# Medicare
## Carriers Manual
## Part 3 - Claims Process

**Department of Health & Human Services (DHHS)**
**Centers for Medicare & Medicaid Services (CMS)**

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**CHANGE REQUEST 2060, 2269, 2150, and 2734**

| HEADER SECTION NUMBERS | PAGES TO INSERT | PAGES TO DELETE |
|---|---|---|
| 2323 – 2323 (Cont.) | 2-123 – 2-124 (2 pp.) | 2-123 – 2-124 (2 pp.) |
| Table of Contents - Chapter IV | 4-4.1 – 4-4.6 (6 pp.) | 4-4.1 – 4-4.6 (6 pp.) |
| 4119 – 4120 | 4-33 – 4-34 (2 pp.) | 4-33 – 4-34 (2 pp.) |
| 4281 – 4281.5 (Cont.) | 4-68.4W – 4-68.4Z (4 pp.) | ----------------- |

**NEW/REVISED MATERIAL--*EFFECTIVE DATE: Not Applicable***
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Section 2323, Foot Care and Supportive Devices for Feet, is revised to add a reference to §4281.

Section 4120, Foot Care, is revised to add a reference to §4281.

Section 4281, Peripheral Neuropathy With Loss Of Protective Sensation (Lops) In People With Diabetes, new section manualizes the following Program Memoranda, AB-02-042, Change Request (CR) 2060; AB-02-096, CR 2269; and AB-02-109, CR 2150.

Section 4281.1, Coverage, new section manualizes the following Program Memoranda, AB-02-042, Change Request (CR) 2060; AB-02-096, CR 2269; and AB-02-109, CR 2150.

Section 4281.2, Applicable Codes, new section manualizes the following Program Memoranda, AB-02-042, Change Request (CR) 2060; AB-02-096, CR 2269; and AB-02-109, CR 2150. The definition of G0247 has been updated to manualize the revision implemented through transmittal AB-03-070, CR 2734.

Section 4281.3, Payment Requirements, new section manualizes the following Program Memoranda, AB-02-042, Change Request (CR) 2060; AB-02-096, CR 2269; and AB-02-109, CR 2150.

Section 4281.4, Standard System Edits, new section manualizes the following Program Memoranda, AB-02-042, Change Request (CR) 2060; AB-02-096, CR 2269; and AB-02-109, CR 2150.

Section 4281.5, CWF Edits, new section manualizes the following Program Memoranda, AB-02-042, Change Request (CR) 2060; AB-02-096, CR 2269; and AB-02-109, CR 2150.

**DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.**

**These instructions should be implemented within your current operating budget.**

(If the claim is for a diagnostic test or examination performed solely for the purpose of establishing a claim under title IV of Public Law 91-173 (Black Lung Benefits), advise the claimant to contact his/her Social Security office regarding the filing of a claim for reimbursement under that program.)

The exclusions apply to eyeglasses or contact lenses and eye examinations for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive errors. The exclusions do not apply to physician services (and services incident to a physician's service) performed in conjunction with an eye disease (e.g., glaucoma or cataracts) or to postsurgical prosthetic lenses which are customarily used during convalescence from eye surgery in which the lens of the eye was removed or to permanent prosthetic lenses required by an individual lacking the organic lens of the eye, whether by surgical removal or congenital disease. Such prosthetic lens is a replacement for an internal body organ (the lens of the eye). (See §2130.)

The coverage of services rendered by an ophthalmologist is dependent on the purpose of the examination rather than on the ultimate diagnosis of the patient's condition. When a beneficiary goes to an ophthalmologist with a complaint or symptoms of an eye disease or injury, the ophthalmologist's services (except for eye refractions) are covered regardless of the fact that only eyeglasses were prescribed. However, when a beneficiary goes to his/her ophthalmologist for an eye examination with no specific complaint, the expenses for the examination are not covered even though as a result of such examination the doctor discovered a pathologic condition.

In the absence of evidence to the contrary, you may carrier may assume that an eye examination performed by an ophthalmologist on the basis of a complaint by the beneficiary or symptoms of an eye disease was not for the purpose of prescribing, fitting, or changing eyeglasses.

Expenses for all refractive procedures, whether performed by an ophthalmologist (or any other physician) or an optometrist and without regard to the reason for performance of the refraction, are excluded from coverage. (See §§4125 and 5217 for claims review and reimbursement instructions concerning refractive services.)

