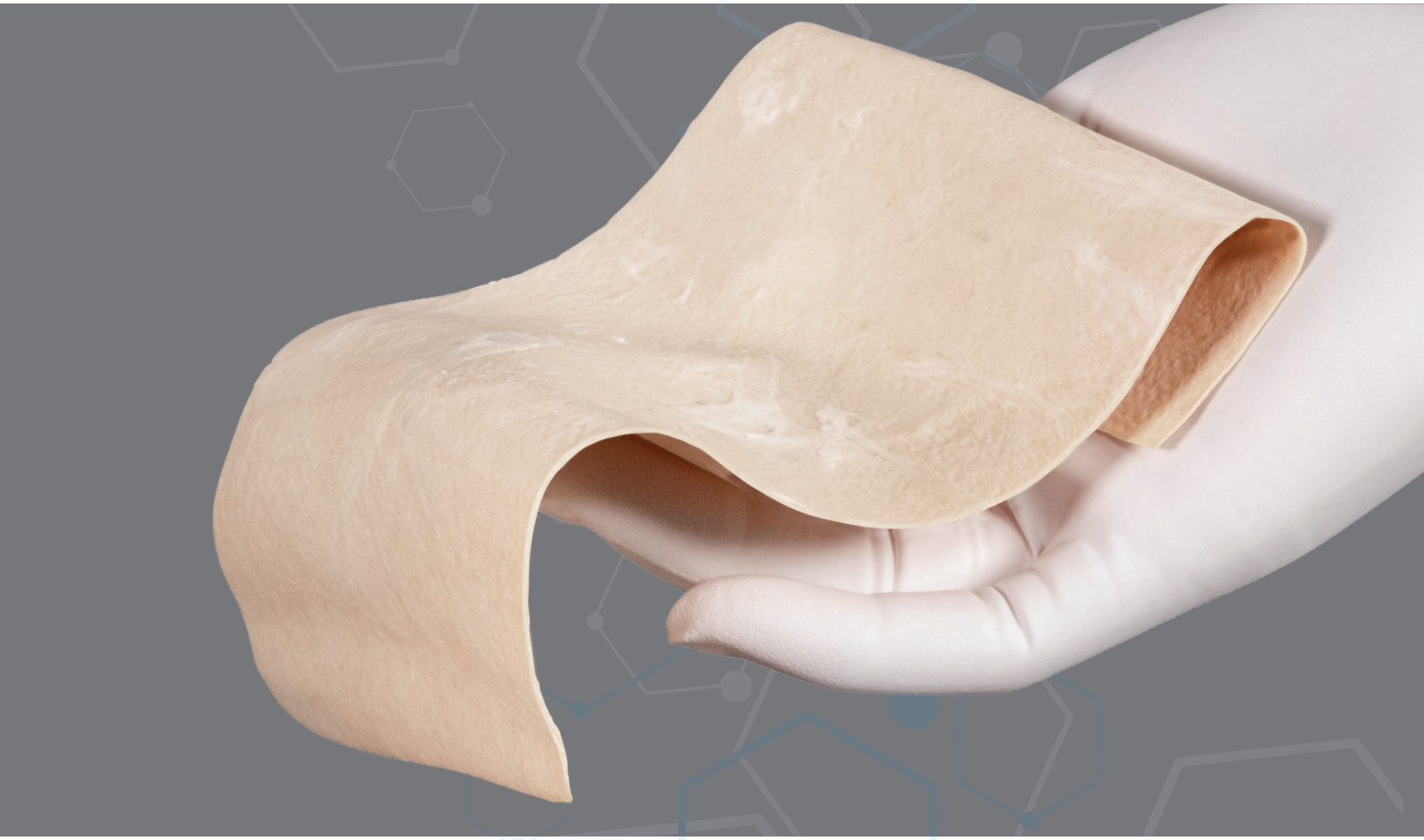
MiroFlex®
Biologic Matrix

2023
Coding and Billing Guide



Disclaimer: This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of January 2023 and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS your local Medicare Administrative Contractor and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payors.

HCPCS and CPT coding is universal, however, coverage and payment of medical and surgical services can vary among government (Medicare, Medicaid, TRICARE) and private health insurance companies. The procedures described in this reimbursement guide are widely covered by government and commercial insurers when MiroFlex Biologic Matrix is applied in hospitals (both in and outpatient), ambulatory surgery centers (ASCs) and clinic-based practices. Accurate coding is important to guide how MiroFlex and the surgical procedures it is used with are covered and paid appropriately. Commercial insurer payment methodologies and payment levels will vary from Medicare and other government payers. It is not possible to capture all insurers' payment methodologies in this guide. Providers should contact their patients' insurers directly to obtain information on unique billing, coverage and payment requirements.

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MiroFlex®
Biologic Matrix

MiroFlex® Biologic Matrix is intended to be implanted to reinforce soft tissue, and is also intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. See Instructions For Use (IFU) for full prescribing information, including indications, contraindications, precautions, and potential complications.

MiroFlex is a biological matrix for soft tissue reinforcement used by surgeons in hernia repair. MiroFlex is manufactured using Reprise Biomedical's proprietary technology, a method to decellularize whole or partial organs and tissues. The technology is based on removing cells while maintaining an extracellular matrix or scaffold with its original architecture and an extensive natural vascular network. MiroFlex was originally cleared for marketing by FDA under the 510(k) program (K134033).

MiroFlex Ordering Information

Model	SIZE (cm)	TOTAL CM^2
BLM-100-01-0608	6cm x 8cm	48
BLM-100-01-0808	8cm x 8cm	64
BLM-100-01-1010	10cm x 10cm	100
BLM-100-01-0816	8cm x 16cm	128
BLM-100-01-1016	10cm x 16cm	160
BLM-100-01-1020	10cm x 20cm	200

PLACING AN ORDER
Email: customerservice@reprisebio.com
Phone: 952-377-8238 or Fax: 952-856-5085

Winter Shipping (October 1st – April 30th):
- All orders (Monday – Friday) ship FedEx2Day (The customer can elect to have product shipped FedEx Priority Overnight and pay the shipping difference)
- Thursday shipments will be delivered on Monday
- Friday shipments will be delivered on Tuesday

Summer Shipping (May 1st – September 30th):
- All orders ship FedEx Priority Overnight, at no extra charge to the customer.
- No Friday shipments unless Saturday delivery is requested, available, and paid for by the customer.

