Balversa® (erdafitinib)
(Oral)

Document Number: IC-0458

Last Review Date: 05/03/2021
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Dates Reviewed: 05/2019, 05/2020, 05/2021

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Balversa 3 mg tablet: 3 tablets daily
- Balversa 4 mg tablet: 2 tablets daily
- Balversa 5 mg tablet: 1 tablet daily

B. Max Units (per dose and over time) [HCPCS Unit]:

- 9 mg daily

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient must be at least 18 years of age; **AND**
- Patient has had a baseline serum phosphate level measurement and it is within normal limits; **AND**

Universal Criteria [1]

- Patient has received ophthalmological examinations (i.e., assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography) at baseline and will be examined periodically throughout therapy; **AND**
- Patient phosphate intake is restricted to less than 800 mg per day; **AND**
- Patient will avoid concomitant use with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will implemented:
  - Moderate CYP2C9 inhibitors (e.g., amiodarone, fluvoxamine, miconazole, etc.)
  - Strong CYP3A4 inhibitors (e.g., clarithromycin, cobicistat, ketoconazole, etc.)
  - Moderate CYP2C9 or CYP3A4 inducers (e.g., carbamazepine, rifampin, bosentan, modafinil, etc.); **AND**

- Patient will not be on concomitant therapy with any of the following:
  - Strong CYP2C9 or CYP3A4 inducers (e.g., rifampicin, etc.)
  - Serum phosphate level-altering agents before the initial dose increase period based on serum phosphate levels (e.g., potassium phosphate supplements, vitamin D supplements, antacids, phosphate-containing enemas or laxatives, certain medications, etc.); **AND**

Bladder Cancer/Urothelial Carcinoma [1,3-6] † ‡

- Must be used as a single agent; **AND**
- Patient has a susceptible gene mutation or fusions in the FGFR-2 or FGFR-3 (fibroblast growth factor receptor) gene, as determined by an FDA-approved or CLIA-compliant test **§**; **AND**
- Patient has one of the following diagnoses:
  - Locally advanced or metastatic urothelial carcinoma **†**; **OR**
  - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder; **OR**
  - Metastatic or local bladder cancer recurrence post-cystectomy; **OR**
  - Metastatic upper genitourinary tract tumors; **OR**
  - Metastatic urothelial carcinoma of the prostate; **OR**
  - Metastatic or recurrent primary carcinoma of the urethra; **AND**
    - Patient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes; **AND**
- Used as subsequent therapy after first-line platinum-containing chemotherapy followed by avelumab maintenance therapy; **OR**
- Used as second-line therapy after one of the following:
  - After at least one prior line of platinum-containing chemotherapy*; **OR**
  - After at least one prior line of checkpoint inhibitor-containing chemotherapy; **OR**
  - After first-line therapy other than platinum or an immune checkpoint inhibitor

Note: [4,7]

- *If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or carboplatin-ineligible comorbidities).*
  - *Cisplatin-ineligible comorbidities may include the following: GFR < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, or grades ≥ 2 peripheral neuropathy. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR <60 mL/min or a PS of 2.*
  - *Carboplatin-ineligible comorbidities may include the following: CrCl < 30 mL/min, PS ≥ 3, grade ≥ 3 peripheral neuropathy, or NYHA class ≥ 3, etc.*

§ *If confirmed using an FDA approved assay* - http://www.fda.gov/companiondiagnostics

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s)

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication specific criteria as identified in section III; **AND**
- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED), severe hyperphosphatemia, etc.; **AND**
- Patient serum phosphate level is < 7.0 mg/dL

V. Dosage/Administration [1]

Indication	Dose
Urothelial Carcinoma	The recommended starting dose is 8 mg (two 4 mg tablets) orally once daily, with a dose increase to 9 mg (three 3 mg tablets) once daily based on serum phosphate (PO_4) levels and tolerability at 14 to 21 days. Continue therapy until disease progression or unacceptable toxicity occurs.
Note: Assess serum phosphate levels 14 to 21 days after initiating treatment. Increase the dose of Balversa to 9 mg once daily if serum phosphate level is < 5.5 mg/dL and there are no ocular disorders or Grade 2 or greater adverse reactions. Monitor phosphate levels monthly for hyperphosphatemia.	

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, not otherwise specified
- C9399 – Unclassified drugs or biologicals *(for hospital outpatient use ONLY)*

NDC:

- Balversa 3 mg tablets: 59676-0030-xx
- Balversa 4 mg tablets: 59676-0040-xx
- Balversa 5 mg tablets: 59676-0050-xx

VII. References

1. Balversa [package insert]. Horsham, PA; Janssen Products, LP; April 2020. Accessed April 2021.
2. Qiagen. *therascreen®* FGFR RGQ RT-PCR Kit Companion Diagnostic Test. www.qiagen.com/fgfr-lab-finder. Accessed April 2019
3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) erdafitinib. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL

COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2021.

4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 2.2021. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2021.
5. Siefker-Radtke AO, Necchi A, Park SH, et al. First results from the primary analysis population of the phase 2 study of erdafitinib (ERDA; JNJ-42756493) in patients (pts) with metastatic or unresectable urothelial carcinoma (mUC) and FGFR alterations (FGFR alt). JCO 2018 36:15_suppl, 4503-4503
6. Loriot Y, Necchi A, Park SH, et al. Erdafitinib in locally advanced or metastatic urothelial carcinoma. N Engl J Med 2019;381:338-348.
7. Gupta S, Sonpavde G, Grivas P, et al. Defining "platinum-ineligible" patients with metastatic urothelial cancer (mUC). J Clin Oncol. 2019 Mar 1;37(7_suppl):451.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder

ICD-10	ICD-10 Description
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra
D09.0	Carcinoma in situ of bladder
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC