Autologous Cellular Immunotherapy Treatment (NCD 110.22)

Guideline Number: MPG022.06
Approval Date: September 9, 2020

Terms and Conditions

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Policy Summary

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Overview

The Food and Drug Administration (FDA) approved Sipuleucel-T (PROVENGE®; APC8015), for patients with castration-resistant, metastatic prostate cancer. The posited mechanism of action, immunotherapy, is different from that of anti-cancer chemotherapy such as docetaxel. This is the first immunotherapy for prostate cancer to receive FDA approval.

The goal of immunotherapy is to stimulate the body's natural defenses (such as the white blood cells called dendritic cells, mononuclear cells and T-lymphocytes) in a specific manner so that they attack and destroy, or at least prevent, the proliferation of cancer cells. Specificity is attained by intentionally exposing a patient's white blood cells to a particular protein (called an antigen) associated with the prostate cancer. This exposure "trains" the white blood cells to target and attack the prostate cancer cells. Clinically, this is expected to result in a decrease in the size and/or number of cancer sites, an increase in the time to cancer progression, and/or an increase in survival of the patient.

Sipuleucel-T differs from other infused anti-cancer therapies. Most such anti-cancer therapies are manufactured and sold by a biopharmaceutical company and then purchased by and dispensed from a pharmacy. In contrast, once the decision is made to treat with Sipuleucel-T, a multi-step process is used to produce Sipuleucel-T. Sipuleucel-T is made individually for each patient with his own white blood cells. The patient's white blood cells are removed via a procedure called leukapheresis. In a laboratory the white blood cells are exposed to PA2024, which is a molecule created by linking prostatic acid phosphatase (PAP) with granulocyte/macrophage-colony stimulating factor (GM-CSF). PAP is an antigen specifically associated with prostate cancer cells; GM-CSF is a protein that targets a receptor on the surface of white blood cells. Hence, PAP serves to externally manipulate the immunological functioning of the patient's white blood cells while GM-CSF serves to stimulate the white blood cells into action. In the FDA's clinical review, each dose of Sipuleucel-T contains a minimum of 40 million treated white blood cells, however there is "high inherent variability" in the yield of Sipuleucel-T from leukapheresis to leukapheresis in the same patient as well as from patient to patient. The treated white blood cells are then infused back into the same patient. The FDA-approved dosing regimen is three doses with each dose administered two weeks apart. The total treatment period is four weeks.

Guidelines

Nationally Covered Indications

The Centers for Medicare and Medicaid Services (CMS) proposes that the evidence is adequate to conclude that the use of autologous cellular immunotherapy treatment - Sipuleucel-T; PROVENGE® improves health outcomes for Medicare beneficiaries with asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer, and thus is reasonable and necessary for this on-label indication under 1862(a)(1)(A) of the Social Security Act.

Other

Coverage of all off-label uses of autologous cellular immunotherapy treatment – Sipuleucel-T; PROVENGE® for the treatment of prostate cancer is left to the discretion of the local Medicare Administrative Contractors.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

Diagnosis Code	Description
Primary Code	
C61	Malignant neoplasm of prostate
Secondary Code	
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
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
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

Diagnosis Code	Description
Secondary Code	
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.82	Secondary malignant neoplasm of genital organs

References

CMS National Coverage Determinations (NCDs)

NCD 110.22 Autologous Cellular Immunotherapy Treatment

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A52926 Sipuleucel-T Provenge® - Coverage Criteria for Prostate Cancer – Clarification	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A55719 Sipuleucel-T (Provenge®) - Coverage Criteria for Prostate Cancer – Clarification	Noridian	AS, CA, GU, HI, NV, MP	AS, CA, GU, HI, NV, MP
L34093 Chemotherapy and Biologicals Retired 06/07/2020	A52422 Billing and Coding for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer Retired 06/07/2020	CGS	KY, OH	KY, OH
L35094 Services That Are Not Reasonable and Necessary Retired 07/01/2020	A56967 Billing and Coding for Services That Are Not Reasonable and Necessary Retired 07/01/2020	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX

CMS Claims Processing Manual

Chapter 32; § 280 Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer

CMS Transmittal(s)

Transmittal 2380, Change Request 7431, Dated January 6, 2012 Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer
Transmittal 2394, Change Request 7659, Dated 01/25/2012 (CWF Editing for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (PROVENGE®))

MLN Matters

Article MM7431, Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer

Other(s)

Biologics Blood Vaccines/Cellular Gene Therapy Products - Provenge®
CMS Billing and Coding Guideline for HONC-010 Chemotherapy Drugs and their Adjuncts, CMS Website
NCCN Drugs & Biologics Compendium (NCCN Compendium), NCCN Website

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update • Reformatted policy; transferred content to new template
09/09/2020	Supporting Information • Updated *References* section to reflect the most current information • Archived previous policy version MPG022.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided.

UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.