

Notice to 340B Covered Entities Related to Axumin™ (NDC # 69932-0001-01)

July 22, 2019

This notice provides information for eligible 340B Covered Entities related to the acquisition of Axumin (fluciclovine F 18) at 340B ceiling prices.

Axumin is an FDA-approved radioactive diagnostic agent indicated for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment. Due to the characteristics and specialized manufacturing requirements for Axumin as a radioactive diagnostic, Blue Earth Diagnostics (BED) has implemented a limited distribution network for distribution of Axumin to customers.

To facilitate 340B orders, Blue Earth Diagnostics (BED) has established a designated email address to process these orders through PETNET, BED's distributor for Axumin. Orders by 340B Covered Entities are required to submit orders for Axumin at 340B prices by contacting the PETNET Scheduling Team at petnetscheduling.healthcare@siemens.com. Please include your 340B ID with your request to access the 340B ceiling price.

Upon receipt of a qualifying 340B order for Axumin, PETNET will facilitate the delivery of Axumin to the Covered Entity. BED seeks to ensure that Axumin is available to 340B covered entities in the same manner in which the product is available to other entities. If you have any questions regarding the limited distribution of Axumin, please contact Blue Earth Diagnostics US Compliance at uscompliance@blueearthdx.com or call (781) 552-3409.