XTANT MEDICAL

Silex Reimbursement Resource Guide

Prepared by Musculoskeletal Clinical Regulatory Advisers, LLC. (MCRA) Ver. 2017.

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Technology Description
Silex® Soft Tissue Shield Technique

The Silex® soft tissue shield technique procedure, per the product guide, begins with a lateral incision along the posterior sacral wall, approximately 3-5mm in length and Steinmann pin inserted, placement is radiographically confirmed and a soft tissue shield is placed over the Steinmann pin. A drill is used to access the SI joint and placement is again confirmed radiographically. Decortication of the SI joint prepares the space for bony arthrodesis. The bone graft is inserted into the implant and is inserted through the soft tissue shield and Steinmann pin, under fluoroscopy, to the desired depth. Additional bone graft may be inserted through a bone graft funnel. The procedure is repeated for the second and third implant.

Technology Description
Silex® Open or Mini-Open Technique

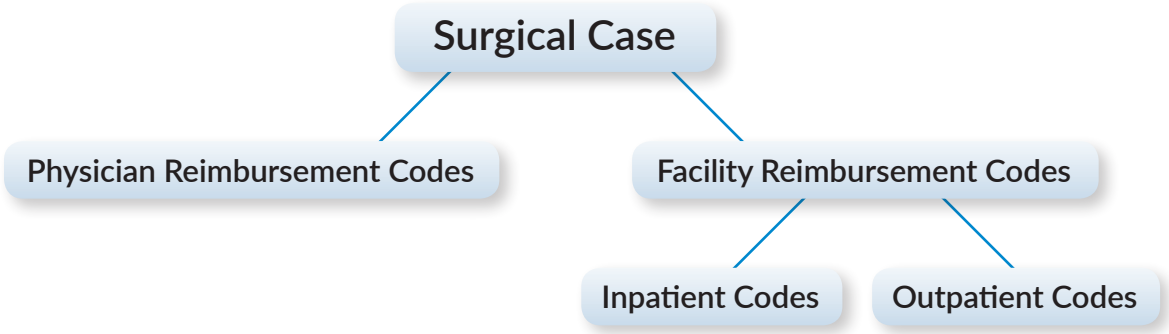
The Silex® open technique procedure, per the product guide, begins with an incision along the posterior two-thirds of the iliac crest following the posterior superior iliac spine. The surgeon uses the preferred retraction method to access and visualize the symptomatic SI Joint. The surgeon then cuts into the ilium and removes a block of bone as well as any relative cartilage. Once the cartilage removal is complete, the surgeon places the bone back so it contacts the sacral bone, making sure the block is secure in order to prepare the SI Joint for boney arthrodesis. A Right- Angled Curette or any other preferred medical instrument is used to decorticate, remove cartilage and prepare the SI Joint for boney arthrodesis. The SI joint is decorticated and prepared for boney arthrodesis under direct visualization. After decortication is complete, a lateral incision is made along the posterior sacral wall, approximately 3-5mm in length and the Steinmann pin inserted, placement is radio graphically confirmed and the implants placed. Further decortication and visualization of the SI joint is performed and bone graft is implanted. The procedure is repeated for the second and third implant.

The use and reporting of Xtant Silex® technology and products are supported by this reimbursement resource guide. FDA premarket clearance 510k letters are provided in the Reimbursement Tool Kit as part of this resource guide.

This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of November 2015 and is based upon publicly available source information.

Whenever code assignment is discussed for new or existing procedures or technologies, the different coding and reimbursement pathways and types of code sets used should be reviewed. Distinct code sets are used to report various aspects of procedures and technologies for reimbursement depending on the entity billing the case.

Reimbursement pathways and appropriate code sets take two directions resulting in two separate reimbursements for a single patient encounter when performed in a facility. Physicians report their work separately from the facility where the procedure is performed. This in turn creates unique coding pathways for each side of the equation that results in appropriate reimbursement from third party payors (such as Medicare or private payors).



Surgeon Codes – Physician services and surgical procedures are reported using Common Procedural Terminology (CPT) codes. These codes are created by the American Medical Association (AMA). The creation and adoption of CPT codes involves a process controlled by the AMA/CPT Editorial Panel that approves new codes and code descriptions per a set of defined standards and review process criteria.[1] New technologies and procedures are evaluated and assigned codes depending on the opinions of this panel, relevant society input and clinical literature establishing efficacy of the procedure. This is in addition to FDA approval, which must be obtained prior to consideration for a new code.

Following adoption of a new CPT code (either a Permanent CPT code or a Temporary (Category III) CPT code) the process of evaluating the code begins. The Centers for Medicare and Medicaid Services (CMS) works alongside the AMA/CPT process and commonly (but not always) adopts CPT codes created by the AMA Editorial Panel. Through its Relative Value Scale Update Committee (RUC) the AMA then begins the valuation of the code by establishing Relative Value Units (RVUs) based on a complex system that incorporates surgeon experience reports, work involved, time elements, skill measurements and a host of other factors on which to base Medicare reimbursement.[2] Although CMS adopts the RVU value, this is also often used by private payors to create their physician fee schedules and payments.

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[1] American Medical Association Website. CPT-Current Procedural Terminology. Available at: http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page. (Accessed December 2016).

[2] American Medical Association Website. The RVS Update Committee. Available at: http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-recource-based-relative-value-scale/the-rvs-update-committee.page. (Accessed December 2016)

Permanent (Category I) CPT Codes both existing and newly created, for physician procedures and services, have met the qualifications outlined by the AMA/CPT Editorial Panel and typically have established RVU values that can be directly used to determine reimbursement. These RVU values are multiplied by a conversion factor (published yearly by CMS or established per contract by private payors) to provide payment for surgeon services within coverage guidelines. Just because a permanent CPT code exists does not mean that it will be paid. All reimbursement is subject to coverage guidelines and payor policies.

Temporary (Category III) CPT "T" Codes for physician procedures and services, have met the qualifications outlined by the AMA/CPT Editorial Panel for temporary code status. New technologies that do not qualify for a new permanent CPT code are often assigned these "T" codes to provide a means of tracking procedures and collecting data essential to becoming a permanent CPT code. "T" codes are not assigned RVU values, do not have established national Medicare reimbursement rates and are set to "sunset" or retire in 5 years unless there is a change requested to extend usage or transition to permanent CPT codes. Reporting temporary codes for reimbursement requires that additional information to be submitted to the payor following their guidelines.

"Unlisted" CPT Codes "Unlisted" permanent CPT codes are used to report procedures that do not precisely fall into the description of a current CPT code per CPT/AMA guidelines. CPT coding guidelines require that CPT codes be assigned to procedures that exactly match the current use and description of a published code. Unlisted codes are often used for new technologies as they come to market and require that surgeons reporting these codes provide the payor with an explanation of the procedure as performed and a request for reimbursement based on the detail and medical necessity of the case.

Facility Codes Surgical procedures are performed in either the outpatient or inpatient setting of care, as determined by the physician. Each setting utilizes a different code set to report their services to the payor for reimbursement. This is in addition to the surgeon, who reports his services separately with CPT codes.

Outpatient APC Codes are based on the same CPT codes reported by physicians but these are typically mapped to or placed into a second code set called APC Codes. Ambulatory Payment Classification (APC) codes combine CPT procedure services into like groupings that utilize similar resources in the outpatient setting and are paid an established rate for the APC. These APC code sets can be reported and reimbursed singularly or in inclusive groupings, as determined by payor guidelines. Government payors and some private payors use this system but reimbursement guidelines can differ considerably depending on the payor and contracted agreements. Medicare reimbursement rates are determined by the Outpatient Prospective Payment System (OPPS) and are published semi-annually.[3]

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[3] Centers for Medicare & Medicaid Services Medicare Learning Network. Hospital Outpatient Prospective Payment System. Available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HospitalOutpaysysfctsht.pdf. (Accessed December 2016)

HCPCS Level II Codes Outpatient reporting also requires that implantable devices and biologics used in procedures be coded separately using the Healthcare Common Procedure Coding System (HCPCS) Level II Codes. This code set allows line item reporting of products used in procedures that are not already included within the reimbursement rate for the reported APC. This system differs for government payors where a pass-through payment code must be adopted and valued by CMS, and private payors, who use the HCPCS code to determine contracted rates with more generalized codes.

Inpatient ICD-10-CM Codes International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code set was implemented on October 1, 2015. This change impacts the specificity of diagnosis coding. When reporting procedures after October 1st 2015, care should be taken to include ICD-10-CM diagnosis coding specifics for all procedures. ICD-10-CM diagnosis codes report the patient diagnoses for each inpatient stay. These codes are always patient specific and provide this important information to payors when establishing the MS-DRG for inpatient reimbursement. Note that this diagnosis system will also be used by surgeons to report patient diagnoses and should be consistent with any facility reported diagnosis codes.

Inpatient ICD-10-PCS Codes International Classifications of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) code set reporting inpatient procedures performed on the patient during the hospital stay, was implemented on October 1, 2015. These hospital procedure codes are more specific in reporting the procedure performed as to approach used and anatomic level than the previous ICD-9 code set. Specific diagnoses and detailed procedure coding is important to ensure correct assignment of the MS-DRG code that determines the total inpatient reimbursement. It is important that all ICD-10-PCS procedure codes be reported to capture the use of a device and map to the appropriate MS-DRG reported.

MS-DRG Codes Medicare Severity, Diagnosis Related Grouping (MS-DRG) codes are used to report hospital inpatient stays for reimbursement. These codes are groupings that represent the entire patient stay at the inpatient facility, inclusive of all services, costs and devices utilized during the episode of care. There are typically no line item reimbursements for devices as in the outpatient setting of care.

