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 #: 3595

Corresponding Measures:

De.2. Measure Title: Hydroxyurea Use Among Children with Sickle Cell Anemia

Co.1.1. Measure Steward: University of Michigan

De.3. Brief Description of Measure: The percentage of children ages 1 to 18 years with sickle cell anemia (SCA) who were dispensed hydroxyurea for at least 300 days within the measurement year.

1b.1. Developer Rationale: Children with sickle cell anemia (SCA) experience common and excruciating pain crises. Daily receipt of the oral medication hydroxyurea substantially reduces the incidence of these pain crises, as well as acute chest syndrome. Prior studies indicate that hydroxyurea rates are low. This measure establishes a claims-based methodology for identifying hydroxyurea use among children with SCA. The performance scores calculated through this measure will identify areas in need of improvement in hydroxyurea use among children with SCA.

S.4. Numerator Statement: The number of children ages 1 to 18 years with sickle cell anemia (SCA) who were dispensed hydroxyurea for at least 300 days within the measurement year.

S.6. Denominator Statement: The number of children ages 1 to 18 years with sickle cell anemia (SCA) within the measurement year.

S.8. Denominator Exclusions: NA

De.1. Measure Type: Process

S.17. Data Source: Claims

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?

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

- This is a new process measure utilizing claims data at the health plan level to assess the percentage of children ages 1 to 18 years with sickle cell anemia (SCA) who were dispensed hydroxyurea for at least 300 days within the measurement year.
- The developer provides a logic model depicting that daily receipt of hydroxyurea results in substantial reduction of the incidence of pain crises and acute chest syndrome among children with SCA.
- The developer cites a Clinical Practice Guideline recommendation from the National Heart, Lung, and Blood Institute to support the daily use of hydroxyurea in substantially reducing the incidence of pain crises and acute chest syndrome among children with sickle cell anemia.
- Strong Recommendation, High-Quality Evidence for ages 9-42 months and Moderate Recommendation, Moderate-Quality Evidence for children >42 months and adolescents.
- The developer cited Randomized Controlled Trials (RCT) and observational studies including children with SCA.

Exception to evidence

- Not Applicable

Questions for the Committee:

- What is the relationship of this measure to patient outcomes?
- How strong is the evidence for this relationship?
- Is the evidence directly applicable to the process of care being measured?

Guidance from the Evidence Algorithm

Process measure based on systematic review (Box 3) → QQC presented (Box 4) → Quantity: high; Quality: high; Consistency: high (Box 5a) → High

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

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

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

- The developer presented the rates of *hydroxyurea dispensed for at least 300 days within the measurement year for children with sickle cell anemia in Michigan Medicaid program (2010-2018):*

  (Year: Numerator / Denominator = Rate)

  2010: 16/300 = 5.33%

  2011: 13/303 = 4.29%

  2012: 10/281 = 3.56%

  2013: 7/294 = 2.38%

  2014: 11/294 = 3.74%

  2015: 12/319 = 3.76%

  2016: 19/407 = 4.67%

  2017: 26/351 = 7.41%

  2018: 18/366 = 4.92%

Disparities

- The developer indicated that datasets for the performance scores are derived from Medicaid, therefore disparities by insurance or socioeconomic status were not identified. However, due to the disproportionate burden among minorities, sickle cell anemia is often considered to be an indicator of a health disparity.

Questions for the Committee:

- Is there a gap in care that warrants a national performance measure?
- Are you aware of evidence that disparities exist in this area of healthcare?

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.

- This is a process measure assessing receipt of hydroxyurea for at least 300 days in each calendar year for ages 1-18.
- rating for evidence high
- Process measure. There is high (9-42 months of age) or moderate quality evidence (>42 Months) to reduce incidence of crisis and acute chest syndrome in children with sickle cell anemia.
- Evidence supports the measure.
- No major concerns
- This is a new process measure. The systematic evidence review is that conducted for the National Heart, Lung, and Blood Institute's "Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014." Two RCTs and 33 observational studies including children with SCA were reviewed. In this report, there are 11 recommended actions regarding treatment of people with sickle cell anemia (SCA) with hydroxyurea. The guideline supports the daily use of hydroxyurea in substantially reducing

the incidence of pain crises and acute chest syndrome among children with sickle cell anemia. For ages 9 - 42 months, there is a strong recommendation based on high quality evidence. For ages greater than 42 months including adolescents, there is a moderate recommendation based on moderate quality evidence.

- Evidence is strong for the question.
- Evidence is strong for the measure. Process measure.
- Process Measure, evidence rating high

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?

- data from the MI medicaid program shows low performance.
- opportunity for improvement
- There is a documented performance gap (most recent data 2018 with ~5% of children using hydroxyurea). Disparities are not identified.
- Performance data provided that demonstrates a gap.
- Yes, gap exists
- Rates of hydroxyurea dispensed for at least 300 days within the management year for children with SCA in the Michigan Medicaid Program between 2010 and 2018 varied from 2.38% to 7.41% (with no trend apparent). Medicaid data does not identify disparities by insurance or socioeconomic status. However, due to the disproportionate burden among minorities, sickle cell anemia is often considered to be an indicator of a health disparity.
- Performance gap is very large.
- Only tested in the Michigan Medicaid population - so disparities across populations were not provided. The Michigan Medicaid data did identify disparities in care.
- A significant performance gap exists

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:

2d. Empirical analysis to support composite construction. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

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

Evaluators: NQF Staff

Staff Review

Evaluation Summary:

Reliability

- A separate method of reliability testing was not provided by the developer since empirical validity testing was conducted.
- For some measure types, separate reliability testing of the data elements is not required if empirical validity testing of the data elements is conducted (and results are adequate). Data element validity was used to support the reliability of this measure.

Validity

- The developer conducted data element testing using both ICD-9-CM and ICD-10-CM diagnosis codes.
    - ICD-9-CM denominator was validated via comparison with the gold standard of newborn screening results for the state of Michigan for children enrolled in Michigan Medicaid in 2010 and 2011 with at least one SCD-related healthcare claim within their enrollment year(s).
        - Results: In 2010, a case definition of three Hb SS (282.61, 282.62) claims within the year was 91.4% sensitive and 80% specific in identifying children with sickle cell anemia (Hb SS) (PPV: 80.4%; NPV: 91.3%).
    - ICD-10-CM denominator was validated through a four step process: (a) developing candidate SCA case definitions; (b) identifying a test population for the definitions; (c) testing the accuracy of candidate case definitions; and (d) testing case definitions within an independent population. Measures of performance (sensitivity, specificity, area under ROC curve) were calculated using newborn screening results as the gold standard.
        - Results: Across the 23 case definitions, measures of performance varied, with sensitivities from 0.02-0.97 and specificities from 0.88-1.0. The case definition of ≥1 outpatient visit with a SCA-related (D5700, D5701, D5702) or D571 code had the highest area under the ROC curve, with a sensitivity of 95% and specificity of 92%.
    - Results from both ICD-9-CM and ICD-10-CM diagnosis codes indicate that children with sickle cell anemia can be identified with a high level of accuracy in administrative data.
- The numerator (children with sickle cell anemia that have at least 300 days of filled hydroxyurea within the year) was validated by identifying all filled prescriptions for children in the denominator (children with sickle cell anemia), identifying all NDCs that were not related to hydroxyurea and comparing this list to RxNorm to manually assess that all remaining NDCs were not related to hydroxyurea.
        - Results: 67 NDCs for hydroxyurea within administrative claims were identified, which is interpreted by the developer as a high level of validity for identifying children within the numerator.

