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COLLEGE of AMERICAN
PATHOLOGISTS

September 19, 2017

National Government Services
Contractor Medical Director
P.O. Box 7108
Indianapolis, IN 46207-7108

Re: Coverage for Therapeutic Pheresis Procedures – NCD 110.14

Dear Dr. Clark,

We are writing because evidence has recently been brought to our attention which suggests NGS' August 24, 2017 directive related to "Coverage for Therapeutic Pheresis Procedures – NCD 110.14" may be based on a misinterpretation of admittedly ambiguous language in the 1992 NCD on which it is based. Specifically, the NCD, which was last updated in 1992, states, "[a]ll nonphysician services are furnished under the direct, personal supervision of a physician." The operative phrase is the somewhat confusing one "direct, personal supervision." The confusion arises from this appearing simultaneously to refer to two substantially different levels of supervision, each relevantly defined in the online Medicare Benefit Policy Manual, Chapter 6 - Hospital Services Covered Under Part B (Rev. 215, 12-18-15) <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c06.pdf>.

Direct supervision: "... 'direct supervision' means the definition specified in the PFS at 42 CFR 410.32(b)(3)(ii). The supervisory physician must remain present within the office suite where the service is being furnished and must be immediately available to furnish assistance and direction throughout the performance of the procedure. The supervisory physician is not required to be present in the room where the procedure is being performed."

Personal supervision: "'Personal supervision' means the definition specified at 42 CFR 410.32(b)(3)(iii), that is, the physician must be in attendance in the room during the performance of the service or procedure."

42 CFR 410.32(b)(3)

Levels of supervision:

When direct or personal supervision is required, physician supervision at the specified level is required throughout the performance of the test.

(ii) Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

(iii) Personal supervision means a physician must be in attendance in the room during the performance of the procedure.

This ambiguity (of “direct, personal”) was directly addressed in 2011 by the American Society for Apheresis (ASFA) with the agency (see attached section of the most recent “ASFA 2017 Reimbursement Guide”) as follows:

“In order to help clarify this situation, ASFA’s Public Relations and Advocacy committee submitted a request for clarification to CMS. The CMS section responsible for this portion of the 1992 NCD convened internally and with their contract medical directors to address this issue. They clarified the intent of the wording as follows:”

“The intent of "direct, personal" was more generic with reference to "personal", and means literally the regulatory definition of "direct" supervision. It was not intended to require the more recent regulatory definition of "personal supervision" in 42 CFR 410.32(b)(3)(iii).”

Moreover, CMS stated that:

“There was no definition of "personal" supervision until after 1997.”

Rather than interpreting the ambiguous phraseology of the 1992 NCD as intending direct supervision, it would appear NGS has interpreted the 1992 NCD to require personal supervision. This position is not consistent with prior understanding of the terms as they apply to the 1992 NCD or prevailing practice.

Based on these three sources of information, therefore, we request reconsideration and revision of the NGS directive, to reflect that direct rather than personal supervision is required by the NCD. In doing so, this change would also entail withdrawing the strictures against payment of these services to nonphysician practitioners. The three sources of information we adduce in support of this request are:

1) the clarifying CMS communication to ASFA (including the point that personal supervision had no regulatory meaning at the time of the issuance of the NCD). ASFA considers the clarification of the issue in their 2011 memo to be unambiguous and definitive. They will be happy to help NGS verify ASFA’s publically distributed 2011 clarification with CMS if NGS has doubts or wants to confirm facts;

2) the AMA RUC database specification of the physician time and the nonphysician time involved in these apheresis procedures, which was accepted by CMS in the valuation of these procedures, and which functionally precludes any expectation of personal supervision (as presently defined) by the physician, and makes clear that direct supervision is inherent in the valuation of these services;

	Physician Total Time	Other Clinical Labor Time
36511	75	243*
36512	75	243*
36513	75	186*
36514	75	183*
36516	50	338*
36522	87	195*

* Expert panel estimated, service time typically performed in the facility setting as per expert panel of Apheresis Medicine Physicians

3) in some ways most importantly, the standard of practice as described in the 2017 Therapeutic Apheresis - a physician's handbook, published jointly by AABB/ASFA (ISBN 978-1-56395-931-8), confirms that apheresis medicine physicians do indeed provide their services appropriately and safely through direct supervision of nonphysician providers.

“Typically, the apheresis *medicine* physician creates the treatment plan. [T]he apheresis physician medical director must be present during critical aspects of the patient-care episode and be immediately available to the technical staff during any apheresis procedure for the procedure to qualify for reimbursement. CMS clarified that this accessibility is not defined as physician presence at the bedside throughout the procedure. However, CMS did not specify time and/or distance to fulfill this criteria, ... [a]lthough there are clearly circumstances that would constitute lack of availability (such as personally performing a procedure that cannot be interrupted while a procedure on a second patient is being performed elsewhere).”

A physician that furnishes therapeutic apheresis provided the following explanation of his typical practice, which is consistent with the AABB/ASFA publication and supports the widespread understanding that the NCD calls for the direct supervision of the procedure:

“For a patient already scheduled for an apheresis procedure, I review the medical record, review pertinent labs, and decide if the procedure continues to be indicated. Depending on the specific procedure, I may make decisions about the volume to exchange, changing the replacement fluid (e.g., FFP or 5% albumin for a plasma exchange procedure), requirements for premedication (e.g., the need for diphenhydramine to prevent allergic reactions), or requirements for additional lab tests (e.g., hemoglobin, platelet count, fibrinogen). I may or may not see the patient prior to starting the procedure, depending on the clinical situation. During the

procedure, I see the patient several times, evaluate how the patient feels, review the vital signs, and discuss how the procedure is going with the apheresis nurse. I am available at all times to react to an adverse reaction. During or soon after the completion of the procedure, I write a progress note in the patient's chart, documenting key points and indicating the ongoing plan for future procedures. The apheresis nurse sets up the instrument, achieves vascular access, and operates the apheresis instrument, based on the apheresis physician's orders. Before committing to an apheresis procedure, or to a series of procedures, I always review the medical record, discuss the case physician-to-physician with the requesting physician, decide if apheresis is indicated (using evidenced based guidelines) and agree on the type, number and/or the frequency of procedures. Pre-treatment decisions include clinical evaluation of the patient, evaluation of vascular access, volumes to exchange, replacement fluids, and medications needed before and during the procedure. Informed consent is obtained from the patient. Apheresis orders are written. This initial evaluation of the patient is usually handled as an evaluation and management service, separate from the actual apheresis procedure or series of procedures."

While we believe the foregoing information should suffice for reconsideration of the NGS directive, we ask at least that its implementation be postponed until you have had the opportunity to investigate the points raised above: if NGS' recent directive were to be interpreted as requiring "personal supervision" throughout the entirety of the procedure, we believe this would adversely impact patients' accessibility to this important therapeutic modality.

If any questions about these reasons for revision remain in your mind, we will gladly arrange a conference call to discuss and elaborate on any or all the above.

Respectfully,

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