MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 3620

Corresponding Measures:

De.2. Measure Title: Adult Immunization Status

Co.1.1. Measure Steward: National Committee for Quality Assurance

De.3. Brief Description of Measure: The percentage of adults 19 years of age and older who are up-to-date on Advisory Committee on Immunization Practice (ACIP) recommended routine vaccines for influenza, tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap), zoster and pneumococcal.

1b.1. Developer Rationale: This measure assesses the provision of critical routine immunizations for adults 19 and older per clinical guidelines. The intent of the measure is to improve primary prevention of vaccine-preventable diseases including influenza, tetanus, diphtheria, pertussis, herpes zoster and pneumococcal disease.

S.4. Numerator Statement: Adults age 19 and older who are up-to-date on recommended routine vaccines for influenza, tetanus (Td) or tetanus, diphtheria or acellular pertussis (Tdap), herpes zoster and pneumococcal based on age and recommendations.

S.6. Denominator Statement: Adults ages 19 years and older.

S.8. Denominator Exclusions: Adults with immunocompromising conditions who are contraindicated for certain vaccines and those who were in hospice during the measurement period.

De.1. Measure Type: Process

S.17. Data Source: Claims, Electronic Health Data, Electronic Health Records, Enrollment Data, Management Data, Registry Data

S.20. Level of Analysis: Health Plan

IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date:

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? N/A

Criteria 1: Importance to Measure and Report

1a. Evidence

1a. Evidence. The evidence requirements for a ***structure, process or intermediate outcome*** measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- **Systematic Review of the evidence specific to this measure?** ☐ **Yes** ☐ **No**
- **Quality, Quantity and Consistency of evidence provided?** ☒ **Yes** ☐ **No**
- **Evidence graded?** ☐ **Yes** ☒ **No**

Evidence Summary

- The developer provided individual clinical practice guidelines from the Advisory Committee on Immunization Practices (ACIP) for each vaccination: Influenza Vaccine, Tetanus Toxoid, and Reduced Diphtheria Toxoid, and Acellular Pertussis (Td/Tdap) for ages 19 years and older, and Herpes Zoster for ages 50 years and older, and Pneumococcal for ages 65 years and older. The developer did not grade the evidence and stated that ACIP did not provide grade recommendations for the guideline evidence. Minimal quantity and quality, and no consistency (QCC) findings for the evidence are provided. They developer states ACIP vaccine work groups periodically review the available data and evidence on immunogenicity, efficiency, effectiveness, and safety of influenza vaccines. The developer also states that CDC vaccine recommendations are developed using an explicit evidence-based method based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.
    - **Influenza Vaccine Recommendations**. The *Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020–21 Influenza Season* (DOI: http://dx.doi.org/10.15585/mmwr.rr6908a1) states that routine annual influenza vaccination is recommended for all persons aged ≥6 months that is appropriate for the recipient's age and health status, including those who do not have contraindications.
    - **Td/Tdap Vaccine Recommendations**. The guideline, *Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccines: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2019* (DOI: http://dx.doi.org/10.15585/mmwr.mm6903a5) recommends Td/Tdap for ages 19 years and older to ensure continued protection against tetanus and diphtheria, booster doses of either Td or Tdap should be administered every 10 years throughout life, with three initial doses at four week and six to twelve week intervals, or a "catch up" dose.
    - **Herpes Zoster Vaccine Recommendations**. The *Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines* (DOI: http://dx.doi.org/10.15585/mmwr.mm6703a5) recommends two doses of herpes zoster vaccine for all adults aged ≥50 years between two to six months apart.
    - **Pneumococcal Vaccine Recommendations**. The Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years: Updated Recommendations of the Advisory Committee on Immunization Practices (DOI:

http://dx.doi.org/10.15585/mmwr.mm6846a5) recommends that all adults aged ≥65 years receive 1 dose of PPSV23. For persons who previously received PPSV23 aged <65 years and for whom an additional dose PPSV23 is indicated when aged ≥65 years, this subsequent PPSV23 dose should be given ≥1 year after PCV13 and ≥5 years after the most recent dose of PPSV23. The 13-Valent Pneumococcal Conjugate Vaccine (PVC13) is no longer routinely recommended.

- The developer states that performance is determined by "up-to-date in routine vaccines per clinical guidelines", yet the measure does not specify the selection of individual vaccines based on patient-specific needs, such as immunocompromise, allergy, pregnancy, chronic conditions, and other examples:
    - The numerator for Measure 2 (Td/Tdap) has a look back of up to nine years from the start of the measurement period to capture vaccine administration.
    - Measure 4 (pneumococcal) has a look back of up to six years, starting on or after the patient's 60th birthday.
    - Measure 4 does not include patients less than 65 years with chronic conditions as recommended by ACIP guidelines. This measure is only calculated for Medicare patients.
- The developer modified the conceptual framework or foundational evidence from the previously submitted composite #3483, *Recommended Adult Immunization Schedule for ages 19 years or older, United States, 2021* (https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html#note-varicella), to individual vaccine-specific guidelines in the multi-item submission. In the #3483 submission, ACIP also recommends adults receive measles, mumps, and rubella (MMR) and Varicella vaccinations, which are not included in the measure constructs.
- The developer provides the evidence from the four respective guidelines without details of other study or literature reviews. They also do not state patient-specific needs for vaccine selection and appropriateness. Subsequently, exceptions to the evidence are not provided.

Questions for the Committee:

- What was the conceptual underpinnings for the measure based on other measures in the inventory? Should MMR and Varicella vaccinations also be included in the measure?
- Does the evidence support patient-specific vaccine selection and appropriateness criterion?
- For structure, process, and intermediate outcome measures:
    - What is the relationship of this measure to patient outcomes?
    - How strong is the evidence for this relationship?
- For possible exception to the evidence criterion:
    - Are there, or could there be, performance measures of a related health outcome, OR evidence-based intermediate clinical outcomes, intervention/treatment?
    - Does the SC agree that it is acceptable (or beneficial) to hold providers accountable without empirical evidence?

Guidance from the Evidence Algorithm

The measure does not assess a health outcome or PRO (Box 1) → The measure assesses four processes of care based on clinical practice guidelines for each measure (Box 3) → The empirical evidence submitted is not systematically reviewed (Box 7) → The evidence reflects the guidelines without other studies (Box 8) → The evidence indicates high certainty of benefits clearly outweighing undesirable effects → Moderate

Preliminary rating for evidence: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

RATIONALE:

The developer does not grade or provide a comprehensive QCC for the evidence, however, offer the authority or expertise of the guideline's authoring organization (ACIP) as a replacement for the systematic review (SR) and grading of the body of evidence. They also do not provide indication of additional searches, selection, or syntheses of other evidence to assess exceptions to the evidence. The evidence indicates high certainty of benefits clearly outweighing undesirable effects.

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developers cite significant performance gaps from the 2015 National Health Interview Survey (NHIS) of self-reported influenza vaccine receipt of adults 19 and older at 45%. reported that they received the influenza vaccine during the 2014–2015 flu season, 64% of aged 65 and older PPSV23 or PCV13, 23% of adults aged 19 years and older received Td/Tdap, and 31% adults aged 60 years and older ever having the herpes zoster vaccine.
- 2018 Healthcare Effectiveness Data and Information Set (HEDIS) data from Commercial (71, 80,330), Medicaid (21, 36,250), and Medicare (44, 11,648) plans and median eligible population were used to depict respective measure performance. Performance was provided by mean, 10th, 25th, 50th, 75th, 90th, and Interquartile Range (IQR) as the difference between the 25th and 75th percentile for the four vaccines. The IQRs for Medicare was 13, Medicaid was 6, and Commercial was 8.
- Medicaid performed the lowest with 10th percentile at 2.8, 4.9, and 0.0 for Influenza, Td/Tdap, and Herpes Zoster respectively, and Medicare performed the highest for the 90th percentiles at 30.1, 56.4, 39.5, and 55.4 for Influenza, Td/Tdap, Herpes Zoster, and Pneumococcal (Medicare only). Overall measure performance data vaccination was not provided across health plans.
- Numerator performance is calculated with both timed vaccine administration and previous adverse reactions, rather than excluding for previous adverse reactions as in other immunization measures.
- For Measure 4, the previous composite submission (#3483) included "both the 13-valent pneumococcal conjugate vaccine [PVC13] and the 23-valent pneumococcal polysaccharide vaccine [PPSV23] at least 12 months apart, with the first occurrence after the age of 60, before or during the Measurement Period" or experienced an adverse reaction. Both PVC13 and PPSV23 were included in the numerator. Due to a 2020 evidence shift, the current submission removed the PVC13 vaccine and defines the numerator with only the PPSV23 vaccine, yet identical pneumococcal performance data is provided in both submissions.

  Adult Immunization Status: Pneumococcal Medicare, 2018: Mean (20.3), 10th (5.4), 25th (8.1), 50th (10.8), 75th (22.5), 90th (55.4), and Interquartile Range 14.4.

Disparities

- The developers cite multiple studies that reports racial and ethnic disparities in adult vaccinations, using the NHIS data which found Whites were more likely to be vaccinated for Influenza than Blacks and Hispanics (47 to 37 and 33 percent). For Tdap and Td boosters, pneumococcal, and herpes zoster vaccinations were higher in Whites adults aged 19 years and older than Black, Hispanic, and Asian adults particularly due to increased vaccinations among White older persons.
- From the varied date element sources used to calculate performance, the developer does not offer disparities data beyond plan stratification, which is uses as a proxy for socioeconomic status. NQF measure evaluation guidance provides additional guidance and context for Population Health measures, stating "If health disparities have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender)" (p. 68).

Questions for the Committee:

- How is performance effected with adverse reactions included in the numerator for all vaccines, rather than excluded from the denominator?
- How would the identified performance gaps be used to target needed populations considering the evidence-based reported disparities, including providers who have not implemented EHRs?
- Does the presented 2018 Medicare Pneumococcal Vaccine performance data also include PVC13 performance data? If so, is additional data available to differentiate the two different populations?
- Does the Committee feel the demonstrated performance gaps and disparities in the four individual vaccines as presented warrant a national performance measure, and can differentiate performance among and between populations?

Preliminary rating for opportunity for improvement: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:

Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence to Support Measure Focus: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures –are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission? For measures derived from a patient report: Measures derived from a patient report must demonstrate that the target population values the measured outcome, process, or structure.

- Evidence provided for Zoster and Pneumococcal vaccines has age recs of >=50 and >=65, respectively. Why would this metric lower to 19+? Also, why are MMR and varicella not included?
- This measure is a process measure. The outcome measure is: Percentage of adults 19 years of age and older who are up-to-date on recommended routine vaccines for influenza, tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap), zoster and pneumococcal. The intent of the measure is to improve primary prevention of vaccine-preventable diseases including influenza, tetanus, diphtheria, pertussis, herpes zoster and pneumococcal disease. The developer provided individual clinical practice guidelines from the Advisory Committee on Immunization Practices (ACIP) for each vaccination: Influenza Vaccine, Tetanus Toxoid, and Reduced Diphtheria Toxoid, and Acellular Pertussis (Td/Tdap) for ages 19 years and older, and Herpes Zoster for ages 50 years and older, and Pneumococcal for ages 65 years and older.

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- Variability is described by insurance type and race/ethnicity.
- A performance gap exists: To demonstrate meaningful differences in performance, NCQA calculated an inter-quartile range (IQR) for each indicator. The IQR provides a measure of the dispersion of performance. The IQR can be interpreted as the difference between the 25th and 75th percentile on a measure. To determine if this difference is statistically significant, NCQA calculated an independent sample t-test of the performance difference between two randomly selected plans at the 25th and 75th percentile. The t-test method calculates a testing statistic based on the sample size, performance rate, and standardized error of each plan. The test statistic is then compared against a normal distribution. If the p value of the test statistic is less than 0.05, then the two plans' performance is significantly different from each other. Using this method, we compared the performance rates of two randomly selected plans, one plan in the 25th percentile and another plan in the 75th percentile of performance. We used these two plans as examples of measures entities. However, the method can be used for comparison of any two measured entities.

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Composite measures only:

Complex measure evaluated by Scientific Methods Panel (SMP)? ☐ **Yes** ☒ **No**

Reliability

- 2a1. Specifications
    - NQF's measure evaluation criteria states, "Measures with multiple measure components that are assessed for each patient, but that result in multiple scores for an accountable entity, rather than a single score [are not composite measures]. These generally should be submitted as separate measures and indicated as paired/grouped measures" (p. 51).
    - The data element sources used in the measures include claims, registry, abstracted from an electronic health record (EHR), and management data. It is not clear how the varied data elements were used for all four vaccines, nor if data from inpatient or long-term care are used to identify vaccines received and performance calculations. Although data element validity testing was not conducted by the developer, it is not clear if the developer intended for the measure to be used by non-EHR providers. Health Information Exchange (HIE) and Enrollment Data are reported in the submission, though they are not identified in the data sources.
    - Patients are excluded from receiving a vaccine if they are immunocompromised or in hospice during the measurement period. Unlike other vaccination measures, patients with adverse reactions to any of the individual vaccines are *included in the numerator* for all individual vaccines, rather than excluded from the denominator.

- 2a2. Reliability Testing
    - The developer used 2018 HEDIS data from health plans with median eligible patients per plan including commercial (71, 80,330), Medicaid (21, 36,250), and Medicare (44, 11,648) in geographically diverse areas. No other data descriptives or specifics are provided. They also note the described data sources that were "in line with NCQA's HEDIS Electronic Clinical Data Systems reporting method". The developer states that HIE and enrollment data was also used in the submission, which are not identified in the data sources.
    - For performance score reliability testing, the developer uses signal to noise to confidently distinguish the performance of one accountable entity from another. Scores range from 0.0 to 1.0 and a reliability score greater than or equal to 0.7 is considered very good. Overall reliability, minimum, 10^{th}, 25^{th}, 50^{th}, 75^{th}, 90^{th}, and maximum reliability was reported.
    - Overall, minimum, and maximum reliability for the four vaccines by plan (commercial; Medicaid; and Medicare) is provided, which includes two vaccines (i.e., Influenza (1.000, 0.961, 1.000; 1.000, 0.976, 1.000; 1.000. 0.838, 1.000) and Td/Tdap (1.000, 0.988, 1.000;

1.000, 0.988, 1.000; 1.000, 0.904, 1.000)) were tested for aged 19+ years, one for aged 50+ years (i.e., Herpes Zoster (0.999, 0.902, 1.000; 0.999, 0.686, 1.000; 1.000, 0.928, 1.000), and one for 66+ years across commercial (i.e., Pneumococcal – Medicare only 1.000, 0.951, 1.000).

- All provided results are above the threshold of 0.7 except the Medicaid minimum for the herpes zoster rate, which is 0.686.

Questions for the Committee regarding reliability:

- Does the Committee have any concerns with the submission of a measure with four performance scores rather than four individual grouped submissions?
- Does the Committee have concerns with the inclusion of adverse reactions used to calculate positive performance in the numerator for all four vaccines, rather than an exclusion in the denominator?
- Should all previous adverse reactions be considered for each vaccine if alternative vaccines are available for select adverse reactions (e.g., Influenza live attenuated vaccine (LAIV4) egg allergy for influenza vaccine)?
- Does the Committee have concerns with the varied sources of the data elements used for each of the four varying vaccines? As this is not an electronically specified clinical quality measure (eCQM), does the Committee have any reliability concerns about the use of abstracted data from paper record? How is health plan performance and measure reliability effected when data is not sourced from an EHR or standardized immunization registry?
- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- The staff questions related to the specifications may affect the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

Validity

- The developer conducted face validity and empirical construct validity testing of measure performance for whether the indicators within this measure were correlated to each other, as well as to other measure correlates.
- Face validity was performed with a seven-member Adult Immunization Measurement Advisor Panel (MAP), a 12-member Technical Measurement Advisory Panel (TMAP), and a 21-member Committee on Performance Measurement (CPM) whose work is reviewed by the developers Board of Directors. Of the 15 CPM members who voted (zero abstained or opposed), all proposed the measure for public comment. After comments were reviewed, 16 CPM members voted to approve (zero abstained or opposed) the measure for HEDIS plan reporting. The developers reported their Board of Directors approved the measure without vote details. The developer does not provide details on whether the measure: (1) demonstrates the data elements are correct, (2) calculates the score correctly, (3) reflects the quality of care provided, and (4) adequately identifying differences in quality. No Adult Immunization MAP or TMAP discussions or findings are provided. They do state that the 2016 Field Test was used for face validity without additional details.
- Construct validity testing was conducted in two ways: (1) among the vaccinations of the measure to detail the strength of associations to each other, and (2) Pearson Correlation Coefficients other NQF endorsed measures previously developed from the developer by health plan category (i.e., commercial, Medicaid, and Medicare). Developers hypothesized that health plans that perform well on the measure should perform well on vaccine measures for pregnant women, adolescents, adults, and older adults.
- Pearson's correlation coefficients were conducted to assess the association of the vaccines to each other within the measure (i.e., Influenza, Td/Tdap, Herpes Zoster, and Pneumococcal) by commercial,

Medicaid, and Medicare plans based on patient age for each vaccine. All results by plan ranged from 0.58 to 0.95 inclusive with p-values < 0.05 for all associations.

- Interpretations for Pearson's correlation are from -1 to +1 with 1 indicating a perfect direct linear dependence, 0 indicating no linear association, values of -1 indicates a perfect indirect linear relationship. Coefficients < 0.3 are generally considered weak associations and values of ≥ 0.3 denote moderate to strong associations. The p-value indicates the probability of obtaining a difference at least as large as the one observed due to chance alone with a threshold of ≤ 0.05. The developer provides a second interpretation in 2b1.4, "For the purposes of this analysis and the intended use of this measure to evaluate the quality of care for members across health plans, correlation was considered high (strong) if the correlation coefficient is 0.75 to 1, moderate if 0.25 to 0.75, and low (weak) if 0 to 0.25."
- For commercial plans, construct validity was tested against composite *#3484* Prenatal Immunization Status (i.e., Influenza, Tdap, and both vaccines). Results ranged from 0.40 to 0.79; and *#1407* Immunizations for Adolescents (i.e., Meningococcal, Tdap, Human Papillomavirus, and all three vaccines) ranged from 0.29 to 0.69. Commercial plans demonstrated weak performance was demonstrated for *#1407* Meningococcal Td/Tdap (0.31) and Herpes Zoster (0.29) and *#1407* Tdap to Herpes Zoster (0.31). Commercial plans performed lower than Medicaid plans in *#3484* and *#1407*. All other results were moderate to low/moderate.
- For Medicaid plans, construct validity was tested against composite *#3484* Prenatal Immunization Status (i.e., Influenza, Tdap, and both vaccines). Results for *#3484* ranged from 0.54 to 0.87; and *#1407* Immunizations for Adolescents (i.e., Meningococcal, Tdap, Human Papillomavirus, and all three vaccines) ranged from 0.30 to 0.75. For Medicaid plans, weak performance was demonstrated *#1407* Meningococcal to Td/Tdap (0.30) and Herpes Zoster (0.30) and p-values, not specifically defined, were > 0.5. All other results were moderate to low/moderate.
- For Medicare, construct validity was tested against Flu Vaccination for Older Adults [which is assumed a performance rate of *#0039* Flu Vaccinations for Adults Ages 18 and Older] and unendorsed *#0043* Pneumococcal Vaccinations for Older Adults (endorsement was removed June 24, 2016) for Medicare plans. Results to *#0039* ranged from 0.36 to 0.46 and for *#0043* ranged from 0.06 (p-values, not specifically defined, were > 0.5) to 0.41, with *#0043* to Influenza at 0.06 and Herpes Zoster at 0.31. All other results were low/moderate.
- Field testing was conducted in 2016 for analysis of exclusions of the overall measure score. exclusion, in three health plans for each of the plan categories stratified by age with minimum and maximum eligible patients across the category plans provided.
- The developer provides detailed descriptive analyses of exclusions, defined by their measurement advisory panels, from the initial population for commercial (71, 3%), Medicaid (21, 6%), and Medicare (44, 11%) plans. The developer stated Medicare members would be excluded at higher numbers as the population is more likely to meet the specified exclusions. The 2016 Field Test of three commercial, Medicaid, and Medicare plans demonstrated with and without applied exclusion performance rates with very minimal differences in all plans.
- Meaningful differences in performance were calculated with an independent sample t-test and an inter-quartile range (IQR), interpreted as the difference between the 25th and 75th percentile on a measure, for each vaccine and each plan. Commercial plans demonstrated IQRs for Influenza (5.7), Td/Tdap (9.8), and Herpes Zoster (2.4), Medicaid (7.5, 10.9, 1.0), and Medicare (13.4, 13.9, 13.6, 14.4) with the fourth IQR for pneumococcal. All p-values < 0.001.
- The developer states that analyses of missing data were performed, though details are not provided, including impacts to measure constructs (numerator, denominator, denominator exclusions, and timeframes for vaccinations) and data sources.
- NQF Population Health measures should show meaningful differences among and between diverse populations. The measure results are only stratified by vaccines which are defined by age and health

plan in the individual vaccines. No other social factors are provided in the array of data element sources. As a process measure, no risk adjustment is required.

Questions for the Committee regarding validity:

- Does the Committee have concerns with the developer selecting construct validity correlate measures that were also developed by the developer, the composite components to as correlates (i.e., *#3484*) and performance rates within a measure (i.e., *#0039*), or the use of non-endorsed as a measure correlate (i.e., *#0043)*?
- Does the Committee have concerns with the weak/low Pearson's results for the following?
    - Commercial plans *#1407* Meningococcal Td/Tdap (0.31) and Herpes Zoster (0.29) and *#1407* Tdap to Herpes Zoster (0.31).
    - Medicaid plans *#1407* Meningococcal to Td/Tdap (0.30) and Herpes Zoster (0.30) and p-values, not specifically defined, were > 0.5.
    - Medicare Plans *#0043* to Influenza at 0.06 (p-values, not specifically defined, were > 0.5) and Herpes Zoster at 0.31.
- Do you have any concerns regarding the validity of the measure (e.g., exclusions analyses, absence of missing data analysis, and meaningful differences in performance analyses)?
- Should the measure stratify performance by other demographic and social risk data to understand meaningful differences in populations?
- The staff has questions with the correlate selection and validity findings for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

- Although the accountable entity/measure score reliability testing results were high, questions related to the specification lowered the score to moderate.

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- None
- Used signal-to-noise analysis No issues.
- We used the Beta-binomial model to assess how well one can confidently distinguish the performance of one accountable entity from another. Conceptually, the Beta-binomial model is the ratio of signal to noise. The signal is the proportion of the variability in measured performance that can be explained by real differences in performance. The Beta-binomial model is an appropriate model when estimating the reliability of simple pass/fail rate measures as is the case with most HEDIS measures. Reliability scores range from 0.0 to 1.0. A score of zero implies that all variation is attributed to measurement error (i.e., noise), whereas a reliability of 1.0 implies that all variation is caused by a real difference in performance (across accountable entities). The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one plan from another. A reliability score greater than or equal to 0.7 is considered very good.

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure?

- None
- No concerns.

2b1. Validity - Testing: Do you have any concerns with the testing results?

- In a context of vaccine hesitancy, it will be important to calibrate/assess within sub-populations that might be particularly hesitant including both racial and ethnic minority communities and conservative, white communities.
- No

2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data) 2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

- None
- No

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment) 2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure? 2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- None
- Not needed. This is a process measure.

Criterion 3. Feasibility

3. **Feasibility** is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.
    - The developer conducted a Field Test in 2016 to determine the feasibility of wide array of data collection sources and to assess provider burden. Data element sources and data from varied sources from administrative claims, immunization registries, abstracted from EHRs, and management data, which the developer states are readily available in clinical care documentation. The developer also mentions HIE and enrollment data, as well as HEDIS conforming sources, which are not identified in the data sources. The developer does not mention data from inpatient or long-term care to identify administered vaccines.
    - The developer does not provide the methods or results of the provider burden assessment for a multi-item measure, without the composite score, in the presence of other related and competing measures with these same concepts.
    - The measure is for use in HEDIS Electronic Clinical Data Systems Reporting Method, although it is not clear if it is also intended for use by non-EHR providers as abstracted data is not sourced from paper medical records, or the barriers when an immunization registry is not available.
    - The measure does not appear to account for self-reported vaccine administration for any of the four measures, which may lower performance scores and add administrative implementation burden to providers without available immunization registries.
    - The developer does not discuss look-back and catch-up vaccinations (e.g., Td/Tdap, Herpes Zoster, and Pneumococcal) or the mechanisms for timing between vaccines.

Questions for the Committee:

- Does the Committee have concerns with availability or burden of data collection and implementation for the four vaccines without assessing for patient-specific recommendations or with other existing related or competing measures?
- How was provider implementation burden assessed in the field test? What were the results?
- What is the data collection burden without an EHR and standardized immunization registry?
- Should/Are self-reported vaccines be included in the multi-sourced data elements?
- Are the required data elements routinely generated and used during care delivery?
- If an eCQM, does the eCQM Feasibility Score Card demonstrate acceptable feasibility in multiple EHR systems and sites?

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

3. Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?

- No concerns re: burden, but I would like to explore the potential inclusion of self-reported vaccines.
- The developer conducted a Field Test in 2016 to determine the feasibility of wide array of data collection sources and to assess provider burden. Data element sources and data from varied sources from administrative claims, immunization registries, abstracted from EHRs, and management data, which the developer states are readily available in clinical care documentation. The developer also mentions HIE and enrollment data, as well as HEDIS conforming sources, which are not identified in the data sources. The developer does not mention data from inpatient or long-term care to identify administered vaccines.

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☒ **Yes** ☐ **No**

Quality Improvement (Internal to the specific organization) Healthcare Effectiveness Data and Information Set (HEDIS) https://www.ncqa.org/hedis/using-hedis-measures/

Current use in an accountability program? ☐ **Yes** ☒ **No** ☐ **UNCLEAR**

OR

Planned use in an accountability program? ☒ **Yes** ☐ **No**

Accountability program details

- The developer states they are currently assessing the number of plans that can report the measure; whether measure results are as anticipated; whether results seem indicative of true performance; and whether performance indicates an opportunity for improvement for the industry overall. Because this measure uses the newer HEDIS Electronic Clinical Data Systems Reporting Method, NCQA's timeline and plan are to assess these issues after each year of the measure's reporting and anticipate the measure will be approved for public reporting and eligible program use in the next several years.
- In the previous composite review, the SC stated that individual providers, mainly primary care and pharmacists, will be responsible for accountability, even though it is health plan specified measure.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured, and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure.

Feedback on the measure by those being measured or others

- Health plans that report HEDIS calculate performance rates when submitting measures which are publicly reported and benchmarked across all plans to help plans understand how they perform relative to other plans. Public reporting and benchmarking are effective quality improvement methods.

Additional Feedback:

- As a previously submitted composite *(#3483*), the measure was reviewed by the Scientific Methods Panel (SMP) the measure was discussed based on the developer's selection of "Integrated Delivery System" (IDS) as a level of analysis, along with "health plan", although testing was only provided by the health plan. Although the measure was tested in health plan IDs', the measure could be used in non-IDS settings and the developer removed the IDS level of analysis. SMP members raised a second issue: the developer's reliability testing results indicate a nearly perfect reliability score (0.999) for some health plans, using the beta binomial approach (i.e., Adams' method). One SMP member pointed out that the application of this equation at the health plan level, rather than the patient level, contributed to some inflation of the score; however, given the large sample size, this overestimation would likely not have a significant impact on the reliability score, which would still be relatively high.
- The Committee reviewed measure at the fall 2010 Prevention and Population Health Standing Committee meeting and voted "consensus not reached" on the quality construct of the composite. The developer was deferred to a later cycle.

***Questions for the Committee**:*

- Is the measure intended for individual provider accountability use in future implementation plans as the level of analysis for the specification and the accompanied testing is the health plan?
- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare beyond existing measures in the portfolio?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

RATIONALE:

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

- **4b. Usability** evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities. During a recent public comment posting held during the measure development process, most of the comments from measured entities supported the new measure. In general, respondents found the measures to be relevant and clearly specified.

The Centers for Disease Control and Prevention (CDC), the federal National Vaccine Program Office and the American Immunization Registry Association supported the measure in recent public commenting during the measure development highlighting the need for measures assessing routine adult immunizations as many adults still do not receive these important vaccines.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

- Health plans that report HEDIS calculate their rates and know their performance when submitting to NCQA. NCQA publicly reports rates across all plans and creates benchmarks, published on the HEDIS Quality Compass tool, in order to help plans understand how they perform relative to other plans. Public reporting and benchmarking are effective quality improvement methods. Technical Assistance is provided to users.

Improvement results

Improvement results are not provided by the developer.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- The developer reported no unintended findings were identified for this measure during testing or since implementation.

Potential harms:

- The developer reported no unintended or potential harms were identified for this measure during testing or since implementation.

Additional Feedback:

Questions for the Committee*:*

- As a Health Plan level of analysis, does the developer intend to submit this measure for use in The CMS Merit-based Incentive Payment System (MIPS) as an individual eligible clinician measure, specifically for patients without insurance or coverage shifts?
- Does adding the adverse reactions to numerator, rather than using as a denominator exclusion as with other immunization measures, affect the usability and utility of the measure? What was the impetuous for the construct change?
- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided? 4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- Measure currently under consideration for use in accountability programs and "several orgs" have provided feedback.
- Use: For public reporting and program accountability

4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations? 4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- No concerns.
- The Work Group reviewed vaccine safety—compared to the morbidity and mortality risks associated with pneumonia—for studies published from 2004-2014 and concluded that “benefits outweigh harms.”

Criterion 5: Related and Competing Measures

Related or competing measures
0039: Flu Vaccinations for Adults Ages 18 and Older
0041: Preventive Care and Screening: Influenza Immunization
0043: Pneumococcal Vaccination Status for Older Adults (PNU)
0431: INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL
0680: Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)
0681: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (Long Stay)
0682: Percent of Residents or Patients Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay)
0683: Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Long-Stay)
1653: Pneumococcal Immunization
1659: Influenza Immunization

Harmonization

- Other measures exist in the inventory specific to influenza that utilize the same or similar measure concepts and constructs.
- This measure assesses vaccines provided in the outpatient setting at the health plan level while the related vaccination measures focus only on either pneumococcal or influenza vaccination.
- This measure is specified to use electronic clinical data, while other related measures are specified to use survey data in which patients must recall whether they had received a vaccine.
- This measure assesses whether health plan members received the appropriate type and doses of vaccines at the right time according to clinical guidelines rather than rely on patient recall.

