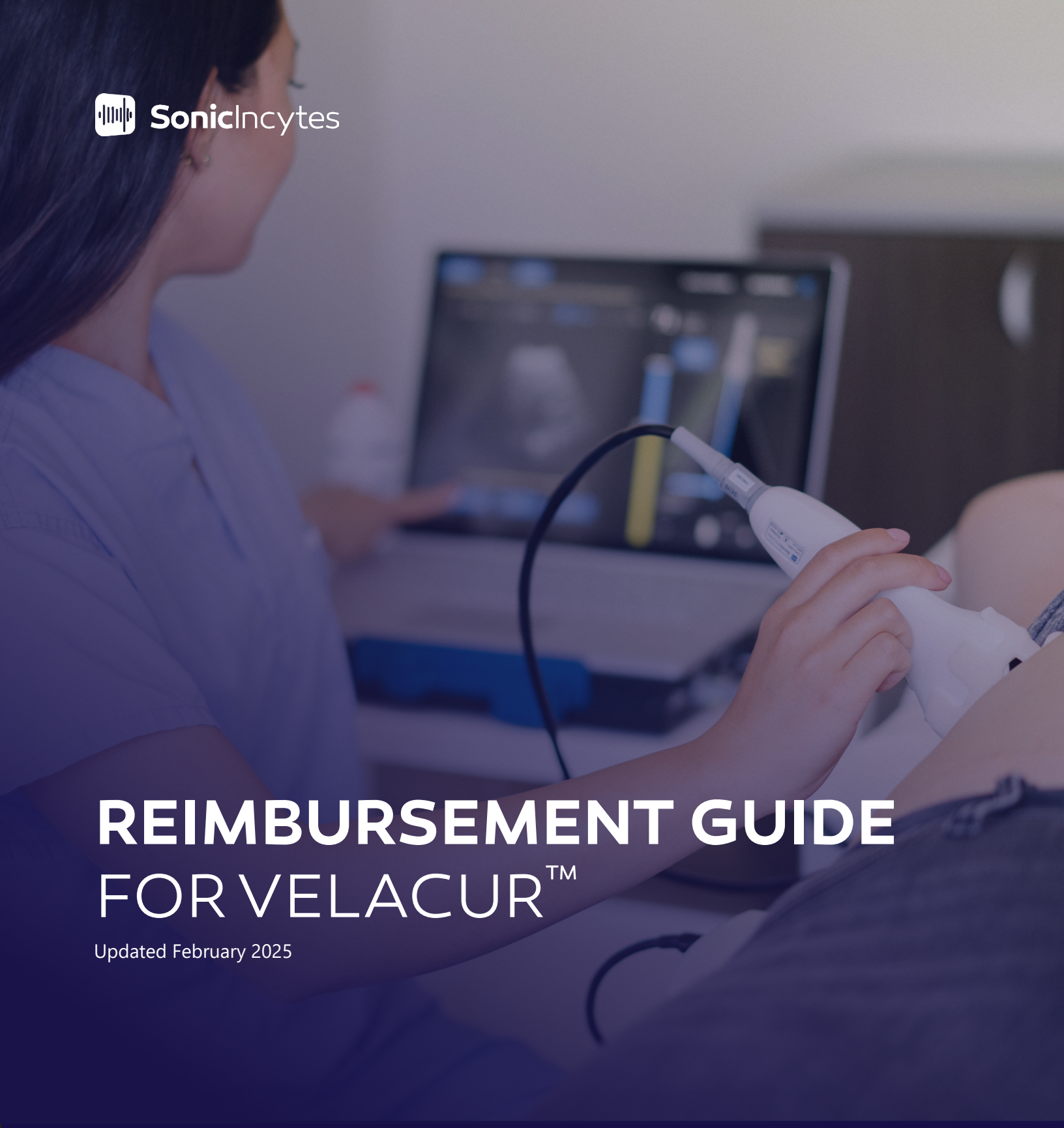

SonicIncytes

# REIMBURSEMENT GUIDE FOR VELACUR™

Updated February 2025

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MRK-0002

# ABOUT VELACUR

Created by Sonic Incytes Medical Corp, VELACUR is an AI guided 3D S-WAVE ultrasound elastography device that measures key indicators of fatty liver disease: Velacur Determined Fat Fraction (VDFF), liver stiffness and attenuation. VELACUR's AI guidance enables confident measurements - even in high BMI patients or with inexperienced operators.  With real-time results, a low up-front cost and AI guidance, VELACUR makes liver imaging at the point of care affordable and accessible.

