pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
June 13, 2016	June 13, 2016	*See below

SUBJECT

Prior Authorization of Provenge (sipuleucel-T) - Pharmacy Service

BY

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Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate their MA enrollment every 5 years. Providers should log into PROMISe to check their revalidation date and submit a revalidation application at least 60 days prior. Enrollment (revalidation) applications may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Providers who enrolled on or before SEPTEMBER 25, 2011 must complete the revalidation process as soon as possible. DHS must complete the revalidation for all providers enrolled on or before September 25, 2011 by September 25, 2016.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers that the Department will require prior authorization of prescriptions for Provenge (sipuleucel-T).

2. Issue handbook pages that include the type of information needed to evaluate requests for prior authorization of prescriptions for Provenge (sipuleucel-T) for medical necessity.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service (FFS) delivery system, including pharmacy services to residents of long term care facilities.

*01-16-17	09-16-16	27-16-15	
02-16-15	11-16-15	30-16-15	
03-16-15	14-16-15	31-16-18	
08-16-16	24-16-16	32-16-14	33-16-15

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

BACKGROUND:

The Department of Human Services (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

DISCUSSION:

During the March 23, 2016 meeting, the DUR Board recommended that the Department require a clinical prior authorization of Provenge (sipuleucel-T), and proposed guidelines to determine medical necessity and limits on dose and duration of therapy to ensure appropriate drug utilization. The requirement for prior authorization, guidelines to determine medical necessity, and limits on dose and duration of therapy, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization, clinical review guidelines to determine the medical necessity of Provenge (sipuleucel-T), and limits on dose and duration of therapy are included in the attached updated provider handbook pages.

PROCEDURE:

The procedures for prescribers to request prior authorization of Provenge (sipuleucel-T) are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Provenge (sipuleucel-T)) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Provenge (sipuleucel-T)

I. Requirements for Prior Authorization of Provenge (sipuleucel-T)

A. Prescriptions That Require Prior Authorization

All prescriptions for Provenge (sipuleucel-T) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Provenge (sipuleucel-T), the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Is prescribed Provenge (sipuleucel-T) by a hematologist/oncologist or urologist

AND

2. Has a diagnosis that is:

    a. Indicated in the FDA-approved package insert, **OR**

    b. Listed in nationally recognized compendia for the determination of medically-accepted indications for off-label uses of Provenge (sipuleucel-T)

AND

3. Has a testosterone level <50ng/dL unless treated with bilateral orchiectomy

AND

4. Does not use narcotics for cancer-related pain

AND

5. Has a documented ECOG performance status of 0-1

AND

6. Has a life expectancy >6 months

AND

7. Has no hepatic metastases

AND

8. Will not be using concurrent chemotherapy or immunosuppressive agents

OR

9. Does not meet the clinical review guidelines listed above but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for Provenge (sipuleucel-T). If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

E. Dose and Duration of Therapy

Requests for prior authorization of Provenge (sipuleucel-T) will be approved as follows:

1. One course of therapy (3-doses given at approximately 2-week intervals).

F. References

1. NCCN Drugs & Biologics Compendium. Accessed January 29, 2016
2. NCCN Clinical Practice Guideline in Oncology (NCCN Guidelines), Prostate Cancer, Version 1.2016
3. Kantoff, P.W. Immunotherapy for castration-resistant prostate cancer. Up To Date. Accessed January 29, 2016
4. Provenge prescribing information. Dendreon Corporation. October, 2014