- The proposed measure also includes four separate rates for each recommended routine adult vaccine, which provides a more complete picture of adult vaccinations at the health plan level.

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- Unsure
- There are competing measures. They are not harmonized. Their proposed measure is more specific than several of the other adult vaccination measures because it assesses whether health plan members received the appropriate type and doses of vaccines at the right time according to clinical guidelines. Other vaccine measures that require the use of survey data are less specific because they rely on patient recall of whether they had received a vaccine. Their proposed measure includes four separate rates for each recommended routine adult vaccine, which provides a more complete picture of adult vaccinations at the health plan level.

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 06/17/2021

- No NQF Members have submitted support/non-support choices as of this date.
- No Public or NQF Member comments submitted as of this date.

Scientific Acceptability: Preliminary Analysis Form

Measure Title: Adult Immunization Status

Measure is:

☒ **New** ☐ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☐ **Yes** ☒ **No**

   Submission document: "MIF_xxxx" document, items S.1-S.22

2. **Briefly summarize any concerns about the measure specifications.**

   - NQF's measure evaluation criteria states, "Measures with multiple measure components that are assessed for each patient, but that result in multiple scores for an accountable entity, rather than a single score [are not composite measures]. These generally should be submitted as separate measures and indicated as paired/grouped measures" (p. 51).
   - The data element sources used in the measures include claims, registry, abstracted from an electronic health record (EHR), and management data. It is not clear how the varied data elements were used for all four vaccines, nor if data from inpatient or long-term care are used to identify vaccines received and performance calculations. Although data element validity testing was not conducted by the developer, it is not clear if the developer intended for the measure to be used by non-EHR providers. Health Information Exchange (HIE) and Enrollment Data are reported in the submission, though they are not identified in the data sources.

- Patients are excluded from receiving a vaccine if they are immunocompromised or in hospice during the measurement period. Unlike other vaccination measures, patients with adverse reactions to any of the individual vaccines are *included in the numerator* for all individual vaccines, rather than excluded from the denominator.

RELIABILITY: TESTING

Type of measure:

☐ **Outcome (including PRO-PM)** ☐ **Intermediate Clinical Outcome** ☒ **Process**

☐ **Structure** ☐ **Composite** ☒ **Cost/Resource Use** ☐ **Efficiency**

Data Source:

☐ **Abstracted from Paper Records** ☒ **Claims** ☒ **Registry**

☒ **Abstracted from Electronic Health Record (EHR)** ☐ **eMeasure (HQMF) implemented in EHRs**

☐ **Instrument-Based Data** ☒ **Enrollment Data** ☐ **Other Health Information Exchange and Case Management Data**

Level of Analysis:

☐ **Individual Clinician** ☐ **Group/Practice** ☐ **Hospital/Facility/Agency** ☒ **Health Plan**

☐ **Population: Regional, State, Community, County or City** ☐ **Accountable Care Organization**

☐ **Integrated Delivery System** ☐ **Other (please specify)**

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☒ **Measure score** ☐ **Data element** ☐ **Neither**
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure** ☐ **Yes** ☒ **No**
5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of **patient-level data** conducted?

   ☐ **Yes** ☐ **No**
6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2.2

   - The developer used 2018 HEDIS data from health plans with median eligible patients per plan including commercial (71, 80,330), Medicaid (21, 36,250), and Medicare (44, 11,648) in geographically diverse areas. No other data descriptives or specifics are provided. They also note the described data sources that were "in line with NCQA's HEDIS Electronic Clinical Data Systems reporting method". The developer states that HIE and enrollment data was also used in the submission, which are not identified in the data sources.
   - For performance score reliability testing, the developer uses signal to noise to confidently distinguish the performance of one accountable entity from another. Scores range from 0.0 to 1.0 and a reliability score greater than or equal to 0.7 is considered very good. Overall reliability, minimum, 10th, 25th, 50th, 75th, 90th, and maximum reliability was reported.

7. **Assess the results of reliability testing**

   Submission document: Testing attachment, section 2a2.3

   - Overall, minimum, and maximum reliability for the four vaccines by plan (commercial; Medicaid; and Medicare) is provided, which includes two vaccines (i.e., Influenza (1.000, 0.961, 1.000; 1.000, 0.976,

1.000; 1.000. 0.838, 1.000) and Td/Tdap (1.000, 0.988, 1.000; 1.000, 0.988, 1.000; 1.000, 0.904, 1.000)) were tested for aged 19+ years, one for aged 50+ years (i.e., Herpes Zoster (0.999, 0.902, 1.000; 0.999, 0.686, 1.000; 1.000, 0.928, 1.000), and one for 66+ years across commercial (i.e., Pneumococcal – Medicare only 1.000, 0.951, 1.000).

- All provided results are above the threshold of 0.7 except the Medicaid minimum for the herpes zoster rate, which is 0.686.

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   Submission document: Testing attachment, section 2a2.2

   ☐ **Yes**

   ☐ **No**

   ☒ **Not applicable** (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and **all** testing results):

    ☐ **High** (NOTE: Can be HIGH **only if** score-level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has **not** been conducted)

    ☐ **Low** (NOTE: Should rate **LOW** if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: Should rate **INSUFFICIENT** if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**

    Although the accountable entity/measure score reliability testing results were high, questions related to the specification lowered the score to moderate.

VALIDITY: TESTING

12. **Validity testing level: ☒ Measure score ☐ Data element ☐ Both**

13. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?**
    NOTE that data element validation from the literature is acceptable.

    Submission document: *Testing attachment, section 2b1.*

    ☐ **Yes**

    ☐ **No**

    ☒ **Not applicable** (data element testing was not performed)

14. **Method of establishing validity of the measure score:**

    ☒ **Face validity**

    ☒ **Empirical validity testing of the measure score**

    ☐ **N/A (score-level testing not conducted)**

15. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

Submission document: Testing attachment, section 2b1.

☐ **Yes**

☒ **No**

☐ **Not applicable** (score-level testing was not performed)

16. **Assess the method(s) for establishing validity**

- The developer conducted face validity and empirical construct validity testing of measure performance for whether the indicators within this measure were correlated to each other, as well as to other measure correlates.
- Face validity was performed with a seven-member Adult Immunization Measurement Advisor Panel (MAP), a 12-member Technical Measurement Advisory Panel (TMAP), and a 21-member Committee on Performance Measurement (CPM) whose work is reviewed by the developers Board of Directors. Of the 15 CPM members who voted (zero abstained or opposed), all proposed the measure for public comment. After comments were reviewed, 16 CPM members voted to approve (zero abstained or opposed) the measure for HEDIS plan reporting. The developers reported their Board of Directors approved the measure without vote details. The developer does not provide details on whether the measure: (1) demonstrates the data elements are correct, (2) calculates the score correctly, (3) reflects the quality of care provided, and (4) adequately identifying differences in quality. No Adult Immunization MAP or TMAP discussions or findings are provided. They do state that the 2016 Field Test was used for face validity without additional details.
- Construct validity testing was conducted in two ways: (1) among the vaccinations of the measure to detail the strength of associations to each other, and (2) Pearson Correlation Coefficients other NQF endorsed measures previously developed from the developer by health plan category (i.e., commercial, Medicaid, and Medicare). Developers hypothesized that health plans that perform well on the measure should perform well on vaccine measures for pregnant women, adolescents, adults, and older adults.
- Pearson's correlation coefficients were conducted to assess the association of the vaccines to each other within the measure (i.e., Influenza, Td/Tdap, Herpes Zoster, and Pneumococcal) by commercial, Medicaid, and Medicare plans based on patient age for each vaccine. All results by plan ranged from 0.58 to 0.95 inclusive with p-values < 0.05 for all associations.
- Interpretations for Pearson's correlation are from -1 to +1 with 1 indicating a perfect direct linear dependence, 0 indicating no linear association, values of -1 indicates a perfect indirect linear relationship. Coefficients < 0.3 are generally considered weak associations and values of ≥ 0.3 denote moderate to strong associations. The p-value indicates the probability of obtaining a difference at least as large as the one observed due to chance alone with a threshold of ≤ 0.05. The developer provides a second interpretation in 2b1.4, "For the purposes of this analysis and the intended use of this measure to evaluate the quality of care for members across health plans, correlation was considered high (strong) if the correlation coefficient is 0.75 to 1, moderate if 0.25 to 0.75, and low (weak) if 0 to 0.25."

Submission document: Testing attachment, section 2b2.2

17. **Assess the results(s) for establishing validity**

Submission document: Testing attachment, section 2b2.3

- For commercial plans, construct validity was tested against composite *#3484* Prenatal Immunization Status (i.e., Influenza, Tdap, and both vaccines). Results ranged from 0.40 to 0.79; and *#1407* Immunizations for Adolescents (i.e., Meningococcal, Tdap, Human Papillomavirus, and all three

vaccines) ranged from 0.29 to 0.69. Commercial plans demonstrated weak performance was demonstrated for *#1407* Meningococcal Td/Tdap (0.31) and Herpes Zoster (0.29) and *#1407* Tdap to Herpes Zoster (0.31). Commercial plans performed lower than Medicaid plans in *#3484* and *#1407*. All other results were moderate to low/moderate.

- For Medicaid plans, construct validity was tested against composite *#3484* Prenatal Immunization Status (i.e., Influenza, Tdap, and both vaccines). Results for *#3484* ranged from 0.54 to 0.87; and *#1407* Immunizations for Adolescents (i.e., Meningococcal, Tdap, Human Papillomavirus, and all three vaccines) ranged from 0.30 to 0.75. For Medicaid plans, weak performance was demonstrated *#1407* Meningococcal to Td/Tdap (0.30) and Herpes Zoster (0.30) and p-values, not specifically defined, were > 0.5. All other results were moderate to low/moderate.
- For Medicare, construct validity was tested against Flu Vaccination for Older Adults [which is assumed a performance rate of *#0039* Flu Vaccinations for Adults Ages 18 and Older] and *#0043* Pneumococcal Vaccinations for Older Adults (endorsement was removed June 24, 2016) for Medicare plans. Results to *#0039* ranged from 0.36 to 0.46 and for *#0043* ranged from 0.06 (p-values, not specifically defined, were > 0.5) to 0.41, with *#0043* to Influenza at 0.06 and Herpes Zoster at 0.31. All other results were low/moderate.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

18. **Please describe any concerns you have with measure exclusions.**

Submission document: Testing attachment, section 2b2.

- Field testing was conducted in 2016 for analysis of exclusions of the overall measure score in three health plans for each of the plan categories stratified by age with minimum and maximum eligible patients across the category plans provided.
- The developer provides detailed descriptive analyses of exclusions, defined by their measurement advisory panels, from the initial population for commercial (71, 3%), Medicaid (21, 6%), and Medicare (44, 11%) plans. The developer stated Medicare members would be excluded at higher numbers as the population is more likely to meet the specified exclusions. The 2016 Field Test of three commercial, Medicaid, and Medicare plans demonstrated with and without applied exclusion performance rates with very minimal differences in all plans.
- No concerns with the exclusion analysis.

19. **Risk Adjustment**

Submission Document: Testing attachment, section 2b3

19a. **Risk-adjustment method** ☐ **None** ☐ **Statistical model** ☒ **Stratification**

The measure uses the age parameters of the individual vaccines for the health plans to stratify demographic and socioeconomic status, respectively.

19b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☐ Yes ☐ No ☒ Not applicable

19c. **Social risk adjustment:**

19c.1 Are social risk factors included in risk model? ☐ Yes ☐ No ☒ Not applicable

19c.2 Conceptual rationale for social risk factors included? ☐ Yes ☐ No

19c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☐ No

19d. **Risk adjustment summary:**

19d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No

19d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion?
☐ Yes ☐ No

19d.3 Is the risk adjustment approach appropriately developed and assessed? ☐ Yes ☐ No

19d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration)
☐ Yes ☐ No

19d.5. Appropriate risk-adjustment strategy included in the measure? ☐ Yes ☐ No

19e**. Assess the risk-adjustment approach**

20. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

Submission document: Testing attachment, section 2b4.

- Meaningful differences in performance were calculated with an independent sample t-test and an inter-quartile range (IQR), interpreted as the difference between the 25th and 75th percentile on a measure, for each vaccine and each plan. Commercial plans demonstrated IQRs for Influenza (5.7), Td/Tdap (9.8), and Herpes Zoster (2.4), Medicaid (7.5, 10.9, 1.0), and Medicare (13.4, 13.9, 13.6, 14.4) with the fourth IQR for pneumococcal. All p-values < 0.001.
- NQF Population Health measures should show meaningful differences among and between diverse populations. The measure results are only stratified by vaccines which are defined by age and health plan in the individual vaccines. No other social factors are provided in the array of data element sources. As a process measure, no risk adjustment is required.

21. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**
Submission document: Testing attachment, section 2b5.

- The developer did not report comparability of data from multiple sources.

22. **Please describe any concerns you have regarding missing data.**

Submission document: Testing attachment, section 2b6.

- The developer states that analyses of missing data were performed, though details are not provided, including impacts to measure constructs (numerator, denominator, denominator exclusions, and timeframes for vaccinations) and data sources.

23. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

☐ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

☐ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

☒ **Low** (NOTE: Should rate LOW if you believe that there **are** threats to validity and/or relevant threats to validity were **not assessed OR** if testing methods/results are not adequate)

☒ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level **is required**; if not conducted, should rate as INSUFFICIENT.)

24. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

The correlate measures for the constructs included unendorsed components in a composite, individual performance rates within a specified measure, unendorsed measures, and the results demonstrated low weak associations in:

- Commercial plans *#1407* Meningococcal Td/Tdap (0.31) and Herpes Zoster (0.29) and *#1407* Tdap to Herpes Zoster (0.31).
- Medicaid plans *#1407* Meningococcal to Td/Tdap (0.30) and Herpes Zoster (0.30) and p-values, not specifically defined, were > 0.5.
- Medicare Plans *#0043* to Influenza at 0.06 (p-values, not specifically defined, were > 0.5) and Herpes Zoster at 0.31

ADDITIONAL RECOMMENDATIONS

25. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

    No other concerns than what is previously defined.

Developer Submission

NQF #: 3620

Corresponding Measures:

De.2. Measure Title: Adult Immunization Status

Co.1.1. Measure Steward: National Committee for Quality Assurance

De.3. Brief Description of Measure: The percentage of adults 19 years of age and older who are up-to-date on Advisory Committee on Immunization Practice (ACIP) recommended routine vaccines for influenza, tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap), zoster and pneumococcal.

1b.1. Developer Rationale: This measure assesses the provision of critical routine immunizations for adults 19 and older per clinical guidelines. The intent of the measure is to improve primary prevention of vaccine-preventable diseases including influenza, tetanus, diphtheria, pertussis, herpes zoster and pneumococcal disease.

S.4. Numerator Statement: Adults age 19 and older who are up-to-date on recommended routine vaccines for influenza, tetanus (Td) or tetanus, diphtheria or acellular pertussis (Tdap), herpes zoster and pneumococcal based on age and recommendations.

S.6. Denominator Statement: Adults ages 19 years and older.

S.8. Denominator Exclusions: Adults with immunocompromising conditions who are contraindicated for certain vaccines and those who were in hospice during the measurement period.

