LCD - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
National Government Services, Inc.	MAC - Part A	06101 - MAC A	J - 06	Illinois
National Government Services, Inc.	MAC - Part B	06102 - MAC B	J - 06	Illinois
National Government Services, Inc.	MAC - Part A	06201 - MAC A	J - 06	Minnesota
National Government Services, Inc.	MAC - Part B	06202 - MAC B	J - 06	Minnesota
National Government Services, Inc.	MAC - Part A	06301 - MAC A	J - 06	Wisconsin
National Government Services, Inc.	MAC - Part B	06302 - MAC B	J - 06	Wisconsin
National Government Services, Inc.	A and B and HHH MAC	13101 - MAC A	J - K	Connecticut
National Government Services, Inc.	A and B and HHH MAC	13102 - MAC B	J - K	Connecticut
National Government Services, Inc.	A and B and HHH MAC	13201 - MAC A	J - K	New York - Entire State
National Government Services, Inc.	A and B and HHH MAC	13202 - MAC B	J - K	New York - Downstate
National Government Services, Inc.	A and B and HHH MAC	13282 - MAC B	J - K	New York - Upstate
National Government Services, Inc.	A and B and HHH MAC	13292 - MAC B	J - K	New York - Queens
National Government Services, Inc.	A and B and HHH MAC	14111 - MAC A	J - K	Maine
National Government Services, Inc.	A and B and HHH MAC	14112 - MAC B	J - K	Maine
National Government Services, Inc.	A and B and HHH MAC	14211 - MAC A	J - K	Massachusetts
National Government Services,	A and B and HHH	14212 - MAC B	J - K	Massachusetts

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Inc.	MAC			
National Government Services, Inc.	A and B and HHH MAC	14311 - MAC A	J - K	New Hampshire
National Government Services, Inc.	A and B and HHH MAC	14312 - MAC B	J - K	New Hampshire
National Government Services, Inc.	A and B and HHH MAC	14411 - MAC A	J - K	Rhode Island
National Government Services, Inc.	A and B and HHH MAC	14412 - MAC B	J - K	Rhode Island
National Government Services, Inc.	A and B and HHH MAC	14511 - MAC A	J - K	Vermont
National Government Services, Inc.	A and B and HHH MAC	14512 - MAC B	J - K	Vermont

LCD Information

Document Information

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LCD Title
Drugs and Biologicals, Coverage of, for Label and Off-Label Uses

Proposed LCD in Comment Period
N/A

Source Proposed LCD
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For services performed on or after 10/01/2015

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For services performed on or after 11/01/2022

Revision Ending Date
N/A

Retirement Date

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

N/A

Notice Period Start Date
09/15/2022

Notice Period End Date
10/31/2022

Issue

Issue Description

An off-label/unlabeled use of a drug is defined as a use for a non-FDA approved indication, that is, one that is not listed on the drug's official label/prescribing information. An indication is defined as a diagnosis, illness, injury, syndrome, condition, or other clinical parameter for which a drug may be given. Off-label use is further defined as giving the drug in a way that deviates significantly from the labeled prescribing information for a particular indication. This includes but is not necessarily limited to, dosage, route of administration, duration and frequency of administration, and population to whom the drug would be administered. Drugs used for indications other than those in the approved labeling may be covered under Medicare if it is determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literatures and/or accepted standards of medical practice. Determinations as to whether medication is reasonable and necessary for an individual patient are made on appeal on the same basis as all other such determinations (i.e., with support from the peer-reviewed literature, with the advice of medical consultants, with reference to accepted standards of medical practice, and in consideration of the medical circumstance of the individual case).

Based on Pub 100-02, Chapter 15, Section 50.4.5 D and Pub 100-02, Chapter 15, Section 50.4.5 B, the Nivolumab and Filgrastim articles which represent 100% antineoplastic drugs are being removed from this LCD. Also, the Rituximab and IVIG articles will be removed and will become new LCDs. Additionally, references and provisions related to these four drug articles will be removed from the LCD.

