Blood and Blood Derivatives

Page updated: August 2020

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

HCPCS Code	Description	Product Name	Reimbursement
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 codes D68.0, D68.03 D68.09, D68.022, D68.023, D68.029››
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

Table of Blood Factor HCPCS Codes (continued)

HCPCS Code	Description	Product Name	Reimbursement
J7190	Factor VIII (antihemophilic factor, human), per IU	Hemofil-M *, Koate® DVI, Monarc-M™*, Monoclate-P® *	Not Applicable
J7192	Factor VIII (antihemophilic factor, recombinant), per IU	Advate *, Helixate® FS *, Kogenate® FS *, Recombinate *, ReFacto	Not Applicable
J7193	Factor IX (antihemophilic factor, purified, nonrecombinant), per IU.	Mononine® *, AlphaNine® SD	Not Applicable
J7194	Factor IX complex per IU.	Bebulin® VH *, Profilnine® SD *	Not Applicable
J7195	Injection, factor IX (antihemophilic factor, recombinant) per IU, not otherwise specified (Benefix®)*	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™)	Not Applicable	Not Applicable
J7202	Injection, factor IX, albumin fusion protein, (recombinant), Idelvion®, 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® *	Not Applicable

Table of Blood Factor HCPCS Codes (continued)

HCPCS Code	Description	Product Name	Reimbursement
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), 1 IU	Nuwiq®	Not Applicable
J7210	Injection, factor VIII (antihemophilic factor, recombinant), 1 IU*	Afstyla®	Not Applicable
J7211	Injection, factor VIII (antihemophilic factor, recombinant), 1 IU	Kovaltry®,	Not Applicable
J7212	Injection, factor VIIa (antihemophilic factor, recombinant)-jncw 1 mcg	Sevenfact®	Not Applicable
J7213	Injection, coagulation factor IX (recombinant), Ixinity®, 1 IU	Not Applicable	Not Applicable
‹‹J7214	Injection, factor VIII /von Willebrand factor complex, recombinant per factor VIII IU	ALTUVIIIO™	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:

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.

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*).

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.

‹‹ Red Blood Cells, Leukocytes Reduced, Oxygen / Carbon Dioxide Reduced

Blood container set used to process and store CP2D/AS-3 red blood cells, leukocytes reduced, and O2 /CO2 reduced.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code P9027 (Red blood cells, leukocytes reduced, oxygen/ carbon dioxide reduced, each unit).››

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).‹‹This includes the drug used for ECP.››

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.

Plasminogen, Human-tvmh (Ryplazim®)

Policy for plasminogen, human-tvmh injection (HCPCS code J2998) is located in the *Injections: Drugs P-Q Policy* section in the Part 2 manual.

‹‹Prothrombin complex concentrate, human-lans (BALFAXAR)

Policy for prothrombin complex concentrate, human-lans (HCPCS code J7165) is located in the *Injections: Drugs P-Q Policy* section in the appropriate Part 2 manual.››

COVID-19 Convalescent Plasma

COVID-19 convalescent plasma is human plasma collected by the U.S. Food and Drug Administration (FDA) registered or licensed blood establishments from individuals whose plasma contains high titers of anti-SARS-CoV-2 antibodies, and who meet all donor eligibility requirements (21 CFR 630.10 and 21 CFR 630.15) and qualifications. Convalescent plasma is qualified and labeled as having high titer anti-SARS-CoV-2 antibodies based on testing accepted by the FDA under this Emergency Use Authorization (EUA). Qualification of COVID-19 convalescent plasma as high titer is based on serologic correlates of neutralizing activity, for example, the ability of the donor antibodies to block infection by reference strains of the SARS-CoV-2 virus in laboratory tests.

‹‹Authorized Use

FDA has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies, for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, in either the outpatient or the inpatient setting.

Available data suggests that use of COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies may be effective in treating COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment. For the purposes of this EUA, immunosuppressive treatment does not include immunosuppressive treatment administered specifically for the purpose of treating COVID-19
(for example: systemic corticosteroids, interleukin-6 inhibitors).

Limitations of Authorized Use

COVID-19 convalescent plasma is not authorized to treat immunocompetent patients with COVID-19. Results from randomized controlled trials in hospitalized patients indicate that these patients are unlikely to benefit from COVID-19 convalescent plasma. In addition, alternative therapies in immunocompetent patients prior to hospitalization are authorized for emergency use and have more consistently demonstrated clinical benefit.

Dosage and Administration

Dosage

- Health care providers must administer COVID-19 convalescent plasma according to standard hospital procedures and institutional medical and nursing practices.
- Clinical dosing may first consider starting with one unit of COVID-19 convalescent plasma (about 200 ml), with administration of additional convalescent plasma units based on the prescribing physician’s medical judgment and the patient’s clinical response.
- Patients with impaired cardiac function and heart failure may require a smaller volume or more prolonged transfusion times.

For *Required Reporting for Serious Adverse Events*, see the Fact Sheet for Health Care Providers.››

‹‹Billing

HCPCS code: C9507 (fresh frozen plasma, high titer COVID-19 convalescent, frozen within 8 hours of collection, each unit)

Important Instructions: For Hospitals Receiving COVID-19 Convalescent Plasma, and Health Care Providers Administering the Plasma

- Hospitals and health care providers receiving authorized COVID-19 convalescent plasma must ensure that they are aware of the letter of authorization, the terms in it, and that the authorized fact sheets are made available to health care providers and to patients and caregivers.
- Healthcare facilities and healthcare providers must ensure that appropriate storage and cold chain is maintained until the product is administered
- Hospitals and health care providers administering COVID-19 convalescent plasma must track serious adverse events that are considered to be potentially attributable to COVID-19 convalescent plasma use and must report these to FDA in accordance with the Fact Sheet for Health Care Providers. Health care providers must maintain records and conduct a thorough investigation of adverse reactions after transfusion of convalescent plasma, and must report fatalities related to transfusion, as required under 21 CFR 606.170
- Through a process of inventory control, hospitals must maintain records regarding the administered authorized COVID-19 convalescent plasma (for example: donation identification number, quantity, receiving site, receipt date), product storage, and maintain patient information (for example: patient name, age, disease manifestation, number of doses administered per patient, other drugs administered)
- Hospitals must ensure that any records associated with this EUA are maintained until notified by Assistant Secretary for Preparedness and Response (ASPR) and/or FDA. Such records must be made available to ASPR, the U.S. Department of Health and Human Services (HHS), and FDA for inspection upon request

Resources

Fact Sheet for Health Care Providers

Fact Sheet for Patients, Parents and Caregivers

Product Availability Information

Health care providers or acute care facilities should obtain convalescent plasma from an FDA registered or licensed blood establishment››

Legend

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

Symbol	Description
‹‹	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