Local Coverage Article:
Sipuleucel-T (Provenge®) - Coverage Criteria for Prostate Cancer – Clarification (A55719)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

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Article Information

General Information

Article ID
A55719

Article Title
Sipuleucel-T (Provenge®) - Coverage Criteria for Prostate Cancer – Clarification

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Article Effective Date
10/01/2015

Revision Effective Date
10/19/2018

Revision Ending Date
N/A

Retirement Date
N/A

Article Guidance

Article Text:

Sipuleucel-T (Provenge®) is an autologous cellular immunotherapy, FDA-approved for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

The production of Sipuleucel-T involves collection of the patient's own cells (leukapheresis), culture with a proprietary antigen complex, and re-infusion of the "antigen-activated" patient cells back to the donor. Provenge® is administered as three intravenous infusions, generally two weeks apart. When infused back into the patient, usually three days after leukapheresis, the patient-specific medication (autologous cellular therapy) stimulates a positive immunogenic response against the prostate cancer.

For coverage, patient records must document that the product is being used according to the NCD 110.22. ***If the documentation does not describe the criteria above, does not meet all the requirements of the NCD on sipuleucel-T,is inconsistent with the FDA label and/or is not received, the services will be denied. Off-label use of this treatment is not covered unless it meets the requirements for off-label use of chemotherapeutic drugs in the Internet Only Manual 100-02 (Benefit Policy), Chapter 15 (Covered Services), Section 50.4.5.***

Noridian may cover *sipuleucel-T* for the above condition when all requirements are met including the following coding instructions. (NOTE: Noridian will not allow payment for any off-label use of this treatment):

For dates of service on/after July 1, 2011, use the following HCPCS code: Q2043 Sipuleucel-T auto CD54+.

For dates of service prior to July 1, 2011, use one of the following HCPCS code: J3490, J3590 or C9273 (being replaced by Q2043).

The payment of HCPCS Q2043 includes collection of patients' cells, activation with PAP-CM-CSF, including leukapheresis and all other preparatory procedures associated with ***sipuleucel-T***. The code Q2043 does not include the *administration* of the treatments. CPT® code 96365, intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to one (1) hour will be allowed for the administration of Q2043.

Medicare will allow a maximum of three (3) infusions per lifetime.

Sources: Internet Only Manual (IOM) Medicare National Coverage Determinations (NCD) Manual, Publication 100-03, Chapter 1, Section 110.22, IOM Medicare Claims Processing Manual, Publication 100-04, Chapter 32, Section 280; Transmittal 133, Change Request (CR)7431 dated July 8, 2011; Transmittal 2254, CR 7431 dated July 8, 2011.

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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.

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 article, 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 article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes
Group 1 Paragraph: N/A

Group 1 Codes:

Group 1 CPT/HCPCS Code	Group 1 CPT/HCPCS Code Description
Q2043	SIPULEUCEL-T, MINIMUM OF 50 MILLION AUTOLOGOUS CD54+ CELLS ACTIVATED WITH PAP -GM-CSF, INCLUDING LEUKAPHERESIS AND ALL OTHER PREPARATORY PROCEDURES, PER INFUSION

ICD-10 Codes that are Covered
Group 1 Paragraph: N/A

Group 1 Codes:
ICD-10 Codes that are covered Information Table

Code	Description
C61	Malignant neoplasm of prostate

Group 2 Paragraph:

And at least one of the following:

Group 2 Codes:
ICD-10 Codes that are covered Information Table

Code	Description
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis

Code	Description
C79.10	Secondary malignant neoplasm of unspecified urinary organs
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.82	Secondary malignant neoplasm of genital organs

ICD-10 Codes that are Not Covered N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
10/19/2018	R1	The article is revised to follow the NCD criteria for this procedure.

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Related National Coverage Document(s) NCD(s) 110.22 - Autologous Cellular Immunotherapy Treatment

Statutory Requirements URL(s) N/A

Rules and Regulations URL(s) N/A

CMS Manual Explanations URL(s) N/A

Other URL(s) N/A

Public Version(s) Updated on 10/17/2018 with effective dates 10/19/2018 - N/A Updated on 09/09/2017 with effective dates 10/01/2015 - N/A Back to Top

Keywords

- Q2043
- Sipuleucel-T
- Provenge
- Prostate Cancer

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