

**i FUTURE Local Coverage Article:  
Rituximab (Rituxan®) (effective 2010) - Related to LCD L33394 (A52452)**

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**Contractor Information**

Contractor Name	Contract Number	Contract Type	Jurisdiction
National Government Services, Inc.	13202	A and B and HHH MAC	J - K

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**Article Information**

**General Information**



**Article ID**  
A52452

**Original ICD-9 Article ID**  
[A49636](#)

**Article Title**  
Rituximab (Rituxan®) (effective 2010) - Related to LCD L33394

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**Jurisdiction**  
New York - Downstate

**Original Effective Date**  
10/01/2015

**Revision Effective Date**  
10/01/2015

**Revision Ending Date**  
N/A

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N/A

## Article Guidance

### Article Text:

This article defines coding and coverage for rituximab including off-label indications. National Government Services Local Coverage Determination (LCD) "Coverage of Drugs and Biologicals for Label and Off-Label Uses" allows coverage for off-label indications only if the United States Pharmacopeia Drug Information (USP-DI), the American Hospital Formulary Services (AHFS) and/or Thomson Healthcare DrugPoints® (as described in the LCD) define such indications or if National Government Services has published an article or LCD expanding such coverage. Effective for dates of service on or after 11/25/2008, American Hospital Formulary Services (AHFS), Clinical Pharmacology, NCCN Drugs and Biologics Compendium and/or Thomson Micromedex DrugDex® compendium has replaced the USP-DI and Thomson Healthcare DrugPoints®. Providers may request approval for additional off-label indications by submitting this request in writing with supporting medical literature. The aforementioned National Government Services LCD, which describes the requirements for such a request, can be accessed through our contractor Web site at [www.NGSMedicare.com](http://www.NGSMedicare.com) or on the Medicare Coverage Database at [www.cms.gov/medicare-coverage-database](http://www.cms.gov/medicare-coverage-database).

### Indications:

Rituximab is a CD20-directed cytolytic antibody indicated for the treatment of the following:

#### Non-Hodgkin's Lymphoma (NHL)

Rituxan® (rituximab) is indicated for the treatment of patients with:

- Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and in patients achieving a complete or partial response to rituxan® in combination with chemotherapy, as single-agent maintenance therapy
- Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent, after first-line CVP chemotherapy
- Previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP or other anthracycline-based chemotherapy regimens.

Rituximab in combination with methotrexate is indicated for the treatment of adult patients with moderately-to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Rituximab is also used in combination with ibritumomab tiuxetan for both the diagnostic (treatment planning) and therapeutic administrations.

Acute lymphocytic leukemia  
 Acquired blood factor deficiency  
 Autoimmune hemolytic anemia  
 B-cell lymphoma  
 Central nervous system cancers – leptomeningeal metastases  
 Chronic lymphoid leukemia, in combination for first-line treatment  
 Chronic lymphoid leukemia, relapsed or refractory  
 Evans syndrome, refractory to immunosuppressive therapy  
 Graft-versus-host disease, chronic, Steroid-refractory  
 Hodgkin's disease CD20-positive, as monotherapy  
 Human herpesvirus 8 (HHV-8) infection  
 Minimal change disease, refractory, steroid-dependent or steroid-resistant  
 Multicentric Castleman's disease (MCD)  
 Pemphigus vulgaris and other autoimmune blistering skin diseases (for example, pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquisita and paraneoplastic pemphigus) when refractory  
 Post-transplant lymphoproliferative disorder  
 Primary Sjögren's syndrome  
 Relapsing-remitting multiple sclerosis  
 Systemic lupus erythematosus, refractory to immunosuppressive therapy  
 Thrombocytopenic purpura, immune or idiopathic  
 Waldenstrom's macroglobulinemia  
 Wegener's granulomatosis (severe), refractory, in combination with corticosteroids

### Indications expanded by this article:

Pre-transplant to suppress panel reactive anti- HLA antibodies in individuals with high panel reactive antibody (PRA) levels to human leukocyte antigens (HLA).

Neuromyelitis optica

Dermatomyositis and polymyositis in patients who have been refractory to other standard therapies.

For the treatment of patients who are refractory to the standard therapies for Grave's disease/ophthalmopathy.

