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Whether chemotherapy drugs should be reimbursed under part B of the Medicare Act

I. Specific authority that says chemotherapy drugs should be reimbursed under part B and not Part D of the Medicare Act.

The relevant Statutory provision under Part B,*42 USCS § 1395k*, Scope of benefits; definitions, states in relevant part

(a) Scope of benefits. The benefits provided to an individual by the insurance program established by this part [*42 USCS § § 1395j* et seq.] shall consist of--

(1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part [*42 USCS § § 1395j* et seq.]) **for medical and other health services**, except those described in subparagraphs (B) and (D) of paragraph (2) and subparagraphs (E) and (F) of section 1842(b)(6) [*42 USCS § 1395u(b)(6)(E),* (F)]; and

(2) entitlement to have payment made on his behalf (subject to the provisions of this part [*42 USCS § § 1395j* et seq.]) for-……

The section has enumerated the exceptions to eligibility for benefits etc. We do not seem to be hit by these exceptions; therefore, it is necessary to look at the definition of "**medical and other health services"**

(b) Definitions. For definitions of "spell of illness", "medical and other health services", and other terms used in this part [*42 USCS § § 1395j* et seq.], see section 1861 [*42 USCS § 1395x*].

42 USCS § 1395x defines "medical and other health services":

(s) Medical and other health services. The term "medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)

(A**) services and supplies (**including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, or kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1847B [*42 USCS § 1395w-3b*]);

(B) **hospital services** (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;……

(t) Drugs and biologicals.

(1) The term "drugs" and the term "biologicals", except for purposes of subsection (m)(5) and paragraph (2) of this section, include only such drugs

(including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

(2)

(A) **For purposes of paragraph (1), the term "drugs" also includes any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication** (as described in subparagraph (B))…….

It seems apparent from the statutory provision itself that drugs such as those used by are client will fall within the ambit of Part B of the Act. These drugs are not self-administered and form part of the services and supplies furnished as an incident to a physician's professional service. What may be important is to establish that " they are **commonly** either rendered without charge or included in the physicians' bills."

In AMERICAN MEDICAL ASSOCIATION et al., *429 F. Supp. 117,* the court summarized the applicability of Part B:

> Part B of Medicare, *42 U.S.C.S. § 1395j*-1395w, establishes a voluntary supplemental insurance program for aged and disabled individuals. It provides protection against the costs of physicians' services and a variety of medical services and equipment which are furnished in and out of medical institutions and which are not covered by the basic plan. This "supplementary Medicare" program covers only the cost of drugs and biologicals which (1) cannot be self-administered, (2) are

> incidental to a physician's services to patients in his office or to hospital outpatients, (3) are of a kind commonly furnished in physicians' offices, and (4) are commonly rendered without charge or included in the physician's bill. *42 U.S.C.S. § § 1395k*, 395x(s) (2). Thus, only a small percentage of drugs, such as injections, are covered under Part B of Medicare. In sum, both Part A and Part B of Medicare generally limit coverage to those drugs which have a close nexus to supervised institutional care.

A search of federal and state case law revealed that four[1] of the drugs have been classified as Part B drugs in litigation. While none of the cases actually decides whether or not these drugs are Part B drugs as opposed to Part D, they do reveal that these drugs have been categorized as Part B drugs in the past and thus lend credit to the argument that they continue to be properly classified under Part B. All the cases are recent ranging from the time periods between 2003-2006.

In addition, the Medicare Act requires the United States Pharmacopeia (USP) to develop a list of categories and classes that may be used by drug plans as they design their formularies. See *42 USCS § 1395w-104*:

§ 1395w-104. Beneficiary protections for qualified prescription drug coverage

§ 1395w-104(b)(3)(C)(ii) (ii) Model guidelines. The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

[1] Aranesp, Cytoxan, Hemarin and Leukine

In addition to creating the Model Guidelines, the Medicare Act also designates USP "to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and additions of new covered part D drugs."

USP's website includes a drug list table which includes examples of drugs in the USP model guidelines[2]. Interestingly this listing did include 5 of the 7 drugs listed in Paragraph 18 of the Complaint.

To summarize:

- The statute itself supports the view that Part B covers the cost of drugs and biologicals which (1) cannot be self-administered, (2) are incidental to a physician's services to patients in his office or to hospital outpatients, (3) are of a kind commonly furnished in physicians' offices, and (4) are commonly rendered without charge or included in the physician's bill. *42 U.S.C.S. § § 1395k,* 395x(s) (2). Also, the definition of "drugs and biologicals" includes drugs used in chemotherapy.
- A number of federal court cases have revealed that four of the drugs listed in paragraph 18 of the Complaint have been previously classified as Part B drugs in litigation.
- The newly enacted MMA has given the USP powers for "to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and

[2] http://www.usp.org/healthcareInfo/mmg/revisions.html

the additions of new covered part D drugs." **The drug list table at the website of USP does list 5 out of the 7 drugs listed in paragraph 18 of the Complaint.**

- A drug is a part D drug if it meets two tests. First, it must be a drug or biological product that can only be dispensed upon a written prescription. Second, it must be approved by the FDA. In addition, certain classes of drugs, such as prescription vitamins, are excluded from coverage as covered part D drugs. Importantly, covered part D drugs do not include drugs that are covered under parts A or B of the Medicare program; those drugs remain covered under the traditional Medicare program. (42 U.S.C. 1395w-101(a) (1) (2005).