

REPORT 6 OF THE COUNCIL ON MEDICAL SERVICE (A-19)
Preventive Prostate Cancer Screening
(Resolution 226-A-18)
(Reference Committee A)

EXECUTIVE SUMMARY

At the 2018 Annual Meeting, the House of Delegates referred Resolution 226, “Model State Legislation for Routine Preventive Prostate Cancer Screening,” which was sponsored by the American Urological Association (AUA), the American Association of Clinical Urologists, and the Virginia Delegation. Resolution 226 asked that the American Medical Association (AMA) develop model state legislation for screening of asymptomatic men ages 55-69 for prostate cancer after informed discussion between patients and their physicians without annual deductible or co-pay. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2019 Annual Meeting.

Prostate cancer is one of the most common types of cancer that affects men. In the United States, men’s lifetime risk of being diagnosed with prostate cancer is approximately 11 percent and their lifetime risk of dying of prostate cancer is 2.5 percent. African-American men and men with a family history of prostate cancer have an increased risk of prostate cancer compared with other men. In fact, older age, African-American race, and family history of prostate cancer are the most important risk factors for the development of prostate cancer. This report examines prostate cancer screening in the context of general costs of care concerns, the legal basis for coverage of preventive services without patient cost-sharing, whether prostate cancer screening has been shown to meet the criteria for benefits provided without patient cost-sharing, key clinical practice guidelines for prostate cancer screening, and the AMA’s approach to cancer prevention and expanding affordable access to care.

The Council recommends that our AMA encourage payers to ensure coverage for prostate cancer screening when the service is deemed appropriate following informed physician-patient shared decision-making. Additionally, the Council recommends that our AMA encourage national medical specialty societies to promote public education around the importance of informed physician-patient shared decision-making regarding medical services that are particularly sensitive to patient values and circumstances, such as prostate cancer screening. The Council also recommends updating and expanding AMA policy regarding prostate cancer screening to encourage scientific research to address critical evidence gaps. In addition, the report describes extensive AMA policy that speaks to the resolves of referred Resolution 226-A-18. Accordingly, the Council recommends reaffirmation of policies which support: aligning clinical and financial incentives for high-value care, the role national medical specialty societies can play in helping to shape value-based insurance design (VBID) plans that decrease cost-sharing to encourage utilization of high-value services, VBID plans that explicitly consider the clinical benefit of a given service when determining cost-sharing structures or other benefit design elements, physician-patient shared decision-making and physician value-based decision-making, and coverage for evidence-based preventive services and genetic/genomic precision medicine.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 6-A-19

Subject: Preventive Prostate Cancer Screening
(Resolution 226-A-18)

Presented by: James G. Hinsdale, MD, Chair

Referred to: Reference Committee A
(John Montgomery, MD, MPH, Chair)

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2 Legislation for Routine Preventive Prostate Cancer Screening,” which was sponsored by the
3 American Urological Association (AUA), the American Association of Clinical Urologists, and the
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5 model state legislation for screening of asymptomatic men ages 55-69 for prostate cancer after
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9
10 This report examines prostate cancer screening in the context of general costs of care concerns, the
11 legal basis for coverage of preventive services without patient cost-sharing, whether prostate cancer
12 screening has been shown to meet the criteria for benefits provided without patient cost-sharing,
13 key clinical practice guidelines for prostate cancer screening, and the AMA’s approach to cancer
14 prevention and expanding affordable access to care.

15 16 BACKGROUND

17
18 Prostate cancer is one of the most common types of cancer that affects men.¹ In the United States,
19 men’s lifetime risk of being diagnosed with prostate cancer is approximately 11 percent and their
20 lifetime risk of dying of prostate cancer is 2.5 percent.² African-American men and men with a
21 family history of prostate cancer have an increased risk of prostate cancer compared with other
22 men. In fact, older age, African-American race, and family history of prostate cancer are the most
23 important risk factors for the development of prostate cancer.³ As highlighted in the I-18 Joint
24 Report of CMS and the Council on Science and Public Health (CSAPH), “Aligning Clinical and
25 Financial Incentives for High-Value Care,” more must be done to align incentives to support early
26 prevention, detection, and treatment of disease, including cancer.

27
28 To ensure that patients get the medical care they need, they must be able to afford the full spectrum
29 of care that they could require, from risk factor identification, to screening, to preventive
30 interventions, to treatment of diagnosed disease. Even when a service is covered by a health plan,
31 patients may incur significant costs in the form of co-payments, coinsurance, and/or large medical
32 bills that they must pay before meeting their deductible. Such costs have been shown to cause
33 people, especially those in low-income and vulnerable populations, to forgo not only unnecessary
34 but also necessary care.⁴ Cost-related non-adherence (CRN) refers to a state in which patients are
35 unable to pursue recommended medical care due to financial barriers.⁵ Sub-optimal use of
36 evidence-based medical services can lead to negative clinical outcomes, increased disparities, and

1 in some cases, higher aggregate costs.⁶ CRN has been identified across the entire continuum of
2 clinical care – physician visits, preventive screenings, prescription drugs, etc. – and it is especially
3 problematic for vulnerable populations, such as those with multiple chronic conditions, and for
4 socioeconomically and racially disparate populations.⁷

