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## Blood and Blood Derivatives

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This section describes the policy and billing instructions for blood and blood derivative products. For additional help, refer to the *Blood and Blood Derivatives Billing Examples* section of this manual.

### **Designated Blood Donation**

Additional payment for the handling of blood designated by the donor for a specific patient is not a Medi-Cal benefit. Claims for this service will be denied.

### **Blood Factors Billing for Bleeding and Clotting Disorders:**

Blood factor billing codes differ depending on the provider type. Pharmacists must bill using National Drug Codes (NDC). All other providers must bill according to physician-administered drug policy, which may be found in the *Physician-Administered Drugs – NDC* section in this manual. For physician claim form completion instructions, refer to the *Physician-Administered Drugs – NDC: CMS-1500 Billing Instructions*, or *Physician-Administered Drugs – NDC: UB-04 Billing Instructions* section in the appropriate Part 2 manual.

Blood factor reimbursement is based on the lesser of:

- The manufacturer's reported Average Sales Price (ASP), which is updated quarterly, plus 20 percent OR
- The provider's billed Actual Acquisition Cost plus applicable professional dispensing fee.
  - Claims submitted by federally recognized Hemophilia Treatment Centers must use the 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.
  - Claims submitted by all other providers must use the 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.

Coagulation factors for bleeding disorders, such as hemophilia, represent the first class of specialty drugs to utilize provider contracts. These products are identified in *Welfare and Institutions Code (W&I Code) 14105.86(a)(2)(A)*. The Department of Health Care Services (DHCS) will contract with any specialty pharmacy that will sign a contract to meet a list of performance obligations. These include, but are not limited to, delivery time requirements, providing patient education and submitting quarterly and yearly reports to DHCS. A provider who does not sign an agreement to become a provider under these provisions will no longer be allowed to provide the specialized drug to Medi-Cal, California Children's Services (CCS) or Genetically Handicapped Persons Program (GHPP) recipients.

## **Contract Blood Factors**

The following blood factors, covered by Medi-Cal, are listed by product name «next to» their respective HCPCS code.

«Table of Blood Factor HCPCS Codes»

<b>HCPCS Code</b>	<b>Description</b>	<b>Product Name</b>	<b>Reimbursement</b>
J7175	Injection, factor X, (human), 1 IU *	«Not Applicable»	«Not Applicable»
J7179	Injection, von Willebrand factor (recombinant), (Vonvendi®), 1 IU *	«Not Applicable»	«Not Applicable»
J7180	Injection factor XIII (anti-hemophilic factor, human), 1 IU	Corifact® *	«Not Applicable»
J7181	Injection, factor XIII a-subunit, (recombinant), per IU *	«Not Applicable»	«Not Applicable»
J7182	Injection, factor VIII, antihemophilic factor, (recombinant), (Novoeight), per IU *	«Not Applicable»	«Not Applicable»
J7183	Injection, von Willebrand factor complex (human), wilate per IU VWF:RCO.	«Not Applicable»	Reimbursable in conjunction with ICD-10-CM code D68.0
J7185	Factor VIII (antihemophilic factor, recombinant), per IU	Xyntha™	«Not Applicable»
J7186	Antihemophilic factor VIII/von Willebrand factor complex (human), per factor VIII IU	Alphanate®	Reimbursable with ICD-10-CM codes D66, D68.0 and D68. 4
J7187	Von Willebrand Factor Complex, human	Humate P® *	«Not Applicable»
J7188	Injection, factor VIII (antihemophilic factor, recombinant), (obizur), per IU *	«Not Applicable»	«Not Applicable»
J7189	Factor VIIa (antihemophilic factor, recombinant), per mcg*	NovoSeven® *, NovoSeven® RT *	«Not Applicable»
J7190	Factor VIII (antihemophilic factor, human), per IU	Hemofil-M *, Koate® DVI, Monarc-M™*, Monoclote-P® *	«Not Applicable»
J7192	Factor VIII (antihemophilic factor, recombinant), per IU	Advate *, Helixate® FS *, Kogenate® FS *, Recombinate *, ReFacto	«Not Applicable»

**Table of Blood Factor HCPCS Codes (continued)**

<b>HCPCS Code</b>	<b>Description</b>	<b>Product Name</b>	<b>Reimbursement</b>
J7193	Factor IX (antihemophilic factor, purified, nonrecombinant), per IU.	Mononine <sup>®</sup> *, AlphaNine <sup>®</sup> SD	Not Applicable
J7194	Factor IX complex per IU.	Bebulin <sup>®</sup> VH *, Profilnine <sup>®</sup> SD *	Not Applicable
J7195	Injection, factor IX (antihemophilic factor, recombinant) per IU, not otherwise specified (Benefix <sup>®</sup> ), (Ixinity <sup>®</sup> ) *	Not Applicable	Not Applicable
J7197	Antithrombin III (human), per IU *	Thrombate III *	Not Applicable
J7198	Antiinhibitor, per IU *	Feiba VH *	Not Applicable
J7200	Injection, factor IX, (antihemophilic factor, recombinant), Rixubis, per IU *	Not Applicable	Not Applicable
J7201	Injection, factor IX, Fc fusion protein (recombinant), per IU (Alprolix <sup>™</sup> )	Not Applicable	Not Applicable
J7202	Injection, factor IX, albumin fusion protein, (recombinant), Idelvion <sup>®</sup> , 1 IU*	Not Applicable	Not Applicable
J7203	Injection Factor IX, (antihemophilic factor, recombinant), glycopegylated, (Rebinyn), 1 IU *	Not Applicable	Not Applicable
J7204	Injection, Factor VIII, antihemophilic factor (recombinant), (Esperoct), glycopegylated-exei, per IU)	Esperoct <sup>®</sup> *	Not Applicable

«Table of Blood Factor HCPCS Codes (continued)»

<b>HCPCS Code</b>	<b>Description</b>	<b>Product Name</b>	<b>Reimbursement</b>
J7205	Injection, factor VIII fc fusion (recombinant), per iu	Not Applicable	Not Applicable
J7207	Injection, factor VIII, (antihemophilic factor, recombinant), PEGylated, 1 IU*	Not Applicable	Not Applicable
J7208	Injection, Factor VIII, (antihemophilic factor, recombinant), PEGylated-aucl, (Jivi®), 1 IU	Not Applicable	Not Applicable
J7209	Injection, factor VIII, (antihemophilic factor, recombinant), Nuwiq®, 1 IU	Not Applicable	Not Applicable
J7210	Injection, factor VIII (antihemophilic factor, recombinant), Afstyla®, 1 IU*	Not Applicable	Not Applicable
J7211	Injection, factor VIII (antihemophilic factor, recombinant), Kovaltry®, 1 IU	Not Applicable	Not Applicable
«J7212	Injection, factor VIIa (antihemophilic factor, recombinant)-jncw (Sevenfact®), 1 mcg	Sevenfact®	Not Applicable»

## **Blood Factors Billing: Non-Pharmacists**

The above listed HCPCS Level II codes are for blood factors billed by physicians, hospital outpatient departments, clinics and blood banks.

Failure to use the above codes when billing for factors VIIa, VIII or IX may result in claim denial. «Other codes such as P9010 thru P9012, P9016, P9019 thru P9023, P9025, P9026, P9031 thru P9040, P9043, P9044, P9048, P9050 thru P9058 and Z7610 are not to be used when billing for blood factors.»

## **NDC Billing Requirement Billing Guidelines**

Providers must bill according to the physician-administered drug policy, which may be found in the Physician-Administered Drugs – NDC section in this manual. For physician claim form completion instructions, refer to *the Physician-Administered Drugs – NDC: CMS-1500 Billing Instructions*, or *Physician-Administered Drugs – NDC: UB-04 Billing Instructions* sections in the appropriate Part 2 manual. Non-pharmacy providers must use the appropriate HCPCS injection codes and modifiers (when required) to bill for all immunizations and injections listed in the *Injections: Code List* section in the appropriate Part 2 manual.

