JOINT REPORT OF THE COUNCIL ON MEDICAL SERVICE AND THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CMS/CSAPH Joint Report A-18

Subject: Coverage for Colorectal Cancer Screening

(Resolution 822-I-17)

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Presented to: Reference Committee A

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- 1 At the 2017 Interim Meeting, the House of Delegates referred Resolution 822, "Elimination of All
- 2 Cost-Sharing for Screening Colonoscopies," which was sponsored by the Georgia Delegation. The
- 3 Board of Trustees assigned this item to the Council on Medical Service (CMS) and the Council on
- 4 Science and Public Health (CSAPH) for a report back to the House of Delegates at the 2018
- 5 Annual Meeting. Resolution 822 asked: That the American Medical Association (AMA) develop
- 6 model national policy that supports the voluntary removal of all cost-sharing associated with
- 7 screening colonoscopies in all commercial and Medicare Advantage product lines and advocate for
- 8 the adoption of these policies nationwide.

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10 This report explains sources of confusion regarding insurance coverage for colorectal cancer screening (CRCS), summarizes relevant AMA policy and advocacy, and presents policy 11

recommendations. The Councils developed this report in the context of a broader joint report they 12 13

are preparing for the 2018 Interim Meeting regarding improving alignment of cost-sharing

14 incentives for high-value services, such as CRCS.

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BACKGROUND

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18 The American Cancer Society estimates that colorectal cancer will be the third leading cause of 19 cancer deaths among men and women in the US in 2018. If a colorectal cancer patient is diagnosed with localized-stage disease, the five year survival rate is 90 percent, but unfortunately, 20 21 only 39 percent of colorectal cancer patients are diagnosed at this early stage. ² CRCS reduces 22 colorectal cancer mortality both by decreasing the incidence of disease and by increasing the likelihood of survival.³ 23

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United States Preventive Services Task Force (USPSTF) CRCS Recommendation

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28 29 In June of 2016, the USPSTF published a final recommendation on colorectal cancer screening. The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years. ⁴ The recommendation received an "A" grade, meaning that the USPSTF recommends the service and there is high certainty that the net benefit is substantial.

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The screening methods examined by the USPSTF included stool based tests: guaiac-based fecal occult blood test (gFOBT), fecal immunochemical tests (FITs), and multitargeted stool DNA testing (FIT-DNA) as well as direct visualization tests: colonoscopy, flexible sigmoidoscopy, CT

CMS/CSAPH Joint Rep. A-18 -- page 2 of 8

colonography, and flexible sigmoidoscopy with FIT. The USPSTF noted that risks and benefits of different screening methods vary. However, given the lack of evidence from head-to-head comparative trials that any of the screening strategies have a greater net benefit than the others, the USPSTF encourages clinicians to engage patients in informed decision-making about the screening strategy that would most likely result in completion, with high adherence over time, taking into consideration both the patient's preferences and local availability. However, given the USPSTF noted that risks and benefits of different screening strategies have a greater net benefit than the others, the USPSTF encourages clinicians to engage patients in informed decision-making about the screening strategy that would most likely result in completion, with high adherence over time, taking into consideration both the patient's preferences and local availability.

Barriers to Screening

 Despite the large body of evidence indicating the effectiveness of CRCS and the variety of screening options available, ⁷ one in three people are not up to date with CRCS. ⁸ Barriers to CRCS are more common among people with fewer financial resources, leading to disparities in care. ⁹ Moreover, there is substantial evidence that inadequate insurance coverage is associated with lower rates of screening. ¹⁰ Insurance coverage advances under the Affordable Care Act (ACA) tried to address under utilization rates of CRCS, but coverage of CRCS is uniquely complex, which poses barriers to care.

Coverage of CRCS, including colonoscopies, has been fraught with confusion and consternation for two key reasons. First, a colonoscopy is a rare example of how a single service can inherently incorporate screening, diagnosis, and treatment. In just one colonoscopy, an asymptomatic patient could be screened and one or more concerning polyp(s) removed for biopsy, making insurance coverage of CRCS uniquely confusing. This report both explains what leads to this confusion and makes recommendations regarding how the confusion can be ameliorated.