### Coding Information:

#### For claims submitted to the Part B MAC:

Rituximab should be billed using chemotherapy administration codes and is payable in the following places of service: office (11), skilled nursing home for patients in a Part A stay (31) [if the drug is supplied by the facility, no claims for the drug should be submitted to the Part B MAC], nursing facility for patients not in a Part A stay (32) and independent clinic (49) only when supplied as an "incident to" service by the physician.

### Sources of Information:

American Society of Health-System Pharmacists, Inc. *AHFS Drug Information*®. Bethesda, MD: 2007.

Clinical Pharmacology Web site. <http://www.clinicalpharmacology.com/>. Accessed 11/13/2013.

Cree S, Lamb K, Morgan A, Chen E, Waubant, Genain C. An open label study of the effects of rituximab in neuromyelitis optica. *Neurology*. 2005;64:1270-1272.

National Comprehensive Cancer Network Web site. <http://www.nccn.org/index.asp>. Accessed 11/13/2013.

Tyde G, Genberg H, Tollemar J, et al. A randomized, doubleblind, placebo-controlled, study of single-dose rituximab as induction in renal transplantation. *Transplantation*. 2009;87:1325-1329.

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U.S. Food and Drug Administration label approved 10/16/2009. Drugs@FDA Web site. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>. Accessed 12/04/2009.

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Vo AA, Peng A, Toyoda M, et al. Use of intravenous immune globulin and rituximab for desensitization of highly HLA-sensitized patients awaiting kidney transplantation. *Transplantation*. 2010;89(9):1095-1102.

Based on a reconsideration the following sources have been added:

Chung L, Genovese MC, Fiorentino DF. A pilot trial of rituximab in the treatment of patients with dermatomyositis. *Arch Dermatol*. 2007;143:763-767.

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Mok CC, Ho Ly, To CH. Rituximab for refractory polymyositis: An open-label prospective study. *J Rheumatol*. 2007;34:1864-1868.

Noss EH, Hausner-Sypek DL, Weinblatt ME. Rituximab as therapy for refractory polymyositis and dermatomyositis. *J Rheumatol*. 2006;33:1021-1026.

Khanna D, Chong KKL, Affyan NF, et al. Rituximab treatment of patients with severe, corticosteroid-resistant thyroid-associated ophthalmopathy. *Ophthalmology*. 2010;117(1):133-139.e2.

Salvi M, Vannucchi G, Campi I, et al. Treatment of Graves' disease and associated ophthalmopathy with the anti-CM20 monoclonal antibody rituximab: an open study. *European Journal of Endocrinology*. 2007;156:33-40.

The following sources were added as a result of a reconsideration request received July 24, 2012:

Irani SR, Michell AW, Lang B, et al. Faciobrachial dystonic seizures precede Lgi1 antibody limbic encephalitis. *Ann Neurol*. 2011;69:892-900.

Vernino S, Geschwind M, Boeve B. Autoimmune encephalopathies. *The Neurologist*. 2007;13:140-147.

The following sources were added as a result of a reconsideration request received December 26, 2012:

Münch C, Anagnostou P, Meyer R, Haas J. Rituximab I chronic inflammatory demyelinating polyneuropathy associated with diabetes mellitus. *Journal of the Neurological Sciences*. 2007;256:100-102.

Benedetti L, Briani C, Franciotti D, et al. Rituximab in patients with chronic inflammatory demyelinating polyradiculoneuropathy: a report of 13 cases and review of the literature. *J Neural Neurosurg Psychiatry*. 2011;82:306-308.doi:10.1136/mnp.2009.188912.

Cocilo D, Grimaldi S, Paolasso I, et al. Immunosuppressive treatment in refractory chronic inflammatory demyelinating polyradiculoneuropathy. A nationwide retrospective analysis. *European Journal of Neurology*. 2011;10:1417-1421.

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Knecht H, Baumberger M, Tobón A, Steck A. Sustained remission of CIDP associated with Evans syndrome. *Neurology*. 2004;63(4):730-732.

Pestronk A, Florence J, Miller T, Choksi R, Al-Lozi MT, Levine TD. Treatment of IgM antibody associated polyneuropathies using rituximab. *J Neurol Neurosurg Psychiatry*. 2003;74(4):485-489.

Levine TD, Pestronk A. IgM antibody-related polyneuropathies: B-cell depletion chemotherapy using rituximab. *Neurology*. 1999;52(8):1701-1704.