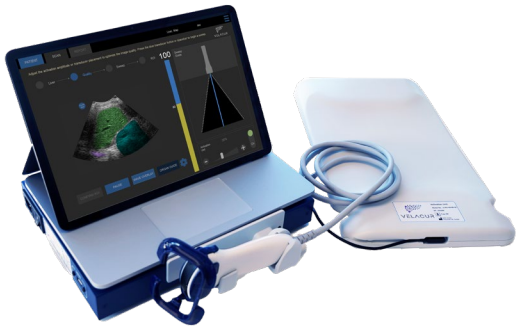
## INTENDED USE

Velacur is a point of care solution that combines the principles of MRI with handheld ultrasound to measure liver tissue stiffness and attenuation. It can be used in conjunction with other clinical indicators to aid in the management of patients with chronic liver disease.

## INDICATIONS FOR USE

Velacur is indicated to non-invasively determine Velacur Determined Fat Fraction (VDFF), liver tissue stiffness and attenuation. Patients contraindicated for Velacur are those with electronic implantable devices, e.g., pacemakers or internal defibrillators.

VELACUR
by Sonic Incytes



## PURPOSE OF THIS GUIDE

Sonic Incytes Medical Corp. is committed to providing you with reimbursement information for Velacur. This guide includes key information to support coding and billing professionals in their work with Velacur.

**Inside this guide you can find:**

- Procedure Code, Definition and Medicare
- Payment Rates
- Physician Supervision Requirements
- Payment Methodologies for Elastography Services
- Documentation Requirements

## REIMBURSEMENT SUPPORT

For questions about reimbursement or support, please contact us.

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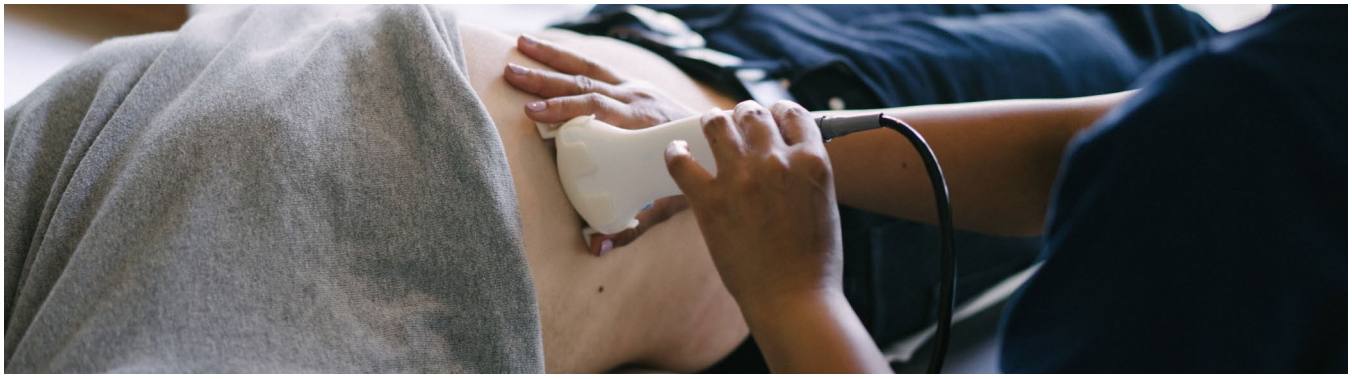


# PROCEDURE CODE, DEFINITION AND MEDICARE PAYMENT RATES

Velacur is an ultrasound solution that provides imaging based liver elastography through mechanically induced shearwaves. CPT® code 76981 applies to its use.

**76981 - Ultrasound, elastography; parenchyma (e.g., organ)**

Code 76981 applies to Velacur as the system produces ultrasound elastography images and output data for review, interpretation and report by a physician. Since 2019, 76981 is a standalone CPT® code describing the evaluation of a solid organ using ultrasound elastography. The physician is examining and evaluating images of the organ and elastographic images.

Although Code 76981 resides within the Diagnostic Ultrasound section of the CPT® code publication, the potential uses of this procedure applies to providers in an office setting, an outpatient hospital setting and an Ambulatory Surgery Center (ASC) setting.