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?

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

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?

- no risk adjustment.
- na
- empirical validity used to comment on reliability
- Data elements are clear. No concerns.
- No major concerns
- Data comes from Medicaid claims at the health plan level (Michigan, New York State, Medicaid MAX). The denominator is the number of children ages 1 to 18 years with SCA within the measurement year. The numerator is the number of children ages 1 to 18 years with SCA who were dispensed hydroxyurea for at least 300 days within the measurement year. The identification of children with SCA is different under ICD-9 and ICD-10 but these processes are defined.
- I believe the measure can be consistently implemented.
- The data elements should be available. The developer's data was moderate to support the reliability of the measure.
- No concerns

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

- no
- na
- No
- No concerns.
- No major concerns
- "If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required."
- Reliability appears to be moderate.
- Empirical validity testing was completed. No concerns with reliability testing though would like to see other programs/populations being included in the tests other than just Medicaid.
- No concerns

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

- no concerns
- empirical validity testing
- No
- No concerns
- No major concerns
- Critical data element analysis using both ICD-9-CM and ICD-10-CM diagnosis codes showed that children with SCA can be identified with a high level of accuracy in administrative data.
- No concerns about validity.

- Data element testing was used by the developer for validity testing. 91.4% sensitive and 80% specific in identifying children with sickle cell anemia. I would like to see stronger validity.
- No concerns

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?

- no risk adjustment.
- na
- Noted that sickle cell anemia is associated with a health disparity
- No exclusions.
- No major concerns
- There were no exclusions or risk adjustments/stratification.
- At present, I see no issues with exclusions or risk adjustment.
- No concerns with exclusion criteria.
- No concerns

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?

- will need restricted use data agreements which could constitute a threat if unable to obtain from some jurisdictional .
- na
- no concerns
- No threats to validity.
- No major concerns
- We used Medicaid MAX data to determine if differences at the state health plan level could be assessed using this measure. Using the MAX data, the proportion of children dispensed at least 300 days of hydroxyurea was calculated for each state health plan. We limited the denominator population to children with sickle cell anemia that had evidence of hydroxyurea use (i.e., had a greater than 30-day supply within the year). Using a chi-square test and resulting p-values, it is possible to determine meaningful differences in performance scores across state health plans. There was only one set of specifications. Although information regarding prescriptions or diagnosis codes may be missing, we are unable to ascertain the extent of such missing data. We do not anticipate that any missing data would differ in any systematic manner across children with SCA.
- At present no specific concerns.
- No identified threats to validity.
- No concerns

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 data elements required for the measure are routinely generated and used during care delivery and all data elements used in the measure are in defined fields in electronic claims.
- The primary information needed for this measure includes basic demographics, diagnosis codes, and procedure codes and dates. These data are widely available, although obtaining them often requires a restricted-use data agreement.
- Acquisition of data directly from states requires the cooperation of those jurisdictions.

Questions for the Committee:

- Is the data collection strategy ready to be put into operational use?

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?

- data elements should be available. Would like to know how individuals are managed if they don't enter care for >65 days (these would be automatic fallouts).
- data elements used in the measure are in defined fields in electronic claims
- no concerns
- Data elements are routinely generated during care delivery. No concerns
- No major concerns
- All data elements are in defined fields in electronic claims. When the measure is used at the single-state level, state health departments can use their own Medicaid data.
- Seems very feasible.
- No concerns with feasibility. All data elements needed to calculate the measure should be available in administrative or electronic form.
- Process measure, data elements routinely generated in the delivery of care

Criterion 4: Usability and Use

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.

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

Accountability program details

- The developer noted that the State of Michigan Medicaid Program will be implementing this measure for purposes of building a health plan collaborative to improve the care of children with sickle cell anemia in Michigan.
- The developer noted that program implementation was delayed due to COVID-19 and anticipates reporting to occur in 2021.

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

- Specifications and technical assistance were provided to Michigan Medicaid health plans and the State of Michigan Medicaid Program.
- The developer noted that feedback was sought from Michigan Medicaid after introduction to health plans and provided any necessary clarifications regarding implementation of this measure.

***Questions for the Committee**:*

- How has the measure been vetted in real-world settings by those being measured or others?

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

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.

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

Improvement results

- The developer noted that there has been no improvement, as this measure has not been applied for purposes of quality improvement at a state level.
- Further, these rates are exceedingly low and have much opportunity for improvement.

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

- No unintended negative consequences to individuals or populations were identified during testing.

Potential harms

- None identified

***Questions for the Committee**:*

- 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 to be used by MI medicaid. feedback obtained from MI medicaid.
- Planned use in an accountability program
- pending use and accountability. Public comments have been sought from Michigan Medicaid
- Plans to be used in State of Michigan but **delay** due to COVID
- No major concerns
- The State of Michigan Medicaid Program will be implementing this measure for purposes of building a health plan collaborative to improve the care of children with SCA. This program is currently being implemented. We anticipate reporting to occur in 2021. Program implementation was delayed due to COVID-19. Specifications and technical assistance were provided to Michigan Medicaid health plans and the State of Michigan Medicaid Program. Michigan Medicaid has indicated no concerns from health plans in implementing this measure but there is no description of a means of formally soliciting feedback from users or testers of this measure.
- Meets the requirements for Use.
- The State of Michigan Medicaid Program will be implementing the measure in 2021. Feedback on the measure was sought from the Michigan Medicaid Program. Information on how feedback was used by the developer was not provided.
- Planned use

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 harms.
- na
- Most likely very usable. Few harms with room for significant benefits for individuals and populations
- No harms
- No major concerns
- This measure has not yet been applied for purposes of quality improvement at a state level. As the rates of daily use of hydroxyurea in children and youth with SCA are so low, there is expectation of substantial improvement in hydroxyurea treatment adherence with the implementation of this measure that could lead to a substantial reduction in the rate of pain crises and acute chest syndrome attacks. No unintended negative consequences to individuals or populations were identified during testing.
- Appears to meet the requirements for Usability.
- Rate are very low so there is room for improvement. It is a new measure, however, the results could be used for improving quality of care and efficiency in healthcare. No identified harms were provided.

- No concerns

Criterion 5: Related and Competing Measures

Related or competing measures

- 2797 : Transcranial Doppler Ultrasonography Screening Among Children with Sickle Cell Anemia
- 3166 : Antibiotic Prophylaxis Among Children with Sickle Cell Anemia

Harmonization

- The developer states the measure specifications have been harmonized.
- Different age categories are included in the measures. For example, antibiotic prophylaxis is recommended by NHLBI for ages 0 until 5; TCD screening from ages 2 until 16; and hydroxyurea beginning at 9 months of age.
- The numerator specifications differ across each measure.

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?

