Bristol Myers Squibb™

January 22, 2024

Re: Draft Scoping Document "Imetelstat for Anemia in Myelodysplastic Syndrome"

Submitted electronically via: publiccomments@icer.org

Dear ICER Review Team,

Bristol Myers Squibb (BMS) acknowledges the importance of fully and accurately understanding the value that innovative therapies provide to patients, and we appreciate the opportunity to comment on the Institute for Clinical and Economic Review's (ICER) draft scoping document titled "Imetelstat for Anemia in Myelodysplastic Syndrome." At BMS, we are inspired by a single vision—transforming patients' lives through science. Our mission is aimed towards discovery, development and delivery of innovative medicines that help patients prevail over serious diseases.

Below are our comments in response to specific ICER statements within the Draft Scoping Document of this ICER assessment.

1. **BMS recommends that any reference to luspatercept be based on data from the MEDALIST trial and not the COMMANDS trial.**

    - On Page 1, ICER states that: "Luspatercept was recently approved as a first-line treatment for low-risk MDS patients with anemia and is particularly effective in patients with the ring sideroblast phenotype." The first-line approval in 2023 was based on the COMMANDS trial.[1] Reblozyl was first approved in MDS in 2020 based on the MEDALIST trial for the treatment of anemia in second line or beyond (2L+) failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell (RBC) units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).[2] Since imetelstat is studied in the 2L+ patient population, any reference to Reblozyl should also be in the 2L+ patient population (e.g. Medalist trial data).[3,4]

2. **BMS recommends that the stated population be modified as "adults with lower risk myelodysplastic syndromes without the del(5q) mutation who are transfusion dependent and ineligible/refractory/relapsed to ESAs"**

    - On Page 3, ICER states that "The population of focus for the review is adults with lower risk myelodysplastic syndromes without the del(5q) mutation who are transfusion dependent despite best supportive care including the use of ESAs when

indicated." However, imetelstat is specifically studied in patients with ESA-ineligible/refractory/relapsed LR-MDS.[3]

3. **Due to differences in patient population and endpoints, there may be limitations when comparing data from MEDALIST and IMerge. BMS recommends taking the following key elements into consideration in ICER's analysis plan to minimize biases and misinterpretation of results.**

Table 1: Baseline characteristics of patient populations and primary endpoints in MEDALIST and IMerge[3,4,5,6]

	MEDALIST[4,5]	**IMerge[3,6]**
Age and ECOG status	Both trials enrolled patients 18 years or older who required RBC transfusion and had an ECOG score of 0, 1, or 2.	
Prognostic Risk Score	*Very-low*, low, or intermediate-risk MDS according to IPSS-R criteria	Low or intermediate-risk MDS according to IPSS criteria
Ring Sideroblast status	Patients diagnosed with MDS *with ring sideroblasts* (MDS-RS+) per WHO or FAB criteria	Patients diagnosed with MDS, without specifying criteria for RS, per WHO criteria
Transfusion Burden	At least *2* RBC units per 8 weeks	At least *4* RBC units per 8 weeks
Primary endpoint	RBC transfusion independence for 8 weeks or longer *during weeks 1 through 24*	RBC transfusion independence for at least 8 consecutive weeks starting on the day of randomization for entire treatment period until subsequent anti-cancer therapy, if any.

ECOG, Eastern Cooperative Oncology Group; French American British, FAB; IPSS-R, International prognostic scoring system-revised; RBC, red blood cell; World Health Organization, WHO;

4. **BMS recommends that any cost effectiveness analysis between luspatercept and imetelstat should apply lifetime horizon vs the proposed shorter time duration of 5 years.**

- The mean age of patients enrolled in MEDALIST and IMerge was 71 years and 72 years, respectively. Mean life expectancies at 71 years are 12.94 years for males and 15.08 years for females, and at 72 years are 12.3 years for males and 14.36 years for

females.[7] Therefore, calculating cost effectiveness with 5-year time horizons may not be appropriate.

