Contractor Information

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09102

Contractor Type
MAC - Part B

LCD Information

LCD ID Number
L29202

LCD Title
Interferon

Contractor's Determination Number
J9212

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CMS National Coverage Policy
Language quoted from CMS National Coverage Determinations (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:

CMS Manuals Pub 100-02, Chapter 15, Section 50-50.1

Primary Geographic Jurisdiction
Florida
Indications and Limitations of Coverage and/or Medical Necessity

Interferons are naturally occurring small proteins with both antiviral and antiproliferative properties. Interferons exert their cellular effects by binding to specific membrane receptors on the cell surface and subsequently initiate a complex sequence of intracellular events.

Interferon alfacon-1 is a recombinant non-naturally occurring type-1 interferon. Interferon alfa-2B is sterile protein product produced by recombinant DNA techniques. The exact mechanism of action is unknown, but appears to involve direct antiproliferative action against tumor cells or viral cells to inhibit replication, modulation of the host immune response by enhancing the phagocytic activity of macrophages, and augmentation of specific cytotoxicity of lymphocytes for target cells.

Alfa-N3 is a naturally occurring antiviral agent derived from human leukocytes. It attaches to membrane receptors and causes cellular changes, including increased protein synthesis. Gamma-1B, a biological response modifier, is a single-chain polypeptide containing 140 amino acids.

Interferon beta-1a (Q3025)

Medicare will consider the administration of Interferon beta-1a medically reasonable and necessary for the following indication: multiple sclerosis.

Interferon alfacon-1 (J9212)

Medicare will consider the administration of Interferon alfacon-1 medically reasonable and necessary for the following indications: chronic hepatitis C and hairy cell leukemia.

Interferon alfa-2B (J9214)
Medicare will consider the administration of Interferon Alfa-2B medically reasonable and necessary for the following indications: acute or chronic hepatitis C, chronic hepatitis B, condylomata acuminata, hairy cell leukemia, malignant melanoma, AIDS-related Kaposi’s sarcoma, head and neck cancer, bladder cancer, brain cancer, carcinoid syndrome, chronic lymphocytic leukemia, chronic myelocytic leukemia, cutaneous T-cell lymphoma, esophageal cancer, renal cancer, multiple myeloma, non-Hodgkin’s lymphoma, mycosis fungoides, essential thrombocytosis, essential thrombocythemia, osteosarcoma, ovarian cancer, pancreatic cancer, skin cancer, colorectal cancer, polycythemia vera, and laryngeal papillomatosis.

Medicare will consider the administration of Interferon Alfa-2B medically necessary for the off-label indication of peritoneum cancer.

**Interferon alfa-N3 (J9215)**

Medicare will consider the administration of Interferon alfa-N3 medically reasonable and necessary for the following indications: chronic hepatitis C, condylomata acuminata, hairy cell leukemia, malignant melanoma, AIDS-related Kaposi’s sarcoma, bladder cancer, carcinoid syndrome, chronic myelocytic leukemia, renal cancer, multiple myeloma, non-Hodgkin’s lymphoma, mycosis fungoides, essential thrombocytosis, ovarian cancer, and laryngeal papillomatosis.

Medicare will consider the administration of Interferon alfa-N3 medically necessary for the off-label indication of peritoneum cancer.

**Interferon gamma-1B (J9216)**

Medicare will consider the administration of Interferon gamma-1B medically reasonable and necessary for the following indications: chronic granulomatous disease.

**Limitations:**

The self-administration of Interferons alfacon-1, alfa-2B, alfa-N3, and gamma-1B are noncovered by Medicare.

**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 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.

**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.
CPT/HCPCS Codes

J9212  INJECTION, INTERFERON ALFACON-1, RECOMBINANT, 1 MICROGRAM
J9214  INJECTION, INTERFERON, ALFA-2B, RECOMBINANT, 1 MILLION UNITS
J9215  INJECTION, INTERFERON, ALFA-N3, (HUMAN LEUKOCYTE DERIVED), 250,000 IU
J9216  INJECTION, INTERFERON, GAMMA 1-B, 3 MILLION UNITS
Q3025  INJECTION, INTERFERON BETA-1A, 11 MCG FOR INTRAMUSCULAR USE

ICD-9 Codes that Support Medical Necessity

For Q3025 (Interferon beta-1a):
340  MULTIPLE SCLEROSIS

For J9212 (Interferon Alfacon-1):
070.54  CHRONIC HEPATITIS C WITHOUT HEPATIC COMA
202.40 - 202.48  LEUKEMIC RETICULOENDOTHELIOSIS UNSPECIFIED SITE - LEUKEMIC RETICULOENDOTHELIOSIS INVOLVING LYMPH NODES OF MULTIPLE SITES

For J9214 (Interferon alfa-2B):
070.41  ACUTE HEPATITIS C WITH HEPATIC COMA
070.44  CHRONIC HEPATITIS C WITH HEPATIC COMA
070.51  ACUTE HEPATITIS C WITHOUT MENTION OF HEPATIC COMA
070.54  CHRONIC HEPATITIS C WITHOUT HEPATIC COMA
070.59  OTHER SPECIFIED VIRAL HEPATITIS WITHOUT HEPATIC COMA
078.11  CONDYLOMA ACUMINATUM
140.0 - 149.9  MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE LIP AND ORAL CAVITY
150.0 - 150.9  MALIGNANT NEOPLASM OF CERVICAL ESOPHAGUS - MALIGNANT NEOPLASM OF ESOPHAGUS UNSPECIFIED SITE
153.0 - 153.9
MALIGNANT NEOPLASM OF HEPATIC FLEXURE - MALIGNANT NEOPLASM OF COLON UNSPECIFIED SITE

154.0 - 154.8 MALIGNANT NEOPLASM OF RECTOSIGMOID JUNCTION - MALIGNANT NEOPLASM OF OTHER SITES OF RECTUM RECTOSIGMOID JUNCTION AND ANUS

157.4 MALIGNANT NEOPLASM OF ISLETS OF LANGERHANS

158.8 MALIGNANT NEOPLASM OF SPECIFIED PARTS OF PERITONEUM

158.9 MALIGNANT NEOPLASM OF PERITONEUM UNSPECIFIED

161.0 - 161.9 MALIGNANT NEOPLASM OF GLOTTIS - MALIGNANT NEOPLASM OF LARYNX UNSPECIFIED

170.0 - 170.9 MALIGNANT NEOPLASM OF BONES OF SKULL AND FACE EXCEPT MANDIBLE - MALIGNANT NEOPLASM OF BONE AND ARTICULAR CARTILAGE SITE UNSPECIFIED

172.0 - 172.9 MALIGNANT MELANOMA OF SKIN OF LIP - MELANOMA OF SKIN SITE UNSPECIFIED

173.0 - 173.9 OTHER MALIGNANT NEOPLASM OF SKIN OF LIP - OTHER MALIGNANT NEOPLASM OF SKIN SITE UNSPECIFIED

176.0 - 176.9 KAPOSI'S SARCOMA SKIN - KAPOSI'S SARCOMA UNSPECIFIED SITE

183.0 - 183.9 MALIGNANT NEOPLASM OF OVARY - MALIGNANT NEOPLASM OF UTERINE ADNEXA UNSPECIFIED SITE

184.4 MALIGNANT NEOPLASM OF VULVA UNSPECIFIED SITE

188.0 - 188.9 MALIGNANT NEOPLASM OF TRIGONE OF URINARY BLADDER - MALIGNANT NEOPLASM OF BLADDER PART UNSPECIFIED

189.0 MALIGNANT NEOPLASM OF KIDNEY EXCEPT PELVIS

189.1 MALIGNANT NEOPLASM OF RENAL PELVIS

191.0 - 191.9 MALIGNANT NEOPLASM OF CEREBRUM EXCEPT LOBES AND VENTRICLES - MALIGNANT NEOPLASM OF BRAIN UNSPECIFIED SITE

200.00 - 200.88 RETICULOSARCOMA UNSPECIFIED SITE - OTHER NAMED VARIANTS OF LYMPHOSARCOMA AND RETICULOSARCOMA INVOLVING LYMPH NODES OF MULTIPLE SITES

202.00 - 202.98
NODULAR LYMPHOMA UNSPECIFIED SITE - OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE INVOLVING LYMPH NODES OF MULTIPLE SITES

203.00 - 203.82 MULTIPLE MYELOMA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER IMMUNOPROLIFERATIVE NEOPLASMS, IN RELAPSE

204.10 CHRONIC LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION

204.12 CHRONIC LYMPHOID LEUKEMIA, IN RELAPSE

205.10 CHRONIC MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION

205.12 CHRONIC MYELOID LEUKEMIA, IN RELAPSE

238.4 POLYCYTHEMIA VERA

238.71 ESSENTIAL THROMBOCYTHEMIA

259.2 CARCINOID SYNDROME

289.9 UNSPECIFIED DISEASES OF BLOOD AND BLOOD-FORMING ORGANS

For J9215 (Interferon alfa-N3):