- there are other sickle cell measures but different focus
- two other related measured identified. question about harmonization
- Age ranges for inclusion are different with this measure and measure 2797 and 3166, but appropriately so.
- Related measures have different specifications esp**.** age
- None identified
- There are two other NQF measures that apply to children with SCA: NQF #2797 - Transcranial Doppler Ultrasonography Screening Among Children with Sickle Cell Anemia and NQF #3166 - Antibiotic Prophylaxis Among Children with Sickle Cell Anemia. There are different age criteria. The numerators of these three measures identify different events. These multiple measures for children with SCA are justified.
- Harmonized with other related measures.
- Two competing measures were referenced: 2797 Transcranial Doppler Ultrasonography Screening Among Children with Sickle Cell Anemia and 3166: Antibiotic Prophylaxis Among Children with Sickle Cell Anemia. The develop states that the measures have been harmonized. No additional steps needed.
- No concerns

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 01/21/2021

- 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 Number: 3595

Measure Title: Hydroxyurea Use among Children with Sickle Cell Anemia

Type of measure:

☒ **Process** ☐ **Process: Appropriate Use** ☐ **Structure** ☐ **Efficiency** ☐ **Cost/Resource Use**
☐ **Outcome** ☐ **Outcome: PRO-PM** ☐ **Outcome: Intermediate Clinical Outcome** ☐ **Composite**

Data Source:

☒ **Claims** ☐ **Electronic Health Data** ☐ **Electronic Health Records** ☐ **Management Data**
☐ **Assessment Data** ☐ **Paper Medical Records** ☐ **Instrument-Based Data** ☐ **Registry Data**
☐ **Enrollment Data** ☒ **Other: Newborn Screening Records**

Level of Analysis:

☐ **Clinician: Group/Practice** ☐ **Clinician: Individual** ☐ **Facility** ☒ **Health Plan**
☐ **Population: Community, County or City** ☐ **Population: Regional and State**
☐ **Integrated Delivery System** ☐ **Other**

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.**

   No concerns

RELIABILITY: TESTING

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

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

   Submission document: Testing attachment, section 2a2.3

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.**

    Precise specifications (Box 1) → Empirical reliability testing (Box 2) → Patient level data validity (Box 3) → (Box 9 of validity algorithm) → Appropriate method to assess data elements (Box 10) → Moderate certainty that the data used in the measure are valid (Box 11a) → Highest possible rating is Moderate.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

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

    Submission document: Testing attachment, section 2b2.

    No exclusions

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

    Submission document: Testing attachment, section 2b4.

    The developer calculated the proportion of children dispensed at least 300 days of hydroxyurea for each state health plan using a chi-square test and resulting p-value to assess results. The results suggest that it is possible to determine meaningful differences in performance scores across state health plans.

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

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

    Submission document: Testing attachment, section 2b6.

    None identified

16. **Risk Adjustment**

    16a. **Risk-adjustment method** ☒ **None** ☐ **Statistical model** ☐ **Stratification**

    16b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

    ☐ Yes ☐ No ☒ Not applicable

    16c. **Social risk adjustment:**

    16c.1 Are social risk factors included in risk model? ☐ Yes ☐ No ☐ Not applicable

16c.2 Conceptual rationale for social risk factors included? ☐ Yes ☐ No

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☐ No

16d. **Risk adjustment summary:**

16d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No

16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No

16d.3 Is the risk adjustment approach appropriately developed and assessed? ☐ Yes ☐ No

16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☐ Yes ☐ No

16d.5. Appropriate risk-adjustment strategy included in the measure? ☐ Yes ☐ No

16e. **Assess the risk-adjustment approach**

VALIDITY: TESTING

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

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

☐ Face validity

☐ Empirical validity testing of the measure score

☒ N/A (score-level testing not conducted)

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

Submission document: Testing attachment, section 2b2.2

- The developer conducted data element testing using both ICD-9-CM and ICD-10-CM diagnosis codes.
    - ICD-9-CM denominator was validated via comparison with the gold standard of newborn screening results for the state of Michigan for children enrolled in Michigan Medicaid in 2010 and 2011 with at least one SCD-related healthcare claim within their enrollment year(s).
    - ICD-10-CM denominator was validated through a four step process: (a) developing candidate SCA case definitions; (b) identifying a test population for the definitions; (c) testing the accuracy of candidate case definitions; and (d) testing case definitions within an independent population. Measures of performance (sensitivity, specificity, area under ROC curve) were calculated using newborn screening results as the gold standard.
- The numerator (children with sickle cell anemia that have at least 300 days of filled hydroxyurea within the year) was validated by identifying all filled prescriptions for children in the denominator (children with sickle cell anemia), identifying all NDCs that were not related to hydroxyurea and comparing this list to RxNorm to manually assess that all remaining NDCs were not related to hydroxyurea.

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

Submission document: Testing attachment, section 2b2.3

- **ICD-9-CM denominator validation:** The developer shared that in 2010, a case definition of three Hb SS (282.61, 282.62) claims within the year was 91.4% sensitive and 80% specific in identifying children with sickle cell anemia (Hb SS) (PPV: 80.4%; NPV: 91.3%).
- **ICD-10-CM denominator validation:** The developer shared that across the 23 case definitions, measures of performance varied, with sensitivities from 0.02-0.97 and specificities from 0.88-1.0. The case definition of ≥1 outpatient visit with a SCA-related (D5700, D5701, D5702) or D571 code had the highest area under the ROC curve, with a sensitivity of 95% and specificity of 92%. Figure 1 illustrates a breakdown of performance for Candidate Case Definitions.

- Through the methodology used to assess the numerator, the developer identified 67 NDCs for hydroxyurea within administrative claims.
- The developer notes that using both ICD-9-CM and ICD-10-CM diagnosis codes, children with sickle cell anemia can be identified with a high level of accuracy in administrative data.
- The developer also notes that their methodology for identifying all potential NDCs related to hydroxyurea results in a high level of validity for identifying children within the numerator.

21. **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)

22. **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)

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.**

Potential threats to validity assessed (Box 1)→ Empirical validity testing conducted using the measure as specified (Box 2) → Testing NOT conducted at the measure score level (Box 5) → Testing conducted with patient-level data elements (Box 9) → Appropriate method to assess data elements (Box 10) → High certainty that the data used in the measure are valid (Box 11a) → Highest possible rating is MODERATE.

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.**

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

2020-11-02_Reeves_Hydroxyurea_NQF_evidence_attachment_508_Compliant.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.

1a. Evidence (subcriterion 1a)

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

Measure Title: Hydroxyurea Use among Children with Sickle Cell Anemia

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

Date of Submission:

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: Hydroxyurea Use among Children with Sickle Cell Anemia

☐ 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.

Daily receipt of hydroxyurea results in substantial reduction of the incidence of pain crises and acute chest syndrome among children with sickle cell anemia (SCA).

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.)

N/A

****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)

X 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

Evidence

Source of Systematic Review:

- Title
- Author
- Date
- Citation, including page number
- URL

National Heart, Lung, and Blood Institute. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014;71-78. https://www.nhlbi.nih.gov/health-pro/guidelines/sickle-cell-disease-guidelines.

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.

RECOMMENDATIONS

1. Educate all patients with SCA and their family members about hydroxyurea therapy. (See consensus treatment protocol on page 145).

