American Society for
Gastrointestinal Endoscopy

The Delivery of Gastrointestinal Endoscopy in the United States

ASGE Policy Recommendations for the Biden-Harris Administration and the 117th Congress

January 2021

ASGE.org

Advancing patient care and digestive health by promoting excellence and innovation in endoscopy.

2020-2021 ASGE GOVERNING BOARD

President
KLAUS MERGENER, MD, PhD, MBA, FASGE
University of Washington – Seattle

President-elect
DOUGLAS K. REX, MD, MASGE
Indiana University Medical Center – Indianapolis

Secretary
BRET T. PETERSEN, MD, MASGE
Mayo Clinic – Rochester

Treasurer
PRATEEK SHARMA, MD, FASGE
University of Kansas – Kansas City

Secretary-elect
AMITABH CHAK, MD, FASGE
University Hospitals Cleveland Medical Center – Cleveland

Past Presidents
STEVEN A. EDMUNDOWICZ, MD, MASGE
Aurora, Colorado

JOHN J. VARGO II, MD, MPH, MASGE
Cleveland, Ohio

Councilors
TODD H. BARON, SR., MD, FASGE
Chapel Hill, North Carolina

JENNIFER A. CHRISTIE, MD, FASGE
Atlanta, Georgia

JONATHAN COHEN, MD, FASGE
New York, New York

ASHLEY L. FAULX, MD, FASGE
Cleveland, Ohio

ANNE MARIE LENNON, MD, PhD, FASGE
Baltimore, Maryland

WALTER G. PARK, MD, FASGE
Stanford, California

Chair of the ASGE Foundation
JOHN L. PETRINI, MD, MASGE
Santa Barbara, California

***Gastrointestinal Endoscopy* – Editor**
MICHAEL B. WALLACE, MD, MPH, FASGE
Jacksonville, Florida

Chief Executive Officer
DONALD PALMISANO, JR., JD, CAE
Downers Grove, Illinois

Health and Public Policy Committe Chair
BRUCE HENNESSY, MD, FASGE
Ohio Gastroenterology, Inc
Columbus, Ohio

For More Information Contact

LAKITIA MAYO
Chief Policy and Member Engagement Officer
lmayo@asge.org

CAMILLE BONTA, MHS
Washington Representative
cbonta@summithealthconsulting.com

INTRODUCTION

The American Society for Gastrointestinal Endoscopy (ASGE) was founded in 1941 and is dedicated to advancing patient care and digestive health by promoting excellence in gastrointestinal endoscopy.

With a member of more than 14,000 physicians worldwide, ASGE promotes the highest standards for endoscopic training and practice, develops clinical and quality guidelines and standards for infection control, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education.

Gastroenterologists care for patients with some of the most common, costly and consequential diseases facing the American public and the world today. Roughly 60 to 70 million people in the United States are affected by digestive diseases.[1] A 2008 report from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) looked at the burden of digestive diseases in the United States.[2] In 2004, the total direct cost of digestive diseases was estimated to be $97.8 billion.

Endoscopy procedures, performed by ASGE members, play a significant role in the prevention, diagnosis and management of digestive diseases, including many of the deadliest, or recalcitrant, cancers including colorectal, pancreatic, liver, gastric and esophageal cancers.

ASGE members provide endoscopic procedures predominantly in ambulatory endoscopy centers and ambulatory surgery centers (ASCs). ASGE members also deliver hospital inpatient and outpatient procedure-based care, and provide office-based care and services, such as infusions for the treatment of intestinal inflammatory disease.

Issues confronting ASGE members and their patients are wide-ranging, many of which are not specific to gastroenterology. **ASGE, however, is the foremost society in endoscopic care and is eager to work with the Biden Administration and Congress to advance policies and initiatives that address critical issues of health inequity and cancer prevention and early diagnosis, and to offer unique perspectives on payment and coverage policies, regulatory requirements and patient access to gastrointestinal care.**

1 Digestive Diseases Statistics for the United States. National Institute of Diabetes and Digestive and Kidney Diseases. *https://www.niddk.nih.gov/health-information/health-statistics/digestive-diseases* Accessed Jan. 4, 2021.