5 6 ACA REQUIREMENTS & PREVENTIVE SERVICES BENEFIT MANDATES

7
8 A factor mitigating patient concerns about the cost of preventive care is the Affordable Care Act’s
9 (ACA) requirement that health plans cover select preventive services without any patient cost-
10 sharing (zero-dollar). CMS and CSAPH recently examined the ACA’s zero-dollar preventive
11 services requirement in three joint reports:

- 12
- 13 • A-17, “Value of Preventive Services” (A-17 Joint Report);
- 14 • A-18, “Coverage for Colorectal Cancer Screening” (A-18 Joint Report); and
- 15 • I-18, “Aligning Clinical and Financial Incentives for High-Value Care” (I-18 Joint Report).
- 16

17 As detailed in the A-17 Joint Report, the ACA required all private, non-grandfathered health
18 insurance plans to provide zero-dollar coverage for the preventive services recommended by four
19 expert organizations: the United States Preventive Services Task Force (USPSTF), the Advisory
20 Committee on Immunization Practices (ACIP), the Women’s Preventive Services Initiative, and
21 Bright Futures (collectively, the Expert Organizations). The report also described the varied
22 methods used by the Expert Organizations for developing preventive service guidelines. The A-17
23 report established Policy H-460.894, which encouraged the Expert Organizations to develop their
24 recommendations with transparency, clarity and specificity.

25
26 The A-18 Joint Report on colorectal cancer screening is highly relevant in the current context as
27 another close examination of a cancer screening that has been recently evaluated by the USPSTF
28 and other medical guideline issuing organizations. Notably, the USPSTF had already recommended
29 colorectal cancer screening with an “A” grade, making the screening eligible for zero-dollar
30 coverage for some patients with ACA-compliant health plans. A critical challenge addressed in the
31 A-18 Joint Report was inconsistency in ACA-compliant and Medicare coverage. Accordingly, the
32 A-18 Joint Report established Policy H-330.877, which supports Medicare coverage for colorectal
33 cancer screenings consistent with ACA-compliant plan coverage requirements.

34
35 The I-18 Joint Report explored various challenges that the health care industry has faced in
36 implementing the zero-dollar coverage requirement, and it established Policy D-185.979 to help
37 address those challenges. Specifically, Policy D-185.979 supports clinical nuance in value-based
38 insurance design (VBID) to respect individual patient needs, aligning financial incentives across
39 physician payment initiatives and benefit design initiatives, and encouraging national medical
40 specialty societies to identify high-value services and collaborate with payers to experiment with
41 benefit plan designs that align patient financial incentives with utilization of high-value services.

42
43 The ACA’s mandated zero-dollar coverage for select preventive services enjoys strong bipartisan
44 support. A recent poll found that the ACA provision eliminating out-of-pocket costs for certain
45 preventive services was favored by 83 percent of Americans.⁸ However, before a service is
46 mandated as a zero-dollar benefit in accordance with the ACA, it must be recommended by one of
47 the Expert Organizations based on their review of the scientific evidence.

1 *Meaning of USPSTF Recommendation Grading*

2
3 Critically, to qualify for mandated zero-dollar coverage based on a USPSTF recommendation, a
4 health care service must receive an “A” or “B” recommendation. Services that receive a “C”
5 recommendation are supported by the USPSTF for certain patients, but they do not qualify for the
6 ACA’s zero-dollar coverage. The evidence supporting a given service determines the
7 recommendation grade it receives. “A,” “B,” and “C” recommendations from the USPSTF all
8 encourage provision of the service at issue, to some extent, with the recommendations varying
9 based on the strength of the evidence in support of the service:

- 10
- 11 • “A” recommendations mean: “The USPSTF recommends the service. There is high
12 certainty that the net benefit is substantial.” Accordingly, the USPSTF recommends that
13 practitioners, “offer or provide this service.”
 - 14 • “B” recommendations mean: “The USPSTF recommends the service. There is high
15 certainty that the net benefit is moderate or there is moderate certainty that the net benefit
16 is moderate to substantial.” As with an A recommendation, the USPSTF recommends that
17 practitioners, “offer or provide this service.”
 - 18 • “C” recommendations are a bit more nuanced, and notably, the USPSTF’s approach to “C”
19 recommendations has evolved over the past two decades. Currently, a “C”
20 recommendation means: “The USPSTF recommends selectively offering or providing this
21 service to individual patients based on professional judgment and patient preferences.
22 There is at least moderate certainty that the net benefit is small.” Accordingly, the USPSTF
23 recommends that practitioners, “Offer or provide this service for selected patients
24 depending on individual circumstances.” In describing the evolution of the “C”
25 recommendation, the USPSTF explains, “Grade C recommendations are particularly
26 sensitive to patient values and circumstances. Determining whether or not the service
27 should be offered or provided to an individual patient will typically require an informed
28 conversation between the clinician and patient.”⁹

29
30 The USPSTF can also issue a negative recommendation, a “D” recommendation, meaning: “The
31 USPSTF recommends against the service. There is moderate or high certainty that the service has
32 no net benefit or that the harms outweigh the benefits.” Accordingly, the USPSTF recommends
33 that practitioners, “Discourage the use of this service.”¹⁰

34
35 Finally, the USPSTF can issue an “I” statement which means, “The USPSTF concludes that the
36 current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence
37 is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be
38 determined.” For these services, the USPSTF recommends that providers, “Read the clinical
39 considerations section of USPSTF Recommendation Statement. If the service is offered, patients
40 should understand the uncertainty about the balance of benefits and harms.”¹¹

41
42 *Few Cancer Screenings are Eligible for Zero-Dollar Coverage*

43
44 Resolution 226-A-18 asserts that, “screening for breast cancer and colonoscopies are covered
45 preventive services for patients without an annual deductible or co-pay.” While that is true for
46 some patients screened for breast and colorectal cancer, it is not true for many patients. Some
47 cancer screenings (such as breast and colorectal cancer) for some patient populations have received
48 an “A” or “B” recommendation from the USPSTF and are therefore provided for some patients
49 without patient cost-sharing. This zero-dollar coverage, however, only results from the fact that the
50 USPSTF has found evidence supporting an “A” or “B” level recommendation, indicating the net
51 benefit of those services, for those populations. Accordingly, the cancer screenings that are

1 provided without patient cost-sharing are limited to those for which the existing evidence meets the
 2 USPSTF’s standards.

