113	83%	\$1.77
		1+ (secondary)	1,651	17%	\$0.36
Total	22,516		22,516		\$2.67

Source: Milliman analysis of 2009-2013 MarketScan commercial data. See methodology section of this report. Allowed cost includes the amount contracted by the payer with the provider, including the member's cost sharing payment. Cost of decompressions and fusions for inpatient procedures includes all allowed cost (facility and professional) from admission through discharge date and for outpatient procedures, all allowed costs on the day of the outpatient procedure.

Using the assumptions in Table 3, we considered the potential cost impact of replacing a portion of LSS related primary lumbar fusions with the cost of a decompression and ILS device.

Table 3: Cost Assumptions for Replacing a Portion of Lumbar Fusions with Decompression and ILS device

	Allowed Cost Based on MarketScan 2013 Analysis
Average cost of a lumbar fusion	\$65,509
Average cost of a decompression without ILS device*	\$12,749
Average cost of ILS device**	\$7,000
Allowed \$PMPM for "primary" lumbar fusions	\$1.77
Allowed total population \$PMPM	\$403.07

Source: Milliman analysis of 2013 MarketScan commercial data. See methodology section of this report. Allowed cost includes the amount contracted by the payer with the provider, including the member's cost sharing payment. Cost of decompressions and fusions for inpatient procedures includes all allowed cost (facility and professional) from admission through discharge date and for outpatient procedures, all allowed costs on the day of the outpatient procedure. Primary fusion are those without fusion or decompression claims in prior 4 years. ILS: intralaminar stabilization device. Average cost of a lumbar fusion and decompression is based on the average cost of the combined primary and secondary cases for each surgery.

* Fewer than 10 of the decompression cases had a claim for an ILS device.

**Cost of ILS device was provided by Paradigm Spine, LLC.

Based on the assumptions in Table 3, Table 4 provides the potential PMPM cost impact associated with 20%, 30% and 40% replacement of primary fusions with the cost of decompressions and ILS device. We assumed that there was no difference in post-operative costs when replacing lumbar fusions. We assumed no difference in the impact on revision/reoperations based on a 2015 published study reporting no statistically significant difference in 4 year revision/reoperation rates following LSS-related decompression with spinal fusion versus LSS-related decompression with an ILS device.¹⁰ We assumed that the average cost of a decompression found in our MarketScan analysis accurately reflects a decompression that does not include ILS device costs, because we found that fewer than 10 decompressions in our analysis had a claim for an ILS device.

Table 4: Potential Cost Impact of Replacement of Primary Fusions with Decompression and ILS Device

	20% Replacement	30% Replacement	40% Replacement
Potential allowed \$PMPM impact associated with replacing primary fusions with the cost of decompression and ILS device	(\$0.25)	(\$0.37)	(\$0.49)

Source: Milliman analysis of 2013 MarketScan commercial data. See methodology section of this report. Allowed cost includes the amount contracted by the payer with the provider, including the member's cost sharing payment. Cost of decompressions and fusions for inpatient procedures include all allowed cost (facility and professional) from admission through discharge date and for outpatient procedures, all allowed costs on the day of the outpatient procedure. Primary fusions are those without fusion or decompression claims in prior 4 years. ILS: intralaminar stabilization device. Average cost of a lumbar fusion and decompression is based on the average cost of the combined primary and secondary cases for each surgery. Fewer than 10 of the decompression cases had a claim for an ILS device.

Increasing utilization and significant regional variation in rates of spinal fusion surgery have been reported over the past 25 years. A Dartmouth Atlas publication reported a 67% increase in the rate of spinal fusion surgery for LSS among Medicare FFS beneficiaries from 2001 to 2011 with the rate varying by a factor of more than fourteen across hospital referral regions.¹¹ A United Health Care commercial claim data analysis, based on a 25 million member population, reported an overall 41% increase in lumbar fusions for lumbar spine conditions (not limited to LSS) between 2004 and 2009 and regional variation in the rate of spinal fusion being 2.5 times as high in some regions compared to others.¹² An investigation by payers and employers for opportunities to impact these patterns appears warranted.

This report was commissioned by Paradigm Spine, which manufactures Coflex, an intralaminar stabilization device indicated for use in decompression surgeries for LSS. One of the authors, Tyler Engel, is a member of the American Academy of Actuaries and meets its qualification standards for this communication. The findings reflect the research of the authors; Milliman does not intend to endorse any product or organization. If this report is reproduced, we ask that it be reproduced in its entirety, as pieces taken out of context can be misleading. As with any economic or actuarial analysis, it is not possible to capture all factors that may be significant. Because we present national average data, the findings should be interpreted carefully before they are applied to any particular situation. These results are based on analysis of Truven MarketScan commercial data for procedures performed in 2013. Different data sets, time periods and methodologies will produce different results.

