

Appendix D

Glossary of Terms and Acronyms

List of ACRONYMS

AAPCC	--average adjusted per capita cost
AIDS	--acquired immunodeficiency syndrome
ARC	--AIDS-related complex
AWP	--average wholesale price
AZT	--zidovudine
CAPD	--continuous ambulatory peritoneal dialysis
CBO	--Congressional Budget Office, U.S. Congress
CCPD	--continuous cycling peritoneal dialysis
CFR	--code of federal regulations
CHO	--Chinese hamster ovary
CMP	--competitive medical plan
CPR	--customary, prevailing, and reasonable
DHHS	--Department of Health and Human Services
DNA	--deoxyribonucleic acid
DRG	--diagnosis-related group
ELA	--establishment licensing application
ESRD	--end-stage renal disease
FDA	--Food and Drug Administration, U.S. Department of Health and Human Services
FSS	--Federal Supply Schedule
GMP	--good manufacturing practices
HCFA	--Health Care Financing Administration, U.S. Department of Health and Human Services
HIV	--human immunodeficiency virus
HMO	--health maintenance organization
ITC	--U.S. International Trade Commission
IV	--intravenous
kg	--kilogram
NANBH	--non-A non-B hepatitis
NDA	--new drug application
NMC	--National Medical Care, Inc.
OIG	--Office of the Inspector General, U.S. Department of Health and Human Services
OTA	--Office of Technology Assessment, U.S. Congress
PLA	--product licensing application
PRO	--peer review organization
RCT	--randomized clinical trial
rHuEPO	--recombinant (human) erythropoietin
RNA	--ribonucleic acid

SC	--subcutaneous
VA	--Department of Veterans Affairs

Glossary of Terms

Access: Potential and actual entry of a population into the health care delivery system.

AIDS (acquired immunodeficiency syndrome): A disease caused by the retrovirus human immunodeficiency virus (HIV) and characterized by a deficiency of the immune system. The primary defect in AIDS is an acquired, persistent, quantitative functional depression within the T4 subset of lymphocytes. This depression often leads to infections caused by micro-organisms that usually do not produce infections in individuals with normal immunity or to the development of a rare type of cancer (Kaposi's sarcoma) usually seen in elderly persons or in individuals who are severely immunocompromised from other causes.

Amino acid: A group of 20 molecules that bind together to form proteins. Each type of protein is made up of a specific sequence of amino acids coded for in the DNA.

Autologous donation: A blood donation that is stored and reserved for return to the donor as needed, usually in elective surgery.

Autologous transfusion: Transfusion of blood or blood components drawn from a donor and maintained for subsequent transfusion to that same donor.

Average adjusted per capita cost (AAPCC): The AAPCC is the estimated average per capita amount that would be payable if covered services for Medicare Competitive Medical Plan (CMP) members were furnished in local fee-for-service practices. The AAPCC formula consists of the product of three major components: (1) the U.S. per capita Medicare cost as projected to the current year, (2) an adjustment based on the historical relationship between national Medicare costs and Medicare per capita reimbursements in the local area that a CMP serves, and (3) an adjustment for the differences between persons who choose to enroll in a CMP and the Medicare population at large from which CMP enrollees are drawn.

Biologics: Medicinal preparations made from living organisms and their products, including serums, vaccines, antigens, antitoxins, etc.

Biotechnology: Techniques that use living organisms or substances from organisms to make or modify a product. “New” biotechnology refers to recombinant DNA techniques and other sophisticated tools relying on the ability to harness and manipulate genetic material.

Bone marrow: A highly vascular, modified connective tissue found in the long bones and certain flat bones of vertebrates that is the origin of blood cells.

Clinical trial: A scientific research activity undertaken to define prospectively the effect and value of prophylactic, diagnostic, or therapeutic agents, devices, regimens, procedures, etc., applied to human subjects.