## 2025 MEDICARE NATIONAL PHYSICIAN FEE SCHEDULE

| CPT® Code*/Description | In-Office Physician Fee Schedule[3] | | |
|---|---|---|---|
| | Component** | RVUs | Rate |
| **76981** Ultrasound, elastography; parenchyma (eg., organ) | Professional (-26) | 0.59 | $27.49 |
| | Technical (-TC) | 2.30 | $75.04 |
| | Global | 3.17 | $102.54 |
| **Modifier (-26) is the physician "Professional" component (only); Modifier (-TC) is the physician "Technical" component (only); "Global" fee equals the sum of these professional and technical components.<br>†Physician fee is the product of the RVUs multiplied by the CY 2025 conversion factor of $32.3465. | | | |

**Note:** *The values listed above are a national average. Please check with your specific MAC and specific locality, within that MAC, to find the reimbursement rate for your location.*

# ICD-10 DIAGNOSIS CODES

The table below lists possible ICD-10 diagnosis codes associated with CPT® code 76981 that may apply for patients assessed by Velacur.

This list of possible codes is not exhaustive and is provided for example and discussion only. Fewer, additional, or other codes than those listed may apply. Payer policies on diagnosis codes covered for liver elastography services may vary and should be verified.

| ICD-10 Code | Description |
|---|---|
| B18.0 – B18.9 | Chronic viral hepatitis |
| B19.0 – B19.9 | Unspecified viral hepatitis |
| E83.110 | Hereditary hemochromatosis |
| E88.81 | Metabolic syndrome |
| K70.0 | Alcoholic fatty liver |
| K70.1 | Alcoholic hepatitis without ascites |
| K70.2 | Alcoholic fibrosis and cirrhosis of liver |
| K70.3 | Alcoholic cirrhosis of liver without ascites |
| K70.4 | Alcoholic hepatic failure without coma |
| K70.9 | Alcoholic liver disease, unspecified |
| K71.7 | Toxic liver disease with fibrosis and cirrhosis of liver |
| K73.0 – K73.9 | Chronic hepatitis, not elsewhere classified |
| K74.00 – K74.02 | Hepatic fibrosis |
| K74.2 | Hepatic fibrosis with hepatic sclerosis |
| K74.60 – K74.69 | Other and unspecified cirrhosis of liver |
| K75.4 | Autoimmune hepatitis |
| K75.81 | Nonalcoholic steatohepatitis |
| K75.9 | Inflammatory liver disease, unspecified |
| K76.0 | Nonalcoholic fatty liver disease |
| K76.89 | Other specified disease of liver |
| K76.9 | Liver disease, unspecified |
| R74.8 | Abnormal levels of other serum enzymes |
| R74.9 | Abnormal serum enzyme level, unspecified |
| R76.8 | Other specified abnormal immunological findings in serum |
| R76.9 | Abnormal immunological findings in serum, unspecified |
| R79.0 | Abnormal level of blood mineral |
| R79.89 | Other specified abnormal findings of blood chemistry |
| R79.9 | Abnormal findings of blood chemistry, unspecified |
| R93.2 | Abnormal findings on diagnostic imaging of liver or biliary tract |
| R94.5 | Abnormal results of liver function studies |
| Z48.23 | Encounter for aftercare following liver transplant |
| Z94.4 | Liver transplant status |

# PHYSICIAN SUPERVISION REQUIREMENTS

Physician supervision requirements apply to the technical component of code 76981 performed in the physician office or hospital outpatient setting. These supervision requirements **do not apply** to hospital inpatient services. Previously only physicians (e.g., MDs, ODs) were authorized to supervise the performance of diagnostic tests.

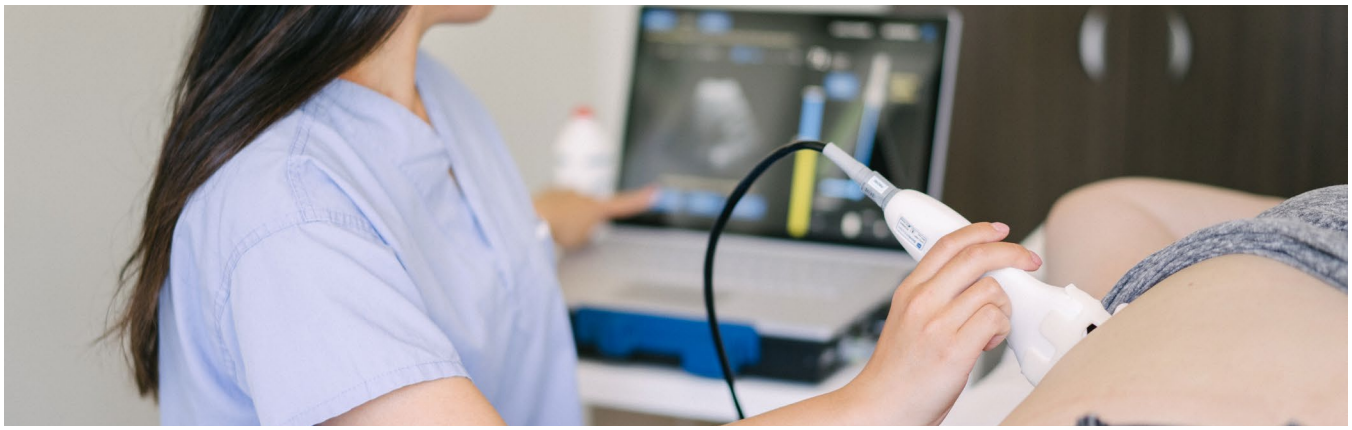
- Since January 2021, **certain Nonphysician Practitioners or NPPs (e.g., NPs, CNSs, PAs) are authorized to supervise the performance of diagnostic tests**, providing the tests fall under applicable state laws and scope of practice.[6]
- For code 76981 for ultrasound elastography, direct physician supervision requirements apply to the performance of the test's technical component meaning the physician must be "immediately available" to furnish assistance and direction but does not need to be physically present in the room.[7]

**In summary, a physician or NPP does not need to be physically present during the procedure but must be "immediately available".**

- Immediately available in the physician office setting means to be physically "present in the office suite".[8]
- While in the hospital setting, immediately available is not limited by a defined physical location or proximity. Rather, this has been described as "interruptible and able to furnish assistance and direction throughout the performance of the procedure but without reference to any particular physical boundary."[8]

**Code 76981 does not fall under Advanced Diagnostic Imaging (ADI) accreditation requirements for the purposes of physician supervision.**

- ADI accreditation requirements do not include x-ray, ultrasound, or fluoroscopy procedures.[9] Providers should defer to their practice's or facility's supervision guidelines.Documentation maintained by the billing provider must be able to demonstrate that the required physician supervision is furnished.



# PAYMENT METHODOLOGIES FOR ELASTOGRAPHY

Medicare may reimburse for elastography services when the services are provided within the scope of practice for the provider's license and are deemed medically necessary. The following describes the various payment methods by site of service.

## PHYSICIAN PAYMENT

### OFFICE SETTING

In the office setting, a physician who, or a physician practice which owns (e.g., owns, leases, rents, contracts a service) the elastography equipment and has the procedure performed on their premises may report the procedure code for global service payment without a -26 modifier (professional component). The unmodified CPT® code billed by the physician will be paid the global service fee rate under the physician fee schedule by Medicare or other payers.

### OUTPATIENT SETTING

When the elastography procedure is performed in the hospital outpatient setting, physicians may not bill the global service to Medicare and other payers because the global service fee includes both the professional and technical components of the service. The physician submits their own bill for the same CPT® code with a -26 modifier signifying that only the professional service component fee is being sought.

### E/M CODES

Elastography can be billed in addition to an E/M code since it is a separately identifiable service. The appropriate level of E/M code can be billed using codes ranging from 99202-99499 with a 25 modifier.

## HOSPITAL OUTPATIENT PAYMENT

When the diagnostic test is performed in the hospital outpatient setting, the hospital may bill for the technical aspects of the elastography service as an outpatient service. The CPT® code billed by the hospital will be assigned to a hospital outpatient Ambulatory Payment Classification (APC), and payment will be based on the APC rate specifically assigned to the encounter.

## AMBULATORY SURGERY CENTER (ASC) PAYMENT

When the diagnostic test is performed in the ASC setting, the facility may bill for the technical aspects of the elastography service as an outpatient service. CPT® code 76981 for ultrasound elastography is payable within the ASC facility setting.[10] Payment is based on the ASC fee schedule rate assigned to the procedure code. Freestanding specialty centers, such as endoscopy and imaging centers, frequently bill as outpatient ASC facilities (e.g., place of service'24').

# DOCUMENTATION REQUIREMENTS

Liver elastography performed with Velacur™ must meet all the following requirements:

- Medical necessity as determined by the payer
- Completeness
- Documented in the patient's medical record

## WRITTEN DOCUMENTATION

**The billing code 76981 requires a separate written record be completed and maintained in the patient medical record**. These records should be permanent.

- The report should identify the patient, facility, examination date, position of the patient and orientation of the ultrasound data acquired.
- If the current study is compared to prior relevant studies, commentary should be included.
- The indications for the procedure, findings and/or interpretation should be recorded.
- Elastography results should be documented by identifying the specific system or transducer used and patient positioning. At a minimum, the number of measurements taken, the median value and the IQR/Median ratio should be reported.[11]

**For example, a physician may follow a template like this:**

*"With patient in a supine position, the Velacur ultrasound probe was placed on an intercostal space lateral to the xyphoid process. Multiple measurements were obtained as the patient held their breath. B-mode liver images indicating elastographic data and measurements were obtained from liver parenchyma."*

## IMAGE DOCUMENTATION

**Production and retention of image documentation is also a requirement.**

- It is recommended that permanent ultrasound and elastographic images, either electronic or hardcopy, be retained in the patient record or other appropriate archive.[12]
- Images must contain information unique to the patient for which the service is provided.
- Stored images do not need to be submitted with a claim, however documentation of the study must be available to an insurer when requested.

Ultimately, providers should defer to their practice's or facility's documentation guidelines.

Retention of images should be consistent with clinical need and relevant legal and local health care facility requirements.

## REFERENCES


1 FDA - 510(k) Premarket Notification K201597 (July 31, 2020): https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201597.pdf

2 AMA/Specialty Society RVS Update Committee, Meeting Minutes, Pp. 22-24 (January 10-13, 2018): https://www.ama-assn.org/system/files/2018-11/4-jan-2018-ruc-meeting-minutes_0.pdf

3 CMS Medicare Physician Fee Schedule Final Rule CY 2021 (CMS-1734-F): Addendum B - Relative Value Units Used in CY 2021Final Rule (Updated 12/29/2020): https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Feder-al-Regulation-Notices-Items/CMS-1715-F.html

4 CMS Hospital Outpatient Prospective Payment Final Rule CY 2021 (CMS-1736-FC): Addendum B - OPPS Payment by HCPCS Code for CY 2021 (12/29/2020): https://www.cms.gov/medicare-medicare-fee-service-paymenthospitaloutpatientppshospital-out-pa-tient-regulations-and-notices/cms-1736-fc

5 CMS Ambulatory Surgery Payment Final Rule CY 2021 (CMS-1736-P): Addendum AA -- Final ASC Covered Surgical Procedures for CY 2021 (December 29, 2020): https://www.cms.gov/medicare-medicare-fee-service-paymentascpaymentasc-regulations-and-notic-es/cms-1736-p

6 CMS Manual System; Pub 100-04 Medicare Claims Processing (Trans 10505-CR 12071), December 4, 2020 (Eff January 1, 2021): https://www.cms.gov/files/document/r10505cp.pdf

7 Medicare Benefit Policy Manual; Chapter 6 - Hospital Services Covered Under Part B, Sec. 20.4.4 - Coverage of Outpatient Diagnostic Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c06.pdf

8 CMS Final Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates (CMS-1504-FC): https://www.govinfo.gov/content/pkg/FR-2010-11-24/html/2010-27926.htm

9 CMS MLN Matters (SE1122 Revised) - Important Reminders about Advanced Diagnostic Imaging (ADI) Accreditation Requirements: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1122.pdf

10 CMS-January 2021 ASC Approved HCPCS Code and Payment Rates - Updated 01/27/2021: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates

11 ACR-SRU Practice Parameter for the Performance of Ultrasound Elastography, 2019, pg. 4: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/US-Elastography.pdf

12 Esposito T, Reed R, Adams RC, et al. Acute Care Surgery Billing, Coding and Documentation Series Part 3: Coding of Additional Select
Procedures; Trauma Surgery & Acute Care Open 2020;5:e000587. doi: 10.1136/tsaco-2020-000587appropriate codes, charges, modifiers and bil


### DISCLAIMER

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Information presented in this document is current as of February 2025. Any subsequent changes which may occur in coding, coverage and payment are not reflected herein. Sonic Incytes Medical Corp. does not guarantee that Medicare or any public or private payer will cover any products or services at any particular level and specifically excludes any representation or warranty relating to reimbursement.

Third-party reimbursement amounts and coverage policies for specific procedures will vary by payer and by locality, and are subject to change without notice. While Sonic Incytes Medical Corp. has made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. It is always the provider's responsibility to determine and submit appropriate codes, charges, modifiers and bills for the services that were rendered. Sonic Incytes Medical Corp. strongly recommends you consult the payer organization for its reimbursement policies.

## REIMBURSEMENT SUPPORT

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