

GUIDE TO COVERAGE AND REIMBURSEMENT

of *Ex Vivo* Lung Perfusion
(EVLP) with XVIVO Perfusion
System (XPS)[™] With
STEEN Solution[™]

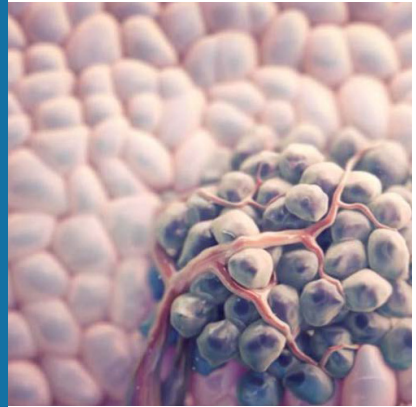


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Introduction^{1,2}

Purpose of the Guide

This guide is intended to serve as a resource to healthcare providers (HCPs) and hospital administrative staff on coding, billing, and cost reporting for EVLP and associated services.

Disclaimer

The information provided in this guide is intended to be used for educational purposes only and is not intended as legal advice or to replace a medical provider's professional judgment. The information is not a guarantee of coverage or reimbursement. It is the sole responsibility of the treating HCP to consult a patient's individual health insurance plan for comprehensive coding and billing parameters for coverage and reimbursement of all transplant-related services and supplies, including EVLP.

Diagnosis and procedure codes and other items reported on medical claims or cost reports to payers must be supported by the information documented in the patient's medical record.

Lung Bioengineering does not guarantee that payers will consider all codes appropriate for all encounter scenarios.

The information in this guide is subject to change and is current as of October 2020.



What is EVLP?

Lung transplant is the only life-saving therapy for patients with certain types of end-stage lung disease. However, the current shortage of donor lungs means several hundred candidates die each year while they await a lung transplant.

EVLP is an innovative device applied to donor lungs outside of the body and prior to transplant. It is intended to evaluate organ function, allow for further assessment of lungs that may otherwise have been discarded as unsuitable, and make more lungs available for transplant.

During EVLP, donor lungs are attached to a ventilator, pump, and filters. The lungs are maintained at normal body temperature and perfused with an acellular solution containing nutrients and proteins. During the process, which takes several hours, lung function is continuously evaluated. If the lung is deemed suitable after EVLP by a transplant physician, the lungs are transplanted into a waiting patient.



What is Lung Bioengineering?

Lung Bioengineering Inc., a subsidiary of United Therapeutics' public benefit corporation Lung Biotechnology PBC, has established full-service EVLP centers in the United States, with facilities which contain everything needed to perform centralized EVLP procedures. The Lung Bioengineering sites for EVLP are located in Silver Spring, Maryland, and Jacksonville, Florida.



Premarket Approval

In 2018, Lung Bioengineering entered into a collaborative agreement with XVIVO Perfusion Inc., manufacturer of the XPS™ With STEEN Solution™. On April 29, 2019, the two companies announced that the Food and Drug Administration granted premarket approval for EVLP using XPS™ With STEEN Solution™.

Please see Important Safety Information on pages 3 and 4

Important Safety Information

Indication

Indicated for use in flushing and temporary continuous normothermic machine perfusion of initially unacceptable excised donor lungs during which time the ex-vivo function of the lungs can be reassessed for transplantation.

Important Safety Information

Warnings and Precautions

General Warnings

The safety and effectiveness of the XPS™ System with STEEN Solution™ Perfusate device were not evaluated with ideal criteria donor lungs.

Risk for Contamination and Mechanical Trauma

The degree of organ manipulation required for airway and vascular cannulation carries the potential for contamination and mechanical trauma of the donor lungs. Even though not contraindicated, it is not recommended to use an organ with evident signs of mechanical trauma or major contamination.

XPS™ Machine Operation-Related Warnings

See Warnings and Precautions in the XPS™ System Instructions for Use manual.

STEEN Solution™ Warnings

The responsibility to adhere to the approved labeling and Instructions for Use rests with the user. The Instructions for Use are only provided as suggestions for procedure. The user must, on the basis of his or her medical training and experience, evaluate the suitability of this procedure. When administered systemically, human serum albumin and Dextran have been associated with rare allergic reactions. However, no such reactions have been reported with either of these substances when used for ex vivo lung preservation.

XVIVO Lung Cannula Set™ Precautions

Store at room temperature. Use only undamaged/unopened containers. Single Use Only.

XVIVO Organ Chamber™ Precautions

Store at room temperature. Use only undamaged/unopened containers. Single Use Only.

XVIVO Disposable Lung Circuit™ Precautions

Store at room temperature. Use only undamaged/unopened containers. Single Use Only.

XVIVO Disposable Lung Kit™ Precautions

Store at room temperature. Use only undamaged/unopened containers. Single Use Only.

XPS™ Machine Operation-Related Precautions

See Warnings and Precautions in the XPS™ System Instructions for Use manual.

STEEN Solution™ Precautions

STEEN Solution™ is intended for single use only and MAY NOT BE REUSED. Any leftover solution must be disposed of after the procedure.

Do not use STEEN Solution™ if the solution is not clear, the bottle is damaged, the flip-tear seal has been tampered with, or if the “use by” date has expired. Transplant Suitability Post-Ex Vivo Lung Perfusion (EVLP)

The responsibility for correct clinical use and interpretation of the lung function evaluations during EVLP in determining transplant suitability resides exclusively with the transplant surgeon.

Like in any other clinical decision, all available data should be taken into consideration when determining the suitability of an organ for transplantation; that is, the transplant surgeon is clinically satisfied with the lung evaluation. This criterion should take priority, since the transplant surgeon is the ultimate responsible person for safely transplanting EVLP lungs. The use of the EVLP lung physiologic evaluations in determining transplantability (e.g., EVLP transplantability criteria) has been evaluated in the clinical studies, including the NOVEL trial (see summary of NOVEL study below). Validation has not occurred as to whether the parameters are adequate as surrogates for in vivo performance.

The use of ex-vivo perfusion/ventilation discrete parameters on their own to determine transplant suitability according to the two sets of transplantability criteria used in the NOVEL and NOVEL EXTENSION respectively have not been validated. Clinicians should exercise discretion when using these criteria as the main decision-making tool for transplantability and instead utilize the perfusion/ventilation trends coupled with EVLP x-rays and bronchoscopies and their clinical expertise to make decisions on transplant suitability. Two different transplant suitability criteria (NOVEL: 2 consecutive delta PaO₂s ≥ 350 vs NOVEL Extension: 2 non-consecutive delta PaO₂s ≥ 350 OR 1 absolute PaO₂ > 400) have been used in the NOVEL and NOVEL EXTENSION respectively, and neither of these criteria have been validated. The transplant suitability criteria between the NOVEL and NOVEL Extension studies have shown no difference in survival and/or incidence of Primary Graft Dysfunction (PGD).

