



340B Notice Regarding Limited Distribution plan for ARIKAYCE® (amikacin liposome inhalation suspension)
October 22, 2018

This notice provides information for 340B covered entities about how to acquire ARIKAYCE® (amikacin liposome inhalation suspension) (NDC Number 71558-590-28), at the calculated 340B ceiling price. Insmmed is committed to both patient safety and compliance with the rules of the 340B program. ARIKAYCE is an aminoglycoside antibacterial indicated in adults who have limited or no alternative treatment options, for the treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy.

To ensure that patients being treated with ARIKAYCE receive the best possible care and to ensure optimal therapeutic adherence, Insmmed has developed a limited distribution plan designed to achieve these goals. All customers – 340B and otherwise – are subject to this plan equally.

Insmmed offers the 340B ceiling price to all covered entities, except those that are ineligible for 340B pricing for drugs, like ARIKAYCE, that are designated by FDA for an orphan use.¹ If your facility is a 340B covered entity that maintains an on-site pulmonologist or infectious disease physician, and dispenses from that location; you may be eligible to order from our specialty distributor partner ASD Healthcare at the 340B ceiling price and inventory ARIKAYCE on-site. For specific terms and conditions of our qualified dispensary program, please call 1-800-746-6273, Fax 1- 800-547-9413 or email asd.customerservice@asdhealthcare.com.

Insmmed takes its participation under the 340B program seriously and makes every effort to ensure that ARIKAYCE is available to all 340B covered entities in a manner that is no more restrictive than for its non-340B entities. This defined distribution network may change from time to time. If you have any questions about this plan, or any difficulty obtaining ARIKAYCE for your patients, please contact Insmmed directly at 1-833-ARIKARE.

¹ These covered entities are free-standing cancer hospitals, critical access hospital, rural referral centers, and sole community hospitals. See 42 U.S.C. § 256b(e).