



Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to sub criterion 1b).

Brief Measure Information

NQF #: 0555

Corresponding Measures:

De.2. Measure Title: INR Monitoring for Individuals on Warfarin

Co.1.1. Measure Steward: Pharmacy Quality Alliance

De.3. Brief Description of Measure: Percentage of individuals at least 18 years of age as of the end of the measurement period with at least 56 days of warfarin therapy who receive at least one International Normalized Ratio (INR) test during each 56-day interval with active warfarin therapy.

1b.1. Developer Rationale: Warfarin remains the most commonly prescribed anticoagulant in the United States overall[1] and among Medicare PDP beneficiaries.[2] Warfarin has a narrow therapeutic range requiring regular monitoring with the INR test and dose adjustment to maintain patient safety by avoiding thromboembolism or bleeding complications. Warfarin has been identified as the leading drug class implicated in emergency hospitalizations for adverse drug events in adults over 65 years of age.[3] Consequences of adverse drug events related to warfarin therapy are serious and can be fatal. One study found a case-fatality rate of 11.3% for venous thromboembolism (VTE).[4] Case fatality rates for patients with major bleeding can range from 8 percent to 11 percent[4-7] and can reach 45 percent to 50 percent for those with intracranial bleeding.[8,9] For patients with stable INRs, clinical practice guidelines recommend frequent and continuous INR monitoring every 4 to 12 weeks.[10,11] This measure aims to promote patient safety through medication management of individuals on warfarin and to encourage providers to conduct regular INR monitoring for these individuals. Regular INR monitoring is associated with increased time in therapeutic range [12-14] and reduced risk of thromboembolism,[14] whereas subtherapeutic INR is correlated with significantly higher total healthcare costs[15, 16] and greater risks of stroke/SE,[17] major bleeding[17,18], thromboembolism,[18] and mortality.[17-19]

Current health plan-level performance indicates a quality gap remains. Using 2016 QHP claims data, we found there is a 15.2% difference between the 10th and 90th percentiles with a median score of 56.6% indicating that just over half of health plan members receive regular INR monitoring. In 2016 Medicare claims data, there is an 18.2% difference between the 10th and 90th percentiles with a median score of 71.4% among prescription drug plans. This is a decrease in performance over time compared to the measure developer's previous testing information using data from Medicare prescription drug plans from 2012, which showed a median score of 75.6% and percentiles (P) of performance as follows: P10=64.8%, P25=68.5%, P50=75.6%, P75=81.0%, P90=83.6% indicating variation in performance and room for improvement.[20]

Studies from the literature also suggest an opportunity for improvement in the management of patients on warfarin. A 2015 retrospective study of 9,433 patients who received warfarin for >6 months found that 39% of INR values were out of range.[15] A 2016 review of 6 meta-analyses evaluating the stability of INR (i.e., greater than or equal to 65% time in therapeutic range [TTR]) for patients on anticoagulation therapy found that there is high variability among patients and when patients achieve the target INR range, they do not remain stable and typically have INR values below the therapeutic range, increasing their risk of adverse drug events.[21] A study published in 2018 provides support for the process-outcome linkage: "Patients with TTR <65% had a higher risk for any stroke/SE (HR: 1.57; 95% CI: 1.41–1.75), major bleeding (HR: 2.78; 95% CI: 2.55–3.03) and all-cause mortality (HR: 1.73; 95% CI: 1.67–1.79)."[17] These findings are similar to another study that found that INR variability was shown to be a predictor of mortality where patients with more TTR had higher survival time.[19] The association between TTR and thromboembolism, major bleeding, and death has also been demonstrated in a sample of patients with mechanical heart valve prosthesis.[18]

The literature combined with our empirical evidence suggests room for improvement in anticoagulation management which this measure supports through INR monitoring by specifying an evidence-based interval of 56 days (8 weeks).[12] Further, NQF 0555 is the only endorsed measure that addresses regular monitoring for individuals on warfarin. While NQF 0555 is related to both NQF

0556 (INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications) and NQF 2732 (INR Monitoring for Individuals on Warfarin after Hospital Discharge), all three measures have different clinical foci and target populations. These measures are discussed further in question 5a.2

Citations

1. US Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National Action Plan for Adverse Drug Event Prevention. Washington, DC: US Department of Health and Human Services; 2014. <https://health.gov/hcq/pdfs/ade-action-plan-508c.pdf>. Accessed June 11, 2018.
2. Centers for Medicare & Medicaid Services. Medicare Part D Drugs. Baltimore, MD: US Department of Health and Human Services; 2017. https://portal.cms.gov/wps/portal/unauthportal/unauthmicrostrategyreportslink?evt=2048001&src=mstrWeb.2048001&documentID=203D830811E7EBD80000080EF356F31&visMode=0¤tViewMedia=1&Server=E48V126P&Project=OIPDA-BI_Prod&Port=0&connmode=8&ru=1&share=1&hiddensections=header,path,dockTop,dockLeft,footer. Accessed October 16, 2018.
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4. Carrier M, Le Gal G, Wells PS, Rodger MA. Systematic review: case-fatality rates of recurrent venous thromboembolism and major bleeding events among patients treated for venous thromboembolism. *Annals of internal medicine*. 2010;152(9):578-589. doi: 10.7326/0003-4819-152-9-201005040-00008.
5. Douketis JD, Arneklev K, Goldhaber SZ, Spandorfer J, Halperin F, Horrow J. Comparison of bleeding in patients with nonvalvular atrial fibrillation treated with Ximelagatran or Warfarin: Assessment of incidence, case-fatality rate, time course and sites of bleeding, and risk factors for bleeding. *Arch Intern Med*. 2006;166(8):853-859. doi: 10.1001/archinte.166.8.853
6. Linkins LA, Choi PT, Douketis JD. Clinical impact of bleeding in patients taking oral anticoagulant therapy for venous thromboembolism: A meta-analysis. *Annals of internal medicine*. 2003;139(11):893-900.
7. Hylek EM, Held C, Alexander JH, et al. Major bleeding in patients with atrial fibrillation receiving apixaban or warfarin: The ARISTOTLE Trial (Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation): Predictors, Characteristics, and Clinical Outcomes. *Journal of the American College of Cardiology*. 2014;63(20):2141-2147. doi: 10.1016/j.jacc.2014.02.549.
8. Hylek EM, Singer DE. Risk factors for intracranial hemorrhage in outpatients taking warfarin. *Annals of internal medicine*. 1994;120(11):897-902.
9. Punthakee X, Doobay J, Anand SS. Oral-anticoagulant-related intracerebral hemorrhage. *Thromb Res*. 2002;108(1):31-36.
10. Holbrook A, Schulman S, Witt DM, et al. Evidence-based management of anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. 2012;141(2 Suppl):e152S-184S. doi: 10.1378/chest.11-2295.
11. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology*. 2014;64(21):e1-76. doi: 10.1016/j.jacc.2014.03.022.
12. Rose AJ, Miller DR, Ozonoff A, et al. Gaps in monitoring during oral anticoagulation: insights into care transitions, monitoring barriers, and medication nonadherence. *Chest*. 2013;143(3):751-757. doi: 10.1378/chest.12-1119.
13. Rose AJ, Park A, Gillespie C, et al. Results of a regional effort to improve warfarin management. *Annals of Pharmacotherapy*. 2017. doi: 10.1177/1060028016681030.
14. Witt DM, Delate T, Clark NP, et al. Nonadherence with INR monitoring and anticoagulant complications. *Thromb Res*. 2013;132(2):e124-130. doi: 10.1016/j.thromres.2013.06.006.
15. Nelson WW, Wang L, Baser O, Damaraju CV, Schein JR. Out-of-range international normalized ratio values and healthcare cost among new warfarin patients with non-valvular atrial fibrillation. *Journal of medical economics*. 2015;18(5):333-340. doi: 10.3111/13696998.2014.1001851.
16. Deitelzweig S, Evans M, Hillson E, et al. Warfarin time in therapeutic range and its impact on healthcare resource utilization and costs among patients with nonvalvular atrial fibrillation. *Curr Med Res Opin*. 2016;32(1):87-94. doi: 10.1185/03007995.2015.1103217.
17. Liu S, Li X, Shi Q, et al. Outcomes associated with warfarin time in therapeutic range among US veterans with nonvalvular atrial fibrillation. *Curr Med Res Opin*. 2018;34(3):415-421. doi: 10.1080/03007995.2017.1384370.
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19. Vanerio G. International Normalized Ratio Variability: A Measure of Anticoagulation Quality or a Powerful Mortality Predictor. *J Stroke Cerebrovasc Dis*. 2015;24(10):2223-2228. doi: 10.1016/j.jstrokecerebrovasdis.2015.05.017.
20. National Quality Forum. Measure Information: #0555 INR Monitoring for Individuals on Warfarin, Last Updated Jul 02, 2015.

