Clinical Policy Title:	sipuleucel-T
Policy Number:	RxA.450
Drug(s) Applied:	Provenge®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Sipuleucel-T (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	50 million autologous CD54+ cells activated with PAP-GM-CSF, in 250 ml of Lactated Ringer's Injection intravenous over 60 minutes given approximately every 2 weeks for 3 doses	50 million autologous CD54+ cells activated with PAP-GM-CSF, in 250 ml of Lactated Ringer's Injection 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 ;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;

4. Member meets one of the following (a or b):
   a. Member has not received Provenge® previously
      i. Member is asymptomatic;
      ii. Member is symptomatic but with ECOG performance status 0-1, estimated life expectancy >6 months, and no visceral metastases;
   b. Member has received Provenge® previously but meets one of the following:
      i. No prior docetaxel and no prior novel hormone therapy;
      ii. Prior docetaxel and no prior novel hormone therapy;
      iii. Prior novel hormone therapy and no prior docetaxel;
5. Member has not received ≥ 3 doses (infusions) of Provenge®.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy, 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

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
ECOG: Eastern Cooperative Oncology Group
LHRH: Luteinizing hormone-releasing hormone

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)
- Examples of novel hormone therapy includes:
  - Yonsa (arbiraterone), Zytiga (arbiraterone), Xtandi (enzalutamide)
- Eastern Cooperative Oncology Group (ECOG) performance status (0-4)
  - 0- Fully active; no performance restrictions.
  - 1--Strenuous physical activity restricted; fully ambulatory and able to carry out light work.
  - 2--Capable of all self-care but unable to carry out any work activities. Up and about >50% of waking hours.
  - 3-Capable of only limited self-care; confined to bed or chair >50% of waking hours.
  - 4-Completely disabled; cannot carry out any self-care; totally confined to bed or chair.

References

1. Provenge® Prescribing Information. Seattle, WA: Dendreon Corporation; July 2017. Available at: http://www.provenge.com/. Accessed July 07, 2021.
2. Sipuleucel-T. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: www.nccn.org. Accessed July 07, 2021.
3. National Comprehensive Cancer Network. Prostate Cancer Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 07, 2021.
4. Clinical Pharmacology [database online]. Available at: https://www.clinicalkey.com/pharmacology/monograph/3566?n=Provenge%20Suspension%20for%20Injection&aprid=51606. Accessed July 07, 2021.

Review/Revision History	Review/Revision 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
Policy was reviewed:	07/07/2021	09/14/2021

1. Dosing Information maximum dose was updated to include “50 million autologous CD54+ cells activated…”. 2. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 3. Initial Approval Criteria I.A.4 was updated to include “Member meets one of the following (a or b)…” 4. Initial Approval Criteria I.A.4.a was updated to include “Member has not received Provenge® previously…” as well as sub-criteria I.A.4.a.i, “Member is asymptomatic” and sub-criteria I.A.4.a.ii, “Member is symptomatic but with…”. 5. Initial Approval Criteria I.A.4.b was updated to include “Member has received Provenge® previously but meets one of the following …” as well as sub-criteria I.A.4.b.i, “Member is asymptomatic” and sub-criteria I.A.4.b.ii, “Prior docetaxel and no prior novel hormone therapy” and sub-criteria I.A.4.b.iii, “Prior novel hormone therapy and no prior docetaxel…”. 6. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 7. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration.		

8. Appendix A was updated to remove abbreviation FDA. 9. Appendix A was updated to include abbreviations ECOG and LHRH. 10. Appendix D was updated to include “Examples of novel hormone therapy includes: Yonsa (arbiraterone), Zytiga (arbiraterone), Xtandi (enzalutamide)…” and “Eastern Cooperative Oncology Group (ECOG) performance status (0-4)…” 11. References were reviewed and updated.		