

PREOPERATIVE AUTOLOGOUS BLOOD DONATION, PROCESSING AND STORAGE

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Overview

An *autologous* blood transfusion is a transfusion in which the donor and the recipient are the same individual. (An *allogeneic* blood transfusion is a transfusion in which the donor and the recipient are not the same individual.) For surgical procedures where transfusion is likely, autologous transfusion can provide some or all of the blood components needed by the patient. Autologous transfusion does not completely eliminate the possibility that a patient might receive allogeneic blood. If the need for transfusion is greater than anticipated, or insufficient autologous blood has been collected, the patient may need blood from the allogeneic supply.

There are several types of autologous blood transfusions including:

- Preoperative autologous donation, processing and storage
- Acute normovolemic hemodilution (also referred to as intraoperative hemodilution)
- Intraoperative blood salvage
- Postoperative blood salvage

Since the recognition that human immunodeficiency virus (HIV) was being transmitted through allogeneic blood transfusion there has been increased interest in autologous blood transfusion. In 1981, the risk of acquiring HIV through an allogeneic blood transfusion was approximately 1 in 100 units of blood transfused. The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety of the blood supply, and the FDA has progressively strengthened the safeguards that protect patients from unsuitable blood and blood products. Donated blood is now tested for syphilis, human immunodeficiency virus-1 (HIV-1) and HIV-2, hepatitis B virus core antigen, hepatitis C virus, West Nile virus and human T lymphocytotropic viruses (HTLV-1 and HTLV-2). Currently, the estimated risk of acquiring HIV through an allogeneic blood transfusion is approximately 1 in 2,100,000 units of blood transfused. As biological products, blood and blood products are likely to always carry an inherent risk of infectious agents. Therefore, zero risk may be unattainable.

Preoperative autologous blood donation is the most common type of autologous transfusion. In preoperative autologous blood donation, a patient donates one or more units of his/her own blood in advance of a planned surgical procedure that has a high likelihood of blood loss, such as coronary artery bypass or total hip replacement. Autologous blood which will be transfused within the same institution in which it is drawn does not need to undergo any infectious disease testing. Autologous blood which will be shipped for transfusion from the collecting facility to the transfusion facility must be tested for infectious agents.

The overall efficacy of preoperative autologous blood donation has been evaluated in randomized clinical trials. Studies show that patients who donate autologous blood

preoperatively are less likely to receive allogeneic blood but more likely to undergo any transfusion with autologous and/or allogeneic blood. This is due both to a lower hematocrit in patients donating blood preoperatively and a more liberal transfusion policy associated with autologous blood donation. (Forgie et al. 1998)

Not all of the risks associated with blood transfusions are avoided through autologous blood donation. The risk of infection from bacterial contamination of blood products far exceeds that from viral agents and has emerged as the greatest residual infectious source of transfusion-related disease. There are currently no effective screening techniques to detect bacterial contamination which comes from skin contaminants and from transient bacteremia. Errors in administration and volume overload are the main cause of mortality from blood transfusion. Errors in administration and volume overload occur with the same frequency with allogeneic and autologous transfusion. The process of donating blood places some patients at risk. One in 16,783 autologous donations is associated with an adverse reaction severe enough to require hospitalization -- 12 times the risk associated with allogeneic donation. (Spiess et al. 1992)

Preoperative autologous blood donation, processing and storage is considerably more expensive than allogeneic blood transfusion. The basis for the higher cost is that autologous blood has special handling requirements, special labeling requirements and separate storage requirements. Typically, unused autologous blood is stored until the patient's discharge or until the blood is outdated (unfrozen blood can only be stored for 42 days). When autologous blood is no longer needed it must be wasted because it is not suitable for transfusion into other patients. Donation in excess of the actual amount transfused is inevitable in order to provide enough blood to meet the needs of the patient, and approximately half of autologous blood is wasted.

Definitions

Acute normovolemic hemodilution (ANH) – a blood conservation technique in which blood is removed from a patient either immediately before or shortly after induction of anesthesia prior to surgery, with the simultaneous infusion of crystalloid to maintain intravascular volume. The amount of blood removed varies. ANH reduces red blood cell loss. The blood that is removed is reinfused into the patient as needed, during or after surgery. ANH may be used alone or in conjunction with other forms of transfusion.

Hematocrit - a blood test that measures the percentage of red blood cells found in whole blood. Normal results vary, but in general a normal hematocrit ranges from 40% to 50% for males and 35% to 45% for females. Abnormally low results may indicate anemia, blood loss (hemorrhage), leukemia, malnutrition, etc. Abnormally high results may indicate dehydration, Polycythemia vera, etc.

Intraoperative blood salvage – a blood conservation technique in which blood that is lost during surgery is recovered, filtered, and washed to produce autologous red blood cells for transfusion to the patient. Several devices, such as Cell-Saver® System (Haemonetics, Inc., Braintree, MA) have been developed to assist in salvaging the patient's blood. Salvaged blood provides not only red blood cells, but more importantly, plasma proteins including clotting factors and platelets. This technique is most often used with cardiopulmonary bypass, since the heart-lung machine can damage clotting factors and platelets.

Postoperative blood salvage – a blood conservation technique in which blood is collected from the surgical cavity as the wound heals. The blood may or may not be processed and returned to the patient.

Covered Services

Preoperative autologous blood donation, processing and storage is not covered for commercial plan members. Preoperative autologous blood donation, processing and storage does not meet FCHP's Technology Assessment Criteria. Specifically, preoperative autologous blood donation, processing and storage has not been shown to be as cost-effective as the established alternatives that achieve similar health outcomes, including allogeneic transfusion, acute normovolemic hemodilution and blood salvage.