   (*Consensus-Panel Expertise*)

2. In adults with SCA who have three or more sickle cell-associated moderate to severe pain crises in a 12-month period, treat with hydroxyurea.

   (Strong Recommendation, High-Quality Evidence)

3. In adults with SCA who have sickle cell-associated pain that interferes with daily activities and quality of life, treat with hydroxyurea.

   (Strong Recommendation, Moderate-Quality Evidence)

4. In adults with SCA who have a history of severe and/or recurrent ACS, treat with hydroxyurea.

   (Strong Recommendation, Moderate-Quality Evidence)

5. In adults with SCA who have severe symptomatic chronic anemia that interferes with daily activities or quality of life, treat with hydroxyurea.

   (Strong Recommendation, Moderate-Quality Evidence)

6. In infants 9 months of age and older, children, and adolescents with SCA, offer treatment with hydroxyurea regardless of clinical severity to reduce SCD-related complications (e.g., pain, dactylitis, ACS, anemia).

   (Strong Recommendation, High-Quality Evidence for ages 9-42 months;

   Moderate Recommendation, Moderate-Quality Evidence for children >42 months and adolescents*).*

   Note: The panel intentionally used the term “offer” realizing that patients’ values and preferences may differ particularly considering treatment burden (e.g., laboratory monitoring, office visits), availability of drug in a liquid form, and cost. Therefore, the panel strongly encourages shared decision-making and discussion of hydroxyurea therapy with all patients.

7. In adults and children with SCD who have chronic kidney disease and are taking erythropoietin, hydroxyurea therapy can be added to improve anemia.

   (Weak Recommendation, Low-Quality Evidence)

8. In females who are pregnant or breastfeeding, discontinue hydroxyurea therapy.

(Moderate Recommendation, Very Low-Quality Evidence)

9. To ensure proper use of hydroxyurea and maximize benefits and safety, use an established prescribing and monitoring protocol.

   (Strong Recommendation, High-Quality Evidence)

10. In people with HbSβ^0-thalassemia or HbSC who have recurrent sickle cell-associated pain that interferes with daily activities or quality of life, consult a sickle cell expert for consideration of hydroxyurea therapy.

    (Moderate Recommendation, Low-Quality Evidence)

11. In people not demonstrating a clinical response to appropriate doses and duration of hydroxyurea therapy, consult a sickle cell expert.

    (Moderate Recommendation, Very Low-Quality Evidence)

*For more information, see the ACS section of the "Managing Acute Complications of Sickle Cell Disease" chapter.

Grade assigned to the **evidence** associated with the recommendation with the definition of the grade

Strong Recommendation, High-Quality Evidence for ages 9-42 months

- **Grade of Recommendation:** Strong Recommendation, High-Quality Evidence
- **Clarity of Risk/Benefit:** Benefits clearly outweigh harms or burdens, or vice versa
- **Quality of Supporting Evidence:** Consistent evidence from well- performed RCTs or exceptionally strong evidence from unbiased observational studies*
- **Implications:** Recommendation can apply to most patients in most circumstances. Further research is very unlikely to change our confidence in the estimate of effect.

Moderate Recommendation, Moderate-Quality Evidence for children >42 months and adolescents. As stated within the NHLBI Clinical Guidelines: "The GRADE framework rates the strength of recommendations as "strong" or "weak." However, the panel modified the GRADE system and used a third category – moderate- when they determined that patients would be better off if they followed a recommendation, despite there being some level of uncertainty about the magnitude of benefit of the intervention or the relative net benefit of alternative courses of action.

Provide all other grades and definitions from the evidence grading system

Strong Recommendation, High-Quality Evidence

- **Clarity of Risk/Benefit:** Benefits clearly outweigh harms or burdens, or vice versa
- **Quality of Supporting Evidence:** Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies*
- **Implications:** Recommendation can apply to most patients in most circumstances. Further research is very unlikely to change our confidence in the estimate of effect.

Strong Recommendation, Moderate-Quality Evidence

- **Clarity of Risk/Benefit:** Benefits clearly outweigh harms or burdens, or vice versa
- **Quality of Supporting Evidence:** Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise evidence), or unusually strong evidence from unbiased observational studies
- **Implications:** Recommendation can apply to most patients in most circumstances. Further research (if performed) is likely to have an impact on our confidence in the estimate of effect and may change the estimate.

Strong Recommendation, Low-Quality Evidence

- **Clarity of Risk/Benefit:** Benefits clearly outweigh harms or burdens, or vice versa
- **Quality of Supporting Evidence:** Evidence for at least one critical outcome from observational studies, from RCTs with serious flaws, or indirect evidence
- **Implications:** Recommendation may change when higher quality evidence becomes available. Further research (if performed) is likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Strong Recommendation, Very Low-Quality Evidence

- **Clarity of Risk/Benefit:** Benefits clearly outweigh harms or burdens, or vice versa
- **Quality of Supporting Evidence:** Evidence for at least one of the critical outcomes from unsystematic clinical observations or very indirect evidence
- **Implications:** Recommendation may change when higher quality evidence becomes available; any estimate of effect, for at least one critical outcome, is very uncertain.

Weak Recommendation, High-Quality Evidence

- **Clarity of Risk/Benefit:** Benefits closely balanced with harms and burdens
- **Quality of Supporting Evidence:** Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies
- **Implications:** The best action may differ depending on circumstances or patient or societal values. Further research is very unlikely to change our confidence in the estimate of effect.

Weak Recommendation, Moderate-Quality Evidence

- **Clarity of Risk/Benefit:** Benefits closely balanced with harms and burdens
- **Quality of Supporting Evidence:** Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise evidence), or unusually strong evidence from unbiased observational studies
- **Implications:** Alternative approaches likely to be better for some patients under some circumstances. Further research (if performed) is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Weak Recommendation, Low-Quality Evidence

- **Clarity of Risk/Benefit:** Uncertainty in the estimates of benefits, harms, and burdens; benefits may be closely balanced with harms and burdens
- **Quality of Supporting Evidence:** Evidence for at least one critical outcome from observational studies, from RCTs with serious flaws, or indirect evidence
- **Implications:** Other alternatives may be equally reasonable. Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Weak Recommendation, Very Low-Quality Evidence

- **Clarity of Risk/Benefit:** Major uncertainty in the estimates of benefits, harms, and burdens; benefits may or may not be balanced with harms and burdens
- **Quality of Supporting Evidence:** Evidence for at least one critical outcome from unsystematic clinical observations or very indirect evidence
- **Implications:** Other alternatives may be equally reasonable. Any estimate of effect, for at least one critical outcome, is very uncertain.