2015.
 21. Schein JR, White CM, Nelson WW, Kluger J, Mearns ES, Coleman CI. Vitamin K antagonist use: evidence of the difficulty of achieving and maintaining target INR range and subsequent consequences. *Thromb J.* 2016;14:14. doi: 10.1186/s12959-016-0088-y.

S.4. Numerator Statement: The number of individuals in the denominator who receive at least one INR monitoring test during each 56-day interval with active warfarin therapy. The number of individuals in the denominator who receive at least one INR monitoring test during each 56-day interval with active warfarin therapy.

S.6. Denominator Statement: Continuously enrolled individuals, at least 18 years of age at the end of the measurement period, with at least 56 days of warfarin therapy during the measurement period.

S.8. Denominator Exclusions: 1. Individuals who are monitoring INR at home. These individuals are excluded because the claims associated with home INR monitoring are associated with up to four INR tests per claim. Therefore, a single claim for home INR monitoring would not be representative of a single INR test and would prohibit being able to distinguish if the home INR test was within the 56-day timeframe specified by the numerator of this measure.

2. Individuals who have first or last warfarin claims with missing days' supply.

De.1. Measure Type: Process

S.17. Data Source: Claims

S.20. Level of Analysis: Health Plan

IF Endorsement Maintenance – Original Endorsement Date: Aug 05, 2009 **Most Recent Endorsement Date:** Jun 10, 2019

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? Not applicable

1. Evidence, Performance Gap, Priority – 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

[NQF_0555_Measure_Evidence_Attachment_-_Final_181029-636764172797235295.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.

Yes

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.

Warfarin remains the most commonly prescribed anticoagulant in the United States overall[1] and among Medicare PDP beneficiaries.[2] Warfarin has a narrow therapeutic range requiring regular monitoring with the INR test and dose adjustment to maintain patient safety by avoiding thromboembolism or bleeding complications. Warfarin has been identified as the leading drug class implicated in emergency hospitalizations for adverse drug events in adults over 65 years of age.[3] Consequences of adverse drug events related to warfarin therapy are serious and can be fatal. One study found a case-fatality rate of 11.3% for venous thromboembolism (VTE).[4] Case fatality rates for patients with major bleeding can range from 8 percent to 11 percent[4-7] and can

reach 45 percent to 50 percent for those with intracranial bleeding.[8,9] For patients with stable INRs, clinical practice guidelines recommend frequent and continuous INR monitoring every 4 to 12 weeks.[10,11] This measure aims to promote patient safety through medication management of individuals on warfarin and to encourage providers to conduct regular INR monitoring for these individuals. Regular INR monitoring is associated with increased time in therapeutic range [12-14] and reduced risk of thromboembolism,[14] whereas subtherapeutic INR is correlated with significantly higher total healthcare costs[15, 16] and greater risks of stroke/SE,[17] major bleeding[17,18], thromboembolism,[18] and mortality.[17-19]

