St. Jude Medical 2014 Neuromodulation Spinal Cord Stimulation (SCS) Reimbursement Prospectus

Medicare's calendar year 2014 (CY 2014) final rules for hospital outpatient, ambulatory surgical center (ASC) and physician fee schedule (PFS) carry with them a number of key changes to payment rate amounts, as well as policy updates that will affect physician, hospital and ASC reimbursement for spinal cord stimulation (SCS) procedures. In this brief prospectus document, St. Jude Medical reflects the new ways in which healthcare providers may manage risk, including potentially lowered fees and new bundled procedure payments.

On November 27, 2013, the Centers for Medicare & Medicaid Services (CMS) released the CY 2014 OPPS/ASC and PFS Final Rules, effective for services on January 1, 2014.[1,2] Under the PFS rule, the sustainable growth rate calculation that adjusts payments to maintain budget neutrality would force a reduction in physician fees of 20.1%; however, Congress has historically provided a reprieve each year regarding the fee reduction. The payment rates listed below assume that Congress will step in again and remove the fee reduction by freezing the 2014 conversion factor utilized to calculate physician payments at 2013 levels.

St. Jude Medical has further analyzed the varying impact to individual CY 2014 facility and physician payments, for SCS procedures. Payment rates for SCS procedures show an effective decrease for physicians performing in-office trials; whereas facilities supporting similar procedures will experience identified increases. Specific settings of care where these procedures are expected to be differently impacted in CY 2014, relative to CY 2013 levels include the following:

Physician Reimbursement Changes

Technology	CPT	Description	2013	2014	
			Facility	Facility	Non-Facility
Leads	63650	Implant neuroelectrodes, percutaneous	$437	$406	$1,282
	63655	Implant neuroelectrodes, laminectomy	$842	$805	NA
	63661	Removal neuroelectrodes, percutaneous array	$326	$313	$555
	63662	Removal neuroelectrodes, spinal plate/paddle	$787	$752	NA
	63663	Revision including replacement neuroelectrodes, percutaneous array	$472	$450	$771
	63664	Revision including replacement neuroelectrodes, spinal plate/paddle	$805	$778	NA
IPG	63685	Insertion or replacement spinal neurostimulator	$370	$355	NA
Programming	95970	Analysis of IPG, no programming	$24	$23	$66
	95971	Analysis of simple IPG, with programming	$40	$39	$58
	95972	Analysis of complex IPG, with programming, first hour	$78	$76	$104
	95973	Analysis of complex IPG, with programming, each additional 30 minutes	$48	$47	$61

[1] Final PFS CY 2014 Rule: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html

[2] Final OPPS/ASC CY 2014 Rule: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/

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OPPS/ASC Changes

	HOSPITAL OUTPATIENT - APC					ASC		
Procedure	APC	Description	Status Indicator	2013	2014	Payment Indicator	2013	2014
Percutaneous Lead	0040	Level I Implantation/ Revision/Replacement of Neurostimulator Electrodes	S	$4,400	$4,627	J8	$3,551	$3,692
Laminectomy Lead	0061	Level II Implantation/ Revision/Replacement of Neurostimulator Electrodes	S	$6,792	$7,424	J8	$5,861	$6,296
IPG	0039	Level I Implantation of Neurostimulator Generator	S	$16,395	$17,233	J8	$15,431	$16,172

S - Not subject to multiple surgical reduction

J8 - Device-intensive procedure; paid at adjusted rate

New Physician Payment Rates for In-Office Spinal Cord Stimulation Trials

CMS has evaluated the cost and payment rates associated with in-office SCS trials, and effective CY 2014 has made a significant change in how spinal cord stimulation trials are billed in a physician's office (a "non-facility" setting). Medicare announced that they would incorporate the cost of the leads, which in the past have typically been billed under HCPCS code L8680 on a per electrode basis, into CPT 63650 as non-facility direct Practice Expense (PE) for 2014. Beginning January 1, 2014, code L8680 will no longer be appropriate for billing Medicare for an in-office trial. CPT 63650 will be billed for each lead implanted and has been revalued to include the cost of trial leads.

Additionally, CPT 63650, which is used to remunerate clinicians for implantation of percutaneous leads, is subject to multiple procedure reduction. This means that CMS will pay the highest value CPT code at 100% and each additional CPT code at 50%. As a result, the base payment for an in-office SCS trial with two percutaneous leads is $1,923 (please note, the payment amounts listed in this prospectus assume that the conversion factor to determine Medicare fee schedule amounts for 2014 will remain consistent with 2013 levels). The table below shows the difference in billing and payment rates for in-office SCS trials between 2013 and 2014:

CPT	Description	Payment 2013	Payment 2014	Difference
63650	Implant neuroelectrodes, percutaneous	$437	$1,282	$844
63650	Implant neuroelectrodes, percutaneous	$219	$641	$422
L8680	Implantable neurostimulator electrode, each (16 contacts)	$6,902	NA	($6,902)
	Total	**$7,588**	**$1,923**	**($5,636)**
	Difference			**-75%**

*Individual provider reimbursement will vary.

Please note these reflect billing and payment changes for Medicare patients for services provided on or after January 1, 2014. Other payers may have different billing instructions and may still require billing L8680 for in-office SCS trials. For other payers besides Medicare, we recommend contacting the payer directly should you have questions regarding the appropriate billing for in-office SCS trials.

For more information on how Medicare's rule making or reform initiatives may impact your facility or institution, please contact the St. Jude Medical Healthcare Economics team at (855) 569-6430 or at HCE@sjm.com.

This update is intended to provide general information to assist the reader in better understanding the CY 2014 OPPS / ASC and PFS Final Rules published by the Centers for Medicare & Medicaid Services. We encourage readers to review the regulation and other interpretive materials for a full and accurate understanding of the contents. This information does not guarantee coverage or payment at any specific level.

This information is provided to assist the recipient to understand the alternative codes and payment amounts that may be available when St. Jude Medical products are used. This information is for reference purposes only. It is not provided or authorized for marketing use. Note that codes, coverage, and payment can vary from setting to setting, and from insurer to insurer. This information does not guarantee that use of any particular codes will result in coverage or payment at any specific level. Insurers make reimbursement decisions according to the insurer's evaluation of the patient's medical needs. The provider should select the code or codes that most accurately describe the patient's conditions and the procedures performed and products used. The provider should fully comply with the insurer requirements in submitting claims. The billing entity is solely responsible for the accuracy of the codes submitted.

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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications for Use: Spinal cord stimulation as an aid in the management of chronic, intractable pain of the trunk and limbs.

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