5. **BMS recommends the impact of treatment attributes on healthcare system, patient and societal burden be incorporated into the cost-effectiveness model and evaluated as part of the Benefits Beyond Health and Special Ethical Priorities.**

    - Treatment attributes outside of efficacy and safety may have differential impacts on healthcare system, patients, and society overall.[8] One example to consider is the route of administration. For instance, luspatercept is administered subcutaneously once every 3 weeks at a dose of 1.0 up to 1.75 mg per kilogram of body weight, whereas imetelstat is administered as a 2- hour intravenous infusion every 4 weeks at a dose of 7.5 mg/kg.[6,9]

6. **BMS urges ICER to appropriately contextualize CEA as merely one aspect of a broader and holistic assessment of value.**

    - Both the ISPOR Value Flower and the 2nd Panel on Cost-Effectiveness in Health and Medicine articulated elements of value that go beyond the impact of a medicine on the healthcare sector.[10,11] In addition to impacting length and quality of life, effective medicines can help patients and caregivers to get back to work, provide a bridge to future medicines, improve the efficiency and quality of care in healthcare systems, inspire innovation in other treatment areas, and improve equity in the population, as well as the impact upon education, the legal system and other sectors of society – and so much more. The value of COVID-19 vaccines was not limited to the reduced incidence of disease and lives saved – they allowed society to reopen, supported innovation in oncology and rare diseases, and inspired efficiencies in other areas of healthcare.

Thank you for the opportunity to review and comment on this draft scoping document.

Sincerely,

Anthony Barisano, PharmD
Vice President | WW Health Economics & Outcomes Research Markets – US

Bristol Myers Squibb™

References:

1. Bristol Myers Squibb. Press Release: U.S. FDA Approves Bristol Myers Squibb's Reblozyl® (luspatercept-aamt) as First-Line Treatment of Anemia in Adults with Lower-Risk Myelodysplastic Syndromes (MDS) Who May Require Transfusions. Available at: https://news.bms.com/news/details/2023/U.S.-FDA-Approves-Bristol-Myers-Squibbs-Reblozyl-luspatercept-aamt-as-First-Line-Treatment-of-Anemia-in-Adults-with-Lower-Risk-Myelodysplastic-Syndromes-MDS-Who-May-Require-Transfusions/default.aspx
2. Bristol Myers Squibb. Press Release: U.S. Food and Drug Administration (FDA) Approves Reblozyl® (luspatercept-aamt), the First and Only Erythroid Maturation Agent, to Treat Anemia in Adults with Lower-Risk Myelodysplastic Syndromes (MDS). Available at: https://news.bms.com/news/corporate-financial/2020/US-Food-and-Drug-Administration-FDA-Approves-Reblozyl-luspatercept-aamt-the-First-and-Only-Erythroid-Maturation-Agent-to-Treat-Anemia-in-Adults-with-Lower-Risk-Myelodysplastic-Syndromes-MDS/default.aspx
3. Platzbecker U, Santini V, Fenaux P, et al. Imetelstat in patients with lower-risk myelodysplastic syndromes who have relapsed or are refractory to erythropoiesis-stimulating agents (IMerge): a multinational, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet.* 2023. doi:10.1016/S0140-6736(23)01724-5
4. Fenaux P, Platzbecker U, Mufti GJ, et al. Luspatercept in patients with lower-risk myelodysplastic syndromes. *N Engl J Med*. 2020a 382(2):140-151. Doi:10.1056/NEJMoz1908892
5. Clinicaltrials.gov. A Study of Luspatercept (ACE-536) to Treat Anemia Due to Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes (MEDALIST). Accessed January 17, 2024. https://clinicaltrials.gov/study/NCT02631070.
6. Clinicaltrials.gov. Study to Evaluate Imetelstat (GRN163L) in Subjects With International Prognostic Scoring System (IPSS) Low or Intermediate-1 Risk Myelodysplastic Syndrome (MDS). Accessed January 17, 2024. https://clinicaltrials.gov/study/NCT02598661.
7. Social Security Administration. Actuarial Life Table. Ssa.gov. Accessed January 17, 2024. https://www.ssa.gov/oact/STATS/table4c6.html
8. Soper J, Sadek I, Urniasz-Lippel A, et al. Patient and caregiver insights into the disease burden of myelodysplastic syndrome. *Patient Relat Outcome Meas*. 2022;13:31–8. doi: 10.2147/prom.s346434
9. Reblozyl® (luspatercept-aamt) [prescribing information]. Celgene Corporation, a Bristol Myers Squibb Company; August 2023.
10. Goring, S., Garrison, L., Jansen, J. P. & Higgs, A. H. 2022. Novel elements of the value flower: fake or truly novel? Value Outcomes Spotlight, 7, 34-39.
11. Neumann, P. J., Sanders, G. D, Russell, L.B., Siegel, J. E. & Ganiats, T.G. (eds). 2016. Cost-Effectiveness in Health and Medicine (2nd ed.). Oxford Academic.

January 24, 2024

Sarah K. Emond, MPP
President & CEO
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Re: Institute for Economic Review ─ Imetelstat for Anemia in Myelodysplastic Syndrome Background and Scope Input Period

Dear Ms. Emond,

On behalf of the Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to people impacted by cancer, we appreciate the opportunity to respond to the request for comments regarding the Institute for Clinical and Economic Review's (ICER) draft background and scope for the clinical effectiveness and value of Imetelstat for anemia in Myelodysplastic Syndrome (MDS).

As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC has a unique understanding of the cancer patient experience. Each year, CSC serves more than one million people affected by cancer through its network of over 190 Cancer Support Community, Gilda's Club, and healthcare partner locations as well as online and over the phone – all at no cost. Overall, we amplify the voices of those impacted by cancer through research and advocacy and create solutions that break down barriers to care and close the healthcare gap for communities whose members are disproportionately affected by cancer.

Additionally, CSC is home to the Research and Training Institute (RTI)—the only entity of its kind focused solely on the experiences of cancer patients and their loved ones. The RTI has contributed to the evidence base regarding the cancer patient experience through its Cancer Experience Registry, various publications and peer-reviewed studies on distress screening, and the psychosocial impact of cancer, and cancer survivorship. This combination of direct services and research uniquely positions CSC to provide valuable patient and evidence-informed feedback on ICER's value assessments.

While CSC recognizes ICER's commitment to value assessments of therapies that are not yet or only recently approved by the Food and Drug Administration (FDA), we believe that such assessments are premature. However, we believe that it is important to present the information we have learned from patients living with the disease. It is our position that value assessments should be updated periodically and ask that ICER routinely revisit value assessments as further evidence evolves. MDS greatly impacts patients' and caregivers' daily lives. Treatment often involves many blood tests and transfusions. Blood transfusion was the most common treatment for MDS among patients in our Cancer Experience Registry.

In a recent multi-national survey of patients with MDS requiring red blood cell transfusions, patients reported significant symptoms leading up to transfusions. Two anemia-related symptoms – fatigue and shortness of breath – were reported as having the most negative impact on quality of life (Vijenthira). While transfusion can improve these symptoms, transfusion also has its own side effects (fluid and iron overload), burden, and cost (Balitsky).

Also, MDS patients report negative effects on their ability to participate in social and family life and to carry out regular daily activities (Escalante; Heptinstall; Stauder). Such symptoms and side effects include disruptive fatigue, decreased mobility, concentration and memory issues, and persistent pain and discomfort (Kurtin). An MDS diagnosis and subsequent treatment have also been shown to negatively affect a patient's mental health, often leading to depression, anxiety, stress, loneliness, and other emotional stressors (Heptinstall; Stauder; Kurtin).

The time-consuming nature and side effects of MDS treatment make caregivers a necessity, as even low-risk MDS patients with mild anemia report fatigue and impairment in physical functioning. Caregivers can be family members, friends, or professional health aids, providing a wide variety of support, from assistance with household chores and social support to medical adherence, scheduling, billing, transportation, and more (Kurtin).

Some MDS patients need transfusions as often as every week or two weeks. Transfusions can take up to several hours to administer. Same-day hospital visits may be long and frequent. MDS patients often find that taking care of their health takes a lot of time. The costs associated with transportation, missed time at work, childcare, and more can be burdensome and overwhelming to both patients and caregivers (Cancer Support Community).

CSC's Cancer Experience Registry – an online survey-based research study that uncovers the emotional, physical, practical, and financial impact of cancer – incorporates the Patient Reported Outcome Information System-29 (PROMIS-v29), which examines how patients describe their quality of life across multiple domains. Scores can be compared to the U.S. population average, and a 3-point difference is considered clinically meaningful. One hundred fifty MDS patients participated in the Cancer Experience Registry from November 2021 through December 2023.

