MYO1®

Continuous Perfusion Sensing Technology

Reimbursement Reference Guide

Indications for Use

The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of the muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.

NOTE:
Refer to MY01 Mobile Application User Manual (REF: MYO-00566-M) The MY01 App and MY01 device must be used in tandem.

The MY01 Mobile Application (MY01 App) provides a graphical user interface for storing and displaying identical pressure values from the MY01 device. The version of the MY01 App that is authorized for use in the US and Canada, in addition to the muscle compartment pressure, calculates and displays the muscle perfusion pressure over time based on manual entries of the patient's diastolic blood pressure. Diagnosis should always be made in conjunction with clinical assessments.

Contraindications

No known contraindications.

2025 Outpatient Coding and Payment

Effective October 1, 2025, the MY01 Continuous Compartmental Pressure Monitor is eligible for separate payment under the Medicare Hospital Outpatient Prospective Payment System (OPPS).

In the October quarterly update, the Centers for Medicare and Medicaid Services (CMS) approved a new device category for The MY01 Continuous Compartmental Pressure Monitor to get a Transitional Pass-Through (TPT) Payment. **CMS agreed that the MY01 Compartmental Pressure Monitor met all criteria to qualify for this additional cost-based payment when billed with an associated procedure code, as defined by CMS. The TPT payment will be effective from October 1, 2025, to September 30, 2028.**

For a new technology to qualify for the TPT program, it must meet the following eligibility requirements established by CMS:

1. The technology must be surgically implanted or inserted into the body
2. Newness: The medical service or technology must be new; which means not described by current or expired device categories.
3. Cost: The medical service or technology must be costly so it is "not insignificant" relative to the Ambulatory Payment Classification (APC) payment
4. Substantial Clinical Improvement: The service or technology must demonstrate a substantial clinical improvement over existing services or technologies.

The MY01 Continuous Compartmental Pressure Monitor was granted Breakthrough Device Designation (BDD) on October 20, 2021. BDD achieves 1/3 of the TPT criteria, newness. For the TPT application, MY01 presented data to prove that their device was distinct from existing and expired device categories that had been eligible for TPT, and that their device was costly enough for the APC rate to be inadequate.

This payment is intended to reimburse hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) for the incremental cost of a device (such as the MY01 Continuous Compartmental Pressure Monitor) when the cost of the device exceeds the current device-related portion of the ambulatory payment classification (APC) payment for the associated procedure as determined by CMS. This incremental payment helps to support access to a new technology while the claims-based cost data are collected to incorporate the cost for the device (e.g. the compartmental pressure monitor for the monitoring of compartment syndrome) into the APC rates for the associated procedures.

** Disclaimer: CMS makes it clear that Medicare TPT status and assignment of a HCPCS code does not imply or guarantee Medicare coverage. Medical necessity decisions will be made separately by the Medicare Administrative Contractors (MACs) based on the patient condition and service provided; the provider is responsible for submitting accurate claims for products and services rendered.*

HCPCS Code	Description	2025 Outpatient and ASC Payments	Effective Date	Device Pass-Through Expiration Date
C1742	Pressure monitoring system, compartmental intramuscular (implantable), continuous, including all components (e.g., introducer, sensor), excludes mobile (wireless) software application	Payment will be calculated by APC + Charges x CCR in the HOPD **and** ASC Payment + MAC-Specific Pricing in the ASC	10/01/2025	09/30/2028

The following CPT code may be appropriate for the use of the MY01 Compartmental Pressure Monitor. Also listed is the Medicare Physician and Hospital Outpatient Prospective Payment System (OPPS) national unadjusted payment rates for CPT code.

CPT Code[i]	Description	2025 Medicare Physician Payment[ii]	2025 OPPS (APC Payment & Status Indicator)
20950	Monitoring of interstitial fluid pressure (includes insertion of device, eg, wick catheter technique, needle manometer technique) in detection of muscle compartment syndrome	$87.02	T $703.59

[i] CPT® is a registered trademark of the American Medical Association (AMA). Copyright 2025 AMA. All CPT codes are owned and licensed by the American Medical Association.
[ii] 2025 Medicare Physician Fee Schedule: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices
[iii] 2025 Medicare Outpatient Hospital Fee Schedule: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates

Hospital Outpatient Status Indicators

T	Procedure or service subject to multiple procedure discounting. Paid under OPPS; separate APC payment.