Billing questions: ap@reprisebio.com or Phone: 763-284-6771

Product Coding

MiroFlex Biologic Matrix does not hold a product-specific HCPCS code. The following codes are options for providers to specifically identify MiroFlex Biologic Matrix.

HCPCS CODE	
HCPCS	**DESCRIPTION**
A4649	Surgical Supply, Miscellaneous

REVENUE CODE Revenue codes are 4-digit numbers used on a hospital bill to provide detail on where a patient received treatment or type of item received.	
REVENUE CODE	**DESCRIPTION**
278	Other implant

Recommendations only. Providers are encouraged to check internal Coding and Charge Master guidance and SOPs for appropriate billing of all procedures and products provided.

Important Billing Instructions:

MiroFlex is not included on the Medicare Part A and B Average Sales Price (ASP) File published quarterly by the Centers for Medicare and Medicaid Services (CMS)

- ASP information is published quarterly by the Centers for Medicare and Medicaid Services (CMS) in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File. Providers are encouraged to review the ASP Pricing files posted quarterly by CMS and listed by the HCPCS on CMS.gov
- The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing. In determining the payment limit based on WAC, the contractors follow the methodology specified in Publication. 100-4, Chapter 17, Drugs and Biologicals, for calculating the AWP, but substitute WAC for AWP.
- Providers should check with local payers to determine if an invoice is required to be submitted with the claim in Box 19.
- Providers should check with local payers regarding appropriate use of modifiers.

Use either JW or JZ Modifiers to detail wastage or lack of wastage:

Providers and suppliers are required to report the JW or JZ modifier on Medicare Part B drug claims for discarded drugs and biologicals. Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical record including:

- Date, time, and location of ulcer treated
- Name of skin substitute and how product supplied
- Approximate amount of product unit used
- Approximate amount of product unit discarded
- Reason for the wastage
- Manufacturer's serial/lot/batch or other unit identification number on graft material

The amount discarded should be billed on a separate line with the JW modifier. The unit field should reflect the amount of tissue discarded. The modifier is not required if no discarded portion is being billed to any payer. (Please refer to: https://www. cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf and the FAQs at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JWModifier-FAQs.pdf).

Use modifier JZ on billing claims to attest there was no discarded amount from the single-dose vial or single-use package that is normally paid under Part B. Reference (IOM 100-4 Chapter 17, Sections 40-40.1) or page 621 of the CMS CY2023 OPPS/ASC Final Rule: https://public-inspection.federalregister.gov/2022-23918.pdf.

Place-of-Service Codes[1]

Place-of-service codes are 2-digit numbers included on health care professional claims to indicate the setting in which a service was provided. The Centers for Medicare and Medicaid Services (CMS) maintain place-of-service codes used throughout the health care industry. Listed below are place-of-service and descriptions that typically apply to our products. These codes should be used on professional claims to specify the entity where service(s) were rendered. Check with individual payors for reimbursement policies regarding these codes.

PLACE-OF-SERVICE CODE	PLACE-OF-SERVICE NAME	PLACE-OF-SERVICE DESCRIPTION
11	**Office**	Location other than hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or Local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
12	**Home**	Location other than a hospital or other facility, where the patient receives care in a private residence.
21	**Inpatient Hospital**	A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical) and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions.
22	**Outpatient Hospital**	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. Description change effective January 1, 2016.
24	**Ambulatory Surgical Center**	A freestanding facility, other than a physician's office, where surgical and diagnostic services are provided on an ambulatory basis.

1. https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set

ICD-10-CM Diagnosis Codes[1]

The ICD-10©-CM codes listed below represent some of the etiology diagnosis codes commonly associated with causes of hernia repair. This is not meant to be an exhaustive list.

ICD-10-CM	DESCRIPTION
K40.00	Bilateral inguinal hernia, with obstruction, without gangrene, not specified as recurrent
K40.01	Bilateral inguinal hernia, with obstruction, without gangrene, recurrent
K40.10	Bilateral inguinal hernia, with gangrene, not specified as recurrent
K40.11	Bilateral inguinal hernia, with gangrene, recurrent
K40.20	Bilateral inguinal hernia, without obstruction or gangrene, not specified as recurrent
K40.21	Bilateral inguinal hernia, without obstruction or gangrene, recurrent
K40.30	Unilateral inguinal hernia, with obstruction, without gangrene, not specified as recurrent
K40.31	Unilateral inguinal hernia, with obstruction, without gangrene, recurrent
K40.40	Unilateral inguinal hernia, with gangrene, not specified as recurrent
K40.41	Unilateral inguinal hernia, with gangrene, recurrent
K40.90	Unilateral inguinal hernia, without obstruction or gangrene, not specified as recurrent
K40.91	Unilateral inguinal hernia, without obstruction or gangrene, recurrent
K41.00	Bilateral femoral hernia, with obstruction, without gangrene, not specified as recurrent
K41.01	Bilateral femoral hernia, with obstruction, without gangrene, recurrent
K41.10	Bilateral femoral hernia, with gangrene, not specified as recurrent
K41.11	Bilateral femoral hernia, with gangrene, recurrent
K41.20	Bilateral femoral hernia, without obstruction or gangrene, not specified as recurrent
K41.21	Bilateral femoral hernia, without obstruction or gangrene, recurrent
K41.30	Unilateral femoral hernia, with obstruction, without gangrene, not specified as recurrent
K41.31	Unilateral femoral hernia, with obstruction, without gangrene, recurrent
K41.40	Unilateral femoral hernia, with gangrene, not specified as recurrent
K41.41	Unilateral femoral hernia, with gangrene, recurrent
K41.90	Unilateral femoral hernia, without obstruction or gangrene, not specified as recurrent
K41.91	Unilateral femoral hernia, without obstruction or gangrene, recurrent
K42.0	Umbilical hernia with obstruction, without gangrene
K42.1	Umbilical hernia with gangrene
K42.9	Umbilical hernia without obstruction or gangrene
K43.0	Incisional hernia with obstruction, without gangrene
K43.1	Incisional hernia with gangrene
K43.2	Incisional hernia without obstruction or gangrene
K43.3	Parastomal hernia with obstruction, without gangrene
K43.4	Parastomal hernia with gangrene
K43.5	Parastomal hernia without obstruction or gangrene
K43.6	Other and unspecified ventral hernia with obstruction, without gangrene
K43.7	Other and unspecified ventral hernia with gangrene
K43.9	Ventral hernia without obstruction or gangrene
K44.0	Diaphragmatic hernia with obstruction, without gangrene
K44.1	Diaphragmatic hernia with gangrene
K44.9	Diaphragmatic hernia without obstruction or gangrene
K45.0	Other specified abdominal hernia with obstruction, without gangrene
K45.1	Other specified abdominal hernia with gangrene
K45.8	Other specified abdominal hernia without obstruction or gangrene
K46.0	Unspecified abdominal hernia with obstruction, without gangrene
K46.1	Unspecified abdominal hernia with gangrene
K46.9	Unspecified abdominal hernia without obstruction or gangrene
Q40.1	Congenital hi atus hernia
Q79.0	Congenital diaphragmatic hernia
Q79.51	Congenital hernia of bladder

