The Centers for Medicare & Medicaid Services (CMS) seeks stakeholder comments on the following clinical quality measure under development:

Title: Non-Recommended PSA-Based Screening

Description: The percentage of adult men who were screened unnecessarily for prostate cancer using a prostate-specific antigen (PSA)-based screening test

We seek comments from the public about the measure concept and specifications, the potential for the measure to improve health care quality, and possible barriers to measure implementation.

This document provides information about the measure, and covers five topics: (1) background about the project developing the measure, (2) measure rationale, (3) next steps for measure development, (4) a summary of the measure specifications, and (5) the full measure specifications presented in the health quality measures format.

Project background

CMS has contracted with Mathematica Policy Research to develop new clinical quality measures for potential use by eligible professionals[1] in CMS quality reporting programs. The proposed measure, Non-Recommended PSA-Based Screening, would assess quality using data from EPs' electronic health records.

Measure rationale

Background on PSA blood tests. The PSA blood test evaluates the presence of an antigen in a patient's blood and has been used to screen for prostate cancer. If results are outside a specified range, providers may perform additional tests, such as a biopsy, to confirm a cancer diagnosis.

The U.S. Preventive Services Task Force (USPSTF) has reviewed evidence on PSA-based screening and concluded that the harms of screening outweigh the benefits in a general (not at-risk) population of men. False-positive results from PSA tests are relatively common, meaning that PSA tests identify some men without cancer. PSA-based screening can also lead to detection of asymptomatic conditions that would have caused no morbidity during a patient's lifetime. For these reasons, men with a positive result on a PSA-based screening might receive unnecessary diagnostic testing or treatment—procedures with risks of complications, including urinary incontinence, erectile dysfunction, or serious cardiovascular events.

[1] Eligible professionals (EPs) are health care professionals who meet the eligibility criteria of CMS quality reporting programs and who report electronic clinical quality measures under these programs. Within the quality reporting programs, the definition of EPs can vary but generally include physicians in medicine or osteopathy, dental surgery or dental medicine, podiatric medicine, optometry, and chiropractic medicine. The Physician Quality Reporting System (PQRS) defines EPs to include physician assistants, nurse practitioners, clinical social workers, and clinical psychologists as well, among others. To see the complete list of EPs under the PQRS and the Electronic Health Record Incentive Programs, please refer to the following: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_List_of_Eligible_Professionals.pdf https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/eligibility.html

Intent of the measure. This measure targets an important area for quality improvement: reducing the use of medical services that have been found to result in more harms than benefits. The intent of this measure is to discourage the use of PSA-based screening in the general population of men. A lower rate on this measure indicates better performance.

Explanation of measure specifications. This measure is based on an existing Healthcare Effectiveness Data and Information Set (HEDIS) measure,[2] which assesses the annual rate of PSA-based screening in men 70 and older (as opposed to men of all ages). The proposed measure was written broadly to include all adult males, based on the USPSTF clinical recommendation statement. However, the team can refine the definition based on measure testing results, including results from this public comment period (see below).

Exclusions for this measure—that is, patient characteristics that would remove a patient from the quality measure calculation—are intended to remove patients who may appropriately receive a PSA test for diagnostic or surveillance purposes. For example, the measure specifications exclude patients with a current diagnosis or history of prostate cancer. The full list of exclusions for this measure is included in the measure specifications that follow. Additional exclusions may be considered.

Next steps for measure development

In addition to seeking feedback through public comment, we plan to conduct interviews and focus groups with providers and patients and to conduct quantitative testing in order to refine the measure and to understand the measure's feasibility, validity, and reliability. This measure has been designed as an electronic clinical quality measure (eCQM) and will be tested in that environment. Testing will examine variation in performance by provider specialty as well as by patient characteristics (for example, age, race, and ethnicity). These results will inform whether the measure scores should be stratified by patient characteristics and could help refine the measure population.

[2] HEDIS is a set of quality measures used by the majority of U.S. health plans to measure performance on important dimensions of care and services. See http://www.ncqa.org/HEDISQualityMeasurement/WhatisHEDIS.aspx.

Summary of measure specifications

eMeasure title	Measure description	Denominator	Numerator	Exclusions and exceptions
Non-Recommended PSA-Based Screening	Percentage of men 18 and older who were screened unnecessarily for prostate cancer using a prostate-specific antigen (PSA)-based screening test	Men 18 and older with an encounter during the measurement period	Men who receive a PSA-based screening test during the measurement period	Exclusions: Men who had any of the following: - An active diagnosis or history of prostate cancer at any time before or during the measurement year - An active diagnosis of dysplasia of the prostate during the measurement year or the year prior to the measurement year - An elevated PSA test result in the year prior to the measurement period (> 4.0 ng/mL) - An active prescription for a 5-alpha reductase inhibitor during the measurement year Exceptions: None