Potential Adverse Events

The XPS™ with STEEN Solution™ Perfusate device is indicated for use only on previously unacceptable excised donor lungs in an ex vivo setting. There is no direct patient contact when this device is used as labeled; however, the device has a direct contact with the lungs that are subsequently transplanted into the recipients. The donor lung quality and optimization after preservation have direct effects on allograft function and survival.

The potential for contamination and mechanical trauma, due to the manipulation and cannulation of the lung airway and vascular structures, may lead to complications after transplantation.

Patients receiving a lung treated with the XPS™ System with STEEN Solution™ Perfusate device may experience adverse events including those experienced with any lung transplant.

Below is a list of the potential adverse effects associated with the use of the device.

- Death
- Renal failure or dysfunction
- Respiratory dysfunction or failure
- Respiratory infection
- Sepsis
- Primary graft dysfunction
- Acute or chronic rejection
- Cardiac arrhythmias
- Bronchiolitis Obliterans Syndrome (BOS)
- Bronchial stenosis/Dehiscence
- Post-operative bleeding/hemorrhage
- Hemothorax
- Pneumothorax
- Re-transplantation

Prescription Information

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. See the Physician Labeling for further detailed information. For further information, please call (303) 395-9171 and/or consult XVIVO's website at www.xvivoperfusion.com.

XVIVOISlhcpMar20

Glossary

CMS: Centers for Medicare & Medicaid Services – Part of the Department of Health and Human Services, CMS is the federal agency that administers the Medicare program and works with states to administer Medicaid.

CTC: Certified transplant center – A Medicare-approved transplant center that provides organ transplantation.

EVLP: Ex vivo lung perfusion – A process to evaluate the function of donor lungs through perfusion and ventilation of the lungs at normal body temperature.

ICD-10-CM: International Classification of Diseases, 10th Revision, Clinical Modification – Code set used to report diagnoses, illnesses, injuries, conditions, symptoms, and causes of illness or injury. HCPs and payers use ICD-10-CM codes to report patient-specific diagnoses to document medical necessity for healthcare services provided across all sites of care.

ICD-10-PCS: International Classification of Diseases, 10th Revision, Procedure Coding System – Set of unique codes used to report procedures and other services performed in the hospital and other facility sites of care.

IPPS: Inpatient Prospective Payment System – Payment system for the operating costs of services provided in the acute hospital inpatient site of care under Medicare Part A.

MACs: Medicare Administrative Contractors – Private companies that contract with CMS to administer Medicare benefits based on regional jurisdictions.

MCR: Medicare cost report – A report completed and submitted annually by most Medicare-certified providers that documents expenses in facilities reimbursable by Medicare including facility characteristics, utilization data, costs and charges by cost center (in total and for Medicare), Medicare settlement data, and financial statement data.

MS-DRG: Medicare Severity Diagnosis-Related Group – A mechanism that classifies hospital stays into predetermined groups according to patient attributes that include principal diagnosis, specific secondary diagnoses, procedures, sex, and discharge status. Medicare will always use the MS-DRG. Other payer types, such as commercial payers or state Medicaid programs, may also pay hospitals based on the MS-DRG assigned to the hospital stay, or based on other reimbursement methodologies, such as All Patient-DRG (AP-DRG), All Patient Refined-DRG (APR-DRG), or contracted rate.

OPO: Organ procurement organization – Organization responsible for coordinating the evaluation and procurement of organs for transplantation.

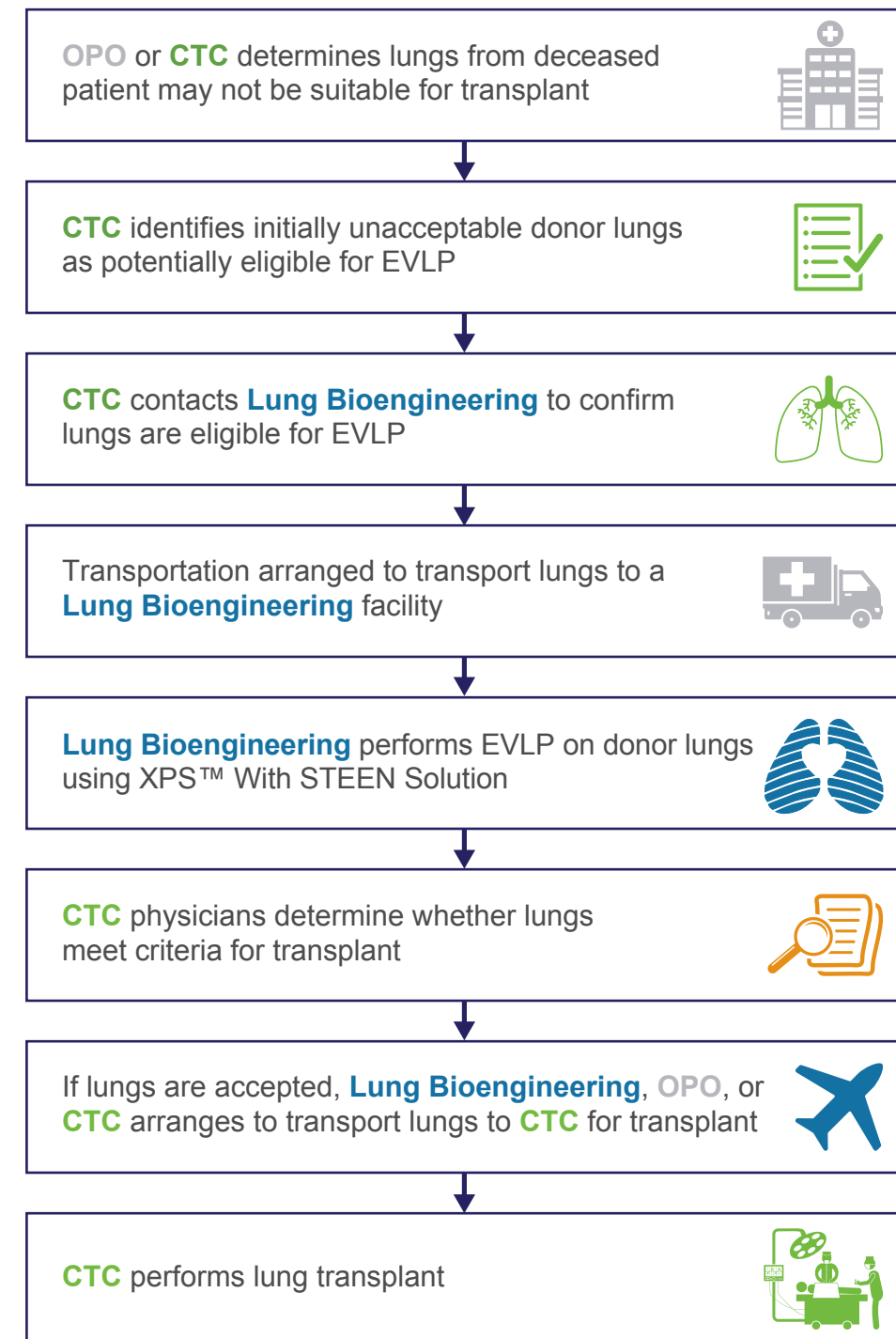
OPTN: Organ Procurement and Transplantation Network – Network established by the United States Congress under the National Organ Transplant Act of 1984.

SAC: Standard acquisition charges – Amount paid by a CTC and reimbursed by CMS based on the average expected reasonable and necessary cost for organ acquisition.

Acquisition Process for Donor Lungs Undergoing EVLP Using XPS™ With STEEN Solution™

Below is a step-by-step overview of the process to acquire lungs and evaluate them with EVLP Using XPS™ With STEEN Solution™ in an effort to increase the number of available lungs for transplant.

Figure 1. Acquisition Process for Lungs Undergoing EVLP Using XPS™ With STEEN Solution™



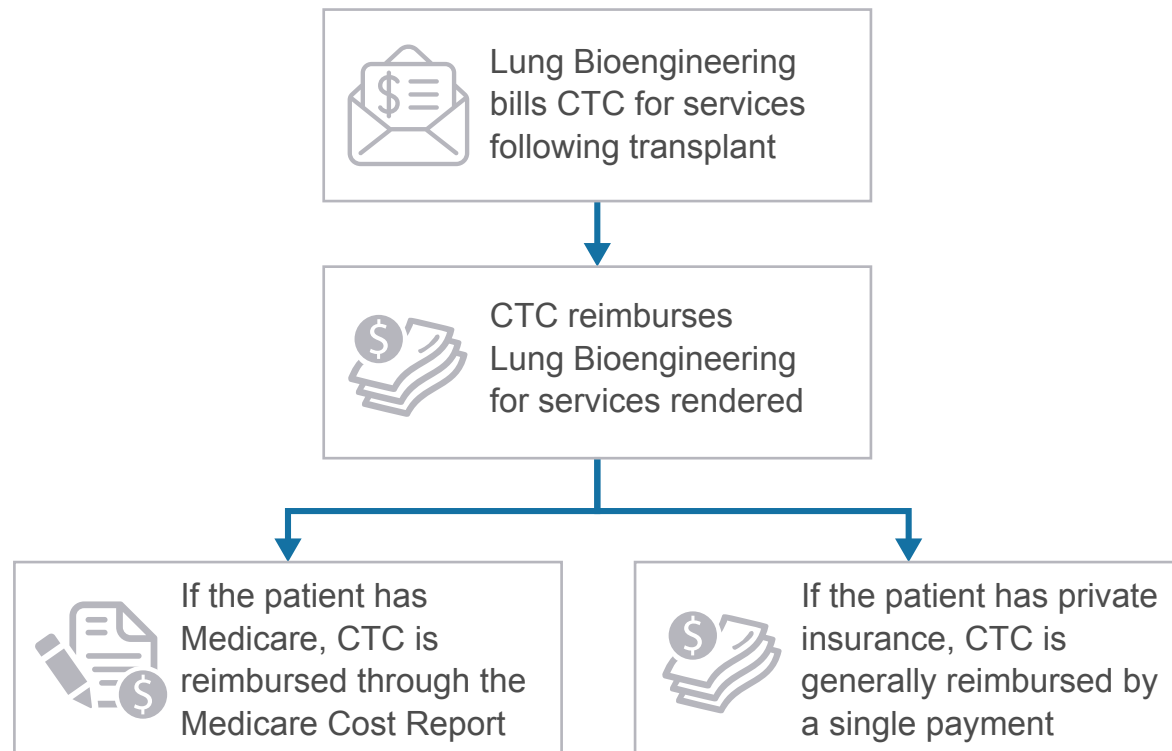
Key: CTC: certified transplant center; EVLP: Ex vivo lung perfusion; OPO: organ procurement organization.

Reimbursement for Services Related to EVLP Using XPS™ With STEEN Solution™ 3-7

Reimbursement Process for Organ Acquisition Costs Related to Lung Bioengineering Services

Below is an overview of how CTCs reimburse Lung Bioengineering for services related to EVLP.

Figure 2. Reimbursement Process for Lung Bioengineering Services



Medicare Reimbursement for Services Related to EVLP Using XPS™ With STEEN Solution™

Hospital inpatient services, products, and procedures covered by Medicare are reimbursed through a Medicare beneficiary's Part A benefit.

Medicare will reimburse CTCs and OPOs when the CTC or OPO is a member of the OPTN.






MS-DRGs as Basis of Medicare Payment for Lung Transplants^{3,4}

Medicare pays CTCs for organ transplantation procedures under the Inpatient Prospective Payment System (IPPS), including any medically reasonable and necessary healthcare services. Medicare uses Medicare Severity Diagnosis-Related Groups (MS-DRGs) to classify hospital stays according to patient attributes such as the principal diagnosis, specific secondary diagnoses, procedures, sex, and discharge status. Medicare will reimburse the CTC for the organ transplant based on the primary MS-DRG applied to the hospital stay.

While the transplant itself would be reimbursed as part of the Medicare MS-DRG, organ procurement and acquisition costs related to transplants, including EVLP, are reimbursed through a separate methodology, described below.

SACs as Basis of Interim Medicare Payments for Organ Procurement⁵

For lung transplantation, the CTC reimburses the OPO a standard acquisition charge (SAC), which is based on average total actual costs that are considered "reasonable and necessary" to procure organs from deceased donors. A CTC may seek reimbursement for the following additional organ acquisition expenses when using organs from a deceased donor:

-  **Cost of organs, if acquired for other providers**
-  **Organ transportation costs**
-  **Surgeon fee for procuring organs from a deceased donor**
-  **Tissue typing and lab services**
-  **Preservation and perfusion costs (eg, EVLP)**

CTCs accrue these costs throughout the year. Medicare provides an interim, biweekly payment based on organ acquisition charges that were filed by the hospital on its Medicare Cost Report (MCR) the previous year and reconciles each year's payments at a later date.⁵

CMS Coverage of EVLP Using XPS™ With STEEN Solution™ as an Organ Procurement Cost

Medically necessary services related to EVLP are eligible for coverage by Medicare and may be reimbursed as transplant organ procurement costs.⁶ CTCs are not required to obtain approval from local Medicare Administrative Contractors (MACs). However, MACs may require additional documentation. To facilitate Medicare reimbursement, please contact your regional Part A MAC for additional information.⁷ See Appendix 1, on page 21 of this guide, for a state-by-state listing of MACs and their contact websites and telephone numbers.

In a memo dated February 18, 2016, the Centers for Medicare and Medicaid Services (CMS) provided additional coverage guidance for EVLP using XPS™ With STEEN Solution™. Per CMS, the EVLP procedure, when used in conjunction with XPS™ With STEEN Solution™, meets the requirements for “reasonable and necessary” organ acquisition costs. That means these costs are covered by Medicare in full when reported as an organ acquisition expense on the Medicare cost report, as long as they meet the agency’s applicable requirements for coverage.⁶

Figure 3. CMS Correspondence Excerpt⁶



We’ve reviewed the information for XPS and it appears the costs listed in the memo meet the requirements for inclusion under our current regulations ... as organ acquisition costs.

– CMS Division of Cost Reporting



To read the full text of the CMS correspondence, please see Appendix 2, on page 22 of this Guide.

Medicare Cost Reporting and Reconciliation

At the end of the year, each CTC or hospital-based OPO prepares an MCR (CMS Form 2552) that details all organ procures costs, including EVLP procedures used in conjunction with XPS™ With STEEN Solution™. Organ acquisition costs incurred by an independent OPO not affiliated with a hospital are included on the appropriate organ acquisition cost center on its MCR, FORM CMS-216. Organ acquisition costs are not paid by Medicare directly to hospital-based OPOs; these OPOs must be reimbursed for their services by a CTC³.

CTCs report organ acquisition costs on Worksheet D-4 (Parts I-IV) of the MCR by organ program (eg, lung, kidney, heart). This includes all inpatient routine and ancillary service costs that the CTC has incurred throughout the year. This information is then summarized on Line 108 on Worksheet A, which sums the total of all direct, allowable organ acquisition costs. On Line 108, salaries for procedure technicians and the time spent by physicians and any allied health staff on pre-transplant services are reported on Column 1 (Salaries). Column 2 (Other) captures other eligible expenses, including perfusion costs, transportation, other fees, and patient pre-transplant workups.

Medicare provides an interim, biweekly payment based on organ acquisition charges that were filed by the hospital on its MCR the previous year. These payments are reconciled each year once the cost report has been accepted and reviewed. Worksheet E-1 (Parts I and II) of the MCR is used to report these interim payments that the CTC already received from Medicare during the year to allow for appropriate reconciling at the end of the cost reporting period.

After a MAC accepts the cost report submission from a CTC, the MAC has 60 days to review it. The MAC may make a tentative settlement based on the CTC’s audit history. Final payment occurs after the MCR is audited by the MAC. The final payment calculation is equal to the total cost for all organ acquisition the CTC incurred through the year for all patients multiplied by the percentage of Medicare patients that received a transplant.

Figure 4a: Medicare Cost Report, Worksheet D-4, Part I⁸

11-17 FORM CMS-2552-10 4090 (Cont.)

COMPUTATION OF ORGAN ACQUISITION COSTS AND CHARGES FOR HOSPITALS WHICH ARE CERTIFIED TRANSPLANT CENTERS

PROVIDER CCN: _____ PERIOD: FROM _____ TO _____ WORKSHEET D-4, PART I

OPO CCN: _____

Check applicable box: HEART LIVER PANCREAS ISLET KIDNEY LUNG INTESTINE

PART I - COMPUTATION OF ORGAN ACQUISITION COSTS (INPATIENT ROUTINE AND ANCILLARY SERVICES)

Computation of Inpatient Routine Service Costs Applicable to Organ Acquisition	Inpatient Routine Organ Charges	Per Diem Costs (from Wkst. D-1, Part II)		Organ Acquisition Days	Cost (col. 2 x col. 3)
		1	2		
1 Adults and Pediatrics		38			1
2 Intensive Care		43			2
3 Coronary Care		44			3
4 Burn Intensive Care Unit		45			4
5 Surgical Intensive Care Unit		46			5
6 Other Special Care (specify)		47			6
7 TOTAL (sum of lines 1 through 6)					7

Computation of Ancillary Service Costs Applicable to Organ Acquisition	Ratio of Cost to Charges (from Wkst. C)	Organ Acquisition Ancillary Charges	Organ Acquisition Ancillary Costs	
				C
8 Operating Room		50		8
9 Recovery Room		51		9
10 Labor Room & Delivery Room		52		10
11 Anesthesiology		53		11
12 Radiology-Diagnostic		54		12
13 Radiology-Therapeutic		55		13
14 Radioisotope		56		14
15 Computed Tomography (CT) Scan		57		15
16 Magnetic Resonance Imaging (MRI)		58		16
17 Cardiac Catheterization		59		17
18 Laboratory		60		18
19 PBP Clinical Laboratory Services-Program Only		61		19
20 Whole Blood & Packed Red Blood Cells		62		20
21 Blood Storage, Processing, & Transfusing		63		21
22 IV Therapy		64		22
23 Respiratory Therapy		65		23
24 Physical Therapy		66		24
25 Occupational Therapy		67		25
26 Speech Pathology		68		26
27 Electrocardiology		69		27
28 Electroencephalography		70		28
29 Medical Supplies Charged to Patients		71		29
30 Implantable Devices Charged to Patients		72		30
31 Drugs Charged to Patients		73		31
32 Renal Dialysis		74		32
33 ASC (non-distinct part)		75		33
34 Other Ancillary (specify)		76		34
35 Rural Health Clinic (RHC)		88		35
36 Federally Qualified Health Center (FQHC)		89		36
37 Clinic		90		37
38 Emergency Room		91		38
39 Observation Beds		92		39
40 Other Outpatient Service (specify)		93		40
41 TOTAL (sum of lines 8 through 40)				41

C = Worksheet C line numbers D = Worksheet D-1 line numbers

FORM CMS-2552-10 (11-2017) (INSTRUCTIONS FOR THIS WORKSHEET ARE PUBLISHED IN CMS PUB. 15-2, SECTIONS 4028.1)

Rev. 12

40-579

Figure 4b: Medicare Cost Report, Worksheet D-4, Part II⁸

4090 (Cont.) FORM CMS-2552-10 11-17

COMPUTATION OF ORGAN ACQUISITION COSTS AND CHARGES FOR HOSPITALS WHICH ARE CERTIFIED TRANSPLANT CENTERS

PROVIDER CCN: _____ PERIOD: FROM _____ TO _____ WORKSHEET D-4, PART II

OPO CCN: _____

Check applicable box: HEART LIVER PANCREAS ISLET KIDNEY LUNG INTESTINE

PART II - COMPUTATION OF ORGAN ACQUISITION COSTS (OTHER THAN INPATIENT ROUTINE AND ANCILLARY SERVICE COSTS)

Computation of the Cost of Inpatient Services of Interns and Residents Not In Approved Teaching Program	Average Cost Per Day (from Wkst. D-2, Part I, col. 4)	Organ Acquisition Days	Organ Acquisition Costs (col. 1 x col. 2)	
				D
42 Adults & Pediatrics (General routine care)				42
43 Intensive Care Unit				43
44 Coronary Care Unit				44
45 Burn Intensive Care Unit				45
46 Surgical Intensive Care Unit				46
47 Other Special Care (specify)				47
48 TOTAL (sum of lines 42 through 47)				48

