

Aliya™
PEF System

2024 Reimbursement & Coding Guide

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BACKGROUND

ABOUT ALIYA SYSTEM FOR PULSED FIELD ABLATION OF SOFT TISSUE

The Aliya™ system is designed to ablate soft tissue through the delivery of pulsed electric fields (PEF) energy to target tissue. The high frequency, short duration energy is delivered to the target tissue to induce cell death while maintaining the extracellular matrix.

INDICATIONS FOR USE

The Aliya system is 510(k) cleared in the United States for the surgical ablation of soft tissue.

DISCLAIMER

Galvanize Therapeutics does not promote the off-label use of its products and nothing herein is intended to promote an off-label use of the Aliya System. The Aliya System is a tool for the surgical ablation of soft tissues, and is not intended to treat, cure, prevent or mitigate any specific disease or condition.

The information provided contains general reimbursement information and is presented for illustrative purposes. The information does not constitute reimbursement or legal advice. It is the provider's sole responsibility to determine medical necessity, the proper site for delivery of any services, and to submit accurate and appropriate codes, charges and modifiers based on the services rendered and the patient's medical condition. It is also the provider's sole responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other specific payer billing requirements established by relevant payers. Payer billing, coding and coverage requirements vary from payer to payer, may be updated frequently, and should be verified before treatment for limitations on diagnosis, coding, or service requirements. Galvanize Therapeutics recommends you consult with payers, reimbursement specialists, and/or legal counsel regarding all coding, coverage, and reimbursement matters. **All coding and billing submissions to the federal government and any other payer must be truthful and not misleading, and require full disclosure for the reimbursement of any service or procedure.** Galvanize Therapeutics specifically disclaims any responsibility for actions or consequences resulting from the use of this information.

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DISCLOSURE

Prior to using the Aliya System, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events. For full prescribing information, please visit www.galvanizetherapeutics.com.

PHYSICIAN, HOSPITAL OUTPATIENT, AND ASC CODING

Medicare 2024 National Average Payment (Not Adjusted Geographically)								
Service Provided		Physician Fee Schedule ¹		ASC ² Payment/Indicator		Hospital ³		
CPT [®]	Description	Non-Facility (OBL)	Facility (-26)			APC/Indicator	APC/Indicator	OPPS Payment
0600T*	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous (Do not report 0600T in conjunction with 76940, 77002, 77013, 77022)	No national payment established		\$6604	J8	5362	J1	\$9808
0601T*	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open (Do not report 0601T in conjunction with 76940, 77002)	No national payment established		\$6481	J8	5362	J1	\$9808

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CATEGORY III CPT[®] CODES

The Aliya PEF procedure may be reported using the Category III CPT[®] codes in the table above. These codes specifically describe irreversible electroporation of tumors via a percutaneous or open approach. If any other type of laproscopic, endoscopic, or bronchoscopic approach is performed an unlisted procedure code may be reported. Unlisted CPT[®] codes or “not otherwise specified” CPT[®] codes allow physicians to report procedures that do not have a more specific CPT[®] code. Reporting an unlisted code correctly with appropriate documentation allows physicians and hospitals to submit coding for a procedure that does not have a specific CPT[®] code. The procedures described by CPT[®] 0600T and 0601T include the imaging guidance procedures. Imaging guidance CPT[®] codes are not separately submitted on the CMS Form 1500 claim form.

Category III CPT[®] Codes are temporary codes for emerging technology, services and procedures that allow for specific data collection associated with those services and procedures. According to the AMA CPT[®], if a Category III code is available, it must be reported instead of a Category I unlisted code¹.

There are no assigned RVU’s or established physician payment for these Category III CPT[®] codes. Reimbursement to the physician is at the payer’s discretion. Payers may request documentation of clinical efficacy to support coverage. Payers that have implemented the new Category III IRE codes may request documentation of clinical efficacy to support coverage. The following items are recommended to support your claim submissions:

- Copy of operative report
- Letter of medical necessity
- Copy of the FDA clearance letter

When submitting a Category III CPT[®] code, it is recommended that providers submit a narrative listing a Category I CPT[®] code that they feel is comparable in time, effort, complexity, and value to the service provided, suggesting that the payer value the service represented by the Category III CPT[®] code based on the value assigned to this comparable Category I CPT[®] code. It will be important to document the services provided in terms of resources and time for appropriate payment consideration for the professional component of the procedure.

