BlueCross BlueShield Arizona

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PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**5/16/2019**
LAST REVIEW DATE:	**5/20/2021**
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BALVERSA™ (erdafitinib)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

BALVERSA™ (erdafitinib)

Criteria:

- **Criteria for initial therapy:** Balversa (erdafitinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     a. Locally advanced or metastatic urothelial carcinoma (mUC), that has susceptible FGFR3 or FGFR2 genetic alterations and has progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neo-adjuvant or adjuvant platinum-containing chemotherapy

     b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  4. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Fibroblast growth factor receptor (FGFR) genetic alteration testing of FGFR 2 or 3
     b. Ophthalmologic examination
     c. Negative pregnancy test in a woman of child bearing potential
     d. Eastern Co-operative Oncology Group (ECOG) performance status of 0-2

  5. Individual is not using medications that are strong CYP2C9 or CYP3A4 inducer

  6. Individual does not have moderate to severe hepatic impairment

  7. Individual does not have severe renal impairment or renal impairment requiring dialysis

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Balversa (erdafitinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual's condition responded while on therapy
     a. Response is defined as:
        i. No evidence of disease progression
        ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

3. Individual has been adherent with the medication

4. Individual has not developed any significant adverse drug effects that may exclude continued use
    a. Significant adverse effect such as:
        i. Ophthalmologic toxicity such as central serious retinopathy/retinal pigment epithelia detachment (CRS/RPED)
        ii. Visual acuity of 20/200 or worse in an affected eye

5. Individual does not have moderate to severe hepatic impairment

6. Individual does not have severe renal impairment or renal impairment requiring dialysis

7. There are no significant interacting drugs

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

    1. **Off-Label Use of a Non-Cancer Medications**

    2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Balversa (erdafitinib) is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has susceptible fibroblast growth factor receptor (FGFR) 3 or FGFR 2 genetic alterations, and has progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neo-adjuvant or adjuvant platinum-containing chemotherapy. The indication is approved under an accelerated approval, based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Select patients for therapy based on an FDA-approved companion diagnostic test for Balversa (erdafitinib). The QIAGEN therascreen® FGFR RGQ RT-PCR Kit, is the FDA-approved test for selection of patients with mUC for Balversa (erdafitinib).

Erdafitinib is a kinase inhibitor that binds to and inhibits the enzymatic activity of FGFR1, FGFR2, FGFR3 and FGFR4 based on *in vitro* data. Erdafitinib also binds to RET, CSF1R, PDGFRA, PDGFRB, FLT4, KIT, and VEGFR2. Erdafitinib inhibited FGFR phosphorylation and signaling and decreased cell viability in cell lines expressing FGFR genetic alterations, including point mutations, amplifications, and fusions. Erdafitinib demonstrated antitumor activity in FGFR-expressing cell lines and xenograft models derived from tumor types, including bladder cancer

BALVERSA™ (erdafitinib)

***Definitions*:**

Neo-adjuvant therapy:
Drugs, radiation, or other forms of supplemental treatment given prior to cancer surgery intended to reduce tumor burden in reparation for surgery

Adjuvant therapy:
Drugs, radiation, or other forms of supplemental treatment following cancer surgery intended to decrease the risk of disease recurrence or to treat residual disease, whether gross or microscopic, following cytoreduction

ECOG Performance status:

Eastern Co-operative Oncology Group (ECOG) Performance Status	
Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead
Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982	

Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0:

Grade 1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
Grade 2	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL*
Grade 3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL**
Grade 4	Life-threatening consequences; urgent intervention indicated
Grade 5	Death related to AE
U.S. department of Health and Human Services, National Institutes of Health, and National Cancer Institute	

BALVERSA™ (erdafitinib)

Activities of daily living (ADL):

Instrumental ADL:

Prepare meals, shop for groceries or clothes, use the telephone, manage money, etc.

Self-care ADL:

Bathe, dress and undress, feed self, use the toilet, take medications, not bedridden

Cytochrome P450 (CYP) (list is not all inclusive):

3A4 inducers:

Strong inducers: carbamazepine, enzalutamide, fosphenytoin, luicaftor, nevirapine, pentobarbital, phenobarbital, phenytoin, primidone, rifampin

2C9 inducers

Strong inducers: aminoglutethimide, barbiturates, bosentan, carbamazepine, griseofulvin, phenytoin, primidone, rifabutine rifampin, rifapentine

Resources:

Balversa (erdafitinib) product information, revised by Janssen Products L.P 07-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on March 25, 2021.

Bellmunt J. Treatment of metastatic urothelial cancer of the bladder and urinary tract. In: UpToDate, Lerner SP, Shah S (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on March 25, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Bladder Cancer Version 2.2021 – Updated March 22, 2021. Available at https://www.nccn.org. Accessed on March 25, 2021.

National Comprehensive Cancer Network (NCCN) Compendium: Balversa. National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021(c); Available at: http://www.nccn.org. Accessed on March 25, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.