Clinical Review Criteria

Extracorporeal Immunoadsorption Using Protein A Columns

- Prosorba Columns

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Criteria

For Medicare Members
See NCD for Extracorporeal Immunoadsorption (ECI) Using Protein A Columns (20.5)

For Non-Medicare Members
Medical necessity review is no longer required for this service.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The Prosorba column is a plastic cylinder that contains protein A bound to an inert silica matrix. Protein A, a component derived from several strains of the *staphylococcus* bacterium, has a strong affinity for high molecular weight IgG and IgM complexes such as rheumatoid factors and circulating immune complexes. The Prosorba device is used with a plasmapheresis machine. Blood is withdrawn from the patient and the plasma is separated and passed through the Prosorba column. Afterwards, the plasma is recombined with the cells and returned to the patient. Treatment generally involves 12 weekly therapy sessions. The rationale for Prosorba treatment is that it reduces harmful antibodies or immune complexes that are present in auto-immune diseases and does not result in systemic immunosuppression (Felson et al., 1999; Levy & Degani, 2003).

Prosorba is most commonly used for treating rheumatoid arthritis (RA), a chronic condition involving inflammation of the lining of the joints (synovium). RA can lead to the destruction of the synovium and the underlying joint, and is associated with chronic pain, loss of function and disability. Other treatments for RA include medication treatment (nonsteroidal anti-inflammatories, analgesics, glucocorticoids or prednisone, disease modifying antirheumatic drugs (DMARDs), and biologic response modifiers such as etanercept, physical therapy, splinting and surgery to correct deformities.

The FDA has approved the use of Prosorba columns for the treatment of idiopathic thrombocytopenic purpura (ITP) in patients with platelet counts less than 100,000 mm$^3$ and in patients with moderate to severe rheumatoid arthritis who have failed or are intolerant to DMARDs.

Medicare approved the use of Prosorba columns for the treatment of ITP in 1987. Effective January 1, 2001, Medicare also covers this treatment for RA in patients meeting certain conditions. Medicare’s approval of Prosorba for the treatment of RA was based on preliminary findings of the Prosorba Trial Investigators study published in Arthritis and Rheumatism (Felson et al., 1999).

Medical Technology Assessment Committee (MTAC)

02/14/2001: MTAC REVIEW
Prosorba Column

Evidence Conclusion: The RCT data reported on in Felson et al., 1999 and Furst et al., 2000 are insufficient to draw conclusions on the effectiveness of Prosorba at treating rheumatoid arthritis. Limitations of this trial are that it had a small sample size, included patients with severe RA only, had only a 69% completion rate, was funded by the manufacturer of the Prosorba column, and compared Prosorba treatment to sham treatment without including
The use of Prosorba Column for treatment of arthritis does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

06/06/2005: MTAC REVIEW
Prosorba Column

Evidence Conclusion: One new empirical study on Prosorba treatment, a case series, was identified since the previous literature search. The case series (Roth, 2004) found that 54% of study completers had a positive response to treatment. However, only 91 out of 131 enrolled patients (69%) completed the study, and the study was uncontrolled and non-blinded. Study duration was 24 weeks, similar to the length of the previously published sham-controlled RCT. To date, no long-term follow-up data are available for Prosorba treatment. Conclusions from the 2001 MTAC review are as follows: “The RCT data reported on in Felson et al., 1999 and Furst et al., 2000 are insufficient to draw conclusions on the effectiveness of Prosorba at treating rheumatoid arthritis. Limitations of this trial are that it had a small sample size, included patients with severe RA only, had only a 69% completion rate, was funded by the manufacturer of the Prosorba column, and compared Prosorba treatment to sham treatment without including a control group that did not receive apheresis. This trial provides fair data that Prosorba treatment has a high rate of adverse effects.”

Articles: Rheumatoid arthritis: There was one additional publication (Gendreau, 2001) on the same randomized controlled trial previously reported on by Felson (1999) and Furst (2000). The Gendreau article did not appear to present new substantive data and was therefore not reviewed. The only other empirical study was a recent case series, conducted by Fresenius HemoCare (Redmond, WA) as part of post-marketing surveillance. This study was critically appraised: Roth S. Effects of Prosorba column apheresis in patients with chronic refractory rheumatoid arthritis. J Rheumatol 2004; 31: 2131-5. See Evidence Table.

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