Second, CRCS suffers from misaligned incentives and expectations in much the same way as many other valuable preventive interventions. While CRCS is provided without cost-sharing for asymptomatic adults 50 years and older who are at average risk of colorectal cancer, it is arguably more valuable that higher-risk individuals be screened and with greater frequency to detect more likely instances of deadly disease at earlier stages. Moreover, for both clinical and financial reasons, a prudent approach can be to initiate CRCS with a non-invasive stool test, and only subject patients to invasive colonoscopies when the procedure is required for complete screening, diagnosis, and/or treatment. Patient cost-sharing models should encourage less invasive screening first, when appropriate, but they currently may not. Similar logic applies to other cancer screenings, management of chronic conditions, etc. This broader issue of aligning incentives for preventive interventions will be explored in detail in the aforementioned joint report of the CMS and the CSAPH at I-18.

Coverage Varies by Insurance

ACA – Commercial Insurance: The Councils previously considered preventive services in CMS/CSAPH Joint Report A-17, "Value of Preventive Services," and explained that the ACA tasked four expert organizations with identifying the preventive services that will be provided with no patient cost-sharing under all private, non-grandfathered health insurance plans. One of these expert organizations is the USPSTF, and the ACA mandates coverage of all of its "A" and "B" recommended services. Despite receiving an "A" recommendation from the USPSTF, implementation of the CRCS recommendation has resulted in confusion. Two key areas have raised concerns: (a) the population included in the no cost-share benefit and (b) the extent of the services included in the no cost-share benefit.

Regarding the population included in the no cost-share benefit, the USPSTF provides some guidance that clarifies implementation of its recommendation. The USPSTF did not review the

evidence on screening populations at increased risk, so the recommendation does not speak to such patients. Specifically, the USPSTF states that its recommendation applies to:

[A]symptomatic adults 50 years and older who are at average risk of colorectal cancer and who do not have a family history of known genetic disorders that predispose them to a high lifetime risk of colorectal cancer . . . , a personal history of inflammatory bowel disease, a previous adenomatous polyp, or previous colorectal cancer. When screening results in diagnosis of colorectal adenomas or cancer, patients are followed up with a surveillance regimen, and recommendations for screening no longer apply. ¹¹

 The USPSTF guidance effectively eliminates vulnerable portions of the population from the valuable no cost-share screenings (eg, individuals who have an elevated risk of colorectal cancer, a history of previous adenomatous polyp, or who are otherwise being followed with a "surveillance regimen.") At the same time, the USPSTF also acknowledges the critical importance of CRCS for individuals at-risk: "[T]his recommendation applies to all racial/ethnic groups, with clear acknowledgment that efforts are needed to ensure that at-risk populations receive recommended screening, follow-up, and treatment." With at-risk populations carved out of the USPSTF recommendation, it is not clear how the needed screening, follow-up, and treatment can be incentivized.

Regarding the extent of services included in the no cost-share benefit, the federal government seemed to recognize that the USPSTF recommendation was vulnerable to confusion when it issued clarifying guidance in 2013. Specifically, guidance prepared jointly by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the Departments) state that cost-sharing may not be imposed when a polyp is removed during a screening colonoscopy pursuant to the USPSTF recommendation:

Based on clinical practice and comments received from the American College of Gastroenterology, American Gastroenterological Association, American Society of Gastrointestinal Endoscopy, and the Society for Gastroenterology Nurses and Associates, polyp removal is an integral part of a colonoscopy. Accordingly, the plan or issuer may not impose cost-sharing with respect to a polyp removal during a colonoscopy performed as a screening procedure. On the other hand, a plan or issuer may impose cost-sharing for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service. ¹³

The Departments' guidance demonstrates how clinical insight from the physicians responsible for delivering a preventive intervention can lead to better alignment between clinical need and insurance coverage. Similarly, medical experts have described screening not as a single test, "but rather a cascade of events" – a stepwise continuum that may begin with a clinician's recommendation that an asymptomatic patient receive testing and conclude with the outcome of the test(s). ¹⁴ The Departments' guidance seems to reflect this "cascade of events" understanding, but confusion surrounding patient cost-sharing for CRCS persists, nevertheless.

While the USPSTF updated its screening for colorectal cancer recommendation in 2016, the updated recommendation hints at, but does not embrace, the "cascade of events" understanding of preventive screening. The recommendation expressly acknowledges that colonoscopy "represents the primary source of harms associated with CRCS," seemingly suggesting that less-invasive tests could represent a safe starting point for screening. Moreover, the recommendation acknowledges that "with all screening methods, positive findings lead to follow-up colonoscopy." To embrace screening that acknowledges a "cascade of events," the USPSTF could have specified that if a less-

CMS/CSAPH Joint Rep. A-18 -- page 4 of 8

invasive screening test is used as a first line preventive method, and that initial test is positive, a colonoscopy should be used to complete the screening process. Including such explicit clarification in its recommendation would ensure that the entire "cascade of events" critical to effective CRCS is included among the ACA benefits provided without cost-sharing. The absence of this clarification contributes to the implementation challenges outlined below.

Medicare: Medicare provides significantly more detailed information about coverage of CRCS. However, as highlighted by HR 1017 and the AMA's support of that legislation, Medicare coverage differs critically from commercial coverage. Specifically, when a polyp or abnormal growth is removed during a colonoscopy, or when a biopsy is done of suspicious-looking tissue, the "screening" colonoscopy becomes "diagnostic," and although the Medicare Part B deductible is waived, beneficiaries are billed co-insurance of 20 percent of the cost of the procedure. This can lead to significant confusion, misaligned expectations, patient financial burden, and patient avoidance of CRCS.

Implementation Challenges

 Given the complicated coding and payment rules surrounding CRCS, it is unsurprising that patients commonly find themselves billed for services they expected to be covered at no cost to them. As a result, health care providers, payers and government agencies can field a significant volume of questions and complaints.

The following are some situations where patients have reported being unexpectedly charged for elements of CRCS:

• If a patient receives a colonoscopy following a positive result in a stool test (such as gFOBT or FIT) or an abnormal double-contrast barium enema or CT colongraphy, patients may incur cost-sharing.

• If a patient is classified as "high-risk" for colorectal cancer, that patient's colonoscopy could incur cost-sharing, whereas the same procedure would be free of cost-sharing for an "average risk" peer.

If a Medicare patient underwent what was thought to be a preventive screening colonoscopy (ie, no cost-sharing), and polyps were removed during the procedure, the patient may be surprised to incur cost-sharing.

Definition, Coding and Payment

There is significant confusion and inconsistency in how preventive interventions, particularly CRCS, are defined, coded and paid, potentially negatively impacting patient care. Whether a colonoscopy is called "screening," "diagnostic," or "therapeutic" can be subjective, and although such classification may not be clinically important, the classification can have a significant financial effect on the patient. Moreover, fear of financial burden may cause patients to forgo necessary care or force them to cope with adverse financial ramifications. Finally, without a common vocabulary that is universally understood among clinicians and payers (and effectively translated to patients), misunderstanding and misaligned expectations are a natural and unfortunate result.

AMA POLICY AND ADVOCACY

The AMA has established a priority of supporting evidence-based preventive services. Policy H-165.840 advocates for evidence-based prevention insurance coverage for all patients, and in all appropriate venues. Policy H-185.960 specifically advocates for health plan coverage of the full range of CRCS. Moreover, Policy D-330.950 supports Medicare coverage for a physician consultation prior to a screening colonoscopy. Echoing the "cascade of events" philosophy, Policy H-425.994 emphasizes the importance of only pursuing testing in patients when adequate treatment and follow-up can be arranged for identified abnormal conditions and risk factors.

