

EvoEndo® Single-Use Endoscopy System



Value Analysis Presentation

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We achieve **big things** through **small scopes**.

Our ultra-slim technology unleashes the potential of sedation-free endoscopy to improve the lives of patients, families, and healthcare professionals.



Limitations of Traditional Upper Endoscopy

Need significant infrastructure and resources for cleaning and reprocessing reusable scopes

Reusable scopes are expensive and require frequent repair ——

Require general anesthesia and are not optimized for Sedation-Free TNE

Pediatric professionals are looking for lower-risk, sedation-free alternatives.

Evidence-Based Practice Summary

- Sedation-free TNE has been available and reported in the United States and around the world since 1994. Multiple studies document its safety, reliability, and ease of learning.
- Studies in the pediatric population have documented reliable biopsies, increased patient safety, improved efficiency, cost/charge savings, high success rate, and high patient satisfaction

Latest Publications

OFFICE-BASED SEDATION-FREE TRANSNASAL ESOPHAGOGASTRODUODENOSCOPY WITH BIOPSIES USING SINGLE-USE GASTROSCOPES: A PEDIATRIC SINGLE-CENTER EXPERIENCE. Smadi Y, Thomas J, Bittar K, Norton H, Friedlander JA, Bornstein J JPGN Reports 2023, 1-6

SAFETY AND EFFICACY OF A NOVEL ULTRATHIN GASTROSCOPE FOR UNSEDATED TRANSNASAL ENDOSCOPY IN CHILDREN AND ADULTS FOR EVALUATION OF UPPER GASTROINTESTINAL DISORDERS Thavamani A, Ryan M, Leinwand K, Ramraj R, Schroeder A, Menard-Katcher P, Bhardwaj V, Franciosi J, Friedlander J, Sabe R iGIE (2024)



Click Here for Additional Literature



The Future of Endoscopy Is Here

The EvoEndo[®] System is the only FDA-cleared product designed specifically for pediatric patients, introducing a sedation-free, lower-risk, cost-effective alternative to traditional endoscopy.



Safety

- Sedation-free TNE eliminates the need for general anesthesia.
- Single-use design decreases the risk of cross-contamination.

Efficiency

- Reduced NPO time, no pre- or postprocedure recovery time.
- A functional scope is always available, no reprocessing time is required.

Affordability

- Lower up-front capital expenses.
- No scope maintenance, repairs, or reprocessing costs.

EvoEndo® Single-Use Endoscopy System Indications for Use

The EvoEndo[®] Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb in patients over the age of five. The gastroscope is a sterile, single-use device and can be inserted orally or transnasally. The EvoEndo[®] Controller is intended for use with an EvoEndo[®] Endoscope for endoscopic diagnosis, treatment, and video observation.

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Up/Down Control Left/Right Control (both wheels) Working Channel

Capture Image (1 sec)

Enhance Image (2 sec)

Suction

Narrow diameter fits smaller nasal anatomyEnables full transnasal EGD

Product Specifications

- Accommodates most standard pediatric accessories
- Reduces risk of scope cross-contamination

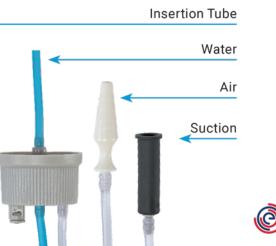
EvoEndo® Model LE Single-Use Gastroscope

Water

Air

Freeze Image (1 sec)

White-Balance (2 sec)



EvoEndo[®] Controller

- Lightweight and portable at 6" x 8.5", 2 lbs
- Easy to set up plug and play
- Easy to scale to multiple sites
- Integrates with some third-party endoscopy reporting software (e.g., Provation)



EvoEndo® Patient Experience Kit

- Virtual reality patient distraction via single-use VR goggles
- Stress-relief squeeze ball
- Curated, age-appropriate video library at evoendo.com/youtube







Patient Benefits

Safe

- No needles, no anesthesia.
- No risk of infection from cross-contamination.

Convenient

- Quicker recovery.
- Less fasting time, less time in clinic, less disruption.
- Reduced burden on caregivers.
- More frequent scoping.

Batient-Centric

- Distraction techniques improve the patient experience.
- Family accompanies patient during the procedure.
- Visual findings can be discussed immediately.