With the exception of vaccinations for pneumococcal pneumonia, hepatitis B, and influenza, which are specifically covered under the law, vaccinations or inoculations are generally excluded as immunizations unless they are directly related to the treatment of an injury or direct exposure such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin, or immune globulin.

## 2323. FOOT CARE AND SUPPORTIVE DEVICES FOR FEET

**NOTE:** See §4281 for the relationship between foot care and the coverage and billing of the diagnosis and treatment of peripheral neuropathy with loss of protective sensation (LOPS) in people with diabetes.

A. Exclusion of Coverage.--The following foot care services are generally excluded from coverage under both Part A and Part B. Exceptions to this general exclusion for limited treatment of routine foot care services are described in subsections A.2 and B. (See §4120 for procedural instructions in applying foot care exclusions.)

1. Treatment of Flat Foot.--The term "flat foot" is defined as a condition in which one or more arches of the foot have flattened out. Services or devices directed toward the care or correction of such conditions, including the prescription of supportive devices, are not covered.

2. Treatment of Subluxation of Foot.--Subluxations of the foot are defined as partial dislocations or displacements of joint surfaces, tendons ligaments, or muscles of the foot. Surgical or nonsurgical treatments undertaken for the sole purpose of correcting a subluxated structure in the foot as an isolated entity are not covered.

This exclusion does not apply to medical or surgical treatment of subluxation of the ankle joint (talo-crural joint). In addition, reasonable and necessary medical or surgical services, diagnosis, or treatment for medical conditions that have resulted from or are associated with partial displacement of structures is covered. For example, if a patient has osteoarthritis that has resulted in a partial displacement of joints in the foot, and the primary treatment is for the osteoarthritis, coverage is provided.

3. Routine Foot Care.--Except as provided in subsection B, routine foot care is excluded from coverage. Services that normally are considered routine and not covered by Medicare include the following:

- The cutting or removal of corns and calluses;

- The trimming, cutting, clipping, or debriding of nails; and

- Other hygienic and preventive maintenance care, such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of either ambulatory or bedfast patients, and any other service performed in the absence of localized illness, injury, or symptoms involving the foot.

B. Exceptions to Routine Foot Care Exclusion.--

1. Necessary and Integral Part of Otherwise Covered Services.--In certain circumstances, services ordinarily considered to be routine may be covered if they are performed as a necessary and integral part of otherwise covered services, such as diagnosis and treatment of ulcers, wounds, or infections.

2. Treatment of Warts on Foot.--The treatment of warts (including plantar warts) on the foot is covered to the same extent as services provided for the treatment of warts located elsewhere on the body.

3. Presence of Systemic Condition.--The presence of a systemic condition such as metabolic, neurologic, or peripheral vascular disease may require scrupulous foot care by a professional that in the absence of such condition(s) would be considered routine (and, therefore, excluded from coverage). Accordingly, foot care that would otherwise be considered routine may be covered when systemic condition(s) result in severe circulatory embarrassment or areas of diminished sensation in the individual's legs or feet. (See subsection C.)

In these instances, certain foot care procedures that otherwise are considered routine (e.g., cutting or removing corns and calluses, or trimming, cutting, clipping, or debriding nails) may pose a hazard when performed by a nonprofessional person on patients with such systemic conditions. (See §4120 for procedural instructions.)

4. Mycotic Nails.--In the absence of a systemic condition, treatment of mycotic nails may be covered.

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1. Carriers should conduct post-payment reviews of x-rays on a sample basis. Prepayment review should be undertaken in all questionable cases.

2. It is the responsibility of the treating chiropractor to make the documenting x-ray(s) available to the carrier's review staff. If x-rays are not made available, or suggest a pattern in failing to demonstrate subluxation for any reason, including unacceptable technical quality, the carrier should conduct prepayment review of x-rays in 100 percent of the subsequent claims for treatments by the practitioner involved until satisfied that the deficiency will no longer occur. Where there is no x-ray documentation of subluxation on prepayment review, the claims, of course, should be denied. (The last sentence of this paragraph only refers to claims with dates of service prior to January 1, 2000.)

3. The x-ray film(s) must have been taken at a time reasonably proximate to the initiation of the course of treatment and must demonstrate a subluxation at the level of the spine specified by the treating chiropractor on the claim. (See §2251.2B.)

