MILESTONE SCIENTIFIC®

COMPUFLO® INSTRUMENTS

Billing and Coding Guide

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DISCLAIMER

The CompuFlo® Billing and Coding guide was developed to assist healthcare providers, and facilities correctly bill for the CompuFlo® technology. All coding information provided in this guide is for educational purposes only and should not be construed as recommendations or guidelines in establishing medical policy, physician or hospital services, or standards of care. The coding options listed within this guide are associated with the use of the CompuFlo technology and are not intended to be an all-inclusive list.

Additionally, the information contained in this guide is in no way intended to guarantee coverage or payment for any procedure, service, or technology or constitute reimbursement or legal advice by Milestone Scientific. It is the responsibility of the provider to consult with their payers and/or legal counsel regarding coding, coverage, and reimbursement matters.

Milestone Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered. It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. Milestone Scientific does not promote the use of its products outside their FDA-approved label. Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. All trademarks are the property of their respective owners.

Milestone Scientific is pleased to offer reimbursement support for the CompuFlo technology. Please contact ssmith@milestonescientific.com

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About the Company

Milestone Scientific Inc., (Roseland, NJ), is a global biotechnology company offering computerized drug delivery systems designed with their proprietary DPS Dynamic Pressure Sensing Technology® system platform. The company is focused on advancing diagnostic and therapeutic injection procedures for healthcare practitioners and patients in the medical and dental arenas.

The CompuFlo® Technology

Designed with the DPS Dynamic Pressure Sensing Technology platform, Milestone's clinically validated, CompuFlo Epidural Computer Controlled Anesthesia System, allows for a more precise, reliable, safe, and effective application of epidural anesthesia. The CompuFlo system is designed to improve the epidural injection procedure through real time, objective needle detection of pressure changes to confirm the epidural space within minutes. CompuFlo technology provides visual and audio feedback to distinguish tissue types for the physician and give precise location guidance.

The CompuFlo epidural instrument is 99% effective in identifying the epidural space on the first attempt. The real time pressure sensing technology aides the physician in objectively differentiating the false versus true loss of resistance encountered in the epidural space identification process. More importantly, the use of the CompuFlo technology increases patient safety by avoiding the potential for dural punctures and other unanticipated, yet highly critical complications which can severely impact the thoracic cervical spine.

Regulatory: FDA Indication for Use

The CompuFlo® Epidural, Computer-Controlled Anesthesia System is a 510(k), class II medical device, cleared for marketing by the US Food and Drug Administration (FDA). [K221702] [https://www.accessdata.fda.gov/cdrh_docs/pdf22/K221702.pdf]

The CompuFlo® Epidural, Computer-Controlled Anesthesia System is intended for use with an epidural needle for the real-time verification of needle placement in the lumbar or thoracic epidural space, inclusive of cervicothoracic junction (CTJ).

It is intended for patients over age of 18 who are required to have epidural needle or catheter placement as part of a medically necessary, in-patient or out-patient procedure, as established by their Health Care Provider (HCP). Once Health Care Provider verifies the epidural needle placement in the epidural space, the HCP continues with the medical procedure.

Coding for CompuFlo® Epidural, Computer-Controlled Anesthesia System

The American Medical Association (AMA) develops Current Procedural Terminology (CPT) codes to identify medical procedures. According to the AMA, a Category III CPT code must be used in place of an unlisted code if the Category III code accurately identifies the service performed. Category III codes are used to track the utilization of emerging technologies, services, and procedures. Category III CPT codes enable healthcare providers (and payers) to accurately report and gather data on clinical efficacy, utilization, and outcomes.

Effective January 1, 2023, AMA Category III CPT code 0777T is the appropriate CPT code for billing the CompuFlo medical procedure.

CPT® Official Code Descriptor

0777T: Real-time pressure-sensing epidural guidance system (List separately in addition to code for primary procedure)

Notes: (Use 0777T in conjunction with 62320, 62321, 62322, 62323, 62324, 62325, 62326, 62327)

Additional Related Information

- CPT® adds +0777T for use of a pressure-sensing epidural guidance system.
- Use 0777T add-on code in conjunction with interlaminar epidural injection codes 62320-62327.
- Report +0777T when the provider uses the CompuFlo device that detects pressure changes during the epidural injection service.
- No Modifier required when submitting 0777T.