FY 2026 Inpatient Coding and Payment

For FY 2026, MY01 US Inc. was granted NTAP (New Technology Add-on Payment) for their Continuous Compartmental Pressure Monitor. NTAP is part of the CMS Inpatient Prospective Payment System (IPPS), and it offers Medicare reimbursement to assist healthcare organizations when they adopt new technology. **For FY 2026, The MY01 Continuous Compartmental Pressure Monitor has a maximum new technology add-on payment of $2,112.50.**

For a new technology to qualify for the NTAP program, it must meet the following eligibility requirements established by CMS:

- The medical service or technology must be new;
- The medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and
- The service or technology must demonstrate a substantial clinical improvement over existing services or technologies.

The MY01 continuous compartmental pressure monitor was granted Breakthrough Device Designation on XXKJSHADJ. BDD achieves 2/3 of the NTAP criteria, substantial clinical improvement and cost. For the NTAP application, MY01 presented data to prove their device was costly enough for the DRG rate to be inadequate.

Inpatient procedures are coded using the ICD-10-PCS coding system. In the inpatient setting, the hospital payment will be determined by the payer using a combination of the ICD-10-CM and ICD-10-PCS codes. Based on these codes submitted, the hospital will be paid one fixed payment based on the assigned Medicare Severity Diagnosis Related Group (MS– DRG). In the inpatient setting, all costs other than physician services are considered part of the facility expenses and would be reported by the facility using the appropriate revenue codes.

Below is a list of possible PCS codes that may be applicable to the use of the Continuous Compartmental Pressure Monitor. These ICD-10-PCS codes are valid through September 30, 2026.

NTAP is an additional payment made to the hospital, on top of the MS-DRG payment for the hospital stay. This additional payment is provided to offset some of the costs of new drugs and devices when certain criteria are met. Add-on payments for devices are limited to the lesser of 65% of the average cost of the product, or 65% of the amount by which the costs of the case exceeds the standard Medicare Severity Diagnosis Related Group (MS–DRG) payment. NTAP designation lasts no more than three years for a specific indication.

NTAP is calculated on each claim and can vary; below is an illustrative example:

Example for tibial fracture (*commonly mapped to DRG 562: FRACTURE, SPRAIN, STRAIN AND DISLOCATION EXCEPT FEMUR, HIP, PELVIS AND THIGH WITH MCC*)

Illustrative Hospital-Level NTAP Calculation	Hospital A	Hospital B	Hospital C
Total Charges of the Entire Hospital Discharge	$42,500	$50,000	$49,000
Hospital-Specific Cost to Charge Ratio	x 0.2064	x 0.2064	x 0.3500
Hospital-Specific Reported Cost of the Hospital Discharge	$8,772	$13,045	$17,150
Hospital-Specific MS-DRG 562 Payment Amount	-$10,500	- $12,000	-$13,200
Difference	$(1,728)	$1,045	$3,950
65% of the Difference	N/A	$679.25	$2,567.50
NTAP Cap: Average Cost of the New Technology x 65%	$2,112.50	$2,112.50	$2,112.50
Incremental NTAP Payment – Lesser of 65% Difference or the Cap	**$0**	**$679.25**	**$2,112.50**
Total Payment – MS-DRG 562 + NTAP Payment	**$10,500**	**$12,679.25**	**$15,312.50**

Effective October 1, 2025, the use of the MY01 Continuous Compartmental Pressure Monitor can be identified by the following new technology section X PCS procedure code.

ICD-10-PCS Code	New Technology PCS Description
XX2F3W9	Monitoring of Musculoskeletal Muscle Compartment Pressure, Micro-Electro-Mechanical System, Percutaneous Approach, New Technology Group 9

Section X (new tech) PCS codes are standalone codes, so reporting additional PCS codes for this technology is not required. However, reporting additional PCS codes for the primary procedure is required to determine the appropriate DRG. The guide below may help identify PCS codes for the primary procedure.

ICD-10-PCS[iv] Procedure Code and Description – Please note: not all Root Operation/Device code combinations may be available.			
0 Medical and Surgical **K** Muscles, **J** Subcutaneous Tissue and Fascia **N** Release			
Body Part	**Approach**	**Device**	**Qualifier**
S Lower Leg Muscle, Right **T** Lower Leg Muscle, Left **V** Foot Muscle, Right **W** Foot Muscle, Left **9** Lower Arm and Wrist Muscle, Right **B** Lower Arm and Wrist Muscle, Left **C** Hand Muscle, Right **D** Hand Muscle, Left **G** Lower Arm, Right **H** Lower Arm, Left **J** Hand, Right **K** Hand, Left **N** Lower Leg, Right **P** Lower Leg, Left **Q** Foot, Right **R** Foot, Left	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External Approach **Z** No Device **Z** No Qualifier	**Z** No Device	**Z** No Qualifier