Based on a reconsideration request the following sources have been added:

Díaz-Manera J, Martínez-Hernández, E, Querol L, et al. Long-lasting treatment effect of rituximab in MuSK myasthenia. *Neurology*. 2012 Jan 17;78(3):189-193. doi:10.1212/WNL.0b013e3182407982. Epub 2012 Jan 4.

Lebrun C, Bourg V, Tieuilie N, Thomas P. Successful treatment of refractory generalized myasthenia gravis with rituximab. *European Journal of Neurology*. 2009 Feb;16(2):246-250. doi:10.1111/j.1468-1331.2008.02399.x.

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De Vita S, Quartuccio L, Isola M, et al. A randomized controlled trial of rituximab for the treatment of severe cryoglobulinemic vasculitis. *Arthritis Rheum*. 2012 Mar;64(3):843-853. doi: 10.1002/art.34331.

Fervenza FC, Leise MD, Roccatello D, Kyle RA. Treatment of the mixed cryoglobulinemia syndrome. [www.uptodate.com](http://www.uptodate.com). ©2013 UpToDate®

Gottenberg JE, Cinquetti G, Larroche C, et al. Efficacy of rituximab in systemic manifestations of primary Sjögren's syndrome: results on 78 patients of the Autoimmune and Rituximab registry. *Ann Rheum Dis*. 2013;72:1026-1031. doi: 10.1136/annrheumdis-2012-202293.

Meijer JM, Meiners PM, Vissink A, et al. Effectiveness of rituximab treatment in primary Sjögren's syndrome: a randomized, double-blind, placebo-controlled trial. *Arthritis Rheum.* 2010 Apr;62(4):960-968. doi: 10.1002/art.27314.

Mekinian A, Ravaud P, Hatron PY, et al. Efficacy of rituximab in primary Sjögren's syndrome with peripheral nervous system involvement: results from the AIR registry. *Ann Rheum Dis.* 2012;71:84-87. doi: 10.1136/annrheumdis-2011-200086.

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Terrier B, Launay D, Kaplanski G, et al. Safety and efficacy of rituximab in nonviral cryoglobulinemia vasculitis: data from the French Autoimmunity and Rituximab registry. *Arthritis Care Res (Hoboken).* 2010 Dec;62(12):1787-1795. doi: 10.102/acr.20318.

Based on a reconsideration request the following sources have been added:

Busch M, Ruster C, Schinköthe C, Gerth J, Wolf G. Rituximab for the second- and third-line therapy of idiopathic membranous nephropathy: a prospective single center study using a new treatment strategy. *Clin Nephrol.* 2013 Aug;80(2):105-113. doi: 10.5414/CN107912.

Cravedi P, Ruggenti P, Sghirlanzoni MC, Remuzzi G. Titrating rituximab to circulating B cells to optimize lymphocytolytic therapy in idiopathic membranous nephropathy. *Clin J Am Soc Nephrol.* 2007 Sep;2(5):932-937.

Cravedi P, Sghirlanzoni MC, Marasá M, Salerno A, Remuzzi G, Reggenenti P. Efficacy and safety of rituximab second-line therapy for membranous nephropathy: a prospective, matched-cohort study. *Am J Nephrol.* 2011;33(5):461-468. doi: 10.1159/000327611.

Fervenza FC, Abraham RS, Erickson SB, et al. Rituximab therapy in idiopathic membranous nephropathy: a 2-year study. *Clin J Am Soc Nephrol.* 2010 Dec;5(12):2188-2198. doi: 10.2215/CJN.05080610.

Fervenza FC, Gosio FG, Erickson SB, et al. Rituximab treatment of idiopathic membranous nephropathy. *Kidney Int.* 2008 Jan;73(1):117-25.

Kattah AG, Fervenza FC, Roccatello D. Rituximab-based novel strategies for the treatment of immune-mediated glomerular diseases. *Autoimmunity Reviews.* 2013 Jun;12(8):854-9. doi: 10.1016/j.autrev.2012.09.002.

Remuzzi G, Chiurciu C, Abbate M, Brusegan V, Bontempelli M, Ruggenti P. Rituximab for idiopathic membranous nephropathy. *Lancet.* 2002 Sep 21;360(9337):923-924.

Ruggenti P, Cravedi P, Chianca A, et al. Rituximab in idiopathic membranous nephropathy. *J Am Soc Nephrol.* 2012 Aug;23(8):1416-1425. doi: 10.1681/ASN.2012020181.