FCHP covers preoperative autologous blood donation, processing and storage for Fallon Senior Plan™ members only, in accordance with Medicare National Coverage Determination for Blood Transfusions.

Codes

Preoperative autologous blood donation, processing and storage is covered for Fallon Senior Plan™ members only. **CPT code 86890 is generally only reimbursed for Fallon Senior Plan™ members when the blood has been predeposited for a planned outpatient procedure and the blood is not transfused.** Reference FCHP's *Preoperative Autologous Blood Donation, Processing and Storage Payment Policy* for billing instructions. Claims for preoperative autologous blood donation, processing and storage for commercial plan members will be denied with the following disposition: *Not Covered – Member Liable.*

Codes	Number	Description
CPT	86890	Autologous blood or component, collection, processing and storage; predeposited

References

1. Medicare National Coverage Determinations Manual. National Coverage Determination for Blood Transfusions (Section 110.7). Effective 10/03/03.
2. Medicare Claims Processing Manual. Billing and Payment for Blood and Blood Products Under the Hospital Outpatient Prospective Payment System (OPPS) (Section 231). Effective 07/05/05.
3. Axelrod FB, Pepkowitz SH, Goldfinger D. Establishment of a schedule of optimal preoperative collection of autologous blood. *Transfusion* 1989;29:677-80.
4. Vanderlinde ES, Heal JM, Blumberg N. Autologous Transfusion. *BMJ* 2002;324(7340):772-5.
5. Forgie MA, Wells PS, Laupacis A, et al. Preoperative Autologous Blood Transfusion Decreases Allogeneic Transfusion but Increases Exposure to all Red Blood Cell Transfusion. Results of a Meta-Analysis. *Arch Intern Med* 1998;158(6):610-16.
6. Etchason J, Petz L, Keeler E, et al. The Cost Effectiveness of Preoperative Autologous Blood Donations. *N Engl J Med* 1995;332(11):719-24.
7. Klein HG. Transfusion Safety: Avoiding Unnecessary Bloodshed. *Mayo Clinic Proc* 2000;75(1):5-7.
8. Goodnough LT. Autologous Blood Donation. *Critical Care* 2004;8(S2):S49-52.

9. Fontaine MJ, Winters JL, Moore SB, et al. Frozen Preoperative Autologous Blood Donation for Heart Transplantation at the May Clinic From 1988 to 1999. *Transfusion* 2003;43(4):476-80.
10. Spiess BD, Sasset R, McCarthy RJ et al. Autologous Blood Donation: Hemodynamics in a High-Risk Patient Population. *Transfusion* 1992;32:17-22.
11. Linden JV, Paul B, Dressler KP. A Report of 104 Transfusion Errors in New York State. *Transfusion* 1992;32:601-6.
12. Monk TG, Goodnough LT. Acute Normovolemic Hemodilution: Methods to Reduce the Use of Allogeneic Transfusions. *Clinical Orthopaedics and Related Research* 1998;357:74-81.
13. Huët C, Salmi R, Fergusson D, et al. A Meta-Analysis of the Effectiveness of Cell Salvage to Minimize Perioperative Allogeneic Blood Transfusion in Cardiac and Orthopedic Surgery. *Anesth Analg* 1999;89:861-9.
14. Rutherford CJ, Kaplan HS. Autologous Blood Donation – Can We Bank On It? *N Engl J Med* 1995;332(11):740-2.
15. Kruskal MS, Pereira A, Comarow A, et al. Cost Effectiveness of Autologous Blood Donation. *N Engl J Med* 1995;333(7):461-3.
16. Nuttall GA, Santrach PJ, Oliver WC Jr., et al. Possible Guidelines for Autologous Red Blood Cell Donations Before Total Hip Arthroplasty Based on the Surgical Blood Order Equation. *Mayo Clinic Proc* 2000;75:10-7.
17. Sazama K. Managing Infectious or Untested Autologous Blood Components. *Arch Pathol Lab Med* 2005;129:1212-3.
18. Brooks JP, Rerrell JE. Legal and Ethical Considerations in the Transfusion of Infected or Untested Autologous Blood. *Am J Clin Pathol* 2007;128(1):135-42.
19. Monk TG, Goodnough LT, Brecher ME, et al. Acute Normovolemic Hemodilution Can Replace Preoperative Autologous Blood Donation as a Standard of Care for Autologous Blood Procurement in Radical Prostatectomy. *Anesth Analg* 1997;85:953-8.
20. Goodnough LT. Autologous Blood Donation. *Anesthesiol Clin North America*. 2005;23(2):263-70.
21. Sugai Y. Current Status of Bacterial Contamination of Autologous Blood for Transfusion. *Transfusion and Apheresis Science* 2003;24(3):255-9.
22. Singbarti G. Preoperative Autologous Blood Donation – Part I. Only Two Clinical Parameters Determine Efficacy of the Autologous Predeposit. *Minerva Anesthesiol* 2007;73(3):143-51.
23. Weisbach V, Corbiere C, Strasser E et al. The Variability of Compensatory Erythropoiesis in Repeated Autologous Blood Donation. *Transfusion* 2001;41(2):179-83.

Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

Committee review dates:

Technology Assessment Subcommittee: 11/23/2004, 09/29/08

Technology Assessment Committee: 03/08/2005, 10/14/2008

IMPORTANT NOTE

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.