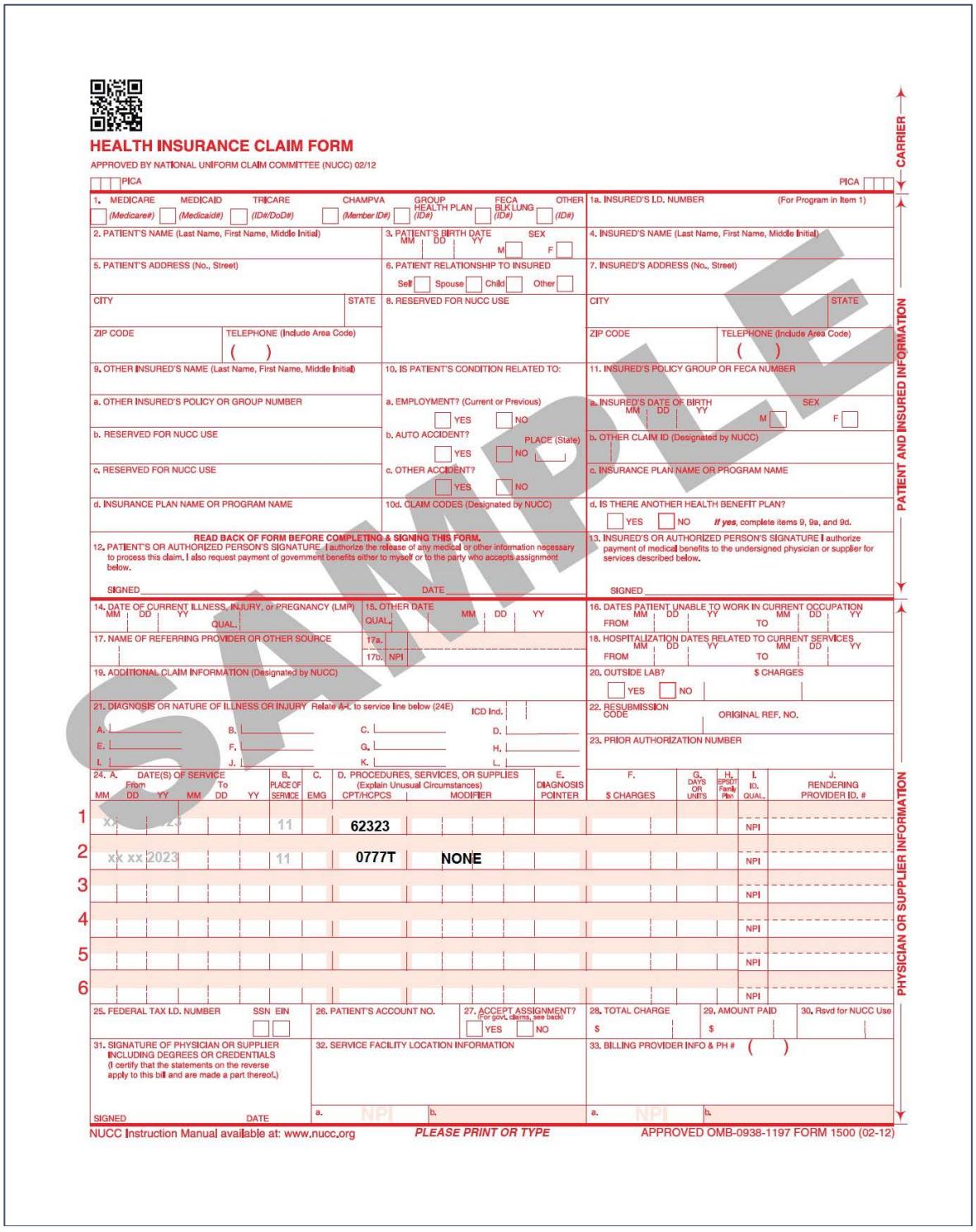
CPT Codes for Epidural Injections Procedures

CPT®	Description
0777T	Real-time pressure-sensing epidural guidance system (List 0777T separately in addition to code for primary procedure) **(Use 0777T in conjunction with 62320, 62321, 62322, 62323, 62324, 62325, 62326, 62327)**
62320	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62321	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT) (Do not report 62321 in conjunction with 77003, 77012, 76942)
62322	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, **lumbar** or sacral (caudal); without imaging guidance
62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), *not including neurolytic substances*, including needle or catheter placement, interlaminar epidural or subarachnoid, **lumbar** or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT) (Do not report 62323 in conjunction with 77003, 77012, 76942)
62324	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), *not including neurolytic substances*, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance.
62325	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT) (Do not report 62325 in conjunction with 77003, 77012, 76942)
62326	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), *not including neurolytic substances, interlaminar epidural or subarachnoid*, **lumbar** or sacral (caudal); without imaging guidance
62327	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), *not including neurolytic substances, interlaminar epidural or subarachnoid*, **lumbar** or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT) (Do not report 62327 in conjunction with 77003, 77012, 76942)

All coding information provided is for educational purposes only. The information is not intended to imply or guarantee coverage or reimbursement by any third-party payer for any codes or services. It is the responsibility of the provider to determine the most appropriate codes to accurately reflect the medically necessary services furnished to the patient as well as understand and adhere to any requirements by the payer.