070.54 CHRONIC HEPATITIS C WITHOUT HEPATIC COMA

078.11 CONDYLOMA ACUMINATUM

158.8 MALIGNANT NEOPLASM OF SPECIFIED PARTS OF PERITONEUM

158.9 MALIGNANT NEOPLASM OF PERITONEUM UNSPECIFIED

161.0 - 161.9 MALIGNANT NEOPLASM OF GlOTTIS - MALIGNANT NEOPLASM OF LARYNX UNSPECIFIED

172.0 - 172.9 MALIGNANT MELANOMA OF SKIN OF LIP - MELANOMA OF SKIN SITE UNSPECIFIED

176.0 - 176.9 KAPOSI'S SARCOMA SKIN - KAPOSI'S SARCOMA UNSPECIFIED SITE

183.0 - 183.9 MALIGNANT NEOPLASM OF OVARY - MALIGNANT NEOPLASM OF UTERINE ADNEXA UNSPECIFIED SITE

188.0 - 188.9 MALIGNANT NEOPLASM OF TRIGONE OF URINARY BLADDER - MALIGNANT NEOPLASM OF BLADDER PART UNSPECIFIED

189.0 MALIGNANT NEOPLASM OF KIDNEY EXCEPT PELVIS

189.1 MALIGNANT NEOPLASM OF RENAL PELVIS

200.00 - 200.88 RETICULOSARCOMA UNSPECIFIED SITE - OTHER NAMED VARIANTS OF LYMPHOSARCOMA AND RETICULOSARCOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
202.00 - 202.98  NODULAR LYMPHOMA UNSPECIFIED SITE - OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE INVOLVING LYMPH NODES OF MULTIPLE SITES

203.00 - 203.82  MULTIPLE MYELOMA, WITHOUT MENTION OF HAVING ACHieved REMISSION - OTHER IMMUNOPROLIFERATIVE NEOPLASMS, IN RELAPSE

205.10  CHRONIC MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION

205.12  CHRONIC MYELOID LEUKEMIA, IN RELAPSE

259.2  CARCINOID SYNDROME

289.9  UNSPECIFIED DISEASES OF BLOOD AND BLOOD-FORMING ORGANS

For J9216 (Interferon gamma-1B):

288.1  FUNCTIONAL DISORDERS OF POLYMORPHONUCLEAR NEUTROPHILS

Diagnoses that Support Medical Necessity
N/A

ICD-9 Codes that DO NOT Support Medical Necessity
N/A

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity
N/A

General Information

Documentation Requirements
Medical record documentation maintained by the ordering/referring physician must substantiate the medical necessity for the use of the specific Interferon by indicating the condition for which it is being administered. The drug name, dosage, and route of administration must also be recorded. This information is normally found in the office/progress notes or medication administration record.

Appendices
Utilization Guidelines
N/A

Sources of Information and Basis for Decision


Advisory Committee Meeting Notes
This Local Coverage Determination (LCD) does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this LCD was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period
10/01/2009

Revision History Number
1

Revision History Explanation
Revision Number:1
Start Date of Comment Period:N/A
Start Date of Notice Period:10/01/2009
Revised Effective Date: 09/04/2009

LCR B2009-092
September 2009 Update
Explanation of Revision: Updated the “ICD-9 Codes that Support Medical Necessity” section to add diagnosis code 238.71 for HCPCS code J9214 (Interferon alfa-2b). The effective date of this revision is based on process date.

Revision Number: Original
Start Date of Comment Period: N/A
Start Date of Notice Period: 12/04/2008
Revised Effective Date: 02/02/2009

LCR B2009-
December 2008 Bulletin

This LCD consolidates and replaces all previous policies and publications on this subject by the carrier predecessors of First Coast Service Options, Inc. (Triple S and FCSO).

For Florida (00590) this LCD (L29202) replaces LCD L5711 as the policy in notice. This document (L29202) is effective on 02/02/2009.

Reason for Change

Last Reviewed On Date

Related Documents
This LCD has no Related Documents.

LCD Attachments
There are no attachments for this LCD.

All Versions
Updated on 09/08/2009 with effective dates 09/04/2009 - N/A
Updated on 11/30/2008 with effective dates 02/02/2009 - N/A