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Citations

1. US Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National Action Plan for Adverse Drug Event Prevention. Washington, DC: US Department of Health and Human Services; 2014. <https://health.gov/hcq/pdfs/ade-action-plan-508c.pdf>. Accessed June 11, 2018.
2. Centers for Medicare & Medicaid Services. Medicare Part D Drugs. Baltimore, MD: US Department of Health and Human Services; 2017. https://portal.cms.gov/wps/portal/unauthportal/unauthmicrostrategyreportslink?evt=2048001&src=mstrWeb.2048001&documentID=203D830811E7EBD80000080EF356F31&visMode=0¤tViewMedia=1&Server=E48V126P&Project=OIPDA-BI_Prod&Port=0&connmode=8&ru=1&share=1&hiddensections=header,path,dockTop,dockLeft,footer. Accessed October 16, 2018.
3. Budnitz DS, Lovegrove MC, Shehab N, Richards CL. Emergency hospitalizations for adverse drug events in older Americans. *N Engl J Med*. 2011;365(21):2002-2012. doi: 10.1056/NEJMsa1103053.
4. Carrier M, Le Gal G, Wells PS, Rodger MA. Systematic review: case-fatality rates of recurrent venous thromboembolism and major bleeding events among patients treated for venous thromboembolism. *Annals of internal medicine*. 2010;152(9):578-589. doi: 10.7326/0003-4819-152-9-201005040-00008.
5. Douketis JD, Arneklev K, Goldhaber SZ, Spandorfer J, Halperin F, Horrow J. Comparison of bleeding in patients with nonvalvular atrial fibrillation treated with Ximelagatran or Warfarin: Assessment of incidence, case-fatality rate, time course and sites of bleeding, and risk factors for bleeding. *Arch Intern Med*. 2006;166(8):853-859. doi: 10.1001/archinte.166.8.853
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10. Holbrook A, Schulman S, Witt DM, et al. Evidence-based management of anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. 2012;141(2 Suppl):e152S-184S. doi: 10.1378/chest.11-2295.
11. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology*. 2014;64(21):e1-76. doi: 10.1016/j.jacc.2014.03.022.
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14. Witt DM, Delate T, Clark NP, et al. Nonadherence with INR monitoring and anticoagulant complications. *Thromb Res*. 2013;132(2):e124-130. doi: 10.1016/j.thromres.2013.06.006.
15. Nelson WW, Wang L, Baser O, Damaraju CV, Schein JR. Out-of-range international normalized ratio values and healthcare cost among new warfarin patients with non-valvular atrial fibrillation. *Journal of medical economics*. 2015;18(5):333-340. doi: 10.3111/13696998.2014.1001851.
16. Deitelzweig S, Evans M, Hillson E, et al. Warfarin time in therapeutic range and its impact on healthcare resource utilization and costs among patients with nonvalvular atrial fibrillation. *Curr Med Res Opin*. 2016;32(1):87-94. doi: 10.1185/03007995.2015.1103217.
17. Liu S, Li X, Shi Q, et al. Outcomes associated with warfarin time in therapeutic range among US veterans with nonvalvular atrial fibrillation. *Curr Med Res Opin*. 2018;34(3):415-421. doi: 10.1080/03007995.2017.1384370.
18. Labaf A, Sjalander A, Stagmo M, Svensson PJ. INR variability and outcomes in patients with mechanical heart valve prosthesis. *Thromb Res*. 2015;136(6):1211-1215. doi: 10.1016/j.thromres.2015.10.044.
19. Vanerio G. International Normalized Ratio Variability: A Measure of Anticoagulation Quality or a Powerful Mortality Predictor. *J Stroke Cerebrovasc Dis*. 2015;24(10):2223-2228. doi: 10.1016/j.jstrokecerebrovasdis.2015.05.017.
20. National Quality Forum. Measure Information: #0555 INR Monitoring for Individuals on Warfarin, Last Updated Jul 02, 2015. 2015.
21. Schein JR, White CM, Nelson WW, Kluger J, Mearns ES, Coleman CI. Vitamin K antagonist use: evidence of the difficulty of achieving and maintaining target INR range and subsequent consequences. *Thromb J*. 2016;14:14. doi: 10.1186/s12959-016-0088-y.

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.

Data
Several sources of data were used in testing the measure. Data representing the target population—members enrolled in Affordable Care Act (ACA) Health Insurance Exchange QHP products—are from four issuers, representing seven QHP products in 2015 and eight products in 2016. Patient-level data representing the target population—members enrolled in Affordable Care Act (ACA) Health Insurance Exchange QHP products—were provided to the Measure Developer from one issuer, henceforth Issuer 1. These data were used to calculate all analyses. A data analytic firm provided QHP analytic results for three issuers, henceforth Issuer 2, Issuer 3, and Issuer 4, in lieu of patient-level data. Additionally, national claims data from Medicare Part B and stand-alone Part D prescription drug plans (PDPs) were used to supplement the QHP analyses since limited QHP data were available for testing.

Analytic Processes

Performance scores on the measure as specified are below. To align with the 2018 Quality Rating System Measure Technical Specifications, all analyses included the following analytic processes:[1,2]

- QHP products with 500 or fewer total members were excluded from all analyses, and
- Denominators had to have at least 30 members in order to show the results of analyses.

The 501 member and 30 minimum denominator rules are not part of the measure specifications. The analyses followed these rules to reflect steps that would be taken if the measure were implemented in the Quality Rating System (QHP data). The 501 member and 30 minimum denominator rules were not applied to the Medicare data since the rules are specific to the Quality Rating System (QHP data).

Performance Scores

Overall, across 4 QHP products from 3 QHP Issuers with sufficient denominators to report measure rates, the performance scores ranged from 48.9% to 62.1% in 2015, and from 43.9% to 59.1% in 2016 (see below). In 2016, there was variation among Medicare PDP measure rates, and measure performance remained suboptimal (average rate of 71.7%) among Medicare PDPs. The performance rates of this measure suggest opportunity for improving care for QHP consumers and Medicare beneficiaries who take warfarin therapy.

RESULTS:

QHP Issuer 1, 2015-2016

The issuer data used to calculate the measure represents 289,136 members and 3 QHP products in 2015, and 223,427 members and 3 QHP products in 2016.

Year / Product / Denominator / Numerator / Rate

2015 / B / 419 / 205 / 48.9%

2016 / B / 326 / 143 / 43.9%

QHP Issuer 2, 2015-2016

The issuer data used to calculate the measure represents 1 product with 45,537 members in 2015, and 30,128 members in 2016.

Year / Product / Denominator / Numerator / Rate

2015 / A / 306 / 190 / 62.1%

2016 / A / 203 / 120 / 59.1%

QHP Issuer 3, 2015-2016

The issuer data used to calculate the measure represents 2 products in 2015 representing 14,093 members, and 3 products in 2016 representing 75,637 members.

Year / Product / Denominator / Numerator / Rate

2015 / A / 57 / 32 / 56.1%

2016 / A / 185 / 105 / 56.8%

2015 / B / Insufficient denominator size for calculation

2016 / B / 126 / 71 / 56.3%

Medicare PDPs, 2012*, 2015, 2016

The Medicare data used to calculate the measure includes 1,140,068 beneficiaries in 2015 and 1,059,826 beneficiaries in 2016. Performance scores from the 2012 data are included for comparison; the scores from 2012 reflect the previous measure specifications submitted to NQF for re-endorsement in 2013.

Plans with at least 100 eligible individuals (minimum denominator for reliability of at least 0.7):

Year / n / Mean / Min / Max / STD / IQR / P10 / P25 / P50 / P75 / P90

2012 / 39 / 74.5% / 59.7% / 88.3% / 7.2% / 12.6% / 64.8% / 68.5% / 75.6% / 81.0% / 83.6%

2015 / 56 / 76.7% / 42.0% / 89.0% / 7.7% / 7.4% / 68.5% / 73.1% / 77.1% / 80.5% / 87.5%

2016 / 51 / 71.7% / 46.4% / 85.1% / 7.5% / 10.1% / 64.0% / 67.3% / 71.4% / 77.4% / 82.2%

*Results from testing using 2012 data were from the prior submission of this measure. Updated testing results are from 2015 and 2016.

