MASSACHUSETTS

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Medical Policy

Cellular Immunotherapy for Prostate Cancer

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Policy Number: 268

BCBSA Reference Number: 8.01.53
NCD/LCD: National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22)

Related Policies

Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer, #333

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Sipuleucel-T therapy may be considered **MEDICALLY NECESSARY** in the treatment of asymptomatic or minimally symptomatic, androgen-independent (castration-resistant) metastatic prostate cancer.

Sipuleucel-T therapy is **INVESTIGATIONAL** in all other situations, including but not limited to treatment of hormone-responsive prostate cancer, treatment of moderate to severe symptomatic metastatic prostate cancer, and treatment of visceral (liver, lung, or brain) metastases.

Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Medical necessity criteria and coding guidance can be found through the link below.

National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22)

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient

Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

HCPCS Codes

HCPCS codes:	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

Description

PROSTATE CANCER

Prostate cancer is the second leading cause of cancer-related deaths among American men, with an estimated incidence of 164,690 cases and an estimated number of 29,430 deaths in 2018. In most cases, prostate cancer is diagnosed at a localized stage and is treated with prostatectomy or radiotherapy. However, some patients are diagnosed with metastatic or recurrent disease after treatment of localized disease.

Treatment

Androgen ablation is the standard treatment for metastatic or recurrent disease. Most patients who survive long enough eventually develop androgen-independent (castration-resistant) prostate cancer. At this stage of metastatic disease, docetaxel, a chemotherapeutic agent, has demonstrated a survival benefit of 1.9 to 2.4 months in randomized clinical trials. Chemotherapy with docetaxel causes adverse events in large proportions of patients, including alopecia, fatigue, neutropenia, neuropathy, and other symptoms. Trials evaluating docetaxel included both asymptomatic and symptomatic patients, and results have suggested a survival benefit for both groups. Because of the burden of treatment and its adverse events, most patients defer docetaxel treatment until cancer recurrence is symptomatic.

Cancer immunotherapy has been investigated as a treatment that could be instituted at the point of detection of androgen-independent metastatic disease before significant symptomatic manifestations have occurred. The quantity of cancer cells in the patient during this time is thought to be relatively low, and it is thought that an effective immune response to the cancer during this interval could effectively delay or prevent progression. Such a delay could allow a course of effective chemotherapy, such as docetaxel, to be deferred or delayed until necessary, thus providing an overall survival benefit.

Summary

For individuals who have asymptomatic or minimally symptomatic, metastatic, castration-resistant prostate cancer who receive sipuleucel-T (Provenge), the evidence includes 3 RCTs and a systematic review of these RCTs. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. The 2 earlier RCTs of sipuleucel-T were not specifically designed to demonstrate a difference in overall mortality but did show a survival

difference. The third RCT, which was designed to demonstrate a mortality difference, showed a similar improvement in overall survival. All 3 studies were consistent in demonstrating that sipuleucel-T does not delay time to a measurable progression of the disease. A meta-analysis of the 3 RCTs found significantly improved overall survival, but not the time to progression, with sipuleucel-T compared with placebo. Serious adverse events did not increase in the sipuleucel-T group. However, the available data suggested, but did not confirm, an increase in stroke risk; this risk is being evaluated in a postmarketing study. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have nonmetastatic, androgen-dependent prostate cancer who receive sipuleucel-T (Provenge), the evidence includes an RCT. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. The RCT did not find a statistically significant difference between sipuleucel-T and a control in time to biochemical failure. The RCT was not designed to evaluate the impact of sipuleucel-T on mortality. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
9/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified.
8/2017	New references added from BCBSA National medical policy.
9/2015	BCBSA National policy review. "Hormone-refractory" changed to the current clinically accepted term "castration-resistant" in the medically necessary policy statement and throughout the policy. Policy statements otherwise unchanged. 9/1/2015.
10/2014	Hormone refractory cancer clarified.
9/2014	New references added from BCBSA National medical policy.
10/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group – Urology, Obstetrics and Gynecology. No changes to policy statements.
7/2011	Reviewed - Medical Policy Group – Hematology and Oncology. No changes to policy statements.
1/1/2011	Medical Policy 268 effective 1/1/2011 describing covered and non-covered indications.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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