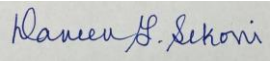
Using these PROMIS measures, our MDS respondents reported worse quality of life across multiple domains compared to the general population and even (in some domains) compared to cancer patients overall in our Cancer Experience Registry. MDS respondents reported elevated symptoms of fatigue, anxiety, and pain as well as deficits in physical and social functioning relative to the U.S. population average (score differences, 7.8, 4.1, 3.6, 7.9, and 5.3, respectively). Furthermore, levels of fatigue, physical functioning, and social functioning were worse for MDS patients than the overall CER sample including patients with other types of hematologic and solid tumor cancers (score differences, 3.1, 3.2, and 2.8, respectively). **Nearly half (43%) of MDS respondents reported moderate to severe impairment in physical function, and 41% reported moderate to severe symptoms of fatigue.**

Many MDS patients expressed concerns encompassing both their physical well-being, including moderate to very serious concern about exercising (53%), fatigue (51%), and mobility (44%), as well as future-oriented concerns such as the progression of cancer (47%), anxiety about the future (46%), and preparations for the end of life (32%) - consistent with the quality of life findings. In light of how transfusion dependence interrupts daily life, 37% of MDS respondents report being moderately to very seriously concerned about changes or disruptions to work, school, or home life. Furthermore, 41% of MDS respondents reported having to cope with their symptoms and concerns without the assistance of a caregiver.

As mentioned in the draft scoping document, MDS can be particularly costly. Financial toxicity refers to the out-of-pocket costs, lost wages, and debt faced by cancer patients, as well as the distress caused by financial strain. Nearly half (48%) of MDS patients in our Cancer Experience Registry reported at least mild financial toxicity, and 14% experienced high (moderate-severe) levels. Almost a third (31%) of MDS respondents reported concerns about health insurance or money. MDS respondents endorsed a variety of strategies to mitigate the financial burden of treatment, including tapping into personal assets: 28% used retirement funds; 15% depleted savings; and 1% filed for bankruptcy. Of those taking prescription medication for MDS in the past 12 months (n=81), 10% reported engaging in medication scrimping to save money in the prior year, such as skipping doses, taking less medication, or delaying a refill.

In closing, thank you for the opportunity to submit these comments. We welcome the opportunity to engage in further discussions with you to ensure the patient and caregiver experience is valued and all patients have access to high-quality health care. We ask that the evidence from our Cancer Experience Registry, which we presented in these comments, be utilized within the assessment. We look forward to commenting on the full assessment. If you have questions regarding our comments, or if we can serve as a resource, please reach out to me at dsekoni@cancersupportcommunity.org.

Sincerely,



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Appendix A – References

Abel GA, Lee S, Stone RM, et al. Development of a disease-specific measure of quality of life in myelodysplastic syndromes (MDS): The "QUALMS-1". *J Clin Oncol*. 2012;30(15):6103-6103. doi:10.1200/jco.2012.30.15_suppl.6103.

Aranesp Medication Guide - Food and Drug Administration (FDA). www.fda.gov/media/73138/download. Accessed January 24, 2024.

Arber DA, Orazi A, Hasserjian R, et al. The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. *Blood.* 2016;127, 2391-405. doi: 10.1182/blood-2016-03-643544.

Babushok DV, Bessler M, Olson TS. Genetic predisposition to myelodysplastic syndrome and acute myeloid leukemia in children and young adults. *Leuk Lymphoma*. 2016;57(3):520-536. doi:10.3109/10428194.2015.1115041.

Balitsky, A. and Arnold, D. (2022), Transfusion thresholds in myelodysplastic syndrome—Helping patients live better. Transfusion, 62: 1313-1314. https://doi.org/10.1111/trf.16985

Bannon SA, DiNardo CD. Hereditary Predispositions to Myelodysplastic Syndrome. *Int J Mol Sci*. 2016;17(6):838. doi:10.3390/ijms17060838.

Barot SV, Patel BJ, Gerds AT. Patient-Reported Outcomes in Myelodysplastic Syndromes: the Move from Life Span to Health Span. *Curr Hematol Malig Rep.* 2020;15:149-154. doi:10.1007/s11899-020-00562-9.

Bell JA, Galaznik A, Blazer M, et al. Economic Burden of Patients Treated for Higher-Risk Myelodysplastic Syndromes (HR-MDS) in Routine Clinical Care in the United States. *Pharmacoecon Open*. 2019;3(2):237-245. doi:10.1007/s41669-018-0100-5.