1. The International Classification of Diseases Clinical Modification Edition 9 is developed by the National Center for Health Statistics (NCHS). ICD-9 CM and ICD-10 CM are copyrighted buy the World Health Organization. WHO is the copyright holder of ICD-10, and can grant licenses for the use of ICD-10 worldwide for comercial and non-commercial uses.

ICD-10-CM Procedure Coding[1]

Hospital inpatient procedures are billed with ICD-10 CM Procedure Codes. These procedure codes are mapped to specific Diagnosis Related Groups (DRGs) for payment. Private payor claims processing protocol can vary, but often use the same DRG Grouper as Medicare resulting in assignment to the same DRGs.

NOTE: This list is not all inclusive. These procedure codes, when combined with appropriate ICD-10 CM diagnosis codes are typically mapped to DRGs for payment. The ICD-10 PCS system provides greater granularity in the reporting of procedures. See DRG Coding and Payment section of this guide for additional details.

ICD-10 PCS PROCEDURE CODES	
INCISIONAL HERNIA REPAIR	
0WQF0ZZ	Repair Abdominal Wall, Open Approach
0WQF3ZZ	Repair Abdominal Wall, Percutaneous Approach
0WQF4ZZ	Repair Abdominal Wall, Percutaneous Endoscopic Approach
REPAIR OF OTHER HERNIA OF ANTERIOR ABDOMINAL WALL	
0WQF0ZZ	Repair Abdominal Wall, Open Approach
0WQF3ZZ	Repair Abdominal Wall, Percutaneous Approach
0WQF4ZZ	Repair Abdominal Wall, Percutaneous Endoscopic Approach
OTHER OPEN INCISIONAL HERNIA REPAIR WITH GRAFT OF PROSTHESIS	
0WUF07Z	Supplement Abdominal Wall with Autologous Tissue Substitute, Open Approach
0WUF0JZ	Supplement Abdominal Wall with Synthetic Substitute, Open Approach
0WUF0KZ	Supplement Abdominal Wall with Nonautologous Tissue Substitute, Open Approach
LAPAROSCOPIC INCISIONAL HERNIA REPAIR WITH GRAFT OR PROSTHESIS	
0WUF47Z	Supplement Abdominal Wall with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0WUF4JZ	Supplement Abdominal Wall with Synthetic Substitute, Percutaneous Endoscopic Approach
0WUF4KZ	Supplement Abdominal Wall with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
OTHER LAPAROSCOPIC REPAIR OF OTHER HERNIA OF ANTERIOR ABDOMINAL WALL WITH GRAFT OR PROSTHESIS	
0WUF47Z	Supplement Abdominal Wall with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0WUF4JZ	Supplement Abdominal Wall with Synthetic Substitute, Percutaneous Endoscopic Approach
0WUF4KZ	Supplement Abdominal Wall with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
OTHER AND OPEN REPAIR OF OTHER HERNIA OF ANTERIOR ABDOMINAL WALL WITH GRAFT OR PROSTHESIS	
0WUF07Z	Supplement Abdominal Wall with Autologous Tissue Substitute, Open Approach
0WUF0JZ	Supplement Abdominal Wall with Synthetic Substitute, Open Approach
0WUF0KZ	Supplement Abdominal Wall with Nonautologous Tissue Substitute, Open Approach
0WUF47Z	Supplement Abdominal Wall with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0WUF4JZ	Supplement Abdominal Wall with Synthetic Substitute, Percutaneous Endoscopic Approach
0WUF4KZ	Supplement Abdominal Wall with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
LAPAROSCOPIC REPAIR OF DIAPHRAGMATIC HERNIA, ABDOMINAL APPROACH	
0BQR4ZZ	Repair Right Diaphragm, Percutaneous Endoscopic Approach
0BQS4ZZ	Repair Left Diaphragm, Percutaneous Endoscopic Approach
REPAIR OF DIAPHRAGMATIC HERNIA, ABDOMINAL APPROACH, NOT OTHERWISE SPECIFIED	
0BQR0ZZ	Repair Right Diaphragm, Open Approach
0BQR3ZZ	Repair Right Diaphragm, Percutaneous Approach
0BQR4ZZ	Repair Right Diaphragm, Percutaneous Endoscopic Approach
0BQS0ZZ	Repair Left Diaphragm, Open Approach
0BQS3ZZ	Repair Left Diaphragm, Percutaneous Approach
0BQR4ZZ	Repair Left Diaphragm, Percutaneous Endoscopic Approach