De.1. Measure Type: Process

S.17. Data Source: Claims, Electronic Health Data, Electronic Health Records, Enrollment Data, Management Data, Registry Data

S.20. Level of Analysis: Health Plan

IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date:

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? N/A

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

AIS_Evidence_Form_.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

No

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 3620

Measure Title: Adult Immunization Status

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:

Date of Submission: **4/16/2021**

1a.1.This is a measure of: (*should be consistent with type of measure entered in De.1*)

Outcome

☐ Outcome:

☐Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors. (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

☐ Intermediate clinical outcome (*e.g., lab value*):

☒ Process: Percentage of adults 19 years of age and older who are up-to-date on recommended routine vaccines for influenza, tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap), zoster and pneumococcal.

☐ Appropriate use measure:

☐ Structure:

☐ Composite:

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Adults age 19 years or older >> routine vaccines for influenza, Td/Tdap, herpes zoster and pneumococcal are given based on recommendations for age, timing and dosing >> prevent disease >> improved length and/or quality of life

1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based

on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☒ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☒ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Table 1. Influenza Vaccine Recommendation

Systematic Review	Evidence
Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including page number** • **URL**	• Title: Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020–21 Influenza Season • Author: Lisa A. Grohskopf, MD[1]; Elif Alyanak, MPH[1,2]; Karen R. Broder, MD[3]; Lenee H. Blanton, MPH[1]; Alicia M. Fry, MD[1]; Daniel B. Jernigan, MD[1]; Robert L. Atmar, MD • Date: August 21, 2020 • Citation: Grohskopf LA, Alyanak E, Broder KR, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020–21 Influenza Season. MMWR Recomm Rep 2020;69(No. RR-8):1–24. • DOI: http://dx.doi.org/10.15585/mmwr.rr6908a1
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications. Vaccination efforts should continue throughout the season because the duration of the influenza season varies, and influenza activity might not occur in certain communities until February or March. Providers should offer influenza vaccine routinely, and organized vaccination campaigns should continue throughout the influenza season, including after influenza activity has begun in the community. Although vaccination by the end of October is recommended, vaccine administered in December or later, even if influenza activity has already begun, might be beneficial in most influenza seasons. Providers should still offer influenza vaccination to unvaccinated persons who have already become ill with influenza during the season because the vaccine might protect them against other circulating influenza viruses. A licensed influenza vaccine that is appropriate for the recipient's age and health status should be used. Table 1 in guidelines: for the 2020-2021 influenza season, all inactivated influenza vaccine (IIV4) formulations are recommended for all adults, with the exception of the new HD-IIV4 and aIIV4 formulations recommended for adults 65 years and older; IIV3 are recommended for adults ages 65 and older; recombinant influenza vaccine (RIV4) are recommended for adults ages 18 and older; and live attenuated influenza vaccine (LAIV) are recommended for people ages 2 through 49 years.
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	ACIP did not provide an overall grade for the evidence underlying this recommendation. ACIP conducts a thorough review of peer-reviewed evidence on vaccine safety and effectiveness, discusses recommendations with professional organizations, and holds regular meetings for experts to vote on proposed recommendations.

Systematic Review	Evidence
Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including page number** • **URL**	• Title: Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020–21 Influenza Season • Author: Lisa A. Grohskopf, MD[1]; Elif Alyanak, MPH[1,2]; Karen R. Broder, MD[3]; Lenee H. Blanton, MPH[1]; Alicia M. Fry, MD[1]; Daniel B. Jernigan, MD[1]; Robert L. Atmar, MD • Date: August 21, 2020 • Citation: Grohskopf LA, Alyanak E, Broder KR, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020–21 Influenza Season. MMWR Recomm Rep 2020;69(No. RR-8):1–24. • DOI: http://dx.doi.org/10.15585/mmwr.rr6908a1
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications. Vaccination efforts should continue throughout the season because the duration of the influenza season varies, and influenza activity might not occur in certain communities until February or March. Providers should offer influenza vaccine routinely, and organized vaccination campaigns should continue throughout the influenza season, including after influenza activity has begun in the community. Although vaccination by the end of October is recommended, vaccine administered in December or later, even if influenza activity has already begun, might be beneficial in most influenza seasons. Providers should still offer influenza vaccination to unvaccinated persons who have already become ill with influenza during the season because the vaccine might protect them against other circulating influenza viruses. A licensed influenza vaccine that is appropriate for the recipient's age and health status should be used. Table 1 in guidelines: for the 2020-2021 influenza season, all inactivated influenza vaccine (IIV4) formulations are recommended for all adults, with the exception of the new HD-IIV4 and aIIV4 formulations recommended for adults 65 years and older; IIV3 are recommended for adults ages 65 and older; recombinant influenza vaccine (RIV4) are recommended for adults ages 18 and older; and live attenuated influenza vaccine (LAIV) are recommended for people ages 2 through 49 years.
Provide all other grades and definitions from the evidence grading system	*

Grade assigned to the **recommendation** with definition of the grade	ACIP did not provide a grade for this recommendation. CDC vaccine recommendations are developed using an explicit evidence-based method based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. Key factors considered in development of recommendations include balance of benefits and harms, type or quality of evidence, values and preferences of the people affected, and health economic analyses. ACIP discusses recommendations with professional organizations and holds regular meetings for experts to vote on proposed recommendations.
Provide all other grades and definitions from the recommendation grading system	*
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	The ACIP Influenza Work Group periodically reviews available data and evidence on immunogenicity, efficiency, effectiveness and safety of influenza vaccines. They also convene twice monthly to review "influenza surveillance, vaccine effectiveness and safety, vaccine coverage, program feasibility, cost-effectiveness, and vaccine supply" in order to provide annual recommendations for the use of influenza vaccines for the prevention and control of influenza. Each year, influenza vaccination guidelines are updated to reflect recent additions to the literature related to recommendations made in previous seasons and minor changes in guidance for the use of influenza vaccines (e.g., guidance for timing of vaccination and other programmatic issues, guidance for dosage in specific populations, guidance for selection of vaccines for specific populations that are already recommended for vaccination, and changes that reflect use that is consistent with indications and prescribing information licensed by the Food and Drug Administration [FDA]). The studies reviewed consist of randomized control trials, case control studies and observational studies, among others.
Estimates of benefit and consistency across studies	The Work Group reviewed vaccine safety—compared to the morbidity and mortality risks associated with influenza—and concluded that all persons aged ≥6 months without contraindications are recommended to receive routine influenza vaccinations. Vaccine type, product, and dose recommendations are based on age and pregnancy status. This includes vaccination of pregnant women with a licensed, recommended, and age-appropriate IIV or RIV4.
What harms were identified?	The Work Group examined the risk of adverse events for each vaccine type and concluded that the influenza vaccine is safe for routine administration, including administration to pregnant women. ACIP identified severe allergic reactions as a contraindication to all types of the influenza vaccine. LAIVs are contraindicated for pregnant women. For adults, the most common safety complaints were injection site pain (that did not interfere with daily activities) and systemic reactions, such as myalgia, headaches, and fatigue. Serious adverse events were uncommon. No specific safety concerns were identified.

Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	There have been no studies published since the guideline that would significantly affect the findings.

*cell intentionally left blank

Table 2. Td/Tdap Vaccine Recommendation

Systematic Review	Evidence
Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including page number** • **URL**	• Title: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccines: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2019 • Author: Havers FP, Moro PL, Hunter P, Hariri S, Bernstein H • Date: January 24, 2020 • Citation: Havers FP, Moro PL, Hunter P, Hariri S, Bernstein H. Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccines: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2019. MMWR Morb Mortal Wkly Rep 2020;69:77–83. • DOI: http://dx.doi.org/10.15585/mmwr.mm6903a5.
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	General recommendations for persons aged ≥19 years: To ensure continued protection against tetanus and diphtheria, booster doses of either Td or Tdap should be administered every 10 years throughout life. Catch-up immunization recommendations for persons aged ≥19 years: If persons aged ≥19 years have never been vaccinated against pertussis, tetanus, or diphtheria, these persons should receive a series of three tetanus and diphtheria toxoid–containing vaccines, which includes at least 1 Tdap dose. The preferred schedule is 1 dose of Tdap, followed by 1 dose of either Td or Tdap at least 4 weeks afterward, and 1 dose of either Td or Tdap 6–12 months later. Persons aged ≥19 years who are not fully immunized against tetanus and diphtheria should receive 1 dose of Tdap, preferably as the first dose in the catch-up series; if additional tetanus toxoid–containing doses are required, either Td or Tdap may be used.
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	ACIP did not provide an overall grade for the evidence underlying this recommendation. ACIP conducts a thorough review of peer-reviewed evidence on vaccine safety and effectiveness, discusses recommendations with professional organizations, and holds regular meetings for experts to vote on proposed recommendations.
Provide all other grades and definitions from the evidence grading system	*

Grade assigned to the **recommendation** with definition of the grade	ACIP did not provide a grade for this recommendation. CDC vaccine recommendations are developed using an explicit evidence-based method based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. Key factors considered in development of recommendations include balance of benefits and harms, type or quality of evidence, values and preferences of the people affected, and health economic analyses. ACIP discusses recommendations with professional organizations and holds regular meetings for experts to vote on proposed recommendations.
Provide all other grades and definitions from the recommendation grading system	*
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	The ACIP Pertussis Vaccines Work Group reviewed available published and unpublished data and evidence from 2004 to 2017, covering topics such as tetanus, diphtheria and pertussis disease epidemiology in the United States, decision analyses, cost-effectiveness, programmatic considerations, vaccine immunogenicity, vaccine safety, and post-licensure vaccine effectiveness. In total, they reviewed 110 studies consisting of randomized control trials and other types of studies on Td and Tdap vaccination. In 2018, the Work Group reviewed clinical trials published during January 2013–June 2019 that examined Tdap vaccination in adolescents and adults who had previously received Tdap.
Estimates of benefit and consistency across studies	The Work Group reviewed vaccine safety—compared to the morbidity and mortality risks associated with pertussis, tetanus and diphtheria—and concluded that "All persons are recommended to receive routine pertussis, tetanus, and diphtheria vaccination. Vaccine type, product, number of doses and booster dose recommendations are based on age and pregnancy status." This includes the vaccination of adults with a single booster tetanus and diphtheria toxoids (Td) vaccine every 10 years.
What harms were identified?	The Work Group examined the risk of adverse events for each vaccine component and concluded that the Td and Tdap vaccines are safe for administration to adolescents and adults, including pregnant women. Any adverse reactions that were observed were limited to minor local reactions, including pain, erythema and swelling; no serious adverse events have been observed. Receipt of Tdap during pregnancy has not been found to be associated with an increased risk for frequency of major malformations, stillbirth, preterm birth, small for gestational age, or hypertensive disorders. ACIP identified two contraindications to the Tdap vaccine: severe allergic reactions or encephalopathy associated with administration of a prior dose of a DTP, DTaP, or Tdap vaccine.

Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	There have been no studies published since the guideline that would significantly affect the findings.

*cell intentionally left blank

Table 3. Herpes Zoster Vaccination

Systematic Review	Evidence
Source of Systematic Review: • Title • Author • Date • Citation, including page number • URL	ACIP 2018 Guidelines for Recombinant Zoster Vaccine: • Title: Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines • Author: Kathleen Dooling, Centers for Disease Control and Prevention, et al. • Date: January 2018 • Citation: Dooling KL, Guo A, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines. MMWR Morb Mortal Wkly Rep 2018;67:103–108. • DOI: http://dx.doi.org/10.15585/mmwr.mm6703a5 ACIP 2008 Guidelines for Zoster Vaccine Live: • Title: Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP) • Author: Rafael Harpaz, Centers for Disease Control and Prevention, et al. • Date: June 6, 2008 • Citation: Harpaz R, Ortega-Sanchez IR, Seward JF. Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Early Release 2008;57[November 2019]:1-2. • URL: https://www.cdc.gov/mmwr/PDF/rr/rr5705.pdf
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	ACIP 2018 Guidelines for Recombinant Zoster Vaccine: "Recombinant zoster vaccine (RZV) is recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged ≥50 years. RZV is recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received zoster vaccine live (ZVL). RZV is preferred over ZVL for the prevention of herpes zoster and related complications. These recommendations serve as a supplement to the existing recommendations for the use of ZVL in immunocompetent adults aged ≥60 years." ACIP 2008 Guidelines for Zoster Vaccine Live: "Licensed zoster vaccine is a lyophilized preparation of a live, attenuated strain of VZV, the same strain used in the varicella vaccines. Zoster vaccine is recommended for all persons aged ≥60 years who have no contraindications, including persons who report a previous episode of zoster or who have chronic

Systematic Review	Evidence
	medical conditions. The vaccine should be offered at the patient's first clinical encounter with his or her health-care provider."
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	ACIP did not provide an overall grade for the evidence underlying this recommendation. ACIP conducts a thorough review of peer-reviewed evidence on vaccine safety and effectiveness, discusses recommendations with professional organizations, and holds regular meetings for experts to vote on proposed recommendations.
Provide all other grades and definitions from the evidence grading system	*
Grade assigned to the **recommendation** with definition of the grade	ACIP did not provide a grade for this recommendation. CDC vaccine recommendations are developed using an explicit evidence-based method based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. Key factors considered in development of recommendations include balance of benefits and harms, type or quality of evidence, values and preferences of the people affected, and health economic analyses. ACIP discusses recommendations with professional organizations and holds regular meetings for experts to vote on proposed recommendations.
Provide all other grades and definitions from the recommendation grading system	*
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	The ACIP Herpes Zoster Vaccines Work Group evaluated studies published from 2015-2017 on the efficacy, cost-effectiveness, and safety of both RZV and ZVL. Their review included 10 studies of RZV, including seven randomized control trials (RCTs). They reviewed 40 studies of ZVL, including 16 high-quality RCTs, 13 RCTs with noted limitations, 10 cohort studies, and 1 case control study.
Estimates of benefit and consistency across studies	The Work Group reviewed vaccine safety—compared to the morbidity and mortality risks associated with herpes zoster—and concluded that "with high efficacy among adults aged ≥50 years, and modest waning of protection over 4 years following vaccination, RZV has the potential to prevent substantial herpes zoster disease burden. Vaccinating adults starting at age 50 will prevent disease incidence in midlife, and the vaccine will likely continue to provide substantial protection beyond 4 years as recipients age."
What harms were identified?	The Work Group examined the risk of adverse events for each vaccine component and concluded that RZV and ZVL are safe for administration to adults. Any adverse reactions that were observed were limited to minor local reactions, including pain, myalgia and fatigue. Overall, serious adverse events occurred at similar rates in vaccinated and placebo groups.

Systematic Review	Evidence
	ACIP identified severe allergic reactions as a contraindication to both RZV and ZVL vaccines. ACIP identified pregnancy and immunocompromising conditions as contraindications for ZVL.
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	There have been no studies published since the guideline that would significantly affect the findings.

