THE HEMOPHILIA ALLIANCE

Summary of Medicaid Notice on Coverage of Drugs and Services for Bleeding Disorders Patients

On June 30, 2017 CMS issued Medicaid Drug Rebate Program Notice Number 182, entitled Medicaid Coverage of Drugs and Services Provided to Blood Disorder Patients. This long-awaited notice provides guidance to states regarding reimbursement for clotting factor medications for the treatment of hemophilia. While the immediate impact of the guidance may be limited since many states have already filed their State Plan Amendments (SPAs) to set their Medicaid drug reimbursement policies for future years, the document provides us with an advocacy tool to use with states in future discussions.

As background, following the release of the Medicaid Covered Outpatient Drug Rule in January 2016, the Hemophilia Alliance (HA) met with key Medicaid staff at the Centers for Medicare and Medicaid Services (CMS) to express our concerns with the regulation and asked CMS to release guidance to states related to clotting factor reimbursement for clotting factor. Several of the issues and suggestions we made at this meeting have been included in the recently released notice.

Highlights of CMS Notice

The CMS Notice reiterates the requirements that provider reimbursement for clotting factor should be based on three components:

1) Product/ingredient cost;
2) Dispensing costs of the product; and, if necessary,
3) Patient-specific costs for ancillary supplies and related clinical services.

Here is how CMS describes the three components:

1. Product/ingredient cost:

This relates to the cost of the drug itself. States may use actual acquisition cost (AAC) or an alternative methodology since factor is not listed in the National Average Drug Acquisition Cost (NADAC). If an alternative cost determination is used, it must be thoroughly documented in the SPA.

2. Dispensing fee

The professional dispensing fee is defined as those costs directly related to the pharmacist's level of effort and handling of services related to the dispensing function. This definition is similar to the definition of dispensing fee used in the Medicaid Covered Outpatient Drug Rule. The dispensing fee should be determined by objective data, such as a cost of dispensing survey. Because of the limited size of the hemophilia population, the fee determination may be calculated from multi-state or national data.

3. Patient-specific additional costs for clinical services

The Notice clarifies that the third component would be covered under a separate state plan benefit category covering disease management services. This is a welcome change, since during our meetings with CMS, staff

indicated support for paying for this third component as part of the pharmacy benefit, like the Medicare Part D drug benefit's Medication Therapy Services (MTM). Allowing payment for disease management services is helpful since it potentially allows for a higher reimbursement level.

During the HA visit with CMS in March 2016, the team suggested CMS allow bundled rates and/or disease management services that recognize the unique services that Hemophilia Treatment Centers (HTCs) provide to their patients. The CMS notice reflects this idea and goes into detail describing the types of HTC services that states could choose to reimburse:

- **Disease Management Services:** States can reimburse for disease management services, which include a number of services. "Those relevant to HTCs include medical assessments, disease and dietary education, instruction in health self-management, and medical monitoring. If a state elected to cover such services, they should update the relevant section of the SPA addressing these opportunities to ensure they would be eligible for federal match."
- **Other Licensed Practitioner Services (OLP):** OLP services are defined in federal regulation as covering "medical or remedial care or services, other than physicians' services, provided by licensed practitioners within the scope of practice as defined under State law." Should a state licensed practitioner (e.g., pharmacist, physical therapist, occupational therapist, etc.) furnish medical or remedial services to address blood disorders, these could also be included in the state's SPA.
- **Preventive Services:** Preventive services as defined by federal regulation includes services that seek to "(1) Prevent disease, disability, and other health conditions or their progression; (2) Prolong life; and (3) Promote physical and mental health and efficiency."

<u>Documentation Requirements</u>

Finally, the notice explains that regardless of how a state may choose to reimburse clotting factor based on the three categories, CMS will expect to see significant documentation with specific details regarding these services, eligible provider types, specific payment rates, and detailed descriptions of service frequency and time periods eligible for coverage and reimbursement. Supporting clinical evidence and references are always part of the supporting documentation expected by CMS when the SPA is submitted.