September 6, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1770-P – Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies
87 Fed. Reg. 45860 (July 29, 2022)

Dear Secretary Becerra and Administrator Brooks-LaSure:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the calendar year (CY) 2023 Medicare Physician Fee Schedule proposed rule. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer.

ACS CAN offers comments on the following policies:

- Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers
- Medicare Potentially Underutilized Services
- Valuation of Chronic Care Management and Treatment (CPM) Bundles
- Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services

Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

CMS proposes two major improvements to its colorectal cancer screening policies. First, consistent with guidelines from the American Cancer Society (ACS), CMS proposes to lower the minimum age of screening for those at average risk for colorectal cancer to 45, instead of the previous recommendation of age 50. Second, CMS proposes to expand the definition of a colorectal cancer screening test to include a follow-on colonoscopy after a positive result from a Medicare-covered non-invasive stool-based colorectal cancer screening test. As a result, Medicare enrollees would not face any cost-sharing for follow-up colonoscopies under these circumstances.

ACS CAN applauds CMS for these proposed policies and urge the Agency to adopt these proposals for the following reasons:

Colorectal cancer is prevalent and can be prevented through screening: In 2022, an estimated 151,030 cases of colon cancer will be diagnosed in the United States, a majority of which will be diagnosed in

American Cancer Society Cancer Action Network, Inc.
655 15th Street, NW, Suite 503, Washington, D.C. 20005
202.661.5700
fightcancer.org

individuals age 45 and older.[1] An estimated 53,200 people will die from the disease this year.[2] Colorectal cancer remains one of the deadliest forms of cancer.[3]

Regular screening is the most effective way of detecting precancerous growths and early colorectal cancer. Cancers that are found at an early stage can be treated more easily, and lead to greater survival.[4] For colorectal cancer, the five-year survival rate is 90 percent for those patients whose cancer is discovered and treated early. In contrast, individuals whose colorectal cancer is found at a later stage, after the cancer has metastasized, have a 14 percent five-year survival rate.[5]

Removing cost-sharing for follow-up colonoscopies will help improve CRC screening rates: We are pleased with Medicare's proposal to remove cost-sharing for follow-up colonoscopies following a positive non-invasive test. Removing this cost-sharing will help to ensure that enrollees complete the recommended colorectal cancer screening continuum.

According to one study, 77.9% of Medicare enrollees incurred cost sharing for colonoscopy after non-invasive stool-based testing.[6] Other data has shown that clinical colorectal cancer screening outcomes improved and stool-based screening was cost-effective or cost-saving when waiving the 20% coinsurance was assumed to modestly (5%) increase adherence rates for total CRC screening and/or a colonoscopy following a positive test.[7] Additionally, studies have demonstrated that increased time to colonoscopy after an abnormal non-invasive screening test is associated with higher risk of colorectal cancer incidence, death, and late-stage colorectal cancer.[8]

CMS proposal aligns Medicare with private insurance requirements: We are pleased the proposal would align Medicare coverage requirements – both in terms of establishing the minimum age of colorectal cancer screening to be 45 and to provide coverage of follow-up colonoscopies at no cost-sharing after a positive stool test – with those in the private market.

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[1] American Cancer Society. *Cancer Facts & Figures 2022*. Atlanta: American Cancer Society; 2022.
[2] American Cancer Society. *Colorectal Cancer Facts & Figures 2020-2022*. Atlanta: American Cancer Society; 2020.
[3] Siegal RL, Miller KD, Fuchs HE Jemal A. Cancer statistics, 2021. *Cancer.* 2021; 71:7-33, doi 10.3322/caac.21654.
[4] American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures 2021-2022*. Atlanta: American Cancer Society; 2021.
[5] Colorectal Cancer Facts & Figures 2020-2022.
[6] Fendrick AM, Princic N, Miller-Wilson L, Wilson K, Limburg P. Out-of-Pocket Costs for Colonoscopy After Noninvasive Colorectal Cancer Screening Among US Adults With Commercial and Medicare Insurance. *JAMA Netw Open.* 2021;4(12):e2136798. doi:10.1001/jamanetworkopen.2021.36798 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2786794.
[7] A. Fendrick, David A. Lieberman, Vahab Vahdat, Jing Voon Chen, A. Burak Ozbay, Paul J. Limburg. Cost-effectiveness of waiving coinsurance for follow-up colonoscopy after a positive stool-based colorectal screening test in a Medicare population. J Clin Oncol 40, 2022 (suppl 16; abstr e13624) doi:10.1200/JCO.2022.40.16_supple.e13642.
[8] San Miguel Y. Demb J. et al. Time to colonoscopy after abnormal stool-based screening and risk for colorectal cancer incidence and mortality. *Gastroenterology*. Feb. 2, 2021. Available at https://www.gastrojournal.org/article/S0016-5085(21)00325-5/fulltext.