Source: Reprinted with permission of the American Thoracic Society. Copyright 2012 American Thoracic Society. Shunemann HJ, Jaeschke R, Cook DJ, Bria WF, El-Solh AA, Ernst A, Fahy BF, Gould MK, Horan KL, Krishnan JA, Manthous CA, Maurer JR, McNicholas WT, Oxman AD, Rubenfeld G, Turino GM, Guyatt G; ATS Documents Development and

Implementation Committee. An official ATS statement; grading the quality of evidence and strength of recommendations in ATS guidelines and recommendations. *Am J Respir Crit Care Med*. 2006 Sep 1:174(5):605-14. Official Journal of the American Thoracic Society.[29]

* Exceptionally strong evidence from unbiased observational studies includes: (1) evidence from studies that yield estimates of the treatment effect that are large and consistent; (2) evidence in which all potential biases may be working to underestimate an apparent treatment effect, and therefore, the actual treatment effect is likely to be larger than that suggested by the study data; and (3) evidence in which a dose-response gradient exists

Grade assigned to the **recommendation** with definition of the grade

Strong Recommendation for children ages 9-42 months; for definition, see evidence grading system above.

Moderate Recommendation for children >42 months and adolescents; for definition, see evidence grading system above.

Provide all other grades and definitions from the recommendation grading system

See above; included within evidence grading system above

Body of evidence:

- Quantity – how many studies?
- Quality – what type of studies?

Two RCTs and 33 observational studies including children with SCA.

As stated within the NHLBI Clinical Guidelines: "For infants, children, and adolescents who have SCA, hydroxyurea treatment results have closely and consistently mirrored those of adults. The first large, prospective, multicenter phase I/II trial (HUG KIDS) of school-aged children who were treated with hydroxyurea escalated to the maximum tolerated dose demonstrated laboratory efficacy, few short-term toxicities, and lack of toxicity for childhood growth and development [Kinney et al., 1999 {see References at the end of this documents}]. Soon after, a prospective phase I/II trial of infants with SCA who were treated with a liquid hydroxyurea formulation at a fixed dose of 20 mg/kg/day generated favorable short-term safety data and evidence suggesting prevention of sickle cell-related organ damage [Wang et al., 2001]. Subsequently, several groups in the United States and Europe published open-label data regarding the laboratory and clinical efficacy of hydroxyurea for young people with SCA, with evidence of sustained laboratory and clinical responses but without apparent long-term toxicities. Taken together, these trials provide almost 15 years of pediatric data on both the safety and efficacy of hydroxyurea for young people (reviewed in Ware, 2010). Most recently, the phase III double-blinded, placebo-controlled infant hydroxyurea study "Pediatric Hydroxyurea Phase III Clinical Trial" [NHLBI, 2000] had equivocal results for preservation of organ function, but confirmed the improvements in laboratory parameters such as total hemoglobin level and HbF level, and decreased numbers of sickle-related acute clinical events such as pain and ACS [Wang et al., 2011]. Long-term observational studies suggest sustained beneficial effects of hydroxyurea for young people without excessive myelotoxicity, deleterious effects on growth and development, altered fertility, accumulation of mutations, or increased carcinogenicity [Zimmerman et al., 2004; Ballas et al., 2009; Flanagan et al., 2010; McGann et al., 2011]."

Estimates of benefit and consistency across studies

See above

What harms were identified?

As stated within the NHLBI Clinical Guidelines: "The evidence for hydroxyurea toxicity in people with SCD is derived from three RCTs that enrolled 517 people and from 47 observational studies that enrolled more than 3,000 people. In people who do not have SCD, toxicity evidence is derived from 21 RCTs that enrolled more than 4,800 individuals and 35 observational studies that enrolled more than 7,500 individuals (see Evidence Profile below)."

Evidence Profile – Evidence of Side Effects in Sickle Cell Anemia

Potential Toxicity: Bone marrow suppression

Quality of the Evidence: High

Treatment Effect: Reversible cytopenias associated with hydroxyurea

Potential Toxicity: Leukemia

Quality of the Evidence: No supporting evidence in SCD populations/Very low

Treatment Effect: The available evidence does not support the association of hydroxyurea treatment with the development of leukemia in adults or children

Potential Toxicity: Leg ulcers

Quality of the Evidence: Adults: Moderate; Children: Low

Treatment Effect: The available evidence does not support the association of hydroxyurea treatment with leg ulcers

Potential Toxicity: Other side effects

Quality of the Evidence: Very low

Treatment Effect: Numerous other side effects were reported in the literature with low frequency and none with certain causality

Potential Toxicity: Reproductive effects

Quality of the Evidence: Very low

Treatment Effect: Minimal human data exist on potential harmful reproductive effects of hydroxyurea in males and females

Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?

N/A

_____

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.*

Children with sickle cell anemia (SCA) experience common and excruciating pain crises. Daily receipt of the oral medication hydroxyurea substantially reduces the incidence of these pain crises, as well as acute chest

syndrome. Prior studies indicate that hydroxyurea rates are low. This measure establishes a claims-based methodology for identifying hydroxyurea use among children with SCA. The performance scores calculated through this measure will identify areas in need of improvement in hydroxyurea use among children with SCA.

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.*

Rates of hydroxyurea dispensed for at least 300 days within the measurement year for children with sickle cell anemia in Michigan Medicaid program (2010-2018):

Michigan

(Year: Numerator / Denominator = Rate)

2010: 16/300 = 5.33%

2011: 13/303 = 4.29%

2012: 10/281 = 3.56%

2013: 7/294 = 2.38%

2014: 11/294 = 3.74%

2015: 12/319 = 3.76%

2016: 19/407 = 4.67%

2017: 26/351 = 7.41%

2018: 18/366 = 4.92%

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.

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.*

The datasets used for performance scores is Medicaid; therefore, there are no disparities identified by insurance or socioeconomic status. However, the majority of children with sickle cell anemia (approximately 90%) have been enrolled in Medicaid at some point in time.

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

Given the disproportionate burden within minority populations, sickle cell anemia is often considered to be an indicator of a health disparity.

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.)*

https://chear.org/research/projects/identifying-opportunities-improve-hydroxyurea-therapy-initiation

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:**
Updated_Sept_8_2020_Hydroxyurea_NQF_testing_attachment_508_Compliant.docx

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**:** Hydroxyuea_Measure_Appendix_Tables_2020-05-20.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:**
Updated_Sept_8_2020_Hydroxyurea_NQF_testing_attachment_508_Compliant-637413882323804016.docx

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.

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.

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.

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 children ages 1 to 18 years with sickle cell anemia (SCA) who were dispensed hydroxyurea for at least 300 days within the measurement year.

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).*

Cases from target population with target process (hydroxyurea dispensed for at least 300 days within the calendar year): Dispensed hydroxyurea is defined as at least 300 days covered within the measurement year, which is the summed total of the number of days' supply within the measurement year (see National Drug Codes (NDC) Table 1).

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

The number of children ages 1 to 18 years with sickle cell anemia (SCA) within the measurement year.

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).*

For calculation of measure using ICD-9: Children with SCA are identified through the presence of at least three separate healthcare encounters related to SCA within the measurement year (ICD-9 codes 282.61, 282.62). Children ages 1 to 18 years are included within the target population (i.e., must not have an 18th birthday within the measurement year). Children must be continuously enrolled within the health plan in which claims are available and must have no other form of health insurance for the entire measurement year.

For calculation of measure using ICD-10: Children with SCA are identified through the presence of at least one outpatient visit with an ICD-10 diagnosis code of D57.1, D57.00, D57.01 or D57.02. Children ages 1 to 18 years are included within the target population (i.e., must not have an 18th birthday within the measurement year). Children must be continuously enrolled within the health plan in which claims are available and must have no other form of health insurance for the entire measurement year.