Coinsurance: That percentage of covered medical expenses, after subtraction of any deductible, for which an insured person is responsible. Under Medicare Part B, after the annual deductible has been met, Medicare will generally pay 80 percent of approved charges for covered services and supplies; the remaining 20 percent is the coinsurance, for which the beneficiary is liable.

Common Costs: Costs that are not traceable to any one specific product.

Continuous ambulatory peritoneal dialysis (CAPD): Peritoneal dialysis is a form of dialysis in which sterile fluid is introduced into the abdominal cavity and the peritoneum acts as the semi-permeable membrane that allows the molecular exchange. In CAPD, the peritoneal dialysis is performed nearly constantly in ambulatory patients who exchange the fluid every 4 to 8 hours.

Continuous cycling peritoneal dialysis (CCPD): A form of peritoneal dialysis in which a machine cycles the dialysate in and out of the peritoneal cavity automatically about every 4 hours overnight as the patient sleeps.

Cost-sharing: That portion of the payment to a provider of health care services that is the initial liability of the patient and that may include deductibles, copayments, coinsurance, and, under Medicare Part B, unassigned liability. Also, the general set of financial arrangements under which health care insurance is contingent on a purchaser’s acceptance of the obligation to pay some

portion of the reimbursements for those services.

Coverage (Medicare): In the Medicare program, coverage refers to the benefits available to eligible beneficiaries and can be distinguished from payment, which refers to the amount and methods of payment for covered services.

Customary, prevailing, and reasonable (CPR) method (Medicare): The method used by carriers to determine the approved charge for a particular Part B service from a particular physician or supplier based on the actual charge for the service, previous charges for the service by the physician or supplier in question, and previous charges by peer physicians or suppliers in the same locality.

Customary charge: In the absence of unusual medical circumstances, the maximum amount that a Medicare carrier will approve for payment for a particular service provided by a particular physician practice. The carrier computes the customary charge on the basis of the actual amount that a physician practice or supplier generally charges for a specific service. **Prevailing charge:** In the absence of unusual medical circumstances, the maximum amount a Medicare carrier will approve for payment for a particular service provided by any physician practice within a particular peer group and locality. Generally, this amount is equal to the lowest charge in an array of customary charges that is high enough to include 75 percent of all the relevant customary charges. **Approved or reasonable charge:** An individual charge determination made by a Medicare carrier on a covered Part B medical service or supply. In the absence of unusual medical circumstances, it is the lowest of: (1) the physician’s or suppliers’ customary charge for that service; (2) the prevailing charge for similar services in the locality; (3) the actual charge made by the physician or supplier; and (4) the carrier’s private business charge for a comparable service. Also called allowed charge or reasonable charge.

Dialysate: The sterile fluid used in dialysis to remove toxic substances from the blood. The chemical composition of the dialysate varies according to the types of substances being removed. According to the basic principle of osmosis, the dialysate generally contains low concentrations of the waste substances.

Dialysis: The process of separating crystalloid and colloids in solution by the differences in their rates of diffusion through a semipermeable membrane.

Efficacy The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use.

Efficient resource allocation: The allocation of resources among alternative uses so that maximum social benefits are derived from the resources.

End-stage renal disease (ESRD): Chronic renal failure that occurs when an individual irreversibly loses a sufficient amount of kidney function so that life cannot be sustained without treatment. Hemodialysis, kidney transplant surgery, and continuous ambulatory peritoneal dialysis are forms of therapy.

Fee-for-service payment: A method of paying for medical services in which each service performed by an individual provider bears a related charge. This charge is paid by the individual patient receiving the service or by an insurer on behalf of the patient.

Fee schedule: An exhaustive list of provider services in which each entry is associated with a specific monetary amount that represents the approved payment level for a given insurance plan.

Glycoprotein: A protein with attached sugar groups.

Good manufacturing practices: Requirements regarding the manufacturing, processing, packing, storage, and other practices involving products under the jurisdiction of the Food and Drug Administration (foods and food additives, cosmetics, drugs, biologics, and medical devices).