Citations:

1. National Committee for Quality Assurance. HEDIS® 2018 Volume 2 Technical Specifications for Health Plans. Washington, DC: National Committee for Quality Assurance; 2018.

2. Centers for Medicare & Medicaid Services. 2018 Quality Rating System Measure Technical Specifications. Baltimore, MD: US Department of Health and Human Services; 2018. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Revised_QRS-2018-Measure-Tech-Specs_20170929_508.pdf. Accessed July 13, 2018.

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.

Not applicable

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.*

Background

Disparities within the QHP data were determined using the limited demographic variables included in our testing data. At this time, information required to calculate certain disparities (e.g., race/ethnicity) is not coded in a standard manner within administrative claims.[1] Further, there is a lack of clarity regarding which entity (e.g., physician, group, plan, and/or employer) is responsible for capturing and reporting these data.[1] Other health plan measures (e.g., HEDIS quality measures) do not currently collect or report quality performance data stratified by sociodemographic factors.[2]

Method

In the disparities analyses for the measure, female is the reference group for gender, white is the reference group for race/ethnicity, the age group 45-64 is the reference for QHP data, 65+ is the reference group for age for Medicare, and Medicare only is the reference group for dual-enrolled status. Results may be interpreted as better, worse, or the same as a reference group.

In order to assess whether disparities in measure performance exist between subpopulations of the measure cohort, we used the method employed by the Agency for Healthcare Research and Quality (AHRQ) for the National Healthcare Quality and Disparities Report. Disparities statistics were only calculated when the comparison and reference denominators both had at least 30 members in the denominator.[1] Disparities between pairs of population groups were considered identified if the following criteria were met:

1. a Z-test for the difference between two proportions, using a pooled estimate of the variance, was significant with an alpha level of less than 0.05,
2. the relative difference between proportions was greater than 10%

P-Value = statistically significant at the alpha <0.05 level two-tailed Z-test)

Relative Difference = [(Comparison group measure score – Reference group measure score) / Reference group measure score] * 100.

Performance scores on the measure as specified are below, stratified by subpopulation. Results are only shown for those that produced results that met the criteria above to be considered a disparity. Overall, the small denominator sizes of the QHP data limited the disparities analyses. Results based on Medicare data are aggregated national measure rates, whereas QHP rates are issuer-product specific.

Results

Among three issuers' QHP products, disparities for sex were not found in either 2015 or 2016. In 2015, in one issuer, and in one product, a disparity by age group was evidenced: the 27 to 44 age group had lower performance compared to the reference group of 45 to 64.

Although statistical significance was found in the results from Medicare PDP data, national measure rates suggest there is not disparity in care between sexes due to a less than 10% relative difference in measure rates in both 2015 and 2016. However, national measure rates among Medicare PDPs suggest that beneficiaries who were younger, did not identify as white, and were dually eligible for Medicare and Medicaid services had lower measure rates.

Overall, the results of disparities analyses support the measurement of the targeted process of care given that disparities were suggested in both QHP and Medicare data.

Issuer 1 – 2015 & 2016: Rates by Age

2015 - Age

A significant relative difference was detected in Product B measure rates between the 27 to 44 age group and the reference age group of 45 to 64 with the younger age group having lower performance. The other two age groups did not have sufficient denominator size for calculation and comparison.

Product / Variable / Denominator / Numerator / Measure rate/ Relative difference / p-value

B / 18 - 26 / Insufficient denominator size for calculation

B / 27 - 44 / 37 / 11 / 29.7% / 41.5 / .0073
B / 45 - 64 / 350 / 178 / 50.9% / Reference / Reference
B / 65+ / Insufficient denominator size for calculation

Medicare Part D Prescription Drug Plans – 2015 & 2016: Rates by Demographics

The following displays the demographic characteristics of the denominator and numerator from national 2015 and 2016 Medicare claims data. National measure rates tended to be significantly lower for beneficiaries who were younger, did not identify as white, and were dually eligible for Medicare and Medicaid services.

2015 - Age

Using the 65 and older category as a reference group, there were significant differences in measure rates when compared to each of the other age groups ($p < 0.0001$ for all 3 comparisons). In addition, the relative difference in measure rates were at least 10% higher for those 65 and older compared to all younger age groups, indicating a disparity in INR monitoring by age with younger age groups less likely to be tested.

Variable / Denominator / Numerator / Measure rate / Relative difference / p-value

18 -26 / 661 / 443 / 67.0% / -13.52 / .0001
27 - 44 / 15,452 / 9,981 / 64.0% / -16.65 / .0001
45 - 64 / 107,147 / 70,747 / 66.0% / -14.80 / .0001
65+ / 1,016,805 / 788,021 / 77.5% / Reference / Reference

2016 - Age

Using the 65 and older category as a reference group, there were significant differences in measure rates when compared to each of the other age groups ($p < 0.0001$ for all 3 comparisons). In addition, the relative difference in measure rates were at least 10% higher for those 65 and older compared to all younger age groups, indicating a disparity in INR monitoring by age with younger age groups less likely to be tested.

Variable / Denominator / Numerator / Measure rate / Relative difference / p-value

18 -26 / 542 / 339 / 62.6% / -13.6 / .0001
27 - 44 / 13,357 / 7,876 / 59.0% / -18.5 / .0001
45 - 64 / 96,342 / 59,610 / 61.9% / -14.5 / .0001
65+ / 949,585 / 687,168 / 72.4% / Reference / Reference

2015 - Race

Significant differences exist between all racial categories when comparing to those who identified as white ($p < 0.0001$ for all 4 comparisons). With the exception of the unknown racial category, the relative differences in measure rates were at least 10% with whites having significantly more INR tests than other racial groups, indicating a disparity in INR monitoring by race.

Variable / Denominator / Numerator / Measure rate / Relative difference / p-value

White / 1,008,019 / 780,361 / 77.4% / Reference / Reference
African American / 87,155 / 58,985 / 67.7% / -12.58 / .0001
Hispanic / 13,739 / 8,630 / 62.8% / -18.86 / .0001
Other / 23,873 / 15,914 / 66.7% / -13.89 / .0001
Unknown / 7,282 / 5,215 / 71.6% / -7.49 / .0001

2016 - Race

Significant differences exist between all racial categories when comparing to those who identified as white ($p < 0.0001$ for all 4 comparisons). With the exception of the unknown racial category, the relative differences in measure rates were at least 10% with whites having significantly more INR tests than other racial groups, indicating a disparity in INR monitoring by race.

