

CHAMPVA POLICY MANUAL

CHAPTER: 2
SECTION: 29.4
TITLE: EXTRACORPOREAL IMMUNOADSORPTION (ECI) WITH PROTEIN A COLUMNS

AUTHORITY: 38 USC 1713; 38 CFR 17.270(a) and 17.272(a)

RELATED AUTHORITY: 32 CFR 199.4

TRICARE POLICY MANUAL: Chapter 3, Section 5.8

I. EFFECTIVE DATE

December 23, 1987

II. DESCRIPTION

Extracorporeal immunoadsorption (ECI) with protein A has been developed for the purpose of selectively removing circulating immune complexes (CICs) and immunoglobulins from the plasma of patients in whom these substances are associated with their disease. The ECI technology commonly involves a continuous-flow immunoadsorption system consisting of online cell separator, protein A columns, and a semiautomatic elution component which may be added. During this process, the patient's whole blood is anticoagulated and pumped through a plasma cell separator from which one to three liters of plasma are collected and then perfused over adsorbent columns containing Staphylococcus aureus protein A covalently bound to one of a variety of solid phase matrices, e.g., silica, collodion-charcoal or sepharose beads. The plasma then rejoins the separated, unprocessed cells and is retransfused.

III. POLICY

A. CHAMPVA may cost-share medically necessary services and supplies for ECI utilizing columns of protein A silica in the treatment of idiopathic thrombocytopenic purpura (ITP) when the medical record demonstrates that:

1. the patient suffers from ITP; and
2. the following standard therapies have either failed or are contraindicated for use:
 - a. corticosteroids,
 - b. cyclophosphamide, vinca alkaloids, azathioprine,

- c. high dose intravenous immune globulin (IVIG),
 - d. splenectomy (except in patients below age 14);
3. The patient suffers from ITP; and
- a. the patient's platelet count is below 100,000 per cubic millimeter;
- and
- b. an urgent or life-threatening hemorrhage or refractory ITP exists which a rapid increase in platelet count is deemed essential to partially resolve the situations.

B. The Food and Drug Administration (FDA) reports only one device, the IMRE ProSORBA column utilizing protein A for immunoabsorption, is regarded as safe and effective for removing immunoglobulins and CICs from plasma.

IV. POLICY CONSIDERATIONS

A. Claims for ECI utilizing columns of protein A silica for ITP are subject to medical review.

B. Reconsiderations received for previously denied claims shall be reprocessed in accordance with this policy.

V. EXCLUSIONS

ECI in the treatment of disease processes other than ITP, (e.g., Bullous Pemphigoid, Pemphigus Vulgaris, Raynaud's Phenomenon, Systemic Lupus Erythematosus (Lupus Nephritis), Systemic Vasculitis, Non-Anti-GBM Rapidly Progressive Glomerulonephritis).

END OF POLICY