Submitting Claims for the CompuFlo procedure

- List primary epidural injection CPT code(s) 62320-62327.
- On separate line, list the add-on CPT code 0777T
- CPT 0777T does not require any modifiers.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	xx xx 2023	11		62323						NPI	
2	xx xx 2023	11		0777T	NONE					NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

SAMPLE

NUCC Instruction Manual available at: www.nucc.org — PLEASE PRINT OR TYPE — APPROVED OMB-0938-1197 FORM 1500 (02-12)

CompuFlo Sample: Operative Note and Medical Necessity Statement

When billing for the CompuFlo technology, it is important for the HCP to include in their medical/operative notes, the clinical decision and rationale to use the CompuFlo technology as part of the patient care/procedure.

SAMPLE OPERATIVE NOTE

OPERATIVE PROCEDURE PERFORMED: Cervical Epidural Steroid Injection **with Epidural Pressure Sensing Guidance System (CompFlo)** under Fluoroscopy

OPERATIVE PROCEDURE NOTE:
(https://classic.clinicaltrials.gov/ct2/show/NCT03826186)

Real-time pressure sensing epidural guidance was used in conjunction with the epidural injection procedure. The needle is advanced through the subcutaneous tissues with the stylet in place until the interspinous ligament is entered, as noted by an increase in tissue resistance. After removing the stylet, flexible tubing from the CompuFlo disposable tubing-syringe set is attached to the hub of the needle instead of the traditional ground-glass syringe. The fluid-filled syringe is placed in the CompuFlo device. The needle is then advanced continuously with the device electronically sensing pressure in real time, providing a numerical value (100 to 150 mm Hg) on the read-out screen. As the tip of the needle enters the posterior epidural space, a sudden loss of resistance (associated with a significant loss of pressure to less than 50 mm Hg or 50% of the starting pressure) is noted. The pressure drop needs to be sustained for at least 5 seconds. An audio signal also signals the acute change in pressure confirming epidural needle placement.

SAMPLE MEDICAL NECESSITY STATEMENT: Includes patient medical condition and reason for patient procedure.

For example: Patient Jane Doe suffered from severe neck pain for 8 weeks; failed to respond to 6 weeks of conservative management to include physical therapy and NSAIDs. The severity of the pain has escalated impacting her daily activities, function, and quality of life. In effort to avoid a more invasive surgical procedure and minimize the need for opioid medications, a CESI procedure was conducted on July XXXXX. with the goal of decreasing her pain level and improve quality of life, function/ADL. As part of the ESI procedure, the CompuFlo® Epidural, Computer-Controlled Anesthesia System was used to provide precise verification of needle placement in the epidural space in real time.

May also want include brief product description: (Refer to *The CompuFlo® Technology* section on Page 3 of this guide.)

Template Payer Letter for Additional Information

Date

Insurance Company
Attn: Medical Claims Department
Address
City, State, Zip

Re: Patient Name:
Subscriber/Insurance ID:
Claim Number:
Date Of Service:
NPI #:

Dear [Insert Insurance Company] Department:

We have received your request for additional information to process the above referenced claim for services rendered to our patient [insert name]. Per your request, the following information is provided for your review:

- Patient Operative report
- Patient Medical Records
- CompuFlo Epidural, Computer-Controlled Anesthesia System Product Information
- Peer-Review articles and supporting references
- Statement of Medical Necessity for the CompuFlo technology procedure

We request your approval of our claim for the clinically appropriate and medically necessary services provided to [patient name].

If you have questions or need additional information, please contact me at the number listed below. Thank you in advance for your consideration.

Sincerely,

Physician

APPEAL LETTER TEMPLATE

Date

Insurance Company
Attn: Medical Claims Appeals Department
Address
City, State, Zip

Re: Coverage denial of CPT 0777T
Patient Name:
Subscriber/Insurance ID:
Claim Number:
Date Of Service:

Dear [Insert Insurance Company] Appeals Department:

We have received your claim denial dated [xx/xx/202x] for medical services provided to our patient [insert patient name] stipulating that the laboratory analyses are *[insert reason for denial language as noted in the denial letter]*. We are appealing your decision and respectfully request your reconsideration of coverage for CPT®[1] procedure code 0777T, real time pressure sensing epidural guidance used in conjunction with the epidural steroid injection procedure CPT [*insert base CPT*].