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ICD-10-CM Procedure Coding[1] (continued)

ICD-10 PCS PROCEDURE CODES	
REPAIR OF DIAPHRAGMATIC HERNIA, THORACIC APPROACH, NOT OTHERWISE SPECIFIED	
0BQR0ZZ	Repair Right Diaphragm, Open Approach
0BQR3ZZ	Repair Right Diaphragm, Percutaneous Approach
0BQR4ZZ	Repair Right Diaphragm, Percutaneous Endoscopic Approach
0BQS0ZZ	Repair Left Diaphragm, Open Approach
0BQS3ZZ	Repair Left Diaphragm, Percutaneous Approach
0BQR4ZZ	Repair Left Diaphragm, Percutaneous Endoscopic Approach
APPLICATION OF THE DIAPHRAGM	
0BQR0ZZ	Repair Right Diaphragm, Open Approach
0BQR3ZZ	Repair Right Diaphragm, Percutaneous Approach
0BQR4ZZ	Repair Right Diaphragm, Percutaneous Endoscopic Approach
0BQS0ZZ	Repair Left Diaphragm, Open Approach
0BQS3ZZ	Repair Left Diaphragm, Percutaneous Approach
0BQR4ZZ	Repair Left Diaphragm, Percutaneous Endoscopic Approach
REPAIR OF PARASTERNAL HERNIA	
0BQR0ZZ	Repair Right Diaphragm, Open Approach
0BQR3ZZ	Repair Right Diaphragm, Percutaneous Approach
0BQR4ZZ	Repair Right Diaphragm, Percutaneous Endoscopic Approach
0BQS0ZZ	Repair Left Diaphragm, Open Approach
0BQS3ZZ	Repair Left Diaphragm, Percutaneous Approach
0BQR4ZZ	Repair Left Diaphragm, Percutaneous Endoscopic Approach
LAPAROSCOPIC REPAIR OF DIAPHRAGMATIC HERNIA, THORACIC APPROACH	
0BQR4ZZ	Repair Right Diaphragm, Percutaneous Endoscopic Approach
0BQS4ZZ	Repair Left Diaphragm, Percutaneous Endoscopic Approach
OTHER AND OPEN REPAIR OF DIAPHRAGMATIC HERNIA, WITH THORACIC APPROACH	
0BQR0ZZ	Repair Right Diaphragm, Open Approach
0BQR3ZZ	Repair Right Diaphragm, Percutaneous Approach
0BQS0ZZ	Repair Left Diaphragm, Open Approach
0BQS3ZZ	Repair Left Diaphragm, Percutaneous Approach

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ICD-10-CM Procedure Coding[1] (continued)

ICD-10 PCS PROCEDURE CODES	
OTHER HERNIA REPAIR	
0DQS0ZZ	Repair Greater Omentum, Open Approach
0DQS3ZZ	Repair Greater Omentum, Percutaneous Approach
0DQS4ZZ	Repair Greater Omentum, Percutaneous Endoscopic Approach
0DQT0ZZ	Repair Lesser Omentum, Open Approach
0DQT3ZZ	Repair Lesser Omentum, Percutaneous Approach
0DQT4ZZ	Repair Lesser Omentum, Percutaneous Endoscopic Approach
0DQS0ZZ	Repair Back Subcutaneous Tissue and Fascia, Open Approach
0JQ73ZZ	Repair Back Subcutaneous Tissue and Fascia, Percutaneous Approach
0JQC0ZZ	Repair Pelvic Region Subcutaneous Tissue and Fascia, Open Approach
0JQC3ZZ	Repair Pelvic Region Subcutaneous Tissue and Fascia, Percutaneous
0JQM0ZZ	Repair Left Upper Leg Subcutaneous Tissue and Fascia, Open Approach
0JQM3ZZ	Repair Left Upper Leg Subcutaneous Tissue and Fascia, Open Approach
0JQN0ZZ	Repair Right Lower Leg Subcutaneous Tissue and Fascia, Open Approach
0JQN3ZZ	Repair Right Lower Leg Subcutaneous Tissue and Fascia, Percutaneous Approach
0WQF0ZZ	Repair Abdominal Wall, Open Approach
0WQF3ZZ	Repair Abdominal Wall, Percutaneous Approach
0WQF4ZZ	Repair Abdominal Wall, Percutaneous Endoscopic Approach
0WUF07Z	Supplement Abdominal Wall with Autologous Tissue Substitute, Open Approach
0WUF47Z	Supplement Abdominal Wall with Synthetic Substitute, Open Approach
OWUF0KZ	Supplement Abdominal Wall with Nonautologous Tissue Substitute, Open Approach
OWUF47Z	Supplement Abdominal Wall with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
OWUF4JZ	Supplement Abdominal Wall with Synthetic Substitute, Percutaneous Endoscopic Approach
OWUF4KZ	Supplement Abdominal Wall with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
OTHER REPAIR OF ABDOMINAL WALL	
0WMF0ZZ	Reattachment of Abdominal Wall, Open Approach
OWQF0ZZ	Repair Abdominal Wall, Open Approach
0WQF3ZZ	Repair Abdominal Wall, Percutaneous Approach
0WQF4ZZ	Repair Abdominal Wall, Percutaneous Endoscopic Approach
0WQFXZZ	Repair Abdominal Wall, External Approach
0WUF07Z	Supplement Abdominal Wall with Autologous Tissue Substitute, Open Approach
0WUF0JZ	Supplement Abdominal Wall with Synthetic Substitute, Open Approach
0WUF0KZ	Supplement Abdominal Wall with Nonautologous Tissue Substitute, Open Approach
0WUF47Z	Supplement Abdominal Wall with Autologous Tissue Substitute, Percutaneous Endoscopic Approach 0WUF4JZ
0WUF4JZ	Supplement Abdominal Wall with Synthetic Substitute, Percutaneous Endoscopic Approach
0WUF4KZ	Supplement Abdominal Wall with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach

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2023 Inpatient Hospital Coding/Payment - Medicare

Hospital inpatient procedures are billed with ICD-10-CM procedure codes. These procedure codes are mapped to specific Medicare Diagnosis Related Groups (DRGs) for payment. Private payer claims processing protocol can vary, but often use the same DRG Grouper as Medicare. Payment for private payers will differ per contract, payer and patient benefits.

