Coverage Summary

Blood, Blood Products and Related Procedures and Drugs

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<thead>
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<tr>
<td>Approved by:</td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date: 10/16/2018</td>
</tr>
</tbody>
</table>

Related Medicare Advantage Policy Guidelines:

- Anti-Inhibitor Coagulant Complex (AICC) (NCD 110.3)
- Apheresis (Therapeutic Pheresis) (NCD 110.14)
- Autogenous Epidural Blood Graft (NCD 10.5)
- Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumor (NCD 110.20)
- Blood Platelet Transfusions (NCD 110.8)
- Blood Transfusions (NCD 110.7)
- Coverage of Drugs and Biologicals for Label and Off-Label Uses
- Extracorporeal Immunoadsorption (ECI) Using Protein A Columns (NCD 20.5)
- Granulocyte Transfusions (NCD 110.5)
- Hemophilia Clotting Factors
- Intravenous Immune Globulin for the Treatment of Mucocutaneous Blistering Diseases (NCD 250.3)
- Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine) (NCD 260.7)
- Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation (NCD 110.16)
- Thrombolytic Agents
- Transfer Factor for Treatment of Multiple Sclerosis (NCD 160.20)

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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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I. COVERAGE

Coverage Statement: Blood transfusions, platelets, blood components and blood clotting factors and blood related services are covered when Medicare coverage criteria are met.
Guidelines/Notes:

1. Examples of covered blood related services include, but are not limited to:
   a. Use and administration of blood and blood components, including but not necessarily limited to:
      - Cryoprecipitate
      - Platelets
      - Fibrinogen
      - Plasma
      - Gamma globulin
      - Albumin
   b. Blood Clotting Factors
      Hemophilia, a blood disorder characterized by prolonged coagulation time, is caused by deficiency of a factor in plasma necessary for blood to clot. Blood clotting factors for hemophilia patients with the following diagnoses may be covered if the patient is competent to use such factors without medical supervision:
         - Factor VIII deficiency (classic hemophilia);
         - Factor IX deficiency (also termed plasma thromboplastin component (PTC) or Christmas factor deficiency); and
         - Von Willebrand’s disease.
      
      See the Medicare Benefit Policy Manual, Chapter 15, §50.5.5 - Hemophilia Clotting Factors. Also see MLN Matters #4229 - Payment for Blood Clotting Factors Administered to Hemophilia Inpatients. (Accessed September 28, 2018)

Utilization Guidelines:

- The Medicare Benefit Policy Manual addressing hemophilia clotting factors does not provide utilization guidelines.
- Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) with utilization guidelines for hemophilia clotting factors exist and compliance with these policies is required where applicable. For the state-specific LCDs/LCAs, refer to the LCD Availability Grid (Attachment A).
- For states with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy for Clotting Factors, Coagulant Blood Products & Other Hemostatics. (IMPORTANT NOTE: After checking the LCD Availability Grid and searching the Medicare Coverage Database, if no state LCD or LCA is found, then use the above referenced policy.)
- Committee approval date: October 16, 2018
- Accessed September 5, 2019

   c. Blood provided through a blood bank on either an inpatient or outpatient basis; see the NCD for Blood Transfusions (110.7). (Accessed September 28, 2018)

   d. Blood collected for covered procedures (e.g., pre-authorized surgery); see the NCD for Blood Transfusions (110.7). (Accessed September 28, 2018)

   e. Cost of blood collected but not used if the physician authorized need; see the NCD for Blood Transfusions (110.7). (Accessed September 28, 2018)

   f. Donor directed blood (e.g., family/friends donate directly for use by the member) transfusion; see the NCD for Blood Transfusions (110.7). (Accessed September 28,
Autologous (self-donated) blood processing costs only for blood collected for a scheduled surgery or transfusion, including storage fees charged as a result of the physician and/or provider cancellations, which are beyond the member’s control. See the **NCD for Blood Transfusions (110.7)**. (Accessed September 28, 2018)

Perioperative blood salvage; see the **NCD for Blood Transfusions (110.7)**. (Accessed September 28, 2018)