3
 4 As a result, many services that may be valuable to patients are not provided without cost-sharing
 5 when the existing evidence does not demonstrate that the net benefit is substantial or moderate
 6 leading to an “A” or “B” recommendation from the USPSTF. Prostate cancer screening is an
 7 excellent example. In assigning prostate cancer screening in men aged 55 to 69 years a “C”
 8 recommendation, the USPSTF explained that prostate cancer screening is recognized as valuable
 9 for some patients, but the evidence of benefits may not outweigh the potential harms for other
 10 patients.¹² Other critical services falling into the USPSTF’s C recommendation category include
 11 screening mammography in women prior to age 50 years¹³ and screening for colorectal cancer in
 12 adults aged 76 to 85 years.¹⁴ Moreover, when the evidence for cancer screenings is lacking, the
 13 screenings receive an “I” recommendation from the USPSTF. Currently, these services include
 14 adult skin cancer,¹⁵ bladder cancer,¹⁶ and oral cancer.¹⁷

15
 16 Currently, the only cancer prevention services with an “A” or “B” recommendations for any patient
 17 population are:

- 18
- 19 • Aspirin Use to Prevent Cardiovascular Disease and Colorectal Cancer,¹⁸
- 20 • BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing,¹⁹
- 21 • Breast Cancer: Medications for Risk Reduction,²⁰
- 22 • Breast Cancer: Screening,²¹
- 23 • Cervical Cancer: Screening,²²
- 24 • Colorectal Cancer: Screening,²³
- 25 • Lung Cancer: Screening,²⁴ and
- 26 • Skin Cancer Prevention: Behavioral Counseling (only applies to young adults, adolescents,
 27 children, and parents of young children).²⁵
- 28

29 Moreover, among the cancer prevention services with “A” or “B” recommendations which are
 30 provided without cost-sharing, the recommendations are limited to specific patient populations.
 31 Accordingly, some patients for whom physicians would recommend these services fall outside the
 32 scope of the USPSTF recommendations, and therefore, the zero-dollar benefits do not apply to
 33 them. Relevant examples that the Council has examined in the A-18 and I-18 Joint Reports are:

- 34
- 35 • Breast cancer screening – “B” rating only applies to average risk women at certain ages.
 36 Screening for younger women is assigned a “C” recommendation, much like prostate
 37 cancer screening.²⁶ Moreover, women at heightened risk do not fall within the scope of the
 38 “B” recommendation. Accordingly, while some women will qualify for zero-dollar
 39 mammograms, others will not.
- 40 • Colorectal cancer screening – “B” rating only applies to average risk adults at certain
 41 ages.²⁷ Screening for older adults is assigned a “C” recommendation, and adults at
 42 heightened risk are outside the scope of the “B” recommendation. Once again, some adults
 43 will be able to receive a zero-dollar colorectal cancer screening, but others will not.
- 44 • Skin cancer prevention – the recommended scope of this cancer prevention service is even
 45 more limited. The USPSTF’s “B” recommendation only applies to counseling, not
 46 screening, and for individuals aged 6 months to 24 years (or their parents). The USPSTF
 47 issued a “C” recommendation regarding counseling for adults with fair skin older than 24
 48 years.²⁸ As a result, some patients can receive zero-dollar counseling regarding skin cancer
 49 prevention, but all skin cancer screenings would incur cost-sharing.

1 These examples illustrate that cost-sharing remains a concern not only for prostate cancer
2 screening, but for other cancer screenings, too. At the same time, while cost-sharing is required,
3 health insurance coverage for cancer screenings can help to defray the cost for insured patients.

4 5 RECOMMENDATIONS REGARDING PROSTATE CANCER SCREENING

6
7 The USPSTF's recommendations regarding prostate cancer screening are well-aligned with those
8 of key medical specialty societies and other health care organizations. Prostate cancer screening
9 has been reviewed repeatedly by the USPSTF,²⁹ and their most recent assessment is consistent with
10 that of the AUA – both organizations recommend discussions of this service between a patient and
11 his physician, and both recommend informed decision-making regarding whether to proceed with
12 testing. Neither organization categorically recommends prostate cancer screening. For the AUA,
13 this recommendation equates to a B on the AUA's scale,³⁰ while for the USPSTF, this
14 recommendation equates to a C on the USPSTF's scale. These recommendations are also
15 consistent with that of the American Cancer Society (ACS).³¹ In addition to providing clinical
16 guidelines, the ACS also takes an advocacy position supporting "insurance coverage" for prostate
17 cancer screening, though it does not specifically call for zero-dollar coverage.³² Notably, none of
18 these three expert guidelines recommend universally screening any men of any age or risk
19 category, and none of these evidence-based specialty guidelines justify a benefit mandate of zero-
20 dollar coverage for prostate cancer screening in asymptomatic men ages 55-69.

