AMERICAN SOCIETY OF HEMATOLOGY
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February 19, 2019

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9926-P
7500 Security Boulevard
Baltimore, MD 21244

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: CMS-9926-P; Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020

Dear Administrator Verma:

The American Society of Hematology is pleased to offer comments on the proposed rule for the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020.

ASH represents over 17,000 clinicians and scientists worldwide, who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients in diverse settings including teaching and community hospitals, as well as private practice.

ASH is concerned with how this proposed rule could adversely impact access to care for patients with hematologic diseases and disorders. The Society's concerns are outlined below.

Prescription Drug Changes

The Centers for Medicare and Medicaid Services (CMS) requested comments on whether plans should have the authority to make generic or therapeutic substitutions for drugs during the plan year. ASH strongly opposes changes that may limit or eliminate a patient's access to therapies.

Specifically, the agency proposes to allow insurers to add a generic equivalent of a drug to a formulary in the middle of the plan year if the insurer is then permitted to remove the equivalent brand drug(s) from the formulary or to move the equivalent brand drug(s) to a different cost-sharing tier on the formulary. ASH opposes allowing insurers to remove a brand name drug mid-year or to move a brand name drug to a different cost-sharing tier mid-year. There is a lack of comparative data on the difference between some generic and branded drugs that treat hematologic diseases. For example, very little data exists on the difference between generic and branded imatinib, used to treat certain types of leukemia, and

some of the studies that have been done actually show that individuals treated with generic imatinib presented higher rate of failure at three months and lower overall survival, progression-free survival, and event-free survival at 24 months.[1] Allowing plans to remove a branded drug or move a branded drug to a different cost-sharing tier could leave a patient without access to a needed medication mid-year and/or make the medication unaffordable. While CMS does propose a detailed appeal process through which the patient could request continued coverage of the brand name drug, this is not a coverage guarantee. Even if the appeal were to succeed, it may still result in a lengthy coverage interruption.

Additionally, CMS is seeking comments on the opportunities and risks associated with reference-based pricing, which occurs when an insurer in a commercial market covers a group of similar drugs, such as within the same therapeutic class, up to a set price, with the enrollee paying the difference in cost if the enrollee desires a drug that exceeds the set (reference) price. One of the risks associated with this concept is the potential for increased out-of-pocket costs, especially for hematology patients who have little choice when it comes to treatments. It is not typical for a hematology patient to "desire" a particular drug, but rather, patients with hematologic diseases and disorders are prescribed specific drugs, many times because it is the only treatment option for that particular disease or disorder. For example, Hemlibra, used to treat hemophilia A, and Soliris, used to treat atypical hemolytic uremic syndrome, are both costly, yet effective, treatments with no alternatives. Reference-pricing, if instituted, could increase out-of-pocket costs for patients using drugs such as Hemlibra and Soliris, which have no alternatives.

Cost-Sharing for Generic Drugs

CMS is proposing that plans that cover both a brand name prescription drug and its generic equivalent could consider the brand name drug not to be an essential health benefit (EHB) if the generic drug is available and medically appropriate. This proposal, if finalized, would permit group health plans and group health insurers to impose lifetime and annual dollar limits on such brand drugs because they would no longer be considered EHB. ASH is opposed to this for the same reason as outlined above, that there is a lack of comparative data on the difference between some generic and branded drugs, and therefore, patients should not be financially penalized for using the most appropriate treatment.

Cost-Sharing and Drug Manufacturer Coupons

ASH is opposed to CMS allowing accumulator adjustment programs because of the implications this has on increasing out-of-pocket costs for patients. Accumulator adjustment programs mean insurers would not have to count any form of direct support from a drug manufacturer towards cost-sharing limits or out-of-pocket costs if a brand name drug has a generic equivalent. These programs cause patients to spend more money out-of-pocket to reach their deductible, potentially making the needed drugs unaffordable. Allowing these programs does nothing to lower the actual cost of the drug but rather changes how much the patient is required to pay for the drug. ASH supports the current practice of not allowing accumulator adjustment programs.

Thank you for the opportunity to provide comments on the proposed rule for the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020. We welcome the opportunity to discuss these comments with you and your team. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager at lbrady@hematology.org or 202-292-0264.

Sincerely,

Roy L. Silverstein, MD
President

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[1] Katia B Pagnano, MD, et. al. Efficacy and Safety of Generic Imatinib Compared to Glivec in Chronic Phase – Chronic Myeloid Leukemia – a Multicenter, Observational Study. https://ash.confex.com/ash/2018/webprogram/Paper113718.html