Blood platelet transfusion is when reasonable and necessary for the individual patient; see the **NCD for Blood Platelet Transfusions (110.8)**. (Accessed September 28, 2018)

Granulocyte transfusions to patients suffering from severe infection and granulocytopenia; accepted indications include:

a. Granulocytopenia with evidence of gram negative sepsis; and
b. Granulocytopenia in febrile patients with local progressive infections unresponsive to appropriate antibiotic therapy, thought to be due to gram negative organisms. See the **NCD for Granulocyte Transfusions (110.5)**. (Accessed September 28, 2018)

Pre-transplant nonselective (random) transfusions and living related donor specific transfusions (DST) in kidney transplantation without a specific limitation on the number of transfusions.

*Note:* Transplant surgeons have established a definite correlation in both cadaver and living-related kidney transplantation between pretransplant transfusions of blood into the recipient and the success of graft retention.

See the **NCD for Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation (110.16)**. (Accessed September 28, 2018)

Lymphocyte immune globulin, anti-thymocyte globulin (equine) for the management of allograft rejection episodes in renal transplantation.

*Note:* Other forms of lymphocyte globulin preparation which the FDA approves for this indication in the future may be covered under Medicare.

See the **NCD for Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine) (260.7)**. (Accessed September 28, 2018)

Intravenous Immune Globulin (IVIG) for the treatment of biopsy-proven (1) Pemphigus Vulgaris, (2) Pemphigus Foliacus, (3) Bullous Pemphigoid, (4) Mucous Membrane Pemphigoid (also known as Cicatricial Pemphigoid), and (5) Epidermolysis Bullosa Acquisita for the following patient subpopulations:

1) Patients who have failed conventional therapy. Contractors have the discretion to define what constitutes failure of conventional therapy;
2) Patients in whom conventional therapy is otherwise contraindicated. Contractors have the discretion to define what constitutes contraindications to conventional therapy; or
3) Patients with rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional agents. In such situations IVIG therapy would be given along with conventional treatment(s) and the IVIG would be used only until the conventional therapy could take effect.
Note: IVIG for the treatment of autoimmune mucocutaneous blistering diseases must be used only for short-term therapy and not as a maintenance therapy. Contractors have the discretion to decide what constitutes short-term therapy.

See the NCD for Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases (250.3). (Accessed September 28, 2018)

Also see the Medicare Benefit Policy Manual, Chapter 15, §50.6 – Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home. (Accessed September 28, 2018)

n. Extracorporeal Immunoadsorption (ECI) using Protein A columns is covered for the treatment of rheumatoid arthritis (RA) under the following conditions:

1) Patient has severe RA. Patient disease is active, having >5 swollen joints, >20 tender joints, and morning stiffness >60 minutes.
2) Patient has failed an adequate course of a minimum of 3 Disease Modifying Anti-Rheumatic Drugs (DMARDs). Failure does not include intolerance.

See the NCD for Extracorporeal Immunoadsorption (ECI) Using Protein A Columns (20.5). (Accessed September 28, 2018)

o. Apheresis (Therapeutic Pheresis) is covered for the following indications:

1) Plasma exchange for acquired myasthenia gravis;
2) Leukapheresis in the treatment of leukemia;
3) Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom);
4) Treatment of hyperglobulinemias, including (but not limited to) multiple myelomas, cryoglobulinemia and hyperviscosity syndromes;
5) Plasmapheresis or plasma exchange as a last resort treatment of thrombotic thrombocytopenic purpura (TTP);
6) Plasmapheresis or plasma exchange in the last resort treatment of life threatening rheumatoid vasculitis;
7) Plasma perfusion of charcoal filters for treatment of pruritus of cholestatic liver disease;
8) Plasma exchange in the treatment of Goodpasture’s Syndrome;
9) Plasma exchange in the treatment of glomerulonephritis associated with antilglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage;
10) Treatment of chronic relapsing polyneuropathy for patients with severe or life threatening symptoms who have failed to respond to conventional therapy;
11) Treatment of life threatening scleroderma and polymyositis when the patient is unresponsive to conventional therapy;
12) Treatment of Guillain-Barre Syndrome; and
13) Treatment of last resort for life threatening systemic lupus erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration.