CPT Code Modifiers In specific cases it is sometimes necessary to submit a CPT code with a modifier. Modifiers indicate that a reported service has been altered by a specific circumstance but that the CPT code description has not changed. Modifiers enable healthcare professionals to report services more accurately and to provide detail and clarity to the third party payor per required guidelines and policies. The following table provides a list of some common CPT code modifiers. Complete lists are available in the AMA/CPT book and online on the Medicare website.

Modifier	Description
-22	**Increased Procedural Services.** When the work required to provide a service is significantly increased beyond the typical work required a modifier -22 may be appended. The documentation must support the increased services and the reasoning. (Examples include; increased time, technical difficulty, severity of patient condition, increased effort.)
-26	**Professional Component.** Some procedures have both a professional and technical component. When the modifier -26 is appended to the professional service the components may be paid separately per payor guidelines.
-50	**Bilateral Procedure.** When CPT codes are not identified as bilateral in the code description or parenthetical a modifier -50 may be appended when the procedure is performed bilaterally.
-51	**Multiple Procedures.** When more than one procedure is performed at the same session a modifier -51 is appended to additional procedures. It is not appended to codes listed as "add-on" codes.
-59	**Distinct Procedural Service.** Modifier -59 is used to report separate services that are distinct or independent and not normally reported together. Documentation must support the distinct service (Example; separate area of injury in extensive injuries)
Effective January, 1 2015 CMS has established four new modifiers to define specific subsets of the -59 modifier. Modifier -59 is still recognized but should not be used when a more descriptive modifier is available. The newly created -X{EPSU} modifiers are below.[4]	
-XE	**Separate Encounter**, A Service That Is Distinct Because It Occurred During A Separate Encounter
-XS	**Separate Structure**, A Service That Is Distinct Because It Was Performed On A Separate Organ/Structure
-XP	**Separate Practitioner**, A Service That Is Distinct Because It Was Performed By A Different Practitioner
-XU	**Unusual Non-Overlapping Service**, The Use Of A Service That Is Distinct Because It Does Not Overlap Usual Components Of The Main Service

[4] MLN Matters®Number MM8863
http://cms.gov/Outreach-and-Education/Medicare-Learning-Network- MLN/MLNMattersArticles/Downloads/MM8863.pdf

Coding pathway information is intended for provider guidance and allows the physician to consider his or her reporting pathways on a case by case basis. Final decision-making regarding coding guidelines for specific third party payors remains in the hands of the provider. Ultimately, the provider has a better understanding of the coding pathways available and how to use them appropriately in the outpatient and inpatient facility settings of care.

Coding Pathways

Silex® Soft Tissue Shield Technique

Diagnosis Coding:

Diagnosis codes are assigned by the physician to accurately report the patient's condition as it relates to the procedure. Below is a list of diagnosis codes and definitions that may apply to patients requiring a sacroiliac joint fusion procedure. This is only a list of possible codes that represent the typical diagnose associated with the procedure and is not intended to be a complete list. No actual patient condition is represented by the examples provided.

ICD-10-CM Diagnosis Code	
ICD-10-CM Code[5]	Diagnosis Description
M46.1	Sacroiliitis, not elsewhere classified

[5] 2017 ICD-10-CM, 2016, AAPC

Physician Coding

Physicians bill Medicare and other payors separately for services performed, regardless of whether the service takes place in the physician's office, a hospital or other outpatient facility. Procedure codes identify the specific treatment that is performed on the patient. It is possible to report more than one procedure code on a claim form, and the type of payor and setting of care often dictate whether the services are paid independently or as a single bundled payment.

Physicians report their surgical work, with CPT codes, separately to payors. The following code pathway would be reported when a soft tissue shield, minimally invasive, sacroiliac joint fusion procedure is performed using the Silex® Sacroiliac Joint Fusion System.

Note that CPT 27279 is a unilateral code. For bilateral procedures, report 27279 with modifier 50. See modifier description in coding basics section of this Resource Guide. If performed bilaterally, some payors require that the service be reported twice with modifier -50 appended to the second code while others require identification of the service only once with modifier -50 appended. Check with individual payors. Modifier -50 identifies a procedure performed identically on the opposite side of the body (mirror image).

Physician Coding Pathways			
CPT-4 Code[6]	**CPT Description**	**RVU's 2017**	**Medicare National Average Payment 2017[7]**
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	19.93	$715.26

[6] CPT 2017 Professional Edition, 2016 American Medical Association (AMA); CPT is a trademark of the AMA

[7] 2017 Medicare Physician Fee Schedule RVU multiplied by 2016 conversion factor, effective January 2017 www.cms.gov

Hospital Outpatient and Ambulatory Surgical Center Coding Pathway

Procedures performed in the hospital outpatient or ASC setting of care are reported to third party payors utilizing a system of CPT code, ambulatory payment classification (APC) codes and comprehensive ambulatory payment classification (C-APC) codes. Payment methodologies differ with payor guidelines including Medicare, government payors and private commercial insurers. Specific payor guidelines should be followed for each case when the physician selects codes for documented procedure.

Hospital Outpatient/ASC Coding Pathways						
			Hospital Outpatient[8]		ASC[9]	
CPT-4 Code	APC Description	APC	Status Indicator	Medicare Payment 2017	Payment Indicator	Medicare Payment 2017
27279	Level V Musculoskeletal Procedures Except Hand and Foot	5116	J1	$14,697.92	J8	$12,552.68

Status Indicator J1 in the hospital outpatient setting of care and payment indicator J8 in the ambulatory surgery center setting of care indicate that the assigned APC is a comprehensive APC (C-APC) and includes all services and procedures performed and supplies utilized during the patient encounter for the primary procedure. The C-APC for the CPT code 27279 is considered a device intensive C-APC and the payment rate includes the devices, grafts and supplies utilized in the procedure.

Hospital Outpatient facilities report procedures with APC or C-APC codes to Medicare. New technologies may use HCPCS Level II codes to report pass through payments to Medicare when they exist. There is currently no specific pass-through "C" code designated by Medicare for systems such as the Silex® Sacroiliac Joint Fusion System. The Silex® Sacroiliac Joint Fusion device is included in the C-APC reimbursement.

Private payors often use this same APC system as well as reporting procedures using CPT codes and HCPCS Level II codes for line item reimbursement for devices and other supplies. While there is no consistent method with which these codes are established or reimbursed there are several codes that are commonly used by leading national payors that are provided below.

HCPCS Coding Pathways	
HCPCS[10]	HCPCS Description
C1713	Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)
L8699	Prosthetic Implant, not otherwise specified

[8] 2017 Medicare Outpatient Prospective Payment System, www.cms.gov

[9] 2017 Medicare ASC Payment Rates, www.cms.gov

[10] 2017 HCPCS, www.cms.gov

Hospital Inpatient Coding Pathway

Medicare reimburses hospital inpatient stays based on the Medicare Severity Diagnosis Related Group (MS-DRG) system. MS-DRGs represent a consolidated prospective payment for all services provided by the hospital during the patient's hospitalization, based on submitted claims data. With limited exceptions, the MS-DRG payment is inclusive of all services, products, and resources, regardless of the final cost to the hospital. Medicare and many private payors use the MS-DRG based system to reimburse facilities for inpatient services.

Medicare establishes MS-DRG groupings depending on the procedure performed, the individual's diagnosis, and the patient condition in order to provide a single reimbursement value for the entire inpatient stay. Certain MS-DRGs account for the possibility of complications and comorbidities present on arrival to the facility or arising during the case, which complicate the case and increase the hospital payment.

Hospital Inpatient coding pathways are established for sacroiliac joint fusion procedures such as performed using the Silex® technology. Similar to the open sacroiliac joint fusion procedure the ICD-10-PCS procedure codes below report an inpatient percutaneous or minimally invasive sacroiliac fusion procedure that requires hospital admission. Though typically this less extensive SI fusion procedure is performed in the outpatient setting of care, specific individual cases may be performed in the inpatient setting as determined by medical necessity documented by the physician.

ICD-10-PCS hospital procedure codes below provide the increased specificity to procedures as to approach and type of graft used in the procedure. This list is not intended to provide all coding options that are available for the procedure and should be considered an example only.

Hospital Procedure Coding Pathways	
ICD-10-PCS Code[11]	**ICD-10-PCS Description**
0SG834Z	Fusion of Left Sacroiliac Joint with Internal Fixation Device, Percutaneous Approach
0SG83JZ	Fusion of Left Sacroiliac Joint with Synthetic Substitute, Percutaneous Approach
0SG83KZ	Fusion of Left Sacroiliac Joint with Nonautologous Tissue Substitute, Percutaneous Approach
0SG837Z	Fusion of Left Sacroiliac Joint with Autologous Tissue Substitute, Percutaneous Approach
0SG73JZ	Fusion of Right Sacroiliac Joint with Synthetic Substitute, Percutaneous Approach
0SG734Z	Fusion of Right Sacroiliac Joint with Internal Fixation Device, Percutaneous Approach

[11] 2017 ICD-10-PCS 2016, AAPC

Hospital Procedure Coding Pathways	
ICD-10-PCS Code[11]	**ICD-10-PCS Description**
0SG73KZ	Fusion of Right Sacroiliac Joint with Nonautologous Tissue Substitute, Percutaneous Approach
0SG73ZZ	Fusion of Right Sacroiliac Joint, Percutaneous Approach
0SG737Z	Fusion of Right Sacroiliac Joint with Autologous Tissue Substitute, Percutaneous Approach

The likely inpatient MS-DRG for the Silex® sacroiliac joint fusion procedure maps to several established MS-DRGs. Note that the MS-DRG assigned will depend on the diagnoses, condition of the patient and reason for the procedure. Many, but not all, private payors follow the Medicare MS-DRG system for hospital stay reimbursement.