Variable / Denominator / Numerator / Measure rate / Relative difference / p-value

White / 937,692 / 679,123 / 72.4% / Reference / Reference
African American / 78,690 / 49,534 / 63.0% / -13.1 / .0001
Hispanic / 12,641 / 7,256 / 57.4% / -20.7 / .0001
Other / 22,384 / 13,471 / 60.2% / -16.9 / .0001
Unknown / 8,419 / 5,609 / 66.6% / -8.0 / .0001

2015 - Dual-Eligible Status

Dual-eligible beneficiaries are those who are eligible for both Medicare and Medicaid due to their percentage of federal poverty

level.[4] Significant differences in measure rates were detected between non-dual-eligible and dual-eligible beneficiaries ($p < 0.001$) with non-dual-eligible beneficiaries having a relative difference of more than 10% more INR tests than dual-eligible beneficiaries, indicating a disparity in INR monitoring by dual-eligible status.

Variable / Denominator / Numerator / Measure rate / Relative difference / p-value

Non-dual-eligible / 890,686 / 696,933 / 78.3% / Reference/ Reference

Dual-eligible / 249,382 / 172,172 / 69.0%/ -11.77 / .0001

2016 - Dual-Eligible Status

Significant differences in measure rates were detected between non-dual-eligible and dual-eligible beneficiaries ($p < 0.001$) with non-dual-eligible beneficiaries having a relative difference of more than 10% more INR tests than dual-eligible beneficiaries, indicating a disparity in INR monitoring by dual-eligible status.

Variable / Denominator / Numerator / Measure rate / Relative difference / p-value

Non-dual-eligible / 839,127 / 611,798 / 72.9% / Reference/ Reference

Dual-eligible / 220,699 / 143,195 / 64.9%/ -11.0 / .0001

Citations:

1. Escarce JJ, Carreon R, Veselovskiy G, Lawson EH. Collection of race and ethnicity data by health plans has grown substantially, but opportunities remain to expand efforts. *Health Aff (Millwood)*. 2011;30(10):1984-1991. doi: 10.1377/hlthaff.2010.1117.
2. National Committee for Quality Assurance. HEDIS® 2017 Volume 2 Technical Specifications for Health Plans. Washington, DC: National Committee for Quality Assurance; 2017
3. Centers for Medicare & Medicaid Services. 2018 Quality Rating System Measure Technical Specifications. Baltimore, MD: US Department of Health and Human Services; 2018. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Revised_QRS-2018-Measure-Tech-Specs_20170929_508.pdf. Accessed July 13, 2018.
4. Centers for Medicare & Medicaid Services. Seniors & Medicare and Medicaid Enrollees. Baltimore, MD: US Department of Health and Human Services; nd. <https://www.medicare.gov/medicaid/eligibility/medicaid-enrollees>. Accessed July 27, 2018.

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

Rose et al. (2013)[1] found that 45% of the 56,490 Veterans Health Administration patients included in their study, who were aged 65 years and older, had at least one gap ≥ 56 days in INR monitoring, representing 44,430 total gaps and 4,482,100 days without INR monitoring over the two-year study period. Predictors of any gaps in monitoring during warfarin therapy that were identified in the study included: younger age (age of 65-69 years versus ≥ 75 years [OR: 1.07; 95%CI: 1.01-1.13]), non-white race (non-Hispanic black race [OR: 1.26; 95%CI: 1.14-1.50], Hispanic race [OR: 1.31; 95%CI: 1.14-1.50], and Native American race [OR: 1.32; 95%CI: 1.01-1.73]), and residence in a zip code with a poverty level below the federal poverty line (poverty level 17.8%-100.0% [OR: 1.24; 95%CI: 1.06-1.45]). The findings from this study are consistent with our analyses of Medicare PDP data that suggest non-dual-eligibles, whites, and older adults have significantly more INR testing compared to dual-eligibles, other racial groups, and younger age groups.

Witt et al. (2013) compared 2,544 patients nonadherent to INR monitoring (≥ 2 missed INR tests in a row) and 4,995 patients adherent to INR monitoring (never missed ≥ 2 INR tests in a row) from Kaiser Permanente Colorado and described patient characteristics associated with INR monitoring nonadherence.[2] The study found that factors associated with nonadherence to INR testing included: younger age (increasing age [per year] OR: 0.96; 95% CI: 0.95-0.97), and male sex (female OR: 0.85; 95%CI: 0.77-0.95). The findings from this study are consistent with our analyses of Medicare PDP data that suggest that older adults have significantly more INR testing compared to younger age groups; however, our analyses did not indicate any disparities by sex based on the two criteria used to define disparities (i.e., significant difference and $>10\%$ relative difference).

Citations

1. Rose AJ, Miller DR, Ozonoff A, et al. Gaps in monitoring during oral anticoagulation: insights into care transitions, monitoring barriers, and medication nonadherence. *Chest*. 2013;143(3):751-757. doi: 10.1378/chest.12-1119.
2. Witt DM, Delate T, Clark NP, et al. Nonadherence with INR monitoring and anticoagulant complications. *Thromb Res*. 2013;132(2):e124-130. doi: 10.1016/j.thromres.2013.06.006.

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):

Cardiovascular

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

Safety, Safety : Medication

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

Elderly, Populations at Risk

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.)

Not applicable

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 Attachment: [0555_INR_CompleteCoding-636764172796610581.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.

Yes

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.

Age specification was changed from at least 18 years of age at the beginning of the measurement period to at least 18 years of age as of the end of the measurement period for the purpose of alignment and harmonization with Healthcare Effectiveness Data and Information Set (HEDIS) quality measures.

National Drug Codes (NDCs) have been updated to include new drugs on the market that are applicable to the measure. Drugs that have been discontinued for more than three years have been removed.

Enrollment criteria were changed from enrollment for 11 out of 12 months to enrollment in a Qualified Health Plan (QHP) product for at least two months, with no gap in enrollment between the first enrolled month and last enrolled month of a calendar year. This was done for two reasons: 1) at least two consecutive months are necessary to create a 56-day interval and 2) to maximize the

number of patients eligible for the measure. The latter rationale adapts the measure for member turnover within QHP products operating in the Health Insurance Exchange. Utilizing the previous specifications of enrollment for 11 out of 12 months resulted in approximately 50% of the members in our QHP sample that would not meet the criteria to be included in the measure.

The following describes the terminology of the units associated with the Health Insurance Exchange used throughout this form: “Issuer” refers to an individual insurance company or insurance organization. The term “product” refers to a package of health coverage benefits that are offered using a particular network type (i.e., health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity). Unique products for each issuer are referred to using alphabetic labeling (e.g., two unique products from the same issuer are referred to as Product A and Product B).

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).

The number of individuals in the denominator who receive at least one INR monitoring test during each 56-day interval with active warfarin therapy. The number of individuals in the denominator who receive at least one INR monitoring test during each 56-day interval with active warfarin therapy.

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).