2 Everhart JE, editor. The burden of digestive diseases in the United States. US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Washington, DC: US Government Printing Office, 2008; NIH Publication No. 09-6443 *https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/burden-of-digestive-diseases-in-united-states*

Advancing Public Health and GI Health Equity

ASGE is a leader in promoting policies, including patient cost-sharing policies, that improve access to and age-appropriate coverage of preventive colorectal cancer screening colonoscopy, especially in historically under-screened populations. ASGE applauded Congress for taking action at the end of the 116th Congress to correct a long-standing oversight in the Affordable Care Act that wrongly held Medicare beneficiaries accountable for out-of-pocket costs when potentially pre-cancerous polyps were removed during their preventive screening colonoscopy. Over eight years, this cost-sharing obligation will be phased-out, removing a financial barrier to life-saving screening colonoscopy.

Despite improved uptake of screening colonoscopy, which is credited for the accelerated decline in colorectal cancer incidence and mortality since 2000, one-third of eligible adults are still not up to date with colorectal cancer screening, and disparities of colorectal cancer among racial and ethnic populations are striking.[3] Incidence and mortality of colorectal cancer in blacks are 20 and 40 percent higher, respectively, than those in non-Hispanic whites.[4] The racial gap among blacks, as well as other racial and ethnic populations, likely reflects differences in uptake and quality of colorectal cancer screening tests and prevalence of colorectal cancer risk factors.

Also of concern is the increase of colorectal cancer incidence in adults under age 50[,5] which has prompted a draft recommendation from the U.S. Preventive Services Task Force (USPSTF) to lower the recommended screening age to 45.[6] Should the USPSTF finalize its recommendation to assign a “B” rating for colorectal cancer screening in adults ages 45 to 49 years, health plans and issuers will be required to waive all associated cost-sharing, consistent with the Section 2713 of the Public Health Act. Section 2713 requires non-grandfathered group health plans and health insurance coverage offered in the individual or group market to provide benefits for and prohibit the imposition of cost-sharing requirements with respect to items or services that have a rating of “A” or “B” in the current USPSTF recommendations.[7]

Recommendation: Increase funding to at least $70 million for the Centers for Disease Control and Prevention’s Colorectal Cancer Control Program to ensure patients, particularly underrepresented populations and those living in medically underserved communities, receive recommended colorectal cancer screening, follow-up, and treatment.

3 American Cancer Society. Colorectal Cancer Facts & Figures 2020-2022. Atlanta: American Cancer Society; 2020. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf

4 Ibid.

5 Screening for Colorectal Cancer: An Evidence Update for the U.S. Preventive Services Task Force. Agency for Healthcare Research and Quality; AHRQ Publication No. 20-05271-EF-1 October 2020. https://uspreventiveservicestaskforce.org/uspstf/index.php/draft-recommendation/colorectal-cancer-screening3#bootstrap-panel--5

6 Draft Recommendation Statement: Colorectal Cancer: Screening; October 27, 2020. https://uspreventiveservicestaskforce.org/uspstf/index.php/draft-recommendation/colorectal-cancer-screening3#bootstrap-panel--5 Accessed Jan. 6, 2021.

7 42 USC 300gg-13: Coverage of preventive health services. https://uscode.house.gov/view.xhtml?req=(title:42%20section:300gg-13%20edition:prelim)

Harnessing the Value of Ambulatory Endoscopy Centers

The Ambulatory Surgery Center (ASC is an important part of the practice of gastroenterology, providing a safe and cost-effective environment for the provision of medical services. The majority of ASCs in which gastroenterologists practice are single specialty endoscopy centers.

Exit and entry of ASCs in the market are driven in large part by Medicare payment policies. Today, ASCs are paid roughly 52 percent of what the same care costs Medicare in a hospital outpatient department.

The Centers for Medicare and Medicaid (CMS made the important change in 2019 to use the hospital market basket, rather than CPI-U, to update annually ASC payments through CY 2023. Using the hospital market basket ensures ASC payments are predictable and reflective of costs that are relevant to the delivery of health care. Still, ASC payments, when compared to payments made to hospital outpatient departments, are less equitable than they should be.

Medicare is roughly 20 percent of ASC revenues, and, according to the Medicare Payment Advisory Commission, growth of ASC-eligible procedures provided to Medicare fee-for-service beneficiaries has been faster in hospital outpatient departments than in ASCs.[8] These data point to the economic disincentives that currently exist for ASCs to provide certain covered ASC services. Medicare payment policies that disincentivize the delivery of services in the ASC setting deny beneficiaries opportunities for lower out-of-pocket costs and limit the savings that could otherwise be realized by Medicare.