In addition, providers must include the number of units provided in the *Remarks* field (Box 80)/*Additional Claim Information* (Box 19) of the claim.

Providers may be reimbursed for the outpatient use of Factor VIIa (HCPCS code J7189). Claims billed with code J7189 must contain an approved TAR unless a manufacturer rebate is provided. Examples of medical justification include but are not limited to:

- Treatment of bleeding episodes in hemophilia A or B with inhibitors and in acquired hemophilia
- Prevention of bleeding in surgical interventions or invasive procedures in hemophilia A or B with inhibitors and in acquired hemophilia
- Treatment of bleeding episodes in congenital Factor VII deficiency
- Prevention of bleeding in surgical interventions or invasive procedures in congenital Factor VII deficiency

## **Blood Factor Billing Pharmacists:**

Pharmacies must bill blood factor products using the National Drug Code (NDC) via a pharmacy claim form. Attachments are not required.

Pharmacy providers who bill for CCS-only, CCS/Healthy Families, GHPP-only eligible beneficiaries, and Medi-Cal/CCS/GHPP eligible beneficiaries who bill with legacy authorizations must bill using the paper *Pharmacy Claim Form (30-1)*. Claims must contain required authorization as required by the Children's Medical Services Branch.

Reimbursement under this method is based on the lesser of the manufacturer's Average Selling Price (ASP) plus 20 percent or the provider's usual and customary charges. Providers should submit claims with their usual and customary charges. The ASP price is updated by the manufacturer quarterly.

## **Continuing Care**

Medi-Cal will provide reimbursement for blood factors marked "authorization required" only with an approved *Treatment Authorization Request (TAR)* or the beneficiary qualifies for continuing care. To be eligible for continuing care and exemption from the authorization requirement, the following conditions must be met:

- The beneficiary must be taking the drug when it is suspended or deleted from the List of Contracted Blood Factors; and
- The California MMIS Fiscal Intermediary must have received a claim for the drug, in the same dosage form and strength, within 100 days prior to the drug's suspension or deletion. Providers may access the Provider Telecommunications Network (PTN) to determine if a beneficiary has been dispensed a continuing care drug that is eligible under continuing care. For complete information on the PTN, see *the Provider Telecommunications Network (PTN)* section in the Part 1 manual.
- To maintain beneficiary eligibility under continuing care, a claim must be submitted for the drug, in the same dosage form and strength, at least every 100 days from the date of service. The beneficiary may switch between brands of the drug in the same dosage form and strength and maintain their continuing care status.

## **Contracted Providers**

To meet the unique specialized care needs of the Medi-Cal population who utilize specialty drugs, only contracted providers are eligible to provide contract blood factors. A list of the contracted specialty providers who are eligible to provide those blood factors included in the contract blood factor list is available on the "Pharmacy Benefits Division and Vision Care Program" page of the DHCS website ([www.dhcs.ca.gov](http://www.dhcs.ca.gov)).

## **Blood Products and Blood Derivatives Other Than Blood Factors**

«Use HCPCS codes P9010 thru P9012, P9016, P9019 thru P9023, P9025, P9026, P9031 thru P9040, P9043, P9044, P9048, P9050 thru P9058 and P9073 to bill for blood products and blood derivatives (for example, platelets, plasma, granulocytes or red blood cells), with the exception of Blood Factors: Bleeding and Clotting Disorders and other exceptions specified on a following page.»

### **Pathogen(s) Test for Platelets**

For information on billing for HCPCS code P9100 (pathogen(s) test for platelets) refer to the *Pathology: Microbiology* section of the appropriate Part 2 manual.

### **Fresh Frozen Plasma**

Use HCPCS codes P9017, P9023, P9059 or P9060 for reimbursement of fresh frozen plasma. Billing with any other code may result in claim denial.

