RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	sipuleucel-T
Policy Number:	RxA.450
Drug(s) Applied:	Provenge®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Provenge® is an autologous cellular immunotherapy.

It is indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Sipuleucel-T (Provenge®)	Asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer	One dose IV over 60 minutes given approximately every 2 weeks for 3 doses Each dose contains a minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, in 250 ml of Lactated Ringer's Injection	1 dose approximately every 2 weeks (max 3 doses)

Dosage Forms

- Suspension for injection: minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, in 250 ml of Lactated Ringer's Injection

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of metastatic castration-resistant (hormone refractory) prostate cancer, as evidenced by disease progression despite bilateral orchiectomy or other androgen deprivation therapy (*see Appendix D*) ;

2. Visceral metastases are not present
3. Prescribed by or in consultation with an oncologist or urologist;
4. Age ≥ 18 years;
5. Member has not received ≥ 3 doses (infusions) of provenge.

Approval Duration
Commercial: 6 months
Medicaid: 6 months
HIM Medical Benefit: 6 months

II. Continued Therapy Approval

A. Prostate Cancer (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance , or documentation supports that member is currently receiving Provenge for prostate cancer and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Member has not received ≥ 3 doses (infusions) of Provenge.

Approval Duration
Commercial: 6 months
Medicaid: 6 months
HIM Medical Benefit: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported
- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Examples of androgen deprivation therapy include:
  - Luteinizing hormone-releasing hormone (LHRH) given with or without an antiandrogen:
    - LHRH agonists: Zoladex® (goserelin), Vantas® (histrelin), leuprolide (Lupron Depot®, Eligard®), and Trelstar® (triptorelin)
    - Anti-androgens: bicalutamide (Casodex®), flutamide (Eulexin®), nilutamide (Nilandron®), Xtandi® (enzalutamide), Erleada® (apalutamide), Nubeqa® (darolutamide)
  - LHRH antagonist: Firmagon® (degarelix)

References

1. Provenge Prescribing Information. Seattle, WA: Dendreon Corporation; July 2017. Available at: http://www.provenge.com/. Accessed July 28, 2020.

2. Sipuleucel-T. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: www.nccn.org. Accessed July 28, 2020.
3. National Comprehensive Cancer Network. Prostate Cancer Version 2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 28, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed 1. Policy table was updated 2. Initial Therapy: Diagnosis updated to metastatic castration-resistant (hormone refractory) prostate cancer 3. Initial Therapy: Dose criteria added 4. Initial Therapy & Continued therapy Approval duration updated to 6 months. 5. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..'' 6. Appendix D added. 7. Reference reviewed and updated	07/28/2020	09/14/2020