ICD-10-PCS[iv] Procedure Code and Description – Please note: not all Root Operation/Device code combinations may be available.			
0 Medical and Surgical **K** Muscles, **J** Subcutaneous Tissue and Fascia **8** Division			
Body Part	**Approach**	**Device**	**Qualifier**
G Lower Arm, Right **H** Lower Arm, Left **J** Hand, Right **K** Hand, Left **N** Lower Leg, Right **P** Lower Leg, Left **Q** Foot, Right **R** Foot, Left **V** Upper Extremity **W** Lower Extremity	**0** Open **3** Percutaneous **4** Percutaneous Endoscopic **X** External Approach	**Z** No Device	**Z** No Qualifier

FY 2026 MS-DRG Payment

Below is a list of possible Medicare Severity Diagnosis Related Groups (MS-DRG) and their national unadjusted payment rates that may be applicable for inpatient cases involving the Continuous Compartmental Pressure Monitor.

MS-DRG[iii]	DRG Description	FY 2026 Medicare Payment
913	TRAUMATIC INJURY WITH MCC	$11,894.59
914	TRAUMATIC INJURY WITHOUT MCC	$6,443.57
917	POISONING AND TOXIC EFFECTS OF DRUGS WITH MCC	$11,412.87
918	POISONING AND TOXIC EFFECTS OF DRUGS WITHOUT MCC	$6,236.91
922	OTHER INJURY, POISONING AND TOXIC EFFECT DIAGNOSES WITH MCC	$12,729.96
923	OTHER INJURY, POISONING AND TOXIC EFFECT DIAGNOSES WITHOUT MCC	$7,405.56
474	AMPUTATION FOR MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE DISORDERS WITH MCC	$31,238.40
475	AMPUTATION FOR MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE DISORDERS WITH CC	$16,559.72
476	AMPUTATION FOR MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE DISORDERS WITHOUT CC/MCC	$8,588.03

510	SHOULDER, ELBOW OR FOREARM PROCEDURES, EXCEPT MAJOR JOINT PROCEDURES WITH MCC	$21,979.45
511	SHOULDER, ELBOW OR FOREARM PROCEDURES, EXCEPT MAJOR JOINT PROCEDURES WITH CC	$15,131.29
512	SHOULDER, ELBOW OR FOREARM PROCEDURES, EXCEPT MAJOR JOINT PROCEDURES WITHOUT CC/MCC	$12,045.95
562	FRACTURE, SPRAIN, STRAIN AND DISLOCATION EXCEPT FEMUR, HIP, PELVIS AND THIGH WITH MCC	$10,367.93
563	FRACTURE, SPRAIN, STRAIN AND DISLOCATION EXCEPT FEMUR, HIP, PELVIS AND THIGH WITHOUT MCC	$6,516.33
003	ECMO OR TRACHEOSTOMY WITH MV >96 HOURS OR PRINCIPAL DIAGNOSIS EXCEPT FACE, MOUTH AND NECK WITH MAJOR O.R. PROCEDURES	$154,450.69

CC – Complications or Comorbidities
MCC – Major Complications or Comorbidities

2025 ICD-10-CM Diagnosis Coding

Diagnosis codes are assigned by the physician to accurately report the patient's condition as it relates to the procedure. Below are some examples of diagnosis codes that may be applicable for the use of Continuous Compartmental Pressure Monitor. This is not meant to be an exhaustive list.

ICD-10-CM	ICD-10-CM Diagnosis Description
S52*	Fracture of forearm
S62*	Fracture at wrist and hand level
S82*	Fracture of lower leg, including ankle
S92*	Fracture of foot and toe, except ankle
T79.A*	Traumatic compartment syndrome
T79.A0*	Compartment syndrome, unspecified
T79.A2*	Traumatic compartment syndrome of lower extremity
T79.A9*	Traumatic compartment syndrome of other sites
T79.A1*	Traumatic compartment syndrome of upper extremity

*Requires additional character(s)

Additional Payment Mechanism FAQ

Transitional Pass-Through (TPT) and New Technology Add-On Payment (NTAP) Introduction

- **How are NTAPs and TPTs different?**
  The primary difference is that NTAP is applicable to the inpatient setting, and TPT is applicable to the outpatient and ASC setting. NTAPs are identified in the inpatient claim by an ICD-10-PCS code, while TPTs are identified by a HCPCS code. They also differ because NTAP payment will apply to some cases depending on the total hospital charges, while TPT applies to every case.