Issue - Explanation of Change Between Proposed LCD and Final LCD

N/A

CMS National Coverage Policy

Language quoted from Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. 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 Section 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 (SSA):

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

CMS Publications

CMS Publication Pub 100-02, *Medicare Benefit Policy Manual,* Chapter 15:

50 - Drugs and Biologicals

50.4.5 - Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

CMS Publication 100-04, *Medicare Claims Processing Manual,* Chapter 17:

10 - Payment Rules for Drugs and Biologicals

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Abstract:

An off-label/unlabeled use of a drug is defined as a use for a non-FDA approved indication, that is, one that is not listed on the drug's official label/prescribing information. An indication is defined as a diagnosis, illness, injury, syndrome, condition, or other clinical parameter for which a drug may be given. Off-label use is further defined as giving the drug in a way that deviates significantly from the labeled prescribing information for a particular indication. This includes but is not necessarily limited to, dosage, route of administration, duration and frequency of administration, and population to whom the drug would be administered. Drugs used for indications other than those in the approved labeling may be covered under Medicare if it is determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literatures and/or accepted standards of medical practice. Determinations as to whether medication is reasonable and necessary for an individual patient are made on appeal on the same basis as all other such determinations (i.e., with support from the peer-reviewed literature, with the advice of medical consultants, with reference to accepted standards of medical practice, and in consideration of the medical circumstance of the individual case).

In the case of drugs used in an anti-cancer chemotherapeutic regimen, off-label uses are covered for a medically accepted indication as defined in the *Medicare Benefit Policy Manual* (CMS publication 100-2, Chapter 15, Section 50.4.5).

In order to meet the requirement that the use of the drug is reasonable and necessary for the treatment of disease, the drugs must be safe and effective. Drugs approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective when used for indications specified on the labeling. Therefore, Medicare pays for the use of a FDA-approved drug, if:

- It was injected on or after the date of the FDA's approval;
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met.

Indications:

A medically accepted indication, which is covered by National Government Services is one of the following:

1. An FDA approved, labeled indication or a use supported in the American Hospital Formulary Service Drug Information (AHFS-DI), NCCN Drugs and Biologics Compendium, Truven Health Analytics Micromedex DrugDex®, Elsevier/Gold Standard Clinical Pharmacology and Wolters Kluwer Lexi-Drugs® as the acceptable compendia based on CMS' Change Request 6191 (Compendia as Authoritative Sources for Use in the Determination of a "Medically Accepted Indication" of Drugs and Biologicals Used Off-Label in an Anti-Cancer Chemotherapeutic Regimen); or
2. Articles or Local Coverage Determinations (LCDs) published by National Government Services.

The compendia listed above will be accepted at the following levels;

- American Hospital Formulary Service-Drug Information (AHFS-DI) – indication is supportive
- NCCN Drugs and Biologics Compendium - indication is a Category 1 or 2A
- Micromedex DrugDex® – indication is Class I, Class IIa, or Class IIb or
- Clinical Pharmacology – indication is supportive
- Lexi-Drugs - indication is rated as “Evidence Level A”

When new off-label uses for drugs are published in the above compendia at the accepted level of recommendation, the effective date for National Government Services coverage of those off-label uses is the date of publication of our revised coverage article, not the date of inclusion in the compendia.

In an effort to limit the number of LCD's or articles related to off label indications for drug use, National Government Services will publish articles relating to drugs approved for off-label use for which there is a need for education or concern about utilization. These articles will include drugs with links to their FDA approved and compendia approved uses as listed in the American Hospital Formulary Services (AHFS), Elsevier/Gold Standard Clinical Pharmacology, NCCN Drugs and Biologics Compendium, Truven Health Analytics Micromedex DrugDex® compendium and/or Wolters Kluwer Lexi-Drugs®. Only off-label uses requested by providers according to the following criteria will be considered for inclusion.