Blood Transfusions. Aplastic Anemia & MDS International Foundation (AAMDS) 2020. www.aamds.org/treatments/therapies/blood-transfusions. Accessed January 24, 2024.

Cancer Support Community. Frankly Speaking About Cancer: Myelodysplastic Syndromes. 2021. https://www.cancersupportcommunity.org/sites/default/files/fsac/Myelodysplastic_Syndromes.pdf. Accessed January 24, 2024.

Cattaneo C, Daffini R, Pagani C, et al. Clinical Characteristics and Risk Factors for Mortality in Hematologic Patients Affected By COVID-19. *Cancer*. doi:10.1002/cncr.33160.

Cogle CR. Incidence and Burden of the Myelodysplastic Syndromes. *Curr Hematol Malig Rep*. 2015 Sep;10(3):272-81. doi:10.1007/s11899-015-0269-y.

DiNardo CD, Garcia-Manero G, Pierce S, et al. Interactions and relevance of blast percentage and treatment strategy among younger and older patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). *Am J Hematol*. 2016;91(2):227-232. doi:10.1002/ajh.24252.

Efficace F, Gaidano G, Sprangers M, et al. Preference for Involvement in Treatment Decisions and Request for Prognostic Information in Newly Diagnosed Patients with Higher-Risk Myelodysplastic Syndromes. *Ann Oncol*. 2014;25(2):447-454. doi:10.1093/annonc/mdt557.

Escalante CP, Chisolm S, Song J, et al. Fatigue, symptom burden, and health-related quality of life in patients with myelodysplastic syndrome, aplastic anemia, and paroxysmal nocturnal hemoglobinuria. *Cancer Med*. 2019;8(2):543-553. doi:10.1002/cam4.1953.

Foran JM and Shammo JM. Clinical Presentation, Diagnosis, and Prognosis of Myelodysplastic Syndromes. *Am J Med.* 2012;125(7):S6-S13. doi:10.1016/j.amjmed.2012.04.015.

Gerds AT, Dennison B, Latsko J, et al. Doctor-Patient Communication and Perception of Treatment Discontinuation in Myelodysplastic Syndromes (MDS) Diverge at the Time of Disease Progression. *Blood.* 2014;124(21):2642. doi:10.1182/blood.V124.21.2642.2642.

Germing U, Oliva EN, Hiwase D, Almeida A. Treatment of Anemia in Transfusion-Dependent and Non-Transfusion-Dependent Lower-Risk MDS: Current and Emerging Strategies. *Hemasphere*. 2019;3(6):e314. Published 2019 Oct 30. doi:10.1097/HS9.0000000000000314.

Greenberg PL, et al. Revised International Prognostic Scoring System for Myelodysplastic Syndromes. *Blood*, vol. 120, no. 12, 2012, pp. 2454–2465., doi:10.1182/blood-2012-03-420489.

Haase D, Stevenson KE, Neuberg D, et al. TP53 mutation status divides myelodysplastic syndromes with complex karyotypes into distinct prognostic subgroups. *Leukemia*. 2019;33(7):1747-1758. doi:10.1038/s41375-018-0351-2.

Heptinstall K. Myelodysplastic Syndromes Foundation, Inc. Quality of life in myelodysplastic syndromes. A special report from the Myelodysplastic Syndromes Foundation, Inc. Oncology (Williston Park). 2008 Feb;22(2 Suppl Nurse Ed):13-8; discussion 19. PMID: 18434977.

John MJ, Jaison V, Jain K, Kakkar N, Jacob JJ. Erythropoietin use and abuse. *Indian J Endocrinol Metab*. 2012;16(2):220-227. doi:10.4103/2230-8210.93739.

Kubasch AS, Schulze F, Giagounidis A, et al. Single agent talacotuzumab demonstrates limited efficacy but considerable toxicity in elderly high-risk MDS or AML patients failing hypomethylating agents. *Leukemia*. 2020 Apr;34(4):1182-1186. doi:10.1038/s41375-019-0645-z.

Kurtin SE. *Building Blocks of Hope: Strategies for Patients and Caregivers Living with MDS*. Myelodysplastic Syndromes Foundation, Inc.; 2020.