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Healthcare Professional Benefits

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Efficiency

- More procedures in less time.
- No waiting for scope reprocessing and repairs.
- Easy to operate, small footprint, highly portable.

Improved Outcomes

- Faster time to diagnosis.
- Better access and fewer barriers to care for patients.
- Well-tolerated by the majority of patients with a 94% - 98% success rate.^{6,8,10}
- Increases patient compliance.

Risk Mitigation

- Reduces complication potential related to anesthesia.
- Eliminates cross-contamination risk from scope reprocessing.

Healthcare System Benefits

Improved Economics

• Adds additional revenue stream via increased procedural throughput.

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- Reduces total cost of ownership.
- Stabilizes operational budget expenditures.

Better Resource Management

- Frees up OR-based treatment areas for higher-margin procedures.
- Reduces procedural backlogs.
- Improves patient no-show rates by decreasing wait times.
- Eliminates staff downtime for reprocessing or repair of reusable scopes.
- Reduces staff required to support the same volume of procedures.

Scalability

- Low capital costs and minimal start-up costs enable rapid program expansion.
- System portability can transform underutilized spaces into revenue-generating procedure sites.



System Implementation Support

Our account management and clinical teams will be with you step by step as you integrate this technology into your practice.



Support Tools include FAQs, Templates, Checklists, Fact Sheets, Best Practices, and Patient Resources.



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Coding and Reimbursement Support

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Reimbursement

codes and Category III codes?

methodology

work.

Frequently Asked Ques

1. Why don't payers provide payment information during the re

patient's health plan for a particular procedure

a. The purpose of a prior authorization is to obtain information about

b. Payer representatives who perform prior authorization services d

c. The provider's internal contracting department may be able to ide

2. How can physician providers establish RVUs, payments, an

a. Cat III and Unlisted codes do not have national RVUs or assigned

b. While there isn't a payment level, if the payer agrees to cover or a

c. Physician charges and RVUs can be established by the specific p

establish a payment, typically based on the charge from the provi

'crosswalking' to similar EGD and Upper GI endoscopies. To supp

Reimbursement Guide provides a list of CPT codes with the phys i. As Unlisted codes and Category III codes are common to u

contracts or other payment information and are not able to discu

within their payer contracts by providing the CPT codes from the

Alternatively, provider services at a particular health plan may be

2024 Coding and Payment Reference Guide

Intended Use / Indications for Use

The EvoEndo® Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb in patients over the age of five years. The gastroscope is a sterile single-use device and can be inserted orally or transnasally

The EvoEndo® Controller is intended for use with an EvoEndo® Endoscope for endoscopic diagnosis, treatment, and video observation

Select CPT Procedure Codes, Hospital Outpatient Sett Categories, Physician Relative Value Units (RVUs), and

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EvoEndo Chargemaster Checklist

- Review the EvoEndo® code and item list below to be sure the codes and item numbers are in the chargemaster
- Identify if the items and codes are assigned to one or more revenue center or department.
- Ensure that charges are updated and consistent based on current manufacturer and payer contracts.
- Ensure that the electronic medical record system includes all procedures and products (including CPT codes, even those that may not be separately paid).

EvoEndo® Model LE Single-Use Endoscopy System

CPT*	Short Descriptor	EvoEndo® Products and Item Number
43197	Esophagoscopy flex dx brush	
43198	Esophagosc flex trnsn biopsy	
43202	Esophagoscopy flex biopsy	
0652T	Egd flx transnasal dx br/wa	
0653T	Egd flx transnasal bx 1/mlt	
0654T	Egd fix transnasal tube/cath	
43235	Egd diagnostic brush wash	
43239	Egd biopsy single/multiple	
43241	Egd tube/cath insertion	

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Select Revenue Codes

Medical/Surgical Supplies and Devices (Also see 062X, an extension of 0. 0270 - General 027X 0271 - Nonsterile

- 062X
- 075X 0750 - Gastrointestinal Services, General

Chargemaster Fact Sheet

What is it?

itemized bill and claim form.

· The "chargemaster" is a list of charges (prices) for all services, tests, procedures, products, medications, and supplies provided by the facility (e.g., hospital, ambulatory

surgical center). It is integral to a facility's billing and contracting process.

