NHIA
National Home Infusion Association
Providing solutions for the home and specialty infusion therapy community

August 12, 2019

The Honorable Seema Verma
Administration
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma,

We write to express our serous concerns that the Centers for Medicare and Medicaid Services (CMS) failed to meet its obligation to provide sufficient public notice and a 60-day comment period for any rule, requirement, or other statement of policy that changes the standard for the payment for services.

Specifically, the Centers for Medicare and Medicaid Services (CMS) recently issued Change Request – 11295 which expanded coverage under the Part B benefit for immunoglobulin replacement therapy in the home setting to an additional 10 primary immune deficiency (PI). As a result, drugs that may have been previously covered under Medicare Part D will be covered under Part B beginning August 13th. This change will apply to both the intravenous immunoglobulin (IVIG) demonstration and to drugs covered under the Durable Medical Equipment policy under part B.

This policy change could have a detrimental effect on patient access, as it could dramatically increase patient's out of pocket costs for these therapies, especially if they do not have a Medicare Supplemental Insurance Plan (Medigap). Based on a 36 gram per month dose of a commonly prescribed immunoglobulin product and publicly published data for Average Sales Price and Average Whole Sale price, patients without supplemental coverage will experience out-of-pocket costs that are 40% higher per year due to this policy change. Patients who enroll in the Part B IVIG demonstration project will have the highest out of pocket burden of all coverage scenarios under Medicare.

Furthermore, this could cause significant access issues in cases where there is a shortage of immunoglobulin. Medicare Part B typically covers drugs only for their FDA-labeled indications and would not allow pharmacists to substitute off-label products. Given the current shortage-related challenges that many providers are experiencing, this policy change could impair beneficiaries access to the products they need.

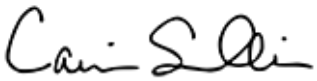
Finally, this policy will have the effect of limiting patient choice and access to care. Part B professional services reimbursements are so low that many home infusion providers would be unable to continue to offer these services, forcing patients to seek treatment in hospital outpatient departments or physicians' offices. These settings are frequently less desirable for patients who have immune deficiencies and are at increased risk for infection.

Given the substantive implications of this change to both beneficiaries and providers, we believe that CMS had an obligation to engage stakeholders through its standard public notice and 60-day comment period. As it did not abide by that process, we call on CMS to immediately withdraw Change Request – 11295 and to work with the home infusion community to expand access to these essential, life-saving therapies.

We welcome the opportunity to discuss this issue. Please contact me at Connie.Sullivan@nhia.org or Sharon Pearce at Sharon.pearce@nhia.org if you would like to arrange a meeting or a call.

Thank you for your consideration of this request.

Sincerely,



Connie Sullivan, B.S. Pharm
President and Chief Executive Officer

CMS recently added 10 new PID diagnoses to the Part B benefit. We need to hear from you: how will this change affect you and your patients? Share your thoughts in the comment section or email info@nhia.org