2018 OPTIONS FOR INDIVIDUAL MEASURES:
REGISTRY ONLY

MEASURE TYPE:
Process

DESCRIPTION:
Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow

INSTRUCTIONS:
This measure is to be submitted a minimum of once per performance period for all myelodysplastic syndrome (MDS) and Acute Leukemia patients seen during the performance period, regardless of when MDS or Acute Leukemia diagnosis was made; the quality action being measured is that baseline cytogenetic testing on bone marrow was performed for each patient with MDS or Acute Leukemia at the time of diagnosis or prior to initiating treatment. It is anticipated that eligible clinicians who provide services for patients with the diagnosis of myelodysplastic syndromes or an acute leukemia (not in remission) will submit this measure.

Measure Submission:
The listed denominator criteria is used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions allowed by the measure. The quality-data codes listed do not need to be submitted for registry submissions; however, these codes may be submitted for those registries that utilize claims data.

DENOMINATOR:
All patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia

DENOMINATOR NOTE: *Signifies that this CPT Category I code is a non-covered service under the Medicare Part B Physician Fee Schedule (PFS). These non-covered services should be counted in the denominator population for registry-based measures

Denominator Criteria (Eligible Cases):
Patients aged ≥ 18 years on date of encounter

AND

Diagnosis for MDS or acute leukemia – not in remission (ICD-10-CM): C91.00, C91.02, C92.00, C92.02, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C93.00, C93.02, C94.00, C94.02, C94.20, C94.22, C95.00, C95.02, D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, D46.A, D46.B, D46.C, D46.Z

AND

Patient encounter during the performance period (CPT): 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241*, 99242*, 99243*, 99244*, 99245*

WITHOUT
Telehealth Modifier: GQ, GT, 95, POS 02

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

NUMERATOR NOTE: Denominator Exception(s) are determined at the time of the diagnosis of MDS or Acute Leukemia or prior to initiating treatment.
Definition:
Baseline Cytogenetic Testing – Testing that is performed at time of diagnosis or prior to initiating treatment (transfusion, growth factors, or antineoplastic therapy) for that diagnosis.

Numerator Options:
Performance Met: Cytogenetic testing performed on bone marrow at time of diagnosis or prior to initiating treatment (3155F)

OR

Denominator Exception: Documentation of medical reason(s) for not performing baseline cytogenetic testing on bone marrow (eg, no liquid bone marrow or fibrotic marrow) (3155F with 1P)

OR

Denominator Exception: Documentation of patient reason(s) for not performing baseline cytogenetic testing on bone marrow (eg, at time of diagnosis receiving palliative care or not receiving treatment as defined above) (3155F with 2P)

OR

Denominator Exception: Documentation of system reason(s) for not performing baseline cytogenetic testing on bone marrow (eg, patient previously treated by another physician at the time cytogenetic testing performed) (3155F with 3P)

OR

Performance Not Met: Cytogenetic testing not performed on bone marrow at time of diagnosis or prior to initiating treatment, reason not otherwise specified (3155F with 8P)

RATIONALE:
For MDS:
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.

For acute leukemias:
In addition to establishing the type of acute leukemia, cytogenetic testing is essential to detect chromosomal abnormalities that have diagnostic, prognostic, and therapeutic significance. Performing cytogenetic analysis on patients with AML identifies a subgroup of patients where further molecular genetics testing is indicated.

CLINICAL RECOMMENDATION STATEMENTS:
The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines:

For MDS:
Bone marrow aspiration with Prussian blue stain for iron and a biopsy are needed to evaluate the degree and relative proportions of hematopoietic cell maturation abnormalities, percentage of marrow blasts, marrow cellularity, presence or absence of ring sideroblasts (and presence of iron per se), and fibrosis. Cytogenetics for bone marrow samples (by standard karyotyping methods) should be obtained because they are of major prognostic importance. (Category 2A Recommendation) (NCCN MDS, 2017)