Hospital Inpatient Likely MS-DRG Assignment		
MS-DRG[12]	**MS-DRG Description**	**Medicare National Average Payment 2017**
028	Spinal Procedures with MCC	$33,060.83
029	Spinal Procedures with CC or Spinal Neurostimulator	$19,012.70
030	Spinal Procedures without CC/MCC	$11,335.34
459	Spinal Fusion Except Cervical with MCC	$39,080.40
460	Spinal Fusion Except Cervical without MCC	$23,790.63
907	Other O.R. Procedures for Injuries with MCC	$23,067.26
908	Other O.R. Procedures for Injuries with CC	$12,275.19
909	Other O.R. Procedures for Injuries without CC/MCC	$7,818.10

Disclaimer: *This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of December 2016, and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. Therefore, health care providers must use great care and validate coding requirements ascribed by payors with whom they work. MCRA assumes no responsibility for coding and cannot recommend codes for specific cases. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation. Xtant Medical does not promote the off-label use of its devices. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payors.*

[12] 2017 MS-DRG relative weight multiplied by 2017 rate per IPPS Final Rule, as calculated by MCRA, payment rates will vary by facility. Calculation includes labor related, non-labor related and capital payment rates.

Coding Pathways

Silex® Open or Mini-Open Technique

Diagnosis Coding:

Diagnosis codes are assigned by the physician to accurately report the patient's condition as it relates to the procedure. Below is a list of diagnosis codes and definitions that may apply to patients requiring a sacroiliac joint fusion procedure. This is only a list of possible codes that represent the typical diagnose associated with the procedure and is not intended to be a complete list. No actual patient condition is represented by the examples provided.

ICD-10-CM Diagnosis Code	
ICD-10-CM Code[13]	Diagnosis Description
M46.1	Sacroiliitis, not elsewhere classified

Physician Coding

Physicians report their surgical work, with CPT codes, separately to payors. The following code pathway options may be reported when an open sacroiliac joint fusion procedure is performed.

Physician Coding Pathways			
CPT-4 Code[14]	CPT Description	RVU's 2017	Medicare National Average Payment 2017[15]
27280	Arthrodesis, sacroiliac joint (including obtaining graft)	39.39	$1,413.66
27299	Unlisted procedure, pelvis or hip joint	-	Carrier determined

CPT code 27280 is considered a unilateral code and bilateral procedures would be reported using a code modifier -50. If performed bilaterally, some payors require that the service be reported twice with modifier -50 appended to the second code while others require identification of the service only once with modifier -50 appended. Check with individual payors. Modifier -50 identifies a procedure performed identically on the opposite side of the body (mirror image).

The use of an unlisted code for procedures that do not exactly match an existing CPT code description may require the submission of a "special report" and "crosswalk" code for valuation by the payor for reimbursement. These reimbursement decisions are payor specific and may require a prior authorization per payor guidelines. An example of a possible physician "special report" and "crosswalk" format has been provided in this resource guide.

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[13] 2017 ICD-10-CM, 2016 AAPC

[14] CPT 2017 Professional Edition, 2016 American Medical Association (AMA); CPT is a trademark of the AMA

[15] 2017 Medicare Physician Fee Schedule RVU multiplied by conversion factor, effective January 1, 2017, www.cms.gov

Hospital Outpatient Coding

CPT code 27280 is currently an inpatient only code per Medicare guidelines. Procedures designated as inpatient only, may only be performed in a hospital for Medicare patients. Medicare does not assign APC codes or value outpatient procedures for inpatient only procedures. Although private payors may allow the procedure in the outpatient setting of care, reimbursements are based on contracted agreements and fee schedules between the outpatient facility and the private payor.

CPT code 27299 (unlisted procedure) would be determined to be either an inpatient or outpatient procedure by the physician. Hospital Outpatient coding pathways are not provided by Medicare for unlisted primary procedures. Private payors would have contracted agreements that would be reviewed at prior authorization for the unlisted code.

Hospital Inpatient Coding Pathways

Hospital inpatient coding pathways are established for sacroiliac joint fusion procedures such as performed using the Silex® technology and open procedure.

Hospital inpatient reimbursement is usually based on the Medicare MS-DRG system. These MS- DRG codes are assigned by groups, taking into account the patient's diagnoses, condition and procedures performed. The hospital is then reimbursed for the hospital stay, the procedure itself, and all services and supplies, based on this MS-DRG grouping.

Hospital ICD-10-PCS procedure codes below reflect coding options for the Silex® sacroiliac joint fusion procedure when performed in the inpatient setting of care. This code factors into the MS- DRG assignment that provides for hospital facility reimbursement per inpatient stay. Bilateral procedures are reported with separate ICD-10-PCS codes for each side. Hospital ICD-10-PCS codes for hospital procedures do not differentiate between unilateral and bilateral procedures when considered for MS-DRG assignment.

ICD-10-PCS hospital procedure codes below provide increased specificity to procedures as to approach and type of graft used in the procedure. This list is not intended to provide all coding options that are available for the procedure and should be considered an example only.

Hospital Procedure Coding Pathways	
ICD-10-PCS Code[16]	**ICD-10-PCS Description**
0SG804Z	Fusion of Left Sacroiliac Joint with Internal Fixation Device, Open Approach
0SG80JZ	Fusion of Left Sacroiliac Joint with Synthetic Substitute, Open Approach
0SG80KZ	Fusion of Left Sacroiliac Joint with Nonautologous Tissue Substitute, Open Approach
0SG807Z	Fusion of Left Sacroiliac Joint with Autologous Tissue Substitute, Open Approach

[16] 2017 ICD-10-PCS, 2016, AAPC

Hospital Procedure Coding Pathways	
ICD-10-PCS Code[16]	**ICD-10-PCS Description**
0SG70JZ	Fusion of Right Sacroiliac Joint with Synthetic Substitute, Open Approach
0SG704Z	Fusion of Right Sacroiliac Joint with Internal Fixation Device, Open Approach
0SG70KZ	Fusion of Right Sacroiliac Joint with Nonautologous Tissue Substitute, Open Approach
0SG70ZZ	Fusion of Right Sacroiliac Joint, Open Approach
0SG707Z	Fusion of Right Sacroiliac Joint with Autologous Tissue Substitute, Open Approach

The likely inpatient MS-DRG for the Silex® sacroiliac joint fusion procedure maps to several established MS-DRGs. Note that the MS-DRG assigned will depend on the diagnoses, condition of the patient and reason for the procedure. Many, but not all, private payors follow the Medicare MS-DRG system for hospital stay reimbursement.

Hospital Inpatient Likely MS-DRG Assignment		
MS-DRG[17]	**MS-DRG Description**	**Medicare National Average Payment 2017**
028	Spinal Procedures with MCC	$33,060.83
029	Spinal Procedures with CC or Spinal Neurostimulator	$19,012.70
030	Spinal Procedures without CC/MCC	$11,335.34
459	Spinal Fusion Except Cervical with MCC	$39,080.40
460	Spinal Fusion Except Cervical without MCC	$23,790.63
907	Other O.R. Procedures for Injuries with MCC	$23,067.26
908	Other O.R. Procedures for Injuries with CC	$12,275.19
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[17] 2017 MS-DRG relative weight multiplied by 2017 rate per IPPS Final Rule, as calculated by MCRA, payment rates will vary by facility. Calculation includes labor related, non-labor related and capital payment rates.

Example – Claim Submittal Letter – Unlisted Code Procedure
Silex® Open or Mini-Open Technique

When a provider determines that no specific CPT code accurately describes a procedure as performed, per CPT coding guidelines, he will report an appropriate unlisted CPT code and provide a special report to the payor that describes the procedure for coverage and reimbursement consideration.

An example of the "special report" format follows, including suggested wording for describing the Silex® open technique technology and positioning of a "crosswalk" code for reimbursement valuation per case specific contracted payor guidelines. The following sample letter is not intended to be used for direct submission for case prior authorization, but provides a guide and format found to be useful when obtaining prior authorizations for unlisted procedures.

Physicians should be mindful of the inappropriate use of template documents in place of case- specific language and description of actual procedures performed. This letter provides one example of how the submission might be formatted to provide a clear and concise explanation of the actual procedure performed and the detail necessary to depict the technology in regard to the patient- specific medical necessity of the procedure as supported with clinical data and case documentation.

[Site Letterhead]

[DATE]

Health Plan Administrator
[HEALTH PLAN NAME]
[ADDRESS / PO BOX]
[CITY], [STATE] [ZIP CODE]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER]

Special Report for unlisted CPT Code: 27299 (Silex® Sacroiliac Joint Fusion Procedure)

On behalf of my patient, [INSERT PATIENT NAME], this letter provides clinical information on this patient's condition, and a formal explanation of the Silex® Sacroiliac Joint Fusion Procedure for medically necessary health care services. [INSERT PATIENT NAME] is a [INSERT AGE AND GENDER] who presented to me with [INSERT DIAGNOSIS HERE].

Description: Unlisted procedure, pelvis or hip joint

Reason for use: No permanent CPT code exists to precisely represent the sacroiliac joint fusion procedure medically necessary for my patient [INSERT PATIENT NAME]. The procedure does not meet the criteria for the permanent CPT code 27280 used in neither traditional open sacroiliac fusions, nor the criteria for the percutaneous sacroiliac fusion CPT code 27279. The proposed technique utilizing the Silex® Sacroiliac Joint Fusion implants is described below.

Description of Procedure: [SURGEON INSERTS DETAILED PROCEDURE DESCRIPTION INCLUDING THE USE OF THE SILEX® IMPLANTS AND TECHNOLOGY]

Device Description: The Silex® Sacroiliac Joint Fusion System is a true bony fusion and arthrodesis system. The implant and instrumentation suite allows for direct exposure and preparation of the SI joint surface, placement of bone graft into the SI joint space under direct visualization, and placement of bone graft directly within the Silex® implant itself.

