THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN 30 1997

The Honorable E. Clay Shaw, Jr.
House of Representatives
Washington, D.C. 20515-0922

Dear Mr. Shaw:

I am responding to your letter regarding the skin lesion local medical review policy (LMRP) issued by the Medicare carrier, Blue Cross and Blue Shield of Florida (FL BC/BS).

The general concerns of the dermatology community are that implementation of the skin lesion LMRP represents a major change from existing Medicare policy, circumvents physician judgement, and may put beneficiaries at risk. At present there is no specific national policy for removal of skin lesions (e.g., actinic keratoses). Under Medicare guidelines, removal of skin lesions is covered when medically necessary. The skin lesion LMRP, based on a review of published literature, describes when it is medically necessary to surgically remove actinic keratoses. In asymptomatic actinic keratosis, surgery is medically unnecessary except in certain, specified situations. We reviewed the Florida policy and believe it is medically sound. The process used by FL BC/BS in developing and implementing the policy was in accordance with Medicare's LMRP process. Additionally, the Health Care Financing Administration's (HCFA's) medical officers reviewed the skin lesion LMRP and believe that, based on the literature, it is clinically sound. The carrier is declining coverage of procedures that do not meet the standards in section 1862 (a)(1)(A) of the Social Security Act (the Act), which requires that services be "reasonable and necessary," and section 1862(a)(10) of the Act, that excludes most cosmetic surgery.

Both HCFA and FL BC/BS invited the dermatology community to come forward with literature supporting the medical necessity for destruction of asymptomatic actinic keratosis in cases other than those printed by the Florida LMRP. To date, neither HCFA nor the carrier has received such literature.

This policy in no way circumvents physician judgement. The skin lesion LMRP seeks to articulate when surgical destruction (e.g., laser treatment, chemical treatments) is medically necessary. There are clinical criteria cited in the skin lesion LMRP that constitute appropriateness. In those cases, Medicare will pay for the procedure. Several of the criteria are:

- When the patient presents with an actinic keratosis that has changed in size, has developed erythema, has thickened, has ulcerated, has eroded, has developed changes at the tumor margins, has become markedly hyperkeratotic, in which pain has developed, or a cutaneous horn has developed;
- When the patient presents with an actinic keratosis of the lower-lip, upper-lip, conjunctivae, nose, ear, or eyelid;
- When the patient presents with an actinic keratosis and has a history of one of the following: chronic immunosuppression, treatment of psoriasis with psolaren-ultraviolet A (PUVA) therapy, xeroderma pigmentosum, albinism, discoid lupus erythematosus, or previous treatment of a biopsy-proven Squamous Cell Carcinoma or other skin malignancy;
- When a patient presents with an actinic keratosis and has a history of significant exposure to therapeutic or occupational radiation therapy;
- When the patient has multiple actinic keratoses and has self-administered 2 percent to 5 percent Efudex topical cream for two to four weeks and the actinic keratoses have not responded to this treatment one to two months following treatment.

There has been considerable misunderstanding of the reference to Efudex, so allow me to clarify an important point. A fundamental principle in the policy is that treatment of asymptomatic actinic keratosis is medically unnecessary. This would be true for any method of treatment, e.g., surgical, laser, or cryogenic destruction, or use of topical creams (chemical destruction). Because literature indicates that lesions failing topical treatment with Efudex suggest a higher likelihood of malignancy, the carrier allowed for coverage in these cases. In other words, a failure of Efudex establishes a lesion as being suspicious versus asymptomatic.

LMRP is generally developed to specify criteria that describe whether the item/service is covered and under what clinical circumstances Medicare coverage is reasonable, necessary and appropriate. Medicare contractors often set local policy priorities based on data analysis which shows utilization and payment data relative to national utilization and payment data. Where services in a contractor's locale are significantly higher than the national average, the contractor must make a reasonable effort to identify the cause of the aberrancy. When the contractor believes that a LMRP is needed, the contractor is required to follow a formal process. Carriers develop and implement LMRPs in accordance with instructions published in the Medicare Carrier Manual.

The actions of FL BC/BS are in accordance with program instructions provided by HCFA. Approximately $40 million was paid in Florida over a 1-year period for 3 procedure codes used in billing for removal of 2.2 million benign skin lesions. The most common diagnosis listed in billing for these procedures was actinic keratoses. The average payments for these 3 procedures per 1,000 Medicare enrollees in Florida was the highest in the country ($9,688), approximately 3 times the national average.

On November 15, HCFA staff met with representatives of the American Academy of Dermatology (AAD) to discuss the medical indications for treatment of actinic keratoses. HCFA proposed to present this topic to HCFA's Technical Advisory Committee (TAC) and the representatives from AAD agreed to provide literature that supports their position. When the literature is provided by AAD for presentation to the TAC, the TAC will review it and determine if a national skin lesion policy is warranted. Following the TAC's recommendation, HCFA will respond accordingly. If a national policy is established, it will take precedence over any local or model policies regarding the removal of skin lesions.

The Florida skin lesion LMRP lays out the criteria for when surgical destruction of skin lesions is medically necessary. The skin lesion LMRP both reduces inappropriate billing and protects beneficiaries from procedures that are not medically necessary. Should additional information become available, providers are always free to contact the carrier and request policy changes. In addition, HCFA continues to offer formal appeal rights to providers who believe their claims are denied because of contractor error.

I hope this response addresses your concerns.

Sincerely,

Donna E. Shalala