



Center for Medicaid and CHIP Services

June 30, 2017

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 182

For State Technical Contacts

Medicaid Coverage of Drugs and Services Provided to Blood Disorder Patients

This release provides guidance to states concerning Medicaid coverage and reimbursement for clotting factors, anti-hemophilia drugs and other services provided to Medicaid beneficiaries with blood disorders (e.g., hemophilia). We hope that this information is helpful to states as they develop their coverage and reimbursement policies.

Reimbursement for hemophilia-related products and services should be based on: 1) the product/ingredient cost; 2) dispensing cost(s) of the product; and, if necessary 3) on a patient specific basis, costs for ancillary supplies and related clinical services that are covered under state plan benefit categories (other than the prescription drug benefit). To be clear, the first two components would be part of the prescription drug benefit under the state plan. The third component(s) would be covered under the appropriate state plan benefit category for the disease management services provided.

Reimbursement for Ingredient and Professional Dispensing Fee Costs

The methodology for the state's ingredient cost reimbursement should be set out in the prescribed drugs section of a state's Medicaid state plan. Generally, reimbursement to pharmacies for drugs dispensed to Medicaid beneficiaries is based on a formula consisting of the ingredient cost of a drug and a professional dispensing fee. As discussed in the Covered Outpatient Drugs Final Rule with Comment Period (81 FR 5290 through 5295), a state can implement an actual acquisition cost (AAC) model of reimbursement based on various pricing methodologies for the ingredient cost of the drug. The state may also specify in its state plan any alternative methodology that will be used in the case when a pricing methodology that represents an AAC model of reimbursement is not available for a specific drug for a specific time period (<https://www.medicare.gov/federal-policy-guidance/downloads/SMD16001.pdf>). Therefore, states may use an alternative methodology to its AAC methodology when an AAC model is not available for drugs used to treat blood disorder patients.

The professional dispensing fee, which is defined at 42 CFR 447.502¹, in general covers the cost of the provider to dispense the drug. As we provided in our covered outpatient drug rule at 42 CFR 447.518, reimbursement for the professional dispensing fee should be based upon an assessment of adequate data, such as an objective survey of the costs to the pharmacy or hemophilia treatment center (HTC) to *dispense* clotting factor and anti-hemophilia drugs in the nation, state, or otherwise justified based on rates established by surrounding comparable states. Further, it must only factor in the level of effort for the pharmacy or HTC to *dispense* the drugs to the patient such as special packaging and handling of the product.

Other Services Provided to the Blood Disorder Patient

On February 25, 2004, CMS issued a State Medicaid Director Letter, SMDL #04-002, on disease management (<https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd022504.pdf>). This SMDL provided guidance on designing and operating disease management services and outlined options for states under capitated and fee-for-service payment arrangements. Common services that could be covered include medical assessments, disease and dietary education, instruction in health self-management, and medical monitoring. Services to address chronic diseases, such as bleeding disorders, may be covered as “disease management” under two different benefit categories as specified in section 1905(a) of the Social Security Act (the Act). Those categories include: section 1905(a)(6) - services of other licensed practitioners and section 1905(a)(13)(c) - preventive services.

States electing to cover these services may need to update the Medicaid state plan in order to ensure that the services are covered under the state plan and, therefore, that federal financial participation (FFP) is available for expenditures for these services. Under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit, states must already make available all medically necessary section 1905(a) services for children under age 21. (Section 1905(a)(4)(B) and section 1905(r) of the Act)

As a reminder, below is information on the two coverage categories for services to address chronic diseases such as blood disorders and options for paying for such services. Under these section 1905(a) benefit categories, all other state Medicaid plan requirements such as state wideness, comparability, and free choice of providers must be met.

Other Licensed Practitioner Services – Section 1905(a)(6)

Other Licensed Practitioner services (OLP) services, defined at 42 CFR 440.60, are “medical or remedial care or services, other than physicians’ services, provided by licensed practitioners within the scope of practice as defined under State law.” If a state licenses practitioners (e.g., pharmacist, physical therapist, occupational therapist, etc.) who furnish medical or remedial

¹ 42 CFR 447.502 Professional dispensing fee means the professional fee which is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed, and includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist’s time in checking the computer for information about an individual’s coverage performing drug utilization review and preferred drug list review activities, measurements or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy. The professional fee does not include administrative costs incurred by the state in the operation of the covered outpatient drug benefit (including systems costs for interfacing with pharmacies).

services to address blood disorders, the state may elect to cover the services of those providers under this section of their state plan even if the providers are not covered under other sections of the plan. A state would need to submit a state plan amendment (SPA) to add the new licensed provider to their state plan and set forth the scope of the medical or remedial benefits that would be covered when furnished by such practitioner. The SPA must describe the provider's qualifications and include a reimbursement methodology for paying the provider for covered services.