21 22 EVIDENCE FOR CLINICAL GUIDELINES THAT INFORM COVERAGE DECISIONS

23
24 While the current evidence-based guidelines do not categorically recommend prostate cancer
25 screening, the USPSTF has repeatedly highlighted evidence gaps, and with additional evidence,
26 new, more precise recommendations, could be issued. When the USPSTF issued its 2018
27 recommendations on prostate cancer screening,³³ it explained that to update its 2012
28 recommendation, it commissioned two new reviews: a systematic review of the evidence regarding
29 the benefits and harms of prostate-specific antigen (PSA)-based screening for prostate cancer and
30 subsequent treatment of screen-detected prostate cancer, and a review of multiple contextual
31 questions, including a review of existing decision analysis models and what they suggest about the
32 potential for mitigating the harms of screening and treatment and the overdiagnosis rate of PSA-
33 based screening. These studies also examined the effectiveness and harms of PSA-based screening
34 in patient subpopulations at higher risk of prostate cancer, including older men, African American
35 men, and men with a family history of prostate cancer. In addition, the USPSTF reviewed evidence
36 from three randomized controlled trials (RCTs) studying PSA-based screening for prostate cancer:
37 the US-based Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial, the
38 European Randomized Study of Screening for Prostate Cancer (ERSPC), and the Cluster
39 Randomized Trial of PSA Testing for Prostate Cancer (CAP). These trials used varying screening
40 intervals (from 1-time screening to every 1 to 4 years) and PSA thresholds (2.5 to 10.0 ng/mL) for
41 diagnostic biopsy. These RCTs each had at least a decade of median follow-up.

42
43 Even with this additional research, the USPSTF emphasized that there are many areas in need of
44 research to improve the evidence-base for screening and treatment of prostate cancer, including:

- 45
- 46 1. Comparing different screening strategies;
- 47 2. Developing, validating, and providing longer-term follow-up of screening and diagnostic
48 techniques;
- 49 3. Screening for and treatment of prostate cancer in African American men, and specifying
50 that given the large disparities in prostate cancer mortality in African American men, this
51 research should be a national priority;

- 1 4. How to better inform men with a family history of prostate cancer about the benefits and
- 2 harms of PSA-based screening for prostate cancer;
- 3 5. How to refine active prostate cancer treatments to minimize harms; and
- 4 6. How to improve informed decision-making.³⁴

5
 6 The USPSTF highlighted these critical research gaps in its November 2018 Report to Congress on
 7 *High-Priority Evidence Gaps for Clinical Preventive Services*.³⁵ Notably, screening for prostate
 8 cancer, especially among African-American men and men with a family history, is one of only
 9 three high-priority cancer-related evidence gaps that the USPSTF highlighted in 2018. This
 10 USPSTF report also explains that the National Institutes of Health (NIH) reviews the research gaps
 11 identified by the USPSTF and utilizes the information in developing future funding opportunities.
 12

13 In addition, growing from a desire to find prostate cancer screening tools that better identify
 14 clinically significant prostate cancer, research into improved screening modalities is rapidly
 15 evolving. A variety of companies are developing urine or blood-based risk assays using precision
 16 medicine to identify aggressive cases of prostate cancer, with some products already available to
 17 physicians and patients.³⁶ For example, ExoDx Prostate (IntelliScore) (EPI) is a non-invasive
 18 urine-based liquid biopsy for prostate cancer which can accurately identify high-grade prostate
 19 cancer at the time of biopsy and at surgery.³⁷ As a “rule out” test, EPI is designed to more
 20 accurately predict whether a patient presenting for an initial biopsy does not have a high-grade
 21 prostate cancer, and therefore could be monitored while avoiding a biopsy at that time.³⁸ Similarly,
 22 MDx Health offers physicians and patients SelectMDx, an epigenetic urine test for prostate cancer
 23 risk stratification.³⁹ Additionally, prostate magnetic resonance imaging (MRI) prior to prostate
 24 biopsy can be used to help reduce overdiagnosis of insignificant cancer and improve detection of
 25 clinically significant cancer. Recent clinical studies⁴⁰ and a consensus statement of the AUA and
 26 the Society of Abdominal Radiology (SAR)⁴¹ support the use of high-quality prostate MRI in
 27 detecting prostate cancer. However, some experts have raised concerns about both the
 28 appropriateness and practicality of advocating for widespread use of MRI to detect prostate cancer,
 29 emphasizing that more research is needed to evaluate the relative aggressiveness of high-grade
 30 tumors missed by prostate MRI, and that both the costs and the subspecialist expertise required to
 31 successfully perform MRI for prostate cancer detection may make widespread implementation of
 32 this tool impractical.⁴² Currently, insurance coverage for precision medicine⁴³ and prostate MRI⁴⁴
 33 can pose challenges for patients and their physicians. Accordingly, continued research into the
 34 efficacy of new and evolving screening and detection methods will be essential to inform clinical
 35 guidelines and standards of care, which can in turn influence insurance coverage determinations.
 36

37 INSURANCE COVERAGE FOR PROSTATE CANCER SCREENING

38
 39 The ACS explains that while some states have slightly different prostate cancer screening coverage
 40 requirements, “most state laws assure annual coverage for men ages 50 and over and for high-risk
 41 men [African-American men and/or men with a family history of prostate cancer], ages 40 and
 42 over.”⁴⁵ Additionally, Medicare covers the PSA blood test and a digital rectal exam (DRE) once a
 43 year for all male beneficiaries age 50 and over. There is no co-insurance and no Part B deductible
 44 for the PSA test. Unlike some cancers where the costs associated with merely screening for the
 45 cancer can be prohibitively expensive (e.g., the myriad fees associated with colonoscopies or the
 46 potential for multiple different imaging fees associated with breast cancer screenings), the cost
 47 associated with a PSA test is relatively minimal. A 2013 study found, “During 2007–2009, the
 48 average annual prostate cancer screening cost per beneficiary was \$36.”⁴⁶ Similarly, the Medicare
 49 2019 Clinical Lab Fee Schedule Payment for PSA is approximately \$20. While \$20-36 is certainly
 50 a barrier for some patients, it pales in comparison to the costs patients could later face if their PSA
 51 test is positive, and it pales in comparison to the cost of a colonoscopy.

1 As explored in the A-18 and I-18 Joint Reports, the current health care system does not
2 successfully identify all high-value preventive services that are worthy of reduced patient cost-
3 sharing, and VBID presents an opportunity for physicians to help shape the identification of
4 additional high-value preventive services. The I-18 Joint Report established Policy D-185.979
5 which encourages national medical specialty societies to identify services that they consider to be
6 high-value and collaborate with payers to experiment with benefit plan designs that align patient
7 financial incentives with utilization of high-value services. Prostate cancer screening could be an
8 excellent example. Given the research gaps that will take time to fill and the powerful first-hand
9 experience that physicians can share, physicians and payers could collaboratively evaluate prostate
10 cancer screening to determine whether it should qualify as a high-value service, at least for certain
11 patients, and be covered with reduced patient cost-sharing to encourage its utilization.

12 13 AMA POLICY

14
15 Many AMA policies support cancer prevention education, awareness, access and/or general
16 insurance coverage, but they do not seek mandated zero-dollar coverage for specific cancer
17 screening services. Key examples include:

- 18
- 19 • Breast and Cervical Cancers: Policies D-55.997, H-525.994, H-440.872, H-525.993,
20 H-55.971, and H-525.977;
- 21 • Colorectal and Anal Cancers: Policies H-55.981, D-55.998, and H-460.913;
- 22 • Lung Cancer: Policy H-185.936;
- 23 • Skin Cancer: Policy H-55.972; and
- 24 • Prostate Cancer: Policies H-425.980 and D-450.957.
- 25

26 AMA policies that call for coverage with no cost-sharing broadly address categories of benefits,
27 rather than individual disease states, including Policy H-185.969 regarding immunizations, Policy
28 D-330.935 regarding Medicare preventive service benefits, and Policy H-290.972 regarding
29 preventive coverage for health savings account holders in the Medicaid program. One exception,
30 where AMA policy does seek zero-dollar coverage for a cancer screening, is for colorectal cancer
31 screening (Policies H-185.960 and H-330.877). Critically, however, Policies H-185.960 and
32 H-330.877 do not seek to establish a new zero-dollar benefit mandate; rather, they build on an
33 ACA benefit mandate, seeking Medicare coverage on par with ACA-recognized evidence-based
34 guidelines.

35
36 Longstanding AMA policy supports well-informed physician-patient shared decision-making
37 regarding whether to pursue prostate cancer screening (Policy H-425.980), which is consistent with
38 USPSTF, AUA, and ACS prostate cancer screening recommendations, as well as with AMA policy
39 regarding many other cancer prevention efforts. Additionally, Policy H-373.997 sets forth core
40 elements of physician-patient shared decision-making, and Policy H-450.938 sets forth the
41 principles to guide physician value-based decision-making, including providing physicians with
42 easy access to costs of care at the point of decision-making.

43
44 Extensive AMA policy supports insurance coverage for evidence-based preventive services
45 (including Policies H-165.840, H-425.997, H-165.848, H-390.849, and H-185.954).
46 Additionally, strong policy supports coverage and payment policies for evidence-based
47 genetic/genomic precision medicine and encouraging national medical specialty societies develop
48 clinical practice guidelines incorporating evidence-based precision medicine (Policy D-185.980).

1 Extensive AMA policy emphasizes the importance of collaboration with national medical specialty
 2 societies. Policies D-330.967 and H-425.987 support continued collaboration with national medical
 3 specialty societies and interest groups to encourage coverage for evidence-based recommendations
 4 regarding preventive services, especially for populations at high risk for a given condition.
 5 Similarly, Policy D-185.979 encourages national medical specialty societies to identify services
 6 that they consider to be high-value and collaborate with payers to experiment with benefit plan
 7 designs that align patient financial incentives with utilization of high-value services. Policy
 8 H-425.988 supports continuing collaboration with the federal government, specialty societies, and
 9 others, to develop guidelines for, and effective means of delivery of, clinical preventive services.

10
 11 Long-standing AMA policy opposes benefit mandates. Policy H-165.856 sets forth principles to
 12 guide health insurance market regulation and states that the regulatory environment should enable
 13 rather than impede private market innovation in product development and purchasing
 14 arrangements, and that benefit mandates should be minimized to allow markets to determine
 15 benefit packages and permit a wide choice of coverage options. At the same time, AMA policy
 16 strongly supports the provision of evidence-based preventive services without patient cost-sharing.
 17 AMA policy does recognize the limitations of the USPSTF and emphasizes the importance of
 18 relevant specialty physician input in guideline development. Policy D-425.992 expresses concern
 19 regarding the effect that USPSTF recommendations can have on limiting access to preventive care
 20 for Americans (e.g., regarding access to screening mammography and prostate specific antigen
 21 screening) and encourages the USPSTF to implement procedures that allow for meaningful input
 22 on recommendation development from specialists and stakeholders in the topic area under study.
 23 Similarly, Policy D-450.957 specifically focuses on prostate cancer and the importance of
 24 including relevant specialty societies in guideline development.

25
 26 Finally, AMA policy strongly supports VBID and innovative insurance design. Policy H-450.938
 27 provides principles to guide physician value-based decision-making. Policy H-155.960 supports
 28 value-based decision-making and encourages third-party payers to use targeted benefit design,
 29 whereby patient cost-sharing is determined based on the clinical value of a health care service or
 30 treatment, with consideration given to tailoring cost-sharing to patient income and other factors
 31 known to impact compliance. Policy H-185.939 supports flexibility in the design and
 32 implementation of VBID programs and outlines guiding principles, including that VBID consider
 33 the clinical benefit of a given service or treatment when determining cost-sharing or other benefit
 34 design elements. Finally, Policy D-185.979 supports clinical nuance in VBID to respect individual
 35 patient needs.

36
 37 **DISCUSSION**

38
 39 The Council lauds the sponsors of referred Resolution 226-A-18 for highlighting the importance of
 40 prostate cancer screening and shares the goal of increasing access to this preventive service for
 41 appropriate patient populations. The Council is committed to developing AMA policy regarding
 42 prostate cancer screening that is consistent with the existing evidence-base, current clinical
 43 guidelines, and AMA policy. To accomplish this goal, the Council believes that the AMA should
 44 encourage public and private payers to ensure coverage for prostate cancer screening when the
 45 service is deemed appropriate following informed physician-patient shared decision-making. Such
 46 policy would be consistent with the ACS recommendations for prostate cancer screening and AMA
 47 policy regarding various common cancers (Policies H-185.936, H-525.993, and H-55.981), as well
 48 as AMA policy regarding shared and value-based decision-making (Policies H-373.997 and
 49 H-450.938). Moreover, the resolution sponsors, the ACS, and the USPSTF all emphasize the
 50 importance of informed physician-patient shared decision-making in the context of prostate cancer
 51 screening, and the Council believes that the AMA should similarly emphasize this service. National

1 medical specialty societies can play a critical role in promoting public education around the
2 importance of informed physician-patient shared decision-making regarding prostate cancer
3 screening, and the Council encourages them to do so. In addition, the Council believes that,
4 coupled with the new policies recommended in this report, reaffirming Policies H-373.997 and
5 H-450.938 will help to emphasize the importance of well-informed shared physician-patient
6 decision-making. Recognizing that the evidence-base for prostate cancer screening is rapidly
7 evolving, and that more research is needed to better understand which patients should be screened,
8 at which intervals, and with which tools, the Council recommends that Policy D-450.957 (see
9 Appendix) be amended to change the title to read, “Clinical Guidelines and Evidence Regarding
10 Benefits of Prostate Cancer Screening and Other Preventive Services,” and to add a new subsection
11 (3) encouraging scientific research to address the evidence gaps highlighted by organizations
12 making evidence-based recommendations about clinical preventive services.

13
14 In addition, as improved, evidence-based methods for detecting clinically significant prostate
15 cancer evolve, it will be essential that insurance coverage for medically necessary tests keep pace.
16 Accordingly, the Council recommends reaffirming Policies D-185.980 and H-425.997 which
17 support coverage for evidence-based genetic/genomic precision medicine and evidence-based, cost-
18 effective preventive services. Moreover, prostate cancer screening, a service that is highly valuable
19 to some patients and less necessary for others, is an outstanding example of how clinical nuance
20 can be deployed through VBID to align clinical and financial incentives around care that is high-
21 value for individual patients, consistent with Policy D-185.979. As also noted in Policy D-185.979,
22 national medical specialty societies should play a key role in helping to shape VBID plans that
23 decrease cost-sharing to encourage utilization of high-value services, and the Council recommends
24 reaffirming that policy. Similarly, the Council believes that reaffirming Policy H-185.939 will
25 emphasize the importance of VBID plans explicitly considering the clinical benefit of a given
26 service when determining cost-sharing or other benefit design elements.

27 28 RECOMMENDATIONS

29
30 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
31 226-A-18 and that the remainder of the report be filed:

- 32
33 1. That our American Medical Association (AMA) encourage public and private payers to
34 ensure coverage for prostate cancer screening when the service is deemed appropriate
35 following informed physician-patient shared decision-making. (New HOD Policy)
36
- 37 2. That our AMA encourage national medical specialty societies to promote public education
38 around the importance of informed physician-patient shared decision-making regarding
39 medical services that are particularly sensitive to patient values and circumstances, such as
40 prostate cancer screening. (New HOD Policy)
41
- 42 3. That our AMA amend Policy D-450.957 to change the title to read, “Clinical Guidelines
43 and Evidence Regarding Benefits of Prostate Cancer Screening and Other Preventive
44 Services,” and to add a new subsection, “(3) encouraging scientific research to address the
45 evidence gaps highlighted by organizations making evidence-based recommendations
46 about clinical preventive services.” (Modify Current HOD Policy)
47
- 48 4. That our AMA reaffirm Policy D-185.979 regarding aligning clinical and financial
49 incentives for high-value care and highlighting the role national medical specialty societies
50 can play in helping to shape value-based insurance design (VBID) plans that decrease
51 cost-sharing to encourage utilization of high-value services. (Reaffirm HOD Policy)

- 1 5. That our AMA reaffirm Policy H-185.939 which supports VBIID plans that explicitly
2 consider the clinical benefit of a given service when determining cost-sharing structures or
3 other benefit design elements. (Reaffirm HOD Policy)
4
- 5 6. That our AMA reaffirm Policy H-373.997, which sets forth core elements of physician-
6 patient shared decision-making and Policy H-450.938, which sets forth the principles to
7 guide physician value-based decision-making, including providing physicians with easy
8 access to costs of care at the point of decision-making. (Reaffirm HOD Policy)
9
- 10 7. That our AMA reaffirm Policy D-185.980, which supports coverage for evidence-based
11 genetic/genomic precision medicine and Policy H-425.997, which supports insurance
12 coverage for evidence-based, cost-effective preventive services. (Reaffirm HOD Policy)

Fiscal Note: Less than \$500.

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APPENDIX

Policies Recommended for Amendment or Reaffirmation

Policy, D-185.979 Aligning Clinical and Financial Incentives for High-Value Care

1. Our AMA supports Value-Based Insurance Design (VBID) plans designed in accordance with the tenets of “clinical nuance,” recognizing that (a) medical services may differ in the amount of health produced, and (b) the clinical benefit derived from a specific service depends on the person receiving it, as well as when, where, and by whom the service is provided.
2. Our AMA supports initiatives that align provider-facing financial incentives created through payment reform and patient-facing financial incentives created through benefit design reform, to ensure that patient, provider, and payer incentives all promote the same quality care. Such initiatives may include reducing patient cost-sharing for the items and services that are tied to provider quality metrics.
3. Our AMA will develop coding guidance tools to help providers appropriately bill for zero-dollar preventive interventions and promote common understanding among health care providers, payers, patients, and health care information technology vendors regarding what will be covered at given cost-sharing levels.
4. Our AMA will develop physician educational tools that prepare physicians for conversations with their patients about the scope of preventive services provided without cost-sharing and instances where and when preventive services may result in financial obligations for the patient.
5. Our AMA will continue to support requiring private health plans to provide coverage for evidence-based preventive services without imposing cost-sharing (such as co-payments, deductibles, or coinsurance) on patients.
6. Our AMA will continue to support implementing innovative VBID programs in Medicare Advantage plans.
7. Our AMA supports legislative and regulatory flexibility to accommodate VBID that (a) preserves health plan coverage without patient cost-sharing for evidence-based preventive services; and (b) allows innovations that expand access to affordable care, including changes needed to allow High Deductible Health Plans paired with Health Savings Accounts to provide pre-deductible coverage for preventive and chronic care management services.
8. Our AMA encourages national medical specialty societies to identify services that they consider to be high-value and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services. (Joint CMS CSAPH Rep. 01, I-18).

Policy, D-185.980 Payment and Coverage for Genetic/Genomic Precision Medicine

1. Our AMA encourages public and private payers to adopt processes and methodologies for determining coverage and payment for genetic/genomic precision medicine that:
 - a. Promote transparency and clarity;
 - b. Involve multidisciplinary stakeholders, including genetic/genomic medicine experts and relevant national medical specialty societies;
 - c. Describe the evidence being considered and methods for updating the evidence;
 - d. Provide opportunities for comment and review as well as meaningful reconsiderations; and
 - e. Incorporate value assessments that consider the value of genetic/genomic tests and therapeutics to patients, families and society as a whole, including the impact on quality of life and survival.
2. Our AMA encourages coverage and payment policies for genetic/genomic precision medicine that are evidence-based and take into account the unique challenges of traditional evidence development through randomized controlled trials, and work with test developers and appropriate clinical experts to establish clear thresholds for acceptable evidence for coverage.
3. Our AMA will work with interested national medical specialty societies and other stakeholders to encourage the development of a comprehensive payment strategy that facilitates more consistent coverage of genetic/genomic tests and therapeutics that have clinical impact.
4. Our AMA encourages national medical specialty societies to develop clinical practice guidelines incorporating precision medicine approaches that support adoption of appropriate, evidence-based services.

5. Our AMA supports continued research and evidence generation demonstrating the validity, meaningfulness, short-term and long-term cost-effectiveness and value of precision medicine. (Joint CMS / CSAPH Rep. 01, I-17 Reaffirmed: CMS Rep. 06, A-18)

Policy, D-450.957 Draft Clinical Quality Measures Non-Recommended PSA-Based Screening

Our AMA will: (1) continue to advocate for inclusion of relevant specialty societies and their members in guideline and performance measure development, including in technical expert panels charged with developing performance measures; and (2) work with the federal government, specialty societies, and other relevant stakeholders to develop guidelines and clinical quality measures for the prevention or early detection of disease, such as prostate cancer, based on rigorous review of the evidence which includes expertise from any medical specialty for which the recommendation may be relevant to ultimately inform shared decision making. (Res. 225, I-15).