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

NA

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.)*

NA

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.)*

NA

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.)*

1. Identify the denominator: Determine the eligible population using administrative claims. The eligible population is all individuals who satisfy all specified criteria, including age, continuous enrollment, and benefit requirements within the measurement year.

2. Identify the numerator: Identify numerator events using administrative claims for all individuals in the eligible population (denominator) within the measurement year.

3. Calculate the rate: (numerator/denominator).

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 does not involve sampling; all SCA cases meeting the inclusion criteria are used in the calculation.

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.

NA

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.

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)*

Other

If other: Any setting represented with prescription medication claims data

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.)*

NA

2. Validity – See attached Measure Testing Submission Form

Updated_Sept_8_2020_Hydroxyurea_NQF_testing_attachment_508_Compliant-637413882416930835.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*)**:**
Measure Title: Hydroxyurea Use among Children with Sickle Cell Anemia
Date of Submission: 8/3/2020

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	

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.*

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:	☒ other: newborn screening records

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*).

- **Michigan Medicaid** administrative claims data provided by the Michigan Department of Health and Human Services (MDHHS)
- **New York State Medicaid** administrative data provided by the New York State Department of Health
- **Medicaid Analytic eXtract (MAX)** administrative claims data for six state Medicaid programs provided by the Centers for Medicare & Medicaid Services (CMS)
- **Michigan Newborn Screening** Results
- **New York State Newborn Screening** Results

1.3. What are the dates of the data used in testing? Michigan Medicaid: 2010, 2011, 2016; New York Medicaid 2016; MAX: 2005-2009; Michigan Newborn Screening 1997-2014; New York State Newborn Screening 2006-2013

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*)

- **Michigan Medicaid:** all Medicaid claims for children ages 1 through 17 continuously enrolled for at least one year in Michigan Medicaid in 2010, 2011, or 2016.
- **New York State Medicaid:** all Medicaid claims for children ages 1 through 17 continuously enrolled in New York Medicaid in 2016.
- **MAX data:** all Medicaid claims reported to CMS for children ages 1 through 17 continuously enrolled for at least one year from 2005-2012 within one of the six following state Medicaid programs with moderate to high prevalence of sickle cell anemia: Florida, Illinois, Louisiana, Michigan, South Carolina, and Texas.
- **Michigan NBS data** consisted of all births within the state of Michigan from 1987-2014.
- **New York State NBS data** consisted of all sickle cell births within the state of New York from 2006-2013.

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*)

- **Michigan Medicaid** data for ICD-9-CM denominator validation (2010 and 2011) included 865 children in 2010 and 863 children in 2011. These children were included if continuously enrolled in either 2010 or 2011, with at least one sickle cell disease-related administrative claim, and a newborn screening result available from 1987-2010.
- **Michigan Medicaid** data for ICD-10-CM denominator validation (2016 only) included 1,597 children with at least one D57x diagnosis code in 2016.
- **New York State Medicaid** data included 2,454 children with at least one D57x diagnosis code in 2016.
- **MAX data** included 7,963 children enrolled for a total of 22,424 person-years. The breakdown of person-years by state is as follows: Florida: 6,816; Louisiana: 3,753; Texas: 3,727; Illinois: 3,298; Michigan: 2,708; South Carolina: 2,122. Children were included if meeting the denominator criteria for sickle cell anemia.
- **Michigan NBS data** included a total of 1,457 children that had both a D57x diagnosis code in 2016 and a Newborn Screening Result available from 2007-2014.
- **New York State NBS data** included 2,454 children with a D57x diagnosis code in 2016 and born between 2006-2013.

Across all datasets, the majority of children were Black, with a similar proportion of males and females.

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.

- Validity testing included Michigan Medicaid, Michigan Newborn Screening, New York State Medicaid, and New York State Newborn Screening data.
- Identification of meaningful differences in performance included MAX data.

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.

The data do not include patient-level social risk factors; however, all children included in the data were enrolled in Medicaid, which is a proxy for low socioeconomic status.

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*)

See Section 2b2 for validity testing of data elements.

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*)

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?*)

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)*

Critical Data Elements

Denominator: The denominator (children with sickle cell anemia) has been validated using both ICD-9-CM and ICD-10-CM diagnosis codes. The **process** for each separate validation (ICD-9-CM and ICD-10-CM) is detailed below:

ICD-9-CM denominator validation: The accuracy of the case definition (at least three claims for sickle cell anemia [Hb SS] within the measurement year) to identify children with sickle cell anemia was assessed through comparison with the gold standard of newborn screening results for the state of Michigan for children enrolled in Michigan Medicaid in 2010 and 2011 with at least one SCD-related healthcare claim within their enrollment year(s). The area under the receiver operating characteristic (ROC) curve, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for the case definition. As a comparison, these values were also calculated for those with a minimum of at least one or two Hb SS claims within each year.

ICD-10-CM denominator validation: We developed, tested, and validated the performance of ICD-10-CM case definitions for SCA through the following 4-step process: (a) developing candidate SCA case definitions; (b) identifying a test population for the definitions; (c) testing the accuracy of candidate case definitions; and (d) testing case definitions within an independent population. Briefly, using specific SCA-related (D5700, D5701, D5702) and non-specific (D571) diagnosis codes, 23 SCA case definitions were applied to Michigan

Medicaid claims (2016) to identify children with SCA. Measures of performance (sensitivity, specificity, area under ROC curve) were calculated using newborn screening results as the gold standard. A parallel analysis was conducted using New York State Medicaid claims and newborn screening data.

Additional details regarding the methodology of validating the ICD-10-CM definition can be found at: Reeves SL, Madden B, Wu M, et al. Performance of ICD-10-CM diagnosis codes for identifying children with Sickle Cell Anemia. Health Serv Res. 2020;55(2):310-317. doi:10.1111/1475-6773.13257

Numerator: The numerator consists of children with sickle cell anemia that have at least 300 days of filled hydroxyurea within the year. Days' supply of hydroxyurea are identified using National Drug Codes (NDCs). We identified potential NDCs for hydroxyurea using a variety of methods: 1) RxNorm (described below); 2) review of relevant literature; 3) online drug NDC identification tools; 4) comparison to NDCs generated from sickle cell surveillance efforts through the Centers for Disease Control and Prevention; and 5) comparison to NDCs generated by New York State for prior work. RxNorm is a normalized naming system for all drugs produced and maintained by the National Library of Medicine, and is the gold standard for identifying current and historical medications contained in administrative data.

Second, to validate our efforts to include all NDCs related to hydroxyurea, we identified all filled prescriptions for children in the denominator. We then identified all NDCs that were **not** related to hydroxyurea based on our comprehensive list. We compared this list to RxNorm to manually assess that all remaining NDCs were not related to hydroxyurea.

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

Critical Data Elements

Denominator: The denominator has been validated using both ICD-9-CM and ICD-10-CM diagnosis codes. The **results** for each separate validation (ICD-9-CM and ICD-10-CM) is detailed below:

ICD-9-CM denominator validation: In 2010, a case definition of **three Hb SS (282.61, 282.62) claims within the year** was 91.4% sensitive and 80% specific in identifying children with sickle cell anemia (Hb SS) (PPV: 80.4%; NPV: 91.3%). These results were replicated with nearly identical precision among the study population in 2011. In comparison, using a case definition of at least one Hb SS claim or at least two Hb SS claims to identify the study population resulted in substantially less specificity.

