CENTER FOR VALUE-BASED INSURANCE DESIGN

Hot Topics:

Ongoing Work in Cancer Screening and Obesity Management

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I PUBLISHED BUT STILL PERISHED

Health Care Costs Are a Top Issue For Purchasers and Policymakers: Solutions must protect consumers, reward providers and preserve innovation

- Innovations to prevent and treat disease have led to impressive reductions in morbidity and mortality
- Irrespective of remarkable clinical advances, cutting health care spending is the primary focus of reform discussions (now more than ever)
- Underutilization of high-value care persists across the entire spectrum of clinical care leading to poor health outcomes and worsening disparities
- Everyone (almost) agrees there is enough money in the US health care system; we just spend it on the wrong services and in the wrong places

My primary focus: use rigorous evidence to guile policymaking that reallocates spending to more on the 'good stuff' and less on the 'bad stuff'



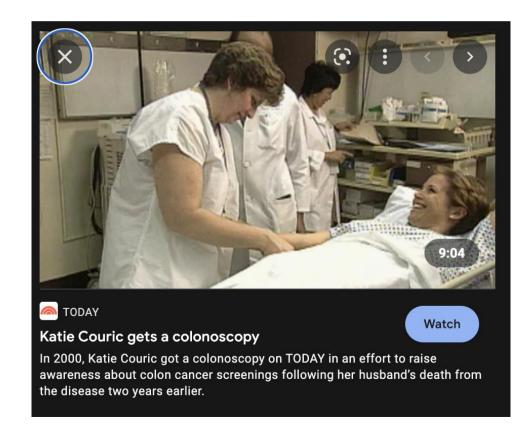
CANCER SCRENING



The Impact of a Celebrity Promotional Campaign on the Use of Colon Cancer Screening

The Katie Couric Effect

Peter Cram, MD, MBA; A. Mark Fendrick, MD; John Inadomi, MD; Mark E. Cowen, MD, SM; Daniel Carpenter, PhD; Sandeep Vijan, MD, MS



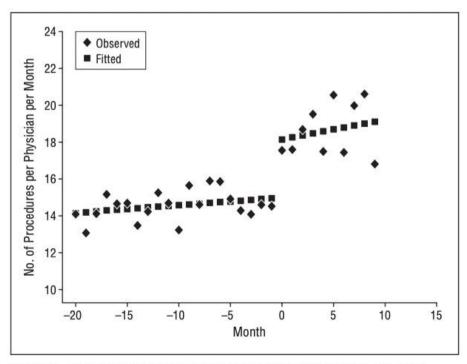


Figure 1. Monthly colonoscopy rates in the Clinical Outcomes Research Initiative database from July 1998 to December 2000. Ms Couric's cancer awareness campaign was televised on the *Today Show* in March 2000 (month 0).

Translating Research into Policy ACA Sec 2713: Selected Preventive Services Provided without Cost-Sharing

- Receiving an A or B rating from the United States
 Preventive Services Taskforce (USPSTF)
 - Includes screening for specific cancers:
 - Breast
 - Cervical
 - Colorectal
 - Lung
- Immunizations recommended by the Advisory Committee on Immunization Practices (ACIP)
- Preventive care and screenings supported by the Health Resources and Services Administration



Commercial insurers and Medicare have separate coverage processes



Removing Financial Barriers for Colorectal Cancer Screening: Waiving Cost-sharing Does not Ensure that Recommendations are Followed

Waiving Cost Sharing for Screening Colonoscopy; Free, but Not Clear

CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 2012:10:767-768

- Even when faced with no out-of-pocket costs, a substantial minority of people do not adhere to potentially lifesaving clinical services
- Cancer screening process may require multiple steps to determine if cancer is present (or not)
- Free doesn't always mean free

When Free Isn't Really Free

Screening for Colorectal Cancer: When Free Isn't Really Free Out-of-pocket Costs for Colonoscopy After Non-invasive CRC screening



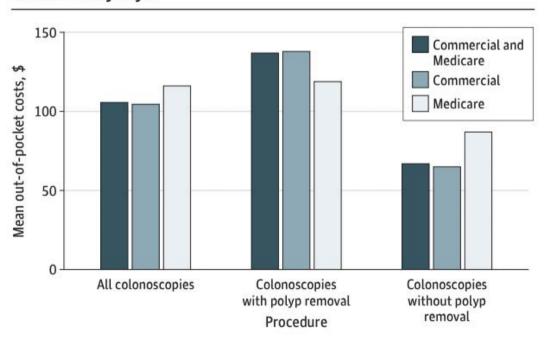
Research Letter | Gastroenterology and Hepatology

Out-of-Pocket Costs for Colonoscopy After Noninvasive Colorectal Cancer Screening Among US Adults With Commercial and Medicare Insurance

A. Mark Fendrick, MD; Nicole Princic, MS; Lesley-Ann Miller-Wilson, PhD; Kathleen Wilson, MPH; Paul Limburg, MD

Out-of-pocket costs for follow-up colonoscopy after a non-invasive screening test were incurred by nearly half of commercially insured patients and > 75% of those covered by Medicare.

Figure. Mean Out-of-Pocket Costs of Subsequent Colonoscopy in the 6 Months After Stool-Based Test With and Without Polypectomy, Overall and by Payer



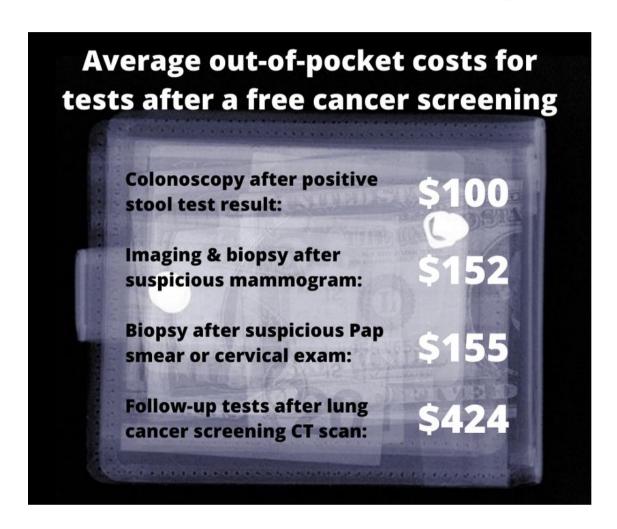
[☐] JAMA Network Open. 2021;4(12):e2136798. doi:10.1001/jamanetworkopen.2021.36798



Your Free Cancer Screen Shows Trouble: What If You Can't Afford the Follow-Up?

UM research shows that out-ofpocket costs are common and nontrivial for necessary follow-up testing after initial, abnormal no-cost cancer screening test.

- Breast
- Cervical ¹
- Colorectal
- Lung
- Prostate
- JAMA Network Open. 2021;4(8):e2121347
- · Obstetrics & Gynecology. 2022;139(1): doi:10.1097/AOG.00000000004582
- JAMA Network Open. 2021;4(12): doi:10.1001/jamanetworkopen.2021.36798
- JACR E-pub ahead of print. 2021.DOI:https://doi.org/10.1016/j.jacr.2021.09.015



Impact of Eliminating Cost-Sharing by Medicare Beneficiaries for Follow-Up Colonoscopy After a Positive Stool-based Colorectal Cancer Screening Test

A. Mark Fendrick¹, David Lieberman², Jing Voon Chen³, Vahab Vahdat³, A. Burak Ozbay³, and Paul J. Limburg³

Significance: A follow-up colonoscopy after a positive stool-based colorectal cancer screening test is necessary to complete the full screening process.

Policies that remove cost barriers to completing colorectal cancer screening may lead to increases in overall participation rates and use of follow-up colonoscopy, improving clinical and economic outcomes.

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 51, FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION

January 10, 2022

Q7: Are plans and issuers required to cover, without the imposition of any cost sharing, a follow-up colonoscopy conducted after a positive non-invasive stool-based screening test or direct visualization test (e.g., sigmoidoscopy, CT colonography)?

Yes. A plan or issuer must cover and may not impose cost sharing with respect to a colonoscopy conducted after a positive non-invasive stool-based screening test or direct visualization screening test for colorectal cancer for individuals described in the USPSTF recommendation. As stated in the May 18, 2021 USPSTF recommendation, the follow-up colonoscopy is an integral part of the preventive screening without which the screening would not be complete.³¹ The follow-up colonoscopy after a positive non-invasive stool-based screening test or direct visualization screening test is therefore required to be covered without cost sharing in accordance with the requirements of PHS Act section 2713 and its implementing regulations.

CMS proposes follow-up colonoscopy after athome test be considered preventive service

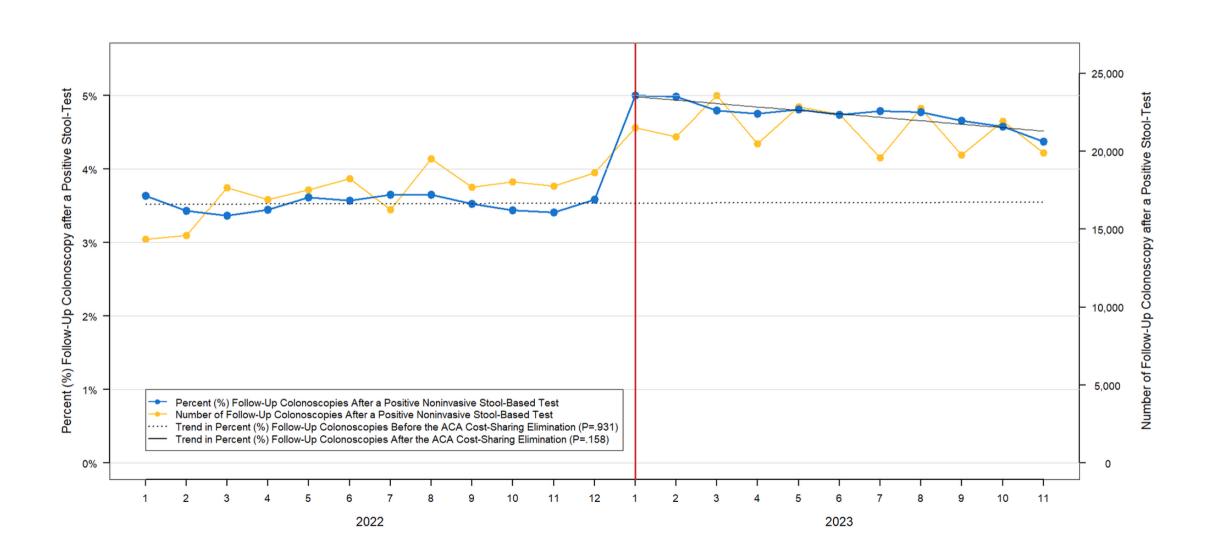
Riz Hatton - Friday, July 8th, 2022

Colorectal Cancer Screening

For CY 2023, we are proposing two updates to expand our Medicare coverage policies for colorectal cancer screening in order to align with recent United States Preventive Services Task Force and professional society recommendations. First, we are proposing to expand Medicare coverage for certain colorectal cancer screening tests by reducing the minimum age payment limitation to 45 years. Second, we are

proposing to expand the regulatory definition of colorectal cancer screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. Both of these proposals reflect our desire to expand access to quality care and to improve health outcomes for patients through prevention and early detection services, as well as through effective treatments.

Impact of Cost-Sharing Elimination on Colonoscopy Utilization by Patients with a Positive Stool-Based Colorectal Cancer Screening



Achieving Population CRC Screening Goals

- Design, implement and evaluated multi-component intervention:
 - Increase initial CRC
 - More screening with stool-based testing (SBT)
 - Fewer colonoscopies for initial screening
 - Increase follow-up colonoscopy with a positive SBT:
 - Patient navigation to improve scheduling and performance of follow-up colonoscopy
 - Reserve colonoscopy appointments for individuals with a positive SBT



First Dollar Coverage of the Entire Cancer Screening Continuum -1 down, 4 to go

Cancer Type	Commercial Insurers	Medicare
(+)		

American Cancer Society Position Statement on the Elimination of Patient Cost-Sharing Associated with Cancer Screening and Follow-up Testing

• It is the position of the ACS that cancer screening should be understood as a continuum of testing rather than a single screening test.



- Screening is a process that includes a recommended screening test and all follow-up tests described as diagnostic and judged to be integral and necessary to resolve the question of whether an adult undergoing screening has cancer.
- Insurers must cover and should not impose cost-sharing for these recommended examinations, regardless of the patient's designated risk.
- These tests should be covered without any patient cost-sharing consistent with the 2022 FAQ specifying no patient cost-sharing for follow-up colonoscopy after a positive non-colonoscopy colorectal cancer screening examination.

Collaborations contributing to policy discussions aimed to improve coverage of the entire cancer screening process

Redefining Cancer Screening Coverage—Screening to Diagnosis

Crystal D. Taylor, MD, MPH, MS¹; A. Mark Fendrick, MD²; Lesly A. Dossett, MD, MPH¹

The Cost to Breathe: Eliminating Cost Sharing Associated with Lung Cancer Screening

3 J'undra N. Pegues^{1,5}, Erin E. Isenberg^{2,4,6}, and A. Mark Fendrick³

Eliminating Consumer Cost-Sharing for the Entire Prostate Cancer Screening Pathway



Coverage for the Entire Cervical Cancer Screening Process Without Cost-Sharing: Lessons From Colorectal Cancer Screening

Allison Ruff, MD, MPHE a.*, Diane M. Harper, MD, MPH, MS b.c.d, Vanessa Dalton, MD c, A. Mark Fendrick, MD, MPH a





Questions and Discussion

Given time constraints, I would enjoy an opportunity to continue this discussion off-line



Obesity Management



Expanding Equitable and Efficient Access to Obesity Management

- The extraordinary demand for breakthrough anti-obesity medications, coupled with their current high acquisition cost present significant challenges to ensuring equitable access.
- Consequently, how best to efficiently allocate these drugs has become a top priority among public and private payers and is being deliberated at the employer, health plan, state, and federal levels.

Goal: Achieve the most weight loss and associated clinical benefits (e.g., reductions in diabetes, cardiovascular disease, sleep apnea, cancer, etc.) - given a certain level of spending.



Expanding Equitable and Efficient Access to Anti-obesity Medications

Incretin Memetics - Pros

- Substantial weight loss
- Beneficiary demand / satisfaction
- Clinically meaningful secondary benefits for several obesity-related conditions (and potentially others)

Evidence Mounts for Potential of GLP-1s in Alzheimer's Disease

Incretin Memetics – Cons

- Side effects, including nausea, vomiting, diarrhea,
- Adverse event associated with continued use, such as loss of skeletal muscle mass among older adults and incidence of pancreatitis
- Lack of long-term safety data
- Cost



The New York Times

How Much Should Weight Loss Drugs Cost?



Federal Budgetary Cost. Authorizing coverage of AOMs in Medicare would increase federal spending, on net, by about \$35 billion from 2026 to 2034.

Expanding Equitable and Efficient Access to Anti-obesity Medications Coverage policies for IMWMs are largely unpredictable and highly variable

 Advocating for generous access, some contend that IMWMs should be classified as a preventive benefit and be covered without consumer cost-sharing

Weight-Loss Drugs Under Consideration At USPSTF

By Luke Zarzecki / April 7, 2025 at 6:33 PM

• The Preventive Services Provision of the ACA requires that services receiving an A or B rating from the United States Preventive Services Taskforce (USPSTF) be provided without consumer cost-sharing



Understanding Insurance Coverage Policies for Incretin Mimetics for Weight Management

Dina H. Griauzde, MD, MSc, DABOM; Eli W. Carter, MPH; Lauren Oshman, MD, MPH, DABOM; Jonathan Gabison, MD, DABOM; Andrew Kraftson, MD; A. Mark Fendrick, MD; and Stephen Lott, PharmD, MS

"The high cost of incretin mimetics for weight management limits insurance coverage and potentiates variation in utilization management strategies to control near-term spending."

Expanding Equitable and Efficient Access to Anti-obesity Medications Coverage policies for IMWMs are largely unpredictable and highly variable

- At the other extreme of the spectrum are many payers including Medicare that have yet to approve IMWMs coverage
- In between are those payers that <u>do</u> cover IMWMs, but typically:
 - impose a mounting list of prerequisites to initiate or continue therapy
 - require high levels of consumer cost-sharing and/or impose coverage limits based on total spending or duration of use (very few are clinically driven)
 - change policies frequently



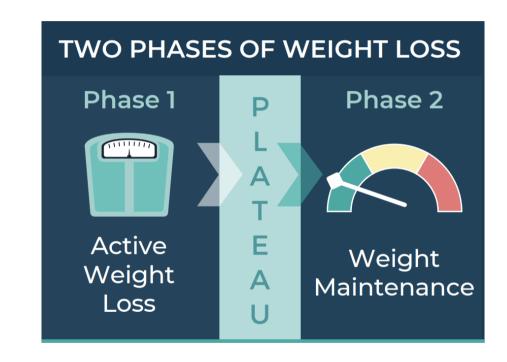


FACT SHEET: Biden-Harris Administration Takes Latest Step to Lower Prescription Drug Costs by Proposing Expanded Coverage of Anti-**Obesity Medications for Americans** with Medicare and Medicaid

An Efficient Approach to Expand Equitable Access to Antiobesity Medications: Deprescribing After Weight Loss Plateau

David D. Kim, PhD; and A. Mark Fendrick, MD

- To date, most of the clinical research and media attention on AOMs has focused on the amount of weight loss (i.e., active weight loss phase).
- Less consideration has been paid to the role of interventions to sustain the weight loss (i.e., weight maintenance phase)
- The distinction between these 2 phases of is essential, as the differences in effectiveness and incremental expense attributable for each phase can be substantially different



Can an alternative weight maintenance program reallocate obesity management resources to produce better clinical and economic outcomes?

- Most projected spending on IMWM is for weight maintenance, not weight loss
- If a less-expensive maintenance program produces comparable results in sustaining weight loss, it would make sense from an efficiency standpoint to devote more IMWMs for active weight loss where superiority has been established instead of maintenance of weight loss.
- We have used step-down approaches in other clinical settings (e.g. PPIs)

ELEMENTS OF AN ALTERNATIVE WEIGHT MANTENANCE PROGRAM

- Decrease GLP-1 dose or different medication
- Behavioral therapy
- Nutrition support
- No / lower consumer cost-sharing

 Unknown effectiveness in maintaining weight



Balancing innovation and affordability in anti-obesity medications: the role of an alternative weight-maintenance program



David D. Kim^{1,*}, Jennifer H. Hwang², A. Mark Fendrick³

- Compared with continuous full-dose IMWM, an alternative weight maintenance program could result in a significant reduction in obesity-related treatment spending and produce minimal reductions in clinical benefits over a wide range of cost and effectiveness estimates.
- When the alternative maintenance program was half the price of continuous full-dose AOM and 30% as effective (i.e., patients regain 70% of weight and lose 70% of the long-term clinical benefit) an estimated net savings of \$35,100 per patient was achieved.
- If these savings were redistributed to patients for active weight loss,
 additional individuals could receive full-dose IM therapy for 1 year.

Will patients agree to an alternative weight maintenance program?

In a survey of 582 self-reported obese individuals, 83% of respondents supported the use of a lower-cost weight maintenance strategy that deintensified discontinued newer IMWMs.

Patient reluctance to switching may be overcome by highlighting the potential advantages of a personalized alternative program:

- (1) reduction in side effects and potential unknown long-term adverse events;
- (2) lower out-of-pocket costs;
- (3) inclusion of supplemental services, such as behavioral/nutritional support
- (4) the option to restart the IMWM when needed.



Coverage of Obesity Medications Can Make America Healthier (Again)







By A. Mark Fendrick & Kirsten Axelsen December 20, 2024

Affordable coverage for obesity medicines is possible with anticipated price reductions resulting from market competition, lower cost strategies to prevent weight regain, and reductions in spending on unnecessary, often harmful, care.

April 4, 2025

Trump Rejects Biden Plan to Expand Medicare Coverage for Obesity Drugs

Administration officials reversed a decision made during the Biden presidency that would have given millions of people access to weight-loss drugs paid for Medicare and Medicaid.

Channel: Marketing

HHS says it may revisit anti-obesity drug policies after dropping Biden-era proposal

Next Steps

Advocate for clinically- (not cost-) driven approaches enable greater access to preferred weight management options—particularly those disadvantaged populations that are disproportionally affected by obesity and its sequelae, who are most likely to benefit from their use.

Build on the groundbreaking work of Dina Griauzde and her team in developing and implementing the Weight Management Program:

Essential elements:

- Clinical: Include the full range of available treatment options, that can be tailored to an individual patient's preferences to optimize weight-loss
- Economic: Preferential use of lower cost/shorter duration options when clinically appropriate

Thank you

Questions?

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