Health maintenance organization (HMO): A health care organization that, in return for prospective per capita (cavitation) payments, acts as both insurer and provider of comprehensive but specified medical services. A defined set of physicians provide services to a voluntarily enrolled population. Prepaid group practices and individual practice associations are types of HMOs.

Hematocrit: The volume occupied by the cellular elements of blood in relation to the total volume.

Hemodialysis: A process by which blood is pumped from the patient's body into a dialyzer and then returned to the body in a continuous extra-

corporeal blood loop. While in the dialyzer the blood flows next to but separate from another fluid, a dialysate. The blood and the dialysate are separated from each other by a semipermeable membrane. By diffusion and osmosis, waste products and other molecules pass through the semipermeable membrane and the blood can again take on its appropriate properties.

Hepatitis: Inflammation of the liver which may be due any of several causes, including viruses.

Hormone: A chemical substance that is released into the circulatory system by a gland that has a specific regulatory effect on another organ; functions regulated include metabolism, growth, and the development of secondary sex characteristics (such as breasts, facial hair).

Medicare carriers: Fiscal agents (typically Blue Shield plans or commercial insurance firms) under contract to the Health Care Financing Administration for administration of specific Medicare tasks. These tasks include computing reasonable charges under Medicare Part B, making actual payments, determining whether claims are for covered services, denying claims for noncovered services, and denying claims for unnecessary use of services.

Medicare intermediaries: Fiscal agents (typically Blue Cross plans or commercial insurance firms) under contract to the Health Care Financing Administration for administration of specific Medicare tasks. These tasks include determining reasonable costs for covered items and services, making payments, and guarding against unnecessary use of covered services for Medicare Part A payments. Intermediaries also make payments for home health and outpatient hospital services covered under Part B.

Non-A, non-B hepatitis (NANBH): A term used to describe hepatitis (inflammation of the liver) in which both hepatitis A and hepatitis B have been excluded. Hepatitis C has been identified as the cause of a substantial portion of NANBH.

Orphan Drug Act: Public Law 97-414, which charges the U.S. Government with identifying and promoting orphan products, defined as drugs and devices for rare diseases.

Out-of-pocket costs: Deductibles and copayments incurred by beneficiaries when services are rendered.

Peritoneal dialysis: A form of dialysis that occurs

within the patient's body, rather than via an extracorporeal blood loop as in hemodialysis. A catheter is inserted into the abdomen and then dialysate is entered through the catheter into the peritoneal cavity. The fluid is allowed to remain for varying periods of time, during which dialysis occurs across the semi-permeable peritoneal membrane. Later, the dialysate is drained out through the catheter and discarded.

Phase I, II, and III drug trials: The sequence of studies in human beings required for new pharmaceutical approval by the Food and Drug Administration. Phase I includes studies in a small number of relatively healthy patients or normal volunteers to determine safety and pharmacologic effects. Phase II includes controlled clinical trials to determine appropriate doses, safety, and effectiveness in a total of about 200 patients. Phase III trials are usually randomized clinical trials.

Protein: A molecule composed of hundreds of linked amino acids in a specific sequence, which is, in turn, determined by the sequence of nucleo-

tides in DNA in the gene coding for the particular protein. Proteins are required for the structure, function, and regulation of the various cells, tissues, and organs in the body.

Quality of care: The degree to which actions taken or not taken increase the probability of beneficial health outcomes and decrease risk and other untoward outcomes, given the existing state of medical science and art.

Randomized clinical trial (RCT): An experiment designed to test the safety and efficacy of a medical technology in which people are randomly allocated to experimental or control groups, and outcomes are compared.

Recombinant DNA (rDNA) technology Techniques involving the incorporation of DNA fragments, generated with the use of restriction enzymes, into a suitable host organism's DNA (a vector). The host is then grown in culture to produce clones with multiple copies of the incorporated DNA fragment. The clones containing this particular DNA fragment can then be selected and harvested.