LeBlanc TW, O'Donnell JD, Crowley-Matoka M, et al. Perceptions of palliative care among hematologic malignancy specialists: a mixed-methods study. *J Oncol Pract*. 2015 Mar;11(2):e230-8. doi:10.1200/JOP.2014.001859.

Liew E, Owen C. Familial myelodysplastic syndromes: a review of the literature. *Haematologica*. 2011;96(10):1536-1542. doi:10.3324/haematol.2011.043422.

Lindquist KJ, Danese MD, Mikhael J, Knopf KB, Griffiths RI. Health Care Utilization and Mortality among Elderly Patients with Myelodysplastic Syndromes. *Ann Oncol.* 2011;22(5): 1181-1188. doi:10.1093/annonc/mdq552.

Ma X, Wang R, Galili N, et al. Cigarette smoking shortens the survival of patients with low-risk myelodysplastic syndromes. *Cancer Cause Control*. 2011;22(4):623-629. doi:10.1007/s10552-011-9735-6.

MDS & Acute Myeloid Leukemia. MD Anderson Cancer Center, 2020 (MD Anderson). www.mdanderson.org/cancermoonshots/cancer-types/Leukemia_MDS_AML.html. Accessed January 24, 2024.

MDS Foundation. www.mds-foundation.org/. Accessed January 24, 2024.

Miller MF, Rogers KP, Goldberg SL, Fortune EE, Morris VG, Iraca T, Saxton C; Goldberg SL Communication that Enables Shared Decision-Making in Myelodysplastic Syndrome is Suboptimal: Early Results from the Cancer Experience Registry. Blood 2023; 142 (Supplement 1): 2435. doi: https://doi.org/10.1182/blood-2023-189592 poster: https://www.cancersupportcommunity.org/sites/default/files/file/2023-11/communication_enables_shared_decision_making_myelodysplastic_syndrome_suboptimal.pdf

Mohammad AA. Myelodysplastic syndrome from theoretical review to clinical application view. *Oncol Rev*. 2018;12(2):397. Published 2018 Dec 7. doi:10.4081/oncol.2018.397.

Myelodysplastic Syndromes (MDS). American Cancer Society (ACS) 2020. www.cancer.org/cancer/myelodysplastic-syndrome.html. Accessed January 24, 2024.

Naqvi K, Garcia-Manero G, Sardesai S, et al. Association of comorbidities with overall survival in myelodysplastic syndrome: development of a prognostic model. *J Clin Oncol*. 2011;29:2240-6. doi:10.1200/JCO.2010.31.3353

Nickolich M, El-Jawahri A, LeBlanc TW. Palliative and End-of-Life Care in Myelodysplastic Syndromes. *Curr Hematol Malig Rep.* 2016;11:434-440. doi:10.1007/s11899-016-0352-z.

Nutrition. Aplastic Anemia & MDS International Foundation (AAMDS) 2020. www.aamds.org/treatments/therapies/blood-transfusions. January 24, 2024.

Oliva EN, Agberemi R, Wintrich S. Assessing Needs for Support in MDS Patients. *Blood.* 2018;132(Supplement 1):2313. doi:10.1182/blood-2018-99-112967.

Platzbecker U. Treatment of MDS. *Blood*. 2019;133(10):1096-1107. doi:10.1182/blood-2018-10-844696.

Poynter JN, Richardson M, Roesler M, et al. Chemical exposures and risk of acute myeloid leukemia and myelodysplastic syndromes in a population-based study [published correction appears in Int J Cancer. 2019 Aug 1;145(3):E15]. *Int J Cancer*. 2017;140(1):23-33. doi:10.1002/ijc.30420.

Raza A, Assal A, Ali AM, Jurcic JG. Rewriting the rules for care of MDS and AML patients in the time of COVID-19. *Leuk Res Rep*. 2020;13:100201. Published 2020 Apr 20. doi:10.1016/j.lrr.2020.100201.

Reblozyl (Luspatercept-aamt) - Food and Drug Administration (FDA). https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761136orig2lbl.pdf. Accessed January 24, 2024.

Returning Home After Your Autologous Stem Cell Transplant. Memorial Sloan Kettering Cancer Center, 2019. https://www.mskcc.org/cancer-care/patient-education/returning-home-after-your-autologous-stem-cell-transplant. Accessed January 24, 2024.