ICD-10-CM denominator validation: Across the 23 case definitions, measures of performance varied, with sensitivities from 0.02-0.97 and specificities from 0.88-1.0. The case definition of **≥1 outpatient visit with a SCA-related (D5700, D5701, D5702) or D571 code** had the highest area under the ROC curve, with a sensitivity of 95% and specificity of 92%. The same definition also had the highest performance in New York Medicaid (n=2,454), with a sensitivity of 94% and specificity of 86% (Figure 1).

Figure 1. Measures of performance for Candidate Case Definitions to Identify Children with Sickle Cell Anemia.

Definition	Description	Michigan Medicaid: Sensitivity	Michigan Medicaid: Specificity	Michigan Medicaid: Area under the ROC curve	New York State Medicaid: Sensitivity	New York State Medicaid: Specificity	New York State Medicaid: Area under the ROC curve
Counts of sickle cell anemia (SCA) claims (D5700,	*	*	*	*	*	*	*

Definition	Description	Michigan Medicaid: Sensitivity	Michigan Medicaid: Specificity	Michigan Medicaid: Area under the ROC curve	New York State Medicaid: Sensitivity	New York State Medicaid: Specificity	New York State Medicaid: Area under the ROC curve
D5701, and D5702)							
A	≥1 claim	0.56	0.94	0.75	0.52	0.92	0.72
B	≥2 claims	0.48	0.96	0.72	0.33	0.97	0.65
C	≥3 claims	0.39	0.97	0.68	0.22	0.99	0.60
SCA-related emergency department (ED) visits (D5700, D5701, and D5702)	*	*	*	*	*	*	*
D	≥1 ED visit	0.45	0.95	0.70	0.22	0.96	0.59
E	≥2 ED visits	0.34	0.97	0.65	0.07	0.99	0.53
F	≥3 ED visits	0.20	0.98	0.59	0.03	1.00	0.51
SCA-related inpatient hospitalizations (D5700, D5701, and D5702)	*	*	*	*	*	*	*
G	≥1 hospitalization	0.33	0.99	0.66	0.34	0.98	0.66
H	≥2 hospitalizations	0.30	0.99	0.65	0.13	1.00	0.57
I	≥3 hospitalizations	0.25	0.99	0.62	0.07	1.00	0.53
SCA-related outpatient visits (D5700, D5701, and D5702)	*	*	*	*	*	*	*

Definition	Description	Michigan Medicaid: Sensitivity	Michigan Medicaid: Specificity	Michigan Medicaid: Area under the ROC curve	New York State Medicaid: Sensitivity	New York State Medicaid: Specificity	New York State Medicaid: Area under the ROC curve
J	≥1 outpatient visit	0.16	0.99	0.58	0.30	0.96	0.63
K	≥2 outpatient visits ≥30 d apart	0.05	1.00	0.53	0.04	1.00	0.52
L	≥3 outpatient visits, each ≥30 d apart	0.03	1.00	0.51	0.01	1.00	0.51
M	≥2 outpatient visits, ≥7 d apart	0.06	1.00	0.53	0.06	1.00	0.53
N	≥3 outpatient visits, each ≥7 d apart	0.03	1.00	0.51	0.03	1.00	0.51
SCA-related outpatient visits, including nonspecific sickle cell code (D5700, D5701, D5702, and D571)	*	*	*	*	*	*	*
O	≥1 outpatient visit	0.94	0.92	0.93	0.94	0.86	0.90
P	≥2 outpatient visits, ≥30 d apart	0.85	0.97	0.91	0.62	0.96	0.79
Q	≥3 outpatient visits, each ≥30 d apart	0.70	0.99	0.85	0.45	0.98	0.71

Definition	Description	Michigan Medicaid: Sensitivity	Michigan Medicaid: Specificity	Michigan Medicaid: Area under the ROC curve	New York State Medicaid: Sensitivity	New York State Medicaid: Specificity	New York State Medicaid: Area under the ROC curve
R	≥2 outpatient visits, ≥7 d apart	0.86	0.97	0.91	0.70	0.95	0.82
S	≥3 outpatient visits, each ≥7 d apart	0.73	0.99	0.86	0.59	0.96	0.78
Counts of SCA claims, including nonspecific sickle cell code (D5700, D5701, D5702, and D571)	*	*	*	*	*	*	*
T	≥1 claim	0.97	0.81	0.89	0.98	0.81	0.89
U	≥2 claims	0.94	0.91	0.92	0.89	0.89	0.89
V	≥3 claims	0.91	0.93	0.92	0.78	0.92	0.85
Combination	*	*	*	*	*	*	*
W	≥2 SCA or D571 outpatient visits, each ≥7 d apart OR ≥1 SCA-related hospitalization	0.87	0.96	0.92	0.75	0.94	0.84

*cell intentionally left blank

Figure 1 from Reeves SL, Madden B, Wu M, et al. Performance of ICD-10-CM diagnosis codes for identifying children with Sickle Cell Anemia. Health Serv Res. 2020;55(2):310-317. doi:10.1111/1475-6773.13257. This figure presents 23 SCA case definitions that were applied to Michigan and New York State Medicaid claims (2016) to identify children with SCA. Measures of performance (sensitivity, specificity, area under the ROC curve) were calculated using newborn screening results as the gold standard. Measures of performance varied, with sensitivities from 0.02 to 0.97 and specificities from 0.88 to 1.0. The case definition of ≥1 outpatient visit with a SCA-related or D571 code had the highest area under the ROC curve, with a sensitivity of 95 percent and specificity of 92 percent. The same definition also had the highest performance in New York Medicaid, with a sensitivity of 94 percent and specificity of 86 percent.

Numerator: Through the methodology described above, we identified 67 NDCs for hydroxyurea within administrative claims.

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?*)

Using both ICD-9-CM and ICD-10-CM diagnosis codes, children with sickle cell anemia can be identified with a high level of accuracy in administrative data. Further, our comprehensive approach to identifying all potential NDCs related to hydroxyurea results in a high level of validity for identifying children within the numerator.

_____

2b2. EXCLUSIONS ANALYSIS

NA ☒ no exclusions — *skip to section 2b4*

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*)

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*)

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*)

_____

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 2b5.

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)*

We used MAX data to determine if differences at the state health plan level could be assessed using this measure. Using the MAX data, the proportion of children dispensed at least 300 days of hydroxyurea was calculated for each state health plan. Prior to 2014, hydroxyurea was only recommended for children with severe sickle cell anemia. Therefore, for the purposes of detecting meaningful differences in performance scores across state health plans, we limited the denominator population to children with sickle cell anemia that had evidence of hydroxyurea use (i.e., had a greater than 30-day supply within the year). We tested the null hypothesis that all state health plans had same performance score, with the alternative hypothesis that at least one state had a performance score different than the other state health plans. We used a chi-square test and resulting p-value to assess results.