BACKGROUND

Symptomatic lumbar spinal stenosis (LSS) is one of the most frequent indications for spinal surgery. LSS is a narrowing of the space within the vertebrae where spinal nerves pass, which can lead to intermittent neurogenic claudication – pain in the leg that occurs during walking or standing and is relieved with sitting down or bending forward. LSS can be congenital or acquired, with the most common cause being acquired age-associated degeneration of the lumbar discs and facet joints. Radiographic CT diagnosed prevalence rates for acquired LSS were reported to be 20% ($\leq 12\text{mm}$) and 4% ($\leq 10\text{mm}$) in < 40 year olds and 42% ($\leq 12\text{mm}$) and 19% ($\leq 10\text{mm}$) in 60-69 year olds, yet the majority of individuals were asymptomatic.¹³

The management of LSS depends on the severity of the symptoms. For mild symptoms, nonoperative treatment with analgesics, physical therapy and exercises, and/or epidural steroid injections is recommended. For more severe symptomatic LSS where nonoperative treatment has failed, surgery is suggested. Decompression surgery is done to relieve pressure on impinged nerves in the spinal column, and decompression surgeries include partial or total laminectomy, hemilaminectomy, laminotomy and medical facetectomy. Insertion of an ILS device at the time of decompression as a motion preserving stabilization device became an option with FDA approval in October, 2012. Fusion, done in conjunction with decompression, joins two or more adjacent vertebrae to stabilize the spine and can be done with or without instrumentation.

Current evidence suggests that spinal surgery for symptomatic LSS is more effective than nonoperative treatment, when nonoperative treatment has failed to relieve symptoms after 6 months.^{1 2 3} Similar clinical benefits with respect to pain, disability or walking ability have been reported in studies comparing decompression with lumbar fusion versus decompression alone in the treatment of symptomatic LSS.⁴ Decompression with lumbar fusion versus decompression alone for LSS results in similar reoperation/revision rates at 2 and 5 years post- surgery (for commercially insured members) and at 2 years post-surgery (for Medicare fee-for-service beneficiaries).^{5 6 7} A 2015 clinical study reported no statistically significant difference in 4 year revision/reoperation rates following LSS related decompression with spinal fusion versus LSS related decompression with an ILS device.¹⁰ Higher rates of major complications, 30 day mortality and resource use have been reported for decompression with lumbar fusion compared to decompression alone.^{7 8 9}

In this context, we analyzed the frequency and cost of LSS-related decompression and lumbar fusion surgeries in a commercially insured population as well as the portion of cases that had a decompression or lumbar fusion in the preceding 4 years. In addition, we calculated the potential cost impact of replacing a portion of primary lumbar spinal fusion surgeries with decompression and ILS.

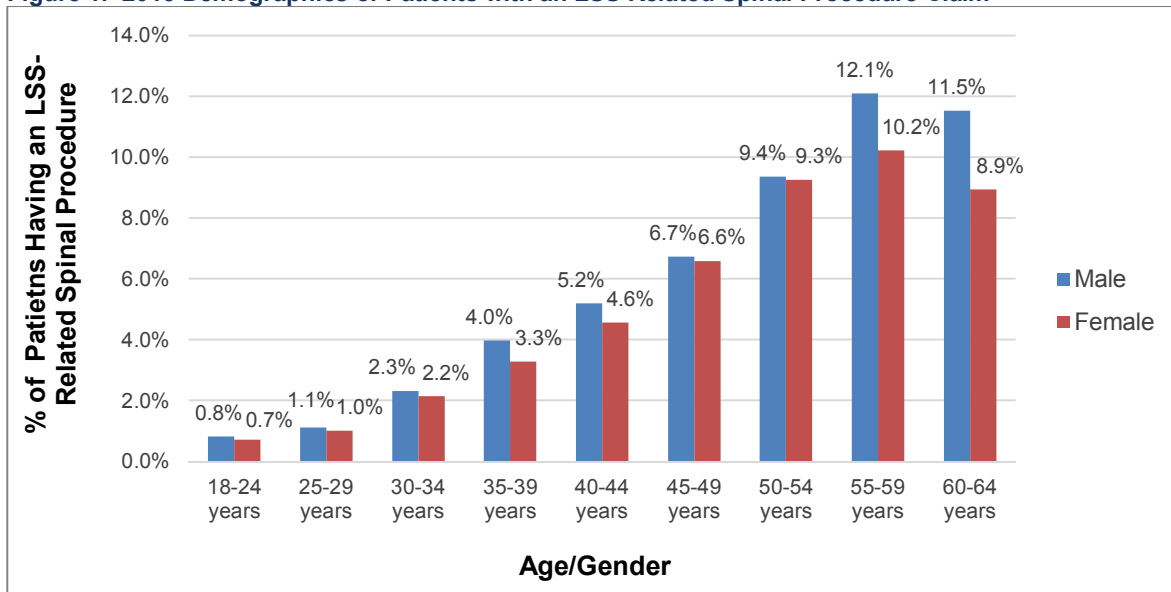
FINDINGS FROM COMMERCIAL CLAIM DATA ANALYSIS

2013 Snapshot analysis

We used the 2013 Truven Health Analytics MarketScan® (MarketScan) commercial data to identify the incidence and annual cost of LSS related spinal procedures including pain injections, epidural injections, decompressions and fusions (see methodology for details of identification criteria).

Figure 1 provides demographic characteristics of the 22,968 members with an LSS-related spinal procedure. The majority of patients are older than 50, and men account for 53.2% of the patients having an LSS-related procedure.

Figure 1: 2013 Demographics of Patients with an LSS Related Spinal Procedure Claim



Source: Milliman analysis of 2013 MarketScan data. See methodology for identification of spinal procedures. Total number of patients with an LSS-related spinal procedure=22,968.
LSS-related procedures include pain injections, epidural steroid injections, decompressions and fusions.

Table 5 provides summary data on the MarketScan 2013 denominator population meeting our standard inclusion criteria (see methodology), as well as the number and incidence rates of patients with an LSS related spinal procedure. Although our interest in this report is LSS related spinal procedures, we also provide incidence of all spinal decompressions and fusions (LSS and non LSS related) to provide context for the portion of total procedures that are LSS related. The counts in Table 5 reflect the number of members with the indicated procedure and do not reflect the count of procedures.

Table 5: 2013 LSS-Related Spinal Procedure Member Count and Incidence

Cohort Description	Member Sample Size and Incidence Rate
2013 MarketScan Denominator Population for Snap Shot Analysis (age 0-64)	29,584,715
Number of 18-64 year olds having a lumbar decompression surgery	26,888
Incidence of 18-64 year olds having a lumbar decompression surgery	0.091%
Number of 18-64 year olds having an LSS-related lumbar decompression surgery	12,236
Incidence of 18-64 year olds having an LSS-related lumbar decompression surgery	0.041%
Number of 18-64 year olds having a lumbar fusion surgery	20,408
Incidence of 18-64 year olds having a lumbar fusion surgery	0.069%
Number of 18-64 year olds having an LSS-related lumbar fusion surgery	9,588
Incidence of 18-64 year olds having an LSS-related lumbar fusion surgery	0.032%
Number of 18-64 year olds having an LSS-related spinal procedure (pain injections, epidural steroid injections, decompressions and fusions)	22,968
Incidence of 18-64 year olds having an LSS-related spinal procedure (pain injections, epidural steroid injections, decompressions and fusions)	0.078%

Source: Milliman analysis of 2013 MarketScan data. See methodology for identification of spinal procedures

Some members had more than one procedure in 2013, and the total number of procedures is shown in Table 6. To calculate the contribution of LSS related spinal procedures to total population spend, we calculated a PMPM cost associated with each procedure based on all claim costs across each procedure type divided by the total population's member months. Cost of decompressions and fusions for inpatient procedures include all allowed cost (facility and professional) from admission through discharge date and for outpatient procedures, all allowed costs on the day of the outpatient procedure. ILS device claims were identified in fewer than 10 decompression cases and were included in the average cost calculation of a decompression. For pain injections and epidural steroid injections, costs include all claim line allowed costs on the procedure claim. Table 6 provides the allowed PMPM cost as well as the utilization/1000 members and the average cost per procedure. The 2013 Denominator Population \$PMPM was \$403.07.

Table 6: 2013 Utilization and Cost of LSS-Related Spinal Procedures by Site of Service

Spinal Procedure Type	Site of Service	Total Procedure Counts	Average Allowed Cost per Procedure	Utilization of each Procedure/ 1000 Members	Allowed \$PMPM for Procedures
Pain Injections	Outpatient	2,852	\$1,062	0.11	\$0.01
Epidural Steroid Injections	Outpatient	18,607	\$1,038	0.74	\$0.06
Surgical Decompressions	Inpatient	3,740	\$20,618	0.15	\$0.26
	Outpatient	9,012	\$9,483	0.36	\$0.28
Surgical Decompressions	All Surgical Decompressions	12,752	\$12,749	0.51	\$0.54
Lumbar Fusions	Inpatient	9,244	\$67,663	0.37	\$2.08
	Outpatient	520	\$27,206	0.02	\$0.05
Lumbar Fusions	All Lumbar Fusions	9,764	\$65,509	0.39	\$2.13
Total		43,975		1.76	\$2.75

Source: Milliman analysis of 2013 MarketScan data. See methodology for identification of spinal procedures. Allowed cost includes the amount contracted by the payer with the provider, including the member's cost sharing payment. Cost of decompressions and fusions for inpatient procedures includes all allowed cost (facility and professional) from admission through discharge date and for outpatient procedures, all allowed costs on the day of the outpatient procedure. For pain injections and epidural steroid injections, cost include all claim line allowed costs on the procedure claim

Table 7 compares the portion of LSS related lumbar fusions and decompressions to all lumbar fusions and decompressions on a procedure count basis and on a PMPM cost basis. The LSS related procedures account for 37% of the decompression \$PMPM and 50% of the spinal fusion \$PMPM.

Table 7: Allowed 2013 \$PMPM for Lumbar Fusions and Decompressions

	All Procedures	LSS related Procedures Only	% Total Procedures that are LSS Related	Allowed \$PMPM for all Procedures	Allowed \$PMPM for LSS Related Procedures	% Total Procedure \$PMPM Contributed by LSS Related Procedures
Surgical Decompressions	28,009	12,752	46%	\$1.45	\$0.54	37%
Lumbar fusions	20,987	9,764	47%	\$4.25	\$2.13	50%
Total	48,996	22,516	46%	\$5.70	\$2.67	47%

Source: Milliman analysis of 2013 MarketScan data. See methodology for identification of LSS related lumbar fusion and decompression. Allowed cost includes the amount contracted by the payer with the provider, including the member's cost sharing payment. Cost of decompressions and fusions for inpatient procedures includes all allowed cost (facility and professional) from admission through discharge date and for outpatient procedures, all allowed costs on the day of the outpatient procedure.

Longitudinal Analysis

We performed a longitudinal analysis in order to identify the portion of 2013 LSS related decompressions and fusions that were “primary” (no prior decompression or fusion in the 4 previous years) and “secondary” (1+ fusion or decompression in the prior 4 years). We performed a 4 year look back to identify the presence of prior decompressions and/or fusions. The look back required that the 2013 snapshot analysis members with decompressions and fusions have eligibility all months of 2009-2012. This limited the 2013 starting denominator population to 6,006,693 and the number of decompressions to 3,393 and fusions to 2,608.