In May 2021, the United States Preventive Services Task Force (USPFTF) released its updated colorectal cancer screening recommendations, recommending that individuals aged 45 and older undergo appropriate colorectal cancer screening,[9] similar to the change in the American Cancer Society colorectal cancer screening guideline update in 2018.[10] As part of these guidelines, the USPSTF clearly stated that "positive results on stool-based screening tests require follow-up with colonoscopy for the screening benefits to be achieved." The ACA section 2713 requires non-grandfathered private plans to provide coverage for, and not impose any cost-sharing requirements for, evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations for the USPSTF.

In January 2022, the Administration issued guidance clarifying that non-grandfathered private plans are required to cover, without cost sharing, a follow-up colonoscopy after a positive non-invasive stool-based screening test, in line with the USPSTF's revised recommendation which clearly states that "the follow-up colonoscopy is an integral part of the preventive screening without which the screening would not be complete."[11]

Aligning the Medicare coverage requirements with those in the private market will help make it easier for stakeholders to educate the public about the importance of colorectal cancer screenings and encourage their utilization for those who qualify.

Future coverage considerations: In 2021, Medicare determined that blood-based biomarker tests are an appropriate colorectal cancer screen for Medicare enrollees who meet certain criteria.[12] At this time there is currently only one FDA-approved blood-based biomarker colorectal cancer screening test on the market and CMS determined that test does not meet the criteria for coverage.[13]

As more research is being undertaken to develop new blood-based colorectal cancer screening tests, at some future point there may be a blood-based test that will meet CMS' criteria for coverage. When that happens, we recognize that follow-up colonoscopies will likely be required for those blood-based screening tests which would necessitate a regulatory change to ensure coverage of follow-up colonoscopies at no cost sharing following a positive Medicare-approved blood-based colorectal cancer test.

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[9] U.S. Preventive Services Task Force. *Screening for Colorectal Cancer*. May 18, 2021. Available at https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.

[10] Wolf AMD, Fontham ETH, Church TR, Flowers CR, Guerra CE, LaMonte SJ, Etzioni R, McKenna MT, Oeffinger KC, Shih YT, Walter LC, Andrews KS, Brawley OW, Brooks D, Fedewa SA, Manassaram-Baptiste D, Siegel RL, Wender RC, Smith RA. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. CA Cancer J Clin. 2018;68: 250-281.

[11] U.S. Department of Labor. FAQs about Affordable Care Act implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act implementation. Jan. 10, 2022. Page 10. Available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf.

[12] Centers for Medicare & Medicaid Services. Medicare National Coverage Determinations Manual. Ch. 1, Part 4, sect. 210.3(B)(3).

[13] Centers for Medicare & Medicaid Services. Decision Memo: Screening for colorectal cancer – blood based biomarker tests. CAG-00454N. Jan. 19, 2021.

Medicare Potentially Underutilized Services

CMS is requesting comments to help identify specific services and to recognize possible barriers to improve access to high value, potentially underutilized services by Medicare beneficiaries.

ACS CAN would like to utilize this opportunity to mention the "high value" patient navigation services could provide to the Medicare program. Oncology patient navigation is defined as the individualized assistance offered to patients, families, and caregivers to help overcome health care system barriers and facilitate timely access to quality health and psychosocial care from pre-diagnosis through all phases of the cancer experience.[14] Patient navigation is absent or limited in many cancer programs and hospital settings due to a lack of clinical reimbursement although studies show that patient navigation programs positively impact patient-reported and clinical outcomes. We look forward to working with the agency to ensure that patients – particularly oncology patients – have access to patient navigation services.