The newly-cleared Silex® system allows for fusion and stabilization of the SI joint in eligible patients whom appropriate non-surgical treatment has failed. The device incorporates a proprietary dual-pitch compression-thread design and titanium plasma coating to stabilize the SI joint in fusion procedures. The design of the implant allows for bone graft to be introduced into the joint and implant in order to achieve a solid fusion.

Per the FDA 510k Instructions for use the Silex® Sacroiliac Joint Fusion System is manufactured from titanium alloy in accordance with ASTM F136 as well as an optional version where exterior surfaces are coated with medical-grade commercially pure titanium (CP Ti) per ASTM F1580. All implants are intended as single use only and are not to be reused under any circumstances.

Patient's Clinical Need for the Silex® Sacroiliac Joint Fusion System Procedure: [PATIENT NAME] is a [AGE] [GENDER] who presented to me with [DESCRIBE SYMPTOMS WITH SPECIFICITY]. Prior treatments have included [TYPE OF CONSERVATIVE THERAPY]. The impact this disability has had on my patient may be described as [DESCRIBE].

[INSERT MR./MS.] experiences [DESCRIBE SYMPTOMS] that has limited [HIS/HER] daily functions that include [INSERT IMPACTS] based on the extent of back and leg pain, and pain-related disability.

This letter has provided you with a better depiction of this patient's clinical history and description of the work involved in the Silex® Sacroiliac Joint Fusion System procedure. It is my sincere hope that this additional information will assist in your valuation of the use of the SI fusion procedure represented by the unlisted code CPT 27299, and explain the "crosswalk" CPT code [INSERT "CROSSWALK" CODE] used to value the sacroiliac joint fusion procedure.

"Crosswalk" Code for Valuation: [INSERT "CROSSWALK" CODE]

Valuation: The appropriate level of physician reimbursement for this procedure, based on relevant 2015 fee schedules for the crosswalk code, is that which is provided for CPT [INSERT "CROSSWALK" CODE]. [PHYSICIAN INSERTS DETAILED SUMMARY OF WORK, TIME AND EXPERTISE THAT IS SIMILAR TO THE "CROSSWALK" CODE (may be from another anatomy)]

Documentation: Attached are operational [OR CLINICAL] notes detailing the procedure as [OR TO BE] performed on [DATE] on [PATIENT NAME].

Summary: Use of CPT code 27299 is necessary as an established CPT code does not represent the sacroiliac procedure to be performed. A "crosswalk" to CPT Code [INSERT "CROSSWALK" CODE], including detailed procedure documentation, is presented for valuation and reimbursement justification.

Given the degenerative nature of the patient's condition, other surgical interventions would not be the best course of care for this case. I believe that the proposed procedure would provide the best result for a return to normal everyday function for [MR/MS]. I have attached the FDA clearance letter. Should you have further questions or concerns, please do not hesitate to call me at [INSERT PHYSICIAN TELEPHONE NUMBER]. Thank you for your immediate attention and anticipated reimbursement of these services for your insured.

Sincerely,

[PHYSICIAN NAME], [DEGREE]
[PRACTICE NAME]

Documentation Support

Documentation of a patient's history, conservative therapies and reason for any service or procedure is the key to a positive reimbursement scenario. When an orthopedic trauma procedure is indicated by the physician, the patient's medical record should clearly state the reason for the procedure as well as the outcomes and recommended therapies to follow. This documentation will support claim review and pre-authorization alike. Follow-up or staged procedures will depend on the initial documentation to support medical necessity. The following general documentation guidelines should be followed for all payors.

Clinical notes should contain the following details:

- Reason for the procedure based on physical exam
- All conservative therapies previously used in the treatment of the current disease
- Specific reason why this treatment is indicated for this patient
- Anticipated outcomes
- Recommended therapies or treatments

Operational notes might include the following:

- History of patient encounters including conservative therapies
- Current diagnosis or history of disease state
- Details of findings on exam
- Reason for procedure relevant to condition
- Usual details of procedure
- Explanation of technology specific to products or devices utilized
- Findings and any anticipated further treatments

A letter of medical necessity (LMN) may be required for pre-authorization of any procedure or for supporting documentation following a request for a claim review. Details of the LMN should include the items on the checklist above. An example LMN is provided in the following section of this guide.

In order to facilitate coverage access for a proposed procedure, the physician may request a pre- authorization from the patient's private insurance carrier. Some health plans require pre- authorization for all surgical procedures. Requesting pre-authorization may only involve a simple contact by the physician's office to verify benefits and acquire an approval number to submit with the claim. Alternatively, pre-authorization may require that the physician provide more substantive information about the case.

To prepare a pre-authorization request that requires additional information beyond basic coding, the physician's staff must provide technical information about the procedure and the unique technology involved. The treating physician must also establish the medical necessity for the procedure, as it applies to the specific patient.

Typically the pre-authorization process and/or appeal process may require submitting some or all of the following documentation:

- Patient clinical notes, including documentation of prior conservative care;
- Supporting technical information in the form of the FDA clearance letter, peer-reviewed clinical literature, clinical trial information and other available technical resources;
- Description of the technology and its use in this patient's case; and
- Description of medical necessity of the procedure for the specific patient.

Stages of the Pre-Authorization Process:

Initiate Pre-Authorization

- Verify benefits and submit clinical information and literature on device.

Peer to Peer

- Opportunity for the treating physician to discuss the medical necessity of the case with a Medical Director at the health plan.

1st Level Appeal

- Expedited/Standard - Opportunity to request a Medical Director that did not review the initial submission. There may be one or two levels of internal appeals.

2nd Level Appeal

- Expedited/Standard - Opportunity to request a Medical Director that did not review the initial submission as well as the peer to peer.

External Appeal

- Following appeal denial at all available internal levels, the patient should pursue an External Appeal with the applicable State Department of Insurance.

SILEX® SACROILIAC JOINT FUSION SYSTEM PRE-AUTHORITZATION LETTER

"Soft Tissue Technique"

Providers, please note: *Coverage requirements will typically vary by payor. Therefore, facilities and physicians should seek pre-authorization for the procedure, during which time health plans will determine whether the procedure is covered as described in the pre-authorization submission. When initiating a pre-authorization request, it is important to remember that payors may require all elements of a procedure to be pre-authorized per their payor guidelines. This sample letter includes technical information regarding the FDA on-label, cleared use of the Silex® Sacroiliac Joint Fusion System per the product instructions for use.*

This template and the information provided herein are intended to provide context for the procedure and related coding. Providers should select the procedure, diagnosis, and technology coding that best represents each patient's medical condition and treatment and should reflect the services and products that are medically necessary for the treatment of that patient. Providers must ensure that all statements made to insurance carriers are true and correct.

[SURGEON LETTERHEAD]

[DATE]

[NAME OF INSURANCE COMPANY]
[ATTN:]
[FAX #:]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER:]
[REFERENCE #:]
[PRIMARY CPT CODE:]
[PRIMARY DX CODE:]

Dear Utilization Manager:

I am writing on behalf of my patient, [PATIENT NAME], to request Pre-authorization of insurance coverage and surgical treatment for use of the Silex® Sacroiliac Joint Fusion System. This letter provides information on the patient's diagnosis and treatment, as well as a formal explanation of the Silex® Sacroiliac Joint Fusion Procedure. I believe that [MR/MS] can benefit substantially from this procedure.

Patient Profile

[PATIENT NAME] is a [AGE/GENDER]. This patient presented to me with symptoms of [DESCRIBE]. [PATIENT NAME]'s diagnostic studies revealed [IMPRESSION FROM IMAGES]. The attached medical records document [PATIENT NAME]'s clinical condition and medical necessity for the Silex® Sacroiliac Joint Fusion Procedure, including failed conservative therapy. [MR/MS] conservative therapy included: [TYPE OF CONSERVATIVE THERAPY]. Risks and benefits were discussed, and the patient wishes to proceed with surgical option.

The Silex® system allows for fusion and stabilization of the SI joint in eligible patients whom appropriate non-surgical treatment has failed. The device incorporates a proprietary dual-pitch compression-thread design and titanium plasma coating to stabilize the SI joint in fusion procedures. The design of the implant allows for bone graft to be introduced into the joint and implant in order to achieve a solid fusion.

Per the FDA 510k Instructions for use the Silex® Sacroiliac Joint Fusion System is manufactured from titanium alloy in accordance with ASTM F136 as well as an optional version where exterior surfaces are coated with medical-grade commercially pure titanium (CP Ti) per ASTM F1580. All implants are intended as single use only and are not to be reused under any circumstances.

Given the degenerative nature of the patient's condition, other surgical interventions would not be the best course of care for this case. I believe that the proposed procedure would provide the best result for a return to normal everyday function for [MR/MS]. I have attached the FDA clearance letter on the Silex® Sacroiliac Joint Fusion System. Should you have further questions, please do not hesitate to call me at [INSERT PHYSICIAN TELEPHONE NUMBER]. Thank you for your immediate attention and anticipated authorization of these services for your insured.