Table 8 provides the incidence of 2013 decompressions and fusions that were primary and secondary based on the 4 year look back. In the 4 years prior to 2013 (2009-2012), 10% of the patients undergoing decompressions in 2013 had a claim for at least one prior decompression or fusion, and 17% of the patients undergoing fusions in 2013 had a claim for at least one prior decompression or fusion.

Table 8: 2013 LSS Related Spinal Procedures by Frequency of Decompression or Fusion in Prior 4 Years

2013 LSS Related Procedure Type	Number of Decompressions in Preceding 4 Years	Number of Fusions in Preceding 4 Years	Total Procedures	Distribution of Procedures by Preceding Number of Decompressions or Fusions
Pain Injections	0	0	594	71%
	1+	0	129	15%
	0	1+	107	13%
	1+	1+	12	1%
Epidural Steroid Injections	0	0	4,095	83%
	1+	0	549	11%
	0	1+	233	5%
	1+	1+	78	2%
Surgical Decompressions	0	0	3,050	90%
	1+	0	267	8%
	0	1+	55	2%
	1+	1+	21	1%
Lumbar Fusions	0	0	2,167	83%
	1+	0	225	9%
	0	1+	185	7%
	1+	1+	31	1%
Total			11,798	

Source: Milliman analysis of 2009-2013 MarketScan data. See methodology for details of longitudinal analysis.

Table 9 provides the years in which the previous decompressions and fusions occurred for those cases with prior decompression and fusions. For decompressions, the majority of the preceding decompressions and fusions occurred in the same or previous year; for fusions, the majority of previous procedures occurred in the same or previous 2 years.

Table 9: Distribution of Prior Surgeries by Longitudinal Years

2013 LSS Related Procedure Type	Number of Decompression / Fusions in Preceding 4 Years	Total 2013 Procedures	Year of Preceding Procedure				
			2009	2010	2011	2012	2013
Surgical Decompressions	0	3,050	N/A	N/A	N/A	N/A	N/A
	1	290	18 (6%)	28 (10%)	39 (13%)	70 (24%)	135 (47%)
	2	43	13 (15%)	8 (9%)	19 (22%)	29 (34%)	17 (20%)
	3+	10	4 (13%)	8 (26%)	4 (13%)	6 (19%)	9 (29%)
Lumbar Fusions	0	2,167	N/A	N/A	N/A	N/A	N/A
	1	359	45 (13%)	55 (15%)	59 (16%)	99 (28%)	101 (28%)
	2	66	10 (8%)	35 (27%)	23 (17%)	35 (27%)	29 (22%)
	3+	16	12 (24%)	10 (20%)	8 (16%)	10 (20%)	10 (20%)

Source: Milliman analysis of 2009-2013 MarketScan data. See methodology for details of longitudinal analysis.

In Table 10, we applied the distribution of LSS related procedures identified as primary and secondary in the longitudinal analysis, to the 2013 snapshot analysis LSS related procedure counts. We calculated a \$PMPM for each category of LSS related spinal procedures. The biggest contributor to LSS related spinal procedures was primary lumbar fusions (no prior decompression or fusion in preceding 4 years) with an amount of \$1.77 PMPM.

Table 10: Application of Longitudinal Analysis Primary and Secondary LSS Related Spinal Procedure Counts to 2013 Snapshot Analysis

LSS Related Spinal Procedure Type	2013 Procedure Count	Number of Decompressions and Fusions in Preceding 4 years	Count of 2013 Procedures by Number of Preceding Decompressions / Fusions	Percentage of 2013 Procedures by Number of Preceding Decompressions/ Fusions	Allowed \$PMPM of Procedures
Pain Injections	2,852	0	2,012	71%	\$0.007
		1	705	25%	\$0.002
		2	105	4%	\$0.000
		3+	30	1%	\$0.000
Epidural Steroid Injections	18,607	0	15,378	83%	\$0.053
		1	2,644	14%	\$0.009
		2	481	3%	\$0.002
		3+	105	1%	\$0.000
Surgical Decompressions	12,752	0	11,463	90%	\$0.487
		1	1,090	9%	\$0.046
		2	162	1%	\$0.007
		3+	38	0%	\$0.002
Lumbar Fusions	9,764	0	8,113	83%	\$1.771
		1	1,344	14%	\$0.293
		2	247	3%	\$0.054
		3+	60	1%	\$0.013
Total	43,975		43,975		\$2.75

Source: Milliman analysis of 2013 MarketScan commercial data. See methodology section.

Allowed cost includes the amount contracted by the payer with the provider, including the member's cost sharing payment. Cost of decompressions and fusions for inpatient procedures includes all allowed cost (facility and professional) from admission through discharge date and for outpatient procedures, all allowed costs on the day of the outpatient procedure. Primary fusion are those without fusion or decompression claims in prior 4 years.

Cost Impact of Replacing LSS-related Primary Lumbar Fusion by Decompression Plus ILS Device

Our goal in this analysis was to consider the potential cost impact of replacing a portion of LSS-related primary lumbar fusions with decompression and intralaminar stabilization (ILS) device.

Table 11 lists our cost assumptions, using the results of our 2013 MarketScan snapshot analysis.

Table 11: Cost Assumptions for Replacing a Portion of Lumbar Fusions with Decompression and ILS device

	Allowed Cost Based on MarketScan 2013 Analysis
Average cost of a lumbar fusion	\$65,509
Average cost of a decompression without ILS device*	\$12,749
Average cost of ILS device**	\$7,000
Allowed \$PMPM for “primary” lumbar fusion	\$1.77
Allowed total population \$PMPM	\$403.07

Source: Milliman analysis of 2013 MarketScan commercial data. See methodology section.

