

340B Notice Regarding Limited Distribution Plan for FIRDAPSE® (amifampridine) tablets

April 2, 2019

This notice provides information for 340B Covered Entities about how obtain to FIRDAPSE® (amifampridine) tablets for eligible Covered Entity patients at the 340B ceiling price. Catalyst Pharmaceuticals, Inc. (Catalyst), the manufacturer of FIRDAPSE, is committed to both patient safety and compliance with the requirements of the 340B program. Specifically, this notice applies to the following NDC packaging configurations for FIRDAPSE:

69616-211-06 (120 ct. blisterpacks)

69616-211-03 (240 ct. bottles)

FIRDAPSE is a potassium channel blocker indicated for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) in adults. Because FIRDAPSE is an orphan drug, it is not available at the 340B ceiling price to free-standing cancer hospitals, critical access hospitals, sole community hospitals, or rural referral centers (for purposes of this notice, “Excluded Entities”). Of course, Excluded Entities may obtain FIRDAPSE through the channels described below at current commercially available prices subject to the other provisions set forth below.

To ensure that patients being treated with FIRDAPSE receive the best possible care and to ensure optimal drug regimen titration, appropriate drug and clinical counseling, and therapeutic adherence, Catalyst has developed an exclusive distribution plan designed to achieve these goals. All customers desiring to dispense FIRDAPSE – 340B-eligible and otherwise – are equally subject to this limited distribution plan. With one exception, Catalyst is using an exclusive specialty pharmacy, AnovoRx Group, LLC, to dispense FIRDAPSE for LEMS patients. The only exception to that exclusive distribution/dispensing arrangement is for provider-based specialty pharmacy operations which have an available neuromuscular specialist physician on-site and which also dispense to over 35 LEMS patients an ongoing fashion.

Any 340B Covered Entity other than an Excluded Entity that does not qualify for the limited exception from the exclusive distribution, BUT wishes to access 340B pricing for its patients, should contact AnovoRx Group, LLC, our exclusive specialty pharmacy for dispensing of FIRDAPSE, at 844-288-5007 extension 5484 to arrange for AnovoRx Group, LLC to service the 340B Covered Entity as a contract 340B pharmacy and to dispense FIRDAPSE directly to the Covered Entity’s patients. Any Covered Entity desiring to contract with AnovoRx Group, LLC as a contract pharmacy is subject to certain contractual terms and conditions established by AnovoRx Group, LLC. Any 340B Covered Entity, other than an Excluded Entity, that has an established outpatient specialty pharmacy operation, maintains an on-site neuromuscular specialist physician, and dispenses for at least 35 LEMS patients on an ongoing basis is eligible to order from our exclusive specialty distributor partner, AnovoRx Distribution, LLC, at the 340B ceiling price and inventory FIRDASE on-site for use with its patients on an outpatient basis. To discuss those qualifications and/or to arrange for such shipments, please contact AnovoRx Distribution, LLC at 1-844-288-5007 extension 2415.

Catalyst takes its obligations under the 340B program seriously and makes every effort to ensure that FIRDAPSE is available to all 340B covered entities in a manner that is no more restrictive than for non-340B covered entities. This limited distribution network may change from time to time.

If you have any questions about this plan, or questions about obtaining FIRDAPSE for your patients, please contact Brian Elsbernd at Catalyst directly at 1-(305)-420-3234.