The table below provides potential MS-DRGs assignments for hospitals when applying MiroFlex Biologic Matrix. These are 2022 Medicare average rates and are provided as a benchmark. Rates nationwide can vary widely.

DRG[1,2]	Description	DRG WEIGHT	MEDICARE PAYMENT[3,4]
326	Stomach, esophageal & duodenal procedures with MCC	5.3163	$31,991
327	Stomach, esophageal & duodenal procedures with CC	2.5647	$16,007
328	Stomach, esophageal & duodenal procedures without CC/MCC	1.6669	$10,360
347	Anal & stomal procedures with MCC	2.4647	$15,863
348	Anal & stomal procedures with CC	1.3481	$8,631
349	Anal & stomal procedures without CC/MCC	0.9793	$6,232
350	Inguinal & femoral hernia procedures with MCC	2.4548	$14,730
351	Inguinal & femoral hernia procedures with CC	1.4927	$9,188
352	Inguinal & femoral hernia procedures without CC/MCC	1.1044	$6,887
353	Hernia procedures except inguinal & femoral with MCC	3.0249	$17,923
354	Hernia procedures except inguinal & femoral with CC	1.7848	$10,949
355	Hernia procedures except inguinal & femoral without CC/MCC	1.3602	$8,576

2023 Medicare payments are based on a factor of $6,249.82 weight of one. They do not include adjustments for Disproportionate Share or Direct or Indirect Medical Education. These allowances are effective as of October 1, 2021.

Hernia repair will routinely fall into one of the these 12 DRGs. The exact assignment is dependent upon the presence or absence of Complications and Comorbidities (CC) or Major Complications or Comorbidities (MCC). These payment assignments also assume the hernia repair is the primary procedure.

Hospital inpatient procedures are billed with ICD-10 CM Procedure Codes. These procedure codes are mapped to specific Diagnosis Related Groups (DRGs) for payment. Private payor claims processing protocol can vary, but often use the same DRG Grouper as Medicare resulting in assignment to the same DRGs.
NOTE: This list is not all inclusive. These procedure codes, when combined with appropriate ICD-10 CM diagnosis codes get mapped to DRGs for payment. The ICD-10 PCS system provides greater granularity in the reporting of procedures.

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2. 2023 MS-DRG relative weight multiplied by 2022 rate of $6,249.82 per IPPS Final Rule as calculated by MCRA, payment rates will vary by facility. Calculation includes labor related, non-labor related and capital rates.
3. Medicare reimburses hospital inpatient stays based on the Medicare Severity Diagnosis Related Group (MS-DRG) system. MS-DRGs represent a consolidated prospective payment for all services provided by the hospital during hospitalization, based on submitted claims data. With limited exceptions, the MS-DRG payment is inclusive of all services, products, and resources, regardless of the final cost to the hospital. Medicare and many private payors use the MS-DRG based system to reimburse facilities for inpatient services.
4. Reference: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-final-rule-home-page#FinalRule

2023 Hospital Outpatient/ASC - Medicare

Hospital outpatient departments and Ambulatory Surgery Centers (ASCs) submit CPT codes to government and private payers. These CPT codes are then mapped to specific comprehensive Ambulatory Payment Classification (APCs) (hospitals) or a fee schedule (ASC) for Medicare payment.

Under Medicare, non-hospitalized hernia repair procedures are categorized into one of the following 3 payments levels for hospitals/ASCs as described below.

See CPT Coding Section of this guide for CPT coding details.

DESCRIPTION*	HOSPITAL OUTPATIENT NATIONAL AVG	ASC NATIONAL AVG
APC: 5341 - Abdominal/Peritoneal/Biliary and Related Procedures	$3,264	$3,183
APC: 5361 - Level 1 Laparoscopy and Related Services	$5,060	$5,192
APC: 5362 - Level 2 Laparoscopy and Related Services	$8,907	$9,139

*These surgeries may be performed via laparoscopy or open procedure.

Coinsurance/Deductibles: As with all products and services paid for under Medicare Parts A & B, Medicare will reimburse 80 percent of the allowable amount. The patient, or secondary/supplemental plan, is responsible for the remaining, 20 percent coinsurance amount. The appropriate annual deductions also apply.

Sequestration: Since April 1, 2013, all Medicare claims with a date-of-service on or after April 1, 2013 are subjected to a 2 percent sequestration amount, which remains in effect in the U.S. budget until 2022. On Friday, December 10, 2021, the President signed into law: S. 610, the "Protecting Medicare and American Farmers from Sequester Cuts Act," which delays the Medicare sequester and make other changes to Medicare payments. The moratorium on sequestration is extended through March 31, 2022, and the sequestration cut is reduced to 1% from April 1 to June 30, 2022. In effect, providers won't see any Medicare payment reductions until April 1, 2022, with the full 2% sequestration cut in effect beginning July 1, 2022.

Geographic Practice Cost Index (GPCI)[1]: The Medicare physician fee schedule amounts are adjusted to reflect the variation in practice costs from area to area. A GPCI has been established for every Medicare payment locality based on the RVUs for work, practice expense, and malpractice. The GPCIs are applied in the calculation of a fee schedule payment amount by multiplying the RVU for each component times the GPCI for that component.

1. Reference: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-final-rule-home-page#FinalRule

2023 Outpatient/ASC Coding and Payment - Medicare

The Current Procedural Terminology (CPT) code set describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payors for administrative, financial, and analytical purposes.

