

REVISED Notice to 340B Covered Entities Regarding BALVERSA[®] Limited Distribution Plan

October 2020

This notice is to inform 340B covered entities of the revised BALVERSA[®] (erdafitinib) Limited Distribution Plan and the availability of 340B pricing.

Janssen manufacturers the following package configurations for BALVERSA[®]:

3mg tablets: NDC 59676-030-56 (bottle of 56), NDC 59676-030-84 (bottle of 84)

4mg tablets: NDC 59676-040-28 (bottle of 28), NDC 59676-040-56 (bottle of 56)

5mg tablets: NDC 59676-050-28 (bottle of 28)

BALVERSA[®] was granted Breakthrough Therapy Designation by the US Food and Drug Administration and is approved for the treatment of urothelial cancer. BALVERSA[®] is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for BALVERSA[®]. Information on FDA-approved tests for the detection of FGFR genetic alterations in urothelial cancer is available at: <http://www.fda.gov/CompanionDiagnostics>.

Janssen provided a public notice in April 2019 of BALVERSA's[®] Limited Distribution Plan. Consistent with the factors discussed in that notice and with additional experience on the market, Janssen has revised this Limited Distribution Plan.

BALVERSA[®] continues to be available to all patients through the Specialty Pharmacy Provider (SPP) US Bioservices. In addition, BALVERSA[®] is now available through Amerisource Bergen to any URAC-accredited SPP owned by a health system or hospital, pharmacies located inside of oncology clinics, in-patient hospital pharmacies, and Government facilities such as VA health system pharmacies. All providers are equally considered under this revised Limited Distribution System, and 340B status is not a factor in determining eligibility to purchase BALVERSA[®].

340B pricing on BALVERSA[®] is available to URAC-accredited SPPs that operate within a 340B hospital. 340B covered entities that are not URAC-accredited can access 340B pricing through contract pharmacy arrangements with US Bioservices. All orders must be placed with Amerisource Bergen who is the single authorized distributor for BALVERSA[®].

To inquire about 340B pricing on BALVERSA[®], please contact Amerisource Bergen at 800-746-6273 or US Bioservices at 888-518-7246.

<https://www.balversahcp.com/>