Significant independent variables for determining survival and AML evolution outcomes were marrow blast percentage, number of cytopenias, and cytogenetic subgroup (good, intermediate, poor). The percentage of marrow blasts was divisible into four categories: 1) less than 5%, 2) 5% to 10%, 3) 11% to 20%, and 4) 21% to 30% (Category 2A). (NCCN MDS, 2017)
For Acute Leukemias:
In addition to morphologic assessment (blood and BM), the pathologist or treating clinician should obtain sufficient samples and perform conventional cytogenic analysis (ie, karyotype), appropriate molecular-genetic and/or FISH testing, and FCIs. The flow cytometry panel should be sufficient to distinguish between acute myeloid leukemia (including acute promyelocytic leukemia), T-ALL (including early T-Cell precursor leukemias), B-cell precursor ALL (B-ALL), and AL of ambiguous lineage for all patients diagnosed with AL. Molecular genetic and/or FISH testing does not, however replace conventional cytogenic analysis. (Strong Recommendation) (CAP/ASH, 2017)

Acute Lymphoblastic Leukemia:
Hematopathology evaluations should include morphologic examination of malignant lymphocytes using Wright-Giemsa-stained slides and hematoxylin and eosin-stained core biopsy and clot sections, comprehensive immunophenotyping with flow cytometry, and assessment of cytogenetic or molecular abnormalities. Identification of specific recurrent genetic abnormalities is critical for disease evaluation, optimal risk stratification, and treatment planning. (Category 2A Recommendation) (NCCN ALL, 2016)

Acute Myeloid Leukemia:
Although cytogenetic information is often unknown when treatment is initiated in patients with de novo AML, karyotype represents the single most important prognostic factor for predicting remission rates, relapse risks, and [overall survival (OS)] outcomes. (Category 2A Recommendation) (NCCN AML, 2017)

The importance of obtaining adequate samples of marrow or peripheral blood at diagnosis for full karyotyping and FISH cytogenetic analysis for the most common abnormalities cannot be overemphasized. Thus, in addition to basic cytogenetic analysis, new molecular markers can help refine prognostics groups, particularly in patients with a normal karyotype. (Category 2A Recommendation) (NCCN AML, 2017)
2018 Registry Flow for Quality ID #67 NQF #0377:
Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow

Denominator

Start

Data Completeness Not Met
Performance Not Met 3155F-6P or Equivalent (20 patients) c

Ineligible Population/Denominator

Patient Age on Date of Encounter ≥ 18 Years

Yes

Cytogenetic Testing Performed on Bone Marrow at Time of Diagnosis or Prior to Initiating Treatment

No

Data Completeness Met + Performance Met 3155F or Equivalent (40 patients) a

Documentation of Medical Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow

Yes

Data Completeness Met + Denominator Exception 3155F-1P or Equivalent (10 patients) b

No

Documentation of Patient Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow

Yes

Data Completeness Met + Denominator Exception 3155F-3P or Equivalent (6 patients) b

No

Documentation of System Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow

Yes

Data Completeness Met + Denominator Exception 3155F-3P or Equivalent (6 patients) b

No

Cytogenetic Testing Not Performed on Bone Marrow at Time of Diagnosis or Prior to Initiating Treatment, Reason Not Otherwise Specified

Yes

Data Completeness Met + Performance Met 3155F-6P or Equivalent (20 patients) c

No

Telehealth Modifier: GO, GT, 95, POS 02

Yes

Not Included in Eligible Population/Denominator

No

Encounter as Listed in Denominator (V1/2016 thru 12/31/2016)

Yes

Diagnosis for MDS or Acute Leukemia (Not in Remission) as Listed in Denominator

No

Include in Eligible Population/Denominator (60 patients) d

SAMPLE CALCULATIONS:

Data Completeness:
Performance Met (a=40 patients) + Denominator Exception (b=b2+b3=10 patients) + Performance Not Met (c=20 patients) = 70 patients = 87.50% Eligible Population / Denominator (d=60 patients)

Performance Rate:
Performance Met (a=40 patients) / Data Completeness Numerator (70 patients) = 40 patients / 60 patients = 66.67%

*See the posted Measure Specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Patient-Process

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The measure diagrams are developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.
2018 Registry Flow for Quality ID
#67 NQF #0377: Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow

Please refer to the specific section of the specification to identify the denominator and numerator information for use in submitting this Individual Specification. This flow is for registry data submission.

1. Start with Denominator

2. Check Patient Age:
   a. If Patient Age is greater than or equal to 18 Years of age at Date of Service equals No during the measurement period, do not include in Eligible Patient Population. Stop Processing.
   b. If Patient Age is greater than or equal to 18 Years of age at Date of Service equals Yes during the measurement period, proceed to check Patient Diagnosis.