Providers may request that a drug be approved for off-label use by submitting this request in writing and including the data supporting its use. The data must include:

a. A use supported by clinical research that appears in at least two Phase III clinical trials that definitively demonstrate safety and effectiveness; or,
b. If no Phase III trial evidence is available, at least two Phase II clinical trials with reasonably large patient samples showing consistent results of safety and efficacy may be considered in certain instances such as use in rare diseases in which a Phase III study might be difficult to complete in a reasonable period of time after completion of the Phase II studies, or when overwhelmingly good evidence of safety and effectiveness is noted in the Phase II studies.
c. A use that is an accepted standard of medical practice. "Are there published recommendations from specialty societies or in other authoritative evidence-based guidelines?" (For example, a state of the art review article published in a recognized textbook or a reputable publication) It should be noted that acceptance by individual health care practitioners, or even a limited group of health care practitioners normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with potential financial conflict of interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality must be evaluated before a conclusion is reached.

The Phase III or Phase II trials must come from different centers and be published in national or international peer-reviewed (editorial committee is comprised of physicians) journals. Peer reviewed medical literature includes scientific and medical publications. It does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts).

In principle, rankings of research design have been based on the ability of each study design category to minimize bias. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series and
- Single case reports

The design, conduct and analysis of trials are important factors as well. For example, a well designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size.

In determining whether there is supportive clinical evidence for a particular use of a drug, the quality of the published evidence must be considered. Such consideration involves the assessment of the following study characteristics:

- The adequacy of the number of subjects;
- The response rate;
- The effect on key status and survival indications. That is, the effect on the patient's well-being and other responses to therapy that indicate effectiveness (e.g., reduction in mortality, morbidity, signs and symptoms);
- The appropriateness of the study design, that is, whether the experimental design in light of the drugs and conditions under investigation is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); and
- The prevalence and life history of the disease when evaluating the adequacy of the number of subjects and the response rate.

After such evidence is received, National Government Services will, with appropriate help of specialty-specific consultants as indicated, make a coverage determination for the non-FDA approved indication (off-label use) of the drug or biological.

National Government Services may determine a drug use to be reasonable and necessary for the treatment of illness or injury if, on the basis of available or presented evidence, if it is shown to be safe and effective and does not violate national or local Medicare determinations and regulations. The approval will include, but is not limited to, diagnosis, dose and route of administration, duration and frequency, and appropriate patient population.

Limitations:

If a use is identified as not indicated by CMS or the FDA, or if a use is specifically identified as not indicated in the American Hospital Formulary Services (AHFS), Elsevier/Gold Standard Clinical Pharmacology, NCCN Drugs and

Biologics Compendium, Truven Health Analytics Micromedex DrugDex® and/or Wolters Kluwer Lexi-Drugs® compendium, the off-label use is not supported and the drug will not be covered.

Regardless of the evidence supporting coverage for a particular off-label use, payment may only be made if the use is reasonable and necessary for the treatment of illness or injury of the specific patient receiving the drug.

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

Upon review, if the drug use is not on the FDA label, does not appear on the American Hospital Formulary Services (AHFS), Elsevier/Gold Standard Clinical Pharmacology, NCCN Drugs and Biologics Compendium, Truven Health Analytics Micromedex DrugDex® and/or Wolters Kluwer Lexi-Drugs® compendium or National Government Services has not published an LCD or article covering the off-label use as listed below, then the drug use is not approved and the use of the drug may be denied. However, determinations as to whether medication is reasonable and necessary for an individual patient may be made on appeal on the same basis as all other such determinations (i.e., with support from the peer-reviewed literature, with the advice of medical consultants, with reference to accepted standards of medical practice, and in consideration of the medical circumstance of the individual case).

The route of administration must be reasonable and necessary as well as the drug. (Pub 100-02, *Medicare Benefit Policy Manual,* Chapter 15, Section 50.2 - Determining Self-Administration of Drug or Biological (Rev. 91; Issued: 06-20-08; Effective/Implementation Date: 07-21-08)). National Government Services will use evidence-based clinical guidelines to determine medical necessity of the route of administration.

