



April 22nd, 2021

340B Notice Exclusive Oncology Distribution Network Update for Iclusig® (ponatinib)

This notice provides updated information for 340B covered entities about how to acquire ICLUSIG® (ponatinib) NDC# 63020-534-30 (45mg, 30 count bottle), NDC# 63020-535-30 (15mg, 30 count bottle), NDC# 63020-533-30 (30mg, 30 count bottle) and NDC# 63020-536-30 (10mg, 30 count bottle) at the 340B ceiling price. Millennium Pharmaceuticals Inc. (“Millennium”), an affiliate of Takeda Pharmaceutical Company Limited (collectively, “Takeda”) distributes ICLUSIG, an orphan drug indicated for the treatment of (i) adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated, and (ii) adult patients with T315I-positive chronic myeloid leukemia (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL.

Takeda has partnered with AcariaHealth, Inc., an Envolve Pharmacy Solutions, and its wholly-owned or affiliated pharmacies (collectively, referred to as “AcariaHealth”) to be the network pharmacy for ICLUSIG. Takeda also maintains a distribution partnership with Foundation Care, an AcariaHealth Solution, to support the distribution of ICLUSIG to Hospitals, Clinics, Health Systems and government entities.

To obtain ICLUSIG, 340B covered entities can visit the ICLUSIGDirect website, <http://iclusigdirect.com>. This website will provide forms and directions pertaining to product purchase. After customer information is obtained and approval confirmation is received, 340B covered entities can begin to place their order either by calling the ICLUSIGDirect phone number listed on the provided website or by faxing in your company approved order form to the dedicated fax line. Once the order request is received, an ICLUSIGDirect representative will process the order and shipment will be received by the “need by” date.

Takeda takes its obligations under the 340B program seriously. We seek to ensure that the ongoing distribution of ICLUSIG is compliant and transparent to HRSA, and that 340B covered entities are aware of the change related to the distribution of ICLUSIG, which will continue to provide access to therapy in a manner that is no more restrictive than it is for non-340b entities. If you have any questions regarding the content herein, please contact Michelle Lucas (617) 444-4315 or Michelle.Lucas@Takeda.com.