Computation of the Cost of Outpatient Services of Interns and Residents Not In Approved Teaching Program	Organ Charges (see instructions)	Ratio of Cost to Charges from Wkst. D-2, Part I, col. 4)	Organ Acquisition Costs (col. 1 x col. 2)	
				D
49 Rural Health Clinic (RHC)				49
50 Federally Qualified Health Center (FQHC)				50
51 Clinic				51
52 Emergency				52
53 Observation Beds				53
54 Other Outpatient Service (specify)				54
55 TOTAL (sum of lines 49 through 54)				55

D = Worksheet D-2, Part I, line numbers

FORM CMS-2552-10 (09-2014) (INSTRUCTIONS FOR THIS WORKSHEET ARE PUBLISHED IN CMS PUB. 15-2, SECTIONS 4028.2)

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Rev. 12

Figure 4b: Medicare Cost Report, Worksheet D-4, Part III & IV⁸

09-14 FORM CMS-2552-10 4090 (Cont.)

COMPUTATION OF ORGAN ACQUISITION COSTS AND CHARGES FOR HOSPITALS WHICH ARE CERTIFIED TRANSPLANT CENTERS

PROVIDER CCN: _____ PERIOD: FROM _____ TO _____ WORKSHEET D-4, PARTS III & IV

OPO CCN: _____

Check applicable box: HEART LIVER PANCREAS ISLET KIDNEY LUNG INTESTINE

PART III - SUMMARY OF COSTS AND CHARGES

	Cost		Charges		
	Part A	Part B	Part A	Part B	
56 Routine and Ancillary from Part I	1	2	3	4	56
57 Interns and Residents (inpatient)					57
58 Interns and Residents (outpatient)					58
59 Direct Organ Acquisition (see instructions)					59
60 Cost of physicians' services in a teaching hospital (see instructions)					60
61 Total (sum of lines 56 through 60)					61
62 Total Usable Organs (see instructions)					62
63 Medicare Usable Organs (see instructions)					63
64 Ratio of Medicare Usable Organs to Total Usable Organs (line 63 ÷ line 62)					64
65 Medicare Cost/Charges (see instructions)					65
66 Revenue for Organs Sold					66
67 Subtotal (line 65 minus line 66)					67
68 Organs Furnished Part B					68
69 Net Organ Acquisition Cost and Charges (see instructions)					69

PART IV - STATISTICS

	Living Related	Cadaveric	Revenue	
				1
70 Organs Excised in Provider (1)				70
71 Organs Purchased from Other Transplant Hospitals (2)				71
72 Organs Purchased from Non-Transplant Hospitals				72
73 Organs Purchased from OPOs				73
74 Total (sum of lines 70 through 73)				74
75 Organs Transplanted				75
76 Organs Sold to Other Hospitals				76
77 Organs Sold to OPOs				77
78 Organs Sold to Transplant Hospitals				78
79 Organs Sold to Military or VA Hospitals				79
80 Organs Sold Outside the U.S.				80
81 Organs Sent Outside the U.S. (no revenue received)				81
82 Organs Used for Research				82
83 Unusable/Discarded Organs				83
84 Total (sum of lines 75 through 83 should equal line 74)				84

(1) Organs procured outside your center by a procurement team from your center are not included in the count.
 (2) Organs procured outside your center by a procurement team from your center are included in the count.

Figure 4c: Medicare Cost Report, Worksheet A⁸

4090 (Cont.) FORM CMS-2552-10

RECLASSIFICATION AND ADJUSTMENT OF TRIAL BALANCE OF EXPENSES			PROVIDER CCN:		PERIOD: FROM _____ TO _____		WORKSHEET A		
COST CENTER DESCRIPTIONS (omit cents)			SALARIES	OTHER	TOTAL (col. 1 + col. 2)	RECLASSIFI- CATIONS	RECLASSIFIED TRIAL BALANCE (col. 3 ± col. 4)	ADJUSTMENTS	NET EXPENSES FOR ALLOCATION (col. 5 ± col. 6)
			1	2	3	4	5	6	7
OTHER REIMBURSABLE COST CENTERS									
94	09400	Home Program Dialysis							
95	09500	Ambulance Services							
96	09600	Durable Medical Equipment-Rented							
97	09700	Durable Medical Equipment-Sold							
98		Other Reimbursable (specify)							
99		Outpatient Rehabilitation Provider (specify)							
100	10000	Intern-Resident Service (not appvd. tchn. prgm.)							
101	10100	Home Health Agency							
SPECIAL PURPOSE COST CENTERS									
105	10500	Kidney Acquisition							
106	10600	Heart Acquisition							
107	10700	Liver Acquisition							
108	10800	Lung Acquisition							
109	10900	Pancreas Acquisition							
110	11000	Intestinal Acquisition							
111	11100	Islet Acquisition							
112		Other Organ Acquisition (specify)							
113	11300	Interest Expense							- 0 -
114	11400	Utilization Review-SNF							- 0 -
115	11500	Ambulatory Surgical Center (Distinct Part)							
116	11600	Hospice							
117		Other Special Purpose (specify)							
118		SUBTOTALS (sum of lines 1-117)							
NONREIMBURSABLE COST CENTERS									
190	19000	Gift, Flower, Coffee Shop, & Canteen							
191	19100	Research							
192	19200	Physicians' Private Offices							
193	19300	Nonpaid Workers							
194		Other Nonreimbursable (specify)							
200		TOTAL (sum of lines 118-199)							- 0 -

Figure 4d: Medicare Cost Report, Worksheet E-1, Part I⁸

4090 (Cont.) FORM CMS-2552-10 03-15

ANALYSIS OF PAYMENTS TO PROVIDERS FOR SERVICES RENDERED			PROVIDER CCN:		PERIOD: FROM _____ TO _____		WORKSHEET E-1, PART I	
Check applicable box:			COMPONENT CCN:					
			<input type="checkbox"/> Hospital		<input type="checkbox"/> Subprovider (Other)			
			<input type="checkbox"/> IPF		<input type="checkbox"/> SNF			
			<input type="checkbox"/> IRF		<input type="checkbox"/> Swing-Bed SNF			
Description	Inpatient Part A		Part B		1	2	3	4
	mm/dd/yyyy	Amount	mm/dd/yyyy	Amount				
1 Total interim payments paid to provider								
2 Interim payments payable on individual bills, either submitted or to be submitted to the intermediary for services rendered in the cost reporting period. If none, write "NONE" or enter a zero								
3 List separately each retroactive lump sum adjustment amount based on subsequent revision of the interim rate for the cost reporting period. Also show date of each payment. If none, write "NONE" or enter a zero. (1)	Program to Provider	01						3.01
		02						3.02
		03						3.03
		04						3.04
		05						3.05
	Provider to Program	50						3.50
		51						3.51
		52						3.52
		53						3.53
		54						3.54
Subtotal (sum of lines 3.01- 3.49 minus sum of lines 3.50-3.98)		99						3.99
4 Total interim payments (sum of lines 1, 2, and 3.99) (transfer to Wkst. E or Wkst. E-3, line and column as appropriate)								4
5 List separately each tentative settlement payment after desk review. Also show date of each payment. If none, write "NONE" or enter a zero. (1)	Program to Provider	01						5.01
		02						5.02
		03						5.03
	Provider to Program	50						5.50
		51						5.51
		52						5.52
Subtotal (sum of lines 5.01-5.49 minus sum of lines 5.50 -5.98)		99						5.99
6 Determined net settlement amount (balance due) based on the cost report (1)	Program to Provider	01						6.01
	Provider to Program	02						6.02
7 Total Medicare program liability (see instructions)								7
8 Name of Contractor	Contractor Number		NPR Date (Month/Day/Year)					8