Sincerely,

[PHYSICIAN NAME], [DEGREE]
[PRACTICE NAME]

SILEX® SACROILIAC JOINT FUSION SYSTEM PRE-AUTHORITZATION LETTER

"Open Technique"

Providers, please note: *Coverage requirements will typically vary by payor. Therefore, facilities and physicians should seek pre-authorization for the procedure, during which time health plans will determine whether the procedure is covered as described in the pre-authorization submission. When initiating a pre-authorization request, it is important to remember that payors may require all elements of a procedure to be pre-authorized per their payor guidelines. This sample letter includes technical information regarding the FDA on-label, cleared use of the Silex® Sacroiliac Joint Fusion System per the product instructions for use.*

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[SURGEON LETTERHEAD]

[DATE]

[NAME OF INSURANCE COMPANY]
[ATTN:]
[FAX #:]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER:]
[REFERENCE #:]
[PRIMARY CPT CODE:]
[PRIMARY DX CODE:]

Dear Utilization Manager:

I am writing on behalf of my patient, [PATIENT NAME], to request Pre-authorization of insurance coverage and surgical treatment for use of the Silex® Sacroiliac Joint Fusion System. This letter provides information on the patient's diagnosis and treatment, as well as a formal explanation of the Silex® Sacroiliac Joint Fusion Procedure. I believe that [MR/MS] can benefit substantially from this procedure.

Patient Profile

[PATIENT NAME] is a [AGE/GENDER]. This patient presented to me with symptoms of [DESCRIBE]. [PATIENT NAME]'s diagnostic studies revealed [IMPRESSION FROM IMAGES]. The attached medical records document [PATIENT NAME]'s clinical condition and medical necessity for the Silex® Sacroiliac Joint Fusion Procedure, including failed conservative therapy. [MR/MS] conservative therapy included: [TYPE OF CONSERVATIVE THERAPY]. Risks and benefits were discussed, and the patient wishes to proceed with surgical option.

The Silex® Sacroiliac Joint Fusion System is a true bony fusion and arthrodesis system. Using the "Open Technique" approach, allows the implant and instrumentation suite to have direct exposure and preparation of the SI joint surface, placement of bone graft into the SI joint space under direct visualization, and placement of bone graft directly within the Silex® implant itself.

The Silex® system allows for fusion and stabilization of the SI joint in eligible patients whom appropriate non-surgical treatment has failed. The device incorporates a proprietary dual-pitch compression-thread design and titanium plasma coating to stabilize the SI joint in fusion procedures. The design of the implant allows for bone graft to be introduced into the joint and implant in order to achieve a solid fusion.

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Given the degenerative nature of the patient's condition, other surgical interventions would not be the best course of care for this case. I believe that the proposed procedure would provide the best result for a return to normal everyday function for [MR/MS]. I have attached the FDA clearance letter on the Silex® Sacroiliac Joint Fusion System. Should you have further questions, please do not hesitate to call me at [INSERT PHYSICIAN TELEPHONE NUMBER]. Thank you for your immediate attention and anticipated authorization of these services for your insured.

Sincerely,

[PHYSICIAN NAME], [DEGREE]
[PRACTICE NAME]

Plan Denial Appeal Process Overview

When a third party health plan denies a procedure in accordance with their medical policy guidelines, there is a process available to appeal that decision. Insurance carriers provide this check and balance to allow for reconsideration of the decision per their plan provisions and applicable state regulations. The process will vary depending on the plan and regulatory requirements; however, there are basic steps that can assist the provider in appealing the initial denial.

To present an effective appeal, follow these steps:

1. Carefully review the denial reason and understand the specific health plan's policy;

2. Write an appeal letter clearly addressing the specific denial reasons;

3. Provide supporting information including product details and FDA clearance; and

4. Submit the appeal on time.

The following additional considerations may be helpful:

1. If the health plan is self-funded (employer based), patients can contact their Human Resources (HR) department to assist in the patient's appeal of the decision. HR departments may have contacts within the health plan that can provide helpful support.

2. The patient can contact the health plan directly and is the policy-holder with an influence on the decision.

3. There are multiple steps in the appeal process and providers and patients may exercise these rights according to their third party payor and state guidelines.

Writing an Appeal Letter

When appealing a denial, the first step is often composing a letter to the health plan that initially reviewed the case. This letter is submitted by the provider on behalf of the patient, with the patient's approval, and should outline the reasons the denial should be overturned.

Detailed information regarding the denial reason should be prepared utilizing the case specific information in the denial, as well as the more general technology specific information and supporting clinical literature.

First, collect all the information required to support the appeal:

- Denial letter
- Health plan contracts and provider agreements
- Applicable medical policy guidelines from the health plan (website access is often a good resource for general policy)
- Literature supporting the technology
- FDA clearance letter
- Safety and effectiveness documentation
- Peer-reviewed literature references (when available)

In drafting an appeal letter, consider the following:

- Did the reviewer miss information about the technology?
- Did the reviewer overlook a case specific detail?
- Does the health plan clearly understand the procedure?
- Was the information provided about the case correctly submitted?
- Review the plan's official policy online for more detailed understanding of the denial reason

Be mindful of details, including:

- Patient's name
- Subscriber's name
- Policy number
- Description of exact service denied
- Date denied

SILEX® SACROILIAC JOINT FUSION SYSTEM PRE-AUTHORITZATION APPEAL LETTER

"Soft Tissue Technique"

Despite the filing of a pre-authorization request, certain commercial health plans may still elect not to cover or grant pre-authorization for this procedure without further information and clinical evidence supporting its use. Should pre-authorization be denied, the physician requesting coverage should immediately file a written appeal with the health plan and request reconsideration of the coverage decision. When requesting a pre-authorization appeal it is important to remember that payors may require all elements of a procedure to be pre-authorized per their payor guidelines. This sample letter includes technical information regarding the FDA on-label use of the Silex® Sacroiliac Joint Fusion System, per the product instructions for use. To assist you, the following example is offered as a starting point for your pre-authorization denial appeal and reconsideration request.

[SURGEON LETTERHEAD]

[DATE]

[NAME OF INSURANCE COMPANY]
[ATTN:]
[FAX #:]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER:]
[REFERENCE #:]
[PRIMARY CPT CODE:]
[PRIMARY DX CODE:]

Dear Utilization Manager:

Please accept this letter on behalf of [PATIENT NAME], as an appeal to [PAYOR NAME]'s decision to deny coverage for the recommended Silex® Sacroiliac Joint Fusion Procedure for [DIAGNOSIS]. It is my understanding, per [PAYOR NAME]'s denial letter dated [INSERT DENIAL LETTER DATE], that this procedure has been denied because [REASON FOR DENIAL].

I respectfully request that [PAYOR NAME] reconsider its denial and provide authorization for this treatment option. I believe this denial was made in error, as the Silex® Sacroiliac Joint Fusion Procedure is well accepted by the clinical community.

Patient Profile

[PATIENT NAME] is a [AGE/GENDER]. This patient presented to me with symptoms of [DESCRIBE]. [PATIENT NAME]'s diagnostic studies revealed [IMPRESSION FROM IMAGES]. The attached medical records document [PATIENT NAME]'s clinical condition and medical necessity for the Silex® Sacroiliac Joint Fusion Procedure, including failed conservative therapy. [MR/MS] conservative therapy included: [TYPE OF CONSERVATIVE THERAPY]. Risks and benefits were discussed, and the patient wishes to proceed with surgical option.

Due to the severity of [DIAGNOSIS], I am recommending surgery using the Silex® Sacroiliac Joint Fusion System. The Silex® system allows for fusion and stabilization of the SI joint in eligible patients whom appropriate non-surgical treatment has failed. The device incorporates a proprietary dual-pitch compression-thread design and titanium plasma coating to stabilize the SI joint in fusion procedures. The design of the implant allows for bone graft to be introduced into the joint and implant in order to achieve a solid fusion.

Per the FDA 510k Instructions for use the Silex® Sacroiliac Joint Fusion System is manufactured from titanium alloy in accordance with ASTM F136 as well as an optional version where exterior surfaces are coated with medical-grade commercially pure titanium (CP Ti) per ASTM F1580. All implants are intended as single use only and are not to be reused under any circumstances.

Thank you for taking the time to review the enclosed information and considering the appeal of [PAYOR NAME]'s denial of coverage for Silex® Sacroiliac Joint Fusion Procedure. I hope that [PAYOR NAME] will respond with a positive decision so that [PATIENT NAME] can benefit from the results of this procedure.

Sincerely,

[PHYSICIAN NAME], [DEGREE]
[PRACTICE NAME]

SILEX® SACROILIAC JOINT FUSION SYSTEM PRE-AUTHORITZATION APPEAL LETTER

"Open Technique"

Despite the filing of a pre-authorization request, certain commercial health plans may still elect not to cover or grant pre-authorization for this procedure without further information and clinical evidence supporting its use. Should pre-authorization be denied, the physician requesting coverage should immediately file a written appeal with the health plan and request reconsideration of the coverage decision. When requesting a pre-authorization appeal it is important to remember that payors may require all elements of a procedure to be pre-authorized per their payor guidelines. This sample letter includes technical information regarding the FDA on-label use of the Silex® Sacroiliac Joint Fusion System, per the product instructions for use. To assist you, the following example is offered as a starting point for your pre-authorization denial appeal and reconsideration request.

[SURGEON LETTERHEAD]

[DATE]

[NAME OF INSURANCE COMPANY]
[ATTN:]
[FAX #:]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER:]
[REFERENCE #:]
[PRIMARY CPT CODE:]
[PRIMARY DX CODE:]

Dear Utilization Manager:

Please accept this letter on behalf of [PATIENT NAME], as an appeal to [PAYOR NAME]'s decision to deny coverage for the recommended Silex® Sacroiliac Joint Fusion Procedure for [DIAGNOSIS]. It is my understanding, per [PAYOR NAME]'s denial letter dated [INSERT DENIAL LETTER DATE], that this procedure has been denied because [REASON FOR DENIAL].

I respectfully request that [PAYOR NAME] reconsider its denial and provide authorization for this treatment option. I believe this denial was made in error, as the Silex® Sacroiliac Joint Fusion Procedure is well accepted by the clinical community.