- **When are the NTAP and TPT effective for the MY01 Continuous Compartmental Pressure Monitor and how long do they last?**
  Both additional payment mechanisms became effective October 1, 2025. NTAP lasts for a minimum of 2 years and up to a maximum of 3 years. TPT will last for three years, until September 30, 2028.

NTAP (Inpatient)

- **What are the billing requirements for a MY01 Continuous Compartmental Pressure Monitor case in the hospital setting?**
  There are no special billing requirements placed on the hospital for processing the NTAP payment, other than using the appropriate ICD-10-PCS X-codes that describe the use of MY01 Continuous Compartmental Pressure Monitor as indicated by the treating physician, which will trigger a calculation of the NTAP payment by your Medicare Administrator Contractor's claims processing system.

  Similarly, for the TPT, the HCPCS code C1742 must be billed to describe the continuous compartmental pressure monitor on an outpatient visit, and this will trigger the trigger a calculation of the TPT payment by your Medicare Administrator Contractor's claims processing system.

- **Is NTAP a fixed amount for each inpatient MY01 Continuous Compartmental Pressure Monitor case?**
  The NTAP amount is not a fixed amount and can vary for each case. It is calculated on a case-by-case basis. CMS has determined that the maximum incremental NTAP amount that a hospital can receive (in addition to the full DRG payment) is $2,112.50 per discharge for FY 2026. The exact payment amount per case is not fixed and depends on the total costs of the discharge.

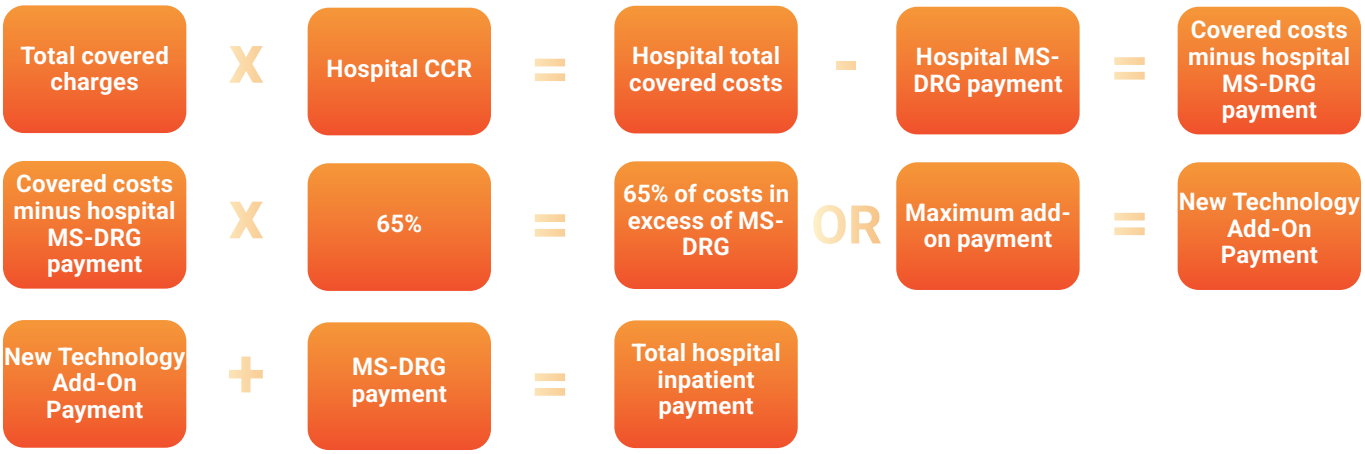
- **Is the MY01 Continuous Compartmental Pressure Monitor NTAP amounts paid per device used, or once per discharge?**
  The NTAP amount is paid once per discharge and not per unit of new technology used; however, the total costs of the new technology (including multiple units) are part of the total case charges that go into the calculation of both the eligibility for NTAP and the NTAP amount.

- **How is the total payment amount of the MY01 Continuous Compartmental Pressure Monitor case calculated if it qualifies for an NTAP?**
  The total payment amount for a MY01 Continuous Compartmental Pressure Monitor case that qualifies for an NTAP will consist of the full MS-DRG payment + 65% of the difference between the reported cost of the discharge and the MS-DRG payment, up to a maximum of $2,112.50 per case. The NTAP payment amount is then added to the MS-DRG payment.

- **Can the NTAP amount be less than the allowed $2,112.50?**
  Yes, the $2,112.50 is the maximum amount allowed for the NTAP portion of the hospital payment. Should the hospital-specific calculation of 65% of the hospital costs minus the DRG payment be less than $2,112.50, then the lower amount is paid.

