Local Coverage Determination (LCD):
Label and Off-label Coverage of Outpatient Drugs and Biologicals (L33915)

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Contractor Information

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LCD Information

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

- Title XVIII of the Social Security Act: Section 1862(a)(1)(A) and Section 1833(e)
- CMS Online Manuals, Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50
- CMS Online Manuals, Pub 100-04, Medicare Claims Processing Manual, Chapter 17, Section 10
- CMS Online Manuals, Pub 100-4, Medicare Claims Processing Manual, Chapter 17, Section 40 and 80.8
- CMS Online Manuals, Pub 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13

Coverage Guidance

**Coverage Indications, Limitations, and/or Medical Necessity**

This local coverage determination (LCD) outlines general coverage criteria for drugs approved for marketing by the Food and Drug Administration (FDA) labeled use, as well as the off-labeled use in the absence of a National Coverage Determination (NCD) or a Medicare Administrative Contractor (MAC) LCD addressing a specific drug. This LCD also emphasizes documentation requirement that support the administration of a drug meets the Benefit category and the threshold of medically reasonable and necessary for the given patient.

The following is an excerpt from the Medicare Program Integrity Manual, Pub 100-08, Chapter 13, Section 13.5.1 and discusses when a service can be considered medically reasonable and necessary:

In order to be covered, a service shall be reasonable and necessary. Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is all of the following:

- Safe and effective; and
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:

1. Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
2. Furnished in a setting appropriate to the patient’s medical needs and condition;
3. Ordered and furnished by qualified personnel;
4. One that meets, but does not exceed, the patient’s medical need; and
5. At least as beneficial as an existing and available medically appropriate alternative.

Drugs approved for marketing by the FDA are considered safe and effective when used for indications specified on the labeling. Therefore, a FDA approved drug is allowed if the drug meets the following criteria:

- It was injected on or after the date of the FDA’s approval
The Medicare program provides limited benefits for outpatient drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them. Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals;
- They are of the type that are not usually self-administered;
- They meet all the general requirements for coverage of items as incident to a physician’s services;
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice;
- They are not excluded as noncovered immunizations; and
- They have not been determined by the FDA to be less than effective.

**Off Label Use of Drugs:**

Medicare Benefit Policy Manual Pub 100-02, Chapter 15, Section 50.4.2 states the following:

An unlabeled use of a drug is a use that is not included as an indication on the drug’s label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. In the case of drugs used in an anti-cancer chemotherapeutic regimen, unlabeled uses are covered for a medically accepted indication as defined in §50.5. These decisions are made by the contractor on a case-by-case basis.

Medicare Benefit Policy Manual Pub 100-02, Chapter 15, Section 50.4.5 states the following:

Effective January 1, 1994, off-label, medically accepted indications of Food and Drug Administration-(FDA) approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen are identified under the conditions described below. A regimen is a combination of anti-cancer agents clinically recognized for the treatment of a specific type of cancer. Off-label, medically accepted indications are supported in either one or more of the compendia or in peer-reviewed medical literature. The contractor may maintain its own subscriptions to the listed compendia or peer-reviewed publications to determine the medically accepted indication of drugs or biologicals used off-label in an anti-cancer chemotherapeutic regimen. Compendia documentation or peer-reviewed literature supporting off-label use by the treating physician may also be requested of the physician by the contractor.

The following listed compendia will be supported at the indicated levels:

- American Hospital Formulary Service-Drug Information (AHFS-DI)- indication is supportive
- NCCN Drugs and Biologicals Compendium- indication is a category 1 or 2A
- Thomson Micromedex DrugDex®-indication is Class 1, Class IIa or Class IIIb
- Clinical Pharmacology- indication is supportive
- Lexi-Drugs – indication is listed as “Use: Off-Label” and rated as “Evidence Level A”

In the absence of a NCD, LCD or coverage article from the contractor, coverage for an off-label indication must be requested in writing and must include data or documentation to support the request of coverage. Supporting documentation should include, but is not limited to the following (also refer to the documentation requirements section of this LCD):

- Published recommendations from specialty societies or other authoritative evidence-based guidelines
- At least one of the CMS approved compendium
- Phase II or phase III trials that have been published in national or international peer reviewed journals. The trials should be from different centers, and should not include publications from the pharmaceutical manufacturing companies.

If the contractor determines that the evidence, as supported by the criteria listed above, is supported, then off-label coverage will be outlined in an LCD or article.
Limitations

If an off-labeled use is determined to be not indicated by CMS or the FDA, or if the use is identified as not indicated by one of the above listed compendium, or if the use is determined not safe and effective based on peer reviewed medical literature, the off-labeled use will be considered by this contractor as not meeting the reasonable and necessary threshold, and therefore not covered. Regardless of the supporting evidence for coverage for an off-labeled use of a drug, payment may only be allowed if the contractor determines the use is reasonable and necessary for the treatment of an illness or injury of a patient receiving the drug.