Patient Profile

[PATIENT NAME] is a [AGE/GENDER]. This patient presented to me with symptoms of [DESCRIBE]. [PATIENT NAME]'s diagnostic studies revealed [IMPRESSION FROM IMAGES]. The attached medical records document [PATIENT NAME]'s clinical condition and medical necessity for the Silex® Sacroiliac Joint Fusion Procedure, including failed conservative therapy. [MR/MS] conservative therapy included: [TYPE OF CONSERVATIVE THERAPY]. Risks and benefits were discussed, and the patient wishes to proceed with surgical option.

Due to the severity of [DIAGNOSIS], I am recommending surgery using the Silex® Sacroiliac Joint Fusion System. The System is a true bony fusion and arthrodesis system. Using the "Open Technique" approach allows the implant and instrumentation suite to have direct exposure and preparation of the SI joint surface, placement of bone graft into the SI joint space under direct visualization, and placement of bone graft directly within the Silex® implant itself.

The Silex® system allows for fusion and stabilization of the SI joint in eligible patients whom appropriate non-surgical treatment has failed. The device incorporates a proprietary dual-pitch compression-thread design and titanium plasma coating to stabilize the SI joint in fusion procedures. The design of the implant allows for bone graft to be introduced into the joint and implant in order to achieve a solid fusion.

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Thank you for taking the time to review the enclosed information and considering the appeal of [PAYOR NAME]'s denial of coverage for Silex® Sacroiliac Joint Fusion Procedure. I hope that [PAYOR NAME] will respond with a positive decision so that [PATIENT NAME] can benefit from the results of this procedure.

Sincerely,

[PHYSICIAN NAME], [DEGREE]
[PRACTICE NAME]

Resources for Technology Support

The following resources can provide support when coding and preparing a pre-authorization for Silex® procedures when performed in the inpatient, outpatient or surgery center setting of care.

Complete understanding of the product and procedure, FDA clearance and directions for use can provide a payor with the information they need to review and approve a procedure.

These resources have been referenced in this guide and can be utilized when required. They can be accessed in the accompanying Tool Kit.

- FDA Product Clearance Letters
- Silex® Brochures
- Instructions for Use (IFU)

The following links can also provide information to assist providers when procedures and technologies are considered for reimbursement.

AMA CPT Code Search Tool

Medicare Physician Fee Schedule Look-up Tool

AAOS Homepage

NASS Homepage

AANS Homepage

National Association of Insurance Commissioners (NAIC) Homepage

OMHA ALJ Appeal Status Information System (AASIS)

Silex® – Sacroiliac Joint Fusion

The following links to published literature may be useful in supporting sacroiliac fusion procedures.

- Lorio MP. "International Society for the Advancement of Spinal Surgery (ISASS) Recommendations for Coverage Criteria for Sacroiliac Joint Fusion. 2015."

Available at: http://www.isass.org/public_policy/2015-03-19-coverage-criteria-for-minimally-invasive-si-joint-fusion-2015.html

- Lindsey D, Kiapour A, Yerby S, Goel V. "Sacroiliac Joint Fusion Minimally Affects Adjacent Lumbar Segment Motion: A Finite Element Study."

Available at: http://ijssurgery.com/10.14444/proof3

- Smith A, Capobianco R, Cher D, Rudolf L, Sachs D, Gundanna M, Kleiner J, Mody M, Shamie NA. "Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison of perioperative measures and clinical outcomes"

Available at: http://www.asir-journal.com/content/7/1/14

- Vanaclocha-Vanaclocha V, Verdu-Lopez F, Sanchez-Pardo M. "Minimally Invasive Sacroiliac Joint Arthrodesis: Experience in a Prospective Series with 24 Patients

Available at: http://www.omicsgroup.org/journals/minimally-invasive-sacroiliac-joint-arthrodesis-experience-in-a-prospective-series-with-patients-2165-7939-3-185.php?aid=33352

- Sachs D, Capobianco R. "Minimally Invasive Sacroiliac Joint Fusion: One-Year Outcomes in 40 Patients.

Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3755432/

- American Spine Society (NASS). "NASS Coverage Policy Recommendations for Percutaneous Sacroiliac Joint Fusion."

- Available at: https://www.spine.org/Documents/PolicyPractice/CoverageRecommendations/PercutaneousSacroiliacJointFusion.pdf.

Sample Billing Forms

When procedures and services utilizing the Silex® technologies (Both soft tissue technique and open technique procedures) are performed they are reported by both the physician and the facility, or setting of care, where the procedure took place. Two billing forms are utilized. The physician reports services on the CMS-1500 claim form and the facility reports their services on the UB-04 form. Each procedure will be unique in the details and should be reported as performed utilizing the appropriate coding pathway for the procedure as documented in the medical record.

The following are examples of typical billing forms for hypothetical Silex® procedures performed by a surgeon (reported on the CMS-1500) and performed in either the outpatient setting of care (reported on the UB-04) or the inpatient setting of care (reported on the UB-04). Note that hospital inpatient and outpatient forms differ in reporting format although both are reported on the UB-04 form.

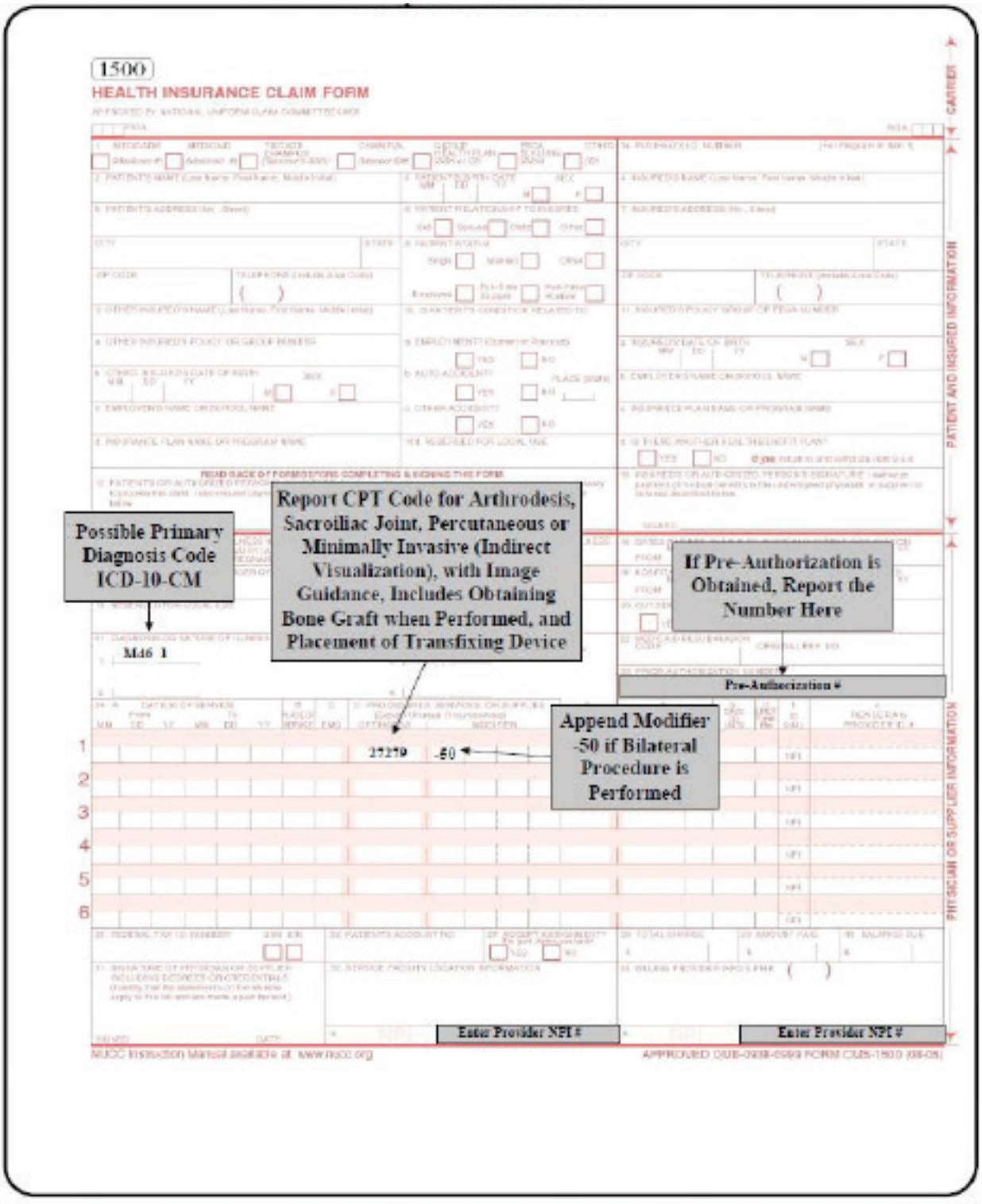
All reporting is subject to individual case specifics and third party payor guidelines. These examples are only to be utilized as guides and do not represent any actual case or procedure utilizing the Silex® technologies.

The following billing forms are created for a hypothetical procedure.