- **What are the MS-DRGs to which cases involving the MY01 Continuous Compartmental Pressure Monitor are assigned?** (Add in final list of DRGs from above)

- **How is the actual cost of the discharge determined?**
  CMS derives the total covered cost of the discharge based on the total covered hospital charges for each case and the hospital's inpatient operating cost-to-charge ratio determined from its cost report. Multiplying the hospital charges by the cost-to-charge ratio will convert the submitted charges to an estimate of the hospital's costs by removing the markup that hospitals apply to their costs.



- **Where can a hospital find the hospital inpatient operating cost-to-charge-ratio (CCR) used in the NTAP payment calculation?**
  The FY 2026 CCRs by provider number are available at:
  https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page
  Download the FY2026 Impact File and search the excel file by Medicare provider number. The CCR is listed in Column AG (Operating CCR).

TPT (Outpatient)

- **MY01 Continuous Compartmental Pressure Monitor and & Transitional Pass-Through Payment (TPT) Payments in the Outpatient Setting**
  On September 22, 2025, Centers for Medicare and Medicaid Services (CMS) approved a new device category for the MY01 Continuous Compartmental Pressure Monitor to get a Transitional Pass-Through (TPT) Payment. CMS agreed that the product met all criteria for TPT category. The TPT is effective as of October 1, 2025.

- **What is a transitional pass-through (TPT) and what is it intended to do?**
  TPT is a pathway created by CMS to allow Medicare patients access to new and innovative technology while claims data is collected. The TPT is designed to reimburse for the incremental cost of a qualifying device (such as the MY01 Continuous Compartmental Pressure Monitor) when the cost of the device exceeds the current device-related portion of the Ambulatory Payment Classification (APC) for the associated procedure as determined by CMS. A TPT allows an HOPD or ASC to receive additional cost-based payment for the use of qualified technology for a period of 3 years.

- **How long will the TPT payment last?**
  We expect the TPT payment to last for 3 years. When the pass-through payment expires, CMS will bundle the payment for the product into the relevant procedure APC. By design, CMS will rely on TPT claims data from this 3-year period to calculate the future rates.

- **When is the device eligible for TPT payments?**
  The TPT is effective October 1, 2025, and will last for 3 years.

- **Is the TPT a fixed amount for each outpatient case?**
  The methodology for calculating the TPT payment amount in the HOPD or ASC is slightly different.

For hospitals, the incremental pass-through payment is determined by taking the hospital's charges for the MY01 Continuous Compartmental Pressure Monitor and converting that to "costs" based on the individual hospital's cost- to-charge (CCR) ratio.

APC Payment for Primary Procedure (minus CMS Specified offset amount*) + **Hospital Charges x Hospital-Specific CCR** = **HOPD TPT Payment**

**CPT code 20950 for the monitoring of interstitual fluid pressure is not currently assigned any device offset, so the full APC would be added.*

For ASCs, the incremental pass-through payment is determined by Medicare Administrative Contractor (MAC) specific pricing, typically covering the acquisition cost of the device (e.g., invoice price).

ASC Procedure Payment (minus CMS-Specified offset amount*) + **MAC-Specific Device Pricing** (typically, the acquisition cost) = **ASC Payment**

**CPT code 20950 for the monitoring of interstitual fluid pressure is not currently assigned any device offset, so the full ASC payment would be added.*

Conclusion

- **How much should my hospital charge for the MY01 Continuous Compartmental Pressure Monitor?**
  Each hospital should determine its own charge for the MY01 Continuous Compartmental Pressure Monitor. However, it is important to understand that CMS will apply the hospital's cost-to-charge ratio (CCR) to the hospital charge to calculate an estimate of the cost of the device. Therefore, to be consistent with its billing practices, a hospital should submit the charges (accounting for their CCRs), not the invoice amount, to CMS on the claim with HCPCS C1602. Otherwise, CMS will calculate an incorrect payment amount for the product. CMS also relies on the charges on claims data for setting payment rates for related procedures when the TPT expires.

- **What should you do if your hospital encounters issues with claims using the ICD-10-PCS or HCPCS code involving the use of the MY01 Continuous Pressure Monitor?**
  The best source of information regarding claims processing issues is the payer, for example the patient's private insurance company, the Medicare Administrative Contractor, or other government payer. Providers should contact the appropriate payer to report the problem and seek clarification.

400 Boul de Maisonneuve Ouest,
Suite 700, Montréal, QC H3A 1L4

855-799-6901 info@my01.io my01.io