AIMED ALLIANCE

June 28, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (Docket CMS-1752-P)

Dear Administrator Brooks-LaSure:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. Thank you for the opportunity to comment on "Docket CMS-1752-P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals . . . " (IPPS Rule).[1] On behalf of patients experiencing life-threatening or uncontrolled bleeding resulting from factor Xa inhibitors, thank you for extending the new technology add-on payment (NTAP) expiration for coagulation factor Xa (recombinant), inactivated-zhzo through FY 2022. **To avoid future disruptions in access to care, we request that CMS identify and put into place a new payment mechanism by the end of FY 2022. If CMS is unable to do so by that point, we request that the NTAP expiration be extended for another year.**

I. Background

Approximately 2.9 million people in the U.S. are treated with factor Xa inhibitors.[2] Factor Xa inhibitors are commonly prescribed to older adults who are at high risk for stroke and venous thrombosis (dangerous blood clots in the blood vessels).[3] Factor Xa inhibitors and other anti-coagulants reduce the body's ability to form blood clots, thereby increasing the risk of uncontrolled bleeding. When this happens, it is often challenging for doctors to stop the bleeding, which can ultimately lead to death.[4] According, to a 2018 analysis of commercial and Medicare databases, around 84,000 patients taking factor Xa inhibitors are hospitalized for major bleeding each year.[5] The most common type of major bleeding includes bleeding in the brain.[6] About 25 percent of patients who experience bleeding in the brain while taking a factor Xa inhibitor die.[7] Coagulation factor Xa (recombinant), inactivated-zhzo is the only medication that is approved by the U.S. Food and Drug Administration for the reversal of factor Xa inhibitor related life-threatening or

[1] https://www.federalregister.gov/documents/2021/05/10/2021-08888/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6049660/
[3] https://www.acc.org/about-acc/press-releases/2018/03/10/12/18/mon-1045am-drug-stops-dangerous-bleeding-in-patients-taking-factor-xa-inhibitors
[4] https://www.federalregister.gov/documents/2021/05/10/2021-08888/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the
[5] *Id.*
[6] *Id.*
[7] *Id.*

uncontrolled bleeding.[8]

II. Solutions To Prevent Future Disruptions in Access to Care

We thank you for extending the NTAP expiration for coagulation factor Xa (recombinant), inactivated-zhzo. As you know, the NTAP was scheduled to expire in fiscal year 2021, which would have likely led to a major disruption in patient access to coagulation factor Xa (recombinant), inactivated-zhzo.[9] Manufacturer projections estimated that, upon expiration, hospitals would likely be paid less than the wholesale acquisition cost for the medication in approximately 59 percent of cases.[10] Rather than take a revenue loss, hospitals may choose not to use this medication. Yet, there are no appropriate alternative medications given that coagulation factor Xa (recombinant), inactivated-zhzo is the only medication indicated for factor Xa inhibitor reversal. As such, we are pleased that CMS acknowledged the importance of ensuring that patients diagnosed with an indication for a factor Xa inhibitor reversal agent have adequate access to necessary treatment for an additional year.

We also agree that the agency should explore options and other mechanisms through which to address low volume high-cost drugs outside of the Medicare Severity Diagnosis Related Group (MS-DRG). As CMS has noted, coagulation factor Xa (recombinant), inactivated-zhzo does not fit neatly within another MS-DRG. The underlying cause of the life-threatening or uncontrolled bleeding can vary. Therefore, even though coagulation factor Xa (recombinant), inactivated-zhzo was used in low volume, it was used for varying principal diagnoses. Yet, MS-DRGs are intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. Sets of claims data are usually identified based on clinical similarity in developing diagnostic-related groups rather than smaller subsets based on the drugs administered. Therefore, while the delayed expiration is certainly helpful, a new solution is needed to update the MS-DRG system to account for rates of use for coagulation factor Xa (recombinant), inactivated-zhzo. **To avoid future disruptions in access to care, we request that CMS identify and put into place such a mechanism by the end of FY 2022. If CMS is unable to do so by that point, we request that the NTAP expiration be extended for another year.**

Thank you for considering our requests. Please contact us at policy@aimedalliance.org if you have any questions.

Sincerely,

Stacey L. Worthy
Counsel

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[8] https://andexxa.com/

[9] https://www.federalregister.gov/documents/2021/05/10/2021-08888/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the

[10] https://www.federalregister.gov/documents/2021/05/10/2021-08888/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the