

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-12-1253

In the case of

Claim for

K.E.D.

(Appellant)

Supplementary Medical
Insurance Benefits (Part B)

(Beneficiary)

(HIC Number)

NHIC, Corp.

(Contractor)

(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated January 31, 2012, which concerned Medicare coverage for an office/outpatient visit (HCPCS/CPT code¹ 99213), biopsy of cervix (57500), and a pap smear (Q0091) furnished to the beneficiary on October 28, 2010. The ALJ determined that Medicare will not cover the pap smear and related services because the appellant did not meet the criteria outlined in the applicable national coverage determination (NCD) to support coverage. The ALJ further found the appellant financially responsible for the non-covered charges. 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.

¹ The Centers for Medicare & Medicaid Services (CMS) has developed the Healthcare Common Procedure Coding System (HCPCS) to establish "uniform national definitions of services, codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40(a). CMS also utilizes the American Medical Association's (AMA's) annual publication of Current Procedural Terminology (CPT) codes.

42 C.F.R. § 405.1112(c). The Council has entered the appellant's request for review into the record as Exhibit (Exh.) MAC-1.²

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The Council has considered the record and exceptions and concludes that the exceptions provide no basis for changing the AL's action. Medicare will not cover the pap smear and related services furnished on October 28, 2010; the appellant does not satisfy the criteria set forth in the applicable statutory provisions and NCD § 210.2. See 42 C.F.R. § 405.1060(a)(4) ("An NCD is binding on fiscal intermediaries, carriers, [Quality Improvement Organizations (QIOs), Qualified Independent Contractors (QICs)], ALJs, and the [Council].").

The ALJ determined that the appellant did not meet any of the criteria set forth in NCD § 210.2 for annual screening pap smears. Dec. at 5. Addressing the appellant's claim that she had post-menopausal uterine bleeding during 2008 and 2009, the ALJ concluded that this alone was not sufficient to justify the services on appeal. *Id.* Further, the ALJ noted that the appellant's testing results in 2009 were negative for cancer and that an episode of post-menopausal bleeding is not a delineated factor under the NCD that supports ongoing annual screening pap smears. *Id.* Finally, the ALJ did not find the appellant's submission of a 1996 article published in the Harvard Guide to Women's Health about obesity and the incidence of endometrial cancer persuasive; the ALJ found that the language in the NCD was intended to be exhaustive. *Id.* As the NCD was revised in 2006 (nearly 10 years after the publication of the article), the ALJ concluded that it was reasonable that the NCD's drafters considered the same studies cited in the journal but nevertheless rejected the notion of obesity as a high risk factor for uterine and vaginal cancers. *Id.* at 5-6. The ALJ therefore found that the pap smear, cervical biopsy, and office visit were not covered by Medicare and that as this was a categorical denial, the appellant was not entitled to a waiver of liability under section 1879 of the Social Security Act (Act). *Id.*

The appellant contends that she had tests and pap smears in 2008, 2009, and 2010. Exh. MAC-1. She asserts that because she experienced vaginal bleeding in 2008 and 2009, she had cause to receive a 2010 examination. *Id.* Further, the appellant explains that during the pap smear in 2010, a polyp growth was

² The appellant submitted documentation with her request for review. This documentation is duplicative of that which is contained in the record. See Exh. 8 at 1-3, 4-7.

discovered by the associate doctor, who in turn called a senior ³ doctor into the office, who recommended removal of the polyp growth. *Id.* The appellant explains that the polyp growth was then sent to the laboratory for a biopsy to determine if it was cancerous. The appellant therefore contends that Medicare should pay \$977 for the cervical biopsy performed on the polyp growth because there is no way to determine cancer without a biopsy. *Id.* Finally, the appellant asserts that she is obese and thus she has one of the primary risk factors for endometrial cancer, consistent with the 1996 Harvard Guide to Women's Health publication.

Section 1861(nn) of the Act sets forth provides the following guidelines with respect to the frequency of screening pap smears:

The term "screening pap smear" means a diagnostic laboratory test consisting of a routine exfoliative cytology test (Papanicolaou test) provided to a woman for the purpose of early detection of cervical or vaginal cancer and includes a physician's interpretation of the results of the test, if the individual involved has not had such a test during the preceding 2 years, or during the preceding year in the case of a woman described in paragraph (3)

(3) A woman described in this paragraph is a woman who—

(A) is of childbearing age and has had a test described in this subsection during any of the preceding 3 years that indicated the presence of cervical or vaginal cancer or other abnormality; or

(B) is at high risk of developing cervical or vaginal cancer (as determined pursuant to factors identified by the Secretary).

Section 1861(nn) of the Act. The applicable NCD, which is binding on ALJs and the Council, sets forth specific coverage requirements, implementing section 1861(nn) of the Act:

A screening pap smear and related medically necessary services provided to a woman for the early detection of cervical cancer (including collection of the sample

of cells and a physician's interpretation of the test results) and pelvic examination (including clinical breast examination) are covered under Medicare Part B when ordered by a physician (or authorized practitioner) under one of the following conditions:

- She has not had such a test during the preceding two years or is a woman of childbearing age (§1861(nn) of the Act).
- There is evidence (on the basis of her medical history or other findings) that she is at high risk of developing cervical cancer and her physician (or authorized practitioner) recommends that she have the test performed more frequently than every two years.

High risk factors for cervical and vaginal cancer are:

- Early onset of sexual activity (under 16 years of age)
- Multiple sexual partners (five or more in a lifetime)
- History of sexually transmitted disease (including HIV infection)
- Fewer than three negative or any pap smears within the previous seven years; and
- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.

NCD § 210.2.

By her own admission and from the medical documentation contained in the record, the appellant does not meet the criteria set forth above for high risk factors; therefore, she does not satisfy the coverage requirements set forth in the NCD for more frequent pap smears. *See Hearing CD.* However, the appellant maintains that she is high risk because of her obesity. Exh. MAC-1. The Council agrees with the ALJ's reasoning for rejecting this assertion: although the record demonstrates that the appellant is obese, the 1996 article does not necessarily prove that obese women are "high risk" to develop cervical or vaginal cancers; the language of the NCD is

clear that the list is intended to be exhaustive; and the NCD ⁵ was revised in 2006, making it likely the drafters of the NCD considered the same arguments set forth in the 1996 article and did not find them persuasive to warrant adding obesity as a high risk factor. Dec. at 5-6.

The appellant's contention that Medicare pay \$977 for the cervical biopsy is unavailing. The services billed, an office/outpatient visit (code 99213), the biopsy of cervix (code 57500), and a pap smear (code Q0091), are meant to encompass a pelvic examination and screening pap smear. This is apparent from the language in the NCD, which states that a "screening pap smear and related medically necessary services provided to a woman for the early detection of cervical cancer (including collection of the sample of cells and a physician's interpretation of the test results) and pelvic examination (including a clinical breast examination)" NCD § 210.2; see also Exh. 1 at 4. The cervical biopsy (code 57500) was performed as an integral part of the pelvic examination for the purpose of a pap smear; if not for the examination, the polyp growth would have not been discovered. Exh. 5 at 8-9. The Council will therefore not allow Medicare coverage for the cervical biopsy.

The denial of coverage in this case is based on a finding that section 1861(nn) of the Act excludes the services from Medicare coverage. Thus, section 1879 of the Act does not apply and the beneficiary is financially responsible for the non-covered costs.

The Council therefore adopts the ALJ decision.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

Date: June 22, 2012