3. Check Patient Diagnosis:
   a. If Diagnosis of MDS or Acute Leukemia (Not in Remission) as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If Diagnosis of MDS or Acute Leukemia (Not in Remission) as Listed in the Denominator equals Yes, proceed to check Encounter Performed.

4. Check Encounter Performed:
   a. If Encounter as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
   b. If Encounter as Listed in the Denominator equals Yes, proceed to check Telehealth Modifier.

5. Check Telehealth Modifier:
   a. If Telehealth Modifier equals Yes, do not include in Eligible Patient Population. Stop Processing.
   b. If Telehealth Modifier equals No, include in the Eligible Population.

6. Denominator Population:
   a. Denominator Population is all Eligible Patients in the Denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d equals 80 patients in the Sample Calculation.

7. Start Numerator

8. Check Cytogenetic Testing Performed on Bone Marrow at Time of Diagnosis or Prior to Initiating Treatment:
   a. If Cytogenetic Testing Performed on Bone Marrow at Time of Diagnosis or Prior to Initiating Treatment equals Yes, include in Data Completeness Met and Performance Met.
   b. Data Completeness Met and Performance Met letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 40 patients in the Sample Calculation.
c. If Cytogenetic Testing Performed on Bone Marrow at Time of Diagnosis or Prior to Initiating Treatment equals No, proceed to Documentation of Medical Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow.

9. Check Documentation of Medical Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow:

a. If Documentation of Medical Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow equals Yes, include in Data Completeness Met and Denominator Exception.

b. Data Completeness Met and Denominator Exception letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b1 equals 10 patients in the Sample Calculation.

c. If Documentation of Medical Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow equals No, proceed to Documentation of Patient Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow.

10. Check Documentation of Patient Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow:

a. If Documentation of Patient Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow equals Yes, include in Data Completeness Met and Denominator Exception.

b. Data Completeness Met and Denominator Exception letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b2 equals 0 patients in the Sample Calculation.

c. If Documentation of Patient Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow equals No, proceed to Documentation of System Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow.

11. Check Documentation of System Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow:

a. If Documentation of System Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow equals Yes, include in Data Completeness Met and Denominator Exception.

b. Data Completeness Met and Denominator Exception letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b3 equals 0 patients in the Sample Calculation.

c. If Documentation of System Reason(s) for Not Performing Baseline Cytogenetic Testing on Bone Marrow equals No, proceed to Cytogenetic Testing Not Performed on Bone Marrow at Time of Diagnosis or Prior to Initiating Treatment, Reason Not Otherwise Specified.

12. Check Cytogenetic Testing Not Performed on Bone Marrow at Time of Diagnosis or Prior to Initiating Treatment, Reason Not Otherwise Specified:

a. If Cytogenetic Testing Not Performed on Bone Marrow at Time of Diagnosis or Prior to Initiating Treatment, Reason Not Otherwise Specified equals Yes, include in Data Completeness Met and Performance Not Met.
b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c equals 20 patients in the Sample Calculation.

c. If Cytogenetic Testing Not Performed on Bone Marrow at Time of Diagnosis or Prior to Initiating Treatment, Reason Not Otherwise Specified equals No, proceed to Data Completeness Not Met.

13. Check Data Completeness Not Met:

a. If Data Completeness Not Met, the Quality Data Code or equivalent was not submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

<table>
<thead>
<tr>
<th>SAMPLE CALCULATIONS:</th>
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<tbody>
<tr>
<td><strong>Data Completeness</strong> = Performance Met (a=40 patients) + Denominator Exception (b₁ + b₂ + b₃ = 10 patients) + Performance Not Met (c=20 patients) = 70 patients = 87.50%</td>
</tr>
<tr>
<td>Eligible Population / Denominator (d=80 patients) = 80 patients</td>
</tr>
<tr>
<td><strong>Performance Rate</strong> = Performance Met (a=40 patients) / Eligible Population = 40 patients / 80 patients = 66.67%</td>
</tr>
<tr>
<td>Data Completeness Numerator (70 patients) – Denominator Exception (b₁ + b₂ + b₃ = 10 patients) = 60 patients</td>
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