Individuals in the denominator who have at least one INR test performed during each 56-day interval with warfarin therapy will be counted in the numerator. All 56-day intervals in which an individual is both prescribed warfarin and continuously enrolled are used to calculate the INR compliance rate for the individual. A 56-day interval with a hospitalization of more than 48 hours is considered an interval with an INR test.

Interval: The first day of the first 56-day interval is the start date of the first warfarin prescription in the measurement period, and the last day of the first 56-day interval is the start date of the first warfarin prescription + 55 days. The subsequent 56-day interval starts on the day after the first 56-day interval and ends 56 days following the first 56-day interval, as long as this end date occurs within the warfarin therapy time frame. This process continues until a calculated 56-day interval end date does not occur within the warfarin therapy time frame. If there are fewer than 56 days of warfarin therapy within the warfarin therapy time frame, those remaining days are not counted in any interval in determining the numerator. Only full 56-day intervals are used for calculating the numerator. “Warfarin usage” or “warfarin therapy” is determined by the start date of the first prescription for warfarin up through the start date of the last prescription for warfarin plus the days’ supply from the last claim.

2015-2017 CODES FOR INR TEST

The specific year of codes used for the measure is dependent upon the measurement year.

CPT code:

85610 – Prothrombin time

LOINC codes:

34714-6 – INR in blood by coagulation assay

5894-1 – Prothrombin time (PT) actual/normal

6301-6 – INR in platelet poor plasma by coagulation assay

38875-1 – INR in platelet poor plasma or blood by coagulation assay

5964-2 – Prothrombin time (PT) in blood by coagulation

5902-2 – Prothrombin time (PT)

6418-0 – INR in capillary blood by coagulation assay [2016 only]

46418-0 – INR in capillary blood by coagulation assay [2017 only]

46417-2 – Prothrombin time (PT) in capillary blood by coagulation assay

52129-4 – INR in platelet poor plasma by coagulation assay—post heparin adsorption

Note: A full list of codes necessary for measure calculation is provided in the attached Excel file.

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

Continuously enrolled individuals, at least 18 years of age at the end of the measurement period, with at least 56 days of warfarin therapy during the measurement period.

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).

The time period of the data is defined as any time during the measurement period (12 consecutive months). “Continuously enrolled” for this measure is defined as enrollment in a QHP product for at least two months, with no gap in enrollment between the first enrolled month and last enrolled month of a calendar year. “Warfarin usage” or “warfarin therapy” is determined by the start date of the first prescription for warfarin through the start date of the last prescription for warfarin plus the days’ supply from the last claim.

ENROLLMENT CRITERIA

Criteria for QHP products: At least two months enrollment in a QHP product, with no gap in enrollment between the first enrolled month and the last enrolled month of a calendar year.

MEDICATION ACTIVE INGREDIENTS

Active Ingredients by Class: Anticoagulants – Warfarin. Note the active ingredient is limited to oral formulations only. A full list of codes necessary for measure calculation is provided in an attached Excel file.

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

1. Individuals who are monitoring INR at home. These individuals are excluded because the claims associated with home INR monitoring are associated with up to four INR tests per claim. Therefore, a single claim for home INR monitoring would not be representative of a single INR test and would prohibit being able to distinguish if the home INR test was within the 56-day timeframe specified by the numerator of this measure.
2. Individuals who have first or last warfarin claims with missing days’ supply.

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.)

2015-2017 INR MONITORING AT HOME HCPCS CODES:

G0248 – Demonstrate Use Home INR Mon

G0249 – Provide Test Mats & Equip Home INR

G0250 – MD INR Test Review Inter Mgmt

Note: A full list of codes necessary for measure calculation is provided in the attached Excel file.

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.)

Not applicable

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.)

Denominator: Continuously enrolled individuals, at least 18 years of age at of the end of the measurement period, with at least 56 days of warfarin therapy during the measurement period.

Create Denominator:

1. Pull individuals who are at least 18 years of age as of the end of the measurement period.
2. Include individuals who meet continuous enrollment criteria as described above in S.7.
3. Of the individuals identified in Step 2, include those who had warfarin claims during the measurement period.
4. Exclude individuals who have warfarin claims with missing days' supply. Exclude individuals who are monitoring their INR at home.
5. Of the individuals who were not excluded in Step 4, calculate the start date and end date of warfarin therapy for each individual and count the days between the start date and the end date inclusive. If an individual's death date is available, then use the death date as the end date.
6. Keep individuals who had at least 56 days of warfarin therapy during the measurement period and calculate the number of full 56-day intervals for each individual.

Numerator: The number of individuals in the denominator who receive at least one INR monitoring test during each 56-day interval with active warfarin therapy.

Create Numerator:

7. Pull all INR test claims from claims data for the current measurement period.
8. From the claims identified in Step 7, keep only those INR test claims for the individuals who are included in the denominator.
9. From claims data, identify and pull all inpatient stays of more than 48 hours during the measurement period (where hours are not available, calculate and keep stays of at least three days).
10. From the claims identified in Step 9, keep those that are for the individuals who are included in the denominator.
11. Combine the INR test claims dataset from Step 8 and the hospitalizations of more than 48 hours dataset from Step 10.
12. Using the start date of warfarin therapy identified in the denominator, determine the subsequent start dates for each of the calculated 56-day interval(s) of warfarin therapy and determine the number of full 56-day intervals designated in the denominator for each individual.
13. From the dataset created in Step 11, create a dataset containing INR tests performed and inpatient stays by unique individual and date of service.
14. Determine which full 56-day intervals have an INR test completed or have an inpatient stay by comparing each date of service from Step 13 to each full 56-day interval for each individual designated in Step 12.
15. From the dataset created in Step 14, calculate the individual's INR monitoring compliance rate as the sum of the number of full 56-day intervals with an INR test divided by the total number of full 56-day intervals.
16. From the dataset created in Step 15, calculate the measure numerator by counting the number of individuals with a 100% INR monitoring compliance rate.

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.

This measure is not based on a sample.

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.

This measure is not based on survey or patient-reported data.

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

If other, please describe in S.18.

Claims

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.

There is no data collection instrument; individual health plans produce administrative claims in the course of providing care to health plan members.

The following sources of data are needed to calculate NQF 0555:

1. QHP products: Claims data from issuers, consisting of hospital and office visits, pharmacy, and laboratory claims (when available); enrollment data; and members' demographic data OR
2. Medicare: Claims data from Medicare Parts A, B and D consisting of inpatient and outpatient claims and prescription drug events; enrollment data; and beneficiaries' demographic data.