Specific Drugs and Biological Coverage

FDA and approved Compendia Uses

The following drugs will be covered for their FDA approved uses as well as their approved compendia uses.

Bevacizumab and biosimilars

Bortezomib

Denosumab (Prolia ™, Xgeva ™)

Hyaluronans Intra-articular Injections of

Omalizumab

Ranibizumab and Aflibercept

FDA, approved Compendia and Off-label Uses

The following drug will be covered for off label uses described below in addition to their FDA approved use and approved compendia uses.

Eculizumab - NGS has approved eculizumab for biopsy proven dense deposit disease.

Ibandronate Sodium - NGS has approved ibandronate for senile osteoporosis in male patients.

Infliximab and biosimilars - NGS has approved infliximab for the following:

- Behçet's Disease (BD), also known as Behçet's Syndrome, in patients without an adequate response to initial therapy, for the treatment of clinical manifestations of BD such as severe ocular involvement, major organ involvement, severe gastrointestinal or neurological involvement and resistant cases of joint or mucocutaneous involvement (i.e., painful oral and genital ulcers).
- Pyoderma gangrenosum with coexisting inflammatory bowel disease.
- Sarcoid refractory to treatment with steroids and other standard drug regimens.
- Severe immune-related colitis that does not respond promptly (within 1 week) to therapy with high-dose steroids. A single dose of infliximab is sufficient to resolve immune-related colitis in most patients.

Luteinizing Hormone-Releasing Hormone (LHRH) Analogs - NGS has approved Leuprolide Acetate for the following:

- Carcinoma, breast (treatment): palliative treatment of advanced breast carcinoma in premenopausal and perimenopausal women
- Suspected endometriosis causing chronic (6 months or more) pelvic pain after an appropriate pretreatment evaluation (to exclude other causes) and failure of initial treatment with OCs and NSAIDs; not to continue beyond 3 months if there is not significant symptomatic improvement
- Head and Neck cancers-salivary gland tumors

Goserelin Acetate - NGS has approved Goserelin Acetate for the following:

- Treatment of leiomyomata: 3.6 mg per month for short duration (3-6 months).

Paclitaxel (e.g., Taxol®/Abraxane ™) - NGS has approved paclitaxel for the following:

- Hormone refractory prostate carcinoma
- Carcinoma of the renal pelvis and ureter
- Rhabdomyosarcoma
- Leiomyosarcoma

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

N/A

Sources of Information

N/A

Bibliography

This bibliography presents those sources that were obtained during the development of this policy. National Government Services is not responsible for the continuing viability of Web site addresses listed below.

Decision Memo for Anticancer Chemotherapy for Colorectal Cancer (CAG-00179N), Appendix B, The Centers for Medicare and Medicaid Services, January 28, 2005.

Based on a reconsideration the following sources have been added:

Jacobsen PB, Bovbjerg DH, Redd WH. Anticipatory anxiety in women receiving chemotherapy for breast cancer. *Health Psychology.* 1993;12(6):469-475.

Osoba D, Zee B, Pater J, Warr D, Latreille J, Kaizer L. Determinants of postchemotherapy nausea and vomiting in patients with cancer. *J Clin Oncol.* 1997;15(1):116-123.

Petrella T, Clemons M, Joy A, Young S, Callaghan W, Dranitsaris G. Identifying patients at high risk for nausea and vomiting after chemotherapy: the development of a practical validated prediction tool. *J Support Oncol.* 2009;7(4):W1-W8.

Shih V, Wan HS, Chan A. Clinical predictors of chemotherapy-induced nausea and vomiting in breast cancer patients receiving adjuvant doxorubicin and cyclophosphamide. *Ann Pharmacother.* 2009;43:444-452.

Tsavaris N, Kosmas C, Mylonakis N, et al. Parameters that influence the outcome of nausea and emesis in cisplatin based chemotherapy. *Anticancer Research.* 2000;20:4777-4784.