*cell intentionally left blank

Table 4. Pneumococcal Vaccination

Systematic Review	Evidence
Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including page number** • **URL**	• Title: Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years: Updated Recommendations of the Advisory Committee on Immunization Practices • Author: Matanock A, Lee G, Gierke R, Kobayashi M, Leidner A, Pilishvili T • Date: November 22, 2019 • Citation: Matanock A, Lee G, Gierke R, Kobayashi M, Leidner A, Pilishvili T. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years: Updated Recommendations of the Advisory Committee on Immunization Practices. MMWR Morb Mortal Wkly Rep 2019;68:1069–1075. • DOI: http://dx.doi.org/10.15585/mmwr.mm6846a5external icon.
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	PCV13: PCV13 vaccination is no longer routinely recommended for all adults aged ≥65 years. Instead, shared clinical decision-making for PCV13 use is recommended for persons aged ≥65 years who do not have an immunocompromising condition, CSF leak, or cochlear implant and who have not previously received PCV13. PPSV23 for adults aged ≥65 years: ACIP continues to recommend that all adults aged ≥65 years receive 1 dose of PPSV23. A single dose of PPSV23 is recommended for routine use among all adults aged ≥65 years. PPSV23 contains 12 serotypes in common with PCV13 and an additional 11 serotypes for which there are no indirect effects from PCV13 use in children. The additional 11 serotypes account for 32%–37% of IPD among adults aged ≥65 years. Adults aged ≥65 years who received ≥1 dose of PPSV23 before age 65 years should receive 1 additional dose of PPSV23 at age ≥65 years, at least 5 years after the previous PPSV23 dose.
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	2: RCTs with important limitations, or exceptionally strong evidence from observational studies.
Provide all other grades and definitions from the evidence grading system	1: Randomized controlled trials (RCTs), or overwhelming evidence from observational studies. 3: Observational studies, or RCTs with notable limitations. 4: Clinical experience and observations, observational studies with important limitations, or RCTs with several major limitations.
Grade assigned to the **recommendation** with definition of the grade	ACIP did not provide a grade for this recommendation. CDC vaccine recommendations are developed using an explicit evidence-based method based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.

Systematic Review	Evidence
	Key factors considered in development of recommendations include balance of benefits and harms, type or quality of evidence, values and preferences of the people affected, and health economic analyses. ACIP discusses recommendations with professional organizations and holds regular meetings for experts to vote on proposed recommendations.
Provide all other grades and definitions from the recommendation grading system	*
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	The ACIP Pneumococcal Work Group evaluated studies published from 2004-2014 on benefits, harms, values and preferences, and cost-effectiveness on PCV13 for routine use among adults aged 65 years and older. Their review included 6 randomized control trials (RCTs) on immunogenicity, 3 RCTs on serious and systemic adverse events and 2 other RCTs that they determined were of high and moderate quality. In 2019, the ACIP Pneumococcal Vaccines Workgroup considered whether PCV13 should be administered routinely to all immunocompetent adults aged ≥65 years in the context of indirect effects from pediatric PCV use experienced to date. The Workgroup reviewed scientific literature published from January 1, 2014-July 3, 2018 evaluating direct and indirect effects of vaccination with PCV13 on invasive pneumococcal disease, pneumonia and mortality, as well as severe adverse events from the vaccine. Sixteen studies (2 RCTs and 14 observational) were included in the GRADE tables review.
Estimates of benefit and consistency across studies	The Work Group reviewed vaccine safety—compared to the morbidity and mortality risks associated with pneumonia—for studies published from 2004-2014 and concluded that "benefits outweigh harms." Vaccine type, number of doses and interval between doses are based on age, prior vaccination history and presence of specific medical conditions. The Workgroup found that updated evidence published since 2014 continues to support that PCV13 is efficacious and effective for preventing invasive and non-invasive PCV13-type disease among adults 65 and older, and no concerning safety signals were detected. They determined that indirect effects from pediatric PCV use reduced PCV13-type disease in older adults to all-time lows prior to 2014; since 2014, PCV13 coverage among adults 65 and older steadily rose to 40% in 2017; and since the introduction of PCV13 for all adults 65 and older, no impact on PCV13-type invasive pneumococcal disease at the population level has been observed and data across studies that measure impact on pneumonia have been inconsistent.
What harms were identified?	The Work Group examined the risk of adverse events for each vaccine component and concluded that PCV13 and PPSV23 are safe for administration to adults. Any adverse reactions that were observed were limited to minor local reactions, including pain, myalgia and fatigue. Overall, serious adverse events occurred at similar rates in vaccinated and placebo groups. ACIP identified severe allergic reactions as a contraindication to both PCV13 and PPSV23 vaccines.

Systematic Review	Evidence
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	There have been no studies published since the guideline that would significantly affect the findings.

*cell intentionally left blank

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

1a.4.2 What process was used to identify the evidence?

1a.4.3. Provide the citation(s) for the evidence.

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

If a COMPOSITE *(e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.*

This measure assesses the provision of critical routine immunizations for adults 19 and older per clinical guidelines. The intent of the measure is to improve primary prevention of vaccine-preventable diseases including influenza, tetanus, diphtheria, pertussis, herpes zoster and pneumococcal disease.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis*. (**This is required for maintenance of endorsement**. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

The following data are extracted from HEDIS data collection reflecting the most recent year of measurement (2018) for this measure. Performance data is summarized at the health plan level and summarized by mean performance and performance at 10th, 25th, 50th, 75th, and 90th percentile. We also calculated the interquartile range (IQR), which can be interpreted as the difference between the 25th?and 75th?percentile. Data is stratified by product line (i.e. commercial, Medicaid and Medicare).

The following data demonstrate the variation in the rate of adult immunization across health plans. For the influenza rate, there was a 13 point difference between plans in the 25th percentile and plans in the 75th percentile for Medicare plans, and 6 and 8 points for commercial and Medicaid plans, respectively. For the Td/Tdap rate, there was a 14 point difference between plans in the 25th percentile and plans in the 75th percentile for Medicare plans, and 10 and 11 points for commercial and Medicaid plans, respectively. Similar gaps in performance occurred for the zoster and pneumococcal immunization rates and these gaps in performance underscore the opportunity for improvement.

Adult Immunization Status: Influenza

Commercial, 2018

Mean | 10th | 25th | 50th | 75th | 90th | Interquartile Range

18.7 | 11.4 | 14.9 | 18.1 | 20.6 | 26.4 | 5.7

Medicaid, 2018

Mean | 10th | 25th | 50th | 75th | 90th | Interquartile Range

11.6 | 2.8 | 7.8 | 11.7 | 15.3 | 20.7 | 26.0 | 7.5

Medicare, 2018

Mean | 10th | 25th | 50th | 75th | 90th | Interquartile Range

18.3 | 5.3 | 8.3 | 12.5 | 21.7 | 30.1 | 13.4

Adult Immunization Status: Td/Tdap

Commercial, 2018

Mean | 10th | 25th | 50th | 75th | 90th | Interquartile Range

29.4 | 18.6 | 20.9 | 25.2 | 30.7 | 46.5 | 9.8

Medicaid, 2018

Mean | 10th | 25th | 50th | 75th | 90th | Interquartile Range

20.9 | 4.9 | 14.1 | 21.1 | 25.0 | 34.4 | 10.9

Medicare, 2018

Mean | 10th | 25th | 50th | 75th | 90th | Interquartile Range

26.5 | 9.5 | 14.8 | 20.7 | 28.7 | 56.4 | 13.9

Adult Immunization Status: Herpes Zoster

Commercial, 2018

Mean | 10th | 25th | 50th | 75th | 90th | Interquartile Range

6.1 | 2.7 | 4.1 | 5.0 | 6.5 | 9.8 | 2.4

Medicaid, 2018

Mean | 10th | 25th | 50th | 75th | 90th | Interquartile Range

1.6 | 0.0 | 0.4 | 0.6 | 1.4 | 5.3 | 1.0

Medicare, 2018

Mean | 10th | 25th | 50th | 75th | 90th | Interquartile Range

12.9 | 0.4 | 0.9 | 5.3 | 14.5 | 39.5 | 13.6

Adult Immunization Status: Pneumococcal

Medicare, 2018

Mean | 10th | 25th | 50th | 75th | 90th | Interquartile Range

20.3 | 5.4 | 8.1 | 10.8 | 22.5 | 55.5 | 14.4

The HEDIS performance data reflect the most recent year of measurement for this measure. Below is a description of the number of health plans that reported this measure and the median eligible population for the measure (stratified by commercial, Medicaid and Medicare).

Commercial, 2018

N Plans | Median Eligible Population

71 | 80,330

Medicaid, 2018

N Plans | Median Eligible Population

21 | 36,250

Medicare, 2018

N Plans | Median Eligible Population

44 | 11,648

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

Estimates of national vaccination coverage are available through the National Health Interview Survey (NHIS), in which a sample of adult's self-report receipt of vaccines. In 2015, 45 percent of adults 19 and older reported that they received the influenza vaccine during the 2014–2015 flu season, well below the Healthy People 2020 target of 70 percent (Williams et al. 2017). 64 percent of adults 65 and older reported having ever received the PPSV23 vaccine and/or the PCV13 vaccine, which is below the Healthy People 2020 target of 90 percent (Williams et al. 2017). Although there is no corresponding Healthy People 2020 goal for routine Tdap or Td vaccination among adults, only 23 percent of adults 19 and older responding to the 2015 NHIS reported receiving the Tdap vaccine within the past 10 years, and 62 percent reported receiving any tetanus toxoid-containing vaccination during the past 10 years (Williams et al. 2017). In 2015, 31 percent of adults ages 60 and older reported ever receiving the herpes zoster vaccine (Williams et al. 2017). Although zoster vaccination coverage meets the Healthy People 2020 target of 30 percent coverage, 70 percent of adults are not receiving this recommended vaccination due to factors that include vaccine shortages shortly after licensure (Hurley et al. 2010), complications in storing the vaccine and cost to consumers (Hurley et al. 2010). Barriers to adult vaccination in general include provider and patient lack of knowledge and awareness of the importance of vaccines, missed opportunities for vaccination and operational and systemic barriers (e.g., cost, lack of access to immunization records) (Ventola 2016; Tan 2015). Having health insurance coverage and a usual place for health care is associated with higher vaccination coverage (Williams et al. 2017).

Hurley, L.P., M.C. Lindley, R. Harpaz, S. Stokley, M.F. Daley, L.A. Crane, et al. 2010. "Barriers to the Use of Herpes Zoster Vaccine." Ann Intern Med. 152:555–60. doi: 10.7326/0003-4819-152-9-201005040-00005.

Ventola, C.L. 2016. "Immunization in the United States: Recommendations, Barriers, and Measures to Improve Compliance: Part 2: Adult Vaccinations." Pharmacy and Therapeutics. 41(8), 492–506.

Williams W.W., P. Lu, A. O'Halloran, et al. 2017. "Surveillance of Vaccination Coverage among Adult Populations—United States, 2015." MMWR Surveill Summ. 66(No. SS-11):1–28. DOI: http://dx.doi.org/10.15585/mmwr.ss6611a1.

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. ***(This is required for maintenance of endorsement.*** *Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for*

improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

HEDIS data are stratified by type of insurance (e.g., Commercial, Medicaid, Medicare). While not specified in the measure, this measure can also be stratified by demographic variables, such as race/ethnicity or socioeconomic status, in order to assess the presence of health care disparities if the data are available to a plan. The HEDIS Race/Ethnicity Diversity of Membership and the Language Diversity of Membership measures were designed to promote standardized methods for collecting these data and follow Office of Management and Budget and Institute of Medicine guidelines for collecting and categorizing race/ethnicity and language data. In addition, NCQA's Multicultural Health Care Distinction Program outlines standards for collecting, storing, and using race/ethnicity and language data to assess health care disparities.

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

There are racial and ethnic disparities in adult vaccination coverage. The 2015 NHIS found that White adults were more likely to have received the influenza vaccine (47 percent) than Blacks (37 percent) and Hispanics (33 percent) (Williams et al. 2017). Tdap and Td booster vaccination coverage was higher for White adults 19 and older than Black, Hispanic and Asian adults (Williams et al. 2017). Similarly, pneumococcal vaccination coverage and zoster vaccination coverage was higher for White older adults than for Black, Hispanic and Asian older adults (Williams et al. 2017). Racial and ethnic disparities in pneumococcal vaccination and herpes zoster vaccination coverage widened from 2014–2015 due to increases in vaccination coverage for older White adults (Williams et al. 2017). Vaccination coverage also varies by age for influenza and Tdap/Td. In the 2015 NHIS survey, older adults were more likely to report receiving the influenza vaccine; 32 percent of adults 19–49 reported receiving the flu vaccine, compared with 49 percent of adults 50–64 and 74 percent of adults 65 and older (Williams et al. 2017); however, adults 65 and older were less likely to report having received the Td or Tdap vaccine than adults 19–64 (Williams et al. 2017).

Williams W.W., P. Lu, A. O'Halloran, et al. 2017. "Surveillance of Vaccination Coverage among Adult Populations—United States, 2015." MMWR Surveill Summ. 66(No. SS-11):1–28. DOI: http://dx.doi.org/10.15585/mmwr.ss6611a1.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, **as specified**, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

De.6. Non-Condition Specific *(check all the areas that apply):*

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

S.1. Measure-specific Web Page *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*

N/A

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

Attachment: 3620_AIS_Value_Sets_Spring_2021.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

No

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

N/A

S.4. Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*

***IF an OUTCOME MEASURE**, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).*

Adults age 19 and older who are up-to-date on recommended routine vaccines for influenza, tetanus (Td) or tetanus, diphtheria or acellular pertussis (Tdap), herpes zoster and pneumococcal based on age and recommendations.

S.5. Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

***IF an OUTCOME MEASURE,** describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).*

The measure calculates a numerator for each vaccine type.

Numerator 1 (influenza): adults 19 and older who received an influenza vaccine on or between July 1 of the year prior to the measurement period and June 30 of the measurement period, or who had a prior influenza virus vaccine adverse reaction any time before or during the Measurement Period.

Numerator 2 (Td/Tdap): adults 19 and older who received at least one Td or one Tdap vaccine between nine years prior to the start of the measurement period and the end of the measurement period, or with a history of at least one of the following contraindications any time before or during the Measurement Period: anaphylaxis due to Tdap vaccine, anaphylaxis due to Td vaccine or its components, or encephalopathy due to Tdap or Td vaccination (post-tetanus vaccination encephalitis, post-diphtheria vaccination encephalitis, post-pertussis vaccination encephalitis).

Numerator 3 (herpes zoster): adults 50 and older who received at least one dose of the herpes zoster live vaccine or two doses of the herpes zoster recombinant vaccine at least 28 days apart, any time on or after the 50th birthday and before or during the Measurement Period, or who had a prior adverse reaction caused by zoster vaccine or its components any time before or during the Measurement Period.

Numerator 4 (pneumococcal): adults 66 and older who received the 23-valent pneumococcal polysaccharide vaccine on or after the 60th birthday and before or during the Measurement Period, or who had a prior pneumococcal vaccine adverse reaction any time before or during the Measurement Period.

See attached code value sets.

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

Adults ages 19 years and older.

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

***IF an OUTCOME MEASURE**, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).*

Adults ages 19 years and older at the start of the measurement period (January 1). The measure calculates a denominator for each vaccine type.

Denominator 1 (influenza): adults 19 and older by the start of the measurement period.

Denominator 2 (Td/Tdap): adults 19 and older by the start of the measurement period.

Denominator 3 (herpes zoster): adults 50 and older by the start of the measurement period.

Denominator 4 (pneumococcal): adults 66 and older by the start of the measurement period.

Note: Commercial and Medicaid plans report denominators for adults 19–65; Medicare plans report denominators for adults 66 and older.

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

Adults with immunocompromising conditions who are contraindicated for certain vaccines and those who were in hospice during the measurement period.

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

Exclude adults with any of the following:

- Active chemotherapy any time during the measurement period.
- Bone marrow transplant any time during the measurement period.
- History of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia & HB-S disease or cerebrospinal fluid leaks any time before or during the measurement period.
- In hospice or using hospice services during the measurement period.

See attached code value sets.

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)*

N/A

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

Better quality = Higher score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*

Step 1: Determine the eligible population. Identify all adults ages 19 and older at the start of the measurement period.

Step 2: Remove adults with any of the following exclusions from the eligible population: active chemotherapy during the measurement period; bone marrow transplant during the measurement period; history of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia and HB-S disease or cerebrospinal fluid leaks any time before or during the measurement period; in hospice or using hospice services during the measurement period.

Step 3: Determine denominators 1-4 based on the age of the adult at the start of the measurement period:

Commercial and Medicaid plans:

- Denominator 1 (influenza): ages 19-65
- Denominator 2 (Td/Tdap): ages 19-65
- Denominator 3 (herpes zoster): ages 50-65
- Denominator 4 (pneumococcal): N/A

Medicare plans:

- Denominator 1 (influenza): ages 66 and older
- Denominator 2 (Td/Tdap): ages 66 and older
- Denominator 3 (herpes zoster): ages 66 and older
- Denominator 4 (pneumococcal): ages 66 and older

Step 4: Determine numerators 1-4:

Commercial and Medicaid plans:

- Numerator 1 (influenza): received an influenza vaccine on or between July 1 of the year prior to the measurement period and June 30 of the measurement period or had a prior influenza virus vaccine adverse reaction any time before or during the Measurement Period.
- Numerator 2 (Td/Tdap): received at least one Td or one Tdap vaccine between nine years prior to the start of the measurement period and the end of the measurement period, or with a history of at least one of the following contraindications any time before or during the Measurement Period: anaphylaxis due to Tdap vaccine, anaphylaxis due to Td vaccine or its components, or encephalopathy due to Tdap or Td vaccination (post-tetanus vaccination encephalitis, post-diphtheria vaccination encephalitis, post-pertussis vaccination encephalitis).

- Numerator 3 (herpes zoster): received at least one dose of the herpes zoster live vaccine or two doses of the herpes zoster recombinant vaccine at least 28 days apart, any time on or after the 50th birthday and before or during the Measurement Period, or had a prior adverse reaction caused by zoster vaccine or its components any time before or during the Measurement Period.
- Numerator 4 (pneumococcal): N/A

Medicare plans:

- Numerator 1 (influenza): received an influenza vaccine on or between July 1 of the year prior to the measurement period and June 30 of the measurement period or had a prior influenza virus vaccine adverse reaction any time before or during the Measurement Period.
- Numerator 2 (Td/Tdap): received at least one Td or one Tdap vaccine between nine years prior to the start of the measurement period and the end of the measurement period, or with a history of at least one of the following contraindications any time before or during the Measurement Period: anaphylaxis due to Tdap vaccine, anaphylaxis due to Td vaccine or its components, or encephalopathy due to Tdap or Td vaccination (post-tetanus vaccination encephalitis, post-diphtheria vaccination encephalitis, post-pertussis vaccination encephalitis).
- Numerator 3 (herpes zoster): received at least one dose of the herpes zoster live vaccine or two doses of the herpes zoster recombinant vaccine at least 28 days apart, any time on or after the 50th birthday and before or during the Measurement Period, or had a prior adverse reaction caused by zoster vaccine or its components any time before or during the Measurement Period.
- Numerator 4 (pneumococcal): received the 23-valent pneumococcal polysaccharide vaccine on or after the 60th birthday and before or during the Measurement Period or had prior pneumococcal vaccine adverse reaction any time before or during the Measurement Period.

Step 5: Calculate the measure rates:

- Numerator 1 / Denominator 1
- Numerator 2 / Denominator 2
- Numerator 3 / Denominator 3
- Numerator 4 / Denominator 4 (N/A for commercial and Medicaid plans)

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

N/A

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

N/A

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Claims, Electronic Health Data, Electronic Health Records, Enrollment Data, Management Data, Registry Data

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g., name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

This measure is specified for administrative claims, electronic health record, registry, health information exchange or case management data collected in the course of providing care to health plan members. NCQA collects the Healthcare Effectiveness Data and Information Set (HEDIS) data for this measure directly from Health Management Organizations and Preferred Provider Organizations via NCQA's online data submission system.

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

No data collection instrument provided

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Health Plan

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Outpatient Services

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

N/A

2. Validity – See attached Measure Testing Submission Form

nqf_testing_attachment_7.1.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** 3620
Measure Title: Adult Immunization Status
Date of Submission: 4/16/2021

Type of Measure:

Measure	Measure (continued)
☐ Outcome (*including PRO-PM*)	☐ Composite – *STOP – use composite testing form*
☐ Intermediate Clinical Outcome	☐ Cost/resource
☒ Process *(including Appropriate Use)*	☐ Efficiency
☐ Structure	*

*cell intentionally left blank

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. ***If there are differences by aspect of testing****,(e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.*

N/A

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure*. *Testing must be provided for* ***all*** *the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

Measure Specified to Use Data From: (***must be consistent with data sources entered in S.17***)	**Measure Tested with Data From:**
☐ abstracted from paper record	☐ abstracted from paper record
☒ claims	☒ claims
☒ registry	☒ registry
☒ abstracted from electronic health record	☒ abstracted from electronic health record
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs
☒ other: management data	☒ other: management data

1.2. If an existing dataset was used, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured, e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

N/A

1.3. What are the dates of the data used in testing? 01/01/2016-12/31/2018

1.4. What levels of analysis were tested? (*testing must be provided for* ***all*** *the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (*must be consistent with levels entered in item S.20*)	Measure Tested at Level of:
☐ individual clinician	☐ individual clinician
☐ group/practice	☐ group/practice
☐ hospital/facility/agency	☐ hospital/facility/agency
☒ health plan	☒ health plan
☐ other:	☐ other:

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

This measure assesses whether adults enrolled in commercial, Medicaid and Medicare health plans are up-to-date on routine vaccines per clinical guidelines. The measure calculates a rate for each specific vaccine type.

Indicators	Ages Reported for Commercial & Medicaid Health Plans	Ages Reported for Medicare Health Plans
Influenza rate: Percentage of adults who received an influenza vaccine on or between July 1 of the year prior to the measurement period and June 30 of the measurement period.	19-65	66 and older
Td/Tdap rate: Percentage of adults who received a Td or Tdap vaccine on or between January 1 of the nine years prior to the measurement period and December 31 of the measurement period.	19-65	66 and older
Herpes Zoster rate: Percentage of adults who received one dose of the herpes zoster live vaccine or two doses of the herpes zoster recombinant vaccine at least 28 days apart on or after the 50th birthday.	50-65	66 and older
Pneumococcal rate: Percentage of adults who were administered the 23-valent pneumococcal polysaccharide vaccine on or after the 60th birthday.	*	66 and older

*cell intentionally left blank

The intended use of the measure is to assess the quality of care in health plans across an adult population. As required by the specified level of accountability, we assessed data from all health plans reporting the HEDIS measure to NCQA in 2018 and conducted a field test with 2016 data from health plans to assess scientific acceptability, usability and feasibility.

2018 HEDIS Data

Data used to assess measure score reliability, construct validity, distribution of exclusions and average percentage of members that were excluded, meaningful differences in performance, and missing data were calculated from all commercial, Medicaid and Medicare health plans submitting data to NCQA for this HEDIS measure. Data came from 71 commercial health plans, 21 Medicaid health plans and 44 Medicare health plans

that were geographically diverse and varied in size. Data from administrative claims, electronic health records, registries, health information exchanges and case management systems were eligible for use in the measure in line with NCQA's HEDIS Electronic Clinical Data Systems reporting method. The plans submitting HEDIS data used a range of data sources: administrative claims, immunization registry, electronic health record and case management data.

2016 Field Test Data

We also analyzed effect of exclusions on overall measure scores using additional data from a field test of the measures. In the field test, three geographically-diverse health plans (each comprising commercial, Medicaid and Medicare product lines) were asked to submit electronic patient-level demographic, enrollment, diagnosis, procedure and medication data to NCQA. Data from administrative claims, electronic health records, registries, health information exchanges and case management systems were eligible for use in the measure in line with NCQA's HEDIS Electronic Clinical Data Systems reporting method. The plans participating in this field test used a range of data sources: administrative claims, immunization registry and electronic health record data.

Systematic Evaluation of Face Validity

The measure was tested for face validity with three independent panels of experts.

- The Adult Immunizations Measurement Advisory Panel included 7 experts in primary care, immunizations and measures development, as well as clinician, health-plan and state/federal representatives.
- The Technical Measurement Advisory Panel includes 12 members, including representation by health plan methodologists, clinicians, HEDIS auditors and state/federal users of measures.
- NCQA's Committee on Performance Measurement (CPM) oversees measures used in NCQA programs and includes representation by purchasers, consumers, health plans, health care providers, and policy makers. This panel is composed of 21 independent members that reflect the diversity of constituencies that performance measurement serves. The CPM's recommendations are reviewed and approved by NCQA's Board of Directors.

1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

2018 HEDIS Data

Data are summarized at the health plan level and stratified by plan type (i.e., commercial, Medicaid, Medicare). Below is a description of the sample. It includes number of health plans submitting the measure for HEDIS and the median eligible population for the measure across plans.

Table 1. Median eligible population for *Adult Immunization Status* by plan type, 2018

Plan Type	Number of Plans	Median Number of Eligible Patients per Plan
Commercial	71	80,330
Medicaid	21	36,250
Medicare	44	11,648

2016 Field Test Data

We stratified the field test data by product line (i.e., commercial, Medicare, Medicaid). Below is a description of the sample. It includes the number of health plans; the minimum and maximum number of adults in the eligible population for the measure; and the median percentage of adults stratified by age.

Table 2. Description of field test sample for *Adult Immunization Status* by plan type, 2016

Measures	Number of plans	Minimum and maximum number of adults 19 and older across plans	Median percentage of adults ages 19-49	Median percentage of adults ages 50-59	Median percentage of adults ages 60-64	Median percentage of adults ages 65 and older
Commercial	3	313,932–1,544,512	65%	22%	10%	2%
Medicaid	3	23,650–537,000	78%	16%	6%	1%
Medicare	3	83,719–3.3 million	2%	3%	6%	91%

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

The 2018 HEDIS data were used to assess measure score reliability, construct validity, distribution of exclusions and average percentage of members that were excluded, meaningful differences in performance, and missing data, as described above. For empirical validity testing, NCQA explored whether the measure rates were correlated with other relevant HEDIS measures that the plans reported in 2018.

The 2016 field test data were used to assess the effect of exclusions on overall measure scores and in our systematic assessment of face validity.

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g., census tract), or patient community characteristics (e.g., percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

We examined measure rates by commercial, Medicaid and Medicare health plans, which serves as a proxy for socioeconomic status. We did not analyze additional social risk factors. Patient-reported data and patient community characteristics were not available in the testing data source.

NCQA is actively engaged with partners including the CMS Office of Minority Health in identifying feasible methods to further integrate social risk factors into health plan quality measures, with a focus on stratification. This is aligned with recent recommendations from MedPAC and ASPE on optimal methods for addressing social risk in quality measurement and programs.1,2 This is an NCQA wide initiative. Our intent is to implement methods to bridge data concerns in the future.

1. Medicare Payment Advisory Commission. (2020). The Medicare Advantage program: Status report. In Report to the Congress: Medicare Payment Policy (p. 397). http://medpac.gov/docs/default-source/reports/mar20_medpac_ch13_sec.pdf
2. Office of the Assistant Secretary for Planning and Evaluation, & U.S. Department of Health & Human Services. (2020). Second Report to Congress on Social Risk and Medicare's Value-Based Purchasing Programs. https://aspe.hhs.gov/social-risk-factors-and-medicares-value-basedpurchasing-programs

2a2. RELIABILITY TESTING

***Note**: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)
☐ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)
☒ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

Reliability Testing of Performance Measure Score: We used the Beta-binomial model[1] to assess how well one can confidently distinguish the performance of one accountable entity from another. Conceptually, the Beta-binomial model is the ratio of signal to noise. The signal is the proportion of the variability in measured performance that can be explained by real differences in performance. The Beta-binomial model is an appropriate model when estimating the reliability of simple pass/fail rate measures as is the case with most HEDIS measures. Reliability scores range from 0.0 to 1.0. A score of zero implies that all variation is attributed to measurement error (i.e., noise), whereas a reliability of 1.0 implies that all variation is caused by a real difference in performance (across accountable entities). The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one plan from another. A reliability score greater than or equal to 0.7 is considered very good.

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e*.g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

Table 3. Distribution of Beta-Binomial Statistics for Each Measure Rate, Commercial Plans—2018

Rate	Overall Reliability	Min	10th	25th	50th	75th	90th	Max
Influenza	1.000	0.961	0.997	0.999	1.000	1.000	1.000	1.000
Td/Tdap	1.000	0.988	0.999	1.000	1.000	1.000	1.000	1.000
Herpes Zoster	0.999	0.902	0.992	0.996	0.999	0.999	1.000	1.000

[1] Adams, J.L. The Reliability of Provider Profiling: A Tutorial. Santa Monica, California: RAND Corporation. TR-653-NCQA, 2009

Table 4. Distribution of Beta-Binomial Statistics for Each Measure Rate, Medicaid Plans—2018

Rate	Overall Reliability	Min	10th	25th	50th	75th	90th	Max
Influenza	1.000	0.976	0.991	0.999	1.000	1.000	1.000	1.000
Td/Tdap	1.000	0.988	0.996	0.999	1.000	1.000	1.000	1.000
Herpes Zoster	0.999	0.686	0.978	0.996	0.999	1.000	1.000	1.000

Table 5. Distribution of Beta-Binomial Statistics for Each Measure Rate, Medicare Plans—2018

Rate	Overall Reliability	Min	10th	25th	50th	75th	90th	Max
Influenza	1.000	0.838	0.995	0.998	1.000	1.000	1.000	1.000
Td/Tdap	1.000	0.904	0.996	0.998	1.000	1.000	1.000	1.000
Herpes Zoster	1.000	0.928	0.998	1.000	1.000	1.000	1.000	1.000
Pneumococcal	1.000	0.951	0.997	0.999	1.000	1.000	1.000	1.000

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)
The values for the overall beta-binomial statistic across all product lines and measure rates are all greater than 0.7, indicating the measure has very good reliability. The distribution of health plan level-reliability on this measure shows that all health plans (across all product lines) are above the threshold of 0.7 except the Medicaid minimum for the herpes zoster rate, which is just below 0.7. Good reliability is demonstrated since most variance is due to signal and not to noise.

2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)
☐ **Critical data elements** (*data element validity must address ALL critical data elements*)

☒ **Performance measure score**

☒ **Empirical validity testing**

☒ **Systematic assessment of face validity of performance measure score as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)*

Empirical Validity Testing of Performance Measure Score

Empiric validity of the results were assessed using Pearson correlation to demonstrate construct validity. This test estimates the strength of the linear association between two variables; the magnitude of correlation ranges from -1 to +1. A value of 1 indicates a perfect linear dependence in which increasing values on one variable is associated with increasing values of the second variable. A value of 0 indicates no linear association. A value of -1 indicates a perfect linear relationship in which increasing values of the first variable is associated

with decreasing values of the second variable. Coefficients with absolute values of less than 0.3 are generally considered indicative of weak associations, whereas absolute values of 0.3 or higher denote moderate to strong associations. The significance of a correlation coefficient is evaluated by testing the hypothesis that an observed coefficient calculated for the sample is different from zero. The resulting p-value indicates the probability of obtaining a difference at least as large as the one observed due to chance alone. We used a threshold of 0.05, as p-values less than this threshold imply it is unlikely that a non-zero coefficient was observed due to chance alone.