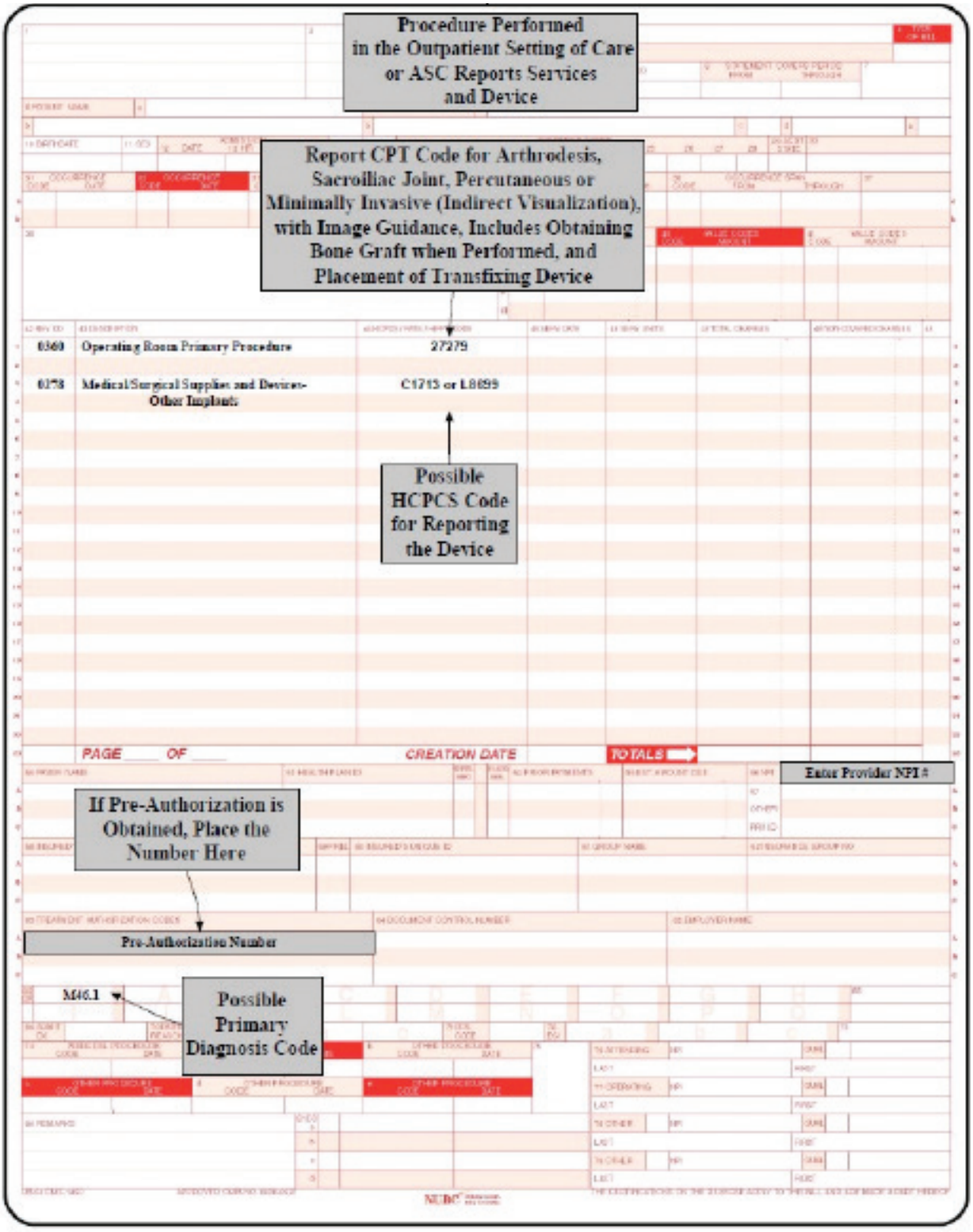
Sample Billing Claims Forms – (CMS 1500, UB-04)

Silex® Soft Tissue Shield Technique

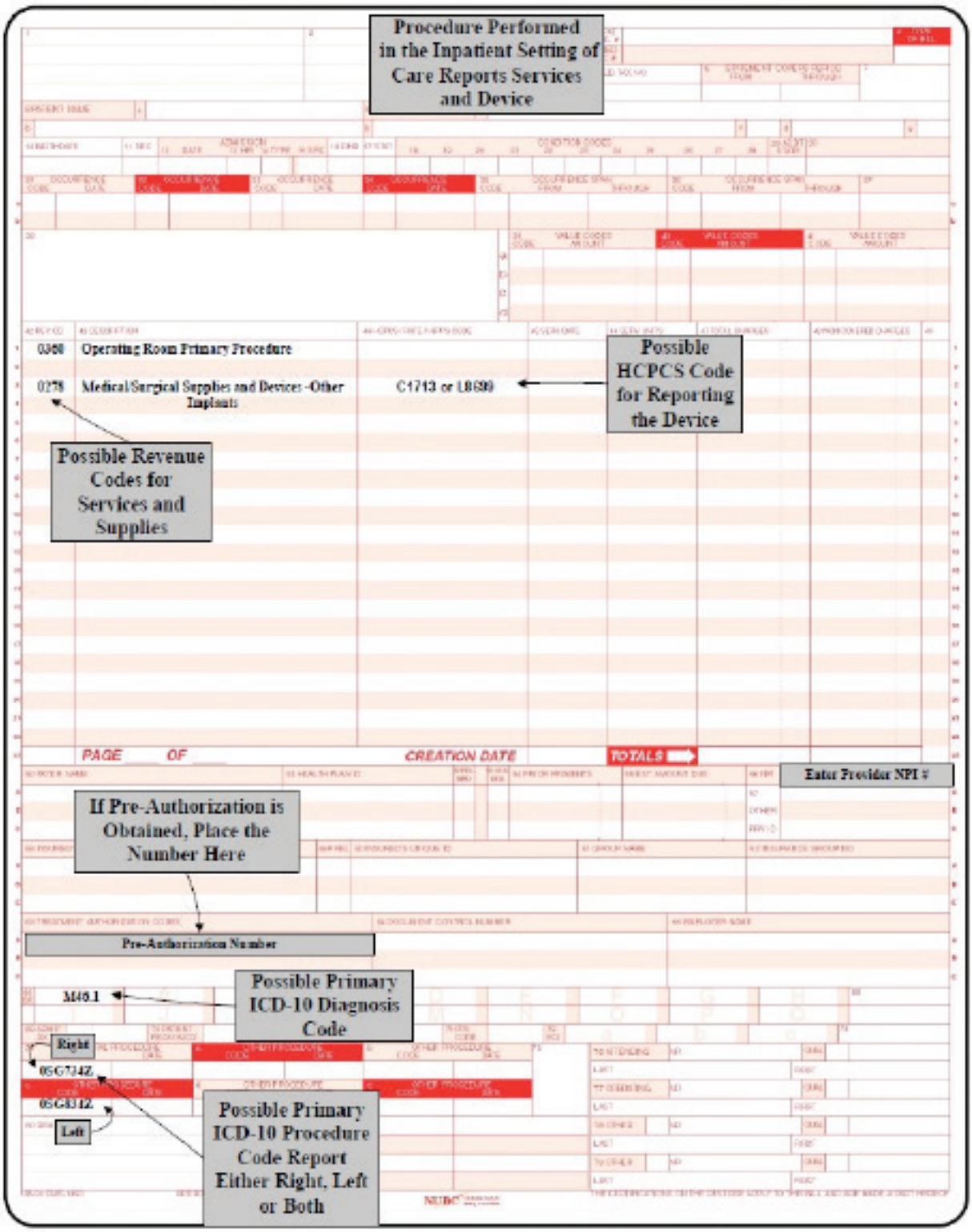
X-spine Silex® Soft Tissue Shield Technique Example
Sample CMS 1500 Form



X-spine Silex® Soft Tissue Shield Technique Example
Sample UB-04 Form (OP/ASC)



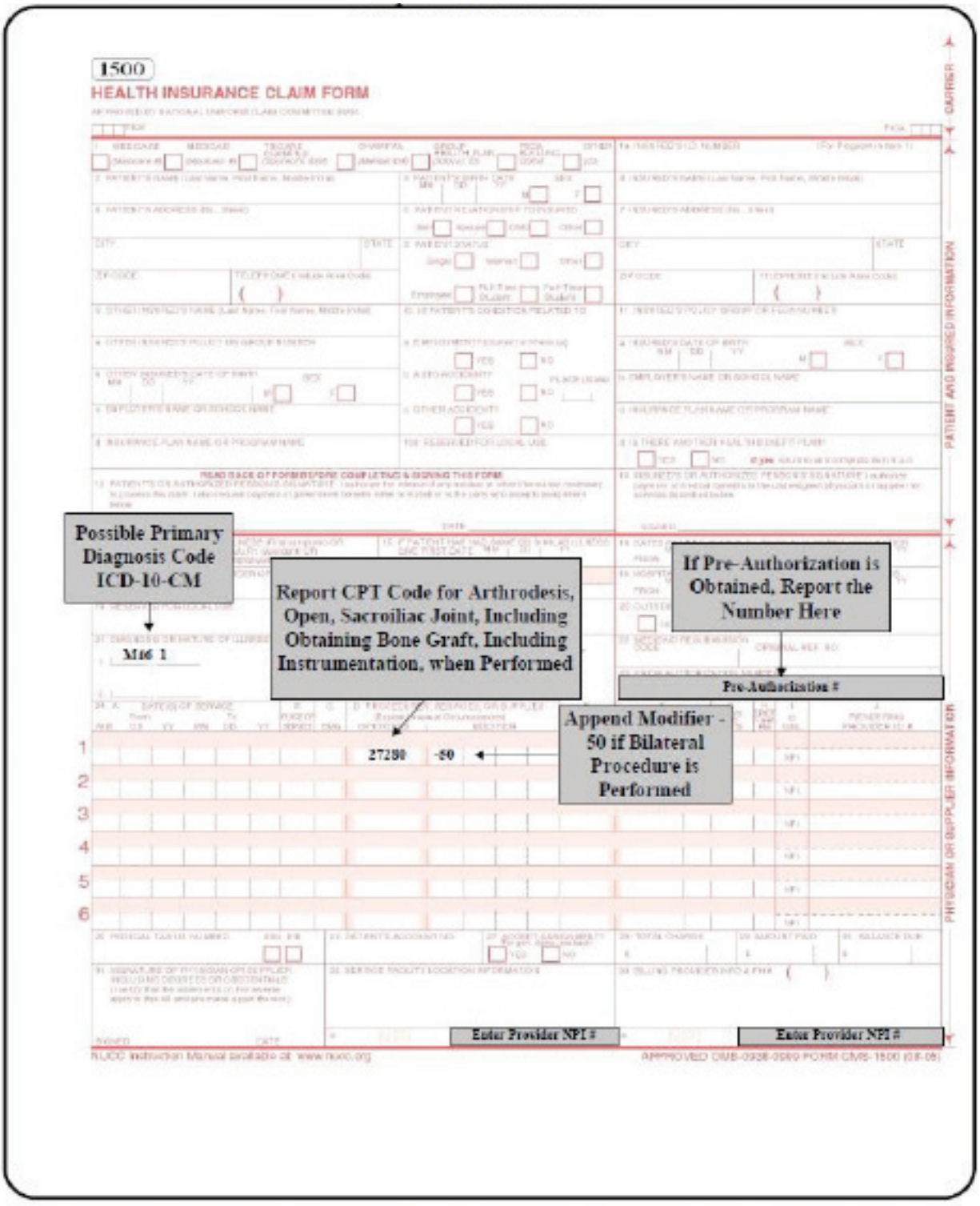
X-spine Silex® Soft Tissue Shield Technique Example
Sample UB-04 Form (Inpatient)