(1) On lines 3, 5, and 6, where an amount is due provider to program, show the amount and date on which the provider agrees to the amount of repayment even though total repayment is not accomplished until a later date.

FORM CMS-2552-10 (03-2015) (INSTRUCTIONS FOR THIS WORKSHEET ARE PUBLISHED IN CMS PUB. 15-2, SECTION 4031.1)
40-588

Figure 4d: Medicare Cost Report, Worksheet E-1, Part II⁸

03-18 FORM CMS-2552-10 4090 (Cont.)

CALCULATION OF REIMBURSEMENT SETTLEMENT FOR HIT			PROVIDER CCN:		PERIOD: FROM _____ TO _____		WORKSHEET E-1, PART II	
Check applicable box:			COMPONENT CCN:					
			<input type="checkbox"/> Hospital		<input type="checkbox"/> CAH			
HEALTH INFORMATION TECHNOLOGY DATA COLLECTION AND CALCULATION								
1	Total hospital discharges as defined in ARRA §4102 (Wkst. S-3, Pt. I, col. 15, line 14)							1
2	Medicare days (Wkst. S-3, Pt. I, col. 6, sum of lines 1 and 8 through 12)							2
3	Medicare HMO days (Wkst. S-3, Pt. I, col. 6, line 2)							3
4	Total inpatient days (Wkst. S-3, Pt. I, col. 8, sum of lines 1 and 8 through 12)							4
5	Total hospital charges (Wkst. C, Pt. I, col. 8, line 200)							5
6	Total hospital charity care charges (Wkst. S-10, col. 3, line 20)							6
7	CAH only - The reasonable cost incurred for the purchase of certified HIT technology (Wkst. S-2, Pt. I, line 168)							7
8	Calculation of the HIT incentive payment (see instructions)							8
9	Sequestration adjustment amount (see instructions)							9
10	Calculation of the HIT incentive payment after sequestration (see instructions)							10
INPATIENT HOSPITAL SERVICES UNDER THE IPPS & CAH								
30	Initial/interim HIT payment(s).							30
31	Initial/interim HIT payment adjustments (see instructions)							31
32	Balance due provider (line 8 or line 10 minus line 30 and line 31) (see instructions)							32

* This worksheet is completed by the contractor for standard and non-standard cost reporting periods at cost report settlement. Providers may complete this worksheet for a standard cost reporting period.

FORM CMS-2552-10 (09-2015) (INSTRUCTIONS FOR THIS WORKSHEET ARE PUBLISHED IN CMS PUB. 15-2, SECTION 4031.2)
40-589

Figure 5. Equation of How Medicare Calculates Annual Reimbursement to CTC for Organ Procurement Costs³

$$\text{Total cost for all lung acquisitions} \times \frac{\text{Medicare usable organs}}{\text{Total usable organs}} = \text{Medicare payment to CTC for organ acquisition costs}$$

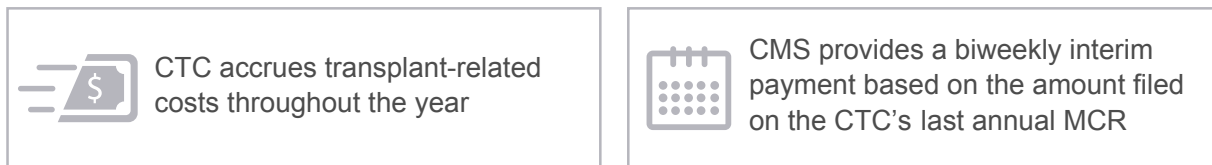
Key: CTC: certified transplant center.

Medicare Reimbursement Processes for Organ Acquisition Costs

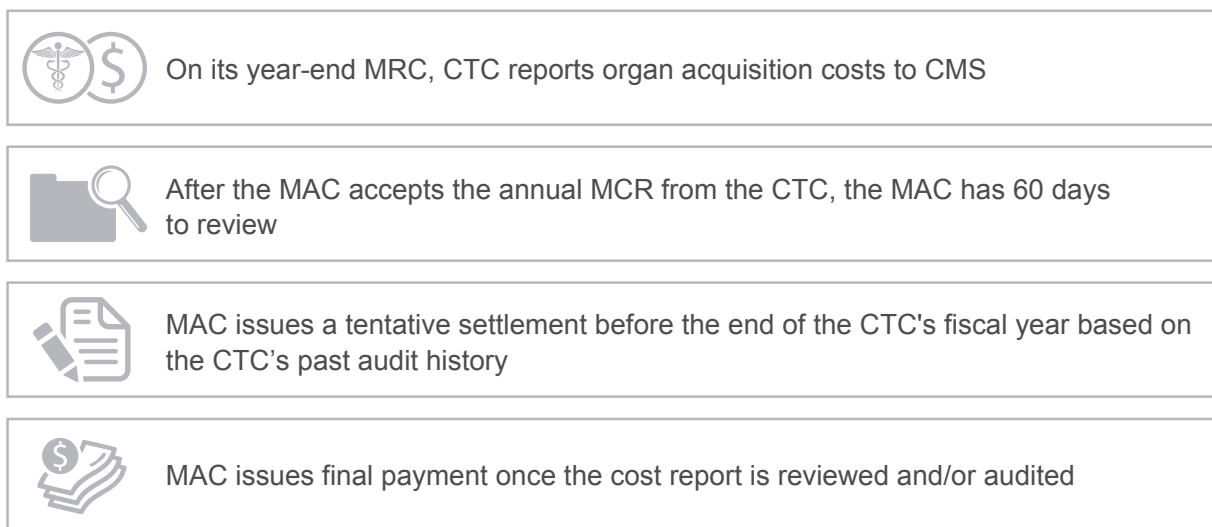
Below is a step-by-step overview of the processes CMSs and CTCs follow to reimburse organ acquisition costs related to lung transplants.