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
11/01/2022	R15	The LCD has been revised to remove all references to rituximab, filgrastim, IVIG and nivolumab.	• Provider Education/Guidance • Public Education/Guidance
11/07/2019	R14	Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A52855. There has been no change in coverage with this LCD revision.	• Revisions Due To Code Removal
08/22/2019	R13	Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization	• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A52855. There has been no change in coverage with this LCD revision.	
12/01/2017	R12	Based on a reconsideration request for coverage for biopsy proven dense deposit disease for eculizumab, the article for Eculizumab (A54548) has been revised to update the "Indications expanded per this article" section and to add ICD-10-CM codes N00.6, N01.6, N02.6, N03.6, N04.6, N07.6 and T86.19 effective for dates of service on or after 12/01/2017. References have been added to the "Sources of Information" section of the article. Treatment of adult patients with generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody positive (Effective October 23, 2017 based on FDA approval) has been added to the "Indications" section of the article. ICD-10-CM codes G70.00 and G70.01 have been added to the Group 1 code section effective for dates of service on or after 10/23/2017. The first paragraph in the "Indications" section of the article has been revised to include Lexi-Drug compendium. Lexi-Drug Web site has been added to the "Sources of Information" section of the article. *DATE (12/01/2017): 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.*	• Reconsideration Request
11/01/2017	R11	Based on a reconsideration request for coverage for immune-mediated colitis for infliximab, the article for Infliximab (A52423) has been revised to update the "Indications expanded per this article" section of the article and to add ICD-10-CM code K52.1 effective for dates of service on or after 11/01/2017. References have also been added to the "Sources of Information" section of the article. An indication for recurrent adult intracranial and spinal ependymoma (excluding subependymoma) has been added to the "NON-OPHTHALMOLOGIC INDICATIONS" section of article A52370 for Bevacizumab. The indication for glioblastoma multiforme of brain has been revised to add "recurrent anaplastic gliomas" and "as a single agent or in	• Reconsideration Request