Across all plan types, we explored whether the indicators within this measure were correlated with each other. We hypothesized that health plans that perform well on one of the rates within the measure should perform well on the other rates within the measure. All of the measure rates represent an underlying quality construct of administering recommended routine vaccines to adults.

We also assessed correlation of *Adult Immunization Status* with other relevant HEDIS vaccine measures that they reported in 2018. For commercial and Medicaid plans, we explored whether the measure rates were correlated with the HEDIS *Prenatal Immunization Status* and *Immunizations for Adolescents* measure rates. These measures assess receipt of recommended vaccines for pregnant women and for adolescents by age 13 years, respectively. We hypothesized that health plans that perform well on the *Adult Immunization Status* measure rates should perform well on vaccine measures for pregnant women and adolescents. For Medicare plans, we explored whether the measure rates were correlated with the HEDIS *Flu Vaccinations for Older Adults* and *Pneumococcal Vaccination Status for Older Adults* measures that assess receipt of immunizations using CAHPS health plan member survey data. We hypothesized that health plans that perform well on the *Adult Immunization Status* measure rates should perform well on similar measures that assess patient-reported vaccination status.

Systematic Assessment of Face Validity

NCQA develops measures using a standardized process. For new measures, face validity is assessed at various steps as described below.

STEP 1: NCQA staff identifies areas of interest or gaps in care. Clinical measurement advisory panels (MAPs), whose members are authorities on clinical priorities for measurement, participate in this process. Once topics are identified, a literature review is conducted to find supporting documentation on their importance, scientific soundness, and feasibility. This information is gathered into a work-up format, which is vetted by the MAPs, the Technical Measurement Advisory Panel (TMAP) and the Committee on Performance Measurement (CPM) as well as other panels as necessary.

STEP 2: Development ensures that measures are fully defined and tested before the organization collects them. MAPs participate in this process by helping identify the best measures for assessing health care performance in clinical areas identified in the topic selection phase. Development includes the following tasks: (1) Prepare a detailed conceptual and operational work-up that includes a testing proposal and (2) Collaborate with health plans to conduct field-tests that assess the feasibility and validity of potential measures. At this step, face validity is systematically determined by the CPM, which uses testing results and proposed final specifications to determine if the measure will move forward to Public Comment. For this measure, the CPM voted to approve moving the proposed measure forward to public comment (15 CPM members approved, 0 members opposed and 0 abstained).

STEP 3: Public Comment is a 30-day period of review that allows interested parties to offer feedback to NCQA about proposed new measures. Public comment offers an opportunity to assess the validity, feasibility, importance and other attributes of a measure from a wider audience. For this measure, a majority of public comment respondents supported the measure. NCQA MAPs and the technical panels consider all comments and advise NCQA staff on appropriate recommendations brought to the CPM. Face validity is then again systematically assessed by the CPM. The CPM reviews all comments before making a final decision and votes

to recommend approval of new measures for HEDIS. NCQA's Board of Directors then approves new measures. For this measure, the CPM voted to approve the measure for HEDIS health plan reporting (16 CPM members approved, 0 members opposed and 0 abstained). The Board of Directors approved the measure.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

Table 6. Health-Plan Level Pearson Correlation Coefficients Among Adult Immunization Measure Performance Scores Within Measure–2018

Measures	*Adult Immunization Status*	Influenza	Td/Tdap	Herpes Zoster	Pneumococcal
Commercial Plans	Influenza	1.00	0.82	0.70	*
*	Td/Tdap	0.82	1.00	0.71	*
*	Herpes Zoster	0.70	0.71	1.00	*
*	Pneumococcal	*	*	*	*
Medicaid Plans	Influenza	1.00	0.89	0.74	*
*	Td/Tdap	0.89	1.00	0.68	*
*	Herpes Zoster	0.74	0.68	1.00	*
*	Pneumococcal	*	*	*	*
Medicare Plans	Influenza	1.00	0.67	0.62	0.58
*	Td/Tdap	0.67	1.00	0.95	0.95
*	Herpes Zoster	0.62	0.95	1.00	0.89
*	Pneumococcal	0.58	0.95	0.89	1.00

Note: All correlations significant at p<0.05

*cell intentionally left blank

Table 7a. Health-Plan Level Pearson Correlation Coefficients Among Adult Immunization Status and Prenatal Immunization Status Measure Performance Scores in Commercial Plans—2018

	Prenatal Immunization Status		
Adult Immunization Status	**Influenza**	**Tdap**	**Receipt of both prenatal vaccines**
Influenza	0.79*	0.54*	0.75*
Td/Tdap	0.74*	0.59*	0.74*
Herpes Zoster	0.61*	0.40*	0.61*

**significant at p<0.05*

Table 7b. Health-Plan Level Pearson Correlation Coefficients Among Adult Immunization Status and Prenatal Immunization Status Measure Performance Scores in Medicaid Plans—2018

	Prenatal Immunization Status		
Adult Immunization Status	**Influenza**	**Tdap**	**Receipt of both prenatal vaccines**
Influenza	0.85*	0.67*	0.85*
Td/Tdap	0.87*	0.60*	0.83*
Herpes Zoster	0.78*	0.54*	0.77*

**significant at p<0.05*

Table 8a. Health-Plan Level Pearson Correlation Coefficients Among Adult Immunization and Adolescent Immunization Measure Performance Scores in Commercial Plans—2018

	Immunizations for Adolescents			
Adult Immunization Status	**Meningococcal**	**Tdap**	**Human Papillomavirus Vaccine**	**Receipt of all vaccines**
Influenza	0.42*	0.41*	0.64*	0.63*
Td/Tdap	0.31*	0.35*	0.69*	0.69*
Herpes Zoster	0.29*	0.31*	0.54*	0.54*

**significant at p<0.05*

Table 8b. Health-Plan Level Pearson Correlation Coefficients Among Adult Immunization Status and Adolescent Immunization Measure Performance Scores in Medicaid Plans—2018

	Immunizations for Adolescents			
Adult Immunization Status	**Meningococcal**	**Tdap**	**Human Papillomavirus Vaccine**	**Receipt of all vaccines**
Influenza	0.57*	0.75*	0.63*	0.69*
Td/Tdap	0.30	0.61*	0.51*	0.54*
Herpes Zoster	0.30	0.45*	0.71*	0.66*

**significant at p<0.05*

9. Health-Plan Level Pearson Correlation Coefficients Among Adult Immunization Status and Flu and Pneumococcal Vaccinations for Older Adults Measure Performance Scores in Medicare Plans—2018

Adult Immunization Status	*Flu Vaccinations for Older Adults*	*Pneumococcal Vaccinations for Older Adults*
Influenza	0.36*	0.06
Td/Tdap	0.46*	0.40*
Herpes Zoster	0.38*	0.31*
Pneumococcal	0.45*	0.41*

**significant at p<0.05*

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i.*e., what do the results mean and what are the norms for the test conducted?*)

For the purposes of this analysis and the intended use of this measure to evaluate the quality of care for members across health plans, correlation was considered high (strong) if the correlation coefficient is 0.75 to 1, moderate if 0.25 to 0.75, and low (weak) if 0 to 0.25.

Correlations were mostly strong among the rates within the measure for commercial, Medicaid and Medicare plans. This suggests that plans that perform well on one rate are likely to perform well on other rates within the measure.

Beyond the within-measure correlations, we saw a moderate/strong relationship with benchmarks on other measures of quality for commercial, Medicaid and Medicare plans.

- For commercial and Medicaid plans, the correlation between the adult immunization measure rates with the prenatal immunization measure rates was mostly strong.
- For commercial and Medicaid plans, the correlation between the adult immunization measure rates with the adolescent immunization measure rates was moderate.
- For Medicare plans, the correlation between the adult immunization measure rates with the *Flu Vaccinations for Older Adults* and *Pneumococcal Vaccination Status for Older Adults* measure rates was mostly moderate.

2b2. EXCLUSIONS ANALYSIS

NA ☐ no exclusions — *skip to section 2b3*

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

The measure specifications for the initial population and the exclusions are as follows:

Definition	Commercial/Medicaid Plans	Medicare Plans
Initial Population	Adults ages 19-65 as of January 1 of the measurement period who were continuously enrolled throughout the measurement period.	Adults ages 66 and older as of January 1 of the measurement period who were continuously enrolled throughout the measurement period.
Exclusions	Adults with any of the following: • Active chemotherapy any time during the Measurement Period. • Bone marrow transplant any time during the Measurement Period. • History of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia and HB-S disease or cerebrospinal fluid leaks any time during the member's history through the end of the Measurement Period. • In hospice or using hospice services during the Measurement Period.	Adults with any of the following: • Active chemotherapy any time during the Measurement Period. • Bone marrow transplant any time during the Measurement Period. • History of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia and HB-S disease or cerebrospinal fluid leaks any time during the member's history through the end of the Measurement Period. • In hospice or using hospice services during the Measurement Period.

We assessed the distribution of the initial population and exclusions for this measure and the average percentage of adults that were excluded from the initial population. To understand the impact of exclusions, a sensitivity analysis was conducted using data from our field test to estimate the effect of the exclusions on the measure rates for Medicare plans. The Medicare rates were calculated with and without the exclusions applied.

2b2.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

Table 10. Distribution of initial population and exclusions—2018

Plan Type: Commercial No. of Plans: 71

Measure Component	Mean	Min	10th	25th	50th	75th	90th	Max
Initial Population: No. of adults age 19-65	162,817	929	10,989	30,306	80,330	213,646	307,159	2,140,744
Exclusions: No. of adults age 19-65 with at least one exclusion	4,886	41	334	867	2,468	6,976	10,184	39,607
Influenza and Td/Tdap Denominator (Initial	157,931	849	10,681	29,438	77,161	207,550	296,688	2,101,137

Measure Component	Mean	Min	10th	25th	50th	75th	90th	Max
population minus exclusions for adults age 19-65)								
Herpes Zoster Denominator (Initial population minus exclusions for adults age 50-65)	57,739	533	4,842	9,893	29,908	75,930	112,318	665,803

Plan Type: Medicaid No. of Plans: 21

Measure Component	Mean	Min	10th	25th	50th	75th	90th	Max
Initial Population: No. of adults age 19-65	92,621	322	1,467	19,095	36,250	73,554	279,199	562,980
Exclusions: No. of adults age 19-65 with at least one exclusion	4,181	40	80	571	1,744	3,511	11,783	26,075
Influenza and Td/Tdap Denominator (Initial population minus exclusions for adults age 19-65)	88,440	282	1,425	18,515	33,234	70,106	267,416	545,752
Herpes Zoster Denominator (Initial population minus exclusions for adults age 50-65)	44,676	203	312	4,553	8,203	19,653	78,349	545,752

Plan Type: Medicare No. of Plans: 44

Measure Component	Mean	Min	10th	25th	50th	75th	90th	Max
Initial Population: No. of adults age 66 and older	34,681	67	810	2,391	11,648	34,584	78,921	502,633
Exclusions: No. of adults age 66 and older with at least one exclusion	3,371	11	74	264	1,376	3,386	7,278	38,086
Influenza, Td/Tdap, Herpes Zoster and Pneumococcal Denominator (Initial Population minus exclusions for adults age 66 and older)	31,310	56	597	2,094	10,272	31,626	72,786	464,547

Table 11. Percentage of members excluded from the initial population—2018

Plan Type	No. of plans	Mean percentage of adults excluded from initial population
Commercial	71	3% of adults age 19-65
Medicaid	21	6% of adults age 19-65
Medicare	44	11% of adults age 66 and older

Table 12. Field test: Medicare plan denominators and performance rates with and without exclusions applied—2016

Medicare Plan	Influenza denominator (i.e., adults age 66 and older) without exclusions applied	Influenza performance rate without exclusions applied	Influenza denominator (i.e., adults age 66 and older) with exclusions applied	Influenza performance rate with exclusions applied
Plan A	2,447,515	27%	2,402,897	27%
Plan B	195,046	7%	189,115	7%
Plan C	77,359	73%	75,197	73%

Medicare Plan	Td/Tdap denominator (i.e., adults age 66 and older) without exclusions applied	Td/Tdap performance rate without exclusions applied	Td/Tdap denominator (i.e., adults age 66 and older) with exclusions applied	Td/Tdap performance rate with exclusions applied
Plan A	2,447,515	3%	2,402,897	3%
Plan B	195,046	19%	189,115	19%
Plan C	77,359	94%	75,197	94%

Medicare Plan	Herpes Zoster denominator (i.e., adults age 66 and older) without exclusions applied	Herpes Zoster performance rate without exclusions applied	Herpes Zoster denominator (i.e., adults age 66 and older) with exclusions applied	Herpes Zoster performance rate with exclusions applied
Plan A	2,447,515	0.1%	2,402,897	0.1%
Plan B	195,046	7%	189,115	7%
Plan C	77,359	85%	75,197	85%

Medicare Plan	Pneumococcal denominator (i.e., adults age 66 and older) without exclusions applied	Pneumococcal performance rate without exclusions applied	Pneumococcal denominator (i.e., adults age 66 and older) with exclusions applied	Pneumococcal performance rate with exclusions applied
Plan A	2,447,515	1%	2,402,897	1%
Plan B	195,046	11%	189,115	11%
Plan C	77,359	62%	75,197	62%

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis.* ***Note****:* ***If patient preference is an exclusion****, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

Removing exclusions had a minimal impact on the number of members in the denominator and no impact on the Medicare plan performance rates. Removing exclusions reduced the initial population, on average, by 3% for commercial plans, 6% for Medicaid plans and by 11% for Medicare plans. We would expect more Medicare members to be excluded because it is a population which may be more likely to meet the specified exclusions.

Experts on our measurement advisory panels recommended specifying the exclusions in the measure based on the clinical rationale and from an accountability perspective, and because it is feasible to collect the data with minimal burden.

_____

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES
If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b4.

2b3.1. What method of controlling for differences in case mix is used?

☐ **No risk adjustment or stratification**

☐ **Statistical risk model with risk factors**

☐ **Stratification by risk categories**

☐ **Other,**

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) **Also discuss any "ordering" of risk factor inclusion**; for example, are social risk factors added after all clinical factors?

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

☐ **Published literature**

☐ **Internal data analysis**

☐ **Other (please describe)**

2b3.4a. What were the statistical results of the analyses used to select risk factors?

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g., prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (*describe the steps—do not just name a method; what statistical analysis was used*)

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.
If stratified, skip to 2b3.9

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

2b3.8. Statistical Risk Model Calibration—Risk decile plots or calibration curves:

2b3.9. Results of Risk Stratification Analysis:

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for the test conducted*)

2b3.11. Optional Additional Testing for Risk Adjustment (***not required****, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)*

To demonstrate meaningful differences in performance, NCQA calculated an inter-quartile range (IQR) for each indicator. The IQR provides a measure of the dispersion of performance. The IQR can be interpreted as the difference between the 25th and 75th percentile on a measure.