Rio-Machin A, Vulliamy T, Hug N, et al. The complex genetic landscape of familial MDS and AML reveals pathogenic germline variants. *Nature Communications.* 2020;11:1044. Published 2020 Feb 25. doi:10.1038/s41467-020-14829-5.

Rogers KP, Miller MF, Fortune EE, Iraca T, Goldberg SL; Financial Toxicity and Cost-Management Behaviors Among Patients with Myelodysplastic Syndromes. Blood 2022; 140 (Supplement 1): 8142–8143. doi: https://doi.org/10.1182/blood-2022-162378 poster: https://www.cancersupportcommunity.org/sites/default/files/file/2022-12/3636_0.pdf

Sánchez AF, Fuentes Armesto AM, Chavez CB, Ruiz Marco. Revisiting Early Palliative Care for Patients With Hematologic Malignancies and Bone Marrow Transplant: Why the Delay? *Cureus.* 2020;12(9):e10504. doi:10.7759/cureus.10504.

SEER Cancer Statistics Review 1975-2017: Myelodysplastic Syndromes (MDS), Chronic Myeloproliferative Disorders (CMD), and Chronic Myelomonocytic Leukemia (CMML) - Section 30. National Cancer Institute. https://seer.cancer.gov/csr/1975_2017/results_merged/sect_30_mds.pdf#search=mds. Accessed January 24, 2024.

SEER*Explorer: Myelodysplastic Syndromes (MDS) Surveillance Research Program, National Cancer Institute. Data source(s): SEER Incidence Data, November 2022 Submission (1975-2020), SEER 22 registries. https://seer.cancer.gov/statistics-network/explorer/application.html?site=409. Accessed January 24, 2024.

Sperr WR, Wimazal F, Kundi M, et al. Comorbidity as prognostic variable in MDS: comparative evaluation of the HCT-CI and CCI in a core dataset of 419 patients of the Austrian MDS Study Group. *Ann Oncol.* 2010;21:114-9. doi:10.1093/annonc/mdp258.

Sridharan A, Jain R, Bachhuber MA, et al. Epidemiologic study of myelodysplastic syndromes in a multiethnic, inner city cohort. *Exp Hematol Oncol*. 2014;3:22. Published 2014 Aug 23. doi:10.1186/2162-3619-3-22.

Stauder R, Yu G, Koinig KA, et al. Health-related quality of life in lower-risk MDS patients compared with age- and sex-matched reference populations: a European LeukemiaNet study. *Leukemia*. 2018;32(6):1380-1392. doi:10.1038/s41375-018-0089-x.

Sweeney MR, Applebaum KM, Arem H, Braffett BH, Poynter JN, Robien K. Medical Conditions and Modifiable Risk Factors for Myelodysplastic Syndrome: A Systematic Review. *Cancer Epidemiol Biomarkers Prev*. 2019 Sep;28(9):1502-1517. doi:10.1158/1055-9965.EPI-19-0106.

Tong H, Hu C, Yin X, Yu M, Yang J, Jin J. A Meta-Analysis of the Relationship between Cigarette Smoking and Incidence of Myelodysplastic Syndromes. *PLoS One*. 2013;8(6):e67537. Published 2013 Jun 21. doi:10.1371/journal.pone.0067537.

The University of Chicago Hematopoietic Malignancies Cancer Risk Team. How I diagnose and manage individuals at risk for inherited myeloid malignancies. *Blood.* 2016; 128 (14): 1800–1813. doi:10.1182/blood-2016-05-670240.

Valent P, Orazi A, Steensma DP, et al. Proposed minimal diagnostic criteria for myelodysplastic syndromes (MDS) and potential pre-MDS conditions. *Oncotarget*. 2017;8(43):73483-73500. doi:10.18632/oncotarget.19008.

Vijenthira A, Starkman R, Lin Y, Stanworth SJ, Bowen D, Harrison L, et al. Multi-national survey of transfusion experiences and preferences of patients with myelodysplastic syndrome. *Transfusion*. 2022; 62(7): 1355–1364. https://doi.org/10.1111/trf.16946

Wang F, Ni J, Wu L, Wang Y, He B, Yu D. Gender disparity in the survival of patients with primary myelodysplastic syndrome. *J Cancer*. 2019;10(5):1325-1332. doi:10.7150/jca.28220.