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 Director

STATE OF NEW JERSEY
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE
AND HEALTH SERVICES

A.A.,	:	
	:	
PETITIONER,	:	ADMINISTRATIVE ACTION
	:	
v.	:	FINAL AGENCY DECISION
	:	
HORIZON NJ HEALTH,	:	OAL DKT. NO. HMA 15482-18
	:	
RESPONDENTS.	:	

As Director of the Division of Medical Assistance and Health Services, I have reviewed the record in this case, including the Initial Decision and the documents in evidence. Neither party filed Exceptions. Procedurally, the time period for the Agency Head to file a Final Agency Decision in this matter is May 30, 2019 in accordance with an Order of Extension. The Initial Decision in this matter was received on February 27, 2019.

This matter arises from Horizon NJ Health's (Horizon) October 16, 2018 denial of Petitioner's request for the medication vedolizumab (ENTYVIO). Horizon Policy 33C.284 (Policy) provides the criteria under which ENTYVIO would be approved: (1) the member must have a moderate to severe disease; (2) the member must be eighteen

years of age or older; and (3) the member has tried and failed at least one of the following conventional treatments or has contraindications to all: systemic corticosteroids, immunomodulators, or aminosalicylates. Horizon's Policy also requires that the medication be prescribed in accordance with the Food and Drug Administration (FDA) established dosing regimens. For the reasons that follow, I am REVERSING the Initial Decision and upholding Horizon's decision to deny Petitioner ENTYVIO.

The parties do not dispute Petitioner's eligibility with regard to the first and third requirements of the Policy. However, the Petitioner is fourteen years old, and therefore, does not meet the second requirement that the member must be eighteen years of age or older. N.J.A.C. 10:51-1.13 prohibits coverage for drugs or drug products not approved by the FDA. N.J.A.C. 10:51-1.13(a)(12). As Dr. Soliman testified, ENTYVIO is not approved by the FDA for pediatric use. (ID at 6). Consequently, Petitioner's age prohibits Horizon from approving her coverage for ENTYVIO.


Furthermore, 42 U.S.C.S. 1396 et seq. empowers states to deny reimbursement for a drug if the prescribed use is not for a medically accepted indication. 42 U.S.C.S. 1396r-8(d)(1)(B)(i). A "medically accepted indication" is any use for a covered outpatient drug which is approved under the Food, Drug and Cosmetics Act (FDCA) or the use of which is supported by one or more citations included or approved for inclusion in any of the following three compendia: the American Hospital Formulary Service – Drug Information (AHFS-DI), the United States Pharmacopeia – national Formulary (or successor publication), and DRUGDEX Information System. 42 U.S.C. 1396r-8(k)(6) and 42 U.S.C. 1396(g)(1)(B)(i). There is no evidence that the use of ENTYVIO in pediatric patients is supported by any of the three compendia. This is consistent with Section 8.4 of the FDA's Medication Guide for ENTYVIO which states

that the safety and effectiveness of ENTYVIO in pediatric patients has not been established. (R-4).

THEREFORE, it is on this 9th day of APRIL 2019,

ORDERED:

That the Initial Decision recommending approval of ENTYVIO for Petitioner is REVERSED.


Meghan Davey, Director
Division of Medical Assistance
and Health Services