EXTRACORPOREAL IMMUNOADSORPTION (ECI) USING PROTEIN A COLUMNS (NCD 20.5)

Guideline Number: MPG110.03
Approval Date: August 9, 2017

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TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

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PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

Related Medicare Advantage Policy Guideline
- Apheresis (Therapeutic Pheresis) (NCD 110.14)

Related Medicare Advantage Coverage Summary
- Blood, Blood Products and Related Procedures and Drugs
UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

POLICY SUMMARY

Overview
Extracorporeal Immunoadsorption (ECI), using Protein A columns, has been developed for the purpose of selectively removing circulating immune complexes (CIC) and immunoglobulin’s (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 re-transfused to the patient. Examples of FDA approved adsorbent column filter devices are Prosorba (Cypress BioScience) and Liposorber LA-15 (Kaneka Pharma America).

Guidelines
Indications and Limitations of Coverage
Medicare covers the use of Protein A columns for the treatment of idiopathic thrombocytopenic purpura (ITP). In addition, Medicare will cover Protein A columns for the treatment of rheumatoid arthritis (RA) under the following conditions:
- Patient has severe RA. Patient disease is active, having >5 swollen joints, >20 tender joints, and morning stiffness >60 minutes.
- Patient has failed an adequate course of a minimum of 3 Disease Modifying Anti-Rheumatic Drugs (DMARDs). Failure does not include intolerance.

Other uses of these columns are currently considered to be investigational and, therefore, not reasonable and necessary under the Medicare law. (See §1862(a) (1) (A) of the Act.).

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>36515</td>
<td>Therapeutic apheresis; with extracorporeal Immunoadsorption and plasma reinfusion</td>
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REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 20.5 Extracorporeal Immunoadsorption (ECI) Using Protein A Columns
Reference NCD: NCD 110.14 Apheresis (Therapeutic Apheresis)

CMS Articles

<table>
<thead>
<tr>
<th>Article</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
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<tr>
<td>A53648 (NCD Extracorporeal Immunoadsorption (ECI) Using Protein A Columns) Palmetto Retired 07/31/2015</td>
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<td>A53578 (NCD Extracorporeal Immunoadsorption (ECI) Using Protein A Columns) Palmetto Retired 07/31/2015</td>
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CMS Claims Processing Manual
Chapter 4; § 231.9 Billing for Apheresis and Apheresis Services
GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

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<th>Date</th>
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<tr>
<td>08/09/2017</td>
<td>• Annual review for MAPG Committee presentation and approval</td>
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