Erdafitinib (Balversa™)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO024

Description

Erdafitinib (Balversa) is an oral kinase inhibitor that inhibits enzymatic activity of FGFR 1-4.

Length of Authorization

- Initial: Three months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit*	DDID
erdafitinib (Balversa)	3 mg tablets	Advanced or metastatic urothelial carcinoma FGFR3 or FGFR2 genetic alteration, second-line after platinum therapy progression	**Maintenance**: 90 tablets/30 days	206400
	4 mg tablets		**Initial**: 28 tablets per 14-day supply for one fill **Maintenance**: 60 tablets/30 days	206401
	5 mg tablets		**Maintenance**: 30 tablets/30 days	206402

*Total daily dose should not exceed 9 mg per day. This may be achieved by 5 mg plus 4 mg, or by three 3mg tablets.

Initial Evaluation

I. Erdafitinib (Balversa) may be considered medically necessary when the following criteria are met:
   A. Member is 18 years of age or older; **AND**
   B. The medication is prescribed by or in consultation with an oncologist or urologist; **AND**
   C. Not to be used in combination with other oncolytic medications (i.e., must be used as a monotherapy for the conditions listed below); **AND**
   D. The provider attests that the member will be treated with a maximum of 8 mg per day for at least two weeks to assess for tolerability before considering a total daily dose of 9 mg per day; **AND**
   E. A diagnosis of urothelial carcinoma when the following are met:
      1. Disease is considered advanced or metastatic; **AND**
      2. Genetic alteration is FGFR**3** point mutation or fusion as detected by an FDA-approved test; **AND (one of i or ii)**
         i. The member has previously progressed during or following at least one line of prior platinum-containing chemotherapy (e.g., cisplatin, carboplatin); **OR**

ii. The member previously progressed during or following neoadjuvant or adjuvant platinum-containing chemotherapy (e.g., cisplatin, carboplatin); **AND**
    a. The platinum-containing chemotherapy was administered within the last 12 months

II. Erdafitinib (Balversa) is considered not medically necessary when criteria above are not met and/or when used for:
    A. Urothelial carcinoma that has FGFR**2** genetic alteration (e.g., fusion or point mutation)

III. Erdafitinib (Balversa) is considered investigational when used for all other conditions, including, but not limited to:
    A. Urothelial carcinoma prior to the advanced or metastatic setting
    B. Urothelial carcinoma without FGFR mutation, or without previous treatment with platinum-based chemotherapy
    C. For urothelial carcinoma, or otherwise, treatment with a dose greater than 9 mg per day
    D. Conditions outside of urothelial carcinoma (e.g., Non-Hodgkin Lymphoma, gliomas, osteosarcoma, histiocytosis, soft tissue sarcoma, etc.)

Renewal Evaluation

I. The medication is prescribed by, or in consultation with, an oncologist or urologist; **AND**
II. The medication is not used in combination with other oncolytic medications (i.e., erdafitinib [Balversa] is used as monotherapy); **AND**
III. Tumor response is documented with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
IV. The member has an absence of unacceptable toxicity from the drug (e.g., ophthalmic disturbances, hyperphosphatemia).

Supporting Evidence

I. Erdafitinib (Balversa) was evaluated in one, single-arm, open-label trial. Eighty-seven subjects (n=87) had advanced or metastatic urothelial carcinoma with FGFR**2** or FGFR**3** genetic alterations. Additionally, subjects must have progressed on or after at least one line of prior platinum-containing chemotherapy. This included those that had received neoadjuvant or adjuvant platinum-containing chemotherapy in the past 12 months.
II. No pediatric patients were included in the trial. Subjects assessed were between the ages of 36 and 87. Ninety-seven percent of subjects had received prior cisplatin or carboplatin, and 10% had received both. Twenty-four percent of subjects had received prior anti-PD-L1/PD-1 therapy (immunotherapy). No concomitant oncolytic medications were allowed during the trial.

III. The study assessed for objective response rate (ORR), including both partial and complete response (PR and CR), and duration of response (DoR). Thirty-two percent of subjects met the ORR (2 patients showed CR), and the median duration of response was 5.4 months.
IV. High rates of dose-reduction and dose-interruption were observed, at 53% and 68% respectively. Serious adverse events including, but not limited to, ophthalmic disturbances, hyperphosphatemia, and fatal myocardial infarction, occurred during the trial (1-20%).

Investigational or Not Medically Necessary Uses

I. The pivotal trial evaluated for the FDA-approved indication of urothelial carcinoma included six patients with a FGFR**2** fusion genetic alteration, and no patients that had FGFR**2** point mutation. None of these six patients showed an ORR on or after treatment with erdafitinib (Balversa). As of April 2019, there is no evidence that this population has responded to therapy.
II. Currently, the available outcomes data for erdafitinib (Balversa) was based on a maximum dose of 9 mg per day. No subjects were on concurrent oncolytic therapies. All subjects were verified to be with FGFR-mutation, and with advanced or metastatic urothelial carcinoma. Safety and efficacy outcomes in patients not previously progressed on or after platinum-containing chemotherapy is unknown at the time of this writing.
III. Erdafitinib (Balversa) is currently in clinical trials for a variety of other conditions (e.g, Non-Hodgkin Lymphoma, gliomas, osteosarcoma, histiocytosis, soft tissue sarcoma, etc.).

References

1. Balversa {Prescribing Information]. Janssen Pharmaceutical Companies: Horsham, PA. April 2019.
2. National Comprehensive Cancer Network. NCCN Guidelines: Bladder Cancer V3.2019. Available at https://www.nccn.org/professionals/physician_gls/default.aspx. Updated April 23, 2019. Accessed April 29, 2019.
3. UpToDate. Overview of the initial approach and management of urothelial bladder cancer. Lerner S.P., Raghavan D. March 2019. Available at: https://www.uptodate.com/contents/overview-of-the-initial-approach-and-management-of-urothelial-bladder-cancer?search=urothelial%20carcinoma&source=search_result&selectedTitle=1~82&usage_type=default&display_rank=1. Accessed April 29, 2019.
4. FDA News Release. FDA approved first targeted therapy for metastatic bladder cancer. April 12, 2019. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-targeted-therapy-metastatic-bladder-cancer. Accessed on April 29, 2019.
5. U.S. National Library of Medicine Clinical Trials. An efficacy and safety study of JNJ-42756493 in participants with urothelial cancer. Clinicaltrials.gov. Last updated March 29, 2019. Available at: https://clinicaltrials.gov/ct2/show/NCT02365597. Accessed on April 29, 2019.

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Policy Implementation/Update:

Date Created	April 2019
Date Effective	August 2019
Last Updated	
Last Reviewed	

Action and Summary of Changes	Date