Self Administered Drugs

CMS has determined that drugs are “usually” self administered if given more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore if a drug is self administered by more than 50 percent of the Medicare population, the drug is excluded from coverage, and the contractor may not allow payment for the drug.

As indicated previously in this LCD, the use of a drug must meet the medical necessity requirements as outlined by CMS, which also includes the route of drug administration. Contractors must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. That is, if a drug is available in both oral and injectable forms, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form. Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration.

In cases where IV versus PO equivalent is an issue, the physician should clearly address in the medical record, the medical rational/justification for the IV choice for a given patient when the PO form would have sufficed. Examples of when medical necessity for using the IV route include but are not limited to a patient with esophageal cancer and cannot swallow; a patient who had had recent head and neck irradiation and has severe mucositis and cannot swallow; a patient who is already suffering from severe nausea and vomiting when the medication is needed.

Medical necessity of an IV equivalent is not demonstrated in the cases where a patient has not taken the prescribed oral medication or for patient or provider convenience purposes.

This LCD summarizes coverage information “incident to” and not self-administered when there is not an active NCD or LCD or applicable CMS manual language.

Services related to non-covered services or drugs are also not covered (e.g. administration services).

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service.

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Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A
Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A
CPT/HCPCS Codes

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

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ICD-10 Codes that Support Medical Necessity

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

ICD-10 Codes that DO NOT Support Medical Necessity N/A

ICD-10 Additional Information [Back to Top]

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**General Information**

Associated Information

**Documentation Requirements**

For a newly approved FDA drug and/or in the absence of a unique HCPCS code, the drug must be billed using the appropriate unlisted drug code. The medical record must clearly support the medical necessity of any drug administered. When an unlisted HCPCs code is billed, the contractor will request documentation from the billing provider. Providers must submit the documentation that is requested in the development letter, which may include, but is not limited to relevant history and physical, any results of pertinent diagnostic tests or procedures, a physician’s order, the name of the drug or biological, the route of administration, the dosage (e.g., mgs, mcgs, cc's or IU’s), the duration of the administration, and any wastage of the drug or biological. When a portion of the drug or biological is discarded, whether from a single or multi-use vial, the medical record must clearly document the amount administered and the amount wasted or discarded.

For drugs with unique HCPCs codes in the absence of a NCD, LCD or published article, the medical necessity must clearly be documented in the patient’s medical record and available to the contractor upon request. The documentation that would support medical necessity may be the same as outlined in the above paragraph.

Request for coverage for any off-label drug usage, the LCD reconsideration process as outlined in the Program Integrity Manual, Pub. 100-08, Chapter 13, Section 13.11 as well as on the FCSO website at https://medicare.fcso.com/Coverage_Find_LCDs_and_NCDs/138575.asp, will be followed in determining the medical necessity for the off-label drug use. Documentation to support the request for coverage should include peer reviewed authoritative literature (full text copies), full copies of one or more of CMS approved compendia, supporting documentation for the dosage, administration, route, and frequency of administration. Also include the ICD-10 CM codes that would support the off-label indication being requested, as well as the administration schedules if different from the FDA approved drug label.

**Utilization Guidelines**

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It is expected that these services would be performed as indicated by current literature and/or standards of practice and should follow the guidelines for administration and safety found in the FDA approved labels for these drugs. When services are performed in excess of established parameters, they may be subject to medical review for medical necessity.

Sources of Information
FCSO reference LCD number – L32094 (PR/VI)

Blue Cross and Blue Shield of Florida medical coverage guideline for off-label use of FDA approved drugs.

National Government Services local coverage determination, L25820, Coverage for Drugs and Biological for label and off-label uses.

Trailblazer Health Enterprises local coverage determination, L26756, Drugs and Biologicals, non-chemotherapeutic.

Bibliography
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Revision History Information

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| 02/10/2016 R1         |                         | **Explanation of revision:** Based on CR 9386 (Medicare Benefit Policy Manual, Pub. 100.02, Chapter 15, Section 50.4.5) the LCD was revised to add Lexi-Drugs to the list of authoritative compendia in the “Indications and Limitations of Coverage and/or Medical Necessity” section of the LCD under “Off Label Use of Drugs”. The effective date of this revision is for claims processed on or after 02/10/16, for dates of service on or after 08/12/15. 07/21/2017: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this policy.

* Provider Education/Guidance

Associated Documents

Attachments N/A
Keywords

N/A Read the LCD Disclaimer Back to Top