Medi-Cal coverage of fresh frozen plasma is restricted to:

- Replacement of isolated coagulation factor deficiencies
- Reversal of warfarin effect
- Massive blood transfusion (although prophylactic administration of fresh frozen plasma does not appear to decrease transfusion requirements in patients who do not have documented coagulation defects)
- Use in antithrombin III deficient conditions
- Treatment of thrombotic thrombocytopenic purpura

### **Services Not Covered**

Fresh frozen plasma should not be used as a volume expander or as a nutritional supplement due to risks accompanying its use. These risks include:

- Post-transfusion hepatitis
- AIDS
- Allergic reactions
- Volume overload
- Alloimmunization

## **Pheresis**

Pheresis, the separation of plasma from the formed elements of the blood by filtration and centrifugation, requires authorization when billed fee-for-service and performed either on an outpatient or an inpatient basis.

### **Plasmapheresis Primary Treatment:**

Plasmapheresis may be authorized as the primary treatment in the following diseases:

- Guillian-Barre Syndrome
- Thrombotic thrombocytopenic purpura
- Goodpasture's syndrome
- Rapidly progressive glomerulonephritis
- Anti-glomerular basement membrane disease
- Waldenstrom's macroglobulinemia
- Multiple myeloma
- Protein-bound poisons



## Secondary Treatment

Plasmapheresis also may be authorized when there is documented evidence of far-advanced disease, unresponsive to drug therapy in patients with the following diseases, most of which are thought to be mediated through immune mechanisms:

- Systemic lupus erythematosus
- Rheumatoid vasculitis
- Myasthenia gravis
- Progressive systemic sclerosis
- Hemolytic anemia
- Immune neutropenia
- Immune thrombocytopenia
- Polymyositis
- Idiopathic thrombocytopenic purpura
- Cryoglobulinemia
- Vasculitis, associated with circulating immune complexes, as seen in hypersensitivity disorders and Henoch-Schonlein purpura
- Chronic inflammatory polyneuropathy
- Relapsing polyneuropathy

## Cytapheresis

Cytapheresis is covered for the following problems:

- Acute or chronic leukemia (cell counts more than 100,000)
- Thrombocytosis (platelet count more than 1,000,000)
- Sickle cell disease in severe crisis, preoperatively or when complicated by pregnancy or priapism

## **Therapeutic Apheresis Billing Procedures:**

CPT® codes 36511 thru 36516 must be billed with modifier AG for any type of therapeutic apheresis. Claims for therapeutic apheresis billed with HCPCS codes P9010 thru P9012, P9016, P9019 thru P9023, P9031 thru P9040, P9043 thru P9044, P9048 and P9050 thru P9058 will be denied. The approved *Treatment Authorization Request* (TAR) determines the number of pheresis treatments allowed.

The HCPCS codes listed above must be used to bill for blood products/blood derivatives (for example: platelets, plasma, granulocytes or red blood cells) collected from donors by apheresis.

## **Administering Plasmapheresis**

All plasmapheresis procedures should be done in a hospital setting, whether on an inpatient or an outpatient basis, with readily available lifesaving equipment. The physician who bills for these procedures should be available to provide help to the plasmapheresis technician or registered nurse at all times during the procedure.

## **Extracorporeal Photopheresis**

Extracorporeal photopheresis (ECP), also called photochemotherapy, involves ex vivo separation of leukocytes from erythrocytes and exposure of the leukocytes to 8-methoxypsoralen and ultraviolet light. 8-MOP is a naturally occurring furocoumarin that is biologically inert, unless exposed to ultraviolet A light, whereupon it becomes photo activated and covalently binds and cross-links DNA. The combination of 8-MOP and UVA radiation causes apoptosis of the treated T cells and may cause preferential apoptosis of activated or abnormal T cells, thus targeting the pathogenic cells of cutaneous T-cell lymphoma (CTCL), chronic graft versus host disease (GVHD), lung transplant rejection or cardiac allograft rejection.

