DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of	**Claim for**
C.A. (Appellant)	Hospital Insurance Benefits (Part A)
**** (Beneficiary)	**** (HIC Number)
Quality Insights of Pennsylvania (QIO) (Contractor)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated July 7, 2009, that concerned a pre-authorization request for coverage of a liver transplant for the beneficiary. A Quality Improvement Organization issued unfavorable initial and reconsidered determinations pursuant to authority granted by section 1854 of the Social Security Act (Act), after the prospective transplant center advised the beneficiary that it expected that Medicare would not cover the procedure. On a request for hearing, the ALJ determined that Medicare would not cover the liver transplant procedure, and that the beneficiary's liability for the costs would not be waived pursuant to Section 1879 of the Act, in the event that she received the noncovered services. The appellant has asked the Medicare Appeals Council to review this action.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c). The appellant's request for review and supporting memorandum will be entered into the record as Exhibit (Exh.) MAC-1.

The appellant contends that the ALJ erred in introducing criteria outside of the applicable National Coverage Determination (NCD 260.1 – Adult Liver Transplantation) to make his decision. The appellant also contends that the ALJ erred by disregarding evidence from some of the beneficiary's physicians; according weight to evidence from a medical witness called by the Office of Medicare Hearings and Appeals; and disregarding evidence that Medicare has covered previous liver transplants for beneficiaries with co-morbidities similar to those of the beneficiary. Exh. MAC-1.

On *de novo* review, the Council reverses the ALJ's decision for the reasons set forth below, and finds that Medicare does cover the liver transplant procedure for the beneficiary.

Legal Standards

Section 1862 of the Act provides that:

> (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items and services -
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> > (1)(A) which . . . are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.

Historically, in making coverage determinations, CMS has interpreted the terms reasonable and necessary to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995). *See also* 52 Fed. Reg. 15560 (Apr. 29, 1987).

The Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that specify whether specific medical items, services, treatment procedures, or technologies may be paid for by Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an

item or service is reasonable and necessary. (*See* preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989), subsequently renamed and recodified as the Foreword to the National Coverage Determinations Manual).

The Foreword to the National Coverage Determinations Manual, Pub. 100-3, describes the purpose of National Coverage Determinations as follows:

> The statutory and policy framework within which National Coverage Decisions are made may be found in title XVIII of the Social Security Act (the Act), and in Medicare regulations and rulings. The National Coverage Determinations Manual describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicaid. National coverage decisions have been made on the items addressed in this manual. All decisions that items, services, etc. are not covered are based on §1862(a)(1) of the Act (the "not reasonable and necessary" exclusion) unless otherwise specifically noted. Where another statutory authority for denial is indicated, that is the sole authority for denial.
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> Where an item, service, etc. is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items or services because they do not meet those specified indications or circumstances are based on §1862(a)(1) of the Act. Where coverage of an item or service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item or service is not mentioned at all in the CMS Manual System the Medicare contractor is to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, based on the law, regulations, rulings and general program instructions
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> The coverage decisions in the manual will be kept current, based on the most recent medical and other scientific and technical advice available to CMS.

The Act and the implementing regulations underscore the fact that National Coverage Determinations are binding when applicable, and may not be disregarded, set aside, or otherwise reviewed by intermediaries, contractors, Quality Improvement Organizations (QIOs), Quality Improvement Contractors (QICs), ALJs, or the Medicare Appeals Council. *See* Section 1869(f)(1)(A)(i) of the Act, and 42 C.F.R. § 405.1060(a)(4), (b), and (c).

The Liver Transplant for This Beneficiary Is Expressly Covered under the Terms of National Coverage Determination 260.1.

National Coverage Determination (NCD) 260.1, revised effective September 1, 2001, provides for Medicare coverage of adult liver transplantation for hepatocellular carcinoma when the following conditions are met:

- The patient is not a candidate for total liver resection;
- The patient's tumor(s) is less than or equal to 5 cm in diameter;
- There is no macrovascular involvement;
- There is no identifiable extrahepatic spread of the tumor to surrounding lymph nodes, lungs, abdominal organs or bone; and
- The transplant is furnished in a facility which is approved by CMS as meeting institutional coverage criteria for liver transplants (see 65 FR 15006).

NCD 260.1.[1] The beneficiary in this case fully meets all five of these criteria for a liver transplant, based on thorough assessments performed at the University of Pittsburgh Medical Center and the Ohio State Medical Center. *See* Exh. 3 at 14-25, 34-35, 39-40, 43-45, 51-53, 55-56; Exh. 7 at 1-4; testimony of Dr. M*** V*** at ALJ Hearing, June 25, 2009 (CD recording). The beneficiary thus meets specified indications and specified circumstances for coverage. There are no limitations in the NCD that would exclude transplants due to concurrent HCV and/or HIV

[1] The National Coverage Determinations can be found online in the MS Medicare Coverage Database at http://www.cms.hhs.gov/mcd/viewncd. The National Coverage Determinations Manual can be viewed online at http://www.cms.hhs.gov/Manuals/IOM/list.asp.

infection, provided, however, that the transplant is furnished in an approved facility that first accepts the prospective patient as a suitable candidate. Therefore, the beneficiary is covered by Medicare for the liver transplant if performed at the University of Pittsburgh Medical Center which has accepted her as a suitable candidate.

In light of this determination, the Council does not need to address the other contentions in the appellant's request for review, concerning how the evidence was presented and weighed at the ALJ hearing. As noted above, the appellant presented a substantial amount of accurate, thorough evidence demonstrating that the appellant meets the criteria in NCD 260.1, as well as meeting additional criteria that the physicians at the University of Pittsburgh Medical Center have stated make her a good candidate for a liver transplant. It is also unnecessary to reach the issue of liability, since the Council has concluded the liver transplant is covered by Medicare.

Decision

It is the decision of the Medicare Appeals Council that, pursuant to National Coverage Determination 260.1, the liver transplant for the beneficiary is covered by Medicare if performed at the University of Pittsburgh Medical Center which has accepted her as a suitable candidate. The decision of the ALJ is reversed.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

/s/ Gilde Morrisson
Administrative Appeals Judge

Date: November 5, 2009