THE CODES BELOW DO NOT PRESUME, ASSUME, OR INTEND TO PROMOTE THE USE OF THIS GENERAL TOOL IN ANY SPECIFIC ANATOMICAL LOCATION OR FOR ANY SPECIFIC TREATMENT BY THE HEALTHCARE PROVIDER. THIS REIMBURSEMENT GUIDE IS ONLY INTENDED TO IDENTIFY GENERAL SOFT TISSUE LOCATIONS.

KIDNEY ICD-10-PCS CODES AND MS-DRGS

ICD-10-PCS Codes (OCT 1, 2023 to SEPT 30, 2024)

The listed ICD-10-PCS codes are examples of codes that may apply for kidney ablation procedures.⁴ Each ICD-10-PCS may be grouped under a Medicare Severity–Diagnosis Related Group (MS-DRGs).⁵

Code	ICD-10-PCS Description ⁴	MS-DRG ⁵
0T500ZZ	Destruction of right kidney, open approach	656 – 661
0T503ZZ	Destruction of right kidney, percutaneous approach	656 – 661
0T504ZZ	Destruction of right kidney, percutaneous endoscopic approach	656 – 661
0T510ZZ	Destruction of left kidney, open approach	656 – 661
0T513ZZ	Destruction of left kidney, percutaneous approach	656 – 661
0T514ZZ	Destruction of left kidney, percutaneous endoscopic approach	656 – 661
0T530ZZ	Destruction of right kidney pelvis, open approach	656 – 661
0T533ZZ	Destruction of right kidney pelvis, percutaneous approach	656 – 661
0T534ZZ	Destruction of right kidney pelvis, percutaneous endoscopic approach	656 – 661
0T540ZZ	Destruction of left kidney pelvis, open approach	656 – 661
0T543ZZ	Destruction of left kidney pelvis, percutaneous approach	656 – 661
0T544ZZ	Destruction of left kidney pelvis, percutaneous endoscopic approach	656 – 661

Medicare Severity–Diagnosis Related Groups (MS-DRGs)^{5,6} (OCT 1, 2023 to SEPT 30, 2024)

The following MS-DRGs may apply to kidney ablation procedures for Medicare patients. Other secondary diagnosis codes corresponding to additional conditions at the time of admission or developing subsequently, and having an effect on the procedures performed or length of stay during the same inpatient admission, may also be reported.

MS-DRG ⁵	MS-DRG Description	Relative Weight	Hospital Payment
656	KIDNEY & URETER PROCEDURES FOR NEOPLASM W/ MCC	3.1376	\$21,968
657	KIDNEY & URETER PROCEDURES FOR NEOPLASM W/ CC	1.8442	\$12,912
658	KIDNEY & URETER PROCEDURES FOR NEOPLASM W/O CC/MCC	1.4804	\$10,365
659	KIDNEY & URETER PROCEDURES FOR NON-NEOPLASM W/ MCC	2.5889	\$18,126
660	KIDNEY & URETER PROCEDURES FOR NON-NEOPLASM W/ CC	1.3459	\$9,423
661	KIDNEY & URETER PROCEDURES FOR NON-NEOPLASM W/O CC/MCC	1.0484	\$7,340

ICD-10-CM⁷ Diagnosis Codes (OCT 1, 2023 to SEPT 30, 2024)

The listed ICD-10-CM diagnosis codes are examples of codes that may apply for kidney ablation procedures.