Please note that Medicare data were used for measure testing to enhance the measure testing results. At the time this form was completed, CMS does not yet have any plan to add this measure to any quality reporting or value-based purchasing programs for Medicare beneficiaries but may consider these measures for the future. However, this measure is being considered for use in the Quality Rating System for Qualified Health Plans.

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.)

Not applicable because this is not a composite performance measure.

2. Validity – See attached Measure Testing Submission Form

[NQF_0555_Measure_Testing_Form_-_Final_181029-636764172797860443.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.

Yes

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.

Yes

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.

No - This measure is not risk-adjusted

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.

Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

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 electronic claims

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).

This measure is specified using administrative claims data. At this time, there is no plan to specify the measure as an 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.

Testing demonstrated the measure was feasible to be specified and calculated using administrative claims data from QHP products and Medicare PDPs. Data used in the calculation of this measure are obtained from administrative claims, which are routinely, reliably, and securely collected for billing purposes. We do not anticipate any feasibility or implementation issues related to data collection for this measure. No threats to the validity of this measure were identified using a limited analysis designed to address missing data.

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).

None

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)

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

Not applicable because the measure is not currently in use.

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 previously in use for the Quality and Resource Use Reports,[1] but has not been in use since the last NQF review in 2013. This measure is now being considered for use in the Quality Rating System for QHPs. The Quality Rating System is intended to inform consumers when choosing a QHP from the Health Insurance Exchange by providing comparisons of the quality of care provided by each health plan. The Quality Rating System is not used for payment or penalty to the health plans.

Citations

1. Centers for Medicare & Medicaid Services. Analysis of 2011 Physician Feedback Program Individual Reports. Retrieved July 19, 2018, from <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/PY2011-Individual-Report.pdf>.

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.)

This measure will be considered for use in the Quality Rating System for QHPs offered on the Exchanges.

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.

The measure is not currently implemented in a public reporting program, and therefore there is no information available regarding feedback during implementation. Our Technical Expert Panel (TEP) reviewed the updated measure evidence, testing, and

performance results and interpretation via several webinar conferences. The TEP is comprised of three representatives from large QHP issuers, and nine individuals from other stakeholder groups, such as organization representatives, clinical and nonclinical experts, and patient/caregiver representatives. A full list of the TEP members' names and organizations is noted under the Additional Information section of this document.

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.

Meetings with the TEP were held throughout 2015-2017. During these meetings, TEP members were provided with updated measure evidence, development, and testing results. Data necessary to judge the validity and usability of the measure were provided, along with the measure algorithm and a complete list of codes used to calculate the measure. Questions that arose from these meetings were addressed either during the meeting or in follow-up communications.

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.

TEP members were encouraged to provide feedback throughout the measure re-evaluation process by means of meeting discussions and voting and through follow-up communications. Members were sent a questionnaire focused on face validity and usability which contained closed-ended response options and free text comment fields.

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

TEP members who represented organizations being measured responded to a questionnaire and indicated that this measure has clear and precise specifications, that health plans will use information from this measure to improve quality of care for patients on warfarin therapy, and that health plans will be able to implement the measure without undue burden for reporting for the Quality Rating System. Those being measured agreed (n=3/3) that the measure can distinguish good from poor plan-level quality related to the process of administering at least one INR monitoring test during each 56-day interval among those with active warfarin therapy (i.e., the measure has face validity). Additionally, one issuer compared this measure against a warfarin measure they currently use (to measure INR re-check intervals) and found this measure, INR Monitoring for Individuals on Warfarin, to be valid when compared to their current measure.

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

TEP members who represented other stakeholder groups responded to a questionnaire and indicated that this measure has clear and precise specifications, that health plans will use information from this measure to improve quality of care for patients on warfarin therapy, and that health plans will be able to implement the measure without undue burden for reporting for the Quality Rating System. Respondents agreed (n=6/6) that the measure can distinguish good from poor plan-level quality related to the process of administering at least one INR monitoring test during each 56-day interval among those with active warfarin therapy (i.e., the measure has face validity). Three members did not respond to the questionnaire. All feedback received regarding this measure indicates that the measure will be useful for health plans to improve quality of care for patients on warfarin therapy and can be implemented without undue burden for reporting for the Quality Rating System.

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.

TEP and workgroup feedback was considered throughout the measure re-evaluation process. Feedback received was unanimously (9/9) in favor of the specifications described in this submission form; therefore, revision of the measure specifications was not necessary.

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.

The measure is not currently implemented in a public reporting program; therefore, we describe how the performance results could be used to further the goal of high-quality care. The low performance rates of the QHP products in our analysis (average rate of 54.0% in 2016) suggest substantial opportunity for improvement in the management of patients on warfarin among QHP products in the Health Insurance Exchange. Among Medicare PDPs, measure rates decreased from 74.5% in 2012 to 71.7% 2016, underscoring the need for performance measurement for patients on warfarin therapy. The performance rates of this measure in both populations suggest opportunity for improving care for patients on warfarin therapy.

This measure is actionable by both providers and plans and can be used to further the goal of high-quality care. The desired outcome for this measure is fewer bleeding and thromboembolic events in individuals on warfarin. Regular INR monitoring is associated with increased time in therapeutic range [1-3] and reduced risk of thromboembolism,[3] whereas subtherapeutic INR is correlated with significantly higher total healthcare costs[4, 5] and greater risks of stroke/SE,[6] major bleeding[6,7], thromboembolism,[7] and mortality.[6-8] Health outcome linkage is further discussed in the Evidence Attachment.

Citations

1. Rose AJ, Miller DR, Ozonoff A, et al. Gaps in monitoring during oral anticoagulation: insights into care transitions, monitoring barriers, and medication nonadherence. *Chest*. 2013;143(3):751-757. doi: 10.1378/chest.12-1119.
2. Rose AJ, Park A, Gillespie C, et al. Results of a regional effort to improve warfarin management. *Annals of Pharmacotherapy*. 2017. doi: 10.1177/1060028016681030.
3. Witt DM, Delate T, Clark NP, et al. Nonadherence with INR monitoring and anticoagulant complications. *Thromb Res*. 2013;132(2):e124-130. doi: 10.1016/j.thromres.2013.06.006.
4. Nelson WW, Wang L, Baser O, Damaraju CV, Schein JR. Out-of-range international normalized ratio values and healthcare cost among new warfarin patients with non-valvular atrial fibrillation. *Journal of medical economics*. 2015;18(5):333-340. doi: 10.3111/13696998.2014.1001851.
5. Deitelzweig S, Evans M, Hillson E, et al. Warfarin time in therapeutic range and its impact on healthcare resource utilization and costs among patients with nonvalvular atrial fibrillation. *Curr Med Res Opin*. 2016;32(1):87-94. doi: 10.1185/03007995.2015.1103217.
6. Liu S, Li X, Shi Q, et al. Outcomes associated with warfarin time in therapeutic range among US veterans with nonvalvular atrial fibrillation. *Curr Med Res Opin*. 2018;34(3):415-421. doi: 10.1080/03007995.2017.1384370.
7. Labaf A, Sjalander A, Stagmo M, Svensson PJ. INR variability and outcomes in patients with mechanical heart valve prosthesis. *Thromb Res*. 2015;136(6):1211-1215. doi: 10.1016/j.thromres.2015.10.044.
8. Schein JR, White CM, Nelson WW, Kluger J, Mearns ES, Coleman CI. Vitamin K antagonist use: evidence of the difficulty of achieving and maintaining target INR range and subsequent consequences. *Thromb J*. 2016;14:14. doi: 10.1186/s12959-016-0088-y.