Figures 6a and 6b. Medicare Reimbursement Process for Organ Acquisition Costs Related to Lung Transplants

6a. Interim Payment:



6b. Year-End Payment and Reconciliation:



Key: CTC: certified transplant center; CMS: Centers for Medicare & Medicaid Services; MCR: Medicare cost report; MAC: Medicare Administrative Contractor.

Other payers, such as private commercial health plans, may reimburse organ procurement costs differently than Medicare. For instance, managed care organizations may reimburse these services based on contracted global payment rates that the hospital negotiates separately with each insurer.

Commercial Reimbursement for Services Related to EVLP Using XPS™ With STEEN Solution™

While Medicare has a cost-based reimbursement model for perfusion services, most commercial insurers pay one lump sum to transplant centers for a transplant patient. This single payment is intended to cover care the patient receives while waitlisted, organ acquisition costs, the transplant, and a post-transplant global period. Post-transplant global periods vary by payer and generally range from 30 to 180 days. After the global period has ended, post-transplant services are covered separately. Payer contracts may also provide additional payments for high-cost, outlier patients.⁹

Coding for Lung Transplants and Organ Procurement, Including EVLP Using XPS™ With STEEN Solution™

In addition to providing guidance regarding the reimbursement for EVLP, the following general coding and billing information may be appropriate for diagnoses, procedures, and services associated with lung transplantation.

Diagnosis Codes⁹

The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code set is used to report patient-specific medical diagnoses. ICD-10-CM diagnosis codes can help to document the medical necessity for healthcare services provided across all sites of care. Billing the appropriate ICD-10-CM diagnosis code(s) for lung transplantation may help to support payer coverage for the services rendered.

Table 1. Sample ICD-10-CM Diagnosis Codes for Lung Transplant Recipients

ICD-10-CM CODE	DESCRIPTION	ICD-10-CM CODE	DESCRIPTION
C34.00–C34.92	Malignant neoplasm of bronchus and lung	J67.4–J67.9	Allergic alveolitis (extrinsic)
C96.6	Unifocal Langerhans-cell histiocytosis	J84.10	Pulmonary fibrosis, unspecified
D86.0	Sarcoidosis of lung	J84.111–J84.117	Idiopathic interstitial pneumonia
D89.810–D89.813	Graft-versus-host disease	J84.170	Interstitial lung disease with progressive fibrotic phenotype in diseases classified elsewhere
E84.0–E84.9	Cystic fibrosis		
E88.01	Alpha-1-antitrypsin deficiency	J84.178	Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere
I27.0	Primary pulmonary hypertension		
I27.83	Eisenmenger's syndrome	J84.81	Lymphangiomyomatosis
J41.8	Mixed simple and mucopurulent chronic bronchitis	J84.89	Other specified interstitial pulmonary diseases
J42	Unspecified chronic bronchitis (bronchiolitis obliterans)	J98.2	Interstitial emphysema
J43.0–J43.9	Emphysema	J99	Respiratory disorders in diseases classified elsewhere
J44.0–J44.9	Chronic obstructive pulmonary disease		
J47.0–J47.9	Bronchiectasis	M34.81	Systemic sclerosis with lung involvement
J60	Coal worker's pneumoconiosis	Q33.0	Congenital cystic lung
J61	Pneumoconiosis due to asbestos and other mineral fibers	Q33.3	Agenesis of lung
		Q33.4	Congenital bronchiectasis
J62.0–J62.8	Pneumoconiosis due to dust containing silica	Q33.6	Congenital hypoplasia and dysplasia of lung
J63.0–J63.6	Pneumoconiosis due to other inorganic dust	Z94.2	Lung transplant status

Please note that this list is not exhaustive, and another ICD-10-CM code or codes may be appropriate. Codes should be reported to the highest level of specificity and must be supported by the information in the patient's medical record. Please contact the patient's health insurance plan to ensure medical claims are accurate, complete, and consistent with approved coverage policies.

Procedure Codes¹⁰

International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) codes are unique codes used to report procedures and other services performed in the hospital site of care.

Table 2. Sample ICD-10-PCS Codes for Lung Procurement and Transplant

SERVICE	ICD-10-PCS CODE AND DESCRIPTOR (Codes are collapsed to include various options)*
Blood gas monitoring	4A[0,1]3[0,3,X]R1 Measurement of arterial saturation, peripheral
Arterial pressure monitoring	4A[0,1]3[0,3,X]B1 Measurement/monitoring of arterial pressure, peripheral
Venous pressure monitoring	4A[0,1]4[3,X]B[0,1] Measurement/monitoring of venous pressure, peripheral
Artery pressure monitoring and artery wedge monitoring	4A[0,1]2[0,3][9,N][6,Z] Measurement of cardiac sampling and pressure or output
Measurement of systemic arterial blood	4A[0,1]3XR1 Measurement of arterial saturation, peripheral
Measurement of mixed venous blood gases	4A[0,1]4[0,3,X]R[0,1,2,3] Measurement of venous saturation
Monitoring of cardiac output by other technique	4A[0,1][2,3][0,3,X]9Z Measurement/monitoring of cardiac output
Monitoring of coronary blood flow	4A[0,1]3[0,3]5C Measurement/monitoring of arterial flow, coronary
X-ray, other and unspecified	B[3,5][0,1][O,R,S,T][0,1,Y,Z]ZZ Plain radiography/fluoroscopy of pulmonary artery/vein
Other bronchoscopy	0BJ[0,K]8ZZ Bronchoscopy, lung
Intubation	0BH[7,8]E,Z Insertion of endotracheal airway into trachea, via natural or artificial opening
Ventilator monitoring	5A19[0,3,4,5]5,[4,Z] Respiratory ventilation
Arterial cannulation	03H[9,A,B,C,V][0,3]3,Z Insertion of infusion device, artery
Venous cannulation	0[2,5,6]H[0,3,4,5,6,S,T,V][0,3][3,D][T,Z] Insertion of infusion device, vein
Lung tissue biopsy	0BB[C,D,F,G,H,J,K,L,M][0,3,4,7,8]ZX Excision, diagnostic (biopsy)
	0BD[C,D,F,G,H,J,K,L,M][4,8]ZX Extraction, diagnostic (biopsy) <i>Lung tissue preservation/preparation (eg, cold preservation) is generally included in lung resection codes</i>
Lung tissue preservation	6ABB0BZ Perfusion of respiratory system donor organ, single
Lung transplantation	0BY[C,D,F,G,H,J,K,L,M]OZ[0,1,2]

*Code ranges included in brackets indicate that an HCP must select one ICD-10 procedure code that most-appropriately describes a procedure performed during an encounter.

MS-DRGs¹¹

In the hospital inpatient site of care, DRGs represent an all-inclusive payment for all procedures, supplies, and services used to treat the patient during a single hospital stay. Medicare determines payment to the CTC for the lung transplant based on the patient's clinical and procedural attributes. MS-DRGs may then be further segmented to include complications/comorbidities (CC) or major complications/comorbidities (MCC).

Table 3. MS-DRG for Lung Transplant

MS-DRG	DESCRIPTOR
007	Lung Transplant

Additional Assistance Information



Sam Popa

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General Manager
Silver Spring, MD



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Center EVLP Process**



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Brandi Zofkie

Associate Director and
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**Southeast US Region Transplant
Center EVLP Process**



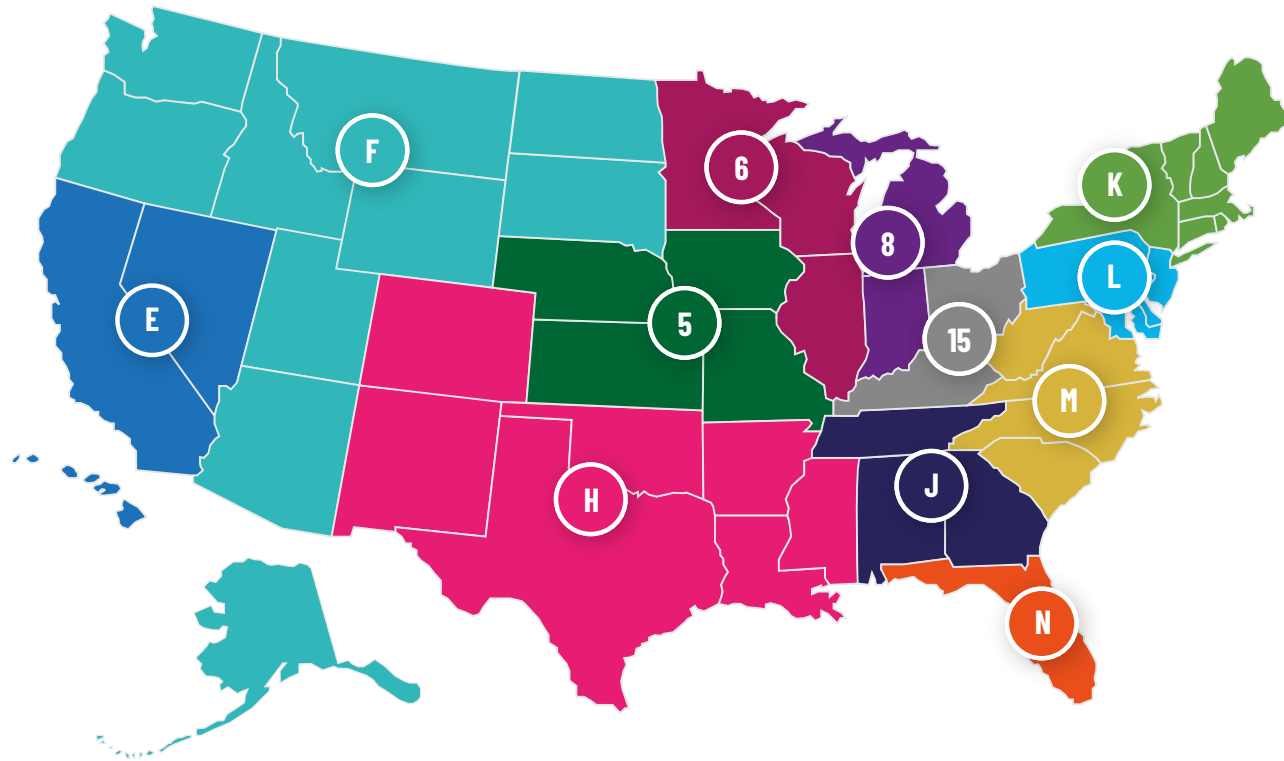
bzofkie@lungbioengineering.com

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Appendix 1

Part A MAC Jurisdictions and Contact Information*



Jurisdiction	Contractor	Website	Part A Phone #
5	WPS	https://www.wpsgha.com	(866) 518-3285
6	NGS	https://www.NGSMedicare.com	(877) 702-0990
8	WPS	https://www.wpsgha.com	(866) 234-7331
15	CGS	https://www.cgsmedicare.com/	(866) 590-6703
E	Noridian	https://med.noridianmedicare.com/	(855) 609-9960
F	Noridian	https://med.noridianmedicare.com/	(877) 908-8431
H	Novitas	https://www.novitas-solutions.com/webcenter/portal/NovitasSolutions	(855) 252-8782
J	Palmetto	https://www.palmettogba.com/	(877) 567-7271
K	NGS	https://www.NGSMedicare.com	(888) 855-4356
L	Novitas	https://www.novitas-solutions.com/webcenter/portal/NovitasSolutions	(877) 235-8073
M	Palmetto	https://www.palmettogba.com/	(855) 696-0705
N	FCSO	https://medicare.fcso.com/	(888) 664-4112

*<https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/AB-Jurisdiction-Map-Jun-2019.pdf>

Appendix 2

CMS Correspondence: Coverage of EVLP Using XPS™ With STEEN Solution™ as an Organ Procurement Cost

From: Rhodes, Deanna M.(CMS/CM) [<mailto:Deanna.Rhodes@cms.hhs.gov>]
Sent: Thursday, February 18, 2016 9:50 AM
To: Martha Morton; Citerone, Amelia R. (CMS/CM)
Cc: Treitel, Michael (CMS/CM); Go, Kimberly (CMS/CM); Cheng, Ing Jye (CMS/CM); Joshua, Michelle (CMS/CM); Carolyn Moora; daniel.martinelli@xvivoperfusion.com
Subject: RE: XVIVO memo

Ms. Morton,

Thank you for sending the detailed and valuable information on the XVIVO Perfusion System (XPS™) with STEEN Solution™ as a follow-up to our call on Friday, February 5, 2016. We appreciate the important work that XVIVO Perfusion Inc. provides to the transplant community in an effort to increase lung transplantation. We've reviewed the information for XPS and it appears the costs listed in the memo meet the requirements for inclusion under our current regulations at 42 CFR 412.100 and CMS Pub. 15-1, chapter 27, section 2770 through 2775.4, as organ acquisition costs.

Under Medicare policy, there are two parts of the payment for organ transplantation. The certified transplant center(CTC) is paid based on a DRG under the hospital inpatient prospective payment system for the transplant. Organ acquisition costs are treated apart from the prospective payment system rate for inpatient operating costs, and payment to the CTC reflects an amount necessary to compensate the hospital under reasonable cost principles for acquiring the organ. We encourage the CTCs to reach out to their Medicare contractors or CMS for any additional questions or guidance relative to XPS.

Thank you again for your interest in this important issue as we work toward our mutual goal of increasing organ donation and transplantation.

Deanna Rhodes

Deputy Division Director
 Division of Cost Reporting
 Centers for Medicare and Medicaid Services

