



Blood Factor Reimbursement Methodology Changes Frequently Asked Questions

Updated June 17, 2020

1. Why is the Department of Health Care Services (DHCS) implementing a new reimbursement methodology for Blood Factor products?

Answer: The Centers for Medicare & Medicaid Services (CMS) Final Rule on Covered Outpatient Drugs (CMS-2345-FC) includes a new requirement that if a state reimburses for blood factor, it must document its blood factor reimbursement methodology in its State Plan. During discussions with CMS in December 2016, DHCS learned that CMS would not accept DHCS' current bundled reimbursement of Average Sales Price (ASP) plus twenty percent.

2. What is the new DHCS reimbursement methodology?

Answer: On January 24, 2020, CMS approved [State Plan Amendment \(SPA\) 19-0015](#) that outlines the blood factor reimbursement methodology. Effective on July 1, 2020 providers will bill and be reimbursed as follows:

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%.

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%.

This payment methodology is applicable to both pharmacy and non-pharmacy clotting factor claims.

3. Does this proposal require a budget or statutory change?

Answer: No. Because the new reimbursement methodology does not exceed the amount allowed under existing law, it can be implemented without changing Welfare & Institutions Code [14105.86\(b\)](#).

4. Why isn't a different ASP "plus a percent" methodology being considered for an alternative drug ingredient cost reimbursement?

Answer: In 2016, DHCS contracted with Mercer Government Human Services Consulting to study drug acquisition costs and costs of dispensing for Medi-Cal pharmacy providers. However, there was insufficient survey data to determine actual blood factor acquisition or dispensing costs. With the new method of requiring providers submit actual acquisition costs, DHCS will ensure providers are reimbursed for the ingredient cost of blood factor products **up to** the maximum amount allowed by Welfare & Institutions Code [14105.86\(b\)](#), which is ASP plus twenty percent.

5. How will DHCS assure that actual acquisition cost is accurately billed?

Answer: Providers must submit actual product invoices to DHCS on a quarterly basis for review, as a contract requirement. In addition, retrospective audits are a tool DHCS can utilize to ensure appropriate billing.

6. Under the new methodology, do claims need to include invoice submission to demonstrate actual acquisition cost?

Answer: No. Invoices must be submitted to DHCS on a quarterly basis, but not with each individual claim.

7. When will the new reimbursement go into effect?

Answer: The new methodology is effective for blood factor claims with dates of service on or after July 1, 2020.

8. Will there be retroactive billing or erroneous payment corrections once the new reimbursement takes effect?

Answer: No. The new reimbursement methodology is being implemented after the state plan amendment was approved by CMS, which included a prospective policy implementation date.

9. Will this change the blood factor reimbursement for hospitals?

Answer: Yes. Hospitals will also be reimbursed using this new methodology.

10. Will this change the blood factor reimbursement for facilities that dispense 340B blood factor product?

Answer: Yes. 340B facilities will also be reimbursed using this new methodology.

11. Will DHCS require prompt pay discounts to be submitted; and if so, will there be a recalculation of providers' reimbursement at the end of the year?

Answer: No, not at this point; however DHCS will be monitoring this issue closely to prevent fraud and price manipulation.

12. Will this affect a new provider applicant to the program?

Answer: No, the provider enrollment process will not change. DHCS will continue to require blood factor providers sign the Medi-Cal Supplemental Provider Contract for Specialty Services to dispense blood factor products to Medi-Cal/CCS/GHPP beneficiaries.