Allowed cost includes the amount contracted by the payer with the provider, including the member’s cost sharing payment. Cost of decompressions and fusions for inpatient procedures includes all allowed costs (facility and professional) from admission through discharge date and for outpatient procedures, all allowed costs on the day of the outpatient procedure. Primary fusions are those without fusion or decompression claims in prior 4 years. ILS: intralaminar stabilization. Average cost of a lumbar fusion and decompression is based on the average cost of the combined primary and secondary cases for each surgery.

*Fewer than 10 of the decompression cases had a claim for an ILS device.

**Cost of ILS device was provided by Paradigm Spine, LLC.

Based on the average cost assumptions in Table 11, we calculated the potential PMPM cost impact associated with 20%, 30% and 40% replacement of primary fusions with decompressions and an ILS device. The cost impact calculations assumes adding the cost of a \$7,000 ILS device to each case. We assumed that there was no difference in post-operative costs for the different surgical options. We also assumed that there was no difference in the rate of revisions or reoperations for the different surgical options. This assumption is based on a 2015 clinical study reporting no statistically significant difference in 4 year revision/reoperation rates following LSS related decompression with spinal fusion versus LSS related decompression with an ILS device.¹⁰ We did not consider any cost impact of adding an ILS device to 2013 *primary* decompressions.

Table 12 shows the results of our calculations. We calculated a potential \$0.25 to \$0.49 PMPM lower cost with replacement of 20-40% of primary lumbar fusions with lumbar decompression and ILS devices.

Table 12: Potential Cost Impact of Replacement of Primary Fusions with Decompression and ILS Device

	20% Replacement	30% Replacement	40% Replacement
Potential allowed \$PMPM impact associated with replacing primary fusions with the cost of decompression and ILS device	(\$0.25)	(\$0.37)	(\$0.49)

Source: Milliman analysis of 2013 MarketScan commercial data. See methodology section.

Allowed cost includes the amount contracted by the payer with the provider, including the member’s cost sharing payment. Cost of decompressions and fusions for inpatient procedures includes all allowed costs (facility and professional) from admission through discharge date and for outpatient procedures, all allowed costs on the day of the outpatient procedure. Primary fusion are those without fusion or decompression claims in prior 4 years. ILS: intralaminar stabilization device. Average cost of a lumbar fusion and decompression is based on the average cost of the combined primary and secondary cases for each surgery. Cost impact assumes adding the cost of ILS to each decompression (\$7000) since fewer than 10 of the decompression cases had a claim for an ILS device.

DISCUSSION

The use of lumbar fusion surgery in the United States has increased significantly over the past 25 years. A retrospective cohort study using national sample administrative data from the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample from 1988 through 2001 reported a 220% increase in lumbar fusions for lumbar spine conditions (not limited to LSS) from 1990 to 2001.¹⁴ A Dartmouth Atlas publication reports a 67% increase in the rate of spinal fusion surgery for LSS among Medicare fee for service beneficiaries from 31.6/100,000 beneficiaries in 2001 to 52.7/100,000 beneficiaries in 2011.¹² A United Health Care commercial claim data analysis, based on a 25 million member population, reported an overall 41% increase in lumbar fusions for lumbar spine conditions (not limited to LSS) between 2004 and 2009, increasing from a rate of 11.6/10,000 members to 16.4/10,000 members. Another Medicare analysis identified a 15 fold increase in complex fusions for LSS between 2002 and 2007 while the rate of simple fusions and decompressions fell.⁸

There is also significant regional variation in the rate of spinal fusion. A Dartmouth Atlas publication reports the rate of spinal fusion surgery for LSS among Medicare fee for service beneficiaries varying by a factor of more than fourteen across hospital referral regions in 2011.¹² A United Health Care commercial claim data analysis based on a 25 million member population, reported 2.5 times as high a rate of lumbar fusions for lumbar spine conditions (not limited to LSS) in some regions compared to others.¹³

Our analysis identified LSS related primary lumbar spinal fusions (that is, lumbar spinal fusion that did not represent a reoperation, based on a 4 year lookback) contribute \$1.77 PMPM of allowed costs for the commercially-insured population. We also identified a \$0.25-\$0.49 lower PMPM associated with replacing 20%-40% of the primary lumbar spinal fusions with surgical decompression and stabilization with an ILS device.

Payers and employers may have an opportunity to favorably impact the cost of care for patients with LSS, without adversely affecting clinical outcomes.

APPENDIX A: METHODOLOGY

Data Source

Truven Health Analytics MarketScan Commercial Claims Database

The Truven Health Analytics MarketScan Commercial Claims Database (MarketScan) contains all paid claims generated by 15-50 million commercially insured lives annually (depending on the year of data). The MarketScan database represents the inpatient and outpatient healthcare service use of individuals nationwide who are covered by the benefit plans of large employers, health plans, government, and public organizations. The data includes diagnosis codes, procedure codes, DRG codes, and NDC codes, along with site of service information and the amounts paid by commercial insurers. The MarketScan database links paid claims and encounter data to detailed patient information across sites and to types of providers. Patient identifiers are consistent over time, allowing for longitudinal studies. The annual medical database includes private sector health data from approximately 100 payers. We used the MarketScan data from 2009-2013.