Code	ICD-10-CM Description (Diagnosis Codes)
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C7A.093	Malignant carcinoid tumor of the kidney
C80.2	Malignant neoplasm associated with transplanted organ

LIVER ICD-10-PCS CODES AND MS-DRGS

ICD-10-PCS Codes (OCT 1, 2023 to SEPT 30, 2024)

The listed ICD-10-PCS codes are examples of codes that may apply for liver ablation procedures.⁴
Each ICD-10-PCS may be grouped under a Medicare Severity-Diagnosis Related Group (MS-DRGs).⁵

Code	ICD-10-PCS Description ⁴	MS-DRG ⁵
0F500ZF	Destruction of liver using irreversible electroporation, open approach	356-358, 405-407
0F503ZF	Destruction of liver using irreversible electroporation, percutaneous approach	356-358, 405-407
0F504ZF	Destruction of liver using irreversible electroporation, percutaneous endoscopic approach	356-358, 405-407
0F510ZF	Destruction of right lobe liver using irreversible electroporation, open approach	356-358, 405-407
0F513ZF	Destruction of right lobe liver using irreversible electroporation, percutaneous approach	356-358, 405-407
0F514ZF	Destruction of right lobe liver using irreversible electroporation, percutaneous endoscopic approach	356-358, 405-407
0F520FZ	Destruction of left lobe liver using irreversible electroporation, open approach	356-358, 405-407
0F523FZ	Destruction of left lobe liver using irreversible electroporation, percutaneous approach	356-358, 405-407
0F524FZ	Destruction of left lobe liver using irreversible electroporation, percutaneous endoscopic approach	356-358, 405-407

Medicare Severity–Diagnosis Related Groups (MS-DRGs)^{5,6} (OCT 1, 2023 to SEPT 30, 2024)

The following MS-DRGs may apply to liver ablation procedures for Medicare patients. Other secondary diagnosis codes corresponding to additional conditions at the time of admission or developing subsequently, and having an effect on the procedures performed or length of stay during the same inpatient admission, may also be reported.

MS-DRG ⁵	MS-DRG Description	Relative Weight	Hospital Payment
356	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W/ MCC	4.2787	\$29,958
357	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W/ CC	2.1968	\$15,381
358	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W/O CC/MCC	1.2811	\$8,970
405	PANCREAS, LIVER & SHUNT PROCEDURES W/ MCC	5.5052	\$38,545
406	PANCREAS, LIVER & SHUNT PROCEDURES W/ CC	2.8874	\$20,216
407	PANCREAS, LIVER & SHUNT PROCEDURES W/O CC/MCC	2.1510	\$15,060

ICD-10-CM⁷ Diagnosis Codes (OCT 1, 2023 to SEPT 30, 2024)

The listed ICD-10-CM diagnosis codes are examples of codes that may apply for liver ablation procedures.

Code	ICD-10-CM Description (Diagnosis Codes)
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.2	Hepatoblastoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C7A.098	Malignant carcinoid tumors of other sites
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors
C7B.02	Secondary carcinoid tumors of liver
C7B.8	Other secondary neuroendocrine tumors
D01.5	Carcinoma in situ of liver, gallbladder and bile ducts

LUNG ICD-10-PCS CODES AND MS-DRGS

ICD-10-PCS Codes (OCT 1, 2023 to SEPT 30, 2024)

The listed ICD-10-PCS codes are examples of codes that may apply for lung ablation procedures.⁴ Each ICD-10-PCS may be grouped under a Medicare Severity-Diagnosis Related Group (MS-DRGs).⁵

Code	ICD-10-PCS Description ⁴	MS-DRG ⁵
0B533ZZ	Destruction of Right Main Bronchus, Percutaneous Approach	163 – 165
0B543ZZ	Destruction of Right Upper Lobe Bronchus, Percutaneous Approach	163 – 165
0B553ZZ	Destruction of Right Middle Lobe Bronchus, Percutaneous Approach	163 – 165
0B563ZZ	Destruction of Right Lower Lobe Bronchus, Percutaneous Approach	163 – 165
0B573ZZ	Destruction of Left Main Bronchus, Percutaneous Approach	163 – 165
0B583ZZ	Destruction of Left Upper Lobe Bronchus, Percutaneous Approach	163 – 165
0B593ZZ	Destruction of Lingula Bronchus, Percutaneous Approach	163 – 165
0B5B3ZZ	Destruction of Left Lower Lobe Bronchus, Percutaneous Approach	163 – 165
0B5C3ZZ	Destruction of Right Upper Lung Lobe, Percutaneous Approach	166 – 168
0B5D3ZZ	Destruction of Right Middle Lung Lobe, Percutaneous Approach	166 – 168
0B5F3ZZ	Destruction of Right Lower Lung Lobe, Percutaneous Approach	166 – 168
0B5G3ZZ	Destruction of Left Upper Lung Lobe, Percutaneous Approach	166 – 168
0B5H3ZZ	Destruction of Lung Lingula, Percutaneous Approach	166 – 168
0B5J3ZZ	Destruction of Left Lower Lung Lobe, Percutaneous Approach	166 – 168
0B5K3ZZ	Destruction of Right Lung, Percutaneous Approach	166 – 168
0B5L3ZZ	Destruction of Left Lung, Percutaneous Approach	166 – 168
0B5M3ZZ	Destruction of Bilateral Lungs, Percutaneous Approach	166 – 168
0B5N3ZZ	Destruction of Right Pleura, Percutaneous Approach	163 – 165
0B5P3ZZ	Destruction of Left Pleura, Percutaneous Approach	163 – 165
0B5T3ZZ	Destruction of Diaphragm, Percutaneous Approach	163 – 165
0B5_OZZ	Destruction of [see above], Open Approach	163 – 165