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**Coding Information**



**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

011x	Hospital Inpatient (Including Medicare Part A)
013x	Hospital Outpatient
085x	Critical Access Hospital

**Revenue Codes:**

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N/A

**CPT/HCPCS Codes**

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

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J9310 INJECTION, RITUXIMAB, 100 MG

**ICD-10 Codes that are Covered**

**Group 1 Paragraph:** NOTE: ICD-10-CM code E05.00 or E05.01 should only be used for patients who are refractory to the standard therapies for Grave's disease/ophthalmopathy

**Group 1 Codes:**

**Show entries:** 100

**Search:**  **Search By:** **Description** **Code**

ICD-10 CODE	DESCRIPTION
B10.89	Other human herpesvirus infection
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
C79.49	Secondary malignant neoplasm of other parts of nervous system
C81.00	Nodular lymphocyte predominant Hodgkin lymphoma, unspecified site
C81.01	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.02	Nodular lymphocyte predominant Hodgkin lymphoma, intrathoracic lymph nodes
C81.03	Nodular lymphocyte predominant Hodgkin lymphoma, intra-abdominal lymph nodes
C81.04	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.05	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.06	Nodular lymphocyte predominant Hodgkin lymphoma, intrapelvic lymph nodes
C81.07	Nodular lymphocyte predominant Hodgkin lymphoma, spleen
C81.08	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of multiple sites
C81.09	Nodular lymphocyte predominant Hodgkin lymphoma, extranodal and solid organ sites
C81.10	Nodular sclerosis classical Hodgkin lymphoma, unspecified site
C81.11	Nodular sclerosis classical Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.12	Nodular sclerosis classical Hodgkin lymphoma, intrathoracic lymph nodes
C81.13	Nodular sclerosis classical Hodgkin lymphoma, intra-abdominal lymph nodes
C81.14	Nodular sclerosis classical Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.15	Nodular sclerosis classical Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.16	Nodular sclerosis classical Hodgkin lymphoma, intrapelvic lymph nodes
C81.17	Nodular sclerosis classical Hodgkin lymphoma, spleen
C81.18	Nodular sclerosis classical Hodgkin lymphoma, lymph nodes of multiple sites
C81.19	Nodular sclerosis classical Hodgkin lymphoma, extranodal and solid organ sites
C81.20	Mixed cellularity classical Hodgkin lymphoma, unspecified site
C81.21	Mixed cellularity classical Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.22	Mixed cellularity classical Hodgkin lymphoma, intrathoracic lymph nodes
C81.23	Mixed cellularity classical Hodgkin lymphoma, intra-abdominal lymph nodes
C81.24	Mixed cellularity classical Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.25	Mixed cellularity classical Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.26	Mixed cellularity classical Hodgkin lymphoma, intrapelvic lymph nodes
C81.27	Mixed cellularity classical Hodgkin lymphoma, spleen
C81.28	Mixed cellularity classical Hodgkin lymphoma, lymph nodes of multiple sites
C81.29	Mixed cellularity classical Hodgkin lymphoma, extranodal and solid organ sites
C81.30	Lymphocyte depleted classical Hodgkin lymphoma, unspecified site
C81.31	Lymphocyte depleted classical Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.32	Lymphocyte depleted classical Hodgkin lymphoma, intrathoracic lymph nodes
C81.33	Lymphocyte depleted classical Hodgkin lymphoma, intra-abdominal lymph nodes
C81.34	Lymphocyte depleted classical Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.35	Lymphocyte depleted classical Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.36	Lymphocyte depleted classical Hodgkin lymphoma, intrapelvic lymph nodes
C81.37	Lymphocyte depleted classical Hodgkin lymphoma, spleen
C81.38	Lymphocyte depleted classical Hodgkin lymphoma, lymph nodes of multiple sites