Claim Data Analysis

Step 1: Identified the 2013 denominator population

The denominator population for the 2013 snapshot analysis included members with:

- At least one month of coverage in 2013
- Prescription drug coverage
- Not covered by a capitated plan
- Not covered by Medicare
- Inclusive of employees and dependents

Step 2: Identified all LSS related spinal procedures occurring in 2013 among 18-64 year olds using the code list below.

List of ICD9 Procedure and CPT/HCPCS codes used to identify LSS related spinal procedures

Procedure Code		Description	Treatment/Procedure Type
HCPCS	20522	Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)	Other Pain Inject
HCPCS	20553	Injection(s); single or multiple trigger point(s), 3 or more muscle(s)	Other Pain Inject
HCPCS	22533	Lateral lumbar spine fusion	Fusion
HCPCS	22534	Lateral thoracic/lumbar additional segment	Fusion
HCPCS	22558	Lumbar spine fusion	Fusion
HCPCS	22585	Additional spinal fusion	Fusion
HCPCS	22586	Presacral fusion w/ instrumentation L5-S1	Fusion
HCPCS	22612	Lumbar spine fusion	Fusion
HCPCS	22614	Spine fusion extra segment	Fusion
HCPCS	22630	Lumbar spine fusion	Fusion
HCPCS	22632	Spine fusion extra segment	Fusion
HCPCS	22633	Lumbar spine fusion combined	Fusion
HCPCS	22634	Spine fusion extra segment	Fusion

Procedure Code		Description	Treatment/Procedure Type
HCPCS	22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)	Fusion
HCPCS	62282	Injection/infusion of neurolytic substance (e.g., alcohol, phenol, iced saline solutions), with or w/o other therapeutic substance; epidural, lumbar, sacral	Other Pain Inject
HCPCS	62311	Inject spine lumbar/sacral	Epidural
HCPCS	62319	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus	Other Pain Inject
HCPCS	63005	Remove spine lamina 1/2 lumbar	Decompression
HCPCS	63017	Remove spine lamina >2 lumbar	Decompression
HCPCS	63030	Low back disk surgery	Decompression
HCPCS	63035	Spinal disk surgery add-on	Decompression
HCPCS	63042	Laminotomy single lumbar	Decompression
HCPCS	63044	Laminotomy additional lumbar	Decompression
HCPCS	63047	Remove spine lamina 1 lumbar	Decompression
HCPCS	63048	Remove spinal lamina add-on	Decompression
HCPCS	63056	Decompress spinal cord lumbar	Decompression
HCPCS	63057	Decompress spine cord add-on	Decompression
HCPCS	64412	Injection, anesthetic agent; spinal accessory nerve	Other Pain Inject
HCPCS	64479	Injection foramen epidural cervical/thoracic	Epidural
HCPCS	64480	Injection foramen epidural add-on	Epidural
HCPCS	64483	Injection foramen epidural lumbar/sacral	Epidural
HCPCS	64484	Injection foramen epidural add-on	Epidural
HCPCS	64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level	Other Pain Inject
HCPCS	64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level (List separately in addition to code for primary procedure)	Other Pain Inject
HCPCS	64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)	Other Pain Inject
HCPCS	64520	Injection, anesthetic agent; lumbar or thoracic (paravertebral sympathetic)	Other Pain Inject
HCPCS	72275	Epidurography, radiological supervision and interpretation	Epidural
HCPCS	0171T	Insertion of posterior spinous process distraction device, single level	Decompression
HCPCS	0172T	Insertion of posterior spinous process distraction device, each additional level	Decompression

Procedure Code		Description	Treatment/Procedure Type
HCCPS	0230T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with us guidance, lumbar or sacral, single level	Epidural
HCCPS	0231T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with us guidance, lumbar or sacral, each additional level	Epidural
HCCPS	0275T	Percutaneous laminotomy/laminectomy, lumbar	Decompression
HCCPS	0309T	Arthrodesis, pre-sacral interbody technique, discectomy, lumbar, L4-5 interspace	Fusion
HCCPS	C1821	Interspinous process distraction device (implantable)	Decompression
ICD-9 Proc	03.02	reopening of laminectomy site	Decompression
ICD-9 Proc	03.09	other exploration and decompression of spinal canal	Decompression
ICD-9 Proc	03.91	anaesthesia inject-spin canal	Epidural
ICD-9 Proc	03.92	spinal canal inject not elsewhere classified	Epidural
ICD-9 Proc	80.50	excision/destruction intervertebral disc not otherwise specified	Decompression
ICD-9 Proc	80.51	excision intervertebral disc	Decompression
ICD-9 Proc	81.00	spinal fusion nos	Fusion
ICD-9 Proc	81.04	dorsal/dorsal-lumbar anterior/anterior fusion anterior/anterior	Fusion
ICD-9 Proc	81.05	dorsal/dorsal-lumbar fusion posterior/posterior	Fusion
ICD-9 Proc	81.06	lumbar/lumbosacral fusion anterior/anterior	Fusion
ICD-9 Proc	81.07	lumbar/lumbosacral fusion posterior/posterior	Fusion
ICD-9 Proc	81.08	lumbar/lumbosacral fusion anterior/posterior	Fusion
ICD-9 Proc	81.30	spinal refusion not otherwise specified	Fusion
ICD-9 Proc	81.34	refusion dorsal/dorsal-lumbar anterior/anterior	Fusion
ICD-9 Proc	81.35	refusion dorsal/dorsal-lumbar posterior/posterior	Fusion
ICD-9 Proc	81.36	refusion lumbar/lumbosacral anterior/anterior	Fusion
ICD-9 Proc	81.37	refusion lumbar/lumbosacral posterior/posterior	Fusion
ICD-9 Proc	81.38	refusion lumbar/lumbosacral anterior/posterior	Fusion
ICD-9 Proc	81.39	refusion of spine not elsewhere classified	Fusion
ICD-9 Proc	84.51	ins spinal fusion device	Fusion
ICD-9 Proc	84.80	insertion/replacement interspine device	Decompression
ICD-9 Proc	84.81	revision interspine device	Decompression
ICD-9 Proc	84.84	Insert/replace facet replacement device	Decompression
ICD-9 Proc	84.85	rev facet replace device	Decompression

