From: Donald Russell
To: AGO - High Cost Prescription Drugs
Cc: Jason Peale
Subject: Azedra Additional Prescription Drug Reporting Submission for Vermont with Attachments
Date: Tuesday, July 2, 2019 4:53:03 PM
Attachments: 20150724-Letter-from-FDA-IND-109663-Grant-Breakthrough-Therapy-Designation-(COR-BREAK-03)-Final-7-24-15.pdf
20171228-Letter-from-FDA NDA-209607 Filing communication.pdf

Dear Attorney General Donovan,

Pursuant to 18 V.S.A.§ 4637 (Notice of Introduction of New High-Cost Prescription Drugs), Riparian, LLC, the third-party processor for Progenics Pharmaceuticals, Inc. is reporting the additional information requested within 30-days of the introduction of the new prescription drug AZEDRA® on June 3, 2019. AZEDRA® is a radiopharmaceutical available in two presentations:

NDC	DRUG DESCRIPTION	INTRODUCED TO MARKET DATE	WAC PRICE AT INTRODUCTION	ADDITIONAL WAC PRICE INFORMATION
71258-0015-02	AZEDRA® (iobenguane I 131) injection (30 mCi)	6/3/2019	$9,060.00	Azedra is priced at $302 per mCi. 71258-0015-02 is a dosimetric presentation containing 30 mCi at calibration time
71258-0015-22	AZEDRA® (iobenguane I 131) injection (337.5 mCi)	6/3/2019	$101,925.00	Azedra is priced at $302 per mCi. 71258-0015-02 is a therapeutic presentation containing 337.5 mCi at calibration time

The additional information requested is below:

1. **a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;**

Marketing Plan Description
Azedra is a high-dose radiopharmaceutical product used to treat pheochromocytoma and paraganglioma (pheo / para), ultra-rare tumors of the adrenal glands that effect fewer than 3,000 patients in the US per year. The vast majority of these patients are able to be treated – and potentially cured – by surgical resection of their tumors.
Azedra is a systemic cancer therapy targeted at pheo / para patients whose tumors are unresectable by surgery, or have spread to other parts of the body, and therefore require systemic treatment. This patient population represents a subset of the overall pheo/para population (estimated 400-800 eligible patients per year for Azedra). The product is a molecule that has had a radioactive isotope attached to it. The Azedra molecule then finds and binds to surface cell receptors of the pheo / para cancer cells, and the isotope is taken up by the cell, killing it.
While the exact dose varies per individual based on their weight, how their organs uptake the Azedra molecule, and other personalized factors, the approximate dose of the drug is between 450 and 500 mCi for an adult patient. A dose of radiation this high requires administration in a lead-lined room, then inpatient hospitalization (also in a lead-lined room) for 3-4 days post treatment while the radiation is cleared from the patient's body. Due to these special administration requirements, there are only a few dozen facilities throughout the US that are capable of administering the product.
Our marketing plan for the product uses a range of tactics to reach patients and providers. We are carrying out certain digital marketing activities aimed at consumers, such as maintaining a website (Azedra.com) to provide information about the condition and the product to consumers. We have also developed relationships with patient advocacy groups for people with this condition to help educate the patient community, such as the Pheo Para Alliance. Occasionally, information about Azedra is shared with members of these groups through digital media, such as Facebook.
With regard to provider-targeted marketing, the company has hired a field-based sales force of fewer than 10 people to call on physicians who treat pheo / para patients. Additionally, the field-based team attends professional conferences on a regular basis to interact with provider-customers, including the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and American Society of Clinical Oncology meetings. Lastly, the company conducts digital and print advertising aimed at a provider audience. For example, there is a section of the Azedra.com website that is targeted towards healthcare professionals, and the company has placed Azedra advertisements in medical journals that are frequently read by prescribers.

Pricing Plan Description
Progenics has priced the report at $302 per mCi. Each vial of the drug contains approximately 337.5 mCi, so the price per vial equates to $101,925 per vial.

2. **the estimated volume of patients who may be prescribed the drug;**

We estimate there are 400-800 patients per year who will be candidates for treatment with Azedra.

3. **whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval; and**

Progenics received orphan status, breakthrough designation and priority review for Azedra. Supporting document is attached.

4. **the date and price of acquisition if the drug was not developed by the manufacturer.**

Not Applicable. Azedra was developed by Progenics Pharmaceuticals, Inc.

Best regards,

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