Additional details regarding this analysis can be found at: Reeves SL, Jary HK, Gondhi JP, Raphael JL, Lisabeth LD, Dombkowski KJ. Hydroxyurea use among children with sickle cell anemia. Pediatr Blood Cancer. 2019;66(6):e27721. doi:10.1002/pbc.27721

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*)

Among children with evidence of hydroxyurea use (greater than 30 days' supply within the year), the proportion of children with at least 300 days of dispensed hydroxyurea ranged from 13.0% to 21.2%. The resulting p-value testing the null hypothesis was 0.0399.

Figure 2. Proportion of Children with Sickle Cell Anemia with at least 300 days of Dispensed Hydroxyurea within a Year among those with Evidence of Hydroxyurea Use

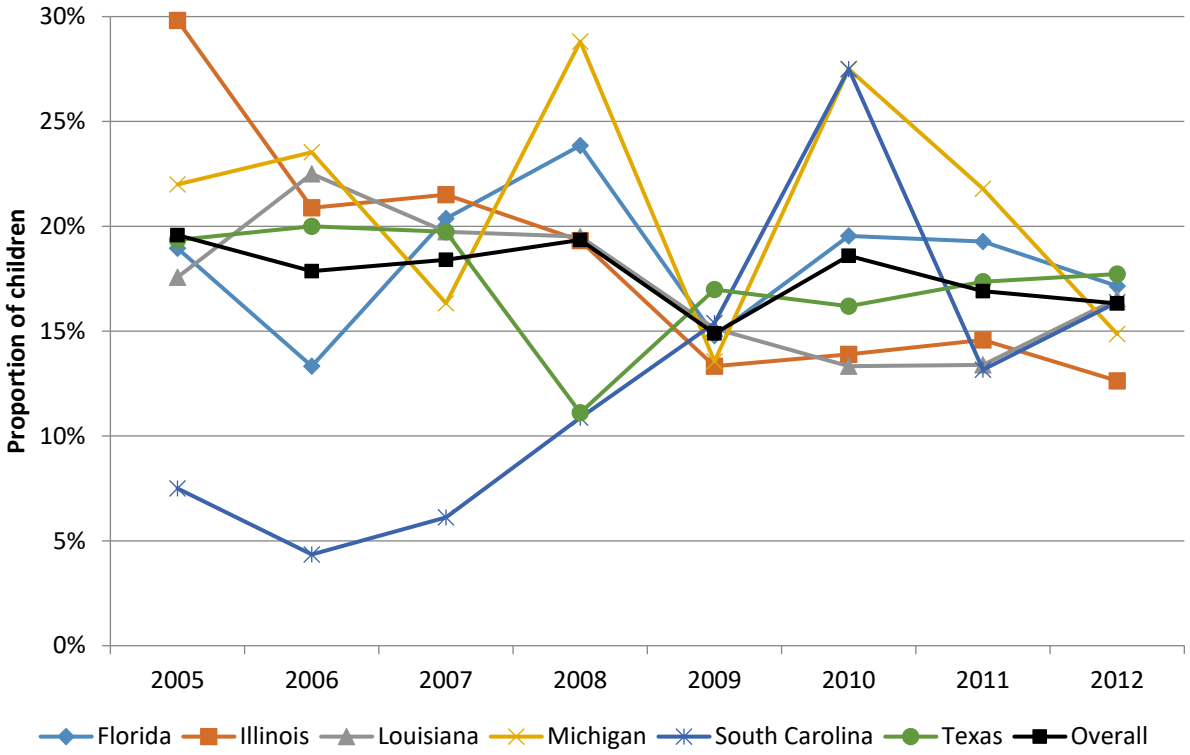

Figure 2 illustrates the proportion of children with sickle cell anemia from six states and overall who received at least 300 days of dispensed hydroxyurea within a year among those with evidence of hydroxyurea use (2005-2012). The six states are Florida, Illinois, Louisiana, Michigan, South Carolina, and Texas. Rates vary from a low of 4% in South Carolina in 2006 to a high of 30% in Illinois in 2005. Overall, rates remained between 15% and 19% during the 8-year period.

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?*)

It is possible to determine meaningful differences in performance scores across state health 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 non-responders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

This measure utilizes administrative claims data. Although information regarding prescriptions or diagnosis codes may be missing, we are unable to ascertain the extent of missingness. However, we do not anticipate that any missing data would differ in any systematic manner across children with sickle cell anemia.

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*)

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 non-responders) 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*)

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).

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.**

This measure was tested using Medicaid administrative claims data. The primary information needed for this measure includes basic demographics, diagnosis codes, and procedure codes and dates. These data are widely available, although obtaining them often requires a restricted-use data agreement. When the measure is used at the single-state level, state health departments can use their own Medicaid data. Acquisition of data directly from states requires the cooperation of those jurisdictions.

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)*.

N/A

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)
Payment Program Quality Improvement (external benchmarking to organizations) Quality Improvement (Internal to the specific organization)	*

*cell intentionally left blank

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

The State of Michigan Medicaid Program will be implementing this measure for purposes of building a health plan collaborative to improve the care of children with sickle cell anemia in Michigan. This program is currently being implemented; we anticipate reporting to occur in 2021.

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?*)

The health plan collaborative is currently being implemented; we anticipate reporting to occur in 2021. Program implementation was delayed due to COVID-19.

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.*)

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.

Specifications and technical assistance were provided to Michigan Medicaid health plans and the State of Michigan Medicaid Program.

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.

The measure development team has provided feedback and clarification when necessary to all users.

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.

We spoke to Michigan Medicaid after introduction to health plans and provided any necessary clarifications regarding implementation of this measure.

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

Michigan Medicaid has indicated no concerns from health plans in implementing this measure.

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

N/A

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.

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.

There has been no improvement, as this measure has not been applied for purposes of quality improvement at a state level. Further, these rates are exceedingly low and have much opportunity for improvement.

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.

No unintended negative consequences to individuals or populations were identified during testing.

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

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)

2797 : Transcranial Doppler Ultrasonography Screening Among Children with Sickle Cell Anemia

3166 : Antibiotic Prophylaxis Among Children with Sickle Cell Anemia

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?

Yes

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

Different age categories are included in the measures. For example, antibiotic prophylaxis is recommended by NHLBI for ages 0 until 5; TCD screening from ages 2 until 16; and hydroxyurea beginning at 9 months of age. Further, the numerators are identifying different events (antibiotics, hydroxyurea, TCD); therefore, the numerator specifications differ across each measure.

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.)

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.

Attachment **Attachment:** 21-UFA01432_UM_Hydroxyurea_Measure_Steward_Agreement_Adden_-1-.pdf

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): University of Michigan

Co.2 Point of Contact: Sarah, Reeves, sleasure@umich.edu, 734-615-8319-

Co.3 Measure Developer if different from Measure Steward: University of Michigan

Co.4 Point of Contact: Sarah, Reeves, sleasure@umich.edu, 734-615-8319-

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.

None

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released:

Ad.3 Month and Year of most recent revision:

Ad.4 What is your frequency for review/update of this measure?

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

Ad.6 Copyright statement:

Ad.7 Disclaimers:

Ad.8 Additional Information/Comments: