

**American Society of Hematology/
Physician Consortium for Performance Improvement®**

**Hematology
Physician Performance Measurement Set**

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Purpose of Measures:

These clinical performance measures, developed by the American Society of Hematology and the Physician Consortium for Performance Improvement® (Consortium), are designed for individual quality improvement. Unless otherwise indicated, the measures are also appropriate for accountability if appropriate methodological, statistical, and implementation rules are achieved.

Accountability Measures:

Myelodysplastic Syndrome (MDS) and Acute Leukemias

Measure #1: Baseline Cytogenetic Testing Performed on Bone Marrow

Myelodysplastic Syndrome (MDS)

Measure #2: Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy

Multiple Myeloma (MM)

Measure #3: Treatment with Bisphosphonates

Chronic Lymphocytic Leukemia (CLL)

Measure #4: Baseline Flow Cytometry

Intended Audience and Patient Population:

These measures are designed for use by physicians and for calculating reporting or performance measurement at the individual physician level. When existing hospital-level or plan-level measures are available for the same measurement topics, the Consortium attempts to harmonize the measures to the extent feasible.

These measures are designed for any physician, particularly hematologists, managing the ongoing care of patients aged 18 years and older with Myelodysplastic Syndrome (MDS), Acute Leukemias, Multiple Myeloma (MM), or Chronic Lymphocytic Leukemia (CLL).

The Consortium also encourages the use of these measures by eligible health professionals, where appropriate.

Measure Specifications

The Consortium seeks to specify measures for implementation using multiple data sources, including paper medical record, administrative (claims) data, and particular emphasis on Electronic Health Record Systems (EHRS). Specifications to report on these measures for Hematology using administrative (claims) data are included in this document. We have identified codes for these measures, including ICD-9 and CPT (Evaluation & Management Codes, Category I and where Category II codes would apply). Specifications for additional data sources, including EHRS, will be fully developed at a later date.

Measure Exclusions:

For ***process measures***, the Consortium provides three categories of reasons for which a patient may be excluded from the denominator of an individual measure:

- **Medical reasons**

Includes:

- not indicated (absence of organ/limb, already received/performed, other)
- contraindicated (patient allergic history, potential adverse drug interaction, other)

- **Patient reasons**

Includes:

- patient declined
- social, or religious reasons
- other patient reasons

- **System reasons**
Includes:
 - resources to perform the services not available
 - insurance coverage/payor-related limitations
 - other reasons attributable to health care delivery system

These measure exclusion categories are not available uniformly across all measures; for each measure, there must be a clear rationale to permit an exclusion for a medical, patient, or system reason. The exclusion of a patient may be reported by appending the appropriate modifier to the CPT Category II code designated for the measure:

- **Medical reasons**: modifier 1P
- **Patient reasons**: modifier 2P
- **System reasons**: modifier 3P

Although this methodology does not require the external reporting of more detailed exclusion data, the Consortium recommends that physicians document the *specific* reasons for exclusion in patients' medical records for purposes of optimal patient management and audit-readiness. The Consortium also advocates the systematic review and analysis of each physician's exclusions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exclusion.

Please refer to documentation for each individual measure for information on the acceptable exclusion categories and the codes and modifiers to be used for reporting.

Measures #1-4 in the Hematology measurement set are process measures.

For **outcome measures**, the Consortium specifically identifies all acceptable reasons for which a patient may be excluded from the denominator. Each specified reason is reportable with a CPT Category II code designated for that purpose.

There are no outcome measures in the Hematology measurement set.

The Consortium continues to evaluate and likely will evolve its methodology for handling exclusions as it gains experience in the use of the measures. The Consortium welcomes comments on its exclusions methodology.

Data Capture and Measure Calculation

The Consortium intends for physicians to collect data on each patient eligible for a measure. Feedback on measures should be available to physicians by patient to facilitate patient management and in aggregate to identify opportunities for improvement across a physician's patient population.

Measure calculations will differ depending on whether a rate is being calculated for performance or reporting purposes.

The method of calculation for performance follows these steps: first, identify the patients who meet the eligibility criteria for the denominator (PD); second, identify which of those patients meet the numerator criteria (A); and third, for those patients who do not meet the numerator criteria, determine whether an appropriate exclusion applies and subtract those patients from the denominator (C). (see examples below)

The methodology also enables implementers to calculate the rates of exclusions and to further analyze both low and high rates, as appropriate (see examples below).

The method of calculation for reporting differs. One program which currently focuses on reporting rates is the Centers for Medicare and Medicaid Services (CMS) Physician Quality Reporting Initiative (PQRI). Currently, under that program design, there will be a reporting denominator determined solely from claims data (CPT and ICD-9), which in some cases result in a reporting denominator that is much larger than the eligible population for the performance denominator. Additional components of the reporting denominator are explained below.

The components that make up the numerator for reporting include all patients from the eligible population for which the physician has reported, including: the number of patients who meet the numerator criteria (A), the number of patients for whom valid exclusions apply (C) and also the number of patients who do not meet the numerator criteria (D). These components, where applicable, are summed together to make up the inclusive reporting numerator. The calculation for reporting will be the reporting numerator divided by the reporting denominator. (see examples below).

Examples of calculations for reporting and performance are provided for each measure.

Calculation for Performance

For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.

Numerator (A) Includes:

Number of patients meeting numerator criteria

Performance Denominator (PD) Includes:

Number of patients meeting criteria for denominator inclusion

Denominator Exclusions (C) Include:

Number of patients with valid medical, patient or system exclusions (where applicable; will differ by measure)

Performance Calculation

$$\frac{A \text{ (# of patients meeting numerator criteria)}}{PD \text{ (# patients in denominator)} - C \text{ (# patients with valid denominator exclusions)}}$$

It is also possible to calculate the percentage of patients excluded overall, or excluded by medical, patient, or system reason where applicable:

Overall Exclusion Calculation

$$\frac{C \text{ (# of patients with any valid exclusion)}}{PD \text{ (# patients in denominator)}}$$

OR

Exclusion Calculation by Type

$$\frac{C_1 \text{ (# patients with medical reason)}}{PD \text{ (# patients in denominator)}}$$

$$\frac{C_2 \text{ (# patients with patient reason)}}{PD \text{ (# patients in denominator)}}$$

$$\frac{C_3 \text{ (# patients with system reason)}}{PD \text{ (# patients in denominator)}}$$

Calculation for Reporting

For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator

Reporting Numerator includes each of the following components, where applicable. (There may be instances where there are no patients to include in A, C, D, or E).

A. Number of patients meeting additional denominator criteria (for measures where true denominator cannot be determined through ICD-9 and CPT Category I coding alone) AND numerator criteria

- C. Number of patients with valid medical, patient or system exclusions (where applicable; will differ by measure)
- D. Number of patients not meeting numerator criteria and without a valid exclusion
- E. All other patients not meeting additional denominator criteria (for measures where true denominator cannot be determined through ICD-9 and CPT Category I coding alone)

Reporting Denominator (RD) Includes:

RD. Denominator criteria (identifiable through ICD-9 and CPT Category I coding)

Reporting Calculation

$\frac{A(\text{\# of patients meeting additional denominator criteria AND numerator criteria}) + C(\text{\# of patients with valid exclusions}) + D(\text{\# of patients NOT meeting numerator criteria}) + E(\text{\# of patients not meeting additional denominator criteria})}{RD (\text{\# of patients in denominator})}$

Hematology
Measure #1: MDS and Acute Leukemias – Baseline Cytogenetic Testing Performed on Bone Marrow

This measure may be used as an Accountability measure.

Clinical Performance Measure
<p>Numerator: Patients who had baseline cytogenetic testing* performed on bone marrow</p> <p><i>*Baseline cytogenetic testing refers to testing that is performed at time of diagnosis or prior to initiating treatment for that diagnosis</i></p> <p>Denominator: All patients aged 18 years and older with a diagnosis of MDS or an acute leukemia</p> <p>Denominator Exclusions: Documentation of medical reason(s) for not performing baseline cytogenetic testing Documentation of patient reason(s) for not performing baseline cytogenetic testing Documentation of system reason(s) for not performing baseline cytogenetic testing</p> <p>Measure: Percentage of patients aged 18 years and older with a diagnosis of MDS or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.</p>
<p>The following clinical recommendation statements are quoted <u>verbatim</u> from the referenced clinical guidelines and represent the evidence base for the measure:</p> <p><i>For MDS:</i> Bone marrow aspiration and biopsy are needed to calculate the degree of hematopoietic cell maturation abnormalities and relative proportions, percentage of marrow blasts, marrow cellularity, presence or absence of ringed sideroblasts (and presence of iron per se), and fibrosis. Marrow cytogenetics should be obtained because they are of major importance for prognosis (Category 2A Recommendation). (NCCN¹)</p> <p>The decision to treat patients having marrow blasts in the range of 20% to 30% with intensive AML therapy is thus complex and should be individualized. The clinician should consider such factors as age, antecedent factors, cytogenetics, comorbidities, pace of disease, and performance status (Category 2A Recommendation) (NCCN¹)</p> <p>A chromosome abnormality confirms the presence of a clonal disorder aiding the distinction between MDS and reactive causes of dysplasia, and in addition has major prognostic value. Cytogenetic analysis should therefore be performed for all patients in whom a bone marrow examination is indicated. (BCSH²)</p> <p><i>For acute leukemias:</i> The initial evaluation has two objectives. The first is to identify the pathology causing the disease including factors such as prior toxic exposure or myelodysplasia, cytogenetics and molecular markers that may have an impact on chemoresponsiveness and propensity for relapse which may guide choice of treatment. The second objective focuses on patient-specific factors including comorbid conditions that may affect an individual's ability to tolerate chemotherapy (Category 2A Recommendation) (NCCN³)</p> <p>Although cytogenetic information is usually unknown when treatment is initiated in patients with de novo AML, karyotype represents the single most important prognostic factor for predicting remission rate, relapse, and overall survival. Therefore, the importance of obtaining sufficient samples of marrow or peripheral blood blasts at diagnosis for this analysis cannot be overemphasized (Category 2A Recommendation) (NCCN³)</p>
<p>Rationale for the measure:</p> <p><i>For MDS:</i> Cytogenetic testing is an integral component in calculating the International Prognostic Scoring System (IPSS) score. Cytogenetic testing should be performed on the bone marrow of patients with MDS in order to guide treatment options, determine prognosis, and predict the likelihood of disease evolution to leukemia.</p> <p><i>For acute leukemias:</i></p>

In addition to establishing the type of acute leukemia, cytogenetic testing is essential to detect chromosomal abnormalities that have diagnostic, prognostic, and therapeutic significance.

Data capture and calculations:

Calculation for Performance

For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.

Numerator (A) Includes:

- Patients who had baseline cytogenetic testing performed on bone marrow

Denominator (PD) Includes:

- All patients aged 18 years and older with a diagnosis of MDS or an acute leukemia

Denominator Exclusions (C) Include:

- Documentation of medical reason(s) for not performing baseline cytogenetic testing
- Documentation of patient reason(s) for not performing baseline cytogenetic testing
- Documentation of system reason(s) for not performing baseline cytogenetic testing

Performance Calculation

$$\frac{\text{A (\# of patients meeting measure criteria)}}{\text{PD (\# of patients in denominator) - C (\# of patients with valid denominator exclusions)}}$$

Components for this measure are defined as:

A	# of patients who had baseline cytogenetic testing performed on bone marrow
PD	# of patients aged 18 years and older with a diagnosis of MDS or an acute leukemia
C	# of patients with documented medical reason(s) for not performing baseline cytogenetic testing; # of patients with documented patient reason(s) for not performing baseline cytogenetic testing; # of patients with documented system reason(s) for not performing baseline cytogenetic testing

Calculation for Reporting

For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator

Reporting Numerator includes each of the following instances:

- A. Patients who had baseline cytogenetic testing performed on bone marrow
- C. Patients who did not have baseline cytogenetic testing performed but for whom there is a documented medical, patient, or system reason for not doing so
- D. Patients who did not have baseline cytogenetic testing performed and there is no documented medical, patient, or system reason for not doing so

Reporting Denominator (RD) Includes:

- Patients aged 18 years and older with a diagnosis of MDS or an acute leukemia

Reporting Calculation

$$\frac{\text{A(\# of patients meeting numerator criteria) + C(\# of patients with valid exclusions) + D(\# of patients NOT meeting numerator criteria)}}{\text{RD (\# of patients in denominator)}}$$

Components for this measure are defined as:

A	# of patients who had baseline cytogenetic testing performed on bone marrow
C	# of patients who did <u>not</u> have baseline cytogenetic testing performed but for whom there is a documented medical reason or patient reason for not doing so
D	# of patients who did <u>not</u> have baseline cytogenetic testing performed and there is <u>no</u> documented reason for not doing so
RD	# of patients aged 18 years and older with a diagnosis of MDS or an acute leukemia

Measure Specifications – Measure #1: MDS and Acute Leukemias – Baseline Cytogenetic Testing Performed on Bone Marrow

Measure specifications will be provided for multiple data sources.

A. Administrative claims data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

(Note: The specifications listed below are those need for performance calculation.)

Denominator (Eligible Population): All patients aged 18 years and older with a diagnosis of MDS or an acute leukemia

ICD-9 diagnosis codes: 204.00, 205.00, 206.00, 207.00, 207.20, 208.00, 238.72, 238.73, 238.74, 238.75

AND

CPT service codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245

Denominator Exclusion:

Documentation of medical reason(s) for not performing baseline cytogenetic testing

- **Append modifier to CPT Category II code: 3155F-1P**

Documentation of patient reason(s) for not performing baseline cytogenetic testing

- **Append modifier to CPT Category II code: 3155F-2P**

Documentation of system reason(s) for not performing baseline cytogenetic testing

- **Append modifier to CPT Category II code: 3155F-3P**

Numerator: Patients who had baseline cytogenetic testing performed on bone marrow

- **Report the CPT Category II code: 3155F – Cytogenetic testing performed on bone marrow at time of diagnosis or prior to initiating treatment**

B. Electronic Health Record System (in development)

C. Paper Medical Record (in development)

Hematology
Measure #2: MDS– Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy

This measure may be used as an Accountability measure.

Clinical Performance Measure	
<p>Numerator: Patients with documentation* of iron stores prior to initiating erythropoietin therapy</p> <p><i>*Documentation includes either bone marrow examination including iron stain OR serum iron measurement by ferritin or serum iron and TIBC</i></p> <p>Denominator: All patients aged 18 years and older with a diagnosis of MDS who are receiving erythropoietin therapy*</p> <p><i>*Erythropoietin therapy includes the following medications: epoetin and darbepoetin</i></p> <p>Denominator Exclusions: Documentation of system reason(s) for not documenting iron stores prior to initiating erythropoietin therapy</p> <p>Measure: Percentage of patients aged 18 years and older with a diagnosis of MDS who are receiving erythropoietin therapy with documentation of iron stores prior to initiating erythropoietin therapy</p>	
<p>The following clinical recommendation statements are quoted <u>verbatim</u> from the referenced clinical guidelines and represent the evidence base for the measure:</p> <p>Anemia related to MDS generally presents as a hypoproliferative macrocytic anemia, often associated with suboptimal elevation of serum Epo levels. Iron repletion needs to be verified before instituting Epo therapy (Category 2A Recommendation). (NCCN⁴)</p>	
<p>Rationale for the measure:</p> <p>To be effective erythropoietin requires that adequate iron stores be present due to iron's importance in red-blood-cell synthesis. Iron deficiency presents a major limitation to the efficacy of erythropoietin therapy.</p>	
<p>Data capture and calculations:</p> <p>Calculation for Performance</p> <p>For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.</p> <p>Numerator (A) Includes:</p> <ul style="list-style-type: none"> • Patients with documentation of iron stores prior to initiating erythropoietin therapy <p>Denominator (PD) Includes:</p> <ul style="list-style-type: none"> • All patients aged 18 years and older with a diagnosis of MDS who are receiving erythropoietin therapy <p>Denominator Exclusions (C) Include:</p> <ul style="list-style-type: none"> • Documentation of system reason(s) for not documenting iron stores prior to initiating erythropoietin therapy 	
<p>Performance Calculation</p> <table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="text-align: center;"> $\frac{A \text{ (# of patients meeting measure criteria)}}{PD \text{ (# of patients in denominator)} - C \text{ (# of patients with valid denominator exclusions)}}$ </td> </tr> </table>	$\frac{A \text{ (# of patients meeting measure criteria)}}{PD \text{ (# of patients in denominator)} - C \text{ (# of patients with valid denominator exclusions)}}$
$\frac{A \text{ (# of patients meeting measure criteria)}}{PD \text{ (# of patients in denominator)} - C \text{ (# of patients with valid denominator exclusions)}}$	

Components for this measure are defined as:

A	# of patients with documentation of iron stores prior to initiating erythropoietin therapy
PD	# of patients aged 18 years and older with a diagnosis of MDS who are receiving erythropoietin therapy
C	# of patients with documented system reason(s) for not documenting iron stores prior to initiating erythropoietin therapy

Calculation for Reporting

For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator

Reporting Numerator includes each of the following instances:

- A.** Patients who are receiving erythropoietin therapy with documentation of iron stores prior to initiating erythropoietin therapy
- C.** Patients who are receiving erythropoietin therapy who did not have documentation of iron stores prior to initiating erythropoietin therapy but for whom there is a documented system reason for not doing so
- D.** Patients who are receiving erythropoietin therapy who did not have documentation of iron stores prior to initiating erythropoietin therapy and there is no documented reason for not doing so
- E.** Patients who are not receiving erythropoietin therapy

Reporting Denominator (RD) Includes:

- Patients aged 18 years and older with a diagnosis of MDS

Reporting Calculation

$$\frac{A(\text{\# of patients meeting numerator criteria}) + C(\text{\# of patients with valid exclusions}) + D(\text{\# of patients NOT meeting numerator criteria}) + E(\text{\# of patients not meeting additional denominator criteria})}{RD(\text{\# of patients in denominator})}$$

RD (# of patients in denominator)

Components for this measure are defined as:

A	# of patients who are receiving erythropoietin therapy with documentation of iron stores prior to initiating erythropoietin therapy
C	# of patients who are receiving erythropoietin therapy who did <u>not</u> have documentation of iron stores prior to initiating erythropoietin therapy but for whom there is a <u>documented system reason for not doing so</u>
D	# of patients who are receiving erythropoietin therapy who did <u>not</u> have documentation of iron stores prior to initiating erythropoietin therapy and there is <u>no</u> documented reason for not doing so
E	# of patients who are not receiving erythropoietin therapy
RD	# of patients aged 18 years and older with a diagnosis of MDS

Measure Specifications – Measure #2: MDS – Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy

Measure specifications will be provided for multiple data sources.

B. Administrative claims data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

(Note: The specifications listed below are those need for performance calculation.)

Denominator (Eligible Population): All patients aged 18 years and older with a diagnosis of MDS who are receiving erythropoietin therapy

ICD-9 diagnosis codes: 238.72, 238.73, 238.74, 238.75

AND

CPT service codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245

AND either

CPT Category II code: 4090F – Patient receiving erythropoietin therapy

OR

HCPCS codes to identify erythropoietin therapy: J0881, J0885

Denominator Exclusion:

Documentation of system reason(s) for not documenting iron stores prior to initiating erythropoietin therapy

- **Append modifier to CPT Category II code: 3160F-3P**

Numerator: Patients with documentation of iron stores prior to initiating erythropoietin therapy

CPT Category II code: 3160F: Documentation of iron stores prior to initiating erythropoietin therapy

B. Electronic Health Record System *(in development)*

C. Paper Medical Record *(in development)*

Hematology
Measure #3: Multiple Myeloma – Treatment with Bisphosphonates

This measure may be used as an Accountability measure.

Clinical Performance Measure
<p>Numerator: Patients who were prescribed or received intravenous bisphosphonate therapy* within the 12 month reporting period.</p> <p><i>*For the purpose of this measure, bisphosphonate therapy includes the following medications: pamidronate and zoledronate</i></p> <p>Denominator: All patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission</p> <p>Denominator Exclusions: Documentation of medical reason(s) for not prescribing bisphosphonates (eg, patients who do not have bone disease, patients with dental disease, patients with renal insufficiency) Documentation of patient reason(s) for not prescribing bisphosphonates</p> <p>Measure: Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12 month reporting period.</p>
<p>The following clinical recommendation statements are quoted <u>verbatim</u> from the referenced clinical guidelines and represent the evidence base for the measure:</p> <p>Based on published data and clinical experience, the guidelines recommend the use of bisphosphonates for all patients with multiple Myeloma who have bone disease, including osteopenia. In 10% to 20% of patients with earlier-stage disease who do not have bone disease, bisphosphonates may be considered but preferably in a clinical trial (Category I Recommendation). (NCCN⁵)</p> <p>Intravenous bisphosphonates should be administered monthly for patients with MM and lytic disease evident on plain radiographs (Grade A, Level II). It is reasonable to start intravenous bisphosphonates in patients with MM who do not have lytic bone disease if there is evidence of osteopenia or osteoporosis on bone mineral density studies (Consensus Recommendation, Level N/A). No randomized clinical trials support the use of bisphosphonates in patients with smoldering MM. We believe that bisphosphonates should be used only in the setting of a clinical trial [in these patients] (Consensus Recommendation, Level N/A). (Mayo Clinic⁶)</p>
<p>Rationale for the measure:</p> <p>Multiple Myeloma is a disease characterized by bone destruction, in the form of diffuse osteopenia and/or osteolytic lesions, which develop in 85% of patients. Bisphosphonates can inhibit bone resorption by reducing the number and activity of osteoclasts and therefore could “reduce pain and bone fractures in people with multiple Myeloma⁷.”</p>
<p>Data capture and calculations:</p> <p>Calculation for Performance</p> <p>For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.</p> <p>Numerator (A) Includes:</p> <ul style="list-style-type: none"> • Patients who were prescribed or received intravenous bisphosphonate therapy within the 12 month reporting period <p>Denominator (PD) Includes:</p> <ul style="list-style-type: none"> • All patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission <p>Denominator Exclusions (C) Include:</p> <ul style="list-style-type: none"> • Documentation of medical reason(s) for not prescribing bisphosphonates (eg, patients who do not have bone disease, patients with dental disease, patients with renal insufficiency) • Documentation of patient reason(s) for not prescribing bisphosphonates

Performance Calculation

$\frac{A \text{ (# of patients meeting measure criteria)}}{PD \text{ (# of patients in denominator)} - C \text{ (# of patients with valid denominator exclusions)}}$
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Components for this measure are defined as:

A	# of patients who were prescribed or received intravenous bisphosphonate therapy within the 12 month reporting period
PD	# of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission
C	# of patients with documented medical reason(s) for not prescribing bisphosphonates (eg, patients who do not have bone disease, patients with dental disease, patients with renal insufficiency); # of patients with documented patient reason(s) for not prescribing bisphosphonates

Calculation for Reporting

For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator

Reporting Numerator includes each of the following instances:

- A. Patients who were prescribed or received intravenous bisphosphonate therapy within the 12 month reporting period
- C. Patients who were not prescribed bisphosphonates but for whom there is a documented medical reason or patient reason for not doing so
- D. Patients who were not prescribed bisphosphonates and there is no documented reason for not doing so

Reporting Denominator (RD) Includes:

- Patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission

Reporting Calculation

$\frac{A(\text{\# of patients meeting numerator criteria}) + C(\text{\# of patients with valid exclusions}) + D(\text{\# of patients NOT meeting numerator criteria})}{RD \text{ (\# of patients in denominator)}}$

Components for this measure are defined as:

A	# of patients who were prescribed or received intravenous bisphosphonate therapy within the 12 month reporting period
C	# of patients who were <u>not</u> prescribed bisphosphonates, but for whom there is a documented medical reason or patient reason for not doing so
D	# of patients who were <u>not</u> prescribed bisphosphonates and there is <u>no</u> documented reason for not doing so
RD	# of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission

Measure Specifications – Measure #3: Multiple Myeloma – Treatment with Bisphosphonates
Measure specifications will be provided for multiple data sources.

C. Administrative claims data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

(Note: The specifications listed below are those need for performance calculation.)

Denominator (Eligible Population): All patients aged 18 years and older with a diagnosis multiple myeloma, not in remission

ICD-9 diagnosis codes: 203.00

AND

CPT service codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245

Denominator Exclusion:

Documentation of medical reason(s) for not prescribing bisphosphonates (eg, patients who do not have bone disease, patients with dental disease, patients with renal insufficiency)

- **Append modifier to CPT Category II code: 4100F-1P**

Documentation of patient reason(s) for not prescribing bisphosphonates

- **Append modifier to CPT Category II code: 4100F-2P**

Numerator: Patients who were prescribed or received intravenous bisphosphonate therapy within the 12 month reporting period

CPT Category II code: 4100F – Intravenous bisphosphonate therapy prescribed or received

B. Electronic Health Record System *(in development)*

C. Paper Medical Record *(in development)*

Hematology
Measure #4: Chronic Lymphocytic Leukemia (CLL) – Baseline Flow Cytometry

This measure may be used as an Accountability measure.

Clinical Performance Measure	
<p>Numerator: Patients who had baseline flow cytometry* studies performed</p> <p><i>*Baseline flow cytometry studies refer to testing that is performed at time of diagnosis or prior to initiating treatment for that diagnosis. Treatment may include antineoplastic therapy.</i></p> <p>Denominator: All patients aged 18 years and older with a diagnosis of chronic lymphocytic leukemia (CLL)</p> <p>Denominator Exclusions: Documentation of medical reason(s) for not performing baseline flow cytometry Documentation of patient reason(s) for not performing baseline flow cytometry Documentation of system reason(s) for not performing baseline flow cytometry</p> <p>Measure: Percentage of patients aged 18 years and older with a diagnosis of chronic lymphocytic leukemia (CLL) who had baseline flow cytometry studies performed</p>	
<p>The following clinical recommendation statements are quoted <u>verbatim</u> from the referenced clinical guidelines and represent the evidence base for the measure: As with all lymphoid neoplasms, adequate hematopathologic review is essential to establish an accurate diagnosis of chronic lymphocytic leukemia and small lymphocytic lymphoma CLL/SLL...a combination of morphologic and flow cytometric studies may provide adequate information to provide a diagnosis. This is particularly true for the diagnosis of CLL. Flow cytometric studies performed on patients with leukemic cell burden include kappa/lambda to [assess] clonality...Distinguishing CLL/SLL from mantle cell lymphoma is essential (Category 2A Recommendation). (NCCN®)</p>	
<p>Rationale for the measure: Due to the distinct pattern of protein antigens expressed in CLL, flow cytometry should be performed in order to confirm the diagnosis, correctly characterize the pathological cells, and determine prognosis. In some instances, flow cytometry may also offer additional therapeutically relevant information.⁹</p>	
<p>Data capture and calculations: Calculation for Performance For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.</p> <p>Numerator (A) Includes:</p> <ul style="list-style-type: none"> • Patients who had baseline flow cytometry studies performed <p>Denominator (PD) Includes:</p> <ul style="list-style-type: none"> • All patients aged 18 years and older with a diagnosis of chronic lymphocytic leukemia (CLL) <p>Denominator Exclusions (C) Include:</p> <ul style="list-style-type: none"> • Documentation of medical reason(s) for not performing baseline flow cytometry studies • Documentation of patient reason(s) for not performing baseline flow cytometry studies • Documentation of system reason(s) for not performing baseline flow cytometry studies 	
<p>Performance Calculation</p> <table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;"> $\frac{A \text{ (# of patients meeting measure criteria)}}{PD \text{ (# of patients in denominator)} - C \text{ (# of patients with valid denominator exclusions)}}$ </td> </tr> </table>	$\frac{A \text{ (# of patients meeting measure criteria)}}{PD \text{ (# of patients in denominator)} - C \text{ (# of patients with valid denominator exclusions)}}$
$\frac{A \text{ (# of patients meeting measure criteria)}}{PD \text{ (# of patients in denominator)} - C \text{ (# of patients with valid denominator exclusions)}}$	

Components for this measure are defined as:

A	# of patients who had baseline flow cytometry studies performed
PD	# of patients aged 18 years and older with a diagnosis of chronic lymphocytic leukemia (CLL)
C	# of patients with documented medical reason(s) for not performing baseline flow cytometry studies; # of patients with documented patient reason(s) for not performing baseline flow cytometry studies; # of patients with documented system reason(s) for not performing baseline flow cytometry studies

Calculation for Reporting

For reporting purposes, this measure is calculated by creating a fraction with the following components: Reporting Numerator and Reporting Denominator

Reporting Numerator includes each of the following instances:

- A. Patients who had baseline flow cytometry studies performed
- C. Patients who did not have baseline flow cytometry studies performed, but for whom there is a documented medical reason, patient reason, or system reason for not doing so
- D. Patients who did not have baseline flow cytometry studies performed and there is no documented reason for not doing so

Reporting Denominator (RD) Includes:

- Patients aged 18 years and older with a diagnosis of chronic lymphocytic leukemia (CLL)

Reporting Calculation

$$\frac{A(\text{\# of patients meeting numerator criteria}) + C(\text{\# of patients with valid exclusions}) + D(\text{\# of patients NOT meeting numerator criteria})}{RD (\text{\# of patients in denominator})}$$

Components for this measure are defined as:

A	# of patients who had baseline flow cytometry studies performed
C	# of patients who did <u>not</u> have baseline flow cytometry studies performed, but for whom there is a documented medical reason, patient reason, or system reason for not doing so
D	# of patients who did <u>not</u> have baseline flow cytometry studies performed and there is <u>no</u> documented reason for not doing so
RD	# of patients aged 18 years and older with a diagnosis of chronic lymphocytic leukemia (CLL)

Measure Specifications – Measure #4: Chronic Lymphocytic Leukemia – Baseline Flow Cytometry
Measure specifications will be provided for multiple data sources.

D. Administrative claims data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

(Note: The specifications listed below are those need for performance calculation.)

Denominator (Eligible Population): All patients aged 18 years and older with a diagnosis chronic lymphocytic leukemia (CLL)

ICD-9 diagnosis codes: 204.10

AND

CPT service codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245

Denominator Exclusion:

Documentation of medical reason(s) for not performing baseline flow cytometry studies

- **Append modifier to CPT Category II code: 3170F-1P**

Documentation of patient reason(s) for not performing baseline flow cytometry studies

- **Append modifier to CPT Category II code: 3170F-2P**

Documentation of system reason(s) for not performing baseline flow cytometry studies

- **Append modifier to CPT Category II code: 3170F-3P**

Numerator: Patients who had baseline flow cytometry studies performed

CPT Category II code: 3170F – Baseline flow cytometry studies performed

B. Electronic Health Record System (*in development*)

C. Paper Medical Record (*in development*)

EVIDENCE CLASSIFICATIONS / RATING SCHEMES

National Comprehensive Cancer Network (NCCN) Recommendation Rating Scale^{1,3,4,5,8}

Category of Consensus	Quality of Evidence	Level of Consensus
1	High	Uniform
2A	Lower	Uniform
2B	Lower	Non-uniform
3	Any	Major disagreement

Category 1: The recommendation is based on high-level evidence (ie, high-powered randomized clinical trials or meta-analyses), and the panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions.

Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II or large cohort studies to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so panel members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based opinions provide an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent.

Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data.

Category 3: Including the recommendation has engendered a major disagreement among the panel members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials (McNeill, 2001). Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data

may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy.

Mayo Clinic Consensus Statement Recommendation Rating Scale⁶ (adapted from American Society of Clinical Oncology Levels of Evidence and Grade of Evidence for Recommendations)¹⁰

Level I	Evidence obtained from meta-analysis of multiple, well-designed, controlled studies. Randomized trials with low false-positive and low false-negative errors (high power)
Level II	Evidence obtained from at least one well-designed experimental study. Randomized trials with high false-positive and/or negative errors (low power).
Level III	Evidence obtained from well-designed, quasi-experimental studies such as nonrandomized, controlled single-group, pre-post, cohort, time, or matched case-control series
Level IV	Evidence from well-designed, nonexperimental studies such as comparative and correlational descriptive and case studies
Level V	Evidence from case reports and clinical examples
Grade A	There is evidence of type I or consistent findings from multiple studies of types II, III, or IV
Grade B	There is evidence of types II, III, or IV and findings are generally consistent
Grade C	There is evidence of types II, III, or IV but findings are inconsistent
Grade D	There is little or no systematic empirical evidence

References

- ¹ National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Myelodysplastic syndromes. Version 4, 2006. Available at: www.nccn.org/professionals/physician_gls/default.asp.
- ² British Committee for Standards in Haematology (BCSH). Guidelines for the diagnosis and therapy of adult myelodysplastic syndromes. *British Journal of Haematology*. 2003; 120: 187-200
- ³ National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Acute myeloid leukemia. Version 1, 2006. Available at: www.nccn.org/professionals/physician_gls/default.asp.
- ⁴ National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Myelodysplastic syndromes. Version 4, 2006. Available at: www.nccn.org/professionals/physician_gls/default.asp.
- ⁵ National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Multiple Myeloma. Version 1, 2006. Available at: www.nccn.org/professionals/physician_gls/default.asp.
- ⁶ Lacy MQ, Dispenzieri A, Gertz MA, et al. Mayo Clinic Statement for the Use of Bisphosphonates in Multiple Myeloma. *Mayo Clinic Proceedings*. 2006; 81(8): 1047-1053.
- ⁷ Djulbegovic B, Wheatley K, Ross J, Clark O, Bos G, Goldschmidt H, Cremer F, Alsina M, Glasmacher A. Bisphosphonates in multiple Myeloma. *Cochrane Database of Systematic Reviews* 2002, Issue 4. Art No.: CD003188. DOI: 10.1002/14651858.CD003188.
- ⁸ National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Non-Hodgkin's Lymphoma. Version 2, 2006. Available at: www.nccn.org/professionals/physician_gls/default.asp.
- ⁹ DiGiuseppe JA, Borowitz MJ. Clinical utility of flow cytometry studies in the chronic lymphoid leukemias. *Semin Oncol*. 1998; 25(1): 6-10.
- ¹⁰ Berenson JR, Hillner BE, Kyle RA, Anderson K, Lipton A, Yee GC, Sybil Biermann J for the American Society of Clinical Oncology Bisphosphonates Expert Panel. American Society of Clinical Oncology Clinical Practice Guidelines: The role of bisphosphonates in multiple myeloma. *Journal of Clinical Oncology*. 2002; 20(17): 3719-3736.