Policy, H-185.939 Value-Based Insurance Design

Our AMA supports flexibility in the design and implementation of value-based insurance design (VBID) programs, consistent with the following principles:

- a. Value reflects the clinical benefit gained relative to the money spent. VBID explicitly considers the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements.
- b. Practicing physicians must be actively involved in the development of VBID programs. VBID program design related to specific medical/surgical conditions must involve appropriate specialists.
- c. High-quality, evidence-based data must be used to support the development of any targeted benefit design. Treatments or services for which there is insufficient or inconclusive evidence about their clinical value should not be included in any targeted benefit design elements of a health plan.
- d. The methodology and criteria used to determine high- or low-value services or treatments must be transparent and easily accessible to physicians and patients.
- e. Coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Educational materials should be made available to help patients and physicians understand the incentives and disincentives built into the plan design.
- f. VBID should not restrict access to patient care. Designs can use incentives and disincentives to target specific services or treatments, but should not otherwise limit patient care choices.
- g. Physicians retain the ultimate responsibility for directing the care of their patients. Plan designs that include higher cost-sharing or other disincentives to obtaining services designated as low-value must include an appeals process to enable patients to secure care recommended by their physicians, without incurring cost-sharing penalties.
- h. Plan sponsors should ensure adequate resource capabilities to ensure effective implementation and ongoing evaluation of the plan designs they choose. Procedures must be in place to ensure VBID coverage rules are updated in accordance with evolving evidence.
- i. VBID programs must be consistent with AMA Pay for Performance Principles and Guidelines (Policy H-450.947), and AMA policy on physician economic profiling and tiered, narrow or restricted networks (Policies H-450.941 and D-285.972). (CMS Rep. 2, A-13 Reaffirmed in lieu of Res. 122, A-15 Reaffirmed in lieu of: Res. 121, A-16 Reaffirmed: CMS Rep. 05, I-16 Reaffirmation I-16 Reaffirmed: Joint CMS/CSAPH Rep. 01, I-17 Reaffirmed: CMS Rep. 07, A-18 Reaffirmed: Joint CMS CSAPH Rep. 01, I-18)

Policy, H-373.997 Shared Decision-Making

Our AMA:

1. recognizes the formal shared decision-making process as having three core elements to help patients become active partners in their health care: (a) clinical information about health conditions, treatment options, and potential outcomes; (b) tools to help patients identify and articulate their values and priorities when choosing medical treatment options; and (c) structured guidance to help patients integrate clinical and values information to make an informed treatment choice;
2. supports the concept of voluntary use of shared decision-making processes and patient decision aids as a way to strengthen the patient-physician relationship and facilitate informed patient engagement in health care decisions;

3. opposes any efforts to require the use of patient decision aids or shared decision-making processes as a condition of health insurance coverage or provider participation;
4. supports the development of demonstration and pilot projects to help increase knowledge about integrating shared decision-making tools and processes into clinical practice;
5. supports efforts to establish and promote quality standards for the development and use of patient decision aids, including standards for physician involvement in development and evaluation processes, clinical accuracy, and conflict of interest disclosures; and
6. will continue to study the concept of shared decision-making and report back to the House of Delegates regarding developments in this area. (CMS Rep. 7, A-10 Reaffirmed in lieu of Res. 5, A-12 Reaffirmation I-14)

Policy, H-425.997 Preventive Services

1. Our AMA encourages the development of policies and mechanisms to assure the continuity, coordination and continuous availability of patient care, including professional preventive care and early-detection screening services, provided the services are cost effective.
2. It is the policy of the AMA that any preventive service that is being considered for inclusion in public or private sector insurance products have evidence-based data to demonstrate improved outcomes or quality of life and the cost effectiveness of the service.
3. Our AMA believes that preventive care should ideally be coordinated by a patient's physician.
(BOT Rep. A, NCCMC Rec. 31, A-78 Reaffirmed: CLRPD Rep. C, A-89 Reaffirmed: Sunset Report and Reaffirmed and Appended: CMS Rep. 7, A-00 Reaffirmed in lieu of Res. 104, A-06 Reaffirmation A-07 Modified and Reaffirmed: Sub. Res. 101, A-08 Reaffirmed: CMS Rep. 03, I-16 Reaffirmed: CMS Rep. 03, I-17)

Policy, H-450.938 Value-Based Decision-Making in the Health Care System

PRINCIPLES TO GUIDE PHYSICIAN VALUE-BASED DECISION-MAKING

1. Physicians should encourage their patients to participate in making value-based health care decisions.
2. Physicians should have easy access to and consider the best available evidence at the point of decision-making, to ensure that the chosen intervention is maximally effective in reducing morbidity and mortality.
3. Physicians should have easy access to and review the best available data associated with costs at the point of decision-making. This necessitates cost data to be delivered in a reasonable and useable manner by third-party payers and purchasers. The cost of each alternate intervention, in addition to patient insurance coverage and cost-sharing requirements, should be evaluated.
4. Physicians can enhance value by balancing the potential benefits and costs in their decision-making related to maximizing health outcomes and quality of care for patients.
5. Physicians should seek opportunities to improve their information technology infrastructures to include new and innovative technologies, such as personal health records and other health information technology initiatives, to facilitate increased access to needed and useable evidence and information at the point of decision-making.
6. Physicians should seek opportunities to integrate prevention, including screening, testing and lifestyle counseling, into office visits by patients who may be at risk of developing a preventable chronic disease later in life. (CMS Rep. 7, A-08 Reaffirmed in lieu of Res. 5, A-12 Reaffirmation I-14 Reaffirmation: I-17)