Step 3: Included only procedures that had:

- An LSS ICD-9 diagnosis code on the procedure claim: 724.00, 724.02, 724.03, 724.09
- OR an LSS associated DRG for the inpatient procedure and LSS coded on 1+ claim during 2013 – see table below
- OR an LSS associated ICD-9 diagnosis code on the primary position of the outpatient procedure and LSS coded on 1+ claim during 2013 – see table below
- Excluded all scoliosis cases identified as procedures coded with the following ICD-9 diagnosis codes in any position of the claim: 737.30-737.34, 737.39

DRGs and Primary ICD-9 Diagnosis codes required for IP and OP Procedures without an LSS diagnosis coded on the procedure

Procedure Code		Description
DRG	028	Spinal procedures w MCC
DRG	029	Spinal procedures w CC or spinal neurostimulators
DRG	030	Spinal procedures w/o CC/MCC
DRG	453	Combined anterior/posterior spinal fusion w MCC
DRG	454	Combined anterior/posterior spinal fusion w CC
DRG	455	Combined anterior/posterior spinal fusion w/o CC/MCC
DRG	456	Spinal fusion except cervical with spinal curvature/malignancy/infection or 9+ fusion w MCC
DRG	457	Spinal fusion except cervical with spinal curvature/malignancy/infection or 9+ fusion w CC
DRG	458	Spinal fusion except cervical with spinal curvature/malignancy/infection or 9+ fusion w/o CC/MCC
DRG	459	Spinal fusion except cervical w MCC
DRG	460	Spinal fusion except cervical w/o MCC
DRG	052	Spinal disorders & injuries w CC/MCC
DRG	053	Spinal disorders & injuries w/o CC/MCC
DRG	490	Back & neck proc except spinal fusion w CC/MCC or disc device/neurostimulator
DRG	491	Back & neck proc except spinal fusion w/o CC/MCC
DRG	518	Back & Neck Proc Except Spinal Fusion W MCC Or Disc Device/Neurostimulator
DRG	519	Back & Neck Proc Except Spinal Fusion W CC
DRG	520	Back & Neck Proc Except Spinal Fusion W/O CC/MCC
DRG	551	Medical back problems w MCC
DRG	552	Medical back problems w/o MCC
DRG	553	Bone diseases & arthropathies w MCC
DRG	554	Bone diseases & arthropathies w/o MCC
DRG	555	Signs & symptoms of musculoskeletal system & conn tissue w MCC

Procedure Code		Description
DRG	556	Signs & symptoms of musculoskeletal system & conn tissue w/o MCC
DRG	559	Aftercare, musculoskeletal system & connective tissue w MCC
DRG	560	Aftercare, musculoskeletal system & connective tissue w CC
DRG	561	Aftercare, musculoskeletal system & connective tissue w/o CC/MCC
DRG	856	Postoperative or post-traumatic infections w O.R. proc w MCC
DRG	857	Postoperative or post-traumatic infections w O.R. proc w CC
DRG	858	Postoperative or post-traumatic infections w O.R. proc w/o CC/MCC
DRG	862	Postoperative & post-traumatic infections w MCC
DRG	863	Postoperative & post-traumatic infections w/o MCC
ICD-9 Diag	338.18	acute postop pain not elsewhere classified
ICD-9 Diag	338.19	acute pain not elsewhere classified
ICD-9 Diag	338.28	chronic postop pain not elsewhere classified
ICD-9 Diag	338.29	chronic pain not elsewhere classified
ICD-9 Diag	338.4	chronic pain syndrome
ICD-9 Diag	344.60	cauda equina syndrome not otherwise specified
ICD-9 Diag	344.61	neurogenic bladder
ICD-9 Diag	353.1	lumbosacral plexus lesion
ICD-9 Diag	353.4	lumbosacral root lesion not elsewhere classified
ICD-9 Diag	355.0	sciatic nerve lesion
ICD-9 Diag	720.81	spondylopathy in other diseases
ICD-9 Diag	721.3	lumbosacral spondylosis
ICD-9 Diag	721.42	Spondylopathy with compression of lumbar spinal cord
ICD-9 Diag	721.8	spinal disorders not elsewhere classified
ICD-9 Diag	721.90	spondylosis not otherwise specified w/o myelopathy
ICD-9 Diag	721.91	spondylosis not otherwise specified w myelopathy
ICD-9 Diag	722.10	lumbar disc displacement
ICD-9 Diag	722.2	disc displacement not otherwise specified
ICD-9 Diag	722.52	lumbar/lumbosacral disc degeneration
ICD-9 Diag	722.6	disc degeneration not otherwise specified
ICD-9 Diag	722.70	disc disease w myelopathy not otherwise specified
ICD-9 Diag	722.73	lumbar disc disease w myelopathy
ICD-9 Diag	722.80	postlaminectomy syndrome not otherwise specified
ICD-9 Diag	722.83	postlaminectomy syndrome-lumbar
ICD-9 Diag	722.90	disc disease not elsewhere classified/not otherwise specified-unspecified
ICD-9 Diag	722.93	disc disease not elsewhere classified c/nos-lumbar
ICD-9 Diag	724.00	spinal stenosis not otherwise specified
ICD-9 Diag	724.02	spinal stenosis, lumbar wo claudication
ICD-9 Diag	724.03	spin stenosis, lumbar w claudication
ICD-9 Diag	724.2	lumbago