Medicare Severity-Diagnosis Related Groups (MS-DRGs)^{5,6} (OCT 1, 2023 to SEPT 30, 2024)

The following MS-DRGs may apply to lung ablation procedures for Medicare patients. Other secondary diagnosis codes corresponding to additional conditions at the time of admission or developing subsequently, and having an effect on the procedures performed or length of stay during the same inpatient admission, may also be reported.

MS-DRG ³	MS-DRG Description	Relative Weight	Hospital Payment
163	MAJOR CHEST PROCEDURES W/ MCC	4.7136	\$33,003
164	MAJOR CHEST PROCEDURES W/ CC	2.5504	\$17,857
165	MAJOR CHEST PROCEDURES W/O CC/MCC	1.8764	\$13,138
166	OTHER RESP SYSTEM O.R. PROCEDURES W/MCC	4.0578	\$28,411
167	OTHER RESP SYSTEM O.R. PROCEDURES W/ CC	1.8198	\$12,742
168	OTHER RESP SYSTEM O.R. PROCEDURES W/O CC/MCC	1.3557	\$ 9 4 9 2

ICD-10-CM⁷ Diagnosis Codes (OCT 1, 2023 to SEPT 30, 2024)

The listed ICD-10-CM diagnosis codes are examples of codes that may apply for lung ablation procedures.

Code	ICD-10-PCS Description ⁴
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites, unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites, right bronchus or lung
C34.82	Malignant neoplasm of overlapping sites, left bronchus or lung
C34.90	Malignant neoplasm of unspecified part, unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part, right bronchus or lung
C34.92	Malignant neoplasm of unspecified part, left bronchus or lung
C37	Malignant neoplasm of thymus
C38.4	Malignant neoplasm of pleura
C45.0	Mesothelioma of pleura
C76.1	Malignant neoplasm of thorax
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum
C7A.090	Malignant carcinoid tumor of the bronchus and lung
C7A.091	Malignant carcinoid tumor of the thymus
D02.20	Carcinoma in situ of unspecified bronchus and lung
D02.21	Carcinoma in situ of right bronchus and lung
D02.22	Carcinoma in situ of left bronchus and lung
D38.1	Neoplasm of uncertain behavior of trachea, bronchus and lung
D38.2	Neoplasm of uncertain behavior of pleura
D38.3	Neoplasm of uncertain behavior of mediastinum
D38.4	Neoplasm of uncertain behavior of thymus

PANCREAS ICD-10-PCS CODES AND MS-DRGS

ICD-10-PCS Codes (OCT 1, 2023 to SEPT 30, 2024)

The listed ICD-10-PCS codes are examples of codes that may apply for pancreas ablation procedures.⁴ Each ICD-10-PCS may be grouped under a Medicare Severity-Diagnosis Related Group (MS-DRGs).⁵

Code	ICD-10-PCS Description ⁴	MS-DRG ⁵
0F5G0ZF	Destruction of pancreas using irreversible electroporation, open approach	405-407, 628-630
0F5G3ZF	Destruction of pancreas using irreversible electroporation, percutaneous approach	405-407, 628-630
0F5G4ZF	Destruction of pancreas using irreversible electroporation, percutaneous endoscopic approach	—

Medicare Severity-Diagnosis Related Groups (MS-DRGs)^{5,6} (OCT 1, 2023 to SEPT 30, 2024)

The following MS-DRGs may apply to pancreas ablation procedures for Medicare patients. Other secondary diagnosis codes corresponding to additional conditions at the time of admission or developing subsequently, and having an effect on the procedures performed or length of stay during the same inpatient admission, may also be reported.

MS-DRG ³	MS-DRG Description	Relative Weight	Hospital Payment
405	PANCREAS, LIVER, & SHUNT PROCEDURES W/ MCC	5.5052	\$38,545
406	PANCREAS, LIVER, & SHUNT PROCEDURES W/ CC	2.8874	\$20,216
407	PANCREAS, LIVER, & SHUNT PROCEDURES W/O CC/MCC	2.1510	\$15,060
628	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W/ MCC	4.0145	\$28,108
629	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W/ CC	2.2628	\$15,843
630	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W/O CC/MCC	1.3963	\$9,776

ICD-10-CM⁷ Diagnosis Codes (OCT 1, 2023 to SEPT 30, 2024)

The listed ICD-10-CM diagnosis codes are examples of codes that may apply for pancreas ablation procedures.

MS-DRG ³	ICD-10-CM Description (Diagnosis Codes)
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified

REIMBURSEMENT SUPPORT

For questions regarding coding, coverage, payment and other reimbursement information, please contact us at: AliyaReimbursement@galvanizetx.com.

REIMBURSEMENT TERMINOLOGY

Term	Description
CMS	Centers for Medicare and Medicaid Services
ASC	Ambulatory Surgical Center
OPPS	Outpatient Prospective Payment System
APC	Ambulatory Payment Classification
J1	Paid under OPPS; all covered Part B services on the claim are packaged with the primary "J1" service for the claim, except services with OPPS status indicator of "F," "G," "H," "L" and "U"; ambulance services; diagnostic and screening mammography; rehabilitation therapy services; services assigned to a new technology APC; self-administered drugs; all preventive services; and certain Part B inpatient services.
J8	Device-intensive procedure; paid at adjusted rate
ICD-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification
ICD-10-PCS	International Classification of Diseases, 10th Revision, Procedure Coding System
IPPS	Inpatient Prospective Payment System
MS-DRG	Medicare Severity Diagnosis Related Group
W/MCC	Major Complications and Comorbidities
W/CC	With Complications and Comorbidities
W/O CC/MCC	Without Complications or Comorbidities, and Without Major Complications and Comorbidities.
Relative Weight	A numeric value that reflects the relative resource consumption for the DRG to which it is assigned

SOURCES

1. CMS Physician Fee Schedule. CMS-1784-F. <https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notice/cms-1784-f>
2. CMS ASC Payment. CMS-1786-FC ASC. <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and/cms-1786-fc>
3. CMS OPPS Payment. CMS-1786-FC. <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice/cms-1786-fc>
4. CMS, 2024 ICD-10 Procedure Coding System (ICD-10-PCS). <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-pcs>
5. CMS, 2024 ICD-10-CM/PCS MS-DRG v41, Definitions Manual. https://www.cms.gov/icd10m/FY2024-nprmversion41.0-fullcode-cms/fullcode_cms/P0001.html
6. CMS, [CMS-1785-F] 2024 Medicare Hospital Inpatient Prospective Payment System (IPPS) Final Rule; Federal Register. <https://www.govinfo.gov/content/pkg/FR-2023-08-28/pdf/2023-16252.pdf>. Payment is calculated based on the national adjusted standardized amount \$7,001.60. Actual Medicare payment rates will vary from adjustments by Wage Index and Geographic Adjustment Factor depending on geographic locality. Also note that any applicable coinsurance, deductible, and other amounts that are patient obligations are included in the payment amount shown.
7. Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). <https://www.cdc.gov/nchs/icd/icd-10-cm.htm>. Updated June 29, 2023.

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician. Important information: Prior to use, refer to the Instructions for Use that are supplied with this device for indications, contraindications, side effects, suggested procedure, warnings and precautions. Galvanize and Aliya are trademarks and may be registered in the US and/or in other countries.

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