C81.39	Lymphocyte depleted classical Hodgkin lymphoma, extranodal and solid organ sites
C81.40	Lymphocyte-rich classical Hodgkin lymphoma, unspecified site
C81.41	Lymphocyte-rich classical Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.42	Lymphocyte-rich classical Hodgkin lymphoma, intrathoracic lymph nodes
C81.43	Lymphocyte-rich classical Hodgkin lymphoma, intra-abdominal lymph nodes
C81.44	Lymphocyte-rich classical Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.45	Lymphocyte-rich classical Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.46	Lymphocyte-rich classical Hodgkin lymphoma, intrapelvic lymph nodes
C81.47	Lymphocyte-rich classical Hodgkin lymphoma, spleen
C81.48	Lymphocyte-rich classical Hodgkin lymphoma, lymph nodes of multiple sites
C81.49	Lymphocyte-rich classical Hodgkin lymphoma, extranodal and solid organ sites
C81.70	Other classical Hodgkin lymphoma, unspecified site
C81.71	Other classical Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.72	Other classical Hodgkin lymphoma, intrathoracic lymph nodes
C81.73	Other classical Hodgkin lymphoma, intra-abdominal lymph nodes
C81.74	Other classical Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.75	Other classical Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.76	Other classical Hodgkin lymphoma, intrapelvic lymph nodes
C81.77	Other classical Hodgkin lymphoma, spleen
C81.78	Other classical Hodgkin lymphoma, lymph nodes of multiple sites
C81.79	Other classical Hodgkin lymphoma, extranodal and solid organ sites
C81.90	Hodgkin lymphoma, unspecified, unspecified site
C81.91	Hodgkin lymphoma, unspecified, lymph nodes of head, face, and neck
C81.92	Hodgkin lymphoma, unspecified, intrathoracic lymph nodes
C81.93	Hodgkin lymphoma, unspecified, intra-abdominal lymph nodes
C81.94	Hodgkin lymphoma, unspecified, lymph nodes of axilla and upper limb
C81.95	Hodgkin lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C81.96	Hodgkin lymphoma, unspecified, intrapelvic lymph nodes
C81.97	Hodgkin lymphoma, unspecified, spleen
C81.98	Hodgkin lymphoma, unspecified, lymph nodes of multiple sites
C81.99	Hodgkin lymphoma, unspecified, extranodal and solid organ sites
C82.00	Follicular lymphoma grade I, unspecified site
C82.01	Follicular lymphoma grade I, lymph nodes of head, face, and neck
C82.02	Follicular lymphoma grade I, intrathoracic lymph nodes
C82.03	Follicular lymphoma grade I, intra-abdominal lymph nodes
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal region and lower limb
C82.06	Follicular lymphoma grade I, intrapelvic lymph nodes
C82.07	Follicular lymphoma grade I, spleen
C82.08	Follicular lymphoma grade I, lymph nodes of multiple sites
C82.09	Follicular lymphoma grade I, extranodal and solid organ sites
C82.10	Follicular lymphoma grade II, unspecified site
C82.11	Follicular lymphoma grade II, lymph nodes of head, face, and neck
C82.12	Follicular lymphoma grade II, intrathoracic lymph nodes
C82.13	Follicular lymphoma grade II, intra-abdominal lymph nodes
C82.14	Follicular lymphoma grade II, lymph nodes of axilla and upper limb
C82.15	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb
C82.16	Follicular lymphoma grade II, intrapelvic lymph nodes
C82.17	Follicular lymphoma grade II, spleen
C82.18	Follicular lymphoma grade II, lymph nodes of multiple sites
C82.19	Follicular lymphoma grade II, extranodal and solid organ sites
C82.20	Follicular lymphoma grade III, unspecified, unspecified site
C82.21	Follicular lymphoma grade III, unspecified, lymph nodes of head, face, and neck
C82.22	Follicular lymphoma grade III, unspecified, intrathoracic lymph nodes
C82.23	Follicular lymphoma grade III, unspecified, intra-abdominal lymph nodes
C82.24	Follicular lymphoma grade III, unspecified, lymph nodes of axilla and upper limb
C82.25	Follicular lymphoma grade III, unspecified, lymph nodes of inguinal region and lower limb

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ICD-10 Codes that are Not Covered


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 **Revision History Information**

**Please note:** The Revision History information included in this Article prior to 06/20/2013 will now display with a Revision History Number of "R1" at the bottom of this table. All new Revision History information entries completed on or after 06/20/2013 will display as a row in the Revision History section of the Article and numbering will begin with "R2".

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
10/01/2015	R1	Updated to include revisions made since April 2014. The following ICD-10-CM codes have been added L13.0 L13.1, L12.2, L40.1, L12.0, L12.8, L12.9, L12.1, L13.8, L14, L13.9, L51.2, M30.0, N02.0 and N04.0.

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**Related Local Coverage Document(s)**

Article(s)

[A52855 - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses - Supplemental Instructions Article](#)

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[L33394 - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses](#)

**Related National Coverage Document(s)**

N/A

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Updated on 03/09/2015 with effective dates 10/01/2015 - N/A

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 **Keywords**

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