Procedure Code		Description
ICD-9 Diag	724.3	sciatica
ICD-9 Diag	724.4	lumbosacral neuritis not otherwise specified
ICD-9 Diag	724.5	backache not otherwise specified
ICD-9 Diag	724.6	disorders of sacrum
ICD-9 Diag	724.8	other back symptoms
ICD-9 Diag	724.9	back disorder not otherwise specified
ICD-9 Diag	737.12	postlaminectomy kyphosis
ICD-9 Diag	737.21	postlaminectomy lordosis
ICD-9 Diag	737.22	other postsurgery lordosis
ICD-9 Diag	756.11	lumbosacral spondylolysis
ICD-9 Diag	756.12	spondylolisthesis
ICD-9 Diag	V57.89	rehabilitation proc not elsewhere classified
ICD-9 Diag	V57.9	rehabilitation procedure not otherwise specified
ICD-9 Diag	V58.78	aftercare surgery musculoskeletal system not elsewhere classified

Step 4: Calculated costs

We identified site of service of LSS related procedures using POS codes 21 for inpatient and 11, 22, 24 for outpatient. All costs from admission through discharge date are included in the cost of an inpatient LSS related decompression and fusion. All costs on the day of an outpatient procedure are included in the cost of an outpatient LSS related decompression and fusion. We calculated the average cost of decompression and fusion using the weighted average of the inpatient and outpatient cases. The average cost of an LSS related outpatient pain injection and epidural treatment reflect all claim line cost for each pain injection and epidural claim. To calculate a \$PMPM cost associated with each procedure, we added the claim cost of all procedures and divided by the total member months of the denominator population.

REFERENCES

- ¹ Kovacs FM, Urrutia G, Alarcon JD. Surgery versus conservative treatment for symptomatic lumbar spinal stenosis: a systematic review of randomized controlled trials. *Spine*. 2011;36:E1335-1351.
- ² May S, Comer C. Is surgery more effective than non-surgical treatment for spinal stenosis, and which non-surgical treatment is more effective? A systematic review. *Physiotherapy*. 2013;99:12-20.
- ³ Weinstein JN, Tosteson TD, Lurie JD et.al. Surgical versus non-surgical therapy for lumbar spinal stenosis. *N Eng J Med*. 2008;358:794-810.
- ⁴ Machado GC, Ferreira PH, Harris IA et al. Effectiveness of surgery for lumbar spinal stenosis: A systematic review and meta-analysis. *PLoS ONE*. 2015;10:1-18.
- ⁵ Lad SP, Huang KT, Bagley JH et. al. Disparities in the outcomes of lumbar spinal stenosis surgery based on insurance status. *Spine*. 2013;38:1119-1127.
- ⁶ Shivanand PL, Babu R, Ugiliweneza B et.al. Surgery for spinal stenosis: long term reoperation rates, health care cost and impact of instrumentation. *Spine*. 2014; 39:978-987.
- ⁷ Deyo RA, Martin BJ, Ching A et.al. Interspinous spacers compared to decompression or fusion for lumbar stenosis: complications and repeat operations in the Medicare population. *Spine*. 2013; 38:865-872.
- ⁸ Deyo RA, Mirza SK, Martin BI et. al. Trends, major medical complications and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA*. 2010;303:1259-1265.
- ⁹ Katz JN, Lipson SJ, Lew RA et.al. Lumbar laminectomy alone or with instrumented or noninstrumented arthrodesis in degenerative lumbar spinal stenosis. Patient selection, costs, surgical outcomes. *Spine*. 1997;22:1123-1131.
- ¹⁰ Bae HW, Laurysen C, Maislin G et. al. Therapeutic sustainability and durability of Coflex interlaminar stabilization after decompression for lumbar spinal stenosis: a four year assessment. *Int J Spine Surg*. 2015 May 11;9:15.
- ¹¹ Martin BI, Tosteson AN, Lurie JD et.al. Variation in the care of surgical conditions: spinal stenosis, A Dartmouth Atlas of Health Care Series. The Dartmouth Institute for Health Policy and Clinical Practice. 2014. Accessed at: http://www.dartmouthatlas.org/downloads/reports/Spinal_stenosis_report_10_29_14.pdf
- ¹² Pannell WC, Savin DD, Scott TP et. al. Trends in the surgical treatment of lumbar spine disease in the United States. *The Spine Journal*. 2015;15:1719-1727
- ¹³ Kalichman L, Cole R, Kim DH et.al. Spinal stenosis prevalence and association with symptoms: The Framingham Study. *Spine*.2009;9:1-12.
- ¹⁴ Deyo RA, Gray DT, Kreuter W. et. al. United States trends in lumbar fusion surgery for degenerative conditions. *Spine*. 2005;30:1441-1445.