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		combination with irinotecan, carmustine/lomustine or temozolomide." ICD-10-CM code C72.0 has been added to Group 1 effective for dates of service on or after 11/01/2017. *DATE (11/01/2017): 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.*	
08/01/2016	R10	Based on a reconsideration request for coverage for suspected endometriosis causing chronic pelvic pain for leuprolide acetate, the Luteinizing Hormone-Releasing Hormone (LHRH) Analogs article (A52453) has been revised to add 10-CM code R10.2 for leuprolide acetate effective for dates of service on or after 08/01/2016. A clarification was added to the indications for Tbo-filgrastim in article A52408 - Filgrastim, Pegfilgrastim, Tbo-filgrastim, Filgrastim-sndz (e.g., Neupogen®, Neulasta ™, Granix ™ Zarxio™). ICD-10-CM code D70.2 was added for filgrastim and filgrastim-sndz retroactive to 10/01/2015. The Hyaluronans Intra-articular Injections of article (A52420) has been revised to clarify repeat courses of injections.	• Provider Education/Guidance
06/01/2016	R9	Based on a reconsideration request for antibody mediated rejection (AMR) for bortezomib, the Bortezomib article (A52371) has been revised to add sources and an indication for non-hodgkin lymphoma – Castleman's disease in addition to adding ICD-10-CM codes. The Filgrastim, Pegfilgrastim, Tbo-filgrastim, Filgrastim-sndz (e.g., Neupogen®, Neulasta ™, Granix ™ Zarxio™) article (A52408) has been revised to add indications for Tbo-filgrastim in addition to adding ICD-10-CM codes.	• Provider Education/Guidance
05/01/2016	R8	Based on a reconsideration request for infliximab, Infliximab article (A52423), the indication for ankylosing spondylitis has been revised to indicate treatment with TNF alpha-inhibitors as "second line" after NSAIDS and the American College of Rheumatology guidelines have been added to the "Sources of Information" section. The Bevacizumab article (A52370) has been revised to add ICD-10-CM codes.	• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
04/01/2016	R7	The LCD has been revised to add article A54862 - Nivolumab (Opdivo®) to the LCD effective for dates of service on or after 04/01/2016. Article A54863 has been added as the Comment and Response document for nivolumab.	• Provider Education/Guidance
02/04/2016	R6	Based on a reconsideration request for graft vs host disease (GVHD) for infliximab, the Infliximab article (A52423) has been revised to add sources. The Rituximab article (A52452) has also been revised to add sources for neuropathy with IgM monoclonal gammopathy based on a reconsideration request. The Denosumab article (A52399) has been revised to add ICD-10-CM codes.	• Provider Education/Guidance
01/01/2016	R5	Based on CMS Transmittal 212, the list of compendia has been updated to add Wolters Kluwer Lexi-Drugs® as an authoritative source for use in the determination of a medically accepted indication of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen effective for services on or after August 12, 2015. Clinical Pharmacology has been revised to Elsevier/Gold Standard Clinical Pharmacology and Thomson Micromedex DrugDex has been revised to Truven Health Analytics Micromedex DrugDex. The following articles have been revised based on ICD-10-CM updates, Denosumab (A52399), IVIG (A52446), Omalizumab (A52448) and Rituximab (A52452) and the following articles have been updated based on the annual 2016 HCPCS update, Filgrastim (A52408) and Hyaluronans (A52420).	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes
12/01/2015	R4	Based on a reconsideration request, the indication for psoriatic arthropathy has been revised in the Infliximab article (A52423). The Bevacizumab article (A52370) has been revised to add an indication for malignant pleural mesothelioma. The Rituximab article (A52452) has been revised to add Microscopic Polyangiitis (MPA) which was inadvertently removed with the last update to the ICD-9-CM article. ICD-10-CM codes have been added to the following drug articles: Bevacizumab (A52370), Paclitaxel (A52450), IVIG (A52446) and Rituximab (A52452).	• Provider Education/Guidance
10/01/2015	R3	The LCD has been revised to add a "Specific Drugs and Biological Coverage" section to the "Coverage Indications, Limitations and/or Medical Necessity" section of the LCD. The following articles have been updated to add ICD-10-CM codes: Ibandronate article (A52421), Infliximab article (A52423) and the Zoledronic Acid article (A52455). The	• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		Filgrastim article (A52408) has been updated to include information on filgrastim-sndz in addition to an ICD-10-CM code addition.	
10/01/2015	R2	Based on provider comment, ICD-10-CM code M85.88 has been added to the Ibandronate article (A52421) and the Zoledronic Acide article (A52455).	• Request for Coverage by a Practitioner (Part B)
10/01/2015	R1	The LCD has been revised to add article A54548 for eculizumab (Soliris®) to the LCD effective for dates of service on or after 10/01/2015. Article A54549 has been added as the Comment and Response document for eculizumab.	• Other

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A52370 - Billing and Coding: Bevacizumab and biosimilars
A52371 - Billing and Coding: Bortezomib
A52399 - Billing and Coding: Denosumab (Prolia ™, Xgeva ™)
A52855 - Billing and Coding: Drugs and Biologicals
A54548 - Billing and Coding: Eculizumab
A52420 - Billing and Coding: Hyaluronans Intra-articular Injections of
A52421 - Billing and Coding: Ibandronate Sodium
A52423 - Billing and Coding: Infliximab and biosimilars
A52453 - Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs
A52448 - Billing and Coding: Omalizumab
A52450 - Billing and Coding: Paclitaxel (e.g., Taxol®/Abraxane ™)
A52451 - Billing and Coding: Ranibizumab, Aflibercept and Brolucizumab-dbll and Faricimab-svoa
A59216 - Response to Comments: Drugs and Biologicals, Coverage of, for Label and Off-Label Uses

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
09/09/2022	11/01/2022 - N/A	Currently in Effect (This Version)
11/01/2019	11/07/2019 - 10/31/2022	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A