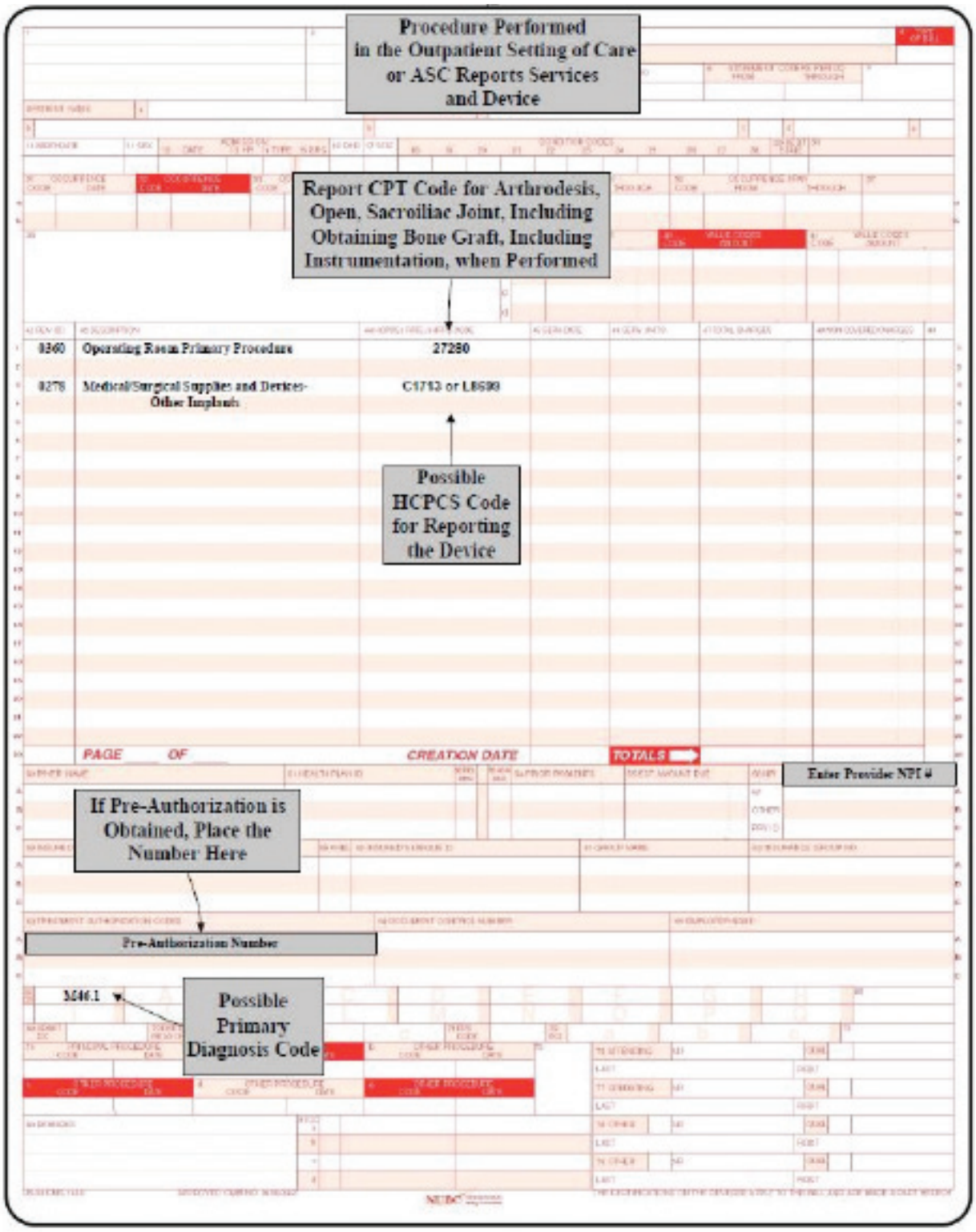
Sample Billing Claims Forms – (CMS 1500, UB-04)

Silex® Open Technique

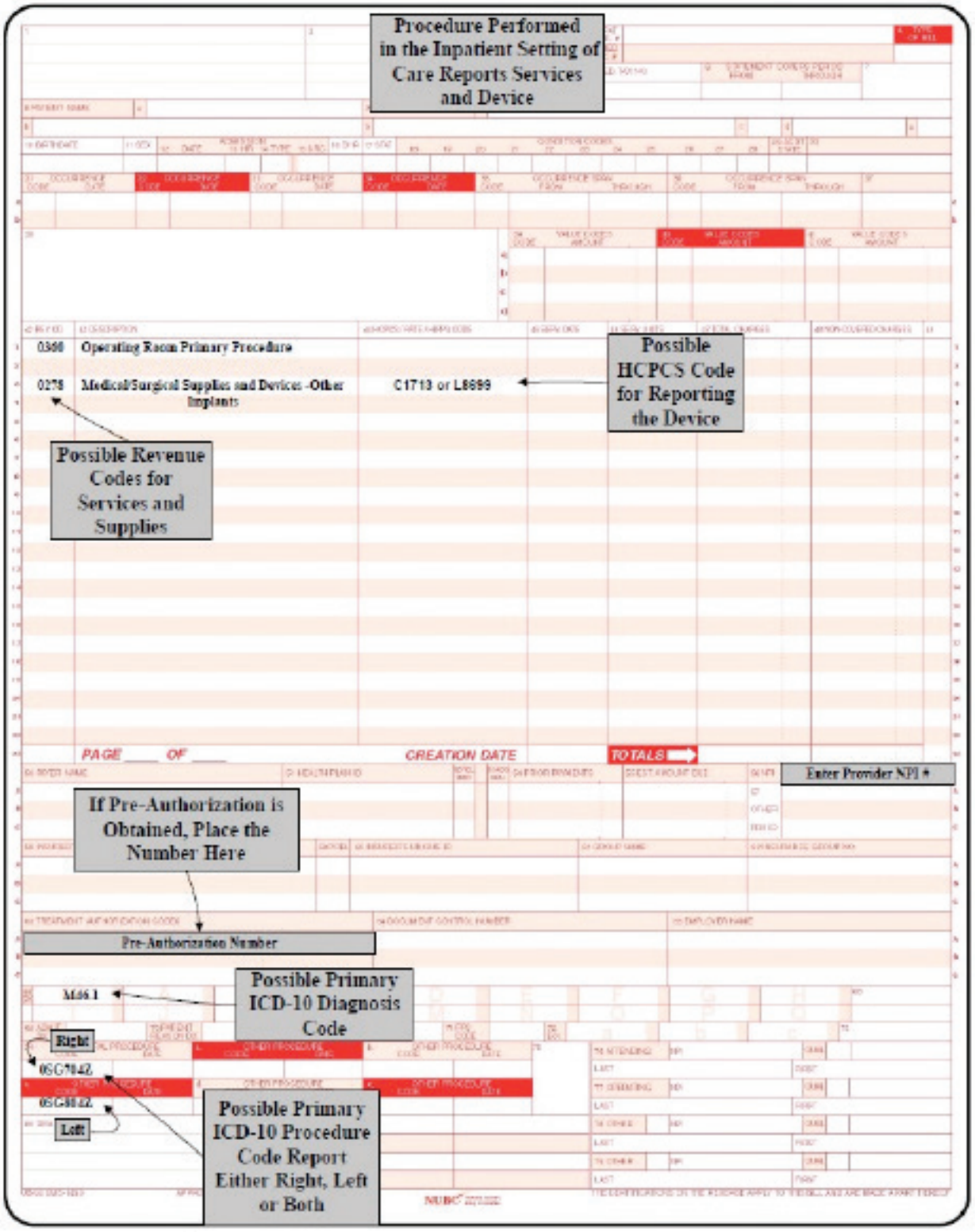
X-spine Silex® Open Approach Example
Sample CMS 1500 Form



X-spine Silex® Open Approach Example
Sample UB-04 Form (OP/ASC)



X-spine Silex® Open Approach Example
Sample UB-04 Form (Inpatient)



Reimbursement Hotline
800-914-7211
reimbursement@xtantmedical.com

XTANT MEDICAL

BACTERIN + X-spine

800.903.0640
CS@xtantmedical.com
xtantmedical.com

Musculoskeletal Clinical
Regulatory Advisers, LLC

PL-16 0012B 12/16

CE 0086

Manufacturer:
X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342 USA