See the NCD for Apheresis (Therapeutic Pheresis) (110.14). (Accessed September 28, 2018)

2. Examples of noncovered blood-related services include, but are not limited:

a. Platelet derived wound-healing formulas, such as Procuren or other similar blood products used in the repair of chronic, non-healing, cutaneous ulcers or wounds. See the Coverage Summary for Wound Treatments.

b. Blood charges associated with noncovered procedures. See the NCD for Blood

d. Transfer factor for the treatment of multiple sclerosis as it is considered experimental for this purpose. See the NCD for Transfer Factor for Treatment of Multiple Sclerosis (160.20) (Accessed September 28, 2018)

Notes:
- Medicare’s Part A 3-pint blood deductible does not apply to UnitedHealthcare Medicare Advantage member. For additional information refer to the member’s Evidence of Coverage (EOC).
- For clarification of Medicare payment for clotting factors and blood while a member is an inpatient, refer to the MLN Matters #MM3681- Blood & Blood Products for Hospital Outpatient. (Accessed September 28, 2018)
- For Erythropoietin Stimulating Factors, see the Coverage Summary for Medications/Drugs (Outpatient/Part B).

II. DEFINITIONS

Apheresis (also known as Pheresis or Therapeutic Pheresis): Medical procedure utilizing specialized equipment to remove selected blood constituents (plasma, leukocytes, platelets, or cells) from whole blood. The remainder is retransfused into the person from whom the blood was taken. For purposes of Medicare coverage, apheresis is defined as an autologous procedure, i.e., blood is taken from the patient, processed, and returned to the patient as part of a continuous procedure (as distinguished from the procedure in which a patient donates blood preoperatively and is transfused with the donated blood at a later date). NCD for Apheresis (Therapeutic Pheresis) (110.14). (Accessed September 28, 2018)


Blood Brain Barrier Osmotic Disruption: The process of disrupting the tight junctions between the endothelial cells that line the capillaries in the brain accomplished by osmotic disruption, bradykinin or irradiation. Theoretically, disruption of the BBB may, in the treatment of brain tumors, increase the concentration of chemotherapy drugs delivered to the tumor and may prolong the drug-tumor contact time. Osmotic disruption of the BBB is the most common technique used. Chemotherapeutic agents are given in conjunction with barrier disruption. The BBBD process includes all items and services necessary to perform the procedure, including hospitalization, monitoring, and repeated imaging procedures. NCD for Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors (110.20). (Accessed September 28, 2018)

Donor Directed Blood Transfusion: The infusion of blood or blood components that have been pre-collected from a specific individual(s) other than the patient and subsequently infused into the specific patient for whom the blood is designated. NCD for Blood Transfusions (110.7). (Accessed September 28, 2018)

Extracorporeal Immunoabsorption (ECI), using Protein A Columns: Technique used for the purpose of selectively removing circulating immune complexes (CIC) and immunoglobulins (IgG) from patients in whom these substances are associated with their diseases. The technique involves pumping the patient's anticoagulated venous blood through a cell separator from which 1-3 liters of plasma are collected and perfused over adsorbent columns, after which the plasma rejoins the separated, unprocessed cells and is retransfused to the patient. NCD for Extracorporeal

**Perioperative Blood Salvage:** The collection and reinfusion of blood lost during and immediately after surgery. *NCD for Blood Transfusions (110.7).* (Accessed September 28, 2018)

**Transfer Factor:** The dialysate of an extract from sensitized leukocytes which increases cellular immune activity in the recipient. *NCD for Transfer Factor for Treatment of Multiple Sclerosis (160.20).* (Accessed September 28, 2018)

### III. REFERENCES


*NCD for Blood Transfusions (110.7).* (Accessed September 28, 2018)


### IV. REVISION HISTORY

- **04/01/2019**
  - Updated policy introduction; added language to clarify:
    - There are instances where [the Coverage Summary] may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG)
    - In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*)
  - Retitled reference link that directs users to UnitedHealthcare *Commercial* policy

- **10/16/2018**
  - Annual review with no updates.