## **Indications**

ECP is indicated for the treatment of any of the following:

- CTCL Stage IIIA or IV
- Cardiac allograft rejection
- Chronic GVHD
- Lung transplant rejection (bronchiolitis obliterans)

ECP is not to be used for the prophylaxis of any of the indications above.

## Authorization

An approved TAR is required for reimbursement.

## Billing

CPT code 36522 (photopheresis, extracorporeal)

## Albumin

Human serum albumin is the most abundant protein in human blood plasma. It is produced in the liver and constitutes about half of the blood serum protein. Among its many functions, albumin transports hormones, fatty acids, and other compounds, buffers pH, and maintains osmotic pressure.

## Billing

### Albumin Billing Codes

HCPCS Code	Description
P9041	Infusion, albumin (human), 5%, 50 ml
P9045	Infusion, albumin (human), 5%, 250 ml
P9046	Infusion, albumin (human), 25%, 20 ml
P9047	Infusion, albumin (human), 25%, 50 ml

## Billing Maximum

### Billing Maximums by Code

HCPCS Code	Maximum
P9041	5 units
P9045	20 units
P9046	25 units
P9047	20 units

## Blood Irradiation: Blood Banks

CPT code 86945 (irradiation of blood product, each unit) with the appropriate split billing modifier must be used by blood banks billing for whole blood or blood product irradiation.

## **«Pathogen Reduced Blood Component Products**

The INTERCEPT® Blood System for Cryoprecipitation is intended to provide a functionally closed system for the production of Pathogen Reduced Cryoprecipitated Fibrinogen Complex and Pathogen Reduced Plasma, Cryoprecipitate Reduced. It treats the blood component soon after collection in order to inactivate any remaining infectious agents. This is to reduce the risk of transmission of viruses, Gram-positive and Gram-negative bacteria, spirochetes and parasites.

### **Pathogen Reduced Plasma, Cryoprecipitate Reduced**

Pathogen Reduced Plasma, Cryoprecipitate Reduced is prepared from INTERCEPT® processed plasma.

#### **Indications**

Pathogen Reduced Plasma, Cryoprecipitate Reduced is indicated for the following:

- Transfusion or therapeutic plasma exchange (TPE) in patients with thrombotic thrombocytopenic purpura (TTP)
- It may be used to provide coagulation factors, except fibrinogen, factor VIII, factor XIII, and von Willebrand factor (vWF), for transfusion support of patients with appropriate clinical indications»

## «Pathogen Reduced Cryoprecipitated Fibrinogen Complex

Pathogen Reduced Cryoprecipitated Fibrinogen Complex is produced from cryoprecipitation of cold, insoluble proteins from plasma that has been processed with the INTERCEPT® Blood System for Plasma.

### Indications

Pathogen Reduced Cryoprecipitated Fibrinogen Complex is indicated for the following:

- Treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency
- Control of bleeding when recombinant and/or specific virally inactivated preparations of factor XIII or von Willebrand factor (vWF) are not available
- Second-line therapy for von Willebrand disease (vWD)
- Control of uremic bleeding after other treatment modalities have failed

### Limitations of Use

Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used for replacement of factor VIII.

## Dosage

FDA-approved dosages

## Authorization

No *Treatment Authorization Request* (TAR) is required for reimbursement.»

**«Billing**

HCPCS code P9025 (plasma, cryoprecipitate reduced, pathogen reduced, each unit)

HCPCS code P9026 (cryoprecipitated fibrinogen complex, pathogen reduced, each unit)

**Billing Instructions for Providers**

- P9025 and P9026 require an invoice submission for reimbursement
- Outpatient claims may be billed by paper claim using CMS 1500 or electronically using ASC X12N 837P v.5010
- Providers must include the medically justified ICD-10-CM diagnosis code on the claim form
- Providers must include an invoice showing the acquisition cost of the product in addition to the product catalog number in the 'Remarks' section of the claim form for appropriate reimbursement.>>

## **Legend**

Symbols used in the document above are explained in the following table.

<b>Symbol</b>	<b>Description</b>
«	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
»	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.
*	Authorization is required