The following CPT codes map to specific APCs and represent the most commonly performed hernia repair procedures. "IP Only" means the procedure is only performed in a hospital inpatient - refer to the section on inpatient hospital coding and payment and physician CPT coding and payment for additional information.

CPT[1,2]	Description	APC	HOPPS Nat Avg	ASC Nat Avg
HERNIA PROCEDURES				
49500	Repair initial inguinal hernia, age 6 months to younger than 5 years, with or without hydrocelectomy, reducible	5341	$3,183	$3,265
49501	Repair initial inguinal hernia, age 6 months to younger than 5 years, with or without hydrocelectomy; incarcerated or strangulated	5341	$3,183	$3,265
49505	Repair initial inguinal hernia, age 5 years or older; reducible	5341	$3,183	$3,265
49507	Repair initial inguinal hernia, age 5 years or older; incarcerated or strangulated	5341	$3,183	$3,265
49520	Repair recurrent inguinal hernia, any age; reducible	5341	$3,183	$3,265
49521	Repair recurrent inguinal hernia, any age; incarcerated or strangulated	5341	$3,183	$3,265
49525	Repair inguinal hernia, sliding, any age	5341	$3,183	$3,265
49550	Repair initial femoral hernia, any age; reducible	5341	$3,183	$3,265
49553	Repair initial femoral hernia, any age; incarcerated or strangulated	5341	$3,183	$3,265
49555	Repair recurrent femoral hernia; reducible	5341	$3,183	$3,265
49557	Repair recurrent femoral hernia; incarcerated or strangulated	5341	$3,183	$3,265
49560	Repair initial incisional or ventral hernia; reducible	5341	$3,183	$3,265
49561	Repair initial incisional or ventral hernia; incarcerated or strangulated	5341	$3,183	$3,265
49565	Repair recurrent incisional or ventral hernia; reducible	5361	$5,060	$5,193
49566	Repair recurrent incisional or ventral hernia; incarcerated or strangulated	5361	$5,060	$5,193
49580	Repair umbilical hernia, younger than age 5 years; reducible	5341	$3,183	$3,265
49582	Repair umbilical hernia, younger than age 5 years; incarcerated or strangulated	5341	$3,183	$3,265
49585	Repair umbilical hernia, age 5 years or older; reducible	5341	$3,183	$3,265
49587	Repair umbilical hernia, age 5 years or older; incarcerated or strangulated	5341	$3,183	$3,265
LAPAROSCOPY PROCEDURES				
44238	Unlisted laparoscopy procedure, intestine (except rectum)	5361	$5,060	$5,193
49650	Laparoscopy, surgical; repair initial inguinal hernia	5361	$5,060	$5,193
49651	Laparoscopy, surgical; repair recurrent inguinal hernia	5361	$5,060	$5,193
49652	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); reducible or 5362 with complexity adjustment $7,741 (ASC payment would be the same)	5361	$5,060	$5,193
49653	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated or 5363 with complexity adjustment	5361	$5,060	$5,192
49654	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible	5362	$8,908	$9,139
49655	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	5362	$8,908	$9,139
49656	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); reducible	5362	$8,908	$9,139
49657	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	5362	$8,908	$9,139
49659	Unlisted laparoscopy procedure, hernioplasty, herniorrhaphy, herniotomy	5361	$5,060	$5,193
44346	Revision of colostomy; simple (release of superficial scar) (separate procedure) with repair of paracolostomy hernia (separate procedure)	5341	$3,183	$3,265

1. Providers are encouraged to reference CMS Global Surgery Booklet for Coding and Billing Guidance: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/GlobalSurgery-ICN907166Printfriendly.pdf
2. Reference: https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1770-f.

2023 Outpatient/ASC Coding and Payment - Medicare (continued)

CPT[1,2]	Description	APC	HOPPS Nat Avg	ASC Nat Avg
LAPAROSCOPIC FUNDOPLASTY				
43280	Laparoscopy, surgical, esophagogastric fundoplasty (e.g., Nissen, Toupet procedures)	5362	$8,907	$9,139
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	5362	$8,907	$9,139
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	5362	$8,907	$9,139
43289	Unlisted laparoscopy procedure, esophagus	5361	$5,060	$5,192
LAPAROSCOPY PROCEDURES (IP ONLY CODES)				
44187	Laparoscopy, surgical; ileostomy or jejunostomy, non-tube	IP Only		
44188	Laparoscopy, surgical, colostomy or skin level cecostomy			
44202	Laparoscopy, surgical; enterectomy, resection of small intestine, single resection and anastomosis			
44203	Laparoscopy, surgical; each additional small intestine resection and anastomosis (List separatelyin addition to code for primary procedure)			
44204	Laparoscopy, surgical; colectomy, partial, with anastomosis			
44205	Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy			
44206	Laparoscopy, surgical; colectomy, partial, with end colostomy and closureof distal segment (Hartmann type procedure)			
44207	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis)			
44208	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis) with colostomy			
44210	Laparoscopy, surgical; colectomy, total, abdominal, without proctectomy, with ileostomy or ileoproctostomy			
44211	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileoanal anastomosis, creation of ileal reservoir (S or J), with loop ileostomy, includes rectal mucosectomy, when performed			
44212	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileostomy			
44213	Laparoscopy, surgical, mobilization (take-down) of splenic flexure performed in conjunction with partial colectomy (List separately in addition to primary procedure)			
44227	Laparoscopy, surgical, closure of enterostomy, large or small intestine, with resection and anastomosis			
LAPAROSCOPIC REPAIR (IP ONLY CODES)				
43332	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; without implantation of mesh or other prosthesis	IP Only		
43333	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; with implantation of mesh or other prosthesis			
43334	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; without implantation of mesh or other prosthesis			
43335	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; with implantation of mesh or other prosthesis			
43336	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; without implantation of mesh or other prosthesis			
43337	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal;with implantation of mesh or other prosthesis			
43338	Esophageal lengthening procedure (e.g., Collis gastroplasty or wedge gastroplasty) (List separately in addition to code for primary procedure)			
OTHER (IP ONLY CODES)				
39540	Repair, diaphragmatic hernia (other than neonatal), traumatic; acute	IP Only		
39541	Repair, diaphragmatic hernia (other than neonatal), traumatic; chronic			
44346	Revision of colostomy; simple (release of superficial scar) (separate procedure) with repair of paracolostomy hernia (separate procedure)			

1. Providers are encouraged to reference CMS Global Surgery Booklet for Coding and Billing Guidance: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/GlobalSurgery-ICN907166Printfriendly.pdf
2. Reference: https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1770-f.