The cost of the tools and equipment (such as hemostatic clips, EUS needles and endoscopic guidewires necessary for a variety of endoscopy procedures exceed current ASC Medicare payments, making those services economically infeasible to provide in the ASC. Because hospital outpatient payments are higher than those paid to ASCs, the cost of expensive medical equipment is captured in hospital payments. ASCs do not have the same purchasing leverage as hospitals to drive down the cost of these necessary endoscopic tools, and the cost of these devices and other tools is rising as manufacturers move increasingly toward disposable equipment.

Recommendation: Current Medicare payment policies are inhibiting the types of procedures that can be safely provided in the ASC at a significant savings to the health care system. CMS should work with ASC and physician stakeholders to ensure reimbursement adequacy for endoscopic services provided in the ASC, including allowing payment of certain endoscopic equipment on a per item basis.

Recommendation: The divergence between ASC and hospital outpatient payments continues. CMS' alignment of the hospital outpatient and ASC update factors makes it easier to see the true effect of the ASC weight scalar — an additional scaling factor that CMS applies to maintain budget neutrality within the ASC payment system. This means increases in ASC volume, including any shift of services from the hospital to the ASC, lead to payment stagnation or a decrease in reimbursement rates. Instead of budget neutrality in silos, CMS should look at hospital outpatient departments and ASCs collectively.

8 Medicare Payment Advisory Commission Public Meeting Transcript. Thursday, December 3, 2020. Pg. 68 http://www.medpac.gov/docs/default-source/meeting-materials/dec2020_public_meeting_transcript_sec.pdf?sfvrsn=0

Supporting Medicare Physician Payment Adequacy

Medicare Physician Fee Schedule

Ensuring patients with diseases of the digestive system have timely access to care requires payment policies that accurately reflect the cost of care. Value-based payment models, when developed with input from the physician community, offer opportunity to reward physicians for high-quality and cost-effective care. The reality is, however, that independent physician practices struggle with payment uncertainty and administrative burden, and when coupled with an aging physician workforce, the escape hatch is practice acquisition and consolidation.

Medicare physician payments have not kept pace with inflation and the zero-sum structure of the Medicare physician fee schedule means the Centers for Medicare and Medicaid Services (CMS) can't improve payment in any area of the fee schedule without cutting it somewhere else. A shortcoming of the fee schedule system was laid bare in 2020 when CMS finalized a more than 10 percent cut to the Medicare conversion factor to maintain budget neutrality while increasing payments for evaluation and management services. ASGE is grateful Congress intervened by passing a suite of provisions to blunt the effect of this cut in the midst of the COVID-19 pandemic. This rescue of physicians from drastic payment reductions gives rise to the need for a thoughtful discussion about ensuring fee schedule payment adequacy and predictability, while also encouraging value-based payment and care delivery.

Payment predictability and adequacy also extend to office-administered Part B drugs. Biologics are the primary treatment for certain disorders of the bowel. These biologics are oftentimes administered in the physician's office and reimbursed under Part B. ASGE is concerned the Most Favored Nation (MFN) Model, as presented in the interim final rule (85 Fed. Reg. 76180), will create situations where physicians are unable to acquire MFN model drugs at prices commensurate with MFN model reimbursement, which could make it impossible for physicians to continue providing certain drugs as treatment options. Alternative drug pricing reform proposals must not impede patient access to essential therapies, and, at the same time, should ensure physicians are adequately reimbursed for providing these treatments.

Recommendation: As a result of physician practice financial instability due to the pandemic, Medicare payment sequestration should be suspended beyond the March 31, 2021 statutory suspension and through at least 2021.

Prior Authorization

Medicare Advantage and other private insurance plans routinely subject complex drugs, including biologics, to cumbersome authorization processes that lead to substantial delays in treatment. Gastroenterologists, who are not given rules or indications of how these authorizations will be adjudicated, often have to utilize specialty pharmacies or authorization specialists to navigate the authorization requirements and must frequently prove a patient failed other therapies, including sometimes one or more drugs in the same category, before the requested therapy will be approved. Prior authorization and step therapy protocols unnecessarily delay patient care and shift costs onto providers who are uncompensated for the administrative time and staff required for authorization and appeals when coverage of a prescribed treatment is denied.