- **09/18/2018**
  - Updated Local Coverage Determination (LCD) Availability Grid; removed instruction to “use the applicable LCD based on member’s residence/place and type of service” (this note only applies when selecting the appropriate DME LCD Policy)

- **10/17/2017**
  - Annual review with the following updates:
    - Guideline 1.b (Blood provided through a blood bank on either an inpatient or outpatient basis) – deleted; duplicate statement
    - Guideline 1.d (Synthetic blood products, only when determined to be medically necessary by a UnitedHealthcare Medical Director or his/her designee and alternative natural blood products are not medically appropriate) - deleted; unable to find CMS reference
    - Guideline 1.e-1.g – added reference to NCD for Blood Transfusions (110.7)
    - Guideline 1.h (Therapeutic bleeding provided by a blood bank) – deleted; unable to find CMS reference.
    - Guideline 2.a (Platelet derived wound-healing formulas, such as Procuren or other similar blood products used in the repair of chronic, non-healing, cutaneous ulcers or wounds) – added cross reference and link to the Wound Treatments Coverage Summary
    - Guideline 2.b (Blood charges incurred by members for services/supplies in conjunction with donating blood for another individual) - deleted; unable to find
CMS reference

- Guideline 2.c (Blood charges associated with noncovered procedures) - added reference to the NCD for Blood Transfusions (110.7)
- Notes Section: (Medicare’s Part A 3-pint blood deductible does not apply to UnitedHealthcare Medicare Advantage member) – added the following language “For additional information refer to the member’s Evidence of Coverage (EOC).”

10/18/2016  Annual review with no updates.
04/19/2016  Re-review; no updates to the guideline content; updated reference links of the applicable LCDs to reflect the condensed link.
11/17/2015  Annual review with no updates.
10/01/2015 Updated reference link(s) to the applicable Medicare Administrative Contractor (MAC) LCDs to reflect the new updated LCD/ID number effective October 1, 2015.
03/12/2015  Formatting change only.
11/18/2014 Annual review with the following updates:
Guideline 1.c (Utilization Guidelines)
- Changed default guidelines for states with no LCDs from Novitas LCD for Hemophilia Factor Products (L32735) to the UnitedHealthcare Medical Policy for Clotting Factors and Coagulant Blood Products
Definitions
- Deleted the definition of:
  - Allogenic Blood Products (Blood Bank) (not used within this coverage summary)
  - Synthetic Blood Products: (no CMS reference available)
  - Blood Derivatives (not used within this coverage summary)
- Updated the definition of:
  - Apheresis: added reference to the NCD for Apheresis (Therapeutic Pheresis) (110.14)
  - Autologous Blood Transfusion: added reference to the NCD for Blood Transfusions (110.7)
  - Blood Brain Barrier Osmotic Disruption: added reference to the NCD for Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors (110.20)
  - Donor Directed Blood Transfusion: added reference to the NCD for Blood Transfusions (110.7)
  - Extracorporeal Immunoadsorption (ECI), using Protein A Columns: added reference to the NCD for Extracorporeal Immunoadsorption (ECI) Using Protein A Columns (20.5)
  - Perioperative Blood Salvage: added reference to the NCD for Blood Transfusions (110.7).
  - Transfer Factor: added reference to the NCD for Transfer Factor for Treatment of Multiple Sclerosis (160.20)

12/17/2013 Annual review with no updates.
10/24/2013 Guidelines #1.c Blood Clotting Factors - added Utilization Guidelines based on the available Local Coverage Determinations (LCDs), using Novitas LCD for Hemophilia Factor Products (L32735) as default LCD for states with no LCDs.
V. ATTACHMENT(S)

### Attachment A - LCD Availability Grid

**Hemophilia Clotting Factors**
CMS website accessed September 5, 2019

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<th>LCD ID</th>
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<td>A and B MAC</td>
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<td>A and B MAC</td>
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<td>A56065</td>
<td>Billing and Coding Guidance for Anti-Inhibitor Coagulant Complex (AICC) National Coverage Determination (NCD) 110.3</td>
<td>A and B MAC</td>
<td>Palmetto GBA</td>
<td>AL, GA, NC, SC, TN, VA, WV</td>
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End of Attachment A