Coverage Summary

Blood, Blood Products and Related Procedures

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<td>Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date: 10/15/2019</td>
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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 Biologics for Label and Off-Label Uses
- Extracorporeal Immunoadsorption (ECI) Using Protein A Columns (NCD 20.5)
- 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)
- Thrombolytic Agents
- Transfer Factor for Treatment of Multiple Sclerosis (NCD 160.20)

This information is being distributed to you for personal reference. The information belongs to UnitedHealthcare and unauthorized copying, use, and distribution are prohibited. This information is intended to serve only as a general reference resource and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the Member’s Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member’s EOC/SB, the member’s EOC/SB provision will govern. The information contained in this document is believed to be current as of the date noted.

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).

INDEX TO COVERAGE SUMMARY

1. **COVERAGE**
   1. Blood and Blood Components
   2. Blood Clotting Factors
   3. Blood Transfusion
   4. Blood Platelet Transfusion
   5. Granulocyte Transfusions
   6. Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation
   7. Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine)
   8. Intravenous Immune Globulin (IVIG)
   9. Extracorporeal Immunoadsorption (ECI) Using Protein A Columns
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. Blood and Blood Components
   Use and administration of blood and blood components that are covered, include but are not limited to:
   - Cryoprecipitate
   - Platelets
   - Fibrinogen
   - Plasma
   - Gamma globulin
   - Albumin

   See the Medicare Benefit Policy Manual, Chapter 15, Section 50.3 Incident to Requirement. (Accessed October 4, 2019)

2. 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 October 4, 2019)

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/LCA 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/LCA 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 15, 2019
- **Accessed January 2, 2020**

3. **Blood Transfusion**
   Medically necessary transfusion of blood, regardless of the type, may generally be a covered service. Coverage does not make a distinction between the transfusion of homologous, autologous, or donor-directed blood. See the [NCD for Blood Transfusions (110.7)](accessed October 4, 2019)

4. **Blood Platelet Transfusion**
   Blood platelet transfusion is when reasonable and necessary for the individual patient; see the [NCD for Blood Platelet Transfusions (110.8)](accessed October 4, 2019)

5. **Granulocyte Transfusions**
   Granulocyte transfusions to patients suffering from severe infection and granulocytopenia are covered for specific indications. See the [NCD for Granulocyte Transfusions (110.5)](accessed October 4, 2019)

6. **Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation**
   Pre-transplant nonselective (random) transfusions and living related donor specific transfusions (DST) in kidney transplantation are covered, without a specific limitation on the number of transfusions. See the [NCD for Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation (110.16)](accessed October 4, 2019)

7. **Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine)**
   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 October 4, 2019)

8. **Intravenous Immune Globulin (IVIG);** see the [Coverage Summary for Medications/Drugs (Outpatient/Part B)].

9. **Extracorporeal Immunoadsorption (ECI) Using Protein A Columns**
   Extracorporeal Immunoadsorption (ECI) using Protein A columns is covered for the treatment of rheumatoid arthritis (RA) when criteria are met. See the [NCD for Extracorporeal Immunoadsorption (ECI) Using Protein A Columns (20.5)](accessed October 4, 2019)

10. **Apheresis (Therapeutic Pheresis)**
    Apheresis (therapeutic pheresis) is covered for specific indications. See the [NCD for Apheresis (Therapeutic Pheresis) (110.14)](accessed October 4, 2019)

11. **Blood Derived Products for Chronic Non-Healing Wounds;** see the [Coverage Summary for Wound Treatments].
12. **Blood Brain Barrier (BBB) Osmotic Disruption for Treatment of Brain Tumors**  
The use of osmotic BBB is not reasonable and necessary when it is used as part of a treatment regimen for brain tumors. See the [NCD for Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors (110.20)](https://example.com/ncd). (Accessed October 4, 2019)

13. **Transfer Factor for the Treatment of Multiple Sclerosis**  
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)](https://example.com/ncd). (Accessed October 4, 2019)

14. **Erythropoietin Stimulating Factors**; see the [Coverage Summary for Medications/Drugs (Outpatient/Part B)](https://example.com/coverage).

**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](https://example.com/mln). (Accessed October 4, 2019)

### II. DEFINITIONS

### III. REFERENCES

*General Information, Eligibility and Entitlement Manual, Chapter 3, § 20.5 - 20.5.4.1.* (Accessed October 4, 2019)

*Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals and §50.5.5 - Hemophilia Clotting Factors.* (Accessed October 4, 2019)
IV. REVISION HISTORY

10/15/2019

- Changed policy title, previously titled Blood, Blood Products and Related Procedures and Drugs

Related Medicare Advantage Policy Guidelines

- Removed reference link to the policies titled (retired):
  - Granulocyte Transfusions (NCD 110.5)
  - Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation (NCD 110.16)

Guideline 1 (Blood and Blood Components)

- Added reference link to the Medicare Benefit Policy Manual, Chapter 15, Section 50.3 Incident to Requirement

Guideline 3 (Blood Transfusions)

- Added language to indicate:
  - Medically necessary transfusion of blood, regardless of the type, generally be a covered service
  - Coverage does not make a distinction between the transfusion of homologous, autologous, or donor-directed blood

- Removed detailed coverage guidelines [duplicative to the language outlined in the referenced National Coverage Determination (NCD) for Blood Transfusions (110.7)]

Guideline 5 (Granulocyte Transfusions)

- Removed detailed coverage guidelines [duplicative to the language outlined in the referenced NCD Granulocyte Transfusions (110.5)]

Guideline 6 [Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation]

- Removed detailed coverage guidelines [duplicative to the language outlined in the referenced NCD for Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation (110.16)]

Guideline 8 [Intravenous Immune Globulin (IVIG)]

- Removed detailed coverage guidelines; added reference link to the UnitedHealthcare Medicare Advantage Coverage Summary titled Medications/Drugs (Outpatient/Part B)

Guideline 9 [Extracorporeal Immunoadsorption (ECI) Using Protein A Columns]

- Removed detailed coverage guidelines [duplicative to the language outlined in the referenced NCD for Extracorporeal Immunoadsorption (ECI) Using Protein A Columns (20.5)]

Guideline 10 [Apheresis (Therapeutic Pheresis)]

- Removed detailed coverage guidelines [duplicative to the language outlined in the referenced NCD for Apheresis (Therapeutic Pheresis) (110.14)]

Guideline 11 (Blood Derived Products for Chronic Non-Healing Wounds)

- Removed language pertaining to:
  - Platelet derived wound healing formulas used in the repair of chronic, non-healing, cutaneous ulcers or wounds
  - Blood charges associated with non-covered procedures (refer to Guideline 3)

Guideline 14 (Erythropoietin Stimulating Factors)
- Added reference link to the UnitedHealthcare Medicare Advantage Coverage Summary titled *Medications/Drugs (Outpatient/Part B)* (relocated from *Guidelines/Notes* section)

**Definitions**
- Removed definition of:
  - Apheresis (also known as Pheresis or Therapeutic Pheresis)
  - Autologous Blood Transfusion
  - Blood Brain Barrier Osmotic Disruption
  - Donor Directed Blood Transfusion
  - Extracorporeal Immunoadsorption (ECI), using Protein A Columns
  - Perioperative Blood Salvage
  - Transfer Factor

**Attachments**
- Updated Local Coverage Determination (LCD) Availability Grid to reflect the most current reference links

## V. ATTACHMENT

**Attachment A - LCD/LCA Availability Grid**

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*Hemophilia Clotting Factors*

CMS website accessed January 2, 2020

End of Attachment A