The chargemaster listed prices are a key reference for facilities when neootiating

contracts and payment rates with private payers and to support the preparation of an

Why is it important to ensure the chargemaster is updated routinely with charges and codes?

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· The chargemaster is the link between services provided and charges on the insurance osts that are "packaged" (not

@evoendo that package individual tems may include Medicaid

"captured" in the global avment Classifications payment. PGs), and Diagnosis Related cally itemize the procedures Failure to fully code and s for the services performed represent charges on the claim will misrepresent the all costs are captured for charges (e.g., costs) to the payer. This affects future accurately reflect procedure payment rates/contracting

Myth

Fact

If payment for a service

is packaged, only the

A packaged payment is

Even if a service is not

separately paid, it is

episode of care.

all-inclusive of services and products used in a patient's

primary procedure

should be reported.

agement department with

Myth

Hospital charges may s (e.g., CPT outpatient vary by health plan. tient ICD-10-PCS procedure orrespond to facility cost

align with the electronic tient episode of care. Line and in turn coding and/or rials managemen tegrity are typically ing pricing.

- 0272 Sterile 0279 - Other supplies/devices Medical/Surgical Supplies - Extension of 027X 0621 - Incident to Radiology
- 0622 Incident to Other Diagnostic services

and claims processing departments (including for pediatric

3. Is the EvoEndo Gastroscope billable to the patient?

- a. The gastroscope is not billable to the patient; the device is included in the procedure.
- b. If the procedure is covered by the insurer, the payment includes the device cost.
- c. If the procedure is not covered by the payer, the provider may bill the patient for the procedure (which includes the device).
- 4. When hospitals are establishing charges, what is an important consideration for the responsible departments (e.g., finance and purchasing, etc.)
 - a. As the EvoEndo Gastroscope is a sterile single-use device, emphasize that it is different from reusable devices. This will highlight the need to use accurate categorization and application of their standard practices when establishing charges for a single-use device (e.g., other sterile single-use scope, implantable devices, etc.).

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Appeal: A request to review a decision by an insurance company that denies a benefit or payment. Appeals may be allowed for a denial for services made prior to a service being rendered or post-service if the insurance claim for the service is denied. Centers for Medicare and Medicaid Services (CMS): The division of the federal Department of Health and Human Services with overall administrative responsibility for Medicare and Medicaid programs.

Medicaid programs and some other non-Medicare pavers.

and costs

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Chargemaster: A database maintained by hospitals and other providers that lists charges for procedures, supplies, drugs, etc. provided in that setting of care.

Ambulatory Patient Classification (APC): A Medicare payment methodology (also adopted by many non-

Medicare commercial payers) that classifies hospital outpatient services that have similar characteristics

Ambulatory Patient Group (APG): A payment methodology that groups hospital outpatient services and

encounters based on patient characteristics and anticipated resource use. Typically used by many state

Reimbursement Glossary

and Acronym Reference

Charges: A fee assigned by the provider for healthcare services and items furnished by a health care provider.

Claims Administrator: Any entity that reviews and determines whether to pay claims to enrollees or physicians on behalf of the health benefit plan.

Claim Form: The form submitted to the payer for billing rendered services, procedures, drugs, etc.

Coding: A system of numeric or alpha numeric uniform language used to accurately describe medical, surgical and diagnostic services when billing for services rendered.

Coinsurance: A type of cost-sharing whereby the insured or covered person pays a percentage of costs.

Copayment: A type of cost-sharing whereby the insured or covered persons pay a specified flat dollar amount.

Cost-Sharing: The share of health care expenses a beneficiary must pay, including deductibles, copayments, and coinsurance.

Coverage: A term used to describe the services, products, and procedures that a health insurer allows. Coverage criteria, restrictions, and limitations may apply. In the absence of coverage, the service will not be paid even if there is a code to describe it.

CPT Codes: A coding system maintained by the American Medical Association (AMA) for reporting medical services and procedures performed by physicians or qualified healthcare providers, and by outpatient facilities including hospital outpatient departments (HOPDs) and Ambulatory Surgery Centers (ASCs) for services rendered.

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Fact Hospital charges are set based on the facility rate setting methodology. Hospitals do not have differing charges for

different payers. What payers pay for services will differ based on the paver type, and for commercial ealth plans, based on the paver contract terms.

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