

CMS Approval SPA 19-0015 Reimbursement Methodology for Clotting Factor Drugs

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The Centers for Medicare & Medicaid Services (CMS) published its Final Rule on Covered Outpatient Drugs (CODs) on February 1, 2016, (81 Fed.Reg. 5170). This rule implements provisions of the 2010 Patient Protection and Affordable Care Act pertaining to Medicaid reimbursement for CODs, and requires states to document the blood factor reimbursement methodology as part of the State Plan.

On February 11, 2019, the Department of Health Care Services (DHCS) received CMS approval of State Plan Amendment (SPA) 19-0015 with an effective date of July 1, 2020. This SPA establishes reimbursement for clotting factor drugs (defined as coagulation factors and their recombinant analogs) as follows:

1. Payment for clotting factor purchased through and dispensed by a federally recognized hemophilia treatment center (HTC) or its contracted pharmacy will be the lower of:
 - a. The HTC's actual acquisition cost for the drug as defined in Welfare and Institutions Code section 14105.46, plus a professional dispensing fee of \$0.14 per unit, or
 - b. The Average Sales Price as reported to the federal Centers for Medicare and Medicaid Services by the manufacturer pursuant to Section 1847A of the federal Social Security Act (42 U.S.C. §1395w-3a), plus 20%.
2. Payment for clotting factor purchased outside of a federally recognized HTC and dispensed by specialty pharmacies, Centers of Excellence, or any other provider will be the lower of:
 - a. The provider's actual acquisition cost for the drug equal to invoice price minus any discounts (excluding a prompt pay discount of less than, or equal to 2%), rebates, or chargebacks, plus a professional dispensing fee of \$0.04 per unit, or
 - b. The Average Sales Price as reported to the federal Centers for Medicare and Medicaid Services by the manufacturer pursuant to Section 1847A of the federal Social Security Act (42 U.S.C. §1395w-3a) plus 20%.

Both the CMS approval letter and approved SPA pages are posted at the following link:https://www.dhcs.ca.gov/formsandpubs/laws/Pages/Approved_2019.aspx

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<https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/Main.aspx>