eMeasure Title	**Non-Recommended PSA-Based Screening**		
eMeasure Identifier (Measure Authoring Tool)	426	**eMeasure Version Number**	0.0.013
NQF Number	None	**GUID**	41163dbe-22bf-497d-9e1e-f3c340362947
Measurement Period	January 1, 20XX, through December 31, 20XX		
Measure Steward	Centers for Medicare & Medicaid Services		
Measure Developer	National Committee for Quality Assurance		
Endorsed By	None		
Description	Percentage of men 18 and older who were screened unnecessarily for prostate cancer using a prostate-specific antigen (PSA)-based screening test		
Copyright	Limited proprietary coding is contained in the measure specifications for user convenience. Users of proprietary code sets should obtain all necessary licenses from the owners of the code sets. CPT(R) contained in the measure specifications is copyright 2004–2014 American Medical Association. LOINC(R) copyright 2004–2014 Regenstrief Institute, Inc. This material contains SNOMED Clinical Terms(R) (SNOMED CT[R]) copyright 2004–2014 International Health Terminology Standards Development Organisation. ICD-10 copyright 2014 World Health Organization. All rights reserved.		
Disclaimer	These performance measures are not clinical guidelines, do not establish a standard of medical care, and have not been tested for all potential applications. THE MEASURES AND SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND. Due to technical limitations, registered trademarks are indicated by (R) or [R] and unregistered trademarks are indicated by (TM) or [TM].		
Measure Scoring	Proportion		
Measure Type	Process		
Stratification	TBD		
Risk Adjustment	None		
Rate Aggregation	None		

Rationale	The United States Preventive Services Task Force (USPSTF) recommends against PSA-based screening for prostate cancer for men of any age because the benefits of testing do not outweigh the harms (Moyer 2012). Research has shown that PSA-based screening is not highly specific. The likelihood of PSA tests producing false-positive results is relatively high; approximately 80 percent of positive tests are false positives when using the cutoff range of 2.5 to 4.0 ng/mL (Schröder et al. 2009). These false positives can result in unnecessary performance of diagnostic procedures (Moyer 2012). Prostate cancer is also subject to overdiagnosis, the detection of a condition that would have caused no morbidity during a patient's lifetime (Carter et al. 2013). Most cases of prostate cancer are slow-growing and remain asymptomatic; even cancers detected by PSA tests may not ultimately affect the patient's quality of life if left untreated (Carter et al. 2013). Two large-scale PSA-based screening studies revealed overdiagnosis rates ranging from 17 percent to 50 percent (Miller 2012). Research has shown that mortality rates are similar for individuals who are screened and individuals who are not screened. Five in 1,000 will die from prostate cancer with no screening, while 4 to 5 in 1,000 will die despite having been screened (Moyer 2012). Thus, the benefits of PSA-based screening are relatively small: screening is estimated to prevent 0 to 1 cancer deaths per 1,000 men screened (Moyer 2012).
Clinical Recommendation Statement	U.S. Preventive Services Task Force (Moyer 2012): "The USPSTF recommends against PSA-based screening for prostate cancer (grade D recommendation). This recommendation applies to men in the general U.S. population, regardless of age." Grade D: The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.
Improvement Notation	A lower rate indicates better quality.
Reference	Carter, H.B., P.C. Albertsen, M.J. Barry, et al. "Early Detection of Prostate Cancer: AUA Guideline." *Journal of Urology,* vol. 190, no. 2, 2013, pp. 419–426. doi: 10.1016/j.juro.2013.04.119.
Reference	Miller, A.B. "New Data on Prostate-Cancer Mortality After PSA Screening." *New England Journal of Medicine,* vol. 366, no. 11, 2012, pp. 1047–1048. doi: 10.1056/NEJMe1200185.
Reference	Moyer, V.A. "Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement." *Annals of Internal Medicine,* vol. 157, 2012, pp. 120–134. Available at http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prostate-cancer-screening.
Reference	Schröder, F.H., J. Hugosson, M.J. Roobol, et al., ERSPC Investigators. "Screening and Prostate-Cancer Mortality in a Randomized European Study." *New England Journal of Medicine,* vol. 360, 2009, pp. 1320–1328. doi: 10.1056/NEJMoa0810084.
Definition	None
Guidance	None
Transmission Format	
Initial Population	Men 18 and older with an encounter during the measurement period

Denominator	Equals initial population
Denominator Exclusions	Men who had any of the following: - An active diagnosis or history of prostate cancer at any time before or during the measurement year - An active diagnosis of dysplasia of the prostate during the measurement year or the year prior to the measurement year - An elevated PSA test result in the year prior to the measurement period (> 4.0 ng/mL) - An active prescription for a 5-alpha reductase inhibitor during the measurement year
Numerator	Men who receive a PSA-based screening test during the measurement period
Numerator Exclusions	Not applicable
Denominator Exceptions	None
Supplemental Data Elements	For every patient evaluated by this measure, also identify payer, race, and ethnicity.