Valuation of Specific Codes

4. Proposed Valuation of Specific Codes for CY 2023

33. Chronic Pain Management and Treatment (CPM) Bundles (HCPCS GYYY1, and GYYY2)

After receiving positive feedback on its request for comment last year, CMS is proposing to create separate coding and payment for chronic pain management (CPM) services beginning January 1, 2023.

ACS CAN supports the addition of a code to adequately compensate providers for the time they spend managing patients' pain and coordinating related care. Managing pain is an integral and necessary part of treating most cancer patients, and ACS CAN works to ensure that cancer patients and survivors have access to all the pain treatments appropriate for their condition and symptoms. Adequately addressing pain at all stages of a patient's treatment is dependent upon having providers who are willing and able to spend the time on pain management. Adding these codes for chronic pain management will be a helpful step towards ensuring access to pain treatment. We also congratulate HHS on using language in this rule that is inclusive of all appropriate types of pain treatment.

We note that a 30-minute, face-to-face visit is required for each month in which the provider uses this billing code, which may be onerous for cancer patients and their providers who are already receiving time-intensive care. To ensure that this requirement does not inhibit providers from providing chronic pain management services, we urge CMS to add the codes to the Medicare Telehealth Services List.

Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services

Medicare pays for dental services if they are an integral part of a covered procedure. CMS is proposing to clarify the interpretation of the Medicare statute related to the limited coverage of dental services. CMS also seeks comments from stakeholders on specific scenarios in which dental services may be inextricability linked to and integral to the clinical success of clinically related services.

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[14] Franklin, E., et al. (2022) "Professional Oncology Navigation Task Force Releases Oncology Navigation Standards of Practice," ONS Voice. Available at: https://voice.ons.org/news-and-views/professional-oncology-navigation-task-force-releases-oncology-navigation-standards.

ACS CAN appreciates CMS' interest in providing additional clarification regarding Medicare's coverage of dental services. Currently, Medicare provides coverage of limited dental services where the dental service is considered to be an integral part of a covered service. Medicare will cover dental services such as a tumor removal of the jaw, provided that the service is performed at the same time as the covered primary service and by the same dentist or physician.[15] Medicare will also cover the extraction of teeth to prepare the jaw for radiation treatments.[16]

Unfortunately, Medicare does not provide coverage of dental services that are specifically related to the treatment of certain types of head and neck cancers. For example, individuals who undergo radiation treatment for certain head and neck cancers may experience problems with tooth decay as a direct result of that treatment, but Medicare does not currently provide coverage of follow-up dental care. Dental examinations and panoramic x-rays are recommended prior to, and while on, bisphosphonate therapy for prevent of skeletal-related events due to bone metastases and should be covered by Medicare.[17] We urge CMS to consider covering medically necessary dental care that is a direct result from Medicare-covered services that were provided to the enrollee.

Because Medicare's coverage of dental services is limited, there can be confusion among providers and enrollees regarding Medicare's coverage. If CMS intends, through this or future rulemaking, to further expand Medicare's coverage of dental services or to further clarify existing coverage, we believe that education and outreach is needed. We urge CMS, to undertake an education campaign with providers, MACs, and enrollees, to educate stakeholders regarding Medicare's coverage of dental services.

CONCLUSION

Thank you for the opportunity to comment on the calendar year 2023 Medicare Physician Fee Schedule proposed rule. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org.

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network

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[15] Medicare Benefit Policy Manual. IOM Pub 100-02, Chapter 15, section 150.
[16] Id.
[17] Ruggiero S, Gralow J, Marx RE, Hoff AO, Schubert MM, Huryn JM, Toth B, Damato K, Valero V. Practical guidelines for the prevention, diagnosis, and treatment of osteonecrosis of the jaw in patients with cancer. J Oncol Pract. 2006 Jan;2(1):7-14. doi: 10.1200/JOP.2006.2.1.7. PMID: 20871729; PMCID: PMC2794643.