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.

This measure is not currently in use, however, previous measure maintenance efforts reported that no unintended negative consequences had been identified in the 2011 Quality and Resource Use Reports.[1]

Citations

1. Centers for Medicare & Medicaid Services. Analysis of 2011 Physician Feedback Program Individual Reports. Baltimore, MD: Centers for Medicare & Medicaid Services; 2012. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/PY2011-Individual-Report.pdf>. Accessed September 12, 2018.

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

The measure has not been in use, and therefore there are no unexpected benefits from implementation to report.

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)

0556 : INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications

2732 : INR Monitoring for Individuals on Warfarin after Hospital Discharge

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

Related measures are endorsed.

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?

Yes

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

The measure under review (NQF 0555) is related to both NQF 0556 (INR for Individuals Taking Warfarin and Interacting Anti-Infective Medications) and NQF 2732 (INR Monitoring for Individuals on Warfarin after Hospital Discharge). All three have the same measure focus, which is INR testing, and their specifications for INR testing are harmonized; however, the three measures have different clinical foci and target populations. The measure under review (NQF 0555) focuses on INR testing during every 56-day interval in which an individual is prescribed warfarin. NQF 0556 focuses on INR testing within three to seven days for patients on warfarin who are prescribed anti-infective medications that are known to interact with warfarin and result in a higher risk for adverse events, and NQF 2732 focuses on INR monitoring within 14 days of hospital discharge for individuals on warfarin who were not yet in the therapeutic range at the time of discharge. Due to the difference in the clinical foci, the timeframe for INR monitoring (three to seven days, 14 days, 56 days) is different among the three measures and complimentary rather than competing with one another.

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.)

Not applicable

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):** Pharmacy Quality Alliance
Co.2 Point of Contact: Lynn, Pezzullo, lpezzullo@pqaalliance.org, 401-474-9706-
Co.3 Measure Developer if different from Measure Steward: Health Services Advisory Group
Co.4 Point of Contact: Melissa, Castora-Binkley, mcastora-binkley@hsag.com, 813-865-3182-

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.

Original Technical Expert Panel (TEP), 2009-2011

1. Douglas Bell, MD, PhD, Associate Professor in Residence, UCLA Department of Medicine, Division of General Internal Medicine and Health Services Research?
2. Jill S. Borchert, PharmD, BCPS, FCCP, Professor, Pharmacy Practice & PGY1 Residency Program Director, Northwestern University, Chicago College of Pharmacy?
3. Anne Burns, RPh, Vice President, Professional Affairs, American Pharmacists Association?
4. Jannet Carmichael, PharmD, BCPS, FCCP, FAPHA, VISN 21 Pharmacy Executive, VA Sierra Pacific Network?
5. Marshall H. Chin, MD, MPH, Professor of Medicine, University of Chicago?
6. Edward Eisenberg, MD, Vice President and Chief Medical Officer, Medicare, Medco Health Solutions?
7. Jay A. Gold, MD, JD, MPH, Senior Vice President and Medicare Chief Medical Officer, MetaStar, Inc.?
8. David Nau, PhD, MS, Senior Director of Research & Performance Measurement, PQA, Inc.
9. N. Lee Rucker, PhD, MS, Senior Strategic Policy Advisor, AARP - Public Policy Institute?
10. Marissa Schlaifer, RPh, MS, Director of Pharmacy Affairs Academy of Managed Care Pharmacy?
11. Brad Tice, PharmD, Chief Clinical Officer, PharmMD Solutions, LLC?
12. Jennifer K. Thomas, PharmD, Manager, Pharmacy Services, Delmarva Foundation for Medical Care/Delmarva Foundation of the District of Columbia?
13. Darren Triller, PharmD, Director, Pharmacy Services, IPRO?
14. Neil Wenger, MD, MPH, Professor of Medicine, UCLA Department of Medicine, Division of General Internal Medicine and Health Services Research

Current Technical Expert Panel (TEP), 2015-2017

1. Andy Amster, MSPH, Kaiser Permanente National Office
2. Marybeth Farquhar, PhD, MSN, RN, URAC
3. Susan Fitzpatrick, RN, BSN, Cigna Healthcare
4. Aparna Higgins, Duke-Margolis Center for Health Policy; Brandeis University
5. Jon Mark Hirshon, MD, PhD, MPH, University of Maryland, School of Medicine
6. Christine Hunter, MD, US Office of Personnel Management
7. Carol Keegan, PhD, Patient representative
8. Dana Mukamel, PhD, University of California, Irvine
9. Chinwe Nwosu, NS, America's Health Insurance Plans
10. Derek Robinson, MD, MBA, FACEP, Health Care Service Corporation
11. Arlene Salamendra, Patient representative
12. Ted von Glahn, MSPH, von Glahn Consulting

The TEP evaluated this medication safety measure drafted by Health Services Advisory Group (HSAG), originally developed by FMQAI, in regard to the four primary measure evaluation criteria used in the NQF consensus endorsement process (importance, scientific acceptability, feasibility, and usability). The TEP discussed the strengths and weaknesses of the measure and made recommendations regarding measure specifications, and inclusion and exclusion criteria.

Measure Developer/Steward Updates and Ongoing Maintenance

- Ad.2 Year the measure was first released:** 2009
Ad.3 Month and Year of most recent revision: 07, 2018
Ad.4 What is your frequency for review/update of this measure? Annually

Ad.5 When is the next scheduled review/update for this measure? 07, 2019

Ad.6 Copyright statement: Limited proprietary coding is contained in the Measure specifications for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets.

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ICD-10 copyright 2017 World Health Organization. All Rights Reserved.

LOINC® copyright 2004-2017 Regenstrief Institute, Inc.

Uniform Bill Codes copyright 2017 American Hospital Association. All rights reserved.

Ad.7 Disclaimers: This performance measure does not establish a standard of medical care and has not been tested for all potential applications.

Ad.8 Additional Information/Comments: Not applicable