Preventive Services – Section 1905(a)(13)(c)

Preventive Services, defined at 42 CFR 440.130(c), are “services recommended by a physician or other licensed practitioner of the healing arts acting within the scope of authorized practice under state law to – (1) Prevent disease, disability, and other health conditions or their progression; (2) Prolong life; and (3) Promote physical and mental health and efficiency.”

A regulatory change that took effect January 1, 2014, permits coverage of preventive services furnished by non-licensed practitioners who meet the qualifications set by the state, as long as the preventive services are recommended by a physician or other licensed practitioner. Under the preventive services benefit, in the state plan, the state should 1) list the services to be provided to ensure that services meet the definition of preventive services as stated in section 4385 of the State Medicaid Manual (including the requirement for the service to involve direct patient care); 2) identify the type(s) of practitioners who may furnish the services; and 3) include a summary of the state's provider qualifications that make the non-licensed practitioners qualified to furnish the services, including any required education, training, experience, credentialing, supervision, oversight and/ or registration.

Payment Arrangements with Providers

CMS generally expects state plan submissions to describe payment arrangements made directly to practitioners (such as bundled payments, per service, or per encounter basis), list any limitations on the frequency of services (initial assessment, follow-up visits, etc.) and describe the setting of services - such as office, home, phone and/or face to face encounters.

In reviewing state plan submissions, CMS generally expects comprehensive reimbursement methodologies that describe either:

1. the actual rates paid to providers;
2. the precise formula that explains how rates are set, allowing providers to reasonably estimate their Medicaid payment. Specifically, the rate-setting formula must refer to a recognized standard for rate-setting (such as Medicare's resource-based relative value scale or RBRVS) or a base rate (i.e. \$20 per 15 minute unit as of July 1, 2016) and an inflation factor (the exact percentage, or a nationally recognized factor) used to update rates on a regular basis (i.e. annually, on January 1). Most States' rates are adjusted based on a legislative appropriation but that is not a comprehensive description of a payment methodology; or
3. the “effective date” of a fee schedule with an active, direct web link to that fee

schedule. To ensure that the state plan comprehensively describes its payment rates, CMS expects the state plan to identify the “effective date” of any fee schedule, the last date on which the schedule was updated and the published location of the fee schedule.

When rates, rate formulas, or fee schedules are updated, the state should submit a SPA to indicate the change, the “effective” date of the change and, if applicable, the published location of the fee schedule.

For services reimbursed by a bundled rate, CMS expects that States will develop bundled rates based upon actual service data maintained by providers. In approving a bundled rate, CMS will require States to describe the development of the rates in the State plan. In reviewing state plan submissions, CMS will look at whether the proposal will:

1. Ensure that providers of a bundled service maintain data that supports a conclusion that the rate developed by the Medicaid agency is economic and efficient. That data normally consists of information:
 - showing the provision by practitioner of the individual **covered** Medicaid services included in the bundled payment and;
 - the cost by practitioner and type of service actually delivered under the bundled rate.
2. Include language in the State plan identifying the data to be maintained by providers, assuring that the state will review that data in order to develop and revise as necessary, economic and efficient rates, and explain how the data was used to develop the rates. Specifically, 42 CFR 431.107 requires that each provider or organization furnishing services agree to keep any records necessary to disclose the extent of services the provider furnishes to beneficiaries and, on request, furnish the Medicaid agency any information maintained and any information regarding payments claimed by the provider for furnishing services under the plan. The State Medicaid Manual in Section 2500.2(A) requires that a State Medicaid agency report “only expenditures for which all supporting documentation is available, in readily reviewable form, which has been compiled and which is immediately available when the claim is filed” on the CMS-64. This section continues by stating that “... supporting documentation includes as a minimum the following: date of service; name of recipient; Medicaid identification number; name of provider agency and person providing the service; nature, extent or units of service; and the place of service.”
3. Include language in the State plan assuring that rates do not include costs related to room and board (for bundled rates paid in residential settings) or other unallowable facility costs.
4. Include in the State plan a description of the State’s proposal for monitoring the provision of services paid under a bundled rate to ensure that (1) the plan covers services that are sufficient in amount, duration, and scope to reasonably achieve the

service's purpose (as required by 42 CFR 440.230), and that (2) the use of bundled rates does not diminish benefits to individuals in violation of the comparability requirements at 42 CFR 440.240.

We hope states find this information useful to providing services to the blood disorder patient. We look forward to hearing from states if they have any questions regarding this letter. Please contact Christine Hinds at (410) 786-4578 for additional information.

Sincerely,

/s/

Michael Nardone
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