CPT 0777T effective January 1, 2023, was assigned by the American Medical Association (AMA), to identify the CompuFlo® Epidural, Computer-Controlled Anesthesia System when used in conjunction with an epidural injection procedure(s).

The FDA 510(k) cleared CompuFlo® Epidural, Computer-Controlled Anesthesia System is a Class II medical device [K221702][2], is intended for use with an epidural needle for the real-time verification of needle placement in the lumbar or thoracic epidural space, inclusive of cervicothoracic junction (CTJ). It is intended for patients over age of 18 who are required to have epidural needle or catheter placement as part of a medically necessary, in-patient or out-patient procedure, as established by their Health Care Provider (HCP).

Medical Necessity statement: *Insert brief statement on patient medical condition and reason for patient procedure. For example: Patient Jane Doe suffered from severe neck pain for 8 weeks. She has failed to respond to 6 weeks of conservative management to include physical therapy and NSAIDs. The severity of the pain has escalated impacting her daily activities, function, and quality of life. In effort to avoid the more invasive surgical procedure and minimize the need for opioid medications, a CESI procedure was conducted on July XXXXX. with the goal*

of decreasing her pain level and improve quality of life, function/ADL. As part of the ESI procedure, the CompuFlo® Epidural, Computer-Controlled Anesthesia System was used to provide precise verification of needle placement in the epidural space in real time.

Included for your review to support the clinical decision and medical necessity for the use of CompuFLo real time pressure sensing guidance with the epidural injection procedure for Jane Doe are:

- Patient Medical Records/history/notes
- Operative report for the DATE of SERVICE
- CompuFlo Product Information
- Peer Reviewed publications list supporting the clinical value of the CompuFlo technology

We respectfully request your review of the supporting documentation and the denial be overturned with coverage granted for the clinically appropriate and medically necessary level of care rendered to this [Insurance company] patient.

Thank you for your consideration. Please feel free to contact me if you would like to discuss further or have additional questions regarding [patient] and/or the CompuFlo medical procedure.

Sincerely,

Dr. Milestone Scientific

References

[1]CPT® codes, descriptions and other data only are copyright 2023 American Medical Association. All Rights Reserved.

[2] https://www.accessdata.fda.gov/cdrh_docs/pdf22/K221702.pdf

CompuFlo Scientific Publications List

Hidalgo, G. (2019) **Epidural Space Identification Using Continuous Real-Time Pressure Sensing Technology (CompuFlo®): A Report of 600 Consecutive Cases**. Open Journal of Anesthesiology, 9, 189-195. https://doi.org/10.4236/ojanes.2019.910018

Capogna, G. (2019) **Differentiating False Loss of Resistance from True Loss of Resistance While Performing the Epidural Block with the CompuFlo® Epidural Instrument**. Hindawi Anesthesiology Research and Practice Volume 2019, Article ID 5185901, 4 pages https://doi.org/10.1155/2019/5185901

Ralf E. Gebhard, MD, Tobias Moeller-Bertram, MD, Douglas Dobecki, MD, Feyce Peralta, MD, Evan G. Pivalizza, MBChB, FFASA, Madhumani Rupasinghe, MBBS, FRCA, Sanja Ilic, MD, and Mark Hochman, DDS (2019). **Objective Epidural Space Identification Using Continuous Real-Time Pressure Sensing Technology: A Randomized Controlled Comparison with Fluoroscopy and Traditional Loss of Resistance**. Anesthesia & Analgesia, November 2019, Vol 129, Number 5. 01-Gehbard-etal-CompuFlo-Multi-Center-Study-Objective_Epidural_Space_Identification_Nov-2019-1.pdf (milestonescientific.com)

Capogna, G., Camorcia, M., Berritta, C., Hochman, M. and Velardo, M. (2020) **Confirmation of Epidural Catheter Location by Epidural Pressure Waveform Recordings by the Compuflo® Cath-Checker System**. Open Journal of Anesthesiology, 10, 171-178. https://doi.org/10.4236/ojanes.2020.105015

G. Capogna, M. Camorcia,a A. Coccoluto,a M. Micaglio,b M. Velardoa **Experimental validation of the CompuFlo epidural controlled system to identify the epidural space and its clinical use in difficult obstetric cases.** International Journal of Obstetric Anesthesia (2018) 36, 28–33 0959-289X/ 2018 Elsevier Ltd. All rights reserved. https://doi.org/10.1016/j.ijoa.2018.04.008