To determine if this difference is statistically significant, NCQA calculated an independent sample t-test of the performance difference between two randomly selected plans at the 25th and 75th percentile. The t-test method calculates a testing statistic based on the sample size, performance rate, and standardized error of each plan. The test statistic is then compared against a normal distribution. If the p value of the test statistic is less than 0.05, then the two plans' performance is significantly different from each other. Using this method, we compared the performance rates of two randomly selected plans, one plan in the 25th percentile and

another plan in the 75th percentile of performance. We used these two plans as examples of measures entities. However, the method can be used for comparison of any two measured entities.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined*)

Table 13. Variation in Performance Across Commercial Plans, 2018

Rate	No. of plans	Mean denom-inator	Mean rate (%)	Min	10th percentile	25th percentile	50th percentile	75th percentile	90th percentile	Max	IQR	p-value
Influenza	71	157,931	18.7	7.7	11.4	14.9	18.1	20.6	26.4	53.6	5.7	<0.001
Td/Tdap	71	157,931	29.4	11.1	18.6	20.9	25.2	30.7	46.5	78.0	9.8	<0.001
Herpes Zoster	71	57,739	6.1	0.7	2.7	4.1	5.0	6.5	9.8	25.2	2.4	<0.001

IQR: Interquartile Range

p-value: p-value of independent samples t-test comparing plans at the 25th percentile to plans at the 75th percentile.

Table 14. Variation in Performance Across Medicaid Plans, 2018

Rate	No. of plans	Mean denom-inator	Mean rate (%)	Min	10th percentile	25th percentile	50th percentile	75th percentile	90th percentile	Max	IQR	p-value
Influenza	21	88,440	11.6	1.1	2.8	7.8	11.7	15.3	20.7	26.0	7.5	<0.001
Td/Tdap	21	88,440	20.9	2.8	4.9	14.1	21.1	25.0	34.4	52.5	10.9	<0.001
Herpes Zoster	21	44,676	1.6	0.0	0.0	0.4	0.6	1.4	5.3	6.7	1.0	<0.001

IQR: Interquartile Range

p-value: p-value of independent samples t-test comparing plans at the 25th percentile to plans at the 75th percentile.

Table 15. Variation in Performance Across Medicare Plans

Rate	No. of plans	Mean denom-inator	Mean rate (%)	Min	10th percentile	25th percentile	50th percentile	75th percentile	90th percentile	Max	IQR	p-value
Influenza	44	31,310	18.3	0.5	5.3	8.3	12.5	21.7	30.1	80.0	13.4	<0.001
Td/Tdap	44	31,310	26.5	3.3	9.5	14.8	20.7	28.7	56.4	89.2	13.9	<0.001
Herpes Zoster	44	31,099	12.9	0.0	0.4	0.9	5.3	14.5	39.5	81.0	13.6	<0.001
Pneumo-coccal	44	29,246	20.3	0.5	5.4	8.1	10.8	22.5	55.5	84.2	14.4	<0.001

IQR: Interquartile Range

p-value: p-value of independent samples t-test comparing plans at the 25th percentile to plans at the 75th percentile.

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i.*e., what do the results mean in terms of statistical and meaningful differences?*)
The IQRs ranged from 2%-9% across the commercial plan rates, 1%-11% across the Medicaid plan rates and 13%-14% across the Medicare plan rates. For example, in commercial plans, the IQR for the influenza rate was 5.7%. This gap represents an average of 9,000 additional patients being up-to-date on the influenza vaccine in high-performing commercial plans compared to low-performing commercial plans.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

If only one set of specifications, this section can be skipped.

Note*: This item is directed to measures that are risk-adjusted (with or without social risk factors)* ***OR*** *to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator).* ***Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.***

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps—do not just name a method; what statistical analysis was used*)

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.*e., what do the results mean and what are the norms for the test conducted*)

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

HEDIS measures apply to enrolled members in a health plan, and NCQA has a rigorous audit process to ensure the eligible population and numerator events for each measure are correctly identified and reported. The audit process is designed to verify primary data sources used to populate measures and ensure specifications are correctly implemented.

The HEDIS Compliance Audit addresses the following functions:

- Information practices and control procedures
- Sampling methods and procedures
- Data integrity
- Compliance with HEDIS specifications
- Analytic file production
- Reporting and documentation

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse;* ***if no empirical sensitivity analysis****, identify the approaches for handling missing data that were considered and pros and cons of each*)

HEDIS addresses missing data in a structured way through its audit process. HEDIS measures apply to enrolled members in a health plan, and NCQA-certified auditors use standard audit methodologies to assess whether data sources are missing data. If a data source is found to be missing data, and the issues cannot be rectified, the auditor will assign a "materially biased" designation to the measure for that reporting plan, and the rate will not be used. Once measures are added to HEDIS, NCQA conducts a first-year analysis to assess the measure's feasibility once widely implemented in the field. This analysis includes an assessment of how many plans report valid rates vs. rates that are materially biased (or have other issues, such as small denominators). These considerations are weighed in the deliberation process before measures are approved for public reporting.

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias**?** (i.*e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted;* ***if no empirical analysis****, provide rationale for the selected approach for missing data*)

All of the commercial, Medicaid and Medicare health plans that reported 2018 HEDIS data for this measure reported valid rates as determined by NCQA-certified auditors through the process described above. This means that auditors did not find any missing data sources for any of the health plan data submissions and determined that none of the rates were materially biased.

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score), Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

ALL data elements are in defined fields in a combination of electronic sources

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

NCQA conducts an independent audit of all HEDIS collection and reporting processes, as well as an audit of the data which are manipulated by those processes, in order to verify that HEDIS specifications are met. NCQA has developed a precise, standardized methodology for verifying the integrity of HEDIS collection and calculation processes through a two-part program consisting of an overall information systems capabilities assessment followed by an evaluation of the MCO's ability to comply with HEDIS specifications. NCQA-certified auditors using standard audit methodologies will help enable purchasers to make more reliable comparisons between health plans.

The HEDIS Compliance Audit addresses the following functions:

1) Information practices and control procedures
2) Sampling methods and procedures
3) Data integrity
4) Compliance with HEDIS specifications
5) Analytic file production

6) Reporting and documentation

In addition to the HEDIS audit, NCQA provides a system to allow "real-time" feedback from measure users. Our Policy Clarification Support System receives thousands of inquiries each year on over 100 measures. Through this system, NCQA responds immediately to questions and identifies possible errors or inconsistencies in the implementation of the measure. This system informs both annual updates to the measures as well as routine re-evaluation of measures. These processes include updating value sets and clarifying the specifications. Measures are re-evaluated on a periodic basis and when there is a significant change in evidence.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm)*.

Broad public use and dissemination of these measures are encouraged and NCQA has agreed with NQF that noncommercial uses do not require the consent of the measure developer. Use by health care physicians in connection with their own practices is not commercial use. Commercial use of a measure requires the prior written consent of NCQA. As used herein, "commercial use" refers to any sale, license, or distribution of a measure for commercial gain, or incorporation of a measure into any product or service that is sold, licensed, or distributed for commercial gain, even if there is no actual charge for inclusion of the measure.

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
Public Reporting Quality Improvement (external benchmarking to organizations)	Quality Improvement (Internal to the specific organization) Healthcare Effectiveness Data and Information Set (HEDIS) https://www.ncqa.org/hedis/using-hedis-measures/

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

HEDIS: The Healthcare Effectiveness Data and Information Set (HEDIS) is one of health care's most widely used performance improvement tools.190 million people are enrolled in health plans across the nation that report HEDIS results. HEDIS measures are used by health plans and other various levels of the health care system for quality improvement initiatives.

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)

This measure was a new HEDIS measure in 2018. NCQA's standard process is to evaluate data for all new measures prior to use for public reporting, benchmarking and/or other programs.

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

As part of new measure evaluation, NCQA works with multi-stakeholder advisory panels to assess the number of plans that have shown they can report the measure; whether measure results match what we expect; whether results seem indicative of true performance; and whether performance indicates an opportunity for improvement for the industry overall. Because this measure uses the newer HEDIS Electronic Clinical Data Systems Reporting Method, NCQA's timeline and plan are to assess these issues after each year of the measure's reporting. We anticipate that the measure will be approved for public reporting and eligible for use in programs within the next several years, but this is pending our continued assessment.

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

Health plans that report HEDIS calculate their rates and know their performance when submitting to NCQA. NCQA publicly reports rates across all plans and also creates benchmarks in order to help plans understand how they perform relative to other plans. Public reporting and benchmarking are effective quality improvement methods.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

NCQA publishes HEDIS results annually in our Quality Compass tool. NCQA also presents data at various conferences and webinars. For example, at the annual HEDIS Update and Best Practices Conference, NCQA presents results from all new measures' first year of implementation or analyses from measures that have changed significantly. NCQA also regularly provides technical assistance on measures through its Policy Clarification Support System, as described in Section 3c.1.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

NCQA measures are evaluated regularly using a consensus-based process to consider input from multiple stakeholders, including but not limited to entities being measured. We use several methods to obtain input, including vetting of the measure with several multi-stakeholder advisory panels, public comment posting, and review of questions submitted to the Policy Clarification Support System. This information enables NCQA to comprehensively assess a measure's adherence to the HEDIS Desirable Attributes of Relevance, Scientific Soundness and Feasibility.

4a2.2.2. Summarize the feedback obtained from those being measured.

During a recent public comment posting held during the measure development process, most of the comments from measured entities supported the new measure. In general, respondents found the measures to be relevant and clearly specified.

4a2.2.3. Summarize the feedback obtained from other users

This measure has been deemed a priority measure by NCQA and other entities such as the Centers for Disease Control and Prevention, the federal National Vaccine Program Office and the American Immunization Registry Association. During a recent public comment posting conducted during the measure development process,

commenters were supportive of the measure and specifically highlighted the need for measures assessing routine adult immunizations. Commenters noted that many adults still do not receive these important vaccines, despite Advisory Committee on Immunization Practices recommendations and national efforts to improve adult immunization rates in the US.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

During measure development, feedback obtained through the mechanisms described in 4a2.2.1 informed how we specified the measure to align with immunization guidelines from the Advisory Committee on Immunization Practices.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

This is a new measure; therefore, we do not yet have data on improvement over time. Adoption of this measure has the potential to improve the immunization rates for adults.

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

There were no identified unintended findings for this measure during testing or since implementation.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

There were no identified unexpected benefits for this measure during testing or since implementation.

5. Comparison to Related or Competing Measures

If a measure meets the above criteria **and** there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

0039 : Flu Vaccinations for Adults Ages 18 and Older

0041 : Preventive Care and Screening: Influenza Immunization

0043 : Pneumococcal Vaccination Status for Older Adults (PNU)

0431 : INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL

0680 : Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)

0681 : Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (Long Stay)

0682 : Percent of Residents or Patients Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay)

0683 : Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Long-Stay)

1653 : Pneumococcal Immunization

1659 : Influenza Immunization

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

No

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

This measure assesses influenza, Td/Tdap, herpes zoster and pneumococcal vaccination for a general adult population. It is a population-based measure that assesses vaccines provided in the outpatient setting at the health plan level. Most of the other NQF-endorsed vaccination measures focus only on either pneumococcal or influenza vaccination. These measures specifically apply to inpatient populations, residents in long-term care/skilled nursing facilities or healthcare personnel or are specified at the provider-level. Moreover, our proposed measure is specified to use electronic clinical data, while other related measures (e.g., NQF 0039) are specified to use survey data in which patients must recall whether they had received a vaccine.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

Our proposed measure is more specific than several of the other adult vaccination measures because it assesses whether health plan members received the appropriate type and doses of vaccines at the right time according to clinical guidelines. Other vaccine measures that require the use of survey data are less specific because they rely on patient recall of whether they had received a vaccine. In addition, our proposed measure includes four separate rates for each recommended routine adult vaccine, which provides a more complete picture of adult vaccinations at the health plan level.

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

No appendix **Attachment:**

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): National Committee for Quality Assurance

Co.2 Point of Contact: Bob, Rehm, rehm@ncqa.org, 202-955-1728-

Co.3 Measure Developer if different from Measure Steward: National Committee for Quality Assurance

Co.4 Point of Contact: Bob, Rehm, rehm@ncqa.org, 202-955-1728-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

ADULT IMMUNIZATION MEASUREMENT ADVISORY PANEL

Alison Chi, American Immunization Registry Association

Nicole Johnson, CareSource Management Group

Sarah Royce, California Department of Health

Krista Ventrone, Excellus Blue Cross/Blue Shield

Kimberly Wildes, ThedaCare Physicians

Walter Williams, Centers for Disease Control and Prevention

Jane Zucker, New York City Department of Health and Mental Hygiene

TECHNICAL MEASUREMENT ADVISORY PANEL?

Andy Amster, MSPH, Kaiser Permanente?

Sarah Bezeredi, MBA, MSHL, UnitedHealth Group

Jennifer Brudnicki, MBA, Inovalon Inc.

Lindsay Cogan, MS, PhD, New York State Department of Health

Mike Farina, MBA, R.Ph, Capital District Physicians' Health Plan

Marissa Finn, MBA, CIGNA?

Scott Fox, MS, Med, FAMIA, The MITRE Corporation?

Carlos Hernandez,?CenCal?Health?

Harmon Jordan, ScD, Westat??

Gigi Raney, LCSW, Center for Medicaid and CHIP Services

Lynne?Rothney-Kozlak, MPH,?Rothney-Kozlak Consulting, LLC?

Laurie Spoll, Aetna

?

COMMITTEE ON PERFORMANCE MEASUREMENT??

Andrew Baskin, MD, Aetna??

Elizabeth Drye, MD, SM, Yale School of Medicine

Andrea Gelzer, MD, MS, FACP, AmeriHealth Caritas

Kate Goodrich, MD, MHS, Centers for Medicare & Medicaid Services

David Grossman, MD, MPH, Washington Permanente Medical Group

Christine Hunter, (Co-Chair), MD, WPS Health Solutions?

David Kelley, MD, MPA, Pennsylvania Department of Human Services

Jeffrey Kelman,?MMSc, MD, Department of Health and Human Services

Nancy Lane, PhD, Independent Consultant

Bernadette Loftus, MD, Freelance

Adrienne Mims, MD, MPH, AGSF, FAAFP, Alliant Health Solutions

Amanda Parsons, MD, MBA, Metroplus

Wayne Rawlins, MD, MBA, ConnectiCare

Misty Roberts, MSN, RN, CPHQ, PMP, Humana

Rudy Saenz, MD, MMM, FACOG, Riverside Medical Clinic

Marcus?Thygeson, (Co-Chair), MD, MPH, Blind On-Demand

JoAnn Volk, MA, Georgetown University

The NCQA Adult Immunizations Measurement Advisory Panel advised NCQA during measure development. They evaluated the way staff specified the measure, reviewed field test results, and assessed NCQA's overall desirable attributes of Relevance, Scientific Soundness, and Feasibility. The advisory panel consisted of a balanced group of experts, including representatives from pediatric care. In addition to this advisory panel, we vetted the measure with a host of other stakeholders, as is our process. Thus, our measures are the result of consensus from a broad and diverse group of stakeholders.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2018

Ad.3 Month and Year of most recent revision: 08, 2020

Ad.4 What is your frequency for review/update of this measure? Approximately every 3 years, sooner if the clinical guidelines have changed significantly.

Ad.5 When is the next scheduled review/update for this measure? 12, 2022

Ad.7 Disclaimers: These performance measures are not clinical guidelines and do not establish a standard of medical care and have not been tested for all potential applications. THE MEASURSE AND SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND.

Ad.8 Additional Information/Comments: NCQA Notice of Use. Broad public use and dissemination of these measures is encouraged and NCQA has agreed with NQF that noncommercial uses do not require the consent of the measure developer. Use by health care physicians in connection with their own practices is not