Recommendation: Consistent with bipartisan legislation — *the Improving Seniors' Timely Access to Care Act of 2019* (H.R. 3107) — introduced in the House during the 116th Congress, the prior authorization processes used by Medicare Advantage plans should be streamlined and standardized.

Recommendation: When denial of prescribed treatment or step therapy requirements lead to a delay of appropriate medical care, insurers should be required to compensate physicians for the time associated with seeking appropriate authorizations. Prior authorization and step-therapy requirements are one-sided with no disincentive for plans to deny or delay care. Medicare Advantage plans must accept some level accountability if appropriate treatment is withheld or delayed.

Telehealth

The COVID-19 pandemic has accelerated advancements in the use of telehealth for care delivery, paving the way for it as an essential part of patient care after the COVID era, including using telehealth to address disparities in access to care and outcomes. Telehealth services that have been added on an interim basis and policy changes that have been made to facilitate telehealth use during the COVID-19 public health emergency should be made permanent at the end of the pandemic.

Recommendations:

- Continue to support clinically appropriate care via telehealth by qualified health care professionals in the future, for both initial and established patient visits.
- Establish reimbursement for virtual and audio-only consultations at parity with in-person visits, in recognition of the expense, expertise, and effort required in providing telehealth services.
- Preserve a health care provider's ability to determine if a clinical situation is appropriate for telehealth.
- Improve access to telehealth for patients across diverse settings and geographic areas, including by addressing disparities that may limit the ability to access or utilize telehealth. To the extent infrastructure or patient ability to utilize simple smart-phone audio-visual links are not feasible, this includes recognition of telephone-only (audio-only) services as equivalent to video visits.
- Expand the use of telehealth to facilitate improved communication and clinical care in areas outside of direct outpatient care, such as provider-to-provider communication, coordination of patient care, and virtual consults.
- Allow physicians and patients the flexibility to choose among easily accessed nonpublic-facing communications platforms, recognizing they may not necessarily be HIPAA compliant, until telehealth platforms can meet HIPAA protections.
- Provide liberalization for health care professionals to perform telehealth services across state lines, as long as physicians meet specific licensure requirements and conditions.

Support Medicare Payment Adequacy: Ensure Medicare beneficiary access to GI care by advocating for Medicare physician payment adequacy, including for the delivery of telehealth services, and reimbursement that reflects appropriate valuation of specialty and gastrointestinal endoscopic care.

Promote the Value of GI Care Provided in Ambulatory Surgery Centers: Align payment and regulatory policies that encourage and facilitate the cost-effective delivery of endoscopic services in ambulatory surgery centers.

Advance Public Health and GI Health Equity: Promote policies, including patient cost-sharing policies, that improve access to and age-appropriate coverage of preventive colorectal cancer screening colonoscopy, especially in historically under-screened populations. Advocate for policies to increase awareness of the value of preventive health care services and improve equality in health care access, quality and outcomes, including through cultural competency training and by addressing racism and social determinants of health.

Alleviate Administration Burden: Improve patient access to timely care by easing regulatory burdens and administrative requirements imposed by Medicare and other payers that interfere with physician decision-making and the practice of gastrointestinal endoscopy, including utilization control mechanisms such as prior authorization and step-therapy.

Promote Value-based Care: Support the delivery of high-quality care through policies that foster meaningful physician participation in value-based care models, including through the use of meaningful measures and availability of physician-led alternative payment models. Advocate for rules and regulations that support value-based GI care and care coordination, including through changes to physician self-referral and Stark Law restrictions.

Support Pandemic Relief: Support for as long as necessary the continuation of regulatory and payment policy flexibilities afforded to physicians during the COVID-19 Public Health Emergency and for financial support to offset the costs of the pandemic, including the cost of personal protective equipment and reduced patient capacity.

Avoid Practice Restrictions: Support policies, including reimbursement rates, that support the delivery of diagnostic and therapeutic services, including office-based imaging, pathology, and anesthesia services regardless of physician ownership or site of service.

Support Medical Research Funding: Increase funding for digestive disease, health equity, and cost-effectiveness research including through the National Institutes of Health.