2023 Physician Services - Medicare

HERNIA PROCEDURES		
CPT Code[1,2]	**Description**	**Medicare National Avg**
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue	YYY*
49500	Repair initial inguinal hernia, age 6 months to younger than 5 years, with or without hydrocelectomy, reducible	$414
49501	Repair initial inguinal hernia, age 6 months to younger than 5 years, with or without hydrocelectomy; incarcerated or strangulated	$603
49505	Repair initial inguinal hernia, age 5 years or older; reducible	$519
49507	Repair initial inguinal hernia, age 5 years or older; incarcerated or strangulated	$584
49520	Repair recurrent inguinal hernia, any age; reducible	$628
49521	Repair recurrent inguinal hernia, any age; incarcerated or strangulated	$711
49525	Repair inguinal hernia, sliding, any age	$570
49550	Repair initial femoral hernia, any age; reducible	$574
49553	Repair initial femoral hernia, any age; incarcerated or strangulated	$628
49555	Repair recurrent femoral hernia; reducible	$601
49557	Repair recurrent femoral hernia; incarcerated or strangulated	$717
49560	Repair initial incisional or ventral hernia; reducible	NA
49561	Repair initial incisional or ventral hernia; incarcerated or strangulated	NA
49565	Repair recurrent incisional or ventral hernia; reducible	NA
49566	Repair recurrent incisional or ventral hernia; incarcerated or strangulated	NA
49580	Repair umbilical hernia, younger than age 5 years; reducible	NA
49582	Repair umbilical hernia, younger than age 5 years; incarcerated or strangulated	NA
49585	Repair umbilical hernia, age 5 years or older; reducible	NA
49587	Repair umbilical hernia, age 5 years or older; incarcerated or strangulated	NA
44187	Laparoscopy, surgical; ileostomy or jejunostomy, non-tube	$1,074
44188	Laparoscopy, surgical, colostomy or skin level cecostomy	$1,196
44202	Laparoscopy, surgical; enterectomy, resection of small intestine, single resection and anastomosis	$1,366
44203	Laparoscopy, surgical; each additional small intestine resection and anastomosis (List separatelyin addition to code for primary procedure)	$236
44204	Laparoscopy, surgical; colectomy, partial, with anastomosis	$1,508
44205	Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy	$1,310
44206	Laparoscopy, surgical; colectomy, partial, with end colostomy and closureof distal segment (Hartmann type procedure)	$1,709
44207	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis)	$1,774
44208	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis) with colostomy	$1,931
44210	Laparoscopy, surgical; colectomy, total, abdominal, without proctectomy, with ileostomy or ileoproctostomy	$1,735
44211	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileoanal anastomosis, creation of ileal reservoir (S or J), with loop ileostomy, includes rectal mucosectomy, when performed	$2,066
44212	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileostomy	$1,980
44213	Laparoscopy, surgical, mobilization (take-down) of splenic flexure performed in conjunction with partial colectomy (List separately in addition to primary procedure)	$181
44227	Laparoscopy, surgical, closure of enterostomy, large or small intestine, with resection and anastomosis	$1,627

1. Providers are encouraged to reference CMS Global Surgery Booklet for Coding and Billing Guidance: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/GlobalSurgery-ICN907166Printfriendly.pdf
2. Reference: CY2023 MPFS: https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1770-f. CMS CY2023 MPFS Conversion factor = $33.0777.

*YYY = Codes with YYY are contractor priced codes for which Medicare Administrative Contractors determine the global period and payment.

2023 Physician Services - Medicare (continued)

LAPAROSCOPY PROCEDURES		
CPT Code[1,2]	**Description**	**Medicare National Avg**
44238	Unlisted laparoscopy procedure, intestine (except rectum)	YYY*
49650	Laparoscopy, surgical; repair initial inguinal hernia	$429
49651	Laparoscopy, surgical; repair recurrent inguinal hernia	$561
49652	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); reducible or 5362 with complexity adjustment $7,741 (ASC payment would be the same)	NA
49653	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated or 5363 with complexity adjustment	NA
49654	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible	NA
49655	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	NA
49656	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); reducible	NA
49657	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	NA
49659	Unlisted laparoscopy procedure, hernioplasty, herniorrhaphy, herniotomy	YYY*
44346	Revision of colostomy; simple (release of superficial scar) (separate procedure) with repair of paracolostomy hernia (separate procedure)	$1,164

LAPAROSCOPIC FUNDOPLASTY PROCEDURES		
CPT Code[1]	**Description**	**Medicare National Avg**
43280	Laparoscopy, surgical, esophagogastric fundoplasty (e.g., Nissen, Toupet procedures)	$1,064
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	$1,513
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	$1,703
43283	Laparoscopy, surgical, esophageal lengthening procedure (e.g., Collis gastroplasty or wedge gastroplasty) (List separately in addition to code for primary procedure)	NA
43289	Unlisted laparoscopy procedure, esophagus	YYY*

LAPAROSCOPIC REPAIR PROCEDURES		
CPT Code[1]	**Description**	**Medicare National Avg**
43332	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; without implantation of mesh or other prosthesis	$1,128
43333	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; with implantation of mesh or other prosthesis	$1,236
43334	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; without implantation of mesh or other prosthesis	$1,211
43335	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; with implantation of mesh or other prosthesis	$1,298
43336	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; without implantation of mesh or other prosthesis	$1,411
43337	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal;with implantation of mesh or other prosthesis	$1,503
43338	Esophageal lengthening procedure (e.g., Collis gastroplasty or wedge gastroplasty) (List separately in addition to code for primary procedure)	$111

1. Providers are encouraged to reference CMS Global Surgery Booklet for Coding and Billing Guidance: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/GlobalSurgery-ICN907166Printfriendly.pdf
2. Reference: CY2023 MPFS: https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1770-f. CMS CY2023 MPFS Conversion factor = $33.0777.

*YYY = Codes with YYY are contractor priced codes for which Medicare Administrative Contractors determine the global period and payment.

2022 Physician Services - Medicare (continued)

INPATIENT PROCEDURES		
CPT Code[1,2]	**Description**	**Medicare National Avg**
39540	Repair, diaphragmatic hernia (other than neonatal), traumatic; acute	$851
39541	Repair, diaphragmatic hernia (other than neonatal), traumatic; chronic	$918
44346	Revision of colostomy; simple (release of superficial scar) (separate procedure) with repair of paracolostomy hernia (separate procedure)	$1,164

Coinsurance/Deductibles: As with all products and services paid for under Medicare Parts A & B, Medicare will reimburse 80 percent of the allowable amount. The patient, or secondary/supplemental plan, is responsible for the remaining, 20 percent coinsurance amount. The appropriate annual deductions also apply.

Sequestration: Since April 1, 2013, all Medicare claims with a date-of-service on or after April 1, 2013 are subjected to a 2 percent sequestration amount, which remains in effect in the U.S. budget until 2022. On Friday, December 10, 2021, the President signed into law: S. 610, the "Protecting Medicare and American Farmers from Sequester Cuts Act," which delays the Medicare sequester and make other changes to Medicare payments. The moratorium on sequestration is extended through March 31, 2022, and the sequestration cut is reduced to 1% from April 1 to June 30, 2022. In effect, providers won't see any Medicare payment reductions until April 1, 2022, with the full 2% sequestration cut in effect beginning July 1, 2022.

Geographic Practice Cost Index (GPCI)[3]: The Medicare physician fee schedule amounts are adjusted to reflect the variation in practice costs from area to area. A GPCI has been established for every Medicare payment locality based on the RVUs for work, practice expense, and malpractice. The GPCIs are applied in the calculation of a fee schedule payment amount by multiplying the RVU for each component times the GPCI for that component.

CMS Global Surgery Guidelines: Physicians are encouraged to reference Global Surgery Booklet for Coding and Billing Guidance: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/GloballSurgery-ICN907166Printfriendly.pdf

Use either JW or JZ Modifiers to detail wastage or lack of wastage: Providers and suppliers are required to report the JW or JZ modifier on Medicare Part B drug claims for discarded drugs and biologicals. Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical record including:

- Date, time, and location of ulcer treated
- Name of skin substitute and how product supplied
- Approximate amount of product unit used
- Approximate amount of product unit discarded
- Reason for the wastage
- Manufacturer's serial/lot/batch or other unit identification number on graft material

The amount discarded should be billed on a separate line with the JW modifier. The unit field should reflect the amount of tissue discarded. The modifier is not required if no discarded portion is being billed to any payer.

Please refer to: https://www. cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf and the FAQs at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JWModifier-FAQs.pdf.

- JW Modifier must be reported for dates of service on or after January 1, 2023.
- JZ Modifier must be reported for dates of service on or after July 1, 2023.

1. Providers are encouraged to reference CMS Global Surgery Booklet for Coding and Billing Guidance: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/GloballSurgery-ICN907166Printfriendly.pdf
2. Reference: CY2023 MPFS: https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1770-f. CMS CY2023 MPFS Conversion factor = $33.0777.
3. 2023 AMA CPT® Professional. Procedure coding should be based upon medical necessity, procedures and supplies provided to the patient. Coding and reimbursement information is provided for educational purposes and does not assure coverage of the specific item or service in a given case. Reprise Biomedical makes no guarantee of coverage or reimbursement of fees. These payment rates are nationally unadjusted average amounts and do not account for differences in payment due to geographic variation. Contact your Medicare Administrative Contractor (MAC) or CMS for specific information as payment rates listed are subject to change. To the extent that you submit cost information to Medicare, Medicaid or any other reimbursement program to support claims for services or items, you are obligate to accurately report the actual price paid for such items, including any subsequent adjustments. CPT five-digit numeric codes, descriptions, and numeric modifiers only are Copyright AMA. (Updated January 2022).

Sample Letter of Medical Necessity

Date
Insurer Name
Insurer Address
City, State, Zip Code

RE: Medical Necessity for MiroFlex Biologic Matrix
Patient's Name:
Policy Number:
Group Number:
Date of Birth:

Dear [Insurance Contact Name]:

I am writing to notify you of my intent to treat Mr./Ms. [Patient's Name] with MiroFlex Biologic Matrix, which is used to reinforce soft tissue and is also intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery.

The patient's medical history is as follows: [include relevant medical history]

MiroFlex Biologic Matrix is an acellular matrix that is derived from the highly vascularized porcine liver and was cleared by the FDA under 510(k) K134033. Reprise Biomedical manufactures MiroFlex Biologic Matrix and is a medical device company focused on the development of clinically relevant biologic medical devices for the surgical and wound care space.

My patient has not responded to conservative care for [time frame] and has not responded to more advanced therapy including [product name(s) & type(s) of products]. More aggressive treatment is medically necessary to prevent further damage and [list risk(s) of non-closure]. I believe my patient will benefit from treatment with MiroFlex Biologic Matrix.

I have enclosed information regarding the clinical utility of MiroFlex.

Please feel free to contact me if additional information is required to process my request for coverage.

Sincerely,
[Name]
[Contact info]

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
Refer to the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions. Information in this material is not a substitute for the product Instructions for Use.

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