4. An x-ray obtained by the chiropractor for his own diagnostic purposes before commencing treatment should suffice for claims documentation purposes. However, when subluxation was for treatment purposes diagnosed by some other means and x-rays are taken to satisfy Medicare's documentation requirement, carriers should ask chiropractors to cone in on the site of the subluxation in producing x-rays. Such a practice would not only minimize the exposure of the patient but also should result in a film more clearly portraying the subluxation.

5. An x-ray will be considered of acceptable technical quality if any individual trained in the reading of x-rays could recognize a subluxation if present.

6. When claims have been denied because the x-ray(s) initially offered failed to document the existence of a subluxation requiring treatment, no review of these decisions should be undertaken on the basis of x-ray(s) subsequently taken. Permitting such reviews could be an inducement to excessive exposure of patients to radiation in cases where the decision to treat was made despite x-rays that did not show a subluxation.

## 4119. DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER (DMERC) INSTRUCTIONS FOR DENYING CLAIMS FOR PRESCRIPTION DRUGS BILLED AND/OR PAID TO SUPPLIERS NOT LICENSED TO DISPENSE PRESCRIPTION DRUGS

A drug used as a supply with DME or a prosthetic device is not covered by Medicare if the drug is dispensed by an entity that is not licensed to dispense the drug. The drug is not considered to be reasonable and necessary because CMS cannot be assured of its safety and effectiveness unless it is dispensed by an entity that has a State license that qualifies it to dispense the drug. The equipment used with the drugs dispensed by a non-licensed entity is also considered to be not reasonable and necessary because of the related safety and efficacy concerns. Physicians are considered to have been “deemed” the right to dispense prescription drugs, and therefore do not require a pharmacy license.

DMERCs should deny claims for a prescription drug (and related equipment when billed on the same claim as the drug) when the National Supplier Clearinghouse’s (NSC’s) files show the supplier is or was not licensed to dispense the drugs on the date of service (DOS).

An exception to this general policy is oxygen claims.

Messages

Assigned Claims:

EOMB: "Medicare cannot pay for this drug/equipment because our records do not show your supplier is licensed to dispense prescription drugs, and, therefore, cannot assure the safety and effectiveness of the drug/equipment. You are not financially liable for any amount for this drug/equipment unless your supplier gave you a written notice in advance that Medicare would not pay for it and you agreed to pay." (EOMB message #8.98; MSN #8.50.)

Remittance for Drugs: "This service/procedure is denied/reduced when performed/billed by this type of provider, in this type of facility, or by a provider of this specialty." (Remittance advice code B6, with group code CO—the provider may not bill the beneficiary.)

Additionally, remark code M143: "We have no record that you are licensed to dispense drugs by the State in which you are located." Should appear on supplier remittance notices.

Non-Assigned Claims:

MSN: "This item or service is not covered when performed or ordered by this provider." (MSN #12.18)

Appeals

Follow instructions in the Medicare Carriers Manual, Part 3-Claims Process, §12000.

4120. FOOT CARE

**NOTE:** See §4281 for the relationship between foot care and the coverage and billing of the diagnosis and treatment of peripheral neuropathy with loss of protective sensation (LOPS) in people with diabetes.

4120.1 Application of Foot Care Exclusions to Physicians' Services.--The exclusion of foot care is determined by the nature of the service (§2323). Thus, reimbursement for an excluded service should be denied whether performed by a podiatrist, osteopath, or a doctor of medicine, and without regard to the difficulty or complexity of the procedure.

When an itemized bill shows both covered services and noncovered services not integrally related to the covered service, the portion of charges attributable to the noncovered services should be denied. (For example, if an itemized bill shows surgery for an ingrown toenail and also removal of calluses not necessary for the performance of toe surgery, any additional charge attributable to removal of the calluses should be denied.)

In reviewing claims involving foot care, the carrier should be alert to the following exceptional situations:

1. Payment may be made for incidental noncovered services performed as a necessary and integral part of, and secondary to, a covered procedure. For example, if trimming of toenails is required for application of a cast to a fractured foot, the carrier need not allocate and deny a portion of the charge for the trimming of the nails. However, a separately itemized charge for such excluded service should be disallowed. When the primary procedure is covered the administration of anesthesia necessary for the performance of such procedure is also covered.

2. Payment may be made for initial diagnostic services performed in connection with a specific symptom or complaint if it seems likely that its treatment would be covered even though the resulting diagnosis may be one requiring only noncovered care.

## 4281. PERIPHERAL NEUROPATHY WITH LOSS OF PROTECTIVE SENSATION (LOPS) IN PEOPLE WITH DIABETES

4281.1 Coverage.--In diabetes, peripheral neuropathy is an anatomically diffuse process primarily affecting sensory and autonomic fibers; however, distal motor findings may be present in advanced cases. Long nerves are affected first, with symptoms typically beginning insidiously in the toes and then advancing proximally. This leads to loss of protective sensation (LOPS), whereby a person is unable to feel minor trauma from mechanical, thermal, or chemical sources. When foot lesions are present, the reduction in autonomic nerve functions may also inhibit wound healing.

Peripheral neuropathy with LOPS, secondary to diabetes, is a localized illness of the feet and falls within the regulation's exception to the general exclusionary rule (see 42 C.F.R. §411.15(l)(l)(i)). Foot exams for people with diabetic peripheral neuropathy with LOPS are reasonable and necessary to allow for early intervention in serious complications that typically afflict diabetics with the disease.

Effective for services furnished on or after July 1, 2002, Medicare covers, as a physician service, an evaluation (examination and treatment) of the feet no more often than every 6 months for individuals with a documented diagnosis of diabetic sensory neuropathy and LOPS, as long as the beneficiary has not seen a foot care specialist for some other reason in the interim. LOPS shall be diagnosed through sensory testing with the 5.07 monofilament using established guidelines, such as those developed by the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. Five sites should be tested on the plantar surface of each foot, according to the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. The areas must be tested randomly since the loss of protective sensation may be patchy in distribution, and the patient may get clues if the test is done rhythmically. Heavily callused areas should be avoided. As suggested by the American Podiatric Medicine Association, an absence of sensation at two or more sites out of 5 tested on either foot when tested with the 5.07 Semmes-Weinstein monofilament must be present and documented to diagnose peripheral neuropathy with loss of protective sensation.

4281.2 Applicable Codes.--

A. HCPCS Codes.--

○ G0245 - Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include:

1. The diagnosis of LOPS.
2. A patient history.
3. A physical examination that consists of at least the following elements:
   (a) Visual inspection of the forefoot, hindfoot, and toe web spaces,
   (b) Evaluation of a protective sensation,
   (c) Evaluation of foot structure and biomechanics,
   (d) Evaluation of vascular status and skin integrity, and
   (e) Evaluation and recommendation of footwear.
4. Patient education.

**NOTE:** Each physician or physician group of which that physician is a member may receive reimbursement only once for G0245 for each beneficiary. However, should that

beneficiary need to see a new physician, that new physician may also be reimbursed once for G0245 for that beneficiary as long as it has been at least 6 months from the last time G0245 or G0246 was paid for the beneficiary, regardless of who provided the service.

- G0246 - Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a LOPS to include at least the following:

  1. A patient history.
  2. A physical examination that includes:

     (a) Visual inspection of the forefoot, hindfoot, and toe web spaces,

     (b) Evaluation of protective sensation,

     (c) Evaluation of foot structure and biomechanics,

     (d) Evaluation of vascular status and skin integrity, and

     (e) Evaluation and recommendation of footwear.

  3. Patient education.

- G0247 – Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include if present, at least the following:

  1. local care of superficial (i.e., superficial to muscle and fascia) wounds;
  2. debridement of corns and calluses; and
  3. trimming and debridement of nails.

**NOTE:** In order for CWF to process and edit LOPS claims correctly, G0247 must be billed on the same claim with the same date of service as either G0245 or G0246 in order to be considered for payment.

B. Short Descriptors.--

G0245 – INITIAL FOOT EXAM PTLOPS
G0246 – FOLLOWUP EVAL OF FOOT PT LOP
G0247 – ROUTINE FOOTCARE PT W LOPS

C. Diagnosis Codes.--The following diagnosis codes should be used in conjunction with this benefit: 250.60, 250.61, 250.62, 250.63, and 357.2.

4281.3 Payment Requirements.--G0245 – G0247 may be furnished and billed by any Medicare provider licensed to provide such services. Deductible and coinsurance apply. Type of service for these codes is 1.

4281.4 Standard Systems Edits.--The following edits are effective for claims with dates of service on or after January 1, 2003.

Edit 1 - Implement diagnosis to procedure code edits to allow payment for the LOPS codes, G0245, G0246, and G0247 only when submitted with one of the diagnosis codes 250.60, 250.61, 250.62, 250.63, or 357.2. Deny these services when submitted without one of the appropriate diagnoses and use the same messages you currently use for procedure to diagnosis code denials.

