Hematology
Measure #2: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy

This measure may be used as an Accountability measure

Clinical Performance Measure
Numerator: Patients with documentation of iron stores* within 60 days prior to initiating erythropoietin therapy Definition: *Documentation of Iron Stores: Includes either: 1) bone marrow examination including iron stain OR 2) serum iron measurement including ferritin, or serum iron and total iron-binding capacity (TIBC). **Denominator**: All patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy* Definition: Erythropoietin Therapy: Includes the following medications: epoetin and darbepoetin for the purpose of this measure. **Denominator Exceptions**: Documentation of system reason(s) for not documenting iron stores prior to initiating erythropoietin therapy **Measure Description**: Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy
The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure: Anemia related to MDS generally presents as a hypoproductive macrocytic anemia, often associated with suboptimal elevation of serum Epo levels. Bone marrow aspiration with iron stain, biopsy, and cytogenetics should be used to determine WHO subtype, iron status, and the level of ring sideroblasts. Patients should also be considered for HLA-DR15 typing as indicated above. Iron repletion needs to be verified before instituting Epo or darbepoetintherapy. (Category 2A Recommendation) (NCCN, 2017[1]) Baseline and periodic monitoring of iron, total iron-binding capacity, transferrin saturation, or ferritin levels and instituting iron repletion when indicated may help to reduce the need for ESAs, maximize symptomatic improvement for patients, and determine the reason for failure to respond adequately to ESA therapy. (ASH, 2010[2])
Rationale for the measure: In comparison with supportive care alone, patients receiving EPO with or without granulocyte colony-stimulating factor plus supportive care had improved erythroid responses, similar survival, and incidence of acute myeloid leukemia transformation 6. Treatment of anemia in MDS with EPO plus G-CSF was associated with significantly improved survival outcome in patients with no or low transfusion need, while not affecting the risk of leukemic transformation. Erythropoiesis-stimulating agents (ESAs: erythropoietin-alfa, darbepoietin) are a key component of the strategy for improving anemia and reducing dependence on red blood cell (RBC) transfusions. Clinical trial results indicate

that approximately 40% of selected patients have a clinically meaningful hemoglobin response to ESAs, with a median two-year response.7   To be effective, erythropoietin therapy requires that adequate iron stores be present due to iron's importance in red-blood-cell synthesis. By promoting the documentation of adequate iron stores in MDS patients requiring EPO therapy, the efficacy of the treatment will be enhanced[1].

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

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Administrative Claims/Registry

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.

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

Patients aged ≥ 18 years on date of encounter
AND
Diagnosis for MDS (ICD-10-CM): 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
AND
Patient receiving erythropoietin therapy: 4090F

Numerator: Patients with documentation of iron stores within 60 days prior to initiating erythropoietin therapy
- **Report CPT Category II code: 3160F** – Documentation of iron stores prior to initiating erythropoietin therapy

Denominator Exceptions:
Denominator Exception(s) are determined during the 60 days prior to initiating erythropoietin therapy.

Documentation of system reason(s) for not documenting iron stores prior to initiating erythropoietin therapy
- **Append modifier to CPT Category II code: 3160F-3P**

EVIDENCE CLASSIFICATIONS / RATING SCHEMES

National Comprehensive Cancer Network (NCCN) Recommendation Rating Scale[1] - - - -

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.

References

[1] National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes. Version I.2018, 2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf

[2] 5 J. Douglas Rizzo, Melissa Brouwers, Patricia Hurley, Jerome Seidenfeld, Murat O. Arcasoy, Jerry L. Spivak, Charles L. Bennett, Julia Bohlius, Darren Evanchuk, Matthew J. Goode, Ann A. Jakubowski, David H. Regan and Mark R. Somerfield. Approved by the American Society of Clinical Oncology Board of Directors on July 7, 2010. Approved by the Executive Committee of the American Society of Hematology on July 14, 2010. Available here: http://www.hematology.org/Practice/Guidelines/2934.aspx.