 Several AMA policies promote education of physicians and the public regarding the benefits of preventive interventions, the continued availability of such services, and insurance coverage of such services, including: H-165.848 supporting a requirement that preventive health care be included in the minimal coverage available to all families; H-425.986 encouraging communication and cooperation among physicians and public health agencies to address challenges in preventive medicine; and Ethical Opinion 8.11 encouraging physicians to keep current with preventive care guidelines. Finally, Policy H-450.938 sets forth Principles to Guide Physician Value-Based Decision-Making and specifically emphasizes that physicians should seek opportunities to integrate prevention, including, screening, testing and lifestyle counseling, into patient office visits.

 Various AMA policies call for first-dollar coverage (payment exclusively by the health plan), including: H-185.969 regarding immunizations, D-330.935 regarding Medicare preventive service benefits, and H-290.972 regarding preventive coverage for health savings account holders in the Medicaid program. Policy D-425.992 demonstrates the potentially negative impact that limiting USPSTF recommended services can have on access to preventive care (in this case, access to screening mammography and prostate specific antigen [PSA] screening). At the same time, Policy H-165.856 calls for benefit mandates to be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options.

 Several AMA policies directly support the goals articulated throughout this report. Specifically, Policy D-330.967 advocates for continued collaboration with national medical specialty societies and interest groups in the context of evidence-based recommendations regarding preventive services, especially for populations at high risk for a given condition. Similarly, Policy H-390.849 advocates for physician payment reform consistent with promoting improved patient access to high-quality, cost-effective care; promoting designs that incorporate input from the physician community; and providing patients with information and incentives to encourage appropriate utilization of preventive services. AMA policy also focuses specifically on the needs of Medicare beneficiaries in this context. Policy D-330.935 states that the AMA will collaborate with relevant stakeholders, including appropriate medical specialty societies, to actively promote to the public and the profession the value of Medicare-covered preventive services and it will support the expansion of first-dollar coverage for a preventive visit and required tests anytime within the first year of enrollment in Medicare Part B. Finally, Policy H-425.992 advocates for revision of current Medicare guidelines to include coverage of appropriate preventive medical services.

In addition, the AMA is engaged in advocacy initiatives to improve Medicare coverage of CRCS. On October 6, 2017, the AMA sent letters to Senator Sherrod Brown (D-OH) and Representative Charlie Dent (R-PA) in support of HR 1017, "Removing Barriers to Colorectal Cancer Screening Act of 2017." HR 1017 would level the playing field across ACA-compliant commercial health insurance plans and Medicare, waiving coinsurance under Medicare for CRCS, regardless of whether therapeutic intervention is required during the screening. The passage of HR 1017 would therefore address current significant barriers to care for the Medicare population.

DISCUSSION

The misaligned expectations surrounding coverage for CRCS drive toward three key opportunities for improvement: (1) pursue changes to benefit design that better align reduced cost-sharing with high-value services; (2) promote common understanding among health care providers, payers, and patients so that all know what will be covered at given cost-sharing levels; and (3) advocate for Medicare coverage consistent with ACA-compliant plan coverage.

Recognizing that much can be done to better align reduced cost-sharing with high-value services that prevent advanced disease, the CMS and CSAPH agreed to the development of a joint Councilinitiated report for I-18, and this report will speak to the first opportunity referenced above. The I-18 CMS/CSAPH joint report will develop consistent and broadly applicable policy that addresses not only the CRCS concerns raised in Resolution 822, but also concerns about access to high-value preventive interventions in general. The Councils plan to expand upon their prior report regarding coverage for preventive services, and they are committed to advocating for changes to benefit design that better align reduced cost-sharing with high-value services.

The second opportunity referenced above is ripe for AMA educational leadership. The complexities in coding CRCS as a USPSTF-recommended preventive service vs. "surveillance" for ACA-compliant plans, and "screening" vs. "diagnostic" for Medicare plans, necessitate reliable coding guidance. The Councils acknowledge that there is currently conflicting guidance issued by credible specialty organizations on this topic. The AMA, as the authority on CPT, is in a unique position to issue educational materials that can be seen as a source of truth in aligning CRCS clinical scenarios to the proper CPT codes for billing. Accordingly, per Recommendation 7, the AMA will collaborate with physicians who specialize in CRCS to develop a coding guide to help physicians correctly bill various CRCS scenarios. A component of this coding guide will encourage specialist physicians to develop additional educational materials consistent with the guide and encourage both the health care provider and public health communities to continue efforts to educate the public about the value of CRCS.

 As described above in the context of AMA advocacy with respect to HR 1017, the AMA is already actively engaged in efforts to address some of the challenges in Medicare coverage for CRCS, and thus already working toward the third opportunity above. Similarly, as described above, the AMA has several policies that firmly support the goals of this report. Accordingly, it is recommended that policies D-330.935, D-330.967, H-185.960, H-390.849, and H-425.992 be reaffirmed. In addition, in Recommendation 6, the Councils support a new policy to codify on-going support of efforts to align coverage under Medicare and ACA-compliant health plans for CRCS.

In Recommendation 8, the Councils propose amending existing policy regarding appropriate screening programs to delete reference to specific types of screening. Since the evidence-base for screening evolves over time, the Councils do not feel it is prudent to outline specific types of screening within AMA policy.

RECOMMENDATIONS

The Council on Medical Service and the Council on Science and Public Health recommend that the following be adopted in lieu of Resolution 822-I-17, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) reaffirm Policy D-330.935, which supports AMA collaboration with relevant stakeholders, including medical specialty societies, to actively promote to the public and the profession the value of Medicare-covered preventive

CMS/CSAPH Joint Rep. A-18 -- page 7 of 8

services, and supports first-dollar coverage under Medicare for preventive visits and required 1 2 tests. (Reaffirm HOD Policy) 3 4 2. That our AMA reaffirm Policy D-330.967, which supports continued collaboration with 5 national medical specialty societies and interest groups in the context of evidence-based recommendations regarding preventive services and especially the provision of preventive 6 7 services to populations at high risk for a given condition. (Reaffirm HOD Policy) 8 9 3. That our AMA reaffirm Policy H-185.960, which advocates for health plan coverage of the full 10 range of colorectal cancer screening tests. (Reaffirm HOD Policy) 11 12 4. That our AMA reaffirm Policy H-330.877, which states that our AMA supports requiring 13 Medicare to waive the coinsurance for colorectal screening tests, including therapeutic intervention(s) required during the procedure. (Reaffirm HOD Policy) 14 15 5. That our AMA continue to support Medicare coverage for colorectal cancer screenings 16 17 consistent with ACA-compliant plan coverage requirements. (New HOD Policy) 18 19 That our AMA seek to eliminate cost-sharing in all health plans for the full range of colorectal 20 cancer screening and all associated costs, including colonoscopy that includes a "diagnostic" 21 intervention (ie the removal of a polyp or biopsy of a mass) as defined by Medicare. To further this goal, the AMA will develop a coding guide to promote common understanding among 22 23 health care providers, payers, health care information technology vendors, and patients. 24 (Directive to Take Action) 25 7. That Policy, H-55.981, "Carcinoma of the Colon and Rectum," be amended to read as follows: 26 27 28 Our AMA supports: (1) Recognizing colon cancer as a leading cause of cancer deaths in the 29 United States and encouraging appropriate screening programs to detect colorectal cancer. (2) 30 Persons at increased risk for CRC (family history of CRC, previous adenomatous polyps, 31 inflammatory bowel disease, previous resection of CRC, genetic syndromes) receiving more 32 intensive screening efforts. (3) Physicians becoming aware of genetic alterations that influence

the development of CRC, and of diagnostic and screening tests that are available in this area.

(4) Physicians engaging their patients in shared decision-making, including consideration of

colorectal cancer and which screening method (or sequence of methods) is most appropriate.

both clinical and financial patient impacts, to determine at what age to begin screening for

Fiscal Note: Less than \$2,000.

(Modify Current HOD Policy)

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CMS/CSAPH Joint Rep. A-18 -- page 8 of 8

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⁶ *Id*.

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 $\overline{^{15}}$ Supra note 11.

¹⁶ Supra note 11.