Edit 2 - Deny the service if G0245 is submitted more than once per beneficiary per physician or group practice, per beneficiary lifetime and return the following messages.

> Medicare Summary Notice (MSN) 17.17 - Medicare already paid for an initial visit for this service with this physician, another physician in his group practice or a provider. Your doctor or provider must use a different code to bill for subsequent visits.
>
> 17.17 - Medicare ya pagó una visita inicial por este servicio con este médico, otro médico de su mismo grupo, o un proveedor. Su médico o proveedor debe usar un código distinto para facturar visitas subsiguientes.
>
> Remittance advice (RA) claim adjustment reason code 96 – Non-covered charges, along with new remark code N113 – You or someone in your group practice has already submitted a claim for an initial visit for this beneficiary. Medicare pays only once per beneficiary per physician, group practice, or provider for an initial visit.

Edit 3 – Deny G0247 if it is not submitted on the same claim as G0245 or G0246 and return the following messages.

> MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.
>
> RA claim adjustment reason code 107 - Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.

4281.5 CWF Edits.--Though G0245 and G0246 have no technical or professional components, for these codes, CWF will post FI claims for bill types 13X, 74X, and 75X as technical, and carrier claims as professional. For bill type 85X with revenue code 940, CWF will post as technical. For 85X bill type with revenue code 98X, (Method II), CWF will post as technical and professional. This will allow both the facility and professional service payments to be approved by CWF for payment when the code and date of service match. Therefore, should a claim from a carrier and an FI be received with the same code and same date of service for the same beneficiary, the second claim submitted will not be rejected as a duplicate.

Due to the billing and payment methodology of Rural Health Clinics - bill type 71X and Federally Qualified Health Centers - bill type 73X, CWF will post these claims as usual, which will correctly allow claims from these entities that are billed to the FI to reject as duplicates when the HCPCS code, date of service, and beneficiary Health Insurance Claim number are an exact match with a claim billed to a carrier.

Carriers must follow current procedures for the disposition of these duplicate claims.

The following CWF utilization edits are effective for claims with dates of service on or after January 1, 2003.

Edit 1

Should CWF receive a claim from an FI for G0245 or G0246 and a second claim from a carrier for

either G0245 or G0246 (or vice versa) and they are different dates of service and less than 6 months apart, the second claim will reject. CWF will edit to allow G0245 or G0246 to be paid no more than every 6 months for a particular beneficiary, regardless of who furnished the service. If G0245 has been paid, regardless of whether it was posted as a facility or professional claim, it must be 6 months before G0245 can be paid again or G0246 can be paid. If G0246 has been paid, regardless of whether it was posted as a facility or professional claim, it must be 6 months before G0246 can be paid again or G0245 can be paid. CWF will not impose limits on how many times each code can be paid for a beneficiary as long as there has been 6 months between each service.

CWF will return a specific reject code for this edit that is identified in the CWF documentation. Based on the CWF reject code, deny the service and return the following messages:

MSN 18.4 -- This service is being denied because it has not been __ months since your last examination of this kind (NOTE**:** Insert 6 as the appropriate number of months.)

RA claim adjustment reason code 96 – Non-covered charges, along with remark code M86 – Service denied because payment already made for similar procedure within set time frame.

Edit 2

CWF will edit to allow G0247 to pay only if either G0245 or G0246 has been submitted and accepted as payable on the same date of service. CWF will return a specific reject code for this edit that is identified in the CWF documentation. Based on this reject code, deny the service and return the following messages:

MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.

RA claim adjustment reason code 107 - Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.

Edit 3

Once a beneficiary’s condition has progressed to the point where routine foot care becomes a covered service, payment will no longer be made for LOPS evaluation and management services. Those services would be considered to be included in the regular exams and treatments afforded to the beneficiary on a routine basis. The physician must then just bill the routine foot care codes along with the appropriate modifier.

CWF will edit to reject LOPS codes G0245, G0246, and/or G0247 when on the beneficiary’s record it shows that one of the following routine foot care codes were billed and paid within the prior six months: 11055, 11056, 11057, 11719, 11720, and/or 11721.

CWF will return a specific reject code for this edit that is identified in the CWF documentation. Based on the CWF reject code, deny the service and return the following messages:

MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.

RA claim adjustment reason code 